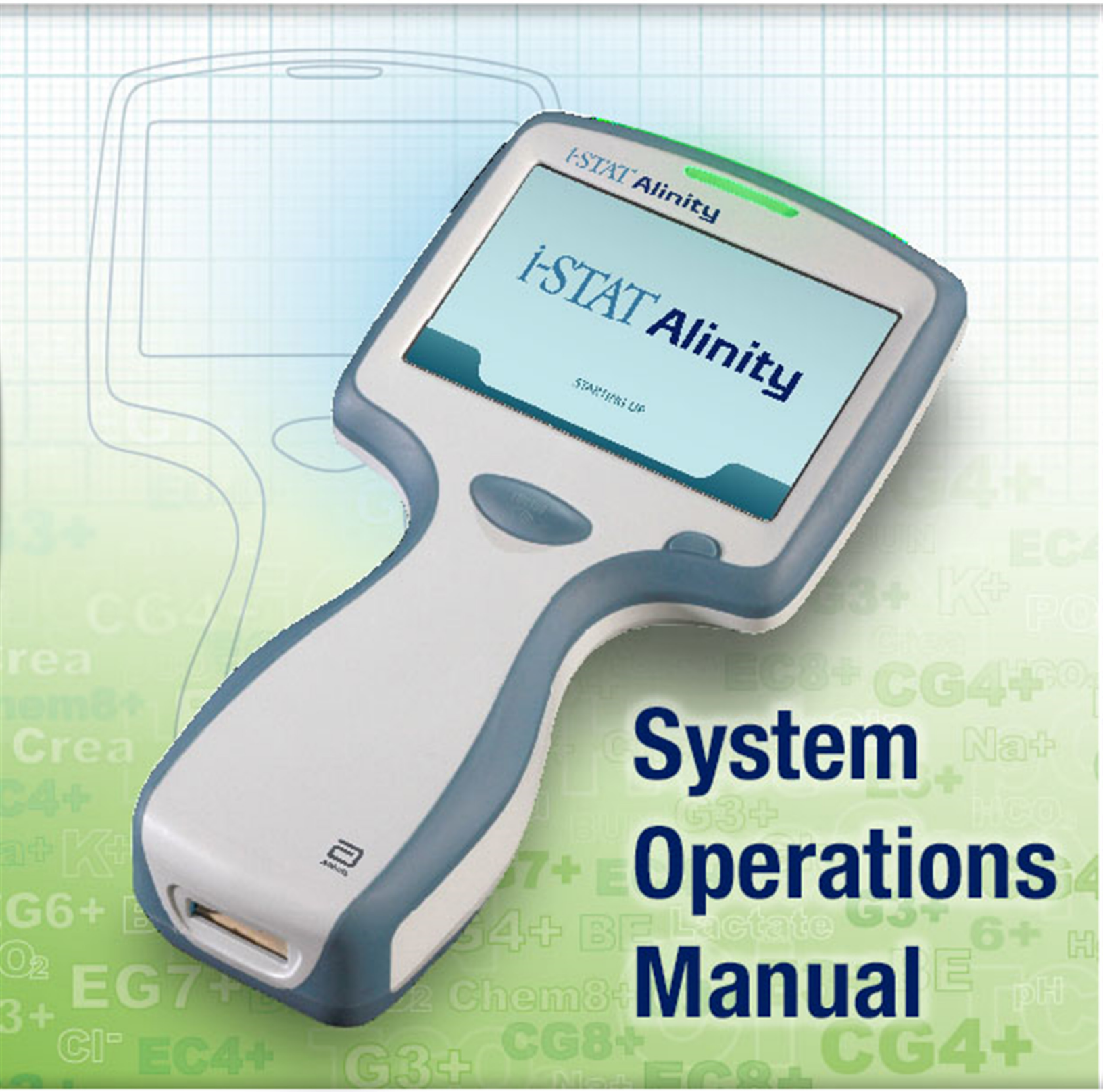
i-STAT Alinity



System Operations Manual

Abbott

This page intentionally left blank.

Patents: www.abbott.us/patents

Abbott Point of Care Inc.
100 & 200 Abbott Park Road
Abbott Park, IL
60064 USA

IVD

CE

EC REP
Emergo Europe
Westervoortsedijk 60
6827 AT Arnhem
The Netherlands

Rx ONLY

i-STAT Alinity ONLY

This page intentionally left blank.

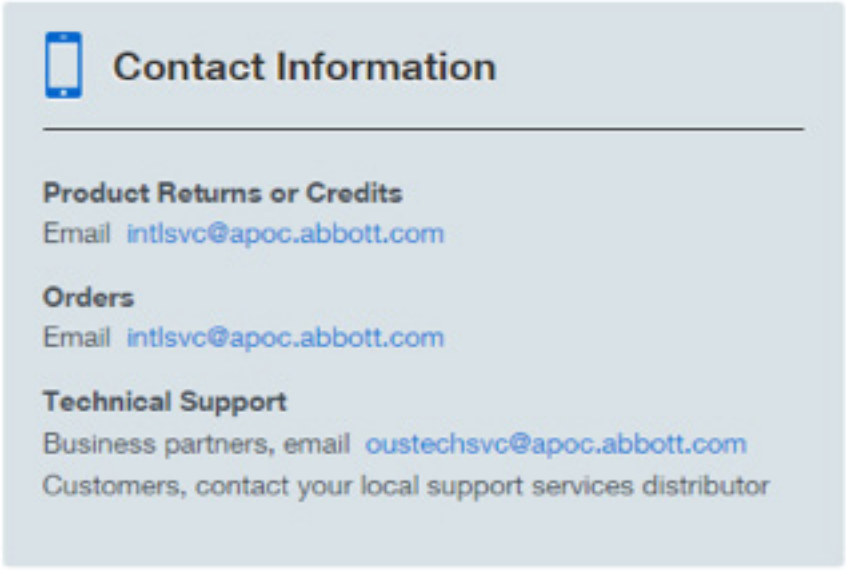
Table of Contents

3 - AlinIQ Customization Workspace for i-STAT (CWi)

Foreword

The Abbott i-STAT Alinity system is designed to function consistently and dependably from day to day. It is supported by dedicated professionals who excel in engineering, medical technology, training, and service.

Abbott Point of Care is dedicated to manufacturing high-quality and reliable instrumentation. We look forward to serving your needs.



i-STAT Alinity Instrument - Warranty

Subject to the warranty exclusions set forth below, Abbott Point of Care Inc. warrants that the i-STAT Alinity instrument and Peripherals (but specifically excluding disposable and consumable supplies, Software (as defined in the EULA below), and firmware) will be free from defects in materials and workmanship for a period of one year from the date that Abbott Point of Care Inc. first ships the applicable instrument or Peripheral. If any i-STAT Alinity instrument or Peripheral does not comply with the warranty set forth in this paragraph and if Abbott Point of Care Inc. receives written notice of such noncompliance within the warranty period, then, as Abbott Point of Care Inc.'s sole and exclusive obligation and buyer's sole and exclusive remedy, Abbott Point of Care Inc. shall, as its option, (i) repair or replace the applicable instrument or Peripheral at no additional charge or (ii) refund the purchase price for the applicable instrument of Peripheral. For purposes of this paragraph, "Peripheral" means each of the following: i-STAT Alinity Base Station kit; i-STAT Alinity Printer kit; i-STAT Alinity Battery; and i-STAT Alinity External Electronic Simulator.

Note: Warranty rights may vary from state to state, province to province and country to country.

Warranty Exclusions

The warranty set forth above shall not apply if:

1. the instrument or Peripheral has been misused, altered, damaged, or used other than in accordance with this manual;
2. the instrument or Peripheral has been used with articles, substances, reagents, batteries, accessories, and/or consumables that are not supplied or recommended by Abbott Point of Care Inc. for use with the instrument or Peripheral;
3. the serial number on the instrument or Peripheral has been altered, defaced, or removed;
4. the instrument or Peripheral has been repaired or maintained by any party not authorized by Abbott Point of Care Inc. to perform such repair or maintenence;
5. the instrument or Peripheral was purchased from an unauthorized distributor; or
6. the defect results, directly or indirectly from:
   A. use of buyer-supplied software or interfacing; or
   B. improper site preparation or maintenance.

THE WARRANTY SET FORTH ABOVE IS EXCLUSIVE, AND ABBOTT POINT OF CARE INC. MAKES NO OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, WARRANTIES AS TO MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, NON-INFRINGEMENT OR ANY OTHER MATTER.

i-STAT ALINITY INSTRUMENT - END USER LICENSE AGREEMENT

Please read the EULA prior to using this device. Your use of the device is conditioned upon your acceptance of the terms of the EULA.

Any use of this device shall indicate your acceptance of the terms of the EULA.

If you do not accept the terms of the EULA, do not use this device.

The Software, and all intellectual property rights therein, is owned by APOC and its licensors. You may not (i) use the Software to access or attempt to access any other APOC systems, programs or data that are not made available for public use; (ii) copy, reproduce, alter, merge, modify, adapt, translate, republish, upload, post, transmit, resell or distribute in any way the Software (or the Devices) or decompile, reverse engineer, disassemble, or otherwise reduce the Software to a human perceivable form; (iii) permit any third party to benefit from the use or functionality of the Software via a rental, lease, time-sharing, service bureau, or other arrangement; (iv) transfer any of the rights granted to you under this EULA; (v) work around any technical limitations in the Software, use any tool to enable features or functionalities that are otherwise disabled in the Software, or decompile, disassemble, or otherwise reverse engineer the Software except as otherwise permitted by applicable law; (vi) perform or attempt to perform any actions that would interfere with the proper working of the Software; or (vii) otherwise use the Software except as expressly allowed under the EULA.

The Software is provided "As Is" without warranty of any kind. TO THE MAXIMUM EXTENT PERMITTED BY APPLICABLE LAW, APOC AND SUPPLIERS SHALL NOT BE LIABLE FOR ANY INDIRECT, SPECIAL, INCIDENTAL, PUNITIVE, EXEMPLARY, OR CONSEQUENTIAL DAMAGES OR FOR ANY DAMAGES RELATING TO LOSS OF BUSINESS, TELECOMMUNICATION FAILURES, THE LOSS, CORRUPTION OR THEFT OF DATA, VIRUSES, SPYWARE, LOSS OF PROFITS OR INVESTMENT, USE OF THE SOFTWARE WITH HARDWARE OR OTHER SOFTWARE THAT DOES NOT MEET APOC'S SYSTEMS REQUIREMENTS OR THE LIKE, WHETHER BASED IN CONTRACT, TORT (INCLUDING NEGLIGENCE), PRODUCT LIABILITY OR OTHERWISE, EVEN IF APOC AND/OR ITS SUPPLIERS, OR EITHER OF THEIR REPRESENTATIVES HAVE BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES, AND EVEN IF A REMEDY SET FORTH HEREIN IS FOUND TO HAVE FAILED OF ITS ESSENTIAL PURPOSE. SOME STATES DO NOT ALLOW THE LIMITATION AND/OR EXCLUSION OF LIABILITY FOR INCIDENTAL OR CONSEQUENTIAL DAMAGES, SO THE ABOVE LIMITATION OR EXCLUSION MAY NOT APPLY TO YOU.

PLEASE READ THIS END USER LICENSE AGREEMENT ("EULA") BEFORE USING THE DEVICE. USE OF THE DEVICE INDICATES END USER'S ACCEPTANCE OF THIS EULA. ACCEPTANCE OF THIS AGREEMENT IS A CONDITION TO THE RIGHTS GRANTED HEREIN. IF END USER DOES NOT AGREE WITH THE TERMS OF THIS EULA, END USER SHOULD NOT USE THE DEVICE.

1. **INTRODUCTION.** Thank you for selecting the i-STAT Analyzer (which includes certain software components (collectively, the "Device"). This EULA is a legal agreement between you ("you", "End User"), and Abbott Point of Care Inc. ("APOC", "we", "our" or "us") that describes the terms and conditions applicable to your use of the software installed on or used in connection with the Device, including any software already pre-installed on the Device, software that you may download from the Support area of the *https://www.globalpointofcare.abbott* website, tools and web-based components, together with all modifications, enhancements, updates or upgrades thereof (collectively, the"Software").
2. **LICENSE GRANT AND RESTRICTIONS.** Subject to the terms and conditions of this EULA, APOC grants you a personal, limited, non-exclusive, non-transferable, non-assignable license, during the Term (as defined in Section 4), to electronically access and use the Software, for the sole purpose of using

the Device solely in accordance with the Systems Operations Manual (the "Manual") . You are not licensed or permitted under this EULA to do any of the following and shall not allow any third party to do any of the following: (i) access or attempt to access any other APOC systems, programs or data that are not made available for public use; (ii) copy, reproduce, alter, merge, modify, adapt, translate, republish, upload, post, transmit, resell or distribute in any way the Software (or the Devices) or decompile, reverse engineer, disassemble, or otherwise reduce the Software to a human perceivable form; (iii) permit any third party to benefit from the use or functionality of the Software via a rental, lease, timesharing, service bureau, or other arrangement; (iv) transfer any of the rights granted to you under this EULA; (v) work around any technical limitations in the Software, use any tool to enable features or functionalities that are otherwise disabled in the Software, or decompile, disassemble, or otherwise reverse engineer the Software except as otherwise permitted by applicable law; (vi) perform or attempt to perform any actions that would interfere with the proper working of the Software; or (vii) otherwise use the Software except as expressly allowed under this Section 2.

3. **RESERVATION OF RIGHTS AND OWNERSHIP.** The Software is licensed not sold, and APOC reserves all rights not expressly granted to you in this EULA. The Software is the proprietary and confidential property of APOC and its licensors and is protected by copyright, trade secret and other intellectual property laws. APOC and its licensors own the title, copyright, and other worldwide intellectual property rights in the Software and all copies of the Software. This EULA does not grant you any rights to trademarks or service marks of APOC.
4. **TERM AND TERMINATION.** The Software is licensed during the time that the Devices are being used by End User, subject to compliance with the terms of this EULA and the Manual (the "Term"). This EULA shall terminate automatically if you fail to comply with any of its terms or conditions, including, without limitation, if you make any attempts to copy the Software, or transfer any copy of the Software or any portion thereof to another party or any attempt to modify the Software in any way. Upon termination you must immediately cease using the Software. Any termination of this EULA shall not affect APOC's rights hereunder.
5. **PRIVACY.** For details about our privacy policies, please refer to the Privacy Policy contained at *www.globalpointofcare.abbott* ("Privacy Policy"). You agree to be bound by the Privacy Policy, as it may be amended from time to time in accordance with its terms.
6. **DISCLAIMER OF WARRANTIES.** EXCEPT AS EXPRESSLY PROVIDED HEREIN, THE SOFTWARE, SERVICES, AND ANY CONTENT ACCESSIBLE THROUGH THE SOFTWARE ARE PROVIDED "AS-IS" AND, TO THE MAXIMUM EXTENT PERMITTED BY APPLICABLE LAW, APOC, ITS AFFILIATES, LICENSORS, THIRD-PARTY CONTENT OR SERVICE PROVIDERS, DEALERS AND SUPPLIERS (IF ANY), (APOC, et al ARE COLLECTIVELY REFERRED TO HEREIN AS THE "SUPPLIERS") DISCLAIM ALL GUARANTEES AND WARRANTIES, WHETHER EXPRESS, IMPLIED OR STATUTORY, REGARDING THE SOFTWARE, SERVICES, CONTENT, AND RELATED MATERIALS, INCLUDING ANY WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE, TITLE, MERCHANTABILITY, AND NON-INFRINGEMENT. WITHOUT LIMITING THE GENERALITY OF THE FOREGOING, APOC MAKES NO WARRANTY, AND PROVIDES NO ASSURANCE, THAT THE SOFTWARE WILL MEET CERTIFICATION REQUIREMENTS OF ANY REGULATORY AUTHORITY OR OTHER ASSOCIATION LICENSING AGENCY, WITHIN OR OUTSIDE OF THE UNITED STATES. APOC DOES NOT WARRANT THAT THE SOFTWARE IS SECURE OR FREE FROM BUGS, VIRUSES, INTERRUPTION, OR ERRORS, OR THAT THE SOFTWARE WILL MEET YOUR REQUIREMENTS. APOC DOES NOT WARRANT THAT THE USE OF THE SOFTWARE WILL BE UNINTERRUPTED OR ERROR FREE. SOME STATES DO NOT ALLOW THE EXCLUSION OF IMPLIED WARRANTIES, SO THE ABOVE EXCLUSIONS MAY NOT APPLY TO YOU. IN THAT EVENT, ANY IMPLIED WARRANTIES ARE LIMITED IN DURATION TO 60 DAYS FROM THE DATE OF PURCHASE OR DELIVERY OF THE SOFTWARE, AS APPLICABLE. HOWEVER, SOME STATES DO NOT ALLOW LIMITATIONS ON HOW LONG AN IMPLIED WARRANTY LASTS, SO THE ABOVE LIMITATION MAY NOT APPLY TO YOU. THIS WARRANTY GIVES

YOU SPECIFIC LEGAL RIGHTS, AND YOU MAY HAVE OTHER RIGHTS THAT VARY FROM STATE TO STATE.

7. **LIMITATION OF LIABILITY AND DAMAGES.** THE ENTIRE CUMULATIVE LIABILITY OF APOC AND SUPPLIERS FOR ANY REASON ARISING FROM OR RELATING TO THIS EULA SHALL BE LIMITED TO FIVE HUNDRED DOLLARS OR THE AMOUNT PAID BY YOU FOR THE SOFTWARE, WHICHEVER IS LESS. TO THE MAXIMUM EXTENT PERMITTED BY APPLICABLE LAW, APOC AND SUPPLIERS SHALL NOT BE LIABLE FOR ANY INDIRECT, SPECIAL, INCIDENTAL, PUNITIVE, EXEMPLARY, OR CONSEQUENTIAL DAMAGES OR FOR ANY DAMAGES RELATING TO LOSS OF BUSINESS, TELECOMMUNICATION FAILURES, THE LOSS, CORRUPTION OR THEFT OF DATA, VIRUSES, SPYWARE, LOSS OF PROFITS OR INVESTMENT, USE OF THE SOFTWARE WITH HARDWARE OR OTHER SOFTWARE THAT DOES NOT MEET APOC'S SYSTEMS REQUIREMENTS OR THE LIKE, WHETHER BASED IN CONTRACT, TORT (INCLUDING NEGLIGENCE), PRODUCT LIABILITY OR OTHERWISE, EVEN IF APOC AND/OR ITS SUPPLIERS, OR EITHER OF THEIR REPRESENTATIVES HAVE BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES, AND EVEN IF A REMEDY SET FORTH HEREIN IS FOUND TO HAVE FAILED OF ITS ESSENTIAL PURPOSE. SOME STATES DO NOT ALLOW THE LIMITATION AND/OR EXCLUSION OF LIABILITY FOR INCIDENTAL OR CONSEQUENTIAL DAMAGES, SO THE ABOVE LIMITATION OR EXCLUSION MAY NOT APPLY TO YOU.
8. **AUDIT.** You agree that APOC may audit End User's use of the Software for compliance with these terms at any time, upon reasonable notice. In the event that such audit reveals any use of the Software by You other than in full compliance with the terms of this EULA, End User shall reimburse APOC for all reasonable expense related to such audit in addition to any other liabilities End User may incur as a result of such non-compliance.
9. **AMENDMENT.** APOC shall have the right, to change or add to the terms of this EULA at any time upon notice by any means APOC determines in its discretion to be reasonable, including posting information concerning any such change, addition, deletion, discontinuance or conditions in Software or on any APOC sponsored web site. Any use of the Software by you after APOC's publication of any such changes shall constitute your acceptance of this EULA as modified.
10. **EXPORT LAW.** The Software is subject to U.S. export control laws and may be subject to export or import regulations in other countries. Unless in compliance with applicable law and specifically authorized in writing by the APOC prior to any Software access, You shall not export the Software under any circumstances whatsoever. In any case, You will indemnify and hold the APOC harmless from any and all claims, losses, liabilities, damages, fines, penalties, costs and expenses (including reasonable attorney's fees) arising from, or relating to, any breach by You of any of Your obligations under this section.
11. **MISCELLANEOUS.** Except as expressly set forth in this EULA, this EULA is a complete statement of the EULA between you and APOC and sets forth the entire liability of APOC and Suppliers, and your exclusive remedy with respect to the Software, and its use. Suppliers and their agents, employees, distributors, and dealers are not authorized to make modifications to this EULA, or to make any additional representations, commitments, or warranties binding on APOC. The waiver by either party of a breach of any provision of this Agreement or the failure by either party to exercise any right hereunder shall not operate or be construed as a waiver of any subsequent breach of that right or as a waiver of any other right. Any waiver of the terms herein by APOC must be in a writing signed by an authorized officer of APOC and expressly referencing the applicable provisions of this EULA. If any provisions of this EULA are determined to be invalid or unenforceable under applicable law, such provision shall be ineffective to the limited extent of such invalidity or unenforceability, without rendering invalid or unenforceable the remaining provisions of this EULA. If a court of competent jurisdiction declares any such provisions to be invalid or unenforceable, the parties hereto shall request that such court reduce the scope, delete specific words or phrases from the provision, or replace the provision with a provision that is valid and enforceable and that comes

closest to expressing the original intention of the parties hereto, and this EULA shall be enforceable as so modified in the court in which the provision was declared invalid or unenforceable. This EULA will be governed by the laws of the state of Illinois as applied to agreements entered into and to be performed entirely within Illinois, without regard to its choice of law or conflicts of law principles that would require the application of law of a different jurisdiction, and applicable federal law. Neither this EULA nor any of Your rights or obligations hereunder may be assigned by You in whole or in part without the prior written approval of APOC. Any other attempted assignment shall be null and void. Headings are included for convenience only, and shall not be considered in interpreting this EULA. As used in this EULA, the word including means including but not limited to. This EULA does not limit any rights that APOC may have under trade secret, copyright, patent or other laws. The provisions of Sections 2, 5, 6, 7, 8 and 11 shall survive the termination of this EULA.

Regulatory Compliance

The i-STAT Alinity system complies with applicable regulations.

Safety Regulations:

USA	Conforms to UL Standard 61010-2-101: Safety Requirements for Electrical Equipment for Measurement, Control and Laboratory Use – Part 2-101: Particular Requirements for In Vitro Diagnostic (IVD) Medical Equipment (IEC Standard 61010-2-101) UL Standard 61010-1 Electrical Equipment for Measurement, Control and Laboratory Use – Part 1: General Requirements
Canada	Certified to CSA Standard C22.2 No. 61010-1-12: Safety Requirements for Electrical Equipment for Measurement, Control and Laboratory Use – Part 1: General Requirements Certified to CSA Standard C22.2 No. 61010-2-101: Safety Requirements for Electrical Equipment for Measurement, Control and Laboratory Use – Part 2-101: Particular Requirements for In Vitro Diagnostic (IVD) Medical Equipment
European Union (EU)	IEC 61010-1: Safety Requirements for Electrical Equipment for Measurement, Control and Laboratory Use – Part 1: General Requirements
European Union (EU)	IEC 61010-2-101: Safety Requirements for Electrical Equipment for Measurement, Control and Laboratory Use – Part 2-101: Particular Requirements for In Vitro Diagnostic (IVD) Medical Equipment
European Union (EU)	IEC 62133: Secondary cells and batteries containing alkaline or other non-acid electrolytes – Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications
International	UN Manual of Tests and Criteria “Recommendations on the Transport of Dangerous Goods,” Section 38.3 “Lithium Batteries”
International	IEC 60950-1: Information Technology Equipment–Safety–Part 1: General Requirements

EMC Regulations:

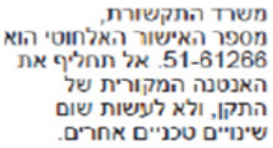
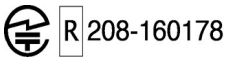
USA	FCC 47 CFR Part 15, Subpart B, Class A (Unintentional Radiators)
Canada	CAN ICES-001 Class A, Industrial, Scientific and Medical Radio Frequency Radiators
European Union (EU)	IEC 61326-1: Electrical Equipment for measurement, control and laboratory use – EMC requirements – Part 1: General requirements.
European Union (EU)	IEC 61326-2-6: Electrical Equipment for measurement, control and laboratory use – EMC requirements – Part 2-6: Particular requirements – In vitro diagnostic (IVD) medical equipment

Radio/Telecommunication Regulations:

Antigua & Barbuda	ABTD Antigua & Barbuda Telecommunications Division Type Approval Certificate Number 25-TAC2513000853
Argentina CNC **CNC ID: C-22657**	Republica Argentina – Poder Ejecutivo Nacional Type Approval C-22657
Aruba	Approved for use in accordance with article 4 of the Telecommunication Regulation. DTZ/910/2017/IZ, Pet nr. 3745
Australia	Complies with Australian Communications and Media Authority as re-quired by the following Notices: • Radiocommunications (Compliance Labelling- Devices) Notice 2014 made under section 182 of the Radiocommunications Act 1992; • Radiocommunications Labelling (Electromagnetic Compatibility) Notice 2008 made under section 182 of the Radiocommunications Act 1992; • Radiocommunications (Compliance Labelling- Electromagnetic Radiation) Notice 2014 made under section 182 of the Radiocommunications Act 1992; and • Telecommunications (Labelling Notice for Customer Equipment and Customer Cabling) Instrument 2015 made under section 407 of the Telecommunications Act 1997.
Bahamas	Utilities Regulation & Competition Authority (URCA) Type Approval UCRA_TA/2017_023 FCC ID: 2AAEX-SDABGN
Barbados	Complies with GOVERNMENT OF BARBADOS, TELECOMMUNICATIONS UNIT, Division of Energy & Telecommunications. MED Approval Number: 1905
Belize	Complies with Telecommunications Act, 2002 Type Approval per SI 152 OF 2002: PUC/APC/0182017/BZE
Bermuda	Type approval and homologation of equipment pursuant to Section 50 of The Electron Communication Act 2011 Type Approval CTYPE-01305 and CTYPE-01306
Bolivia	Autoridad de Regulación y Fiscalización de Telecomunicaciones y Transportes Type Approval ATT-DJ-RA-H-TL-LP 46/2018

Bonaire - Sint Eustatius – Saba	Agentschap Telecom, Minisceñe van Economische Zaken Complies with articles 23 and 56 of the Besluit radio-elektrischein-richtingen BES and article 2 of the Regeling vrijstellingtelecommunicatie-machtiging BES 2016 Type Approval 2017/008/AT and 2017/008a/AT
Botswana	Botswana Communications Regulatory Authority (BOCRA) Type Approval Certificate No: BOCRA/TA/2017/3642
British Virgin Islands	Telecommunications Regulatory Commission Granted Equipment Type Approval for FCC Identifier 2AAEX-SDABGN inaccordance with section 42 of the Telecommunications Act 2006. Type Approval Number: VRGTA/011/2017
Brunei	AITI Authority for Info-communications Technology Industry of Brunei Darussalam Equipment Registration Certificate DRQ-D-BRUSIN-03-1998-7494-LPD-39421
Burkina Faso	ARCEP Type Approval 2017-000031 Autorite de Regulation des Communications Electroniques et des Postes Authority of Regulations of Communications Electronic and Posts
Canada	Industry Canada RSS 210: Licence-Exempt Radio Apparatus: Category I Equipment Certification No.: 7228C-SDABGN
Cayman Islands	Utility Regulation and Competition Office GRANT OF EQUIPMENT AUTHORISATION IN THE CAYMAN ISLANDS Certificate. No: KY1504003
China	Radio Transmission Equipment Type Approval CMIIT ID: 2019AJ8315
Colombia	Communications Regulatory Commission (CRC) - Exempt
Costa Rica	Superintendencia de Telecomunicaciones approval 04979-SUTEL-DGC-2017

Curacao	Director Bureau Telecommunicatie en Post Type Approval Nos. 2017/054/TA and 2017/054a/TA
Dominica	National Telecommunications Regulatory Commission (NTRC) Type Approval No. DMA-0217-0539p
Dominican Republic	Istituto Dominicano de las Telecomunicaciones (INDOTEL) Type Approval 17003658
Ecuador	Agencia de Regulación y Control de las Telecomunicaciones approval ARCOTEL-CCDH-2018-0337-OF
Egypt	NTRA National Telecom Regulatory Authority
El Salvador	Superintendencia General de Elecricidad y Telecomunicaciones approval DBP-046-2017
Ethiopia	The Federal Democratic Republic of Ethiopia Minisitry of Innovation and Technology Type Approval 1263/2019
European Union (EU)	DIRECTIVE 2014/53/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 April 2014 EN 300 328: Wideband transmission systems; Data transmission equipment operating in the 2,4 GHz ISM band and using wide band modulation techniques; Harmonised Standard covering the essential requirements of article 3.2 of Directive 2014/53/EU.** EN 301 893: 5 GHz RLAN; Harmonised Standard covering the essential requirements of article 3.2 of Directive 2014/53/EU.**
Grenada	National Telecommunications Regulatory Commission EQUIPMENT TYPE APPROVAL NTRC REGISTRATION NUMBER: CL 1090 | 17 – TA
Honduras	CONATEL Comision Nacional De Telecomunicaciones 20161024HM32
Hong Kong	CERTIFICATE OF TYPE APPROVAL per HKCA 1039 Issue 6, June 2015
India	Ministry of Communcations & IT Equipment Type Approval, ETA Certification No: ETA – 3319/16-RLO(WR)

Israel 	Ministry of Communications Type Approval Certificate No: 51-61266
Japan 	Article 2 Section 1 No. 19, 19-3, 19-3-2 Radio Type Approval, Construction Designed Certificate No: 208-160178 当該機器には電波法に基づく、技術基準適合証明等を受けた特定無線設備を装着している。
Jordan	The Hashemite Kingdom of Jordan Telecommunications Regulatory Commission Approval TRC/LPD/2017/555
Kuwait	CITRA Communication and Information Technology Regulatory Authority Type Approval Certificate
Lebanon	Ministry of Telecommunications Approval 1031-16-041
Lesotho	Lesotho Communications Authority Lesotho Communications Authority Act 2012, Section 5
Libya	General Authority for Communications Type Approval Certificate No. 343-C1-2017
Madagascar	Autorite de Regulation des Technologies de Communication (ARTEC) No 17/026/ARTEC/DG/DHCT/SSS/test
Maldives	Communications Authority of Maldives Type Approval CAM-TAC2019-03
Mauritius	Information & Communication Technologies Authority (ICTA) Type Approval Certificate Reference Number: TA/2017/0214

Mexico	Instituto Federal de Telecomunicaciones (IFT) Certificate No: RCPISAN18-1533 Certificado de Producto Nuevo de Conformidad con Norma Oficial Mexicana Certificate No: 1802CE09991
Morocco AGREE PAR L'ANRT MAROC Numéro d'agrément : MR 12797 ANRT 2016 Date d'agrément : 11/11/2016	Numéro d'agrément : MR 12797 Date d'agrément : ANRT 2016
Mozambique	Instituto Nacional das Comunicacoes de Mocambique (INCM) Telecommunication and Radiocommunications Agreements approvedby Decree 37/2009 of 13 August No. 1/R/IMS/2017
New Zealand R-NZ	Conforms to: Ministry of Business, Innovation & Employment, Radio Spectrum Management as required by notices under: • Section 134 (1) (g) of the New Zealand Radiocommunications Act 1989
Oman	Telecommunication Regulatory Authority, Approval Number: TRA/TA-R/4501/17
Pakistan Approved by PTA 2017 PTA Pakistan Telecom Authority	Pakistan Telecommunication Authority (PTA), Type Approval Certificate TAC NO: 9.197/2017
Peru	Ministerio De Transportes Y Comunicaciones, Certificado De Homologacion, Code: TRSS39479, Report: 2158-2017-MTC/29.CGH.CH Applied Technical Standard: PNAF-R.M. No. 187-2005-MTC/03, pub. 04/03/2005 – R.M. No. 777-2005-MTC/03, pub. 11/05/2005
Philippines	National Telecommunications Commission Type Acceptance Certificate No. ESD-1714467C

Qatar	Communications Regulatory Authority Certificate of Type Approval CRA/SA/2016/R-5837
Saudi Arabia	Ministry of Communication and Information Technology (MCIT) Conformity Certificate TA 24012017-24012019-18944
Serbia 	Confirmation of Conformity – R&TTE Number P1617182700
Singapore 	Info-communications Media Development Authority Regulation 20(6) of the Telecommunications (Dealers) Regulations (Cap 323, Rg 6) Registration Number: N0123-17 (5 GHz) Registration Number: N0074-17 (2.4 GHz)
South Africa 	Independent Communications Authority of South Africa Radio Equipment Type Approval TA-2018/3846
Sri Lanka	Telecommunications Regulatory Commission of Sri Lanka, TRC/SM/ MISC/00041/17/WIFI-106
St. Lucia	National Telecommunications Regulatory Commission (Saint Lucia) Telecommunications (Terminal Equipment and Public Networks) Regulations, No. 10 or 2002 Certification of Type Approval, Certificate No.:LCT/AP17.118D
St. Maarten	Bureau of Telecommunication and Post Type Approval Certificate no 2017/018-b/TA

St. Vincent & the Grenadines	National Telecommunications Regulatory Commission Telecommunications (Terminal Equipment and Public Networks) Regulations, No. 13 of 2002 Certificate of Type Approval, Certificate No.: SVG_050520171055
Turks and Caicos	Turks and Caicos Islands Telecommunication Commission Approval Certification under TCITC Ordinance PART V
United Arab Emirates TRA REGISTERED No: ER53962/17 DEALER No: 203829	Telecommunications Regulatory Authority Telecom Equipment Registration Certificate ER53962/17 under Law No.3 of 2003
Uganda	Uganda Communications Commission Type Approved
Uruguay	Unidad Reguladora de Servicios de Comunicaciones VU20181105-015044
USA	FCC 47 CFR Part 15, Subpart C - Intentional Radiators FCC 47 CFR Part 15, Subpart E - Unlicensed National Information Infrastructure Devices FCC ID: 2AAEX-SDABGN
Vietnam ABBOTT 031280217AE01A2 ICT	Ministry of Information and Communications Type Approval Certificate No: C0031280217AE01A2

Zambia 	Zambia Information and Communications Technology Authority (ZICTA) Certificate of Type Approval ZMB/ZICTA/TA/2017/4/18 per ICT Act No. 15 of 2009
Zimbabwe	Postal & Telecommunications Regulatory Authority of Zimbabwe (POTRAZ) Certificate of Type Approval No POZ521

SAR / RF Exposure Regulations:

USA	FCC 47 CFR Part 2 Subpart J - Equipment Authorization Procedures, Section 2.1093, Radiofrequency Radiation Exposure Evaluation: Portable Devices. FCC OET-65C: Evaluating Compliance with FCC Guidelines for Human Exposure to Radiofrequency Electromagnetic Fields
Canada	Industry Canada RSS 102 Radio Standards Specification 102, Radio Frequency (RF) Exposure Compliance of Radiocommunication Apparatus (All Frequency Bands)
European Union (EU)	EN 50360: Product standard to demonstrate the compliance of mobile phones with the basic restrictions related to human exposure to electromagnetic fields (Frequency range of 300 MHz - 3 GHz) EN 62209-1: Measurement procedure for the assessment of specific absorption rate of human exposure to radio frequency fields from hand-held and body-mounted wireless communication devices - Part 1: Devices used next to the ear (Frequency range of 300 MHz to 6 GHz) EN 62209-2: Human exposure to radio frequency fields from hand-held and body-mounted wireless communication devices - Human models, instrumentation, and procedures - Part 2: Procedure to determine the specific absorption rate (SAR) for wireless communication devices used in close proximity to the human body (Frequency range of 30 MHz to 6 GHz)

Environmental Regulations:

European Union (EU)	RoHS Directive 2011/65/EU
European Union (EU)	WEEE Directive 2012/19/EU
European Union (EU)	REACH Regulation 1907/2006/EC
European Union (EU)	Packaging and Packaging Waste Directive 94/62/EC

Federal Communications Commission (FCC) Statement

(United States only)

This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to Part 15 of the Federal Communications Commission (FCC) Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment.

This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the operator's manual, can cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case you will be required to correct the interference, at your own expense.

Changes or modifications not expressly approved by the manufacturer could void your authority to operate the equipment.

Canadian Department of Communications Industry Canada Notice

(Canada only)

This Class A digital apparatus complies with Canadian ICES-001.

FCC Part 15 / Industry Canada Information:

This device complies with Part 15 Subpart C and Subpart E of FCC Rules and Industry Canada licence-exempt RSS-210 standard(s). Operation is subject to the following two conditions:

(1) This device may not cause harmful interference, and

(2) This device must accept any interference, including interference that may cause undesired operation of this device.

This product contains transmitter module:

FCC ID: 2AAEX-SDABGN

IC: 7228C-SDABGN

SAR / RF Exposure Notice:

This equipment complies with FCC/IC radiation exposure limits set forth for an uncontrolled environment and meets the FCC radio frequency (RF) Exposure Guidelines in Supplement C to OET-65 and RSS-102 of the IC (Industry Canada) radio frequency (RF) Exposure rules.

Under Industry Canada regulations, this radio transmitter may only operate using an antenna of a type and maximum (or lesser) gain approved for the transmitter by Industry Canada. To reduce potential radio interference to other users, the antenna type and its gain should be so chosen that the equivalent isotropically radiated power (e.i.r.p.) is not more than that necessary for successful communication.

This radio transmitter (identify the device by certification number, or model number if Category II) has been approved by Industry Canada to operate with the antenna types listed below with the maximum permissible gain and required antenna impedance for each antenna type indicated. Antenna types not included in this list, having a gain greater than the maximum gain indicated for that type, are strictly prohibited for use with this device.

For product available in the USA/Canada market, only channels 1-11 can be operated. Selection of other channels is not possible.

If this device is to be operated in the 5.15~5.25GHz frequency range, it is restricted to indoor environments only.

Antenna: Laird Technologies, Mini-NanoBlade

Antenna gain information: Embedded Antenna: 2.5dBi (2.4 GHz), 4.8dBi (5 GHz)

Frequency Tolerance : +/-20ppm

** See website for Declaration of Conformity for associated EMC/RED/LVD standards.

Electromagnetic Compatibility

This equipment is designed for use in a professional healthcare facility environment. This equipment is not intended for use in residential environments and may not provide adequate protection to radio reception in such environments. It is likely to perform incorrectly if used in a home healthcare environment.

It is the user's responsibility to ensure that a compatible electromagnetic environment for the equipment can be maintained in order that the device will perform as intended. The electromagnetic environment should be evaluated prior to operation of the device.

Operating the i-STAT Alinity System outside of the specified ranges may interfere with system operation. Do not use this device in proximity to sources of strong electromagnetic radiation (e.g. unshielded intentional RF sources), as these can interfere with proper operation.

Do not allow devices such as portable phones and transceivers close to the i-STAT Alinity System. In a domestic environment it may cause radio interference, in which case, you may need to take measures to mitigate the interference.

If it is suspected that performance is affected by electromagnetic interference, correct operation may be restored by increasing the distance between the equipment and the source of the interference. In the case of a loss of analyzer functionality or performance, refer to *Messages and Troubleshooting* information in Section 1.2 of this manual. Wireless specifications for the i-STAT Alinity instrument are found in Section 1.2 of this manual.

i-STAT Alinity System - Manufacturer's Declaration of Electromagnetic Compatibility (EMC)

i-STAT Alinity System – Manufacturer's Declaration of Electromagnetic Compatibility (EMC)				
Phenomenon ***(Port)***	**EMC Basic Standard**	**Test Levels IEC 61326-2-6**	**Test Levels IEC 60601-1-2**	**Compliance**
Electrostatic discharge *(Enclosure)*	IEC 61000-4-2	+/-2kV and +/-4kV contact discharge +/-2kV, +/-4kV, and +/-8kV air discharge	+/-8kV contact +/-2kV, +/-4kV, +/-8kV +/-15kV air	Complies to both standards
Radiated RF susceptibility *(Enclosure)*	IEC 61000-4-3	3V/m (80MHz to 1Ghz) 3V/m (1.4GHz to 2Ghz) 1V/m (2GHz to 2.7Ghz)	3V/m (80MHz - 2.7GHz) 80% AM at 1kHz	Complies to both standards
Power frequency magnetic field susceptibility *(Enclosure)*	IEC 61000-4-8	3 A/m (50Hz, 60Hz)	30 A/m (50Hz, 60Hz)	Complies to both standards
Proximity field from RF wireless communications equipment *(Enclosure)*	IEC 61000-4-3	Not specified.	IEC 60601-1-2 Sec. 8.10 Table 9	Complies to 60601-1-2
Voltage dip *(AC power including protective earth)*	IEC 61000-4-11	0% during 1 cycle 40% during 5/6 cycles 70% during 25/30 cycles	0% during 1 cycle 0% during 0.5 cycle (0°,45°,90°,135°,180°,225°, 270°,315°)	Complies to both standards
Short interruptions *(AC power including protective earth)*	IEC 61000-4-11	Less than 5% 250/300 cycles	0% 250/300 cycles	Complies to both standards
Burst transients *(AC power including protective earth)*	IEC 61000-4-4	1kV (5/50 ns, 5kHz)	+/-2kV (100kHz)	Complies to both standards

i-STAT Alinity System – Manufacturer's Declaration of Electromagnetic Compatibility (EMC)				
Phenomenon *(Port)*	**EMC Basic Standard**	**Test Levels IEC 61326-2-6**	**Test Levels IEC 60601-1-2**	**Compliance**
Surges *(AC power including protective earth)*	IEC 61000-4-5	1kV (line to line) 2kV (line to earth)	+/-0.5kV (line to line, line to earth) +/-1kV (line to line, line to earth) +/-2kV (line to earth)	Complies to both standards
Conducted RF *(AC power including protective earth)*	IEC 61000-4-6	3V (150kHz - 80MHz)	3V (0.15Mhz - 80MHz) 6V in ISM bands (0.15Mhz - 80MHz) 80% AM at 1kHz	Complies to both standards
Burst transients *(DC power including protective earth)*	IEC 61000-4-4	1kV (5/50 ns, 5kHz)	+/-2kV (100kHz)	Complies to both standards
Surges *(DC power including protective earth)*	IEC 61000-4-5	1kV (line to line) 2kV (line to earth)	+/-0.5kV (line to line, line to earth) +/-1kV (line to line, line to earth) +/-2kV (line to earth)	Complies to both standards
Conducted RF susceptibility *(DC power including protective earth)*	IEC 61000-4-6	3V (150kHz - 80MHz)	3V (0.15MHz - 80MHz) 6V in ISM bands (0.15MHz - 80Mhz) 80% AM at 1kHz	Complies to both standards
Burst transients *(I/O Signal/Controls)*	IEC 61000-4-4	1kV (5/50 ns, 5kHz)	+/-1kV (100kHz)	Complies to both standards
Surges *(I/O Signal/Controls)*	IEC 61000-4-5	None	+/-2kV (line to earth)	Complies to 60601-1-2
Conducted RF susceptibility *(I/O Signal/Controls)*	IEC 61000-4-6	3V (150kHz - 80MHz)	3V (0.15MHz - 80MHz) 6V in ISM bands (0.15MHz - 80MHz) 80% AM at 1kHz	Complies to both standards
Electrostatic discharge *(I/O Signal/Controls)*	IEC 61000-4-2	None	+/- 8kV contact +/-2kV, +/- 4kV, +/- 8kV air	Complies to 60601-1-2

i-STAT Alinity System – Manufacturer's Declaration of Electromagnetic Compatibility (EMC)				
Phenomenon *(Port)*	**EMC Basic Standard**	**Test Levels IEC 61326-2-6**	**Test Levels IEC 60601-1-2**	**Compliance**
Burst transients *(I/O Signal/Controls connected to mains)*	IEC 61000-4-4	1kV (5/50 ns, 5kHz)	None	Complies to 61326-2-6
Conducted RF susceptibility *(I/O Signal/Controls connected to mains)*	IEC 61000-4-6	3V (150kHz - 80MHz)	None	Complies to 61326-2-6
Proximity magnetic fields 9kHz-14.56Mhz *(Enclosure)*	IEC 60601-1-2 section 8.11	N/A	30KHz, CW, 8A/m 134.5KHz, Pulse, 65A/m 13.56MHz, Pulse, 7.5A/m	Complies to 60601-1-2
IEC CISPR Group 1 Radio frequency emission *(Enclosure)*	IEC CISPR 11 2010-05	Radiated emissions (30-1000MHz)	N/A	Complies with CISPR 11 2010-05
IEC CISPR Group 1 Radio frequency emission *(AC/DC power adaptor)*	IEC CISPR 11 2010-06	Conducted emissions (150KHz - 30MHz)	N/A	Complies with CISPR 11 2010-05
FCC: 47 CFR Part 15 subpart B Class A unintentional radiators *(AC/DC power adaptor)*	FCC: 47 CFR Part 15 subpart B Class A	Conducted emissions (150KHz - 30MHz)	N/A	Complies with FCC: 47 CFR Part 15 Class A
FCC: 47 CFR Part 15 subpart B Class A unintentional radiators *(AC/DC power adaptor)*	FCC: 47 CFR Part 15 subpart B Class A	Radiated emissions (41-2378MHz)	N/A	Complies with FCC: 47 CFR Part 15 Class A

Additional Immunity Testing to 5G FR1 and FR2 Radio Frequencies			
Phenomenon *(Port)*	**Test Purpose**	**Test Levels**	**Compliance**
Proximity field from 5G RF wireless communications equipment *(Enclosure)*	Ad hoc testing for 5G immunity	FR1, 617MHz-7100MHz, 3m, 34V/m	Complies to manufacturer's test plan.
Proximity field from 5G RF wireless communications equipment *(Enclosure)*	Ad hoc testing for 5G immunity	FR2, 24.5-40 GHz, 0.1m, 34V/m	Complies to manufacturer's test plan.

This page intentionally left blank.

Symbols

Table 1: Instrument/Power related

Symbol	Definition/Use
	Keep away from sunlight.
MN or #	Model number. The model number will appear adjacent to this symbol.
	Printer
	Humidity limitation
	On/Off
	Direct current (DC)
	Alternating current (AC)
Rx ONLY	For prescription use only.
i-STAT Alinity ONLY	For use with the i-STAT Alinity Instrument only.
	Battery status - fully charged
	Battery status - approximately ½ charged
	Battery status - charge needed soon
	Battery status - charge immediately
	Battery actively charging
	Indicates battery actively charging

Symbol	Definition/Use
	Software update is available.

Table 2: Alert Icons

Symbol	Definition/Use
	Pass
	Fail
	Warning
	Instrument locked
	Information
	Low battery

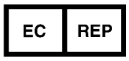
Table 3: Wireless Network Status

Symbol	Definition/Use
	Best
	Very good
	Good
	Fair
	Poor
	No Connection
	Wireless disabled
	Wireless connecting

Table 4: Wired Network Status

Symbol	Definition/Use
	Connected
	Disabled

Table 5: Regulatory and Safety Related; Miscellaneous

Symbol	Definition/Use
	Authorized representative for Regulatory Affairs in the European Community.
	Biological risks
	Temperature limitations. The upper and lower limits for storage are adjacent to upper and lower arms.
	Serial number. The serial number will appear adjacent to this symbol.
	Catalog number, list number, or reference number. The number adjacent to this symbol is used to reorder the product.
	USB
	Do not reuse.
	Date of manufacture
	Manufacturer
	Consult instructions for use or see System Operations Manual for instructions.
	Note the following information.
	*In vitro* diagnostic medical device
	A mark that indicates conformity to the legal requirements of the appropriate European Union (EU) Directive(s) with respect to safety, health, environment and consumer protection.
	Signifies that the product bearing the ETL Listed mark complies with both U.S.and Canadian product safety standards: UL 61010-1:2012 3rd Ed. +R:19Jul2019 CSA C22.2 No. 61010-1-12:2012 3rd Ed. +U1;U2;A1 UL 61010-2-101:2019 3rd Ed. CSA C22.2 No. 61010-2-101:2019 3rd Ed.
	Electrical hazard
	Attention: See instructions for use.

Symbol	Definition/Use
	**CAUTION**: Indicates a hazardous situation, which if not avoided, could result in minor or moderate injury or damage to the equipment.
	**WARNING**: Indicates a biological hazard, which if not avoided, could result in serious injury or death.
	Separate waste collection for this electrical/electronic item indicated; Equipment manufactured / put on the market after 13 August 2005; Indicates compliance with Article 10(3) of Directive 2002/96/EC (WEEE) for the European Union (EU).
	14 days room temperature storage at 18-30° C
	2 months room temperature storage at 18-30° C
	Use by or expiration date. An expiration date expressed as YYYY-MM-DD means the last day the product can be used. An expiration date expressed as YYYY-MM means the product cannot be used past the last day of the month specified.
	Manufacturer's lot number or batch code. The lot number or batch will appear adjacent to this symbol.
	Importer in the European Community.
	Class II Construction.
	Signifies that the product bearing the Federal Communications Commission (FCC) logo complies with the specific requirements set forth by the FCC under Rules and Regulations, Title 47, Part 15 Subpart B, for Class A devices.
	The near-patient testing symbol illustrates that a device can only be used in a near-patient setting by a health worker, professional or trainee.

Table 6: Control related

Symbol	Definition/Use
CONTROL	Control

Table 7: For use on i-STAT Value Assignment Sheets

Symbol	Definition/Use
$\bar{x}$	Mean
R	Range

Table 8: Analytes

Symbol	Test
ACT	Activated Clotting Time
ACT-K	Activated Clotting Time with Kaolin activator
Na	Sodium
K	Potassium
Cl	Chloride
Glu	Glucose
Lac	Lactate
Crea	Creatinine
pH	pH
$\boldsymbol{P}CO_2$	Partial Pressure of Carbon Dioxide.
$\boldsymbol{P}O_2$	Partial Pressure of Oxygen.
iCa	Ionized Calcium
BUN/UREA	Urea nitrogen/Urea
Hct	Hematocrit
Hb	Hemoglobin
TCO_2	Total Carbon Dioxide Concentration.
HCO3	Bicarbonate
BE (b&ecf)	Base excess (b for blood, ecf for extracellular fluid)
AnGap	Anion Gap
sO_2	Oxygen saturation
eGFR	Estimated Glomerular Filtration Rate
eGFR-a	Black/African-American Estimated Glomerular Filtration Rate
GFAP	Glial Fibrillary Acidic Protein
UCH-L1	Ubiquitin Carboxy-terminal Hydrolase L1
cTnI (hs-TnI)	Cardiac Troponin I (High Sensitivity Troponin I)

Table 9: Terminology

Term or Acronym	Definition
AlinIQ CWi	Customization Workspace for i-STAT
AlinIQ NCi	Network Connectivity for i-STAT
APOC	Abbott Point of Care
CLEW	Standardization software
CONT.	Continued
eVAS	Electronic Value Assignment Sheet
GSG	Getting Started Guide
IFU	Instructions for Use
IR	Infrared Radiation
LED	Light Emitting Diode
MQSI	Manufacturer's Quality System Instructions
OSi	Instrument Software
PC	Personal Computer
POC	Point of Care
QC	Quality Control
QCC	Quality Check Code
QCF	Quality Check Failure
QRG	Quick Reference Guide
R-VAS	Rilibak Value Assignment Sheet
ReVAS	Rilibak Electronic Value Assignment Sheet
SU	Software Update
TBI	Traumatic Brain Injury
USB	Universal Serial Bus
VAS	Value Assignment Sheet

Definitions and Terminology

This section defines many of the terms and acronyms used in this guide.

Term or Acronym	Definition
Action Range	Results within the range that require immediate attention; also known as critical range.
Action Range Comment	Customized comment list or free text box displayed when results are in the action range.
ADT	Admit-Discharge-Transfer ADT messages contain patient demographic information.
AlinIQ SDi	AlinIQ Software Delivery for i-STAT Alinity (SDi): a browser-based software application that enables healthcare professionals to manage delivery of files to i-STAT Alinity instruments including software, eVAS, and customization profiles. For information on the purchase, download, or use of the AlinIQ SDi software, please visit *http://www.globalpointofcare.abbott* or contact your local Abbott Point of Care representative.
Analyte	Substance or chemical constituent that is measured during the testing cycle. Analytes are listed on the cartridge pouch. Not all analytes are measured--some are calculated using the measured results of other analytes.
Analyte Settings	Group of features used to define the behavior of an instrument. Selections made in this setting group are considered basic and common to most instruments within a healthcare organization. It is also possible to make selections that are applicable to an entire healthcare organization. This is one of five categories that is required to build a profile.
Assigned	Category applied to a profile or a profile applied to an instrument
Base Station	Component of the i-STAT Alinity system whose primary function is to recharge the battery attached to an instrument. Optional functionality includes providing wired communication, wired connection to the i-STAT Alinity printer and USB connection to the instrument.
BSSID	Basic Service Set Identifier
CA	Certificate Authority
Cartridge Lot Number List	Cartridge lot number list managed within the customer's data management program for i-STAT Alinity
Cartridge Type	Name used to identify a cartridge, for example, CHEM8+, G3+, etc.

Term or Acronym	Definition
Categories	Features to define the behavior of an i-STAT Alinity instrument. Manage and Assemble Profiles section of AlinIQ CWi has ten categories, five required categories and five optional categories. A collection of categories creates a profile for the i-STAT Alinity.
CCMP	Counter Mode with Cipher Block Chaining Message Authentication Code Protocol wireless authentication type
Change (edit)	To make different. Only unassigned categories or profiles may be changed.
CLEW	Standardization software
Collapse All	Compress the view of the hierarchy to display only the roots of each Profile or Category on the Summary.
Connectivity Map	Programming data required to connect another system to the i-STAT Alinity
Connectivity Settings	Group of features used to define the behavior of an instrument. Selections made in this setting group are names, IP addresses and ports of other systems with which the i-STAT Alinity is to communicate information.
CPB	Cardiopulmonary Bypass Surgery Setting. The CPB function adjusts hematocrit and hemoglobin results for the dilutional effect of pump fluid during cardiopulmonary bypass surgery.
Create from Existing	Using a previously created category or profile to create a new one.
CTI	Cartridge and Test Information
Cutoff	An analyte test result threshold value at which a test result is flagged for action. A Cutoff is used to help interpret a test result and can be either a type: - 'Warning' = Test result value at or above the cutoff (up arrow and highlighted yellow) - 'Critical' = Test result value above the cutoff (up arrow and highlighted red)
CWi	Customization Workspace for i-STAT
Data Entry	To enter data using the keypad or by scanning
Delivery System	Method used to deliver oxygen to a patient
DHCP	Dynamic Host Configuration Protocol
Discard	To delete settings prior to publishing
DNS	Domain Name System
Draft	Unfinished settings that can be saved and completed later
EAP	Extensible Authentication Protocol wireless authentication type
eVAS	Electronic Value Assignment Sheet
Expand All	Extension of the view of the hierarchy to display details of the profile or category on the summary.
Features	Options or settings that control the behavior of the i-STAT Alinity instrument
Finish Later	Save the settings defined as a Draft

Term or Acronym	Definition
General Settings	Group of features used to define the behavior of an instrument. Selections made in this setting group are basic and common to most instruments within a healthcare organization. It is also possible to make selections that are applicable to an entire healthcare organization. This is one of five categories that is required to build a profile.
HCO	Healthcare Organization
HIS	Hospital Information System
HTTP	Hypertext Transfer Protocol
IFU	Instructions for Use
Instrument	i-STAT Alinity instrument
IP	Internet Protocol
IP Address	Internet Protocol Address. Identifier for a computer or device
K2EDTA or K3EDTA Setting	Anticoagulant used by the manufacturer of the Laboratory Hematology Instrument to calibrate. For best agreement of i-STAT and hematology analyzer hematocrit results, the i-STAT customization setting is selected according to the calibration of the comparative hematology analyzer (MH-K_2EDTA or MH-K_3EDTA). Note: This setting is not determined by the purple top tube used for patient testing in the laboratory.
LIS	Laboratory Information System
MAC	Media Access Control
Manage Items	Items get responses. An item is an on-screen prompt that requires a response by the operator. Items are grouped together in sets. Sets are assigned to a cartridge type (for example, EG7+, CHEM8+). When cartridge testing is performed, the defined set of items will be displayed, prompting the operator to enter the information.
Manage Sets	Sets are collections of items grouped together and assigned to cartridge types (for example, EG7+, CHEM8+). When a cartridge type is tested, the defined set of items will be displayed, prompting the operator to enter the information.
Mode	Ventilator mode for delivery of oxygen
MSCHAPv2	Microsoft Challenge Handshake Authentication Protocol, Version 2
NC	Network Configuration
Network Port	Part of the system connection that uses a Network Port number to send or receive service request from a client
Observations	Connectivity mapping for test records. Area for entering IP address and network port for the POC data manager.

Term or Acronym	Definition
Operator List	List of certified operators. Cannot be enabled unless a POC data management system or any other system that certifies operators and sets operator permissions is being used.
Operator Settings	Group of features used to define the behavior of an instrument. Selections made in this setting group are considered basic and common to most instruments within a healthcare organization. It is also possible to make selections that are applicable to an entire healthcare organization. This is one of five categories that is required to build a profile.
Patient List	List of registered patients in a healthcare organization. Cannot be enabled unless an Admissions, Discharges, and Transfers (ADT) feed is being used.
Patient Settings	Group of features used to define the behavior of an instrument. Selections made in this setting group are considered basic and common to most instruments within an HCO. It is also possible to make selections that are applicable to an entire HCO. This is one of five categories that is required to build a profile.
Patient Temperature	Patient's temperature during the time of testing. The temperature entered here will be used to calculate patient temperature-adjusted blood gas results.
PEAPv0	Protected Extensible Authentication Protocol, Version 0
PPID	Positive Patient Identification
Profile	There are five required categories: General, Patient, Operator, Analyte and Quality Settings. The remaining five are optional. Profiles are assigned to an instrument through USB. See instructions in the Manage and Assemble Profiles section of this document.
PSK	Pre-Shared Key wireless authentication type
Publish	To make available for use after settings are defined
QC	Quality Control
QC Auto Fail Comment	Option to prompt an operator to enter a comment when QC results are out of range when using QC pass/fail using eVAS
QCF	Quality Check Failure
Quality Settings	Group of features used to define the behavior of an instrument. Consider basing quality settings on the number of instruments in a department requiring QC at the same time. Department specific quality control plans may be defined using IQCP guidelines. This is one of five categories that is required to build a profile.
Ranges	Healthcare organization-defined ranges for reference, action and reportable.

Term or Acronym	Definition
Repeat Test	Option to prompt an operator to repeat a test
Result Notes	Prompts displayed on the screen after results are displayed. Designed to be used if post-analytical actions or comments are needed. They can be mandatory or optional. The notes will be transmitted along with the results to the data manager.
ReVAS	Electronic Value Assignment Sheet for customers in Germany.
Reviewer Name	Healthcare organization-designated connectivity manager for the defined vendor. Found in the Connectivity Settings category. This is a required response.
Selection List or Text Box	User-created list of responses.
SN	Serial Number
SSID	Service Set Identifier
STATNotes	Prompts displayed on the screen during the test cycle. Designed to provide information about the patient's status at the time of testing. STATNotes are used primarily, though not exclusively, for the recording of ventilator parameters. They can be mandatory or optional. The STATNotes will be transmitted along with the results to the data manager.
Summary	Display of all details within a Profile or Category
TKIP	Temporal Key Integrity Protocol wireless network authentication type
TLS	Transport Layer Security
Training Settings	Group of settings used to create the screens that display during a training event.
TTLS	Tunneled Transport Layer Security
UDP	User Datagram Protocol
Units	Standard of measurement for an analyte
USB	Universal Serial Bus
User Defined Message	Message created to display on the instrument before any selections are made.
User Role	There are 3 user roles in the CWi. The roles define what CWi privileges each user has.

Term or Acronym	Definition
User Role-Healthcare Organization Manager-Primary	User with permissions to access all functions of the CWi during the initial setup and creation of other CWi users. Healthcare Organization Manager Primary is the only role that can assign additional healthcare organization managers. This is also the contact person if Abbott Point of Care should need to contact the healthcare organization. It is imperative that this role be updated if this individual needs to be changed. Changing this role requires contacting Abbott Point of Care technical support.
User Role-Healthcare Organization Manager	User who has the permission to access all functions of the CWi, but is limited to creating user roles of Point of Care Coordinator or Point of Care Super User.
User Role-POCC	User who has the permission to access all functions of the CWi, but is limited to creating user role of Point of Care Super User.
User Role-Point of Care Super User	User with view-only permission for functions of the CWi.
Vendor Name	Name of the provider that supplies the information in the connectivity map. For example, RALs, ConWorx, Cerner. It is a required field.
View	To look at an existing setting, in read-only format
WPA	Wi-Fi Protected Access wireless network authentication type
WPA2	Wi-Fi Protected Access II wireless network authentication type

i-STAT Alinity Reference

Abbott

This page intentionally left blank.

1.1 - Complete i-STAT Alinity System Overview

The i-STAT Alinity instrument is an analytical, in vitro diagnostic device. The instrument requires i-STAT single-use cartridges containing electrodes and sensors to perform quantitative diagnostic testing on whole blood or plasma. Together, the instrument and cartridge allow the user to perform clinical testing and related administrative tasks.

The i-STAT Alinity design enables the instrument to be taken to the patient's bedside (point of care), a convenient location near the point of care, or clinical laboratory setting.

After the insertion of a filled test cartridge, the instrument carefully monitors and controls the testing process. The only user intervention is in the form of data entry, performed via the touchscreen or by barcode capture. Throughout the cycle, the instrument performs a series of quality checks. These checks are designed to monitor the status of the instrument and the quality of the cartridge. An i-STAT Alinity instrument, a cartridge with the required test, and two or three drops of blood will allow the caregiver to view quantitative test results within minutes.

For the purposes of this system operations manual, the i-STAT Alinity system components and associated accessories will be discussed. Additional information related to the entire system can be found in the i-STAT Alinity system documentation listed below.

Note: Note Regarding System Reliability: The i-STAT System automatically runs a comprehensive set of quality checks of analyzer and cartridge performance each time a sample is tested. This internal quality system will suppress results if the analyzer or cartridge does not meet certain internal specifications (see Quality Control section in System Operations Manual for detailed information). To minimize the probabilty of delivering a result with medically significant error, the internal specifications are very stringent. It is typical for the system to suppress a very small percentage of results in normal operation given the stringency of these specifications. If however, the analyzer or cartridges have been compromised, results may be persistently suppressed, and one or the other must be replaced to restore normal operating conditions. **Where unavailability of results while awaiting replacement of analyzers or cartridges is unacceptable, APOC recommends maintaining both a back up i-STAT System instrument and cartridges from an alternate lot number.**

i-STAT Alinity Documentation:

- *i-STAT Alinity System Operations Manual, including:*
  - *i-STAT Alinity Reference*
  - *i-STAT Cartridge Instructions for Use*
  - *AlinIQ NCi - Network Connectivity for i-STAT Alinity*
  - *AlinIQ CWi - Customization Workspace for i-STAT Alinity*
- *i-STAT Alinity Quick Reference Guide*
- *i-STAT Alinity Getting Started Guides*:
  - *i-STAT Alinity Base Station*
  - *i-STAT Alinity Rechargeable Battery*
  - *i-STAT Alinity Electronic Simulator*
  - *i-STAT Alinity Printer*

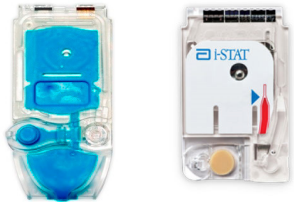
i-STAT Alinity system:

- i-STAT Alinity Instrument
- i-STAT Alinity Base Station
- i-STAT Alinity Rechargeable Battery
- i-STAT Alinity Electronic Simulator
- i-STAT Alinity Printer
- AlinIQ NCi
- AlinIQ CWi
- i-STAT Cartridge
- Liquid Quality Controls and Calibration Verification Solutions

Note: Not all cartridges are available in all regions. Check with your local representative for availability in specific markets.

Note that the component representations shown in the table are not drawn to scale.

i-STAT Alinity System Components	
	**i-STAT Alinity Instrument** Portable, ergonomically designed handheld analytical instrument used to perform in vitro diagnostic testing with the use of i-STAT cartridges.
	**Base Station** Provides recharging, printing, and network connectivity capabilities to the instrument.

i-STAT Alinity System Components	
	**Rechargeable Battery** This Lithium-Ion rechargeable single cell battery is the primary source of power for the instrument. Power levels and charging status are indicated on the screen of the instrument.
	**Cartridges** i-STAT cartridges contain test reagents which are located on sensors on the top of the cartridge. The instrument and cartridge work together to generate a clinically meaningful result.
	**Printer** Provides the ability to print all results (patient tests, quality control, etc.) generated by the i-STAT Alinity.
	**Electronic Simulator** Provides an independent check on the instrument's ability to take accurate and sensitive measurements of voltage, current and resistance from the cartridge.

This page intentionally left blank.

1.2 - i-STAT Alinity Instrument

Intended Use

The i-STAT Alinity instrument is intended for use in the *in vitro* quantification of various analytes in whole blood or plasma in point of care or clinical laboratory settings.

Instrument and cartridges should be used by healthcare professionals trained and certified to use the system and should be used according to the facility's policies and procedures.

Note: Consult the IFU/CTI for details on specific sample types for the cartridge.

For *in vitro* diagnostic use.

Note: Not all cartridges are available in all regions. Check with your local representative for availability in specific markets.

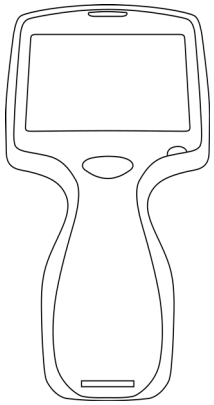
Note: To configure the instrument's printing method, refer to the i-STAT Alinity Printer *Principles of Operation*

Verify the instrument for cartridge testing

Note: Verification is only required once per cartridge type per instrument.

Prior to using an instrument requiring a specific cartridge type, verify the instrument supports the cartridge:

1. Initiate a liquid quality control test per the instructions in *Liquid Quality Controls* of the *System Operations Manual*.
2. Ensure the instrument can successfully scan the cartridge pouch barcode.
3. If the cartridge is not recognized, contact your local representative.



Principles of Operation

The i-STAT Alinity instrument is an analytical, in vitro diagnostic device. The design enables it to be taken to the patient's bedside (point of care), a convenient location near the point of care or clinical laboratory setting. The instrument requires i-STAT single-use cartridges containing sensors to perform quantitative diagnostic testing. After the insertion of a filled test cartridge, the instrument carefully monitors and controls the testing process. The only user intervention is in the form of data entry. Data entry is performed via the touchscreen or by barcode capture. Throughout the cycle, the instrument performs a series of quality checks. These checks are designed to monitor the status of the instrument and the quality of the cartridge. The instrument and cartridge together allow the user to perform clinical testing and administrative tasks related to in vitro quantification of various analytes in a sample.

The i-STAT Alinity instrument includes the following subsystems:

- analytical measurement module: interfaces with the i-STAT single-use test cartridges and controls execution of the measurement test cycle
- user module: a central computing unit with embedded firmware that controls the user interaction with the device and supports communication with outside peripherals
- user interface: allows data input, display of information, audio and visual alerts
- rechargeable battery

Analytical Measurement Module

The core measurement technology of the i-STAT Alinity system is in the micro-fabricated electro-chemical sensors located in the i-STAT single-use disposable cartridges. As a result, the measurement technology used by the instrument and the principles governing operations associated with the generation of test results remain unchanged from the existing on-market i-STAT instruments.

These fully automated dedicated microprocessor controlled operations include:

- Motion control of the fluid via mechanical actuators
- Thermal control of the sensors during the test cycle
- Acquisition of sensor electrical signals (voltage, current or resistance) throughout the test cycle, as well as environmental parameters like temperature and pressure
- Timing and sequence of measurement events
- Signal processing and conversion of sensor and environmental signals into analytical test results
- Instrument self-tests and cartridge quality checks to prevent the delivery of an incorrect result in case of an instrument malfunction or if a cartridge or pre-analytical error is detected

User Module

The i-STAT Alinity instrument is equipped with a dedicated microprocessor to control user interaction with the device, synchronization of the test cycle with the user interface, and communication. The combination of the hardware microprocessor with peripherals and RTOS (Real Time Operating System) offer essential features for control of the instrument.

Operations controlled by the combination of the microprocessor and RTOS include:

- low power audio processor with built-in speakers
- display and navigation of instrument screens
- networking applications

- CMOS-based area array with LED aiming and illumination barcode module:
  - module allows convenient data entry in linear as well as 2D barcode symbology
  - image based barcode scanner does not require precise orientation alignment of the target and the instrument, making scanning much more user friendly
  - image of the barcode is displayed on the LCD screen during the scanning operation to further aid the user and to make scanning easier

User Interface

i-STAT Alinity is designed to maximize the user experience. The design of the user interface was guided by Human Factors Engineering principles.

Both the size and resolution of the display have been increased to improve readability. The instrument employs a five inch diagonal backlit LCD in landscape orientation.

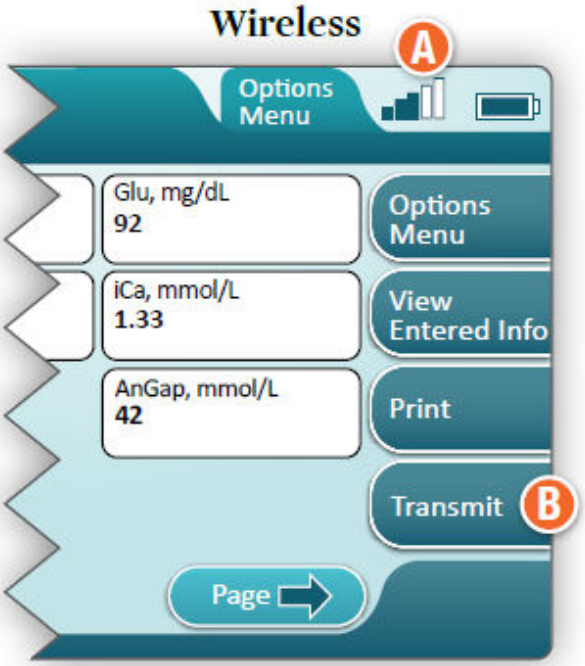
The keypad was implemented with a resistive touchscreen, enabling a user wearing multilayer surgical gloves to perform data entry. A full QWERTY and numeric touchscreen keyboard enhances the informational content that can be entered and stored with a test.

i-STAT Alinity is equipped with a 1D/2D barcode scanner.

i-STAT Alinity features several connectivity options. The instrument contains dual band (2.4GHz, 5GHz) IEEE802.11 a/b/g/n wireless module. Connectivity to the i-STAT Alinity portable printer is available via infrared communication or through wired connection to the printer employing the Base Station.

Determine transmission method:

Wireless

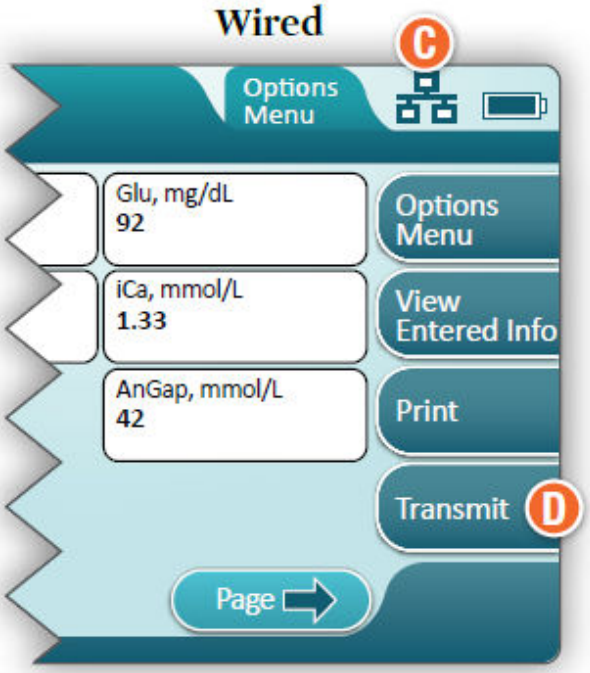


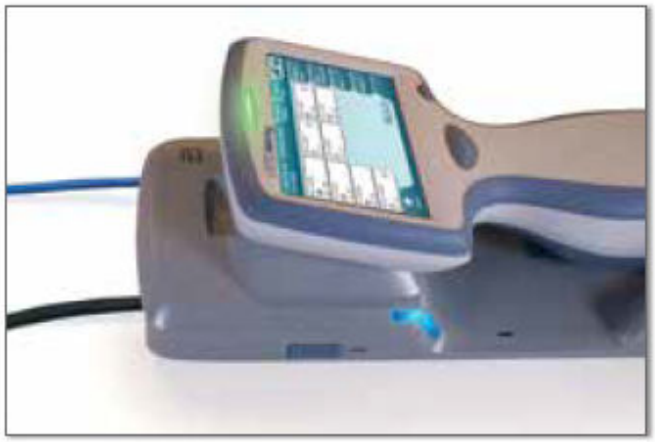
A A signal strength of 3 bars or higher is recommended

B To initiate transmission, touch Transmit

OR

Wired





C Symbol indicates instrument is connected to the network

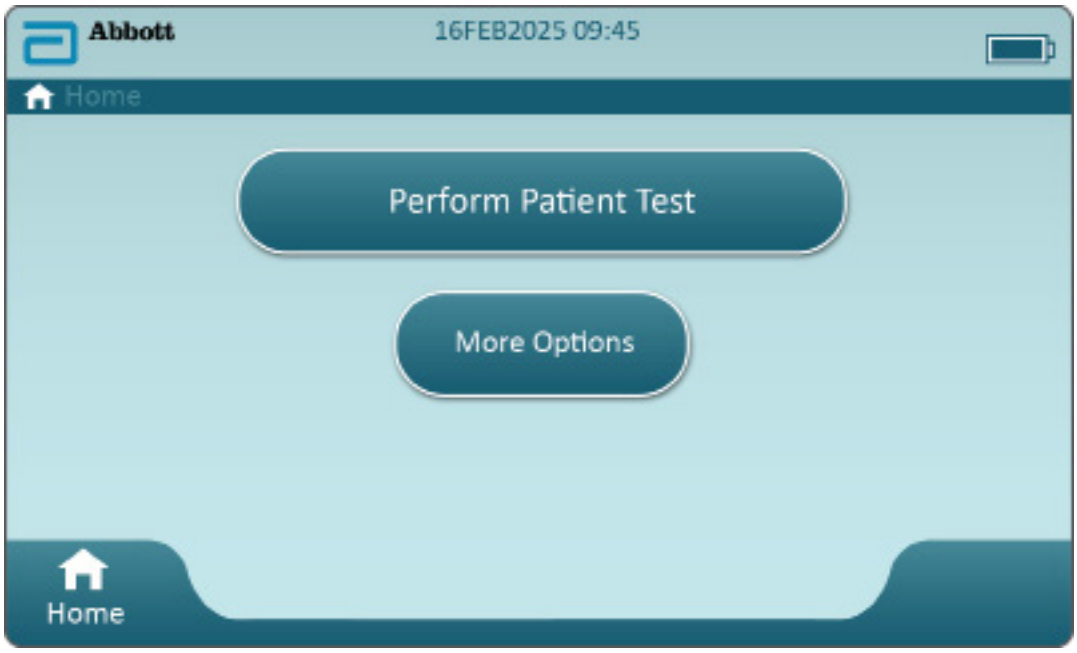
D To initiate transmission, touch Transmit

Rechargeable Battery

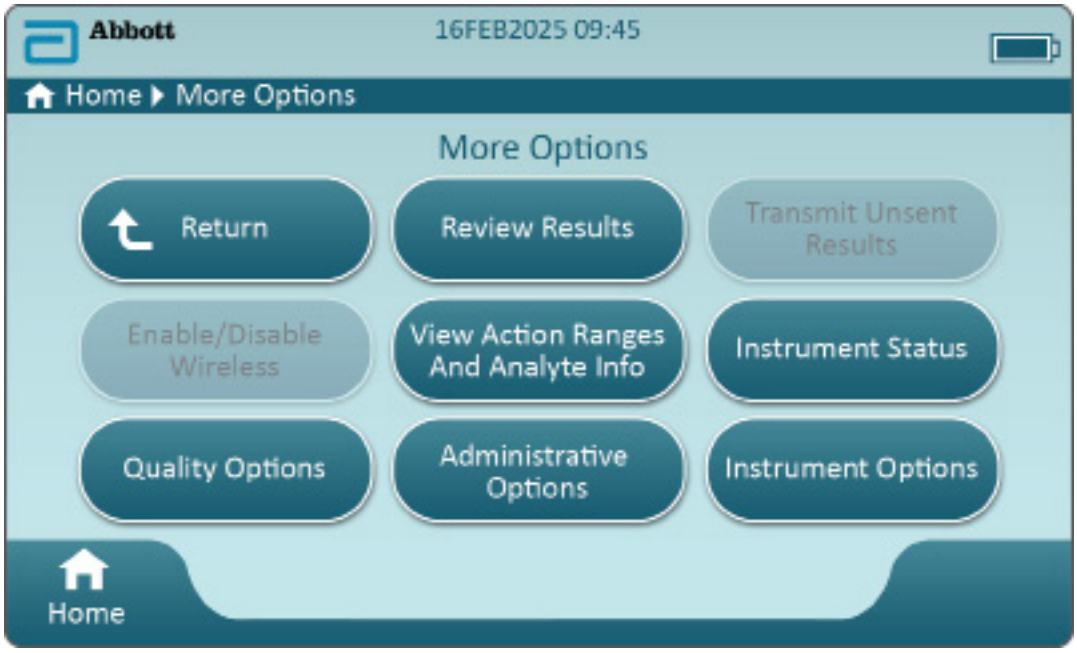
The i-STAT Alinity instrument is powered by a Lithium-Ion rechargeable battery pack which includes the battery cell as well as the charging and fuel gauge electronics. The rechargeable battery pack is directly attached to the bottom of the instrument. The battery pack and Base Station design allows the battery to be charged without detaching it from the instrument. The fuel gauge in the battery pack accurately measures the battery capacity while also providing protection against short circuit, over-current and over-voltage.

More Options

This section describes the selections and information found behind the **More Options** button.



From the **Home Screen** touch **More Options** and this screen displays:



Note:

- A button that is greyed out (light blue button with grey text) indicates that it is either inactive or has no data behind it.
- Data Management system controls permission levels of operators. Many of the selections below will be protected if permission levels are set. If they are not, all selections will be open to all operators. In this case, facility policy should outline what users are allowed to access what functions under **More Options**. If permission levels are set via Data Management, at least one operator must have permission level of Key Operator or Supervisor.

The next section of this document will describe the buttons and options for each. Breadcrumb trail on the instrument screen will help with navigation.

Review Results			
	Last Result	Displays data from the last test performed, cartridge or electronic simulator.	
	Patient Result	Review results based on the following selections:	
		All Patient Results	
		Patient Results by ID	
		Rejected Patient Results	Instrument must be customized to allow for rejection of cartridge results.
	Quality Results	Review results based on the following selections:	
		Quality Control Results	
		Cal/Ver Results	
		Simulator Results	
		Proficiency Results	
		Quality Check Code Results	
		Star-Out Results	
	Canceled Results	Instrument must be customized to allow for the cancelling of a test.	
	All Results	Display of all results on instrument regardless of testing pathway.	

Transmit Unsent Results	
	Force the transmission of all results in the instrument. Instrument must be customized to transmit results via wired or wireless transmission.

Enable/Disable Wireless		
	Enabled	Instrument must be configured for wireless transmission by using the NCi utility. When the instrument is configured, this button will become active and enable is the default.
	Disable	Prevents instrument from communicating via wireless transmission.

View Action Ranges and Analyte Info	
	An individual button is displayed for each analyte available for the i-STAT Alinity system. Those buttons greyed out require activation via a customization profile or are not available at this time. Shown with the analyte is the unit of measure. Units of measure may be modified via a customization profile or on the instrument via **More Options** > **Instrument Options** > **Instrument Settings** > **Set Units**
	Touching an active analyte button displays a second page of information: **Measurement range - Default** is displayed unless a new range is set via a customization profile. **Critical Test - Default** of no will be displayed unless modified via a customization profile.
	Touching the **View Reference Range** button will reveal the ranges set for this analyte via a customization profile. **Note:** No ranges are the default.
	Touching **View Action (Critical) Ranges** will reveal the ranges set for this analyte via a customization profile. **Note:** No ranges are the default.

Instrument Status:	
	Important information such as firmware version, barometric pressure and profile name are listed here.

Quality Options: Quality Control		
	Perform Unscheduled QC	When liquid QC testing is not scheduled via a customization profile or if an additional liquid QC testing event is desired, this is the testing pathway. Follow the prompts on the screen to perform testing.
	Scheduled QC	If liquid QC testing has been set via a customization profile, this is the testing pathway. Follow the prompts on the screen to perform testing.
	Perform Cartridge QC	This feature allows liquid control testing to release cartridges, based on lot number, for patient or proficiency testing. This method of QC testing must be set up via a customization profile as well as activation in the data management system.

Quality Options: Quality Control		
	Perform Electronic Simulator Test	Follow the prompts to perform testing.

Quality Options: Cal Ver		
	Perform Unscheduled Cal Ver	When calibration verification testing is not scheduled via a customization profile or if an additional cal/ver testing event is desired, this is the testing pathway. Follow the prompts on the screen to perform testing
	Scheduled Cal Ver	If calibration verification testing has been set via a customization profile, this is the testing pathway. Follow the prompts on the screen to perform testing.

Quality Options		
	Perform Proficiency Test	Follow the prompts on the screen to perform testing.
	Update eVAS	**Install from USB** - Follow prompts on the screen to install instrument software. **Note:** Some preformatted USB flash drives may not work with the Alinity system. To avoid issues, reformat the drive using a Windows PC before using the USB flash drive with the Alinity system. If the instrument does not detect the base station, try the following: • remove the instrument and re-seat it on the Base Station • check to ensure that the Base Station is getting power (blue light illuminated) If the instrument does not detect the USB drive, try the following: • remove the USB and reinsert • ensure that the USB is formatted **Install from Server**
	View Disabled Cartridges	Cartridges are disabled due to expired QC.

Administrative Options: Operator Management		
	Enable/Disable Training Mode	Enabling allows for operator to enter instrument training mode. Testing pathway screens in training mode are the same as those found in normal operation except for the purple frame around each screen. Although customization is not required for training mode use, there are many additional functions that can be added through customization.
	View Observation Checklist	This function requires creating a customization profile that includes a facility specific list of observable skills. Trainer may use the list to observe a trainee complete listed skills
	Operator Event Log	Reserved for future use.

Administrative Options: Profile Management		
	Install Profile from USB	Follow prompts on the screen to install instrument software. If the instrument does not detect the Base Station, try the following: • remove the instrument and re-seat it on the Base Station • check to ensure that the Base Station is getting power (bluelight illuminated) If the instrument does not detect the USB drive, try the following: • remove the USB and reinsert • make sure the USB is formatted.
	Install Profile from Server	Reserved for future use.
	Delete Profile	Follow prompts on screen to delete the customization profile installed on instrument.
	Profile Status	List of information regarding customization profile loaded on instrument.

Administrative Options: Test Record Management		
	Review Test Record	Functions as a review results Last Result Patient Results Quality Results Canceled Results All results
	Review Training Records	View tests performed while in the training mode.
	Transmit Records	Select the range of records to be transmitted.
	Delete Records	Select the range of records to be deleted.
	Test Record Status	List of information regarding test records stored on instrument.

Administrative Options: List Management		
	Update All Lists	Function used to update patient, operator and cartridge lot list. A customization profile enabling lists must be in use on the instrument.
	Delete Lists	Displays lists to be deleted. Choose list(s) and follow prompts on the screen to complete.
	List Status	Displays information pertaining to patient, operator and cartridge lot list.

Instrument Options		
	Synchronize All	Initiate communications with data management system and Abbott Managed Server to synchronize lists (operator, patient, cartridge) and eVAS/ ReVAS (Germany only) that are enabled on the instrument.
	Software Installation	**Install from USB** - Follow prompts on the screen to install instrument software. If the instrument does not detect the Base Station, try the following: • remove the instrument and re-seat it on the Base Station • check to ensure that the Base Station is getting power (bluelight illuminated). If the instrument does not detect the USB drive, try the following: • remove the USB and reinsert • make sure the USB is formatted (as display message indicates).
		Install Pending - Instruct instrument to install software update.
		Check for Update - When Abbott Managed Server connectivity is set up on the instrument, touching this button causes the instrument to check for new software. If a new version of software is available, the update will automatically start downloading onto the instrument. See *Software* *Updates* section of this manual for complete details for downloading and installing software via the Abbott Managed Server.

Instrument Options		
		Software Status - List of information associated with software and eVAS.

Instrument Options: Instrument Settings		
	Follow prompts on screen to:	
	Set Language	**Note:** When choosing a language that includes diacritical marks in its alphabet, the keypad's appearance will change. See the section *Keypad changes forlanguages using diacritical marks* for details.
	Set Clock	**Note:** When the instrument is configured to communicate with a data manager, the instrument will automatically synchronize its date and time with the data manager's time. See the section *Instrument Clock Date/Time Synchronization* for details.
	Set Units	
	Set Date Format	

Instrument Options: Network Settings		
	Install Network Settings	Follow prompts on screen to install network settings from a USB stick. The NCi utility is used to create the ancc file that will be installed via the USB stick. **Note:** Some preformatted USB flash drives may not work with the Alinity system. To avoid issues, reformat the drive using a Windows PC before using the USB flashdrive with the Alinity system. If the instrument does not detect the Base Station, try the following: • remove the instrument and re-seat it on the Base Station • check to ensure that the Base Station is getting power (bluelight illuminated). If the instrument does not detect the USB drive, try the following: • remove the USB and reinsert • make sure the USB is formatted.

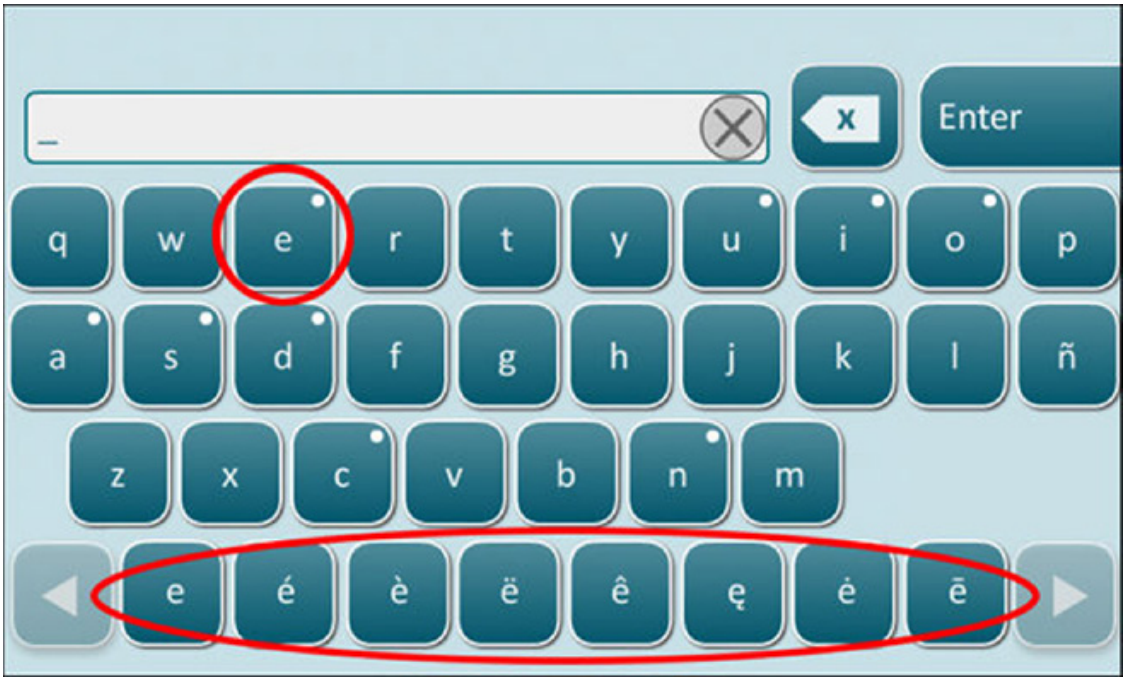
Instrument Options: Network Settings		
	Network Services	To enable retrieving instrument software updates and/or eVAS- from Abbott Point of Care, select **Abbott Managed Server**. Then follow the prompts on the screen to enable/disable eVAS Update and Firmware Delivery as desired. To enable retrieving instrument software updates, eVAS, and/or customization profiles from your facility's AlinIQ Software Delivery for i-STAT (SDi) server, select **Local Server**. Then enter the IP address and port of the SDi server, and follow the prompts on the screen to enable/disable eVAS Update, Firmware Delivery, and/or Profile Update as desired. For additional information related to the use of SDi, see the *AlinIQ SDi User Guide*. In either case, use of the NCi is required to enable the instrument to make a network connection to the chosen server.
	Enable/Disable Wireless	This must be enabled in order for the instrument to have the ability to communicate wirelessly. Use of the NCi utility is required to make the connection between the instrument and the wireless. Disabling stops the instrument from communicating with the wireless
	Delete Network Settings	Follow prompts to complete this action.
	Network Status	List of information associated with wireless and wired communication.

Instrument Options: Instrument Service		
	Reset Instrument	Choose an option on the screen, by touching the text box indicating the action desired. Follow the prompts on the screen to complete the action.
	Export Logs	Follow prompts on screen to export instrument logs to a USB stick.
	View Running Applications - Software information	Used primarily by technical support.
	Set Region Code	Touch this button and follow prompts on screen to complete the region code setup.
	Perform Conditioning Cartridge	Touch this button to perform conditioning procedure using a conditioning cartridge. Contact Technical Support or local representative to obtain the conditioning cartridge and instructions for use.

Keypad changes for languages using diacritical marks

Based on the language chosen during instrument setup (see *Getting Started Guide* for the i-STAT Alinity instrument), the on screen keypad will display keys that have a small white dot in the upper right hand corner, as shown:

Touch the character until the additional options display at the bottom of the keypad:



After several seconds, the additional characters will disappear allowing the operator to continue typing without requiring any additional keystrokes.

Instrument Clock Date/Time Synchronization

When the instrument is configured to transmit test results to a data manager or to receive patient, operator, or cartridge lists from a data manager, the instrument will automatically synchronize the date and time of its clock with the data manager's time. This option eliminates the need to adjust the instrument's clock at the beginning and end of Daylight Saving Time.

To enable communication with data manager:

1. Install a customization profile with one of the following features selected:
    - Test Records
    - Operator List
    - Patient List
    - Cartridge List
2. Use NCi to configure the instrument for wired or wireless connectivity.

Note: When selecting only wireless connectivity ensure that wireless is enabled on both the instrument and in the customization profile.

To ensure instrument time is synchronized with the data manager after a change in Daylight Saving Time, power on the instrument and leave it on the Home screen until the correct time is displayed on the Home screen before performing cartridge testing.

For instrument time synchronization to occur, the instrument must also have a wired or wireless connection to the network hosting the data manager. The instrument may attempt to synchronize time when it is communicating with a data manager to send results or receive lists. The instrument will also attempt to synchronize time at power-on, so long as the Home screen is being displayed.

By default, instrument date/time synchronization is enabled, provided the conditions above are met, and the option to **Synchronize Clock with Data Manager** is enabled. To disable the automatic synchronization of date/time, run the **Set Clock** flow on the instrument and uncheck the box for **Synchronize Clock with Data Manager**. Unchecking this box disables automatic synchronization of date/ time with the data manager and enables the option to manually adjust the date/time. The **Synchronize Clock with Data Manager** check box is only available on the **Set Clock** screen when the instrument is configured to communicate with a data manager.

Calibration of the i-STAT Alinity instrument

The instrument houses the mechanical and electrical systems necessary to control fluid movement within the cartridge, control the temperature, measure barometric pressure, measure electrical signals generated by the sensors, and display and transmit results. The instrument's functions are factory calibrated to specifications that are programmed into the instrument along with acceptability limits, which, when exceeded, cause the instrument to display quality check messages, or to display *** rather than results.

Abbott Point of Care developed the internal simulator that functions as a signal-checking mechanism on every cartridge inserted. The internal simulator is a combination of hardware and software that tests the ability of the instrument to accurately read sensor signals. The instrument performs an internal simulator test on every cartridge run. The internal simulator simulates potentiometric, amperometric, and conductiometric signals at three levels consistent with a range that includes very high and very low concentrations of analytes. The simulation is conducted depending upon the cartridge inserted to perform this testing. Therefore, the set of sensors on the inserted cartridge determines the signals tested.

Specifications

i-STAT Alinity Instrument Specifications	
Dimensions: Height x Width x Depth	10.1 in (25.6 cm) x 5.6 in (14.3 cm) x 3.2 in (8.1 cm)
Weight	1.5 lb (660 g) without battery 1.9 lb (840 g) with battery
Operational range: Temperature and humidity	16 to 30ºC (61 to 86ºF) for clinical testing 10 to 90% non-condensing relative humidity, with maximum saturation temperature of 34ºC (93.2ºF)
Testing Environment	Indoors, on a dry, clean, horizontal, stable surface. Avoid nearby vibration equipment such as centrifuges. Avoid direct sunlight.
Altitude	up to 3,048 meters (10,000 feet)
Storage range: Temperature and humidity	-10 to 60ºC (14 to 140ºF) 10 to 90% non-condensing, with maximum saturation temperature of 50ºC (122ºF)
Display	5 in, 800 x 480 pixels with touchscreen, measured diagonally
Power source	Lithium Ion Rechargeable Battery (i-STAT Alinity Rechargeable Battery Model #RB-500)
Exterior materials	No natural or synthetic rubber latex is used anywhere on the exterior of this product, the product packaging, or the accessories.

i-STAT Alinity Software & Communication Specifications	
Network Standards Supported	IEEE TCP/IP
TCP/IP Data Transfer Rates	10/100 Ethernet Network Interface
Network Connection Modes	802.3 via Base Station RJ45 port 802.11 a/b/g/n Wireless
Serial Connection	USB via Base Station

i-STAT Alinity Software & Communication Specifications	
Printer Connection Modes	RJ11 via Base Station Infrared
USB Modes	v2.0
Operating System & Version	VxWorks 6.9.4

Wireless Labeling

The i-STAT Alinity instrument includes the FCC mark and FCC module identifier.

Table 1–1: Wireless specifications for the i-STAT Alinity instruments

Wireless Characteristic	i-STAT Alinity Instrument	
Network Standard	IEEE 802.11a, IEEE 802.11b, IEEE 802.11g, IEEE 802.11n (1-stream)	
Maximum RF Power	200 mW	
Typical Maximum SAR	765 mW/kg at 0 cm	
Wireless QoS requirements	None. Best-effort delivery service is sufficient.	
Radio Band Center Frequencies	802.11b/g/n 802.11a/n	2.412 – 2.472 GHz 5.180 – 5.825 GHz
Modulation Types	OFDM (64QAM, 16QAM, QPSK, BPSK) DSSS (CCK, DQPSK, DBPSK) DSSS-OFDM (64QAM, 16QAM, QPSK, BPSK)	

Table 1–2: Security Authentication Protocols

Authentication Type	WPA Type	Authentication Method	Cipher Type	
			Groupwise Transient Key	Pairwise Transient Key
WPA Personal	WPA	PSK	TKIP	TKIP
WPA Enterprise	WPA	EAP	TKIP	TKIP
WPA2 Personal	WPA2	PSK	CCMP	CCMP
WPA2 Enterprise	WPA2	EAP	CCMP	CCMP
WPA2/WPA Mixed Personal	WPA2	PSK	TKIP	CCMP
WPA2/WPA Mixed Enterprise	WPA2	EAP	TKIP	CCMP

Precautions and Limitations

For best results, observe the following precautions to prevent damage to the instrument, to ensure the safety of the operator and the integrity of the results.

DO:

- use care when placing the instrument on a surface that is unstable, such as a patient bed. Placing the instrument on an unstable surface may cause the instrument to fall. Place the instrument on a tabletop or counter to minimize the likelihood of a fall.
- always place the instrument and peripherals on a stable surface or in a location where they will not cause injury if dropped.
- use only the accessories and consumables specified or supplied for this system by Abbott Point of Care.
- protect patients from nosocomial infections by disinfecting the instrument periodically and whenever blood is spilled or transferred to an instrument. For more information, see the i-STAT Alinity *Quick Reference Guide*.
- follow site specific guidelines for integration of wireless devices into a hospital environment.
- keep the cartridge and the instrument at the temperature of the room where they are to be used. Condensation on a cold cartridge can prevent proper contact with the instrument.
- check with authorities for local, state, and/or national requirements for disposal.

- charge the battery to clear low battery status indications of  and  prior to initiating a cartridge test – particularly a cartridge test which has a longer test cycle such as ACT-K, TBI, TBI Plasma, and hs-TnI.

DO NOT:

- attempt to remove a cartridge during the testing cycle. The force that would be necessary to do so could damage the instrument. The message `Cartridge Locked in Instrument. Do Not Attempt to Remove the Cartridge.` remains on the screen until the instrument unlocks the cartridge.
- use the instrument in environmental conditions that exceed the operating temperature and humidity specifications.
- make any unauthorized repairs or modifications to this product as this may cause personal injury or damage to the unit.

- attempt to initiate a cartridge test when a low battery status condition of  or  is indicated particularly a cartridge test which has a longer test cycle such as ACT-K, TBI, TBI Plasma, or hs-TnI.

NOTE:

- Protection provided by this equipment may be impaired if used in a manner not specified by Abbott Point of Care.
- Operators should use standard precautions whenever handling the instrument, cartridge, and peripherals to protect themselves from blood-borne pathogens. Standard precautions, such as the wearing of gloves, are designed to protect personnel from blood-borne pathogens and pathogens from other body substances. These precautions are based on the assumption that blood, body fluids, and tissue can contain infectious agents and should therefore be treated as biohazardous materials. For more information, refer to the CDC/NIH manual *Biosafety in Microbiological and Biomedical Laboratories*, 4th edition, 1999, or to the *WHO Laboratory Biosafety Manual*, 2nd edition, 2003.
- The instrument can be rendered inoperative by damage caused by mishandling -- for example, dropping the instrument.
- Clinical settings that demand fail-safe testing should have a backup instrument or test source available.
- The instrument and its peripherals are not listed by any authority with respect to suitability for use in oxygen-enriched atmospheres.

- Synchronizing the instrument date/time to a data manager with an incorrect date/time could render the instrument unusable. To disable automatic date/time synchronization, run the **Set Clock** flow and uncheck the box **Synchronize Clock with Data Manager**. Then press **Set Date/Time Manually** and set the correct date/time.

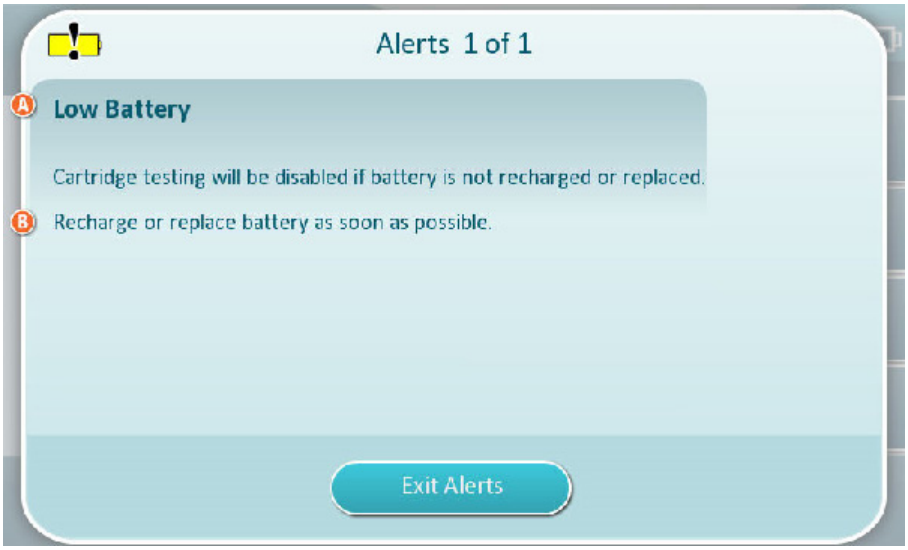
Messages and Troubleshooting

This section contains information to help the operator identify and resolve failures and alerts that might be present in the i-STAT Alinity system. Also included are explanatory and warning messages. At the time of an event, a **Quality Check Failure** (QCF) message and information on how to resolve it is displayed on the instrument. At some time after the QCF occurs, it may be necessary to retrieve this information. To do this, the user can touch **Review Results** to display the QCF and its associated numeric code. These numeric codes and resolutions are listed in the **Quality Check Failure Codes** table in this section. This information will aid the administrator in answering questions for performing troubleshooting.

Alerts

An alert condition presents itself when an action is required. Some alerts need the operator's immediate action (for example, Critically Low Battery) and others may require the administrator's attention (for example, Low Memory). The alert displays on the screen and the display persists until the operator takes action. Touching the **Alert** button displays additional details.

Example of an Alert Screen



Alert Title A

Cause and/or Resolution B

Use the information shown on the screen for appropriate action(s). If alert persists, contact the system administrator.

Quality Check Failure Codes

The instrument continuously performs numerous quality checks to ensure the system is operating properly. Quality Check Failure Codes (QCFs) indicate an issue was detected with the instrument, cartridge, sample or software. The failure of any quality check causes the instrument to display a quality

check failure code consisting of a numeric code, a cause and resolution message, and suggested corrective action.

Although a message is displayed on the instrument when a quality check failure occurs, the details are not available in **Review Results**. The information shown below is to aid the administrator in answering questions or performing troubleshooting.

A Quality Check Failure can occur during patient testing (Patient Pathway), while performing Quality Control (Quality Control Pathway), or when using the Electronic Simulator (Electronic Simulator Pathway).

For instrument issues, follow the instructions on the display. If the instrument has been powered down, the Quality Check Failure code will be stored in **Review Results**. To retrieve it: Power on the instrument and touch **More Options** > **Review Results** > **Quality Results** > **Quality Check Code Results**.

Use the following tables to find the **Quality Check Failure** code and determine the cause and resolution.

1. In the table below, in the first column, find the **QCF code** as found in **Review Results**.
2. Identify the pathway in which the failure occurred, and
   - in the **Cause** column find the cause number, then see *Quality Check Failure Causes* for the description
   - in the **Resolution** column find the resolution letter, then see *Quality Check Failure Resolutions* for corrective action.

Quality Check Failure Codes

Note: An empty cell indicates that there is no applicable information for that pathway and code.

QCF Code shown in Review Results	Patient Pathway		Quality Control Pathway		Electronic Simulator/ Conditioning Cartridge Pathway		QCF Code shown on screen
	Cause	Resolution	Cause	Resolution	Cause	Resolution	
2-01-1.1.1	1	A	1	A			2-01
2-02-1.1.2	1	A	1	A			2-02
8-01-2.1.8		I		I		P / BB	8-01
11-01-2.13.32		B		B		D	11-01
13-01-1.6.1		S		S		S	13-01
17-01-8.2.1	2	E	2	F			17-01
18-01-8.2.2	2	E	2	F			18-01
19-01-8.2.3	2	E	2	F			19-01
20-01-3.1.1[1]		G		F			20-01
21-01-3.1.3	3	G	3	F			21-01
22-01-6.1.3	4	X	4	F			22-01
22-01-6.1.5	4	X	4	F			22-01

QCF Code shown in Review Results	Patient Pathway		Quality Control Pathway		Electronic Simulator/ Conditioning Cartridge Pathway		QCF Code shown on screen
	Cause	Resolution	Cause	Resolution	Cause	Resolution	
22-01-6.1.8	4	X	4	F			22-01
22-01-6.1.9	4	X	4	F			22-01
22-01-6.1.10	4	X	4	F			22-01
22-01-6.1.11	4	X	4	F			22-01
22-01-6.1.12	4	X	4	F			22-01
22-01-6.1.15	4	X	4	F			22-01
23-01-3.3.2[1]		G		F			23-01
24-01-3.1.5		G		F			24-01
25-01-6.1.13	5	X	5	F			25-01
25-01-6.1.14	5	X	5	F			25-01
26-01-6.2.1		X		F			26-01
26-01-6.2.2		X		F			26-01
26-01-6.2.3		X		F			26-01
26-01-6.2.4		X		F			26-01
27-01-4.1.1[1]		G		F			27-01
28-01-4.1.2		G		F			28-01
29-01-4.1.3		G		F			29-01
30-01-6.1.4	6	W	12	F			30-01
30-01-6.1.7	6	W	12	F			30-01
30-02-4.1.4	6	H	12	F			30-02
31-01-4.1.5	7	G	7	F			31-01
31-02-6.1.16	7	X	7	F			31-02
32-01-4.1.6		G		F			32-01
33-01-4.1.8		G		F			33-01
34-01-4.1.11	7	G	7	F			34-01
35-01-4.1.7	8	H	13	F			35-01
36-01-4.1.10	8	H	13	F			36-01
37-01-4.1.9	6	H	12	F			37-01
38-01-4.1.12	9	G	9	F			38-01

QCF Code shown in Review Results	Patient Pathway		Quality Control Pathway		Electronic Simulator/ Conditioning Cartridge Pathway		QCF Code shown on screen
	Cause	Resolution	Cause	Resolution	Cause	Resolution	
39-01-6.1.6	9	G	9	F			39-01
40-01-3.3.3		G		F			40-01
41-01-3.1.2[1]		G		F			41-01
42-01-3.1.6		G		F			42-01
43-01-3.1.4	20	G	20	F			43-01
44-01-6.1.1	5	X	5	F			44-01
46-01-6.1.2	5	X	5	F			46-01
47-01-2.1.7		N		N		J / Z	47-01
48-01-2.13.2		B		B		C / AA	48-01
49-01-3.3.1	14	U	14	V			49-01
50-01-2.1.1		G		F		C / AA	50-01
50-01-2.1.2		G		F		C / AA	50-01
50-01-2.1.3		G		F		C / AA	50-01
50-01-2.1.6		G		F		C / AA	50-01
51-01-2.1.4		G		F		C / AA	51-01
51-01-2.1.9		G		F		C / AA	51-01
52-01-2.1.5		G		F		C / AA	52-01
53-01-2.9.3		T		T		T	53-01
57-01-2.4.1		B		B		D	57-01
59-01-4.5.1		B		B		D	59-01
60-01-1.6.2		B		B		C / AA	60-01
63-01-2.9.1		D		D		D	63-01
63-01-2.9.2		D		D		D	63-01
66-01-2.2.1		B		B		D	66-01
66-01-2.2.2		B		B		D	66-01
66-01-2.2.3		B		B		D	66-01
68-01-2.4.2		B		B		D	68-01
69-01-3.6.1		G		F			69-01
69-02-3.6.2		K		K			69-02

QCF Code shown in Review Results	Patient Pathway		Quality Control Pathway		Electronic Simulator/ Conditioning Cartridge Pathway		QCF Code shown on screen
	Cause	Resolution	Cause	Resolution	Cause	Resolution	
69-03-7.6.1						C / AA	69-03
69-04-7.6.2						L / CC	69-04
70-01-1.6.3		B		B		D	70-01
72-01-2.1.10		D		D		D	72-01
79-01-2.3.1	15	U	15	V			79-01
80-01-3.4.1		G		F			80-01
80-01-3.4.2		G		F			80-01
80-01-3.4.3		G		F			80-01
80-01-3.4.4		G		F			80-01
82-01-1.2.1		B		B		D	82-01
82-01-2.10.3		B		B		D	82-01
87-01-3.2.1		G		F			87-01
88-01-1.6.33		B		B		C / AA	88-01
89-01-2.7.32		B		B		C / AA	89-01
90-01-2.4.3		D		D		D	90-01
90-01-2.4.4		D		D		D	90-01
90-01-2.4.5		D		D		D	90-01
90-01-2.4.6		D		D		D	90-01
90-01-2.4.7		D		D		D	90-01
90-01-2.4.8		D		D		D	90-01
90-01-2.4.9		D		D		D	90-01
90-01-2.4.10		D		D		D	90-01
90-01-2.4.11		D		D		D	90-01
90-01-2.4.12		D		D		D	90-01
90-01-2.4.13		D		D		D	90-01
90-02-2.4.14		B		B		D	90-02
90-02-2.4.16		B		B		D	90-02
90-02-2.4.17		B		B		D	90-02
90-02-2.4.18		B		B		D	90-02

QCF Code shown in Review Results	Patient Pathway		Quality Control Pathway		Electronic Simulator/ Conditioning Cartridge Pathway		QCF Code shown on screen
	Cause	Resolution	Cause	Resolution	Cause	Resolution	
90-03-2.4.15	19	Y	19	Y			90-03
90-04-2.4.19						D	90-04
91-01-2.6.32		B		B		D	91-01
92-01-2.10.1		B		B		D	92-01
92-01-2.10.2		B		B		D	92-01
93-01-2.5.32		B		B		D	93-01
93-01-2.5.33		B		B		D	93-01
94-01-1.6.32		B		B		D	94-01
95-01-1.7.1		R		R			95-01
99-01-2.13.1		G		F		C / AA	99-01
99-02-2.2.4						C / AA	99-02
119-01-5.1.28		G		F			119-01
120-01-5.1.21		G		F			120-01
121-01-5.1.22		G		F			121-01
122-01-5.1.23		G		F			122-01
123-01-5.1.24		G		F			123-01
124-01-5.1.25		G		F			124-01
125-01-5.1.26		G		F			125-01
126-01-5.1.27		G		F			126-01
127-01-5.1.1	17	G	17	F			127-01
127-01-5.1.3	17	G	17	F			127-01
128-01-5.1.5	16	G	16	F			128-01
129-01-5.1.7		G		F			129-01
130-01-5.1.8	9	G	9	F			130-01
131-01-5.1.10	8	H	13	F			131-01
132-01-5.1.15	9	G	9	F			132-01
133-01-5.1.20		G		F			133-01
134-01-5.1.16	9	G	9	F			134-01
134-01-5.1.17	9	G	9	F			134-01

QCF Code shown in Review Results	Patient Pathway		Quality Control Pathway		Electronic Simulator/ Conditioning Cartridge Pathway		QCF Code shown on screen
	Cause	Resolution	Cause	Resolution	Cause	Resolution	
135-01-5.1.12	9	G	9	F			135-01
136-01-5.1.13	9	G	9	F			136-01
136-01-5.1.14	9	G	9	F			136-01
137-01-5.1.11	9	G	9	F			137-01
138-01-5.1.9	9	G	9	F			138-01
142-01-5.2.1	3	G	3	F			142-01
142-01-5.2.7	3	G	3	F			142-01
143-01-5.2.2	3	G	3	F			143-01
143-01-5.2.6	3	G	3	F			143-01
144-01-5.1.19		G		F			144-01
145-01-5.1.2	7	G	7	F			145-01
146-01-5.1.4	6	H	12	F			146-01
146-01-5.1.6	6	H	12	F			146-01
148-01-5.1.18		G		F			148-01
149-01-5.2.3		G		F			149-01
149-01-5.2.8		G		F			149-01
150-01-5.2.4		G		F			150-01
150-01-5.2.9		G		F			150-01
151-01-5.2.5		G		F			151-01
151-01-5.2.10		G		F			151-01
152-01-5.2.11		G		F			152-01
165-01-8.1.1	17	X	17	F			165-01
166-01-8.1.2	18	X	18	F			166-01
167-01-8.1.3	6	W	12	F			167-01
170-01-8.1.4		X		F			170-01
171-01-8.1.5		X		F			171-01
172-01-8.1.6		X		F			172-01
173-01-8.1.7		X		F			173-01
174-01-8.1.8		X		F			174-01

QCF Code shown in Review Results	Patient Pathway		Quality Control Pathway		Electronic Simulator/ Conditioning Cartridge Pathway		QCF Code shown on screen
	Cause	Resolution	Cause	Resolution	Cause	Resolution	
175-01-8.1.9		X		F			175-01

1

Quality Check Failure Causes

Causes	
1	The internal temperature is not within 16 to 30° C (61 to 86° F).
2	No clot was detected during testing.
3	Cartridge was rejected during the testing cycle. Probable causes: • Operator pressed too hard on the center of the cartridge • Used cartridge inserted • Cartridge was frozen and thawed before testing
4	Sample was rejected during the testing cycle. Probable causes: • Bubbles in the sample • Microclots in the sample • Used cartridge inserted • Snap closure not secure
5	Sample was rejected during the testing cycle. Probable causes: • Bubbles in the sample • Too little sample used to fill the cartridge • Clots in the sample
6	Excess blood was added to the cartridge. When filling the cartridge, the blood advanced past the level indicated by the 'fill to' arrow.
7	Sample was rejected during the testing cycle. Probable cause: • Snap closure not secure.
8	An insufficient amount of blood was used to fill the cartridge. When filling the cartridge, the blood did not reach the level indicated by the 'fill to' arrow.
9	Sample was rejected during the testing cycle. Probable causes: • Bubbles in the sample • Insufficient amount of sample used to fill the cartridge

[1]System Administrator Note: If code displays after operator repeats testing, instruct the operator to perform conditioning using a Conditioning Cartridge. Contact Technical Support or local representative for Conditioning Cartridge and instructions for use.

Causes	
10	Sample was rejected during the testing cycle. Probable causes: • Microclots in the sample • Snap closure not secure
11	Reserved for future use.
12	Excess sample was added to the cartridge. When filling the cartridge, the sample advanced past the level indicated by the 'fill to' arrow.
13	An insufficient amount of sample was used to fill the cartridge. When filling the cartridge, the sample did not reach the level indicated by the 'fill to' arrow.
14	Cartridge was rejected. Probable cause: • Instrument cannot lock cartridge in place to begin testing
15	Cartridge was rejected. Probable causes: • Instrument cannot lock cartridge in place to begin testing • Debris on cartridge
16	Sample was rejected during the testing cycle. Probable causes: • Bubbles in the sample • Insufficient mixing of sample used to fill the cartridge • Wrong sample type
17	Cartridge was rejected during the testing cycle. Probable causes: • Excess sample was added to the cartridge • Used cartridge inserted
18	Cartridge was rejected during the testing cycle. Probable causes: • Bubbles in the sample • Microclots in the sample • Used cartridge inserted • Snap closure not secure • Too little sample used to fill the cartridge
19	Cartridge was rejected during the testing cycle. Probable causes: • Cartridge pouch opened too soon after removal from refrigerator • Cartridge not filled immediately after opening pouch
20	Cartridge was rejected during the testing cycle. Probable causes: • Excess sample was added to the cartridge • Operator pressed too hard on the center of the cartridge

Quality Check Failure Resolutions

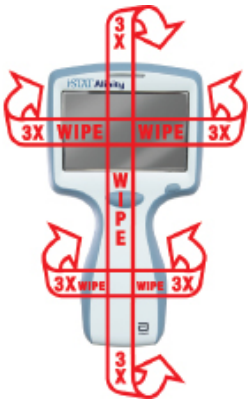
Resolutions	
A	Navigate to the **Home Screen**, then touch **More Options**. Touch **Instrument Status** and assess the instrument's temperature. Move the instrument to an appropriate environment.
B	Perform an Electronic Simulator test. If the test results in a PASS, the instrument is ready for use otherwise contact system administrator for further instruction.
C	Repeat Electronic Simulator testing. If the test results in a PASS, the instrument is ready for use otherwise contact system administrator for further instruction.
D	Contact the system administrator for further instruction.
E	Do not collect the sample for this cartridge in a device that contains anticoagulant. Draw new sample. Repeat testing with a freshly filled cartridge. Carefully observe the help provided throughout the testing pathway. If the same quality check failure displays, contact the system administrator for further instruction.
F	Prepare a new bottle of material per the manufacturer's instruction. Repeat testing with a freshly filled cartridge. Carefully observe the help provided throughout the testing pathway. If the same quality check failure displays, contact the system administrator for further instruction.
G	Repeat testing with a freshly filled cartridge. Carefully observe the help provided throughout the testing pathway. If the same quality check failure displays, contact the system administrator for further instruction.
H	When filling a cartridge, use care to advance blood to the level indicated by the 'fill to' arrow. Repeat testing with a freshly filled cartridge. Carefully observe the help provided throughout the testing pathway. If the same quality check failure displays, contact the system administrator for further instruction.
I	Instrument did not reset correctly. Perform an electronic simulator test. If the test results in a PASS, the instrument is ready for use otherwise contact system administrator for further instruction.
J	The simulator was not fully inserted. Repeat testing. Make sure that the cover retaining ring does not interfere with Electronic Simulator insertion. Ensure the Simulator is fully inserted. The Simulator is fully inserted when the click is heard. If the same quality check failure displays, contact the system administrator for further instruction.
K	Always scan the barcode found on the pouch that contained the cartridge in use. Scanning any other barcode can cause this error. Repeat testing with a freshly filled cartridge. Carefully ob serve the help provided throughout the testing pathway. If the same quality check failure dis plays, contact the system administrator for further instruction.
L	A cartridge was detected when an Electronic Simulator was expected. Repeat testing ensuring to insert an Electronic Simulator. Make sure that the cover retaining ring does not interfere with Simulator insertion. Ensure the Simulator is fully inserted. The Simulator is fully inserted when the click is heard. If the same quality check failure displays, contact the system administrator for further instruction.
M	Reserved for future use.

Resolutions	
N `	The cartridge was not fully inserted. Repeat testing with a freshly filled cartridge. Ensure the cartridge is fully inserted. The cartridge is fully inserted when the click is heard. If the same quality check failure displays, contact the system administrator for further instruction.
P	The instrument did not reset correctly. Repeat electronic simulator testing. If the test results in a PASS, the instrument is ready for use otherwise contact the system administrator for further instruction.
R	Test has been successfully cancelled.
S	OSi software installation required. Contact the system administrator for further instructions.
T	Install the most recent OSi software. Contact the system administrator for further instructions.
U	Power off the instrument. Insert the Latch Return Tool into the cartridge port until it stops. Immediately remove the tool from the instrument. Repeat testing with a freshly filled cartridge. If the same quality check failure displays, contact the system administrator for further instruction.
V	Power off the instrument. Insert the Latch Return Tool into the cartridge port until it stops. Immediately remove the tool from the instrument. Prepare a new bottle of material per the manufacturer's instruction. Repeat testing with a freshly filled cartridge. If the same quality check failure displays, contact the system administrator for further instruction.
W	When filling a cartridge, use care to advance blood to the level indicated by the 'fill to' arrow. Draw new sample. Repeat testing with a freshly filled cartridge. Carefully observe the help provided throughout the testing pathway. If the same quality check failure displays, contact the system administrator for further instruction.
X	Draw new sample. Repeat testing with a freshly filled cartridge. Carefully observe the help provided throughout the testing pathway. If the same quality check failure displays, contact the system administrator for further instruction.
Y	Cartridge pouch must be out of the refrigerator for a minimum of 5 minutes before opening. After opening the pouch, immediately begin to follow the prompts on the screen. If the same quality check failure displays, contact the system administrator for further instruction.
Z	The Conditioning Cartridge was not fully inserted. Repeat conditioning. Ensure the Conditioning Cartridge is fully inserted. The Conditioning Cartridge is fully inserted when the click is heard. If the same quality check failure displays, contact the system administrator for further instruction.
AA	Repeat conditioning with Conditioning Cartridge testing. If conditioning completes successfully, the instrument is ready for use, otherwise contact the system administrator for further instruction.
BB	Instrument did not reset correctly. Repeat conditioning with Conditioning Cartridge. If conditioning completes successfully, the instrument is ready for use, otherwise contact the system administrator for further instruction.
CC	A cartridge was detected when a Conditioning Cartridge was expected. Repeat conditioning ensuring to insert a Conditioning Cartridge. Ensure the Conditioning Cartridge is fully inserted. The Conditioning Cartridge is fully inserted when the click is heard. If the same quality check failure displays, contact the system administrator for further instruction.

Cleaning and Disinfecting

Complete instructions for cleaning and disinfecting are found in the *Quick Reference Guide*. The graphics below are a visual representation of the wiping procedure for disinfection.

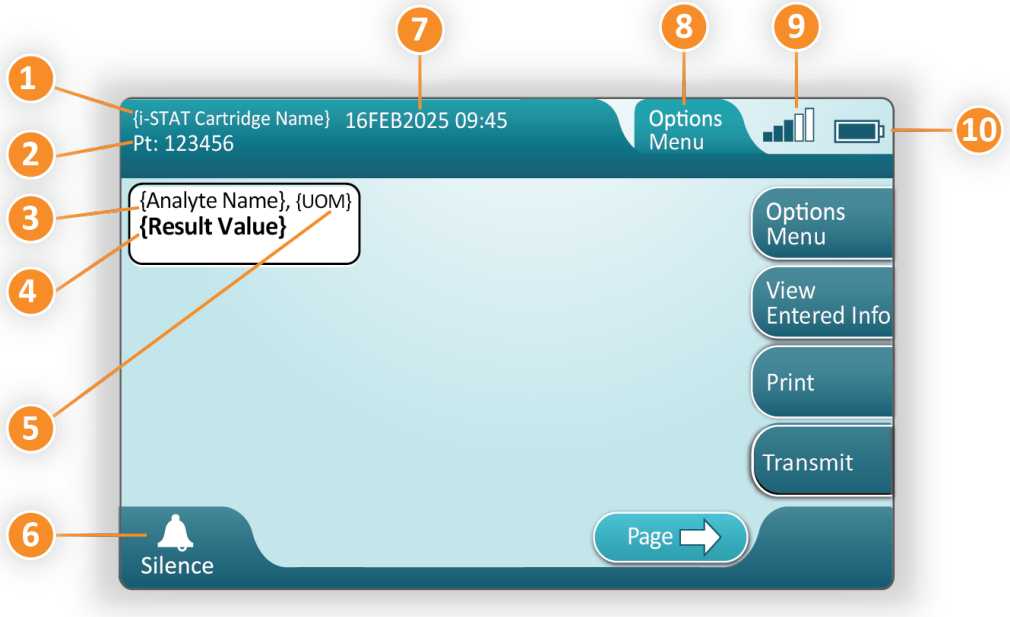
Note: When cleaning and disinfecting the instrument, the rechargeable battery must be attached.



This page intentionally left blank.

1.3 - i-STAT Alinity Results Screen

The content of a result screen is specific to the cartridge type and material being tested. The following screen is an **example** of a patient result screen with a cartridge that contains one test:



Description of the displayed screen;

1. i-STAT Cartridge Name*
2. Sample identification PT: 123456
3. Analyte Name*
4. Result - value*
5. Units of Measurement (UOM)*
6. Audible Que
7. Date and time when test was completed 16FEB2025 09:45
8. Options Menu
9. Wireless Signal strength (when customized)
10. Battery strength

***For information on analytes available in a cartridge configuration, unit of measure and the result value options, see the i-STAT Cartridge IFU.**

On the right side of the screen are action buttons for:	
	Begins another test without returning to Home screen Options Will Include: • Review Results • Transmit Unsent Results • View Action Ranges and Analyte Info ○ Customized Action Range • Instrument Status • Quality Options • Administrative Options • Instrument Options
	Displays information associated with the test
	Prints result to i-STAT Alinity printer

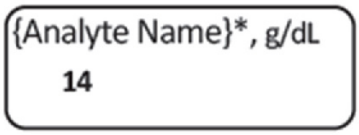
On the right side of the screen are action buttons for:	
	When customized, `Transmits result to Data Manager`
On the bottom of the screen are the icons:	
 touch to display the Home screen.	 touch to display the next screen.

Interpreting Results

The following section provides examples for various analytes. Not all cartridges are available in all regions. Ability to run a cartridge is controlled by the instrument and by region.

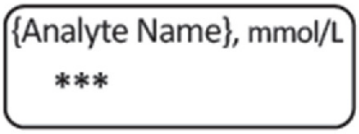
Calculated Result Indicator

A star (*) beside an analyte indicates a calculated result, as shown in the example below:



Suppressed Results - Stars (***)

Various conditions cause results to be suppressed. The instrument displays stars (***), referred to as a “star out”, as shown in the **example** below:



Reasons such as those listed below may produce starred out results:

- an uncharacteristic sensor signal
- a bad sensor
- improperly stored cartridge

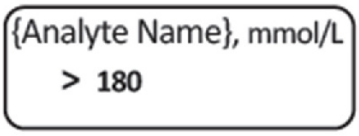
- interfering substance in the sample
- aged sample containing products of metabolism
- cartridge results that are not reportable based on a failed quality check while performing a test

If stars display, take corrective action:

- A star out can be caused if a cartridge is handled improperly by the user. Follow facility policy for handling starred out results.
- If no facility policy is in place, check the supply of cartridges in use with a control solution. If the control is in range, collect a new sample and test immediately. If starred out results display again, there may be an interfering substance in the sample. Refer to the *Cartridge Instructions for Use* for a list of interfering substances with the starred out analyte(s). Use an alternate method for testing.
- If the control is out-of-range or if stars are displayed again, there may be a problem with the cartridge lot. Use another lot if available. If another lot is not available, test patient sample using another method. Contact technical support with regard to lot number in question.

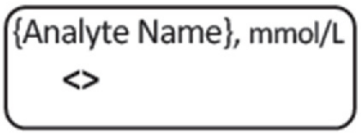
Suppressed Results - Out of range

Under some conditions results may be preceded by the symbols for greater than (>) or less than (<). This can occur when results are outside the system's measurement ranges for the analyte. Facility Policy should be in place to advise end users on additional course of action if necessary. Below is an **example** of a result that is greater than the highest limit of the reportable range (180 mmol/L). The result is shown as **a greater than (>) symbol and the upper limit for the analyte:**



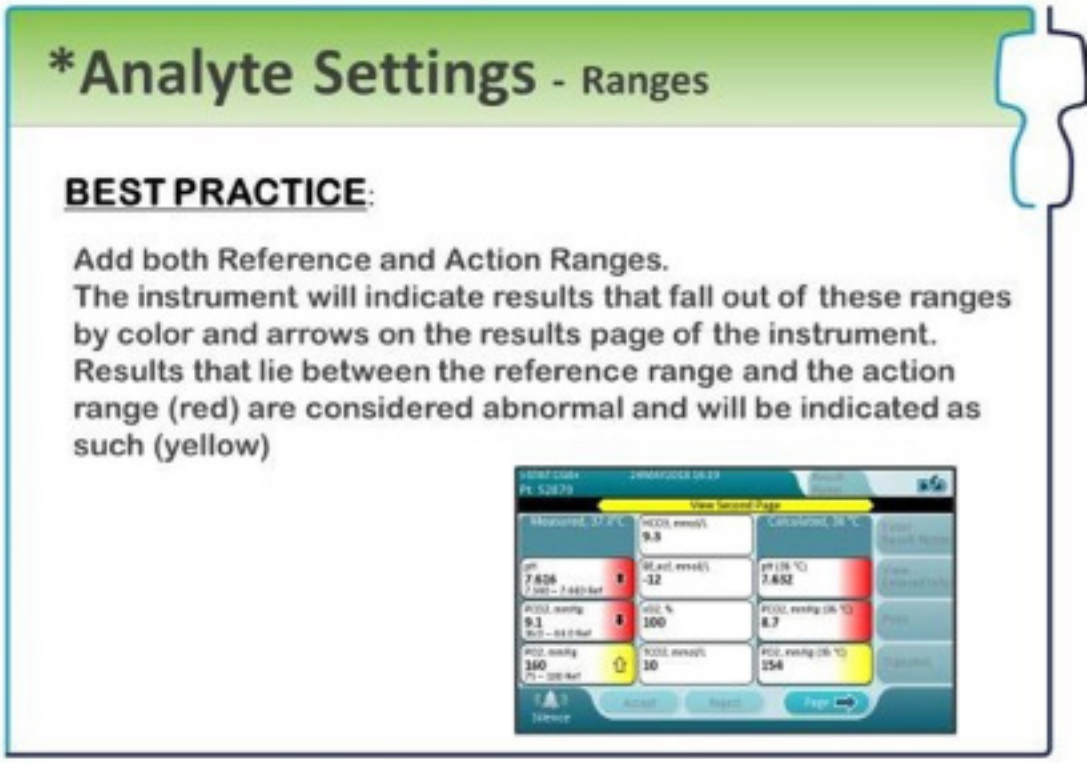
Suppressed Results - Null Set

The < > flag indicates that the results for this test were dependent on the result of a test flagged as greater than (>) or less than (<) reportable range of the test. A null result is shown in the **example** below. **Null results don't include a numerical value**:



Interpreting Results with customization features applied

The following section provides examples for various analytes, when the analyzer is customized with Align IQ CWI. Not all cartridges are available in all regions. Ability to run a cartridge is controlled by the instrument and by region.



- When ranges are customized using AlinIQ CWi, the instrument will indicate results that fall out of these ranges by color and arrows on the results page of the instrument. Results that lie between the reference range and the action range (red) are considered abnormal and will be indicated as such (yellow).
- When the instrument is customized by the system administrator, reference ranges as well as action ranges may be assigned.
- When reference ranges are assigned, they appear under the analyte result followed by “Ref”.
- When action (critical) ranges are assigned, results within this range will be highlighted by both color and an arrow.
  - **Yellow** in the result area indicates that the result is outside of the reference range, but is not within the action range, sometimes known as an abnormal result. The arrow indicates if the result is high (⇧) or low (⇩).
  - **Red** in the result area indicates that the result is within the action (critical) range or above the cutoff. The arrows indicate if the result is high (⬆) or low (⬇).
  - **Red arrow** in page button - indicates one or more results on second page are within the action (critical) range.
  - **Yellow arrow** in page button - indicates one or more results on second page are outside the reference range, but not in the action (critical) range.
  - **White arrow** in page button - indicates all results on second page are within the reference range.

Interpreting Results with Cutoffs

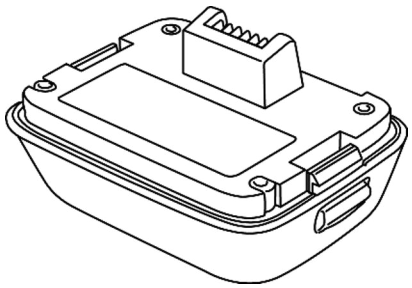
- When a cutoff is in effect for an analyte, the cutoff value will be displayed directly below the analyte result value on the instrument screen.
- An analyte result at or above a Warning cutoff will be highlighted by both a Yellow color and an up arrow on the instrument screen.

- An analyte result above a Critical cutoff will be highlighted by both a Red color and an up arrow on the instrument screen.

1.4 - i-STAT Alinity Rechargeable Battery

Overview

This Lithium-Ion rechargeable battery is designed for use only with the i-STAT Alinity instrument. When attached to the instrument, it is the power source for all functionality. Thumb tabs on either side of the battery enable easy removal and replacement of the battery on the instrument.



For instructions on using the battery, refer to the i-STAT Alinity Rechargeable Battery *Getting Started Guide*.

Description

The rechargeable battery allows the instrument to perform testing. The battery recharges when it is attached to the instrument and docked in a powered Base Station. An indicator on the upper right hand side of the instrument screen indicates the battery level. Testing is disabled when the battery level is insufficient to perform a cartridge test. An alert displays when the battery level approaches the level at which testing is disabled. Instructions for attaching the battery are found in the i-STAT Alinity Rechargeable Battery *Getting Started Guide*. For a full list of all battery icons available for display on the instrument, see the *Quick Reference Guide.*

Principles of Operation

The battery pack contains a Lithium-Ion rechargeable battery cell and electronics for charging and fuel gauge functionality. The fuel gauge predicts the battery capacity while also providing protection against short circuit, over current and over voltage. The battery pack and Base Station are designed to allow for the battery to be charged without detaching from the instrument.

Specifications

i-STAT Alinity Recharg	eable Battery Specifications
Dimensions: Height x Width x Depth	2.7 in (6.9 cm) x 3.6 in (9.1 cm) x 1.9 in (4.8 cm)
Weight	0.4 lb (180 g)
Electrical rating	3.65 VDC, 19.3 Wh (nominal) [ID: 1INP20/66/38] 3.6 VDC, 25.0 Wh (nominal) [ID: 1INR18/65-2]
Operational range: Temperature and humidity	10 to 40ºC (50 to 104ºF) 10 to 90% non-condensing relative humidity, with maximum saturation temperature of 34ºC (93.2ºF)
Storage range: Temperature and humidity	-10 to 60ºC (14 to 140ºF) 10 to 90% non-condensing, with maximum saturation temperature of 50ºC (122ºF)
Altitude	up to 3,048 meters (10,000 feet)

Precautions and Limitations

Batteries have been designed to provide a safe, high-capacity power source in a relatively small lightweight package. However, if misused or abused, these batteries can be dangerous. Follow these guidelines for the safe handling, use and disposal of the rechargeable batteries.

DO:

- refer to the *Getting Started Guide* for proper charging instructions.
- charge a new rechargeable battery pack for 4 hours before initial use. A fully discharged battery will be 100% charged and ready for use after 4 hours.
- use only a rechargeable battery pack purchased from Abbott Point of Care.
- use only the accessories and consumables specified or supplied for this system by Abbott Point of Care.
- keep a spare, charged battery on hand at all times.
- store charged battery in the original packaging.
- check with authorities for local, state, and/or national requirements for disposal or recycling requirements for Lithium-Ion batteries.

DO NOT:

- dismantle, open or shred the battery.
- expose the battery to heat or fire. Avoid storage in direct sunlight.
- short circuit the battery. Do not store batteries in such a manner that they may short circuit each other, or allow metal objects to touch the battery contacts.
- subject the batteries to mechanical shock.
- open, disassemble, modify, crush, burn, shred, or expose to high temperatures. Toxic gases and liquids are present in batteries.
- place the battery in an oxygen-enriched atmosphere.

- make any unauthorized repairs or modifications to this product as this may cause personal injury or damage to the unit.

NOTE:

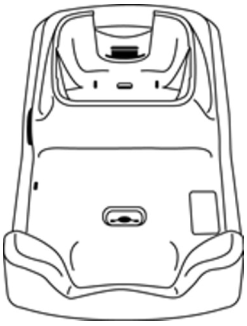
- A fully charged battery, if not periodically recharged, will self-discharge over time. Prevent self-discharge by keeping the rechargeable battery pack in an instrument that is on a powered Base Station.
- Protection provided by this equipment may be impaired if used in a manner not specified by Abbott Point of Care.
- The instrument and its peripherals are not listed by any authority with respect to suitability for use in oxygen-enriched atmospheres.
- In the event of a battery leaking, do not allow any leakage to come into contact with the skin or eyes. If contact has been made, wash the affected area with copious amounts of water and seek medical advice.

This page intentionally left blank.

1.5 - i-STAT Alinity Base Station

Overview

The primary function of the Base Station is to charge the rechargeable battery while it is attached to the i-STAT Alinity instrument. The Base Station is intended for use only with the i-STAT Alinity instrument. When an instrument is not charging in the unit, the Base Station looks as shown in this illustration:



For instructions on installing and using the Base Station, refer to the i-STAT Alinity Base Station *Getting Started Guide*.

Description

The i-STAT Alinity Base Station:

- charges the battery that is attached to the instrument
- powers the instrument when docked
- powers the instrument when the instrument is docked and cartridge testing is being performed
- provides connection to the printer
- provides for wired ethernet connection
- updates software and file transfers via USB port
- light indicates proper connection to power source

Specifications

i-STAT Alinity Base Station Specifications	
Dimensions: Height x Width x Depth	11.8 in (29.9 cm) x 5.9 in (15 cm) x 2.7 in (6.9 cm) without AC adapter
Weight	2.4 lb (1090 g)
Communication Interface	Ethernet 10/100 base t, RS-232, USB 2.0
LED Indicators	Color: Blue Status: Power
Operational range: Temperature and humidity	10 to 40ºC (50 to 104ºF) 10 to 90% non-condensing, with maximum saturation temperature of 34ºC (93.2F)
Testing Environment	Indoors, on a dry, clean, horizontal, stable surface. Avoid nearby vibration equipment such as centrifuges. Avoid direct sunlight.
Altitude	up to 3,048 meters (10,000 feet)
Storage range: Temperature and humidity	-10 to 60ºC (14 to 140ºF) 10 to 90% non-condensing, with maximum saturation temperature of 50ºC (122ºF)
External Power Supply Unit	Input: 110-240 VAC, 50-60 Hz, 1.5A Output: 5.3V DC, 6.6A

Precautions and Limitations

For safety when using the Base Station:

DO:

- use only the accessories and consumables specified or supplied for this system by Abbott Point of Care.
- use only the power supply shipped in the box with the Base Station. Attempting to use a different type of manufacturer's adapter could damage the unit and cause fire or explosion hazards.
- be sure to install all cables and power supplies so they do not pose a trip hazard. Mount equipment so cables and accessories stay clear of walkways.
- always use the Base Station for charging. Refer to the rechargeable battery *Getting Started Guide* on instructions for proper charging.
- connect only Abbott Point of Care provided printers to the Base Station printer port.
- check with authorities for local, state, and/or national requirements for disposal.

DO NOT:

- try to connect any non-electrically isolated equipment to the Base Station.
- connect the Base Station to unauthorized medical devices or other equipment.
- place metal objects on or near the exposed battery charging contacts.
- place the instrument in an oxygen-enriched atmosphere.
- make any unauthorized repairs or modifications to this product, as it may cause personal injury or damage to the unit.

NOTE:

- The AC adapter power supply plug acts as a disconnect device for the Base Station and therefore, the AC socket outlet must be installed (or located) near the Base Station and must be easily accessible if the Base Station needs to be unplugged. When correctly connected to power, the blue light on the Base Station will be illuminated. After an instrument is docked, the blue light above the screen will be illuminated. This may take several seconds. If the blue light does not illuminate, check the power supply. Ensure that the Base Station is connected properly and that the instrument is seated correctly in the Base Station.
- Protection provided by this equipment may be impaired if used in a manner not specified by Abbott Point of Care.
- The instrument and its peripherals are not listed by any authority with respect to suitability for use in oxygen-enriched atmospheres.
- The Base Station must be on a flat, level, horizontal surface such as a table top. Falling equipment may cause injury. Always place the equipment on a stable level surface in a location where it will not cause injury if dropped.

Troubleshooting

The blue light on the side of the Base Station illuminates when it is properly installed. Proper installation is outlined in the i-STAT Alinity Base Station *Getting Started Guide*. If the blue light does not illuminate, check to make sure that the Base Station is plugged into an appropriate power source.

Cleaning and Disinfecting

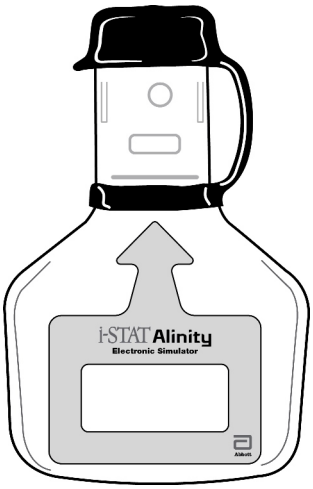
Complete instructions for cleaning and disinfecting are found in the *Quick Reference Guide*. The graphics below are a visual representation of the wiping procedure for disinfection.

1.6 - i-STAT Alinity Electronic Simulator

Overview

The Electronic Simulator is a quality control device used to evaluate the i-STAT Alinity instrument's ability to read the electronic signal from a cartridge. When inserted into an i-STAT Alinity instrument, the Electronic Simulator initiates a suite of self checks which verify the electronic and thermal functionality used with all cartridge types. The Electronic Simulator is designed for use only with the i-STAT Alinity instrument.

Abbott Point of Care requires that a successful Electronic Simulator test is performed every 6 months.



For instructions on using the Electronic Simulator, refer to the i-STAT Alinity Electronic Simulator *Getting Started Guide*. In this document, see information in the section *Perform Electronic Simulator Testing*.

Principles of Operation

The Electronic Simulator has a ceramic insert on the testing end. When the Electronic Simulator pathway is initiated and the simulator is inserted, the instrument contacts the ceramic strip as it would the contact pads on a cartridge. The ceramic strip isolates the pins from the protective grounds allowing the internal electronics to verify measurement of the current used with the cartridges. Additionally, two thermistors in the thermal system are measured to ensure they produce consistent readings.

Specifications

i-STAT Alinity Electronic Simulator Specifications	
Dimensions: Height x Width x Length	2.8 in (6.9 cm) x .6 in (1.6 cm) x 4.3 in (10.8 cm) without cap 2.8 in (6.9 cm) x .6 in (1.6 cm) x 4.4 in (11.1 cm) with cap

i-STAT Alinity Electronic Simulator Specifications	
Operational range: Temperature and humidity	16 to 30ºC (61 to 86ºF) 10 to 90% non-condensing, with maximum saturation temperature of 34ºC (93.2ºF)
Storage range: Temperature and humidity	-10 to 60ºC (14 to 140ºF) 10 to 90% non-condensing, with maximum saturation temperature of 50ºC (122ºF)
Altitude	up to 3,048 meters (10,000 feet)

Precautions and Limitations

For best results, observe the following precautions:

DO:

- use only the accessories and consumables specified or supplied for this system by Abbott Point of Care.
- place the removable cap over the contacts when the Electronic Simulator is not in use or when cleaning or disinfecting.
- check with authorities for local, state, and/or national requirements for disposal.

DO NOT:

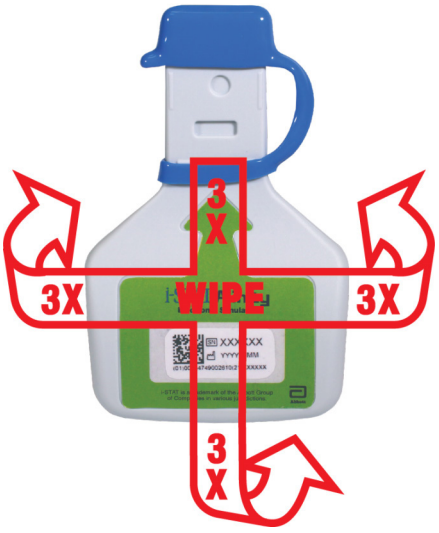
- attempt to remove the Electronic Simulator while a test is being performed.
- drop the Electronic Simulator, as doing so can cause it to malfunction.
- place the Electronic Simulator in an oxygen-enriched atmosphere.
- make any unauthorized repairs or modifications to this product.
- use the Electronic Simulator with any instrument other than the i-STAT Alinity.
- touch the area under the cap.

NOTE:

- Function provided by this equipment may be impaired if used in a manner not specified by Abbott Point of Care.
- The instrument can become contaminated with blood during use. Operators should use standard precautions whenever handling the instrument, cartridge, and peripherals to protect themselves from blood-borne pathogens and pathogens from other body substances. Standard precautions, such as the wearing of gloves, are designed to protect personnel from blood-borne pathogens and patho-gens from other body substances. These precautions are based on the assumption that blood, body fluids, and tissue can contain infectious agents and should therefore be treated as biohazardous materials. For more information, refer to the CDC/NIH manual *Biosafety in Microbiological and Biomedical Laboratories*, 4th edition, 1999, or to the *WHO Laboratory Biosafety Manual*, 2nd edition, 2003.
- The instrument and its peripherals are not listed by any authority with respect to suitability for use in oxygen-enriched atmospheres.

Cleaning and Disinfecting

Complete instructions for cleaning and disinfecting are found in the *Quick Reference Guide*. The graphics below are a visual representation of the wiping procedure for disinfection.



This page intentionally left blank.

1.7 - Perform Electronic Simulator Testing

Although the instrument performs internal electronic checks and calibration during each test cycle, the Electronic Simulator test provides an independent check on the ability of the instrument to take accurate and sensitive measurements of voltage, current and resistance from the cartridge. The instrument will pass or fail this electronic test depending on whether or not it measures these signals within limits specified in the instrument software.

Electronic Simulator

The Electronic Simulator is a quality control device used to evaluate the i-STAT Alinity instrument's ability to read the electronic signal from a cartridge. The test cycle for the Electronic Simulator is approximately 60 seconds.

Relative humidity

The Electronic Simulator test will fail if high humidity interferes with the measurements. It is therefore unnecessary to record humidity where the instruments are in use.

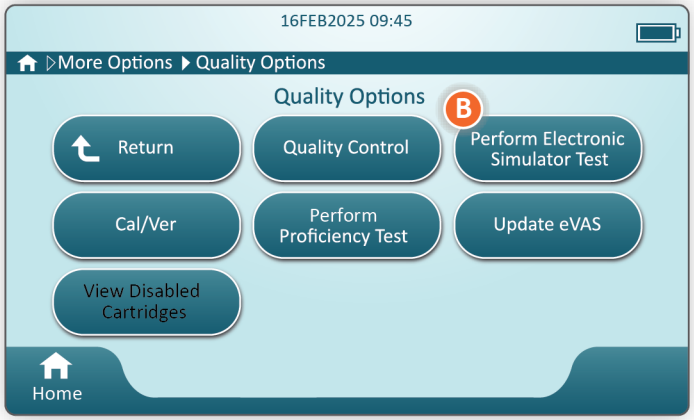
Storing the Electronic Simulator

Store the Electronic Simulator with the cap on in the box in which it was shipped.

HOW TO PERFORM QUALITY TESTING – ELECTRONIC SIMULATOR

Starting from the **Home Screen** touch **More Options** then A **Quality Options**.

Next, touch the B **Perform Electronic Simulator Test** button.



By carefully observing the text and graphic instruction, the user will be able to successfully complete an Electronic Simulator test. In the event that the test does not pass, follow the prompts on the screen.

Use care when handling the E lectronic Simulator. Avoid touching the sensor area. Replace cap after use.

Perform the Thermal Probe Check

Use the procedure below to check the thermal probes on each instrument twice a year.

Note: Please refer to the *Manufacturer's Quality System Instructions (MQSI)* for additional information.

1. If the instrument and Electronic Simulator have been stored separately in areas where the ambient temperature differs by more than 3°C or 5°F, allow the Simulator and instrument to equilibrate to the same temperature, out of drafts, for 30 minutes before inserting the Simulator into the instrument. Minimize handling the Simulator to maintain its thermal uniformity and stability.
2. From the **Home** screen, touch **More Options** > **Quality Options** > **Perform Electronic Simulator Test** and then follow the screen prompts.
3. Remove the cap from the end of the Electronic Simulator and insert the Electronic Simulator into the instrument.
4. When results are displayed, the difference between the thermal probes can be viewed on the instrument's screen by touching the **View Entered Info** tab on the right side of the screen.
5. Interpret the thermal probe check value:
   - **Acceptable**: PASS
   - **Not acceptable**: FAIL message with a Quality Check Failure Code. Repeat the procedure to confim results. If the repeat test fails contact Technical Support.

This page intentionally left blank.

1.8 - i-STAT Alinity Printer

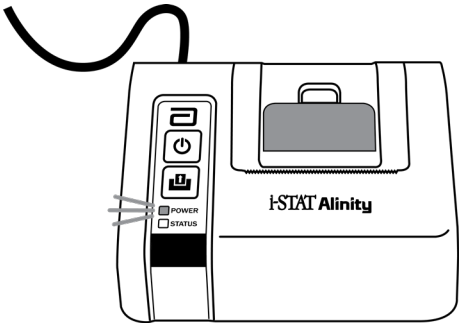
Overview

The portable printer prints information about patient and quality control tests. It is designed to be used only with the i-STAT Alinity instrument. The printer can receive data directly from the instrument through infrared radiation (IR) transmission or through a data cable connected to the Base Station.

You can print information such as:

- Name of test
- Patient ID
- Quality Test ID
- Test result(s)
- Sample type selected
- Date and time the test was performed
- Operator ID
- Lot number of the cartridge
- Lot number of liquid quality material
- Serial number of the instrument
- Application software version in the instrument
- Standardization software in the instrument

The printer is recharged using a power adapter connected to an outlet. For additional information on printer assembly and use, see the i-STAT Alinity printer *Getting Started Guide*.



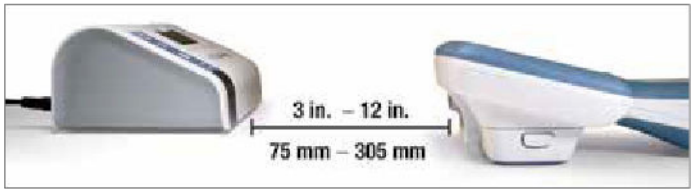
Principles of Operation

To print patient results:

1. From the instrument's **Home** screen, touch **More Options** > **Review Results** > **All Results**
2. Scan or Enter Operator ID.
3. Choose results by touching the checkbox in front of the result identifier. Use **Page** ➡ key to advance the page if applicable.
4. Ensure that the instrument and the printer are on a flat, level and horizontal surface. Align the instrument's IR port with the printer IR window.
5. Touch **Print Selected**. An audible beep is heard when the instrument has successfully transmitte all results to the printer. Printer may still be printing when beep is heard.

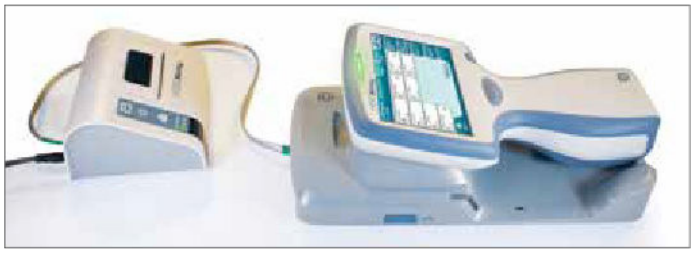
A **Determine printing method:**

Wireless

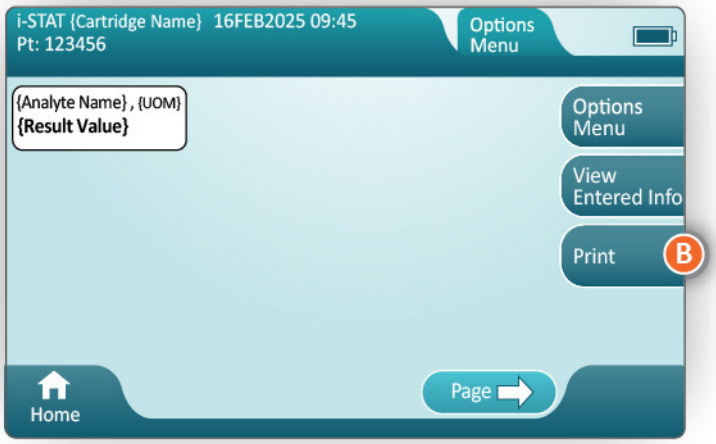


OR

Wired to Base Station



B **With instrument and printer powered up, and the results on the screen, touch Print**



Specifications

Dimensions: Height x Width x Depth	2.9 in (7.2 cm) x 5.4 in (13.6 cm) x 4.7 in (12.0 cm)
Weight	1.1 lb (500 g)
Power ratings (AC adapter)	Input: 100-240 VAC, 50/60Hz, 1.1 A Max Output: 12 VDC, 3.0 A
Power ratings (battery pack)	4.8 V
Operational range: Temperature and humidity	15 to 40ºC (59 to 104ºF) 20 to 90% Non-condensing relative humidity
Storage range: Temperature and humidity	-20 to 50ºC (-4 to 122ºF) 10 to 90% Non-condensing
Communication link	Infrared or Serial/RJ11
Paper	black print thermal paper 5.7 cm wide Available from Abbott Point of Care

Precautions and Limitations

For best results, observe the following precautions when using the i-STAT Alinity printer.
DO:

- use only a rechargeable battery pack purchased from Abbott Point of Care.
- use only the power adapter and supply provided with the i-STAT Alinity printer kit.
- use an i-STAT Alinity printer when attempting to print from an i-STAT Alinity instrument.
- check with authorities for local, state, and/or national requirements for disposal.

DO NOT:

- operate the printer without paper.
- pull paper through the paper mechanism. Damage to the printer can result. Use the paper feed button.
- allow the power supply to become a trip hazard.
- place the printer in an oxygen-enriched atmosphere.
- disturb the instrument or the printer until printing is complete, since this will interrupt the printout. If printing is interrupted, realign the instrument and the printer, or replace the instrument in the Base Station to resume printing.
- place printers side by side. Doing so may cause instrument to printer communication problems.

NOTE:

- The instrument and its peripherals are not listed by any authority with respect to suitability for use in oxygen-enriched atmospheres.
- In the event of a battery leaking, do not allow any leakage to come into contact with the skin or eyes. If contact has been made, wash the affected area with copious amounts of water and seek medical advice.
- If a printout appears inconsistent with a patient's clinical assessment, verify that the correct patient record was selected (patient ID, date and time of test, etc.). If the record is not correct, select the correct record and print. If the printout still does not match the data in the instrument, the printer needs service and the printed results must not be used. If another printer is available, retry.
- Fluorescent light sources can cause interference with communications sent to the i-STAT Alinity printer. When light from a fluorescent source of sufficient proximity or brightness has a direct path into the printer's infrared radiation (IR) window, the printer might fail to respond when records are sent for printing over a serial (wired) connection to a Base Station.

Troubleshooting

This section provides tips for diagnosing and fixing problems with the i-STAT Alinity printer.

Note: Attempting to print from an i-STAT Alinity instrument to any printer other than an i-STAT Alinity printer may be unsuccessful.

When a problem occurs, it may be indicated by the printer's POWER or STATUS lights. To diagnose and correct a problem, refer to the information below:

Printer Problem	Resolution
The printer does not print. The POWER indicator light is green or orange, and the STATUS indicator light is green.	• Check that the results are displayed on the instrument, or that results have been selected from List under **Review Results**. • If printing directly from the instrument, check that the distance between the instrument and the printer is between 1 and 5 inches (2.5 to 12.7 cm). • Perform a printer self-test to ensure that the printer is functioning: **1.** Power off the printer. **2.** While pressing the Paper Feed button, press down on the Power button until the printout begins. Then let go of both buttons. **3.** Check to see that the resulting printout is clear and complete.
The printer is not printing over a wired connection to the Base Station. The POWER indicator light is green or orange, and the STATUS indicator light is green.	If the printer is close to a fluorescent light: • Reposition the printer or shield the infrared radiation (IR) window to prevent direct line-of-sight between the fluorescent light and the IR window. • Relocate the printer or fluorescent light to a greater distance from each other. • Turn off fluorescent lights within close proximity of the printer when printing records over a serial connection. • Print directly from the instrument over an IR connection.
The printer is feeding paper, but nothing is printed.	Check that the paper is feeding from under the roll.
The printer is not printing and the POWER indicator is red.	Recharge the battery.
The printer's POWER indicator does not illuminate when the printer is powered on.	Recharge the battery.
The printer does not print, and the STATUS indicator is orange.	Add paper to the printer.

Printer Problem	Resolution
The printer does not print, and the STATUS indicator is red.	The print head is hot. Allow the print head to cool before attempting to reprint.

When some print problems occur, a message prints that indicates the cause:

Printout Text	System Administrator Action
`Printer Failure. Discard printout. Use another printer. Report failed printer to System Administrator.001`	Reset the failed printer: **1.** Turn off the printer and unplug the power cord. **2.** Open the battery compartment and unplug the battery. **3.** Leave the battery unplugged for at least 10 seconds. Then reconnect the battery and close the battery compartment. **4.** Reconnect the power cord. Then, press the power button to turn the printer on. Attempt to print a record from the instrument. If a printer failure occurs, contact Technical Support.
`Printer Failure. Use another printer. Report failed printer to System Administrator. 002`	Reset the failed printer: **1.** Turn off the printer and unplug the power cord. **2.** Open the battery compartment and unplug the battery. **3.** Leave the battery unplugged for at least 10 seconds. Then reconnect the battery and close the battery compartment. **4.** Reconnect the power cord. Then, press the power button to turn the printer on. Attempt to print a record from the instrument. If a printer failure occurs, contact Technical Support.
`Printer Failure. Use another printer. Report failed printer to System Administrator. 003`	Reset the failed printer: **1.** Turn off the printer and unplug the power cord. **2.** Open the battery compartment and unplug the battery. **3.** Leave the battery unplugged for at least 10 seconds. Then reconnect the battery and close the battery compartment. **4.** Reconnect the power cord. Then, press the power button to turn the printer on. Attempt to print a record from the instrument. If a printer failure occurs, contact Technical Support.

Printout Text	System Administrator Action
`Printer Failure. Use another printer. Report failed printer to System Administrator. 004`	Reset the failed printer: **1.** Turn off the printer and unplug the power cord. **2.** Open the battery compartment and unplug the battery. **3.** Leave the battery unplugged for at least 10 seconds. Then reconnect the battery and close the battery compartment. **4.** Reconnect the power cord. Then, press the power button to turn the printer on. Attempt to print a record from the instrument. If a printer failure occurs, contact Technical Support.

Cleaning and Disinfecting

Complete instructions for cleaning and disinfecting are found in the *Quick Reference Guide*. The graphics below are a visual representation of the wiping procedure for disinfection.

This page intentionally left blank.

1.9 - Manufacturer's Quality System Instructions

The list below defines the i-STAT Alinity System MQSI components.

1	**Check New or Replacement Instruments with the Electronic Simulator** Use the Electronic Simulator to verify operation of a new or replacement instrument before use.
2	**Check Temperature Strip for a New Shipment of Cartridges** Verify that the temperature in transit was maintained by reading the temperature strip included in each shipping container.
3	**Ensure Proper Cartridge Storage** according to these criteria: • Refrigerator storage conditions for stored cartridges range from 2 to 8ºC (35 to 46ºF). • Cartridges are not exposed to temperatures exceeding 30ºC (86ºF). • Cartridges are not used after the expiration date printed on the individual pouch and box. • A cartridge taken from refrigerated storage must stand in its pouch at room temperature for 5 minutes before use. • A box of pouched cartridges must stand at room temperature for one hour before use. • A cartridge allowed to come to room temperature must be labeled with its new expiration date. See *Cartridge Box Information*. • A cartridge is used immediately after it is removed from its pouch.
4	**Ensure Thermal Probe Check is Performed** Ensure the thermal probe check is performed with the electronic simulator every 6 months on each instrument. This check can be performed in conjunction with the instrument's software updates.
5	**Train Staff on Avoidance of Pre- and Post-analytical Errors** Ensure that users are trained to avoid pre-analytical errors such as those associated with sample collection, delays in testing, inadequate sample mixing, and post-analytical errors (results reporting and communication).

There may be additional accreditation organization requirements and individual codes, statutes, or regulations which are not addressed here.

This page intentionally left blank.

1.10 - Liquid Quality Controls

Perform liquid quality control testing in accordance with facility protocols, best practices, and regulatory requirements.

Visit *www.globalpointofcare.abbott* for instructions for use (IFU) related to products not listed in this section.

i-STAT Controls and i-STAT TriControls

Aqueous-based control solutions are available for verifying the integrity of newly received cartridges. **i-STAT Control** Level 1, 2 and 3 are formulated at three clinically relevant levels with defined pH values and hematocrit values (TriControls only) and with known concentrations of:

Sodium	PCO_2	Glucose
Potassium	PO_2	Lactate
Chloride	TCO_2	BUN/Urea
Ionized Calcium		Creatinine

Each level of control is packaged in a box containing 10 individual 1.7 mL glass ampules.

The control solutions do not contain human serum or serum products, but they do contain buffers and preservatives.

Storage

Store refrigerated at 2 to 8ºC (35 to 46ºF) until the printed expiration date on the box and ampule labels.

Unopened ampules of control solutions can also be maintained at room temperature (18 to 30ºC or 64 to 86ºF) for up to 5 days.

Do not use control solutions past the labeled expiration date on the box and ampule labels.

Ampule use

Barcode on the ampule must be scanned before the ampule is opened.

Testing must be performed within 10 minutes of opening the ampule.

Testing must be performed immediately upon opening when testing pH, PCO_2, PO_2 or iCa.

Ranges

Assigned ranges are provided in the form of value assignment sheets (VAS). These are located in the Support area of *www.globalpointofcare.abbott*. Abbott Point of Care makes available both eVAS and ReVAS. ReVAS ranges are provided as a feature for the German market and for those customers who prefer ranges set using Rilibak guidelines.

Electronic value assignment sheets (eVAS or ReVAS) may be downloaded to a customized instrument via the Abbott Managed Server, the SDi, or USB. See the *System Operations Manual* for information and instruction on creating customization profiles. Selection of eVAS or ReVAS must be made during the creation of the profile.

Note: Follow facility policy regarding control results that do not fall within assigned ranges.

Disposal

Check with authorities for local, state, and/or national requirements for disposal.

Procedure for Testing

Prerequisites

- Ampules, cartridges, and instruments must be at the same temperature.

- Controls solutions require different temperature stabilization times depending on whether PO_2 is to be measured. If PO_2 is to be measured, equilibrate the ampule for 4 hours. If not, equilibrate the ampule for approximately 30 minutes at room (ambient) temperature.
- Do not use the solution left in a syringe, ampule or capillary tube for additional testing of cartridges that contain sensors for iCa, pH, PCO_2 or PO_2. However, cartridges without these sensors may be tested with remaining fluids if within 10 minutes of opening the ampule.
- Since aqueous based solutions such as controls lack the buffering capabilities of whole blood, the transfer process from ampule to cartridge must be more expedient than with a patient sample.

Performing Quality Control Testing

1. Press **Power** and allow instrument to power on.

   Note: After powering on the instrument, one or more alert messages may display. Read the message carefully and perform the functions necessary to evaluate and/or clear the alert. The **Home** screen will display when the alerts have been successfully managed.
2. From the **Home** screen touch **More Options** > **Quality Options** > **Quality Control**. Select the button that is appropriate for the testing. Continue to follow the prompts on the screen. There are three pathways available for performing liquid QC tests. The default is unscheduled. The other two options are available when the instrument is customized by the system administrator (see the Customization Workspace for i-STAT (AlinIQ CWi)).
3. Enter the required information by following the prompts on the screen. Prepare the cartridge and control solution for testing.
4. Shake the ampule vigorously for 5 to 10 seconds to equilibrate the liquid and gas phases. To shake, hold the ampule at the tip and bottom with forefinger and thumb to minimize increasing the temperature of the solution. If necessary, tap the tip of the ampule to send solution back into the bottom section of the ampule.
5. Protect fingers with gauze, tissue or glove, or use an ampule breaker to snap off the tip of the ampule at the neck.
6. **Immediately** transfer the solution from the ampule into a capillary tube or syringe (refer to information for transferring the control solution, below), and then **immediately** transfer the solution into a cartridge. Help graphics on the instrument show the transfer of control material to the cartridge via a syringe with a blunt tip needle.

7. **Immediately** close the cartridge and insert it into an instrument – it is important to prevent exposing the solution to room air since this will alter the results.

Transferring the control solution: syringe with blunt tip needle

Plain syringes (1cc or 3cc sterile syringes with blunt tip needles) are recommended to transfer aqueous control solutions from the ampule to the cartridge.

To use a syringe:

1. Place the end of the blunt tip needle into the bottom of the ampule.
2. Slowly remove approximately 1cc of solution from the ampule into the syringe.
   - If air is trapped between the leading edge of the solution and the plunger, do not invert the syringe to expel it; this will not affect solution near the tip of the syringe.
   - If air bubbles are continually drawn into the syringe, or if a bubble is trapped near the tip of the syringe, discard the ampule and syringe.
3. Remove syringe from the ampule and expel one or two drops from the syringe.
4. Place needle into the sample cartridge and fill the cartridge to the fill mark.
5. Close cartridge and begin testing immediately.

Transferring the control solution: capillary tube

Plain capillary tubes are recommended to transfer aqueous control solution from the ampule to the cartridge. Capillary tubes with sufficient fill capacity are required. For example, when filling a cartridge that requires 95 µl, use a 150 µl capillary tube.

To use a capillary tube:

1. Place a clean, dry finger over one end of the tube and insert open end of the tube into the bottom of the ampule.
2. When the open end of the tube touches the bottom of the ampule, tip the ampule slightly. Remove finger from the other end to allow filling by capillary action. Completely fill the tube with the control solution.
3. Place a finger over the open end of the tube. Remove the tube from the ampule.
4. Place open end of the tube into the sample cartridge. Remove finger to allow the control solution to fill the cartridge to the fill mark.
5. Close cartridge immediately after filling.
6. Testing should be started immediately.

Reactive ingredients for i-STAT Control materials:

Analyte	Control Level 1	Control Level 2	Control Level 3
Na (mmol/L)	127	141	169
K (mmol/L)	3.1	4.0	6.8
Cl (mmol/L)	85	100	122
Glu (mmol/L)	2.5	7.3	17
Urea (mmol/L)	18	4	2.7
iCa (mmol/L)	1.6	1.3	0.8

Analyte	Control Level 1	Control Level 2	Control Level 3
Lac (mmol/L)	8.4	2.3	1
Crea (µmol/L)	386	155	46
PCO_2 (mmHg)	66	30	22
PO_2 (mmHg)	61	100	140
H+ (pH)	7.15	7.41	7.60

Reactive Ingredients for i-STAT TriControls Control Solutions:

Analyte	Control Level 1	Control Level 2	Control Level 3
Na (mmol/L)	118	124	150
K (mmol/L)	3.00	4.00	6.30
Cl (mmol/L)	76	94	119
Glu (mg/dL)	285	160	65
Urea (mg/dL)	44	8.4	4.6
iCa (mmol/L)	0.90	1.35	1.58
Lac (mmol/L)	8.30	3.00	1.63
Crea (mg/dL)	4.65	1.59	0.65
PCO_2 (mmHg)	65	40	26
PO_2 (mmHg)	63	120	163
H+ (pH)	7.025	7.390	7.610

Evaluating QC Results

Ranges

The following is an example of the mean and range for level 1 control taken from a Value Assignment Sheet:

```
                              Mean      Range
Na        mmol/L, mEq/L       120       116-125
```

Na is the analyte tested, Na (Sodium).

mmol/L, mEQ/L are the units of measurement.

Mean is the mean or average level of sodium (Na).

Range is the acceptable range of sodium (Na) levels.

i-STAT ACT Controls

The i-STAT ACT Control Level 1 and ACT Control Level 2 are intended for use to verify the integrity of newly received i-STAT ACT cartridges. The controls produce clotting times expected for moderate and high level heparinization to indicate that the cartridges are functioning properly.

Storage

i-STAT ACT controls contain two levels, Level 1 and Level 2. ACT controls consist of two vials for each level of control. One vial contains lyophilized plasma and the other vial contains the diluent (calcium chloride solution). One box contains 5 vials of lyophilized plasma and 5 vials of diluent. Lyophilized plasma and the diluent should be refrigerated at 2 to 8°C (35 to 46°F) until the expiration date printed on the box and vial labels. Do not use beyond the expiration date.

Warnings and Precautions

Handle this product using the same safety precautions used when handling any potentially infectious material. The human plasma used in the preparation of this product has been tested by FDA-approved test methods and found negative/non-reactive for HIV-1, HIV-2, HBsAg, and HCV. However, no known test method can offer complete assurance that products derived from human blood will not transmit infectious disease.

Ranges

Assigned ranges are found on i-STAT Value Assignment Sheets (VAS) located in the Support area of *www.globalpointofcare.abbott*. Follow facility policy regarding control results that do not fall within assigned ranges.

Disposal

Dispose of this product as biohazardous waste according to all local, state, and national regulations.

Reconstitution Instructions

Prior to testing, i-STAT ACT Control vials containing the lyophilized plasma and diluent should stand at room temperature (18° to 30°C or 64° to 86°F) for a minimum of 45 minutes.

Note: Vials left out at room temperature for more than 4 hours should be discarded.

Pour the entire contents of the diluent into the lyophilized plasma vial. See further instructions under *Procedure for Testing*

Procedure for Testing

Prerequisites

- Vials, cartridges, and instruments must be at the same temperature.
- i-STAT ACT Control vials containing the lyophilized plasma and diluent should stand at room temperature (18 to 30°C or 64 to 86°F) for a minimum of 45 minutes.
- i-STAT ACT Control testing must be performed IMMEDIATELY (less than 30 seconds) AFTER COMPLETING THE RECONSTITUTION AND MIXING STEPS.

Procedure for Performing ACT Controls

1. Press **Power** and allow instrument to power on.

   Note: After powering on the instrument, one or more alert messages may display. Read the message carefully and perform the functions necessary to evaluate and/or clear the alert. The **Home** screen will display when the alerts have been successfully managed.

2. From the **Home** screen touch **More Options** > **Quality Options** > **Quality Control**. Three options are available. The default is **Perform Unscheduled QC**.
3. Touch the appropriate button and continue to follow the prompts on the screen.
4. Prepare the control solution as follows:

   Note: Best practice is to reconstitute and use one level at a time.

   A. Allow lyophilized plasma and diluent to stand at room temperature for 45 minutes.
   B. Remove the cap and stopper from lyophilized plasma and remove the cap from the diluent vial.
   C. Pour the entire contents of the diluent into the lyophilized plasma vial. Discard the empty vial.
   D. Place the stopper back on the reconstituted control vial, closing the vial appropriately so that the contents do not leak or spill.
   E. Allow the vial to sit at room temperature for 1 minute.
   F. Mix the contents of the vial by swirling gently for 1 minute, then inverting slowly for 30 seconds.

      Note: To minimize foaming of the control sample, avoid vigorous or rapid mixing motion.

   G. Visually inspect the control vial to ensure the sample is fully reconstituted. If not, discard and repeat from step **A**.
   H. **IMMEDIATELY:**
      - Transfer the solution from the vial into the cartridge using a plastic transfer pipette or a non-anticoagulated plastic syringe.
      - Close the cartridge
      - Insert the cartridge into the instrument.

Transferring the i-STAT ACT Control solution

A plastic transfer pipette, plastic syringe, or plastic capillary tube with no anticoagulant is recommended to transfer i-STAT ACT Control solutions from the vial to the i-STAT ACT cartridge.

To use a transfer device:

1. Place the end of the transfer device into the bottom of the vial.
2. Slowly remove approximately 1cc of solution from the vial into the transfer device.
   - If air bubbles are continually drawn into the transfer device, or if a bubble is trapped near the tip of the transfer device, discard the vial and the transfer device.
3. Remove transfer device from the vial and expel one or two drops from the transfer device.
4. Place the end of the transfer device into the sample well of the cartridge and fill the cartridge to the fill mark.
5. Close cartridge and begin testing immediately.

1.11 - Calibration Verification (Cal Ver)

Calibration Verification is a procedure performed to confirm that the calibration of an instrument or test system has remained stable throughout the reportable range. This procedure is also called a linearity check.

Visit *www.globalpointofcare.abbott* for instructions for use (IFU) related to products not listed in this section.

The following four items are reasons to perform calibration verification:

1. **Validate the reportable range of a test before the test system is put into use.**
   The accuracy of results over the entire reportable range could be assessed by testing the same patient samples on the new system and on a system with known accuracy and comparing results using an acceptable difference criteria.

   The target values have been determined over many lots of cartridges and results on these solutions when compared to the target values indicate the performance of a particular lot of cartridges.
2. **Verify that a change in reagent lot numbers does not affect either the reportable range or control values.**
   Lot-to-lot variation over the entire reportable range for any reagent system could be assessed by testing calibration verification solutions on old and new lots in parallel. Quality controls samples with concentrations at decision points should always be used to assess new lots of reagent before results are reported.
3. **Verify that results have not been affected by maintenance or repair procedures.**
   The user cannot perform any maintenance procedures on the i-STAT Alinity System. The software in the instrument is updated periodically. Calibration verification solutions could be tested to verify that the system performs as before the upgrade.

   Repaired and newly purchased instruments are received with factory calibration. Testing calibration verification samples or comparing patient sample results on a new or repaired instrument with an older instrument will assess cartridge performance. The Electronic Simulator, rather than calibration verification or control solutions, provides better assurance that the instrument is functioning correctly. Any variations in instrument performance will not be statistically discernable above the performance of the cartridges. When multiple instruments are to be used at a facility, Abbott Point of Care Inc. recommends including at least two instruments in any performance verification studies so that statistics reflect the “system.”
4. **Troubleshoot when control values are out-of-range.**
   Should quality control sample results fall outside of the acceptable ranges, the use of calibration verification samples with very low or very high concentrations could be helpful in characterizing a reagent problem. The characteristics of the sensors and results of control solutions are sufficient for Technical Support specialists to help users resolve out-of-range control problems.

Calibration Verification testing and i-STAT TriControls Calibration Verification Solutions

A five-level calibration verification set is available to verify the calibration of i-STAT cartridges throughout the reportable range.

i-STAT Calibration Verification (Cal Ver) Solutions		
Sodium	PCO_2	Glucose
Potassium	PO_2	Lactate
Chloride	pH	BUN/Urea
Ionized Calcium		Creatinine

i-STAT TriControls Calibration Verification Solutions		
Sodium	PCO_2	Glucose
Potassium	PO_2	Lactate
Chloride	TCO_2	BUN/Urea
Ionized Calcium	Hematocrit	Creatinine
pH		

Each set contains four 1.7 mL glass ampules of each level.

Storage

Store refrigerated at 2 to 8°C (35 to 46°F) until the printed expiration date on the box and ampule labels.

Unopened ampules of **i-STAT Calibration Verification** and **i-STAT TriControls Calibration Verification** and solutions can also be maintained at room temperature (18 to 30°C or 64 to 86°F) for up to 5 days.

Do not use **i-STAT Calibration Verification** and **i-STAT TriControls Calibration Verification** solutions past the labeled expiration date on the box and ampule labels.

Ampule use

Barcode on the ampule must be scanned before the ampule is opened.

i-STAT Calibration Verification and **i-STAT TriControls Calibration Verification** ampule testing must be performed within 10 minutes of opening the ampule.

i-STAT Calibration Verification and **i-STAT TriControls Calibration Verification** ampule testing must be performed immediately upon opening the ampule when testing pH, PCO_2, PO_2, iCa.

Ranges

Assigned ranges are provided in the form of value assignment sheets (VAS). These are located in the Support area of *www.globalpointofcare.abbott*.

Abbott Point of Care makes available both eVAS and ReVAS. ReVAS ranges are provided as a feature for the German market and for those customers who prefer ranges set using Rilibak guidelines.

Electronic value assignment sheets (eVAS or ReVAS) may be downloaded to a customized instrument via the Abbott Managed Server, the SDi, or USB. See the *System Operations Manual* for information and instruction on creating customization profiles. Selection of eVAS or ReVAS must be made during the creation of the profile.

Note: Follow facility policy regarding control results that do not fall within assigned ranges.

Disposal

Check with authorities for local, state, and/or national requirements for disposal.

Procedure for Testing

Prerequisites

- Ampules, cartridges, and instruments must be at the same temperature.
- **i-STAT Calibration Verification** and **i-STAT TriControls Calibration Verification** solutions require different temperature stabilization times depending on whether or not PO_2 is to be measured. If PO_2 is to be measured, equilibrate the ampule for 4 hours. If not, equilibrate the ampule for approximately 30 minutes at room (ambient) temperature.
- Do not use the solution left in a syringe, ampule or capillary tube for additional testing of cartridges that contain sensors for iCa, pH, PCO_2, or PO_2. However, cartridges without these sensors may be tested with remaining fluids if within 10 minutes of opening the ampule.
- Since aqueous based solutions such as controls lack the buffering capabilities of whole blood, the transfer process from ampule to cartridge must be more expedient than with a patient sample.
- Refer to the value assignment sheets posted on the Abbott Point of Care website at *www.globalpointofcare.abbott*.

Procedure

1. Press **Power** and allow the instrument to power on.

   Note: After powering on the instrument, one or more alert messages may display. Read the message carefully and perform the functions necessary to evaluate and/or clear the alert. The **Home** screen will display when the alerts have been successfully managed.
2. From the **Home** screen touch **More Options** > **Quality Options** > **Cal/Ver**. Select the button that is appropriate for the testing.
3. Enter the required information by following the prompts on the screen. Prepare the cartridge and control solution for testing.
4. Shake the ampule vigorously for 5 to 10 seconds to equilibrate the liquid and gas phases. To shake, hold the ampule at the tip and bottom with forefinger and thumb to minimize increasing the temperature of the solution. If necessary, tap the tip of the ampule to send solution back into the bottom section of the ampule.
5. Protect fingers with gauze, tissue or glove, or use an ampule breaker to snap off the tip of the ampule at the neck.
6. **Immediately** transfer the solution from the ampule into a capillary tube or syringe (refer to information for transferring the control solution, below), and then **immediately** transfer the solution into a cartridge. Help graphics on the instrument show transfer of Cal Ver material to the cartridge via syringe with blunt tip needle.

7. **Immediately** close the cartridge and insert it into an instrument – it is important to prevent exposing the solution to room air since this will alter the results.

Transferring the Cal Ver solution: syringe with blunt tip needle

Plain syringes (1cc or 3cc sterile syringes with blunt tip needles) are recommended to transfer aqueous Cal Ver solutions from the ampule to the cartridge.

To use a syringe:

1. Place the end of the blunt tip needle into the bottom of the ampule.
2. Slowly remove approximately 1cc of solution from the ampule into the syringe.
   - If air is trapped between the leading edge of the solution and the plunger, do not invert the syringe to expel it; this will not affect solution near the tip of the syringe.
   - If air bubbles are continually drawn into the syringe, or if a bubble is trapped near the tip of the syringe, discard the ampule and syringe.
3. Remove syringe from the ampule and expel one or two drops from the syringe.
4. Place needle into the sample cartridge and fill the cartridge to the fill mark.
5. Close cartridge and begin testing immediately.

Transferring the Cal Ver solution: capillary tube

Plain capillary tubes are recommended to transfer aqueous control solution from the ampule to the cartridge. Capillary tubes with sufficient fill capacity are required. For example, when filling a cartridge that requires 95 µl, use a 150 µl capillary tube.

To use a capillary tube:

1. Place a clean, dry finger over one end of the tube and insert open end of the tube into the bottom of the ampule.
2. When the open end of the tube touches the bottom of the ampule, tip the ampule slightly. Remove finger from the other end to allow filling by capillary action. Completely fill the tube with the Cal Ver solution.
3. Place a finger over the open end of the tube. Remove the tube from the ampule.
4. Place open end of the tube into the sample cartridge. Remove finger to allow the Cal Ver solution to fill the cartridge to the fill mark.
5. Close cartridge immediately after filling.
6. Testing should be started immediately.

Reactive ingredients for i-STAT Calibration Verification materials

Analyte	Cal Ver Level 1	Cal Ver Level 2	Cal Ver Level 3	Cal Ver Level 4	Cal Ver Level 5
Na (mmol/L)	108	127	141	169	187
K (mmol/L)	2.3	3.1	4.0	6.8	8.5
Cl (mmol/L)	71	85	100	122	133
Glu (mmol/L)	1.8	2.5	7.3	17	35
Urea (mmol/L)	44.6	18	4	2.7	1.8

Analyte	Cal Ver Level 1	Cal Ver Level 2	Cal Ver Level 3	Cal Ver Level 4	Cal Ver Level 5
iCa (mmol/L)	2.5	1.6	1.3	0.8	0.2
Lac (mmol/L)	19.5	8.4	2.3	1	0.6
Crea (µmol/L)	1486	386	155	46	17
PCO_2 (mmHg)	95	66	30	22	18
PO_2 (mmHg)	43	61	100	140	400
H+ (pH)	6.81	7.15	7.41	7.60	7.95

Reactive ingredients for i-STAT TriControls Calibration Verification materials

Analyte	Cal Ver Level 1	Cal Ver Level 2	Cal Ver Level 3	Cal Ver Level 4	Cal Ver Level 5
Na (mmol/L)	97	118	124	150	159
K (mmol/L)	2.30	3.00	4.00	6.30	8.20
Cl (mmol/L)	67	76	94	119	134
Glu (mg/dL)	595	285	160	65	53
Urea (mg/dL)	114	44	8.4	4.6	3.0
iCa (mmol/L)	0.40	0.90	1.35	1.58	2.40
Lac (mmol/L)	17.7	8.30	3.00	1.63	1.52
Crea (mg/dL)	15.6	4.65	1.59	0.65	0.55
PCO_2 (mmHg)	96	65	40	26	12
PO_2 (mmHg)	40	63	120	163	500
H+ (pH)	6.550	7.025	7.390	7.610	7.850

Evaluating Cal Ver Results

Ranges

Calibration throughout the reportable range of each analyte is verified if each analyte value falls within the corresponding range in the Value Assignment Sheet.

If a result for a level falls outside the assigned range, follow laboratory policy. Contact Technical Support for troubleshooting information.

Note: If the calibration verification set is to be used to assess linearity, plot the analyte value against the mean value of the acceptable range. The concentrations of analytes in the calibration verification set are not intended or prepared to be equally spaced.

The following is an example of the mean and range for level 2 Cal Ver solution taken from a Value Assignment Sheet:

		Mean	Range
Na	mmol/L, mEq/L	120	116-125

Na is the analyte tested, Na (Sodium).
mmol/L, mEQ/L are the units of measurement.
Mean is the mean or average level of sodium (Na).
Range is the acceptable range of sodium (Na) levels.

1.12 - i-STAT Cartridges

Overview

i-STAT cartridges contain test reagents which are located on sensors on the top of the cartridge. The instrument and cartridge work together to generate a clinically meaningful result.

The cartridges are designed for use with the i-STAT Alinity instrument.

Note:

- Not all cartridges are available in all regions. Check with your local representative for availability in specific markets. Scanning a cartridge that is unavailable will result in a pop-up window that displays **Invalid Cartridge Type.**
- Customization may affect analyte availability.
- For access to cartridge-specific Instructions for Use (IFU) and analyte-specific CTI Sheets, access the Support page on the Abbott Point of Care website *www.globalpointofcare.abbott*.

Cartridge Specifications

Shelf Life: Refrigerated at 2°C to 8°C (35°F to 46°F) until expiration date. Refer to the cartridge box for room temperature storage requirements.

Preparation for Use: Individual cartridges may be used after standing five minutes at room temperature. An entire box of cartridges should stand at room temperature for one hour. All cartridges should be used immediately after opening pouch. If the pouch has been punctured, the cartridge should not be used.

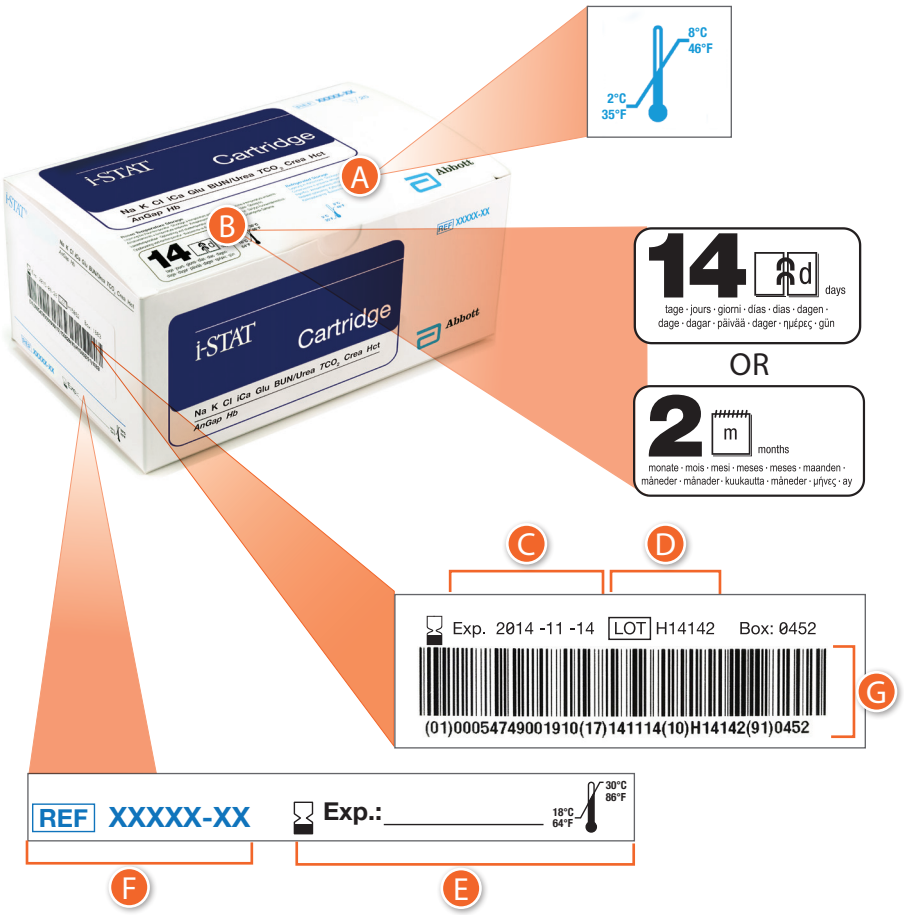
Cartridges stored in refrigerator:

- Temperature must be 2-8°C (35-46°F)
- Cartridges expire on the date printed on the pouch

Cartridges stored at room temperature:

- Temperature must be 18-30°C (64-86°F)
- Once cartridge is at room temperature the expiration date changes
- Cartridge should not be returned to the refrigerator once out for more than 5 minutes.

Cartridge Box Information



ANATOMY OF A BOX:

A Refrigerated storage temperature indicator: 2-8°C (35-46°F)

B Indicates shelf life when stored at room temperature

- Cartridge pouch displaying the  indicates the cartridge expires in 14 days.

  Example: cartridge reaches room temperature on 2025-10-13

  New expiration date is 2025-10-27

- Cartridge pouch displaying the  indicates the cartridge expires in two months

  Example: cartridge reaches room temperature on 2025-12-13

  New expiration date is 2025-12-13

- Room temperature expiration date cannot exceed manufacturer's printed expiration date

C Refrigerated storage expiration date

D Cartridge LOT number

E Location to record room temperature expiration date

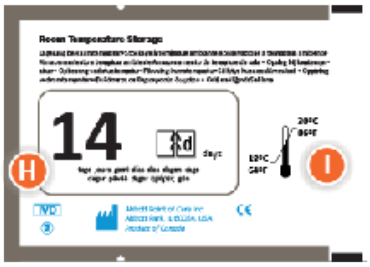
F Cartidge List Number

G Unique Device Identifier (UDI) barcode

Cartridge Pouch Information

Pouch Front

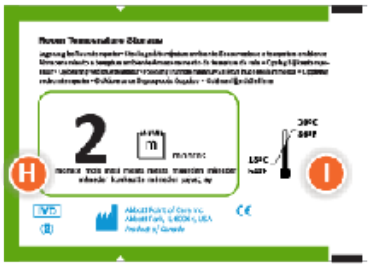
Pouch Back



OR

Pouch Front

Pouch Back



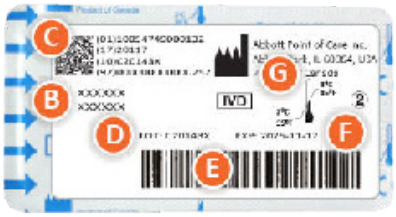
ANATOMY OF A POUCH:

- A Cartridge name
- B Analytes – measured and calculated
- C Location to record room temperature expiration date
- D UDI (2D) barcode; not scannable by instrument
- E Cartridge LOT number
- F Cartridge pouch barcode, scan for test
- G Refrigerated storage expiration date
- H Indicates shelf life when stored at room temperature
- I Room temperature storage range

Cartridge Portion Pack Information

Portion Pack Front

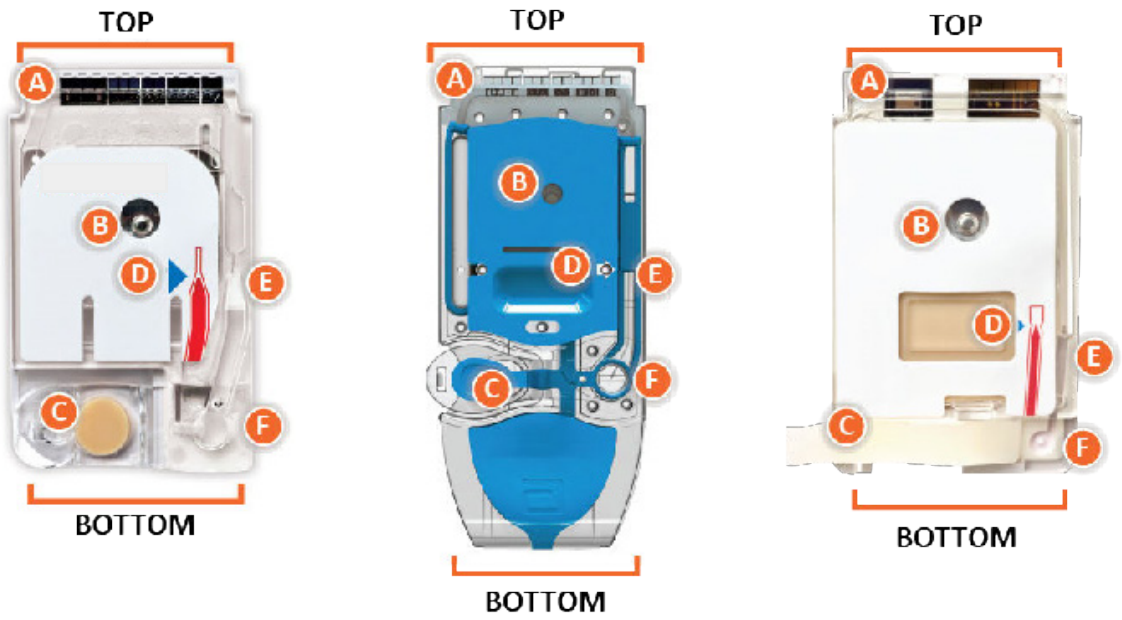
Portion Pack Back



ANATOMY OF A PORTION PACK:

- A Cartridge name
- B Analytes – measured and calculated, if applicable
- C UDI (2D) barcode; not scannable by instrument
- D Cartridge LOT number
- E Cartridge portion pack barcode; scan for test
- F Refrigerated storage expiration date
- G Refrigerated temperature storage range

i-STAT Cartridge Components



Anatomy of a cartridge

- **A** CONTACT PADS & SENSORS (do not touch)
- **B** CALIBRANT PACK OR ANALYSIS FLUID, if applicable (do not touch)
- **C** CARTRIDGE CLOSURE
- **D** FILL TO MARK
- **E** SAMPLE CHAMBER
- **F** SAMPLE WELL

Note:

- Always handle cartridges by the sides or the bottom. Do not touch the sensor area at the top of the cartridge or the calibrant pack area in the middle of the cartridge. Improper handling may damage the cartridge and result in a Cartridge Quality Check Failure instead of results.
- Dispose of used cartridges as biohazardous waste. Follow facility policy for disposal.
- Not all cartridges are available in all regions. Check with your local representative for availability in specific markets.

Contact pads

The contact pads conduct the signals generated by the sensors to the instrument. In order for these to function properly, care must be exercised not to contaminate the contact pads during cartridge handling.

Sensors

The sensors are electrodes microfabricated on silicon chips located within the cartridge. Electrodes have chemically sensitive coatings such as ion-selective membranes and enzyme layers. Each sensor is connected to a contact pad by a signal line. The sensors respond to the calibrant solution and the sample by producing measurable signals related to analyte concentration.

Sensor Channel

The sensor channel directs the sample from the sample chamber to the sensors. An extension of this channel becomes a waste chamber to receive the calibrant solution as it is displaced by the sample.

Air Chamber

An air chamber is located in blood gas/electrolyte/chemistry/hematocrit cartridges between the sample chamber and sensor channel. This creates an air segment between the calibrant solution, if applicable, and the sample to prevent the two from mixing. The size of the air segment is monitored by the instrument.

Calibrant Pack

During the first part of the testing cycle, the calibrant solution is automatically released from the foil pack and is positioned over the sensors. The foil pack may be pierced with improper cartridge handling. If fluid is released prematurely, a Quality Check Failure may occur.

Fill To

The blue arrow on the white label cartridge and the clear arrow on the blue cover cartridge is intended to help the operator fill the cartridge correctly. Samples that fall above or below the indicated level may result in a Quality Check Failure.

Sample Chamber

The sample chamber includes the sample well and the channel leading from the well up to the fill mark. When filled, the sample chamber contains sufficient sample for testing. Sample volume and placement are monitored by the instrument.

Bladder

The bladder is connected to the sample well. The instrument presses on the bladder to displace calibrant solution from the sensors, to move the sample from the sample chamber to the sensors, or to mix sample and reagents.

Sample Well

The area on the cartridge where the sample is introduced into the sample chamber.

Closure

The closure creates an airtight seal necessary for proper fluid movement within the cartridge. The closure also ensures that calibrant and sample remain contained within the cartridge during the testing cycle and subsequent disposal.

Cartridge on the left in the illustration contains natural rubber latex on the snap closure. The cartridge shown on the right is not made with natural rubber latex.

Heating elements

All i-STAT cartridges require thermal control at 37°C (98.6°F), and include heating elements on the underside of the sensor chips which are contacted and heated by the instrument's thermal probes.

Standardization and calibration

Standardization is the process by which a manufacturer establishes "true" values for representative samples. A multi-point calibration curve, the slope or sensitivity of which is defined by coefficients in the CLEW software, is derived for each sensor by this standardization process. These calibration curves are stable over many lots.

A one-point calibration is performed each time a cartridge requiring calibration is used. During the first part of the testing cycle, the calibrant solution is automatically released from its foil pack and is positioned over the sensors. The signals produced by the sensors' responses to the calibrant solution are measured. This one-point calibration adjusts the offset of the stored calibration curve. Next, the instrument automatically moves the sample over the sensors and the signals produced by the sensors' responses to the sample are measured. While coefficients are used rather than graphic calibration curves, the calculation of the result is equivalent to reading the sample's concentration from an adjusted calibration curve.

Types of cartridge sensors

Sensors are thin film electrodes microfabricated onto silicon chips. Sensing functionality is imparted to each electrode by a number of chemically sensitive films coated over the active region of the electrodes.

The cartridges have three different types of sensors built in: potentiometric, amperometric, and conductometric.

Potentiometric sensors

In potentiometric measurements, the difference in potential that exists between an indicator electrode and a reference electrode is measured. Ion-selective electrodes (ISE) are examples of potentiometric sensors. The indicator electrode is designed to be sensitive to a particular ion in a solution. In cases where other ions are sensed by the system, selectivity coefficients can be used to correct for this interference. An enzyme can be added to an ISE to produce ions from analytes of interest that are not themselves ions.

Potentiometric sensors utilize two important concepts. The first concept is the Nernst Equation which relates the measured potential to the activity of the ion being measured. It is written as:

$E = E° + RT/nF \ln a$

Where E is the potential, E° is a constant dependent on the electrode/sensor system, R is the gas constant, T is the absolute temperature, F is Faraday's constant, (n) is the valence (positive or negative charge) for the ion being measured, and (a) is the activity of that ion.

The Nernst equation can be rewritten as:

$E = E° + S \log a$

Where S replaces the constant term which defines the slope of the sensor. The slope is the change in millivolts per tenfold change in the activity of the analyte. For a positively-charged monovalent ion, the theoretical slope would be 59.1 mV at 25°C.

The second concept is Activity versus Concentration where ion-selective electrodes measure activity rather than concentration. Activity (a) is related to concentration (c) through the activity coefficient (γ). It is written as:

$a = \gamma c$

Note: While ion activities, which reflect free rather than total ion concentrations, are the physiologically relevant quantity, activity values are converted to conventional concentration units so that values obtained by direct ISE measurements can be compared to values obtained from methods that measure total ion concentrations. The latter includes the indirect methods, which have activity coefficients close to unity or one, and flame photometric, atomic absorption and titration methods.

Amperometric sensors

In amperometric measurements, a potential is applied to the measuring electrode while current generated by the resulting oxidation or reduction reactions in the test system is measured. The current generated is directly proportional to the concentration of the analyte. An enzyme can be added to a layer on or near an amperometric sensor to produce electroactive species from analytes of interest that cannot themselves be oxidized or reduced.

Conductometric sensors

In conductometric measurements, an alternating current is applied between two electrodes in contact with the test solution and the resulting voltage difference is measured. The conductivity of the solution is proportional to the magnitude of the voltage difference. In aqueous solutions, conductivity is dependent upon the concentration of electrolytes; an increase in the electrolyte concentration causes an increase in conductivity.

Determination of analyte concentration

Potentiometric and amperometric sensors are used for the determination of analyte concentration. For both sensors, the concentration of the analyte can be calculated using:

1. The known value of the analyte concentration in the calibrant solution
2. The measured voltage (potentiometric) or current (amperometric) signal generated by the analyte in the calibrant
3. The measured signal generated by the analyte in the test solution

For potentiometric sensors, the analyte activity in the sample is calculated from the Nernst equation according to:

$E_{sample} - E_{calibrant} = S \log (a_{sample}/a_{calibrant})$

Complex solutions such as blood deviate slightly from Nernstian behavior due to interfering ions and matrix effects that result in junction potentials. By including selectivity coefficients in the Nernst equation (Nikolsky equation), these effects can be minimized. By characterizing the reference electrode in different solutions, effects of matrix on the reference junction potential can also be minimized.

Receiving a New Shipment of Cartridges

i-STAT Alinity quality system includes these steps whenever a new shipment of cartridges is received:

1. **Check Temperature Strip for a New Shipment of Cartridges**
   Verify that the transit temperatures were satisfactory by reading the temperature strip included in each shipping container.
2. **Ensure Proper Cartridge Storage according to these criteria:**
   - Refrigerator storage conditions for stored cartridges range from 2 to 8ºC (35 to 46ºF).
   - Cartridges are not exposed to temperatures exceeding 30ºC (86ºF).
   - Cartridges are not used after the expiration date printed on the individual pouch and box.
   - Cartridges are not outside the refrigerator for longer than the time frame indicated on the cartridge box.
   - A cartridge is used immediately after it is removed from its pouch.
   - A cartridge taken from refrigerated storage is allowed to stand in its pouch at room temperature for 5 minutes before use, or that a box of pouched cartridges stands at room temperature for one hour before use.

Precautions and Limitations

Although cartridges are not fragile, they consist of sensors and other sensitive components that will alter the test results, or generate Quality Check Failure Codes (QCF) codes, if they are not properly filled and handled.

DO:

- dispose of the cartridge in a container for biohazardous waste, in accordance with your facility's policies and with local, state, and national regulatory guidelines.
- keep the cartridge and the instrument at the temperature of the room where they are to be used. Condensation on a cold cartridge can prevent proper contact with the instrument.

DO NOT:

- use a cartridge if either the refrigerated or room temperature dates have passed. Refer to the *Cartridge Box Information*.
- remove a cartridge from its protective pouch until it is at room temperature 18 to 30ºC (or 64 to 86ºF).
- return cartridges to the refrigerator after bringing them to room temperature.
- expose cartridges to temperatures above 30ºC (86ºF).
- use a cartridge that is expired or that shows signs of damage.
- use a cartridge if the foil pouch or clear plastic portion pack has been punctured.
- apply pressure to the central area of the label because the calibrant pack inside could burst prematurely.
- place the cartridges in an oxygen-enriched atmosphere.
- touch the sensors on the top of the cartridge.
- use a cartridge onto which blood or any other fluid has spilled. Avoid filling cartridges on surfaces where the cartridge could pick up fibers, fluid, debris, or other materials that could lodge in the instrument.
- attempt to remove the cartridge while the message `Cartridge Locked in instrument. Do not attempt to remove the cartridge.` remains on the screen.

NOTES:

- The instrument and its peripherals are not listed by any authority with respect to suitability for use in oxygen-enriched atmospheres.

- Follow manufacturer's recommendations for handling and storing samples drawn into lithium or balanced heparin.

This page intentionally left blank.

1.13 - Software Updates

Software updates to the i-STAT Alinity instrument are delivered twice a year. Each software update contains two elements in a single package: CLEW software and application software. These updates may be downloaded and installed in one of three ways:

1. USB memory device via Base Station
2. Abbott Managed Server
3. AlinIQ SDi

Note: Best practice is to enable use of an Operator List to protect the Update Software flows from being executed by unauthorized personnel.

Software Update and Installation using USB memory device via Base Station

Use this procedure to update the instrument software via USB memory device.

Note: This procedure takes approximately 5 to 15 minutes to complete. Therefore, it is recommended this procedure be executed outside of the clinical work area.

Prerequisites:

Equipment:

- i-STAT Alinity instrument(s) to be updated
- Base Station with power cable connected to AC mains power
- Formatted USB memory device
- PC with network connection to the Abbott Point of Care website: *www.globalpointofcare.abbott*

Before attempting to update software from USB, prepare a USB memory device using the following steps:

1. Obtain a FAT32 formatted USB 2.0 memory device[1]
2. Remove any package files (.apkg file extension) from the top level of the directory structure of the memory device.
3. Retrieve the i-STAT Alinity instrument software package from the Support area of the Abbott Point of Care website: *www.globalpointofcare.abbott*
4. Copy the software package to the memory device
5. Safely remove the memory device from your PC

Before attempting to update instrument software from USB, ensure the following:

1. The instrument is placed in the powered Base Station.
   To verify:

   The Base Station and instrument light should be blue and the following battery symbol  in the upper right-hand corner on the instrument should be displayed.

2. The instrument is running software version OSi05 or later.
To verify:

From the Home screen, navigate to: **More Options** > **Instrument Status**

Select page that shows the Firmware and verify the name of the firmware is OSi05 or later (i.e., OSi06, OSi07, OSi08, etc.).

Procedure:

Perform the following steps to download and install a software update using the USB memory device:

CAUTION: During the installation, do not remove the instrument or the USB memory device from the Base Station. When the installation is complete, the instrument will display a message indicating that new software has been installed. The display of this message is the indication that it is safe to remove the instrument and USB memory device from the Base Station.

1. From the Home screen, navigate to: **More Options** > **Instrument Options** > **Software Installation** > **Install From USB**
2. Follow the on-screen instructions.
3. When presented with the name of the software package to be installed, record the name before proceeding (this information may be used at the end of the procedure to verify that the software update has been completed).
   - Press Next to continue with the installation of the software package, **OR**
   - Press Cancel to terminate the installation
4. Continue to follow the on-screen instructions. During the installation process, the instrument screen will go blank and remain blank for several minutes. This is normal.
   - Do not remove the instrument from the Base Station.
   - Do not remove the memory device from the Base Station.
5. When the installation is complete, the instrument screen will illuminate and display a message that new software has been installed. The display of this message is the indication that the installation is complete and it is safe to remove the instrument and USB memory device from the Base Station.

6. Follow the instructions on screen to complete the Electronic Simulator testing, or touch **Exit Alerts** to resume normal operation of the instrument.

Note: It is recommended that Electronic Simulator Test be completed immediately following a software update. Depending on the instrument customization, testing may be disabled until an Electronic Simulator Test with passing result is completed.

Troubleshooting:

If there is any question as to whether or not the software update completed, check the software status page. From the **Home** screen, navigate to: **More Options** > **Instrument Options** > **Software Installation** > **Software Status**

- If the Firmware name displayed on the Software Status page matches that which was recorded during the software update procedure, this indicates that the software update was completed.

Symptom	Action to take
Instrument does not detect the Base Station	• remove the instrument and re-seat it on the Base Station • ensure the Base Station is getting power (blue light illuminated)
Instrument does not detect the USB drive	• remove the USB memory device and reinsert • ensure the USB memory device is formatted as described earlier in this section
Instrument does not detect a software package onthe USB memory device	Verify the following, then repeat the software update procedure: • remove the USB memory device from the Base Station and insert into a Windows PC • verify that one and only one .apkg file is present at the top level of the directory structure of the USB memory device. (The .apkg should not be in a subfolder) • verify the name of the .apkg file is identical to that which is listed on the web page from which it was downloaded (The file must not be renamed)

[1]**Note:** Some preformatted USB memory devices may not work with the i-STAT Alinity system. To avoid issues, reformat the drive using a Windows PC before using the USB memory device with the i-STAT Alinity system. Before reformatting, make sure you copy any files on the USB memory device to a safe location on your PC because reformatting will delete all files from the memory device.

Software Update and Installation via Abbott Managed Server or the AlinIQ SDi, and a Wired Network Connection

Use this procedure to update the instrument software using a wired connection to Abbott's Managed Server or the SDi.

Note:

- The healthcare organization network **must** allow instruments to connect to the Abbott Managed Server or an SDi server.
- This procedure may take between 15 minutes and 1 hour to complete. Therefore, it is recommended this procedure be executed outside of the clinical work area.
- See the *AlinIQ SDi User Guide* for information on use of the SDi to facilitate software delivery to instruments.

Prerequisites:

Equipment:

- i-STAT Alinity instrument(s) with appropriate Network Configuration file installed
- Base Station with power cable connected to AC mains power
- Ethernet cable connected to healthcare organization network and Base Station
- Internet access

Before attempting to update instrument software from the Abbott Managed Server or the SDi, ensure the following:

1. The instrument is configured with a network configuration that allows wired connection to the internet if using the Abbott Managed Server, or to the SDi server.
   See *AlinIQ NCi - Network Connectivity for i-STAT* for instructions on configuring instrument for network connection. The wired connection must be enabled. If the healthcare organization network requires use of a proxy to access the internet, the Proxy Server settings must also be configured.
2. The instrument is placed in the powered Base Station, and the Base Station has a connection to the healthcare organization network.
   To verify:

   A. The Base Station and instrument light should be blue and the following battery symbol  in the upper right-hand corner on the instrument should be displayed.

   B. From the **Home** screen, navigate to: **More Options** > **Instrument Options** > **Network Settings** > **Network Status**

   C. Navigate to **Wired Network Connection** section and verify the wired network interface has an IP address.

3. The instrument is running software version OSi05 or later.
   To verify:

   A. From the **Home** screen, navigate to: **More Options** > **Instrument Status**

   B. Select page that shows the Firmware and verify the name of the firmware is OSi05 or later (i.e., OSi06, OSi07, OSi08, etc.).

4. Network Services for software update enabled on instrument.

To verify:

A. From the **Home** screen, navigate to: **More Options** > **Instrument Options** > **Network Settings** > **Network Services**

B. Enter your Operator ID and sequence through the workflow to view the press **Next** to view the Firmware Delivery option. Verify Enabled is selected.

5. The battery charge level is no less than 51%.
   To verify:

   A. From the Home Screen, navigate to: **More Options** > **Instrument Status**
   B. Locate Battery and verify level is 51% or higher.

Procedure:

Perform the following steps to download and install software update:

CAUTION: During the installation, do not remove the instrument from the Base Station. When the installation is complete, the instrument will display a message indicating that new software has been installed. When installation is complete, the instrument may be removed from the Base Station.

1. From the **Home** screen, navigate to: **More Options** > **Instrument Options** > **Software Installation** > **Check for Update**
2. After the software download is completed, installation of software can begin. Please skip step 3.
3. Software download and installation can be performed at different times if needed. The i-STAT Alinity will display the following symbol  on the Home screen in the lower right hand corner if software is downloaded but not installed. Touch this icon to display the Software Installation menu. Touch the **Install Pending** button to install the software.
4. Follow the on-screen instructions to continue with software installation.
5. When presented with the name of the software package to be installed, record the name before proceeding (this information may be used at the end of the procedure to verify that the software update has been completed).
   - Touch Next to continue with the installation of the software package, **OR**
   - Touch Cancel to terminate the installation
6. Continue to follow the on-screen instructions. During the installation process, the instrument screen will go blank and remain blank for several minutes. This is normal.
   - Do not remove the instrument from the Base Station
7. When the installation is complete, the instrument will display a message indicating that new software has been installed. The display of this message is the indication that it is safe to resume normal operation of the instrument.

8. Follow the instructions on screen to complete the Electronic Simulator testing, or press Exit Alerts to resume normal operation of the instrument.

Note: It is recommended that Electronic Simulator Test be completed immediately following a software update. Depending on the instrument customization, testing may be disabled until an Electronic Simulator Test with passing result is completed.

Troubleshooting:

If there is any question as to whether or not the software update completed, check the software status page. From the Home screen, navigate to: **More Options** > **Instrument Options** > **Software Installation** > **Software Status**

- If the Firmware name displayed on the Software Status page matches that which was recorded during the software update procedure, this indicates that the software update was completed.

Symptom	Action to take
Battery status indicator does not indicate batteryis charging	• Remove the instrument and re-seat it on the Base Station • Ensure the Base Station is getting power (Blue light on Base Station is illuminated)

Symptom	Action to take
Check for Update button is not enabled	Verify the following as described in the prerequisites, then repeat the software update procedure: • The instrument is running software version OSi05 or later • Network Services for software update enabled on instrument • The battery charge level is no less than 51%
Instrument indicates a connection could not be made to the Server service, **OR** Instrument powers off before completing the software download, **OR** Instrument does not power on within 10 minutes after screen going blank	Verify the following as described in the prerequisites, then repeat the software update procedure: • i-STAT Alinity instrument(s) with appropriate Network Configuration file installed • Base Station with power cable connected to AC mains power • Ethernet Cable connected to healthcare organization network • The healthcare organization network is allowing the instrument to connect to the internet in order to have access to the Abbott Managed Server or SDi.
Repeated attempts to update software via wired-network connection fail	Follow the procedure to perform software update using USB memory device

Software Update and Installation via Abbott Managed Server or the AlinIQ SDi, and a Wireless Network Connection

Use this procedure to update the instrument software using a wireless connection to Abbott's Managed Server or the SDi.

Note:

- The healthcare organization network **must** allow instruments to connect to the Abbott Managed Server or an SDi.
- This procedure may take between 15 minutes and 1 hour to complete. Therefore, it is recommended this procedure be executed outside of the clinical work area.
- See the *AlinIQ SDi User Guide* for information on use of the SDi to facilitate software delivery to instruments.

Prerequisites:

Equipment:

- i-STAT Alinity instrument(s) with appropriate Network Configuration file installed
- Wireless network
- Internet access

Before attempting to update instrument software from the Abbott Managed Server or the SDi, ensure the following:

1. The instrument is configured with a network configuration that allows wireless connection to the internet.
   See *AlinIQ NCi - Network Connectivity for i-STAT* for instructions on configuring instrument for network connection. The wireless connection must be enabled. If the healthcare organization network requires use of a proxy to access the internet, the Proxy Server settings must also be configured.
2. The instrument has a wireless connection to the healthcare organization network.
   To verify:

   A. **Home** screen shows  symbol in the upper right-hand corner and the wireless signal strength is 3 solid bars or greater.

   B. From the **Home** screen, navigate to: **More Options** > **Instrument Options** > **Network Settings** > **Network Status**

   C. Locate the Wireless Connection Details section and verify the wireless network interface has an IP address.
3. The instrument is running software version OSi05 or later.
   To verify:

   A. From the **Home** screen, navigate to: **More Options** > **Instrument Status**

   B. Locate the Firmware item and verify the name of the firmware is OSi05 or later (i.e., OSi06, OSi07, OSi08, etc.).
4. Network Services for software update enabled on instrument.
   To verify:

   A. From the **Home** screen, navigate to: **More Options** > **Instrument Options** > **Network Settings** > **Network Services**

B. Enter your Operator ID and sequence through the workflow to view the Firmware Delivery option. Verify Enabled is selected.

5. The battery charge level is no less than 51%.
   To verify:

   A. From the **Home** Screen, navigate to: **More Options** > **Instrument Status**
   B. Locate Battery and verify level is 51% or higher.

Procedure:

Perform the following steps to download and install software update:

CAUTION: During the software installation, do not remove the battery from the instrument. When the installation is complete, the instrument will display a message indicating that new software has been installed. The display of this message is the indication that it is safe to resume normal operation of the instrument.

1. From the **Home** screen, navigate to: **More Options** > **Instrument Options** > **Software Installation** > **Check for Update**
2. After the software download is completed, installation of software can begin. Please skip step 3.
3. Software download and installation can be performed at different times if needed. The i-STAT Alinity will display the following S**ymbol**  on the Home screen in the lower right hand corner if software is downloaded but not installed. Touch this icon to display the Software Installation menu. Touch the **Install Pending** button to install the software.
4. Follow the on-screen instructions to continue with software installation.
5. When presented with the name of the software package to be installed, record the name before proceeding (this information may be used at the end of the procedure to verify that the software update has been completed).
   - Press Next to continue with the installation of the software package, **OR**
   - Press Cancel to terminate the installation
6. Continue to follow the on-screen instructions. During the installation process, the instrument screen will go blank and remain blank for several minutes. This is normal.
   - Do not remove the instrument from the Base Station
7. When the installation is complete, the instrument will display a message indicating that new software has been installed. The display of this message is the indication that it is safe to resume normal operation of the instrument.

8. Follow the instructions on screen to complete the Electronic Simulator testing, or press Exit Alerts to resume normal operation of the instrument.

Note: It is recommended that Electronic Simulator Test be completed immediately following a software update. Depending on the instrument customization, testing may be disabled until an Electronic Simulator Test with passing result is completed.

Troubleshooting:

If there is any question as to whether or not the software update completed, check the software status page. From the Home screen, navigate to:**More Options** > **Instrument Options** > **Software Installation** > **Software Status**

- If the Firmware name displayed on the Software Status page matches that which was recorded during the software update procedure, this indicates that the software update was completed.

Symptom	Action to take
Check for Update button is not enabled	Verify the following as described in the prerequisites, and repeat the software update procedure: • The instrument is running software version OSi05 or later • Network Services for software update enabled on instrument • The battery charge level is no less than 51%

Symptom	Action to take
Instrument indicates a connection could not be made to the Server service, **OR** Instrument powers off before completing the software download, **OR** Instrument does not power on within 10 minutes after screen going blank	Verify the following as described in the prerequisites, and repeat the software update procedure: • The wireless signal strength is 3 solid bars or greater • Instrument is reporting a valid IP address for the wireless connection • i-STAT Alinity instrument(s) with appropriate Network Configuration file installed • The healthcare organization network is allowing the instrument to connect to the internet in order to have access to the Abbott Managed Server or to connect to the SDi
Repeated attempts to update software via wireless network connection fail	Follow the procedure to perform software update using USB memory device

Network Connectivity

Abbott

This page intentionally left blank.

2.1 - AlinIQ NCi - Network Connectivity for i-STAT

The Network Connectivity utility for i-STAT (AlinIQ NCi) is used to configure the instrument to connect to wired and wireless networks. The NCi utility package must be downloaded from the Abbott Point of Care website. It is best practice to load NCi onto a computer that is installed behind the healthcare facility's firewall, and that has antivirus software installed on it.

The following is an overview of the steps required to perform the configuration:

1. Download the NCi from Abbott Point of Care and install on a Windows PC.
2. Use the NCi to create NC (ancc) file that contains the network parameters and security credentials required by the instrument to connect to the facility network.
3. Upload the ancc files to the instruments.

Before beginning:

- Read this document in its entirety.
- Share this document with the IT department. Their help will be needed to:
  - define how the instrument is to connect (wired, wireless, both) to the network
  - define the network to which the instruments are to connect (SSID, authentication protocol)
  - supply network access credentials for the network (that is, username, password, security certificates/keys)
  - identify connection details (proxy server, IP address and DNS server address modes, etc.)
  - a worksheet, found at the end of this section, is provided as an aid to gather the information needed to create the ancc file via the NCi utility.

Have available:

- i-STAT Alinity base station
- FAT32 formatted USB 2.0 memory stick

  Note: Some preformatted USB flash drives may not work with the Alinity system. To avoid issues, reformat the drive using a Windows PC before using the USB flash drive with the Alinity system.

- computer running Microsoft Windows 7 or Windows 10 and Internet Explorer 11 or Edge browser

After securing all of the above:

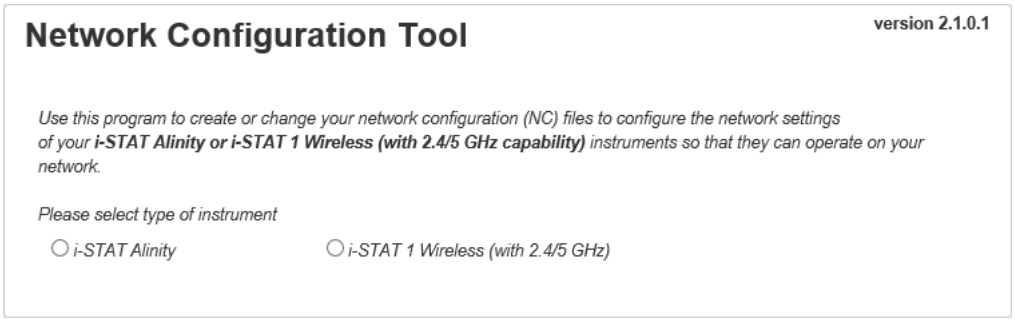
- Download the NCi utility package from the Abbott Point of Care website to your computer. The package will download to your desktop, unless you specify otherwise. See the instruction below.

Installing NCi:

- Navigate to the Abbott Point of Care website
- Find the link to the NCi utility
- Follow the instructions on the screen

When the installation of NCi completes, this icon will appear on the desktop:

To run NCi, double click the icon. On the first screen of the NCi that displays, select the type of instrument as **i-STAT Alinity**.



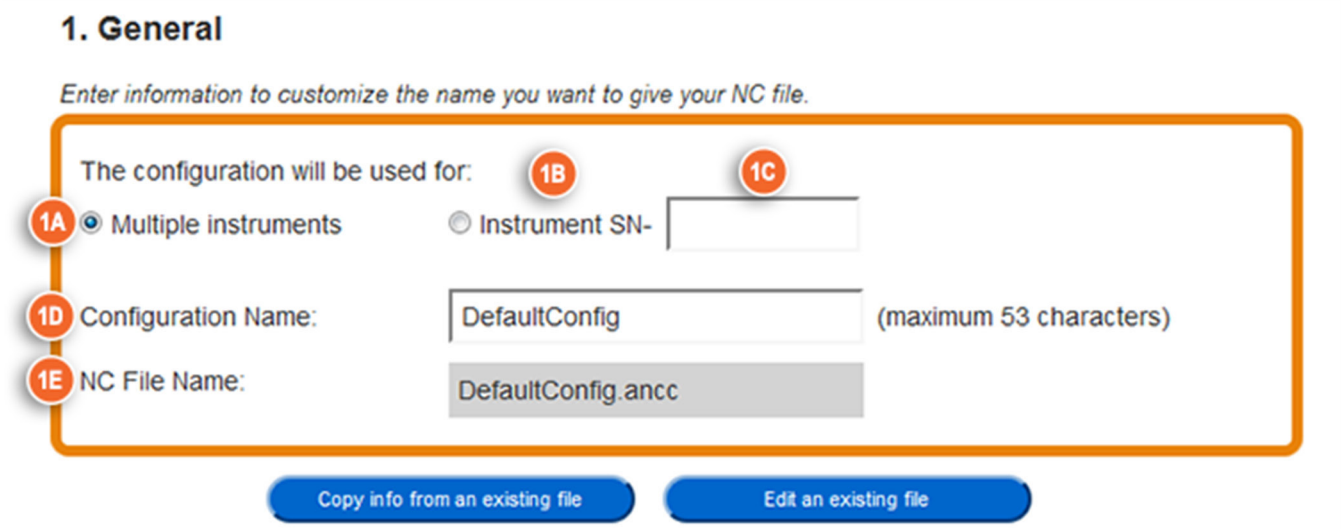
Upon selecting **i-STAT Alinity**, the NCi screen used to create NC files for i-STAT Alinity instruments displays.

Note: NCi consists of one screen for creating NC files, though it must be scrolled to be viewed in its entirety. For this reason, the screen is shown here in sections.

AlinIQ NCi - General Section

On the first section of the NCi screen, specify whether this NC file will be used for multiple i-STAT Alinity instruments or a single instrument. Unless your facility requires that each instrument have its own unique security credentials, a single NC file may be used for all instruments connecting to the same network.

Numbered labels (1A) are used in this section to highlight areas of the screen. These labels are for the purpose of this document only. They are not part of the actual NCi screen.



The configuration will be used for:

Select one of these radio buttons:

1A Multiple instruments

Use this NC file for multiple instruments. This is the default.

Note: This option may not be available if your facility requires individual Enterprise Security Certificates for each instrument.

1B Instrument

This NC file will apply only to one instrument. If this option is selected, the instrument's serial number is required:

1C SN-

Serial number of the instrument to which this NC file applies.
When a serial number is specified, the NC file name will include it, as shown here:
`DefaultConfig.snnnnn.ancc`

1D Configuration Name

Name for the NC file. Specify up to 53 alphanumeric characters.

NC File Name

This field is automatically populated with the NC file name and cannot be changed.

Copy info from an existing file

Click this option to open an existing NC file, copy its contents, and then save it to a new name. Navigate to the folder containing the NC file you wish to copy.

Note: Attempting to rename an NC file causes unpredictable results. Instead, use the function **Copy info from an existing file** and save the file to a new name.

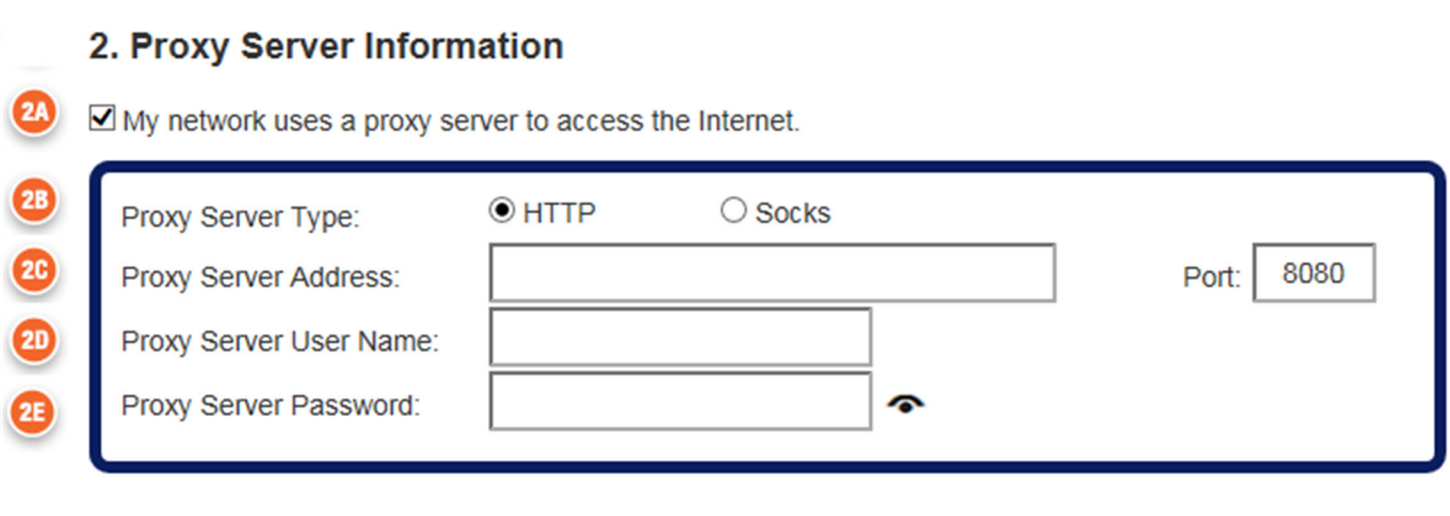
Edit an existing file

Click this option to edit an existing NC file. Navigate to the folder containing the NC file you wish to edit.

The next section of the NCi screen is for configuring a connection to a proxy server.

AlinIQ NCi - Proxy Server Connection

Use this section of the screen to supply information for connecting to the internet using a proxy server. Proxy server information is required if the instrument is to connect to the internet via a proxy server. This may be required to download eVAS directly from Abbott Point of Care to the instrument via the internet.



2A My network uses a proxy server to access the internet

Selecting this check box displays the following prompts:

2B Proxy Server Type:

Select either:

- **HTTP** HTTP proxy intercepts web access
- **Socks** Provides proxy service for UDP data and DNS look up operations in addition to web access.

2C Proxy Server Address:

Required. IP address of the proxy server

- **Port:** Port used by the proxy server. The default is 8080.

2D Proxy Server User Name:

Network name of the proxy server

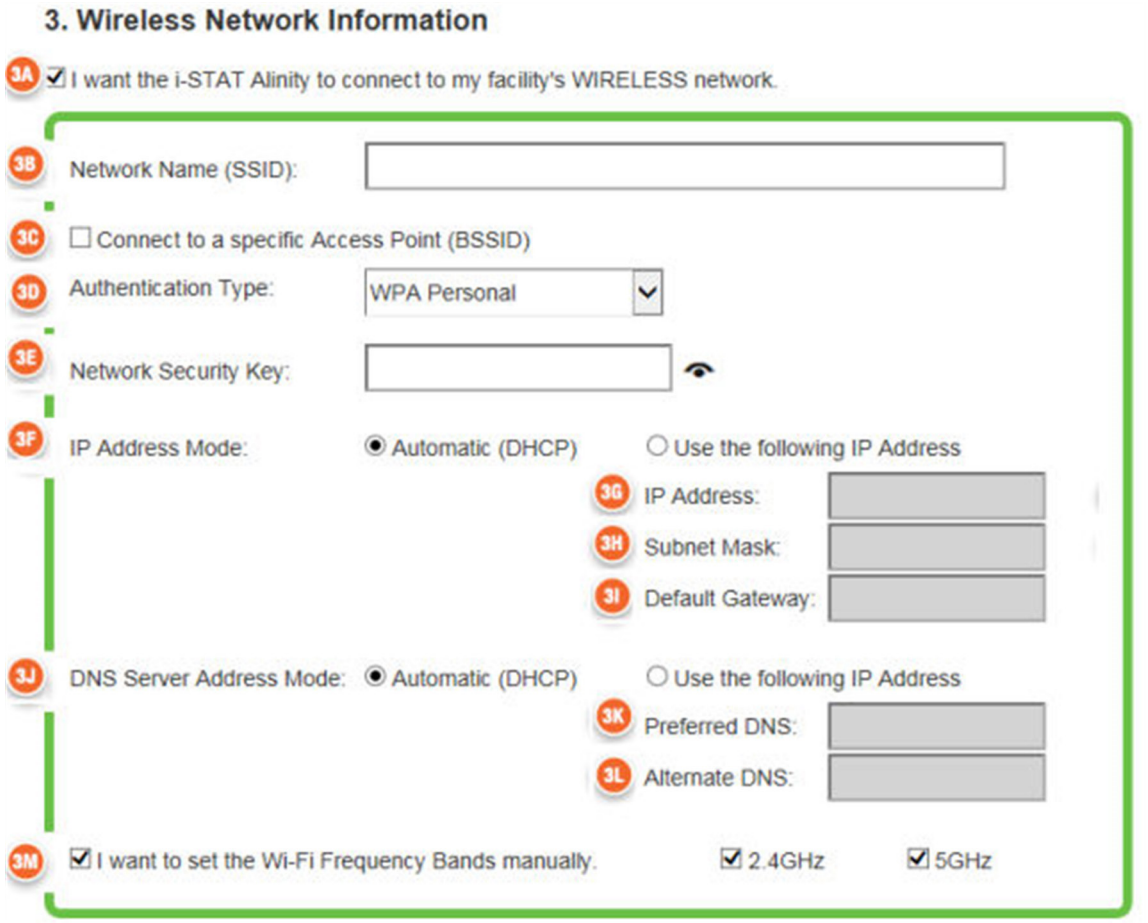
2E Proxy Server Password:

Network password for the proxy server. By default, bullets (••••) are displayed as you type the password. To display the actual password after typing it, click this symbol:

The next section of the NCi screen is for connecting wirelessly.

AlinIQ NCi - Wireless Network Connection

This section of the screen is used to configure connectivity to a wireless network. Some of the options displayed on the screen depend upon the authentication type, and are noted as such.



3A I want the i-STAT Alinity to connect to my facility's WIRELESS network

Select this check box to configure wireless network connectivity.

3B Network Name (SSID):

Name of the wireless local area network (WLAN)

3C Connect to a specific Access Point (BSSID):

Select this check box to connect to a single wireless access point (WAP) by specifying its unique BSSID. Specify the BSSID address in this format: `DD-DD-DD-DD-DD-DD-DD`, where `D` is a hexadecimal digit. Typically this is the media access control (MAC) address or hardware address of the WAP.

Authentication Type:

The selection of Authentication Type controls the WPA Type, Authentication Method, and Cipher Types as shown in this table:

Authentication Type	WPA Type	Authentication Method	Cipher Type	
			Groupwise Transient Key	Pairwise Transient Key
WPA Personal	WPA	PSK	TKIP	TKIP
WPA Enterprise	WPA	EAP	TKIP	TKIP
WPA2 Personal	WPA2	PSK	CCMP	CCMP
WPA2 Enterprise	WPA2	EAP	CCMP	CCMP
WPA2/WPA Mixed Personal	WPA2	PSK	TKIP	CCMP
WPA2/WPA Mixed Enterprise	WPA2	EAP	TKIP	CCMP

Note: When one of the Personal Authentication Types is selected, the Network Security Key field will be enabled. When one of the Enterprise Authentication Types is selected, refer to the **Options for Enterprise Authentication Types** sections for the security credential fields that will be enabled.

Network Security Key

Enter the PSK passphrase, 8 to 63 characters, or 64-digit HEX key. By default, bullets (••••) are displayed as you type the key.

IP Address Mode

Select either:

- **Automatic (DHCP)** Obtain IP addresses and networking parameters automatically from a DHCP server.
- **Use the following IP address** Select this check box if you are using a static IP address. Specify values for:

  - **IP Address** IPv4 address of instrument in decimal dot notation. Example: 172.16.254.1
  - **Subnet Mask** IPv4 mask that defines the Subnet in decimal dot notation. Example: 255.255.255.0

3I Default Gateway IP address for routing device that passes traffic between different subnets and networks in decimal dot notation. Example: 172.16.254.1

3J **DNS Server Address Mode** Select either:

- **Automatic (DHCP)** Obtain IP addresses and networking parameters automatically from a DHCP server.
- **Use the following IP address** Select this check box if you need to specify the DNS server address manually. Specify values for:
  - 3K **Preferred DNS** IPv4 address of the server in decimal dot notation.
  - 3L **Alternate DNS** IPv4 address of the server in decimal dot notation.

3M **I want to set the Wi-Fi Frequency Bands manually.**

Select this check box to configure the instrument to use either the 2.4 or 5 GHz frequency band exclusively. When both values are selected, the instrument will automatically select which band to use.
Select one of the check boxes to limit the instrument to that band only:

2.4G
5G

Options for Enterprise Authentication Types

When **Authentication Type** selected is WPA Enterprise, WPA2 Enterprise, or WPA2/WPA Enterprise, the options shown here are enabled:

EAP Method
Select one of the following:

TLS
TTLS/MSCHAPv2
PEAPv0/EAP-MSCHAPv2

Validate the Server Certificate
Select this check box to configure the instrument to validate the server certificate. Unselect the check box if this is not required.

Server Name
Network name of the authentication server.

CA Certificate File
Name of the file that contains the Certificate Authority certificate.

Client Certificate File
Name of the file that contains the client certificate.

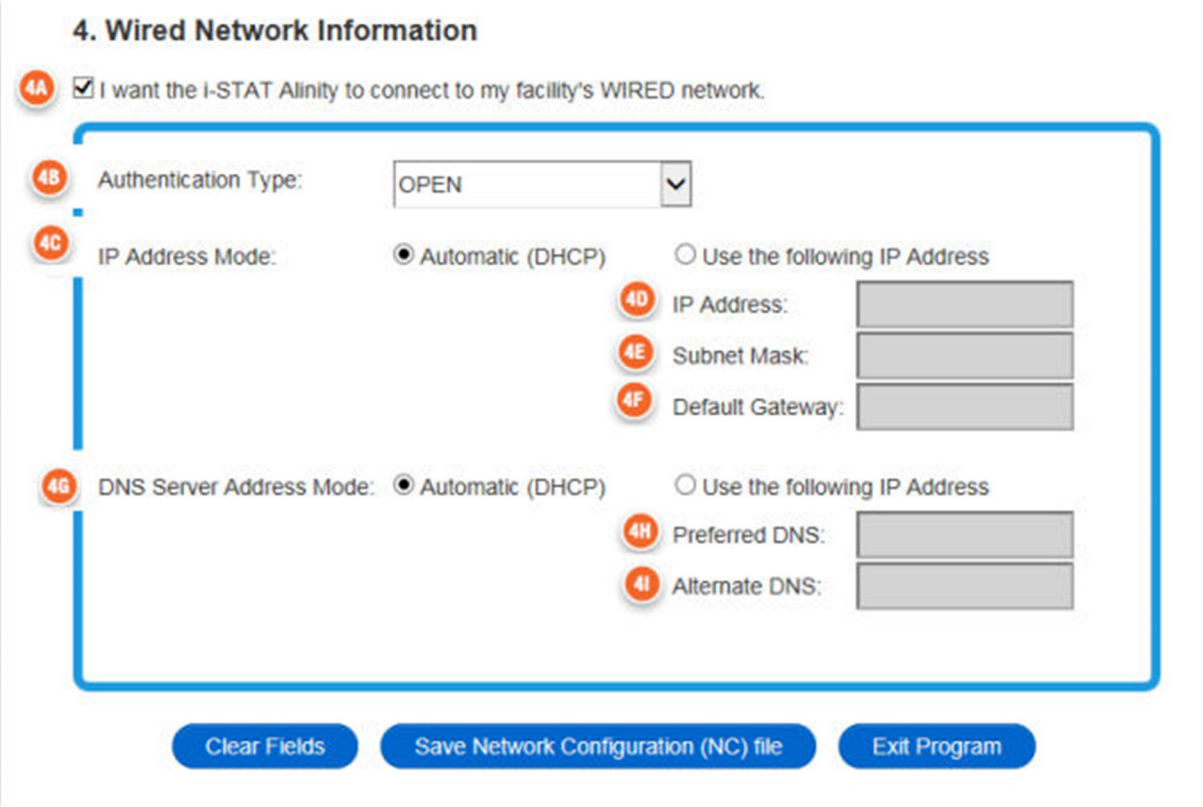
Client Key File
Name of the file that contains the client key.

Client Key Password
Password for the client key.

Username/Identity
Username required by the authentication server.

AlinIQ NCi - Wired Network Connection

Specify the following information for connectivity to a wired network:



4A I want the i-STAT Alinity to connect to my facility's WIRED network

To configure connectivity for a wired network, select this check box and specify values for:

4B Authentication Type

OPEN (this value is not modifiable)

4C IP Address Mode

Select one of these values:

- **Automatic (DHCP)** - Obtain IP addresses and networking parameters automatically from a DHCP server.
- **Use the following IP Address** - Select this button to use a static IP address.

Note: If you specify a static IP address you must also specify DNS addresses.

4D IP Address

IPv4 address of instrument in decimal dot notation.

4E Subnet Mask

IPv4 mask that defines the Subnet in decimal dot notation.

4F Default Gateway

IP address for routing device that passes traffic between different subnets and networks in decimal dot notation.

4G DNS Server Address Mode:

Select one of the following:

- **Automatic (DHCP)** - Obtain IP addresses and networking parameters automatically from a DHCP server.
    - **Use the following IP Address** - Specify values for:

4H Preferred DNS:

IPv4 address of the server in decimal dot notation

4I Alternate DNS:

IPv4 address of the server in decimal dot notation.

Note: You must specify DNS addresses if you specify a static IP address.

AlinIQ NCi - Save the Network Connectivity (ancc) file

After supplying the information for connectivity, you are prompted to save the ancc file. The saved file can then be loaded onto a USB memory stick, and then uploaded to an i-STAT Alinity instrument.

At the bottom of the NCi screen, choose **Save Network Connectivity (ancc) File**, then click **Continue**.

Depending upon the browser in use the ancc file will be saved to the Downloads directory, or, at the bottom of the screen a banner may display with the prompts shown below.

Note: Best practice is to select **Save** which will save the file to the Downloads directory. Opening NC (ancc) files in a text editor is not recommended.

Do you want to open or save *filename*.ancc?

Open

Open the ancc file in a text editor.

Save

Save the file to the Downloads directory.

Save as

Save the file to a specified destination.

Note: If you use this option make note of the destination where the file is saved. This information will be needed to load the ancc file onto the USB memory stick.

Save and open

Not recommended.

Cancel

Do not save the file.

AlinIQ NCi - Copy NC (ancc) file onto a USB memory stick

NC files are uploaded to instruments via USB memory stick as described in the next section.

The following rules apply to the number and type of NC (ancc) files that may reside on the USB memory stick:

- Any ancc file to be uploaded to an instrument must reside at the top level of the directory structure of the USB memory stick. The ancc file should not be in a folder.
- The USB memory stick may contain multiple ancc files created with serial numbers, but the serial numbers must be unique (there cannot be more than one ancc file with the same serial number at top level).
- The USB memory stick may contain one and only one ancc file created without a serial number. If both serialized and non-serialized ancc files are placed on the USB memory stick at the top level, then upon upload to the instrument, the instrument will attempt to upload a serialized ancc file if it finds a serial that matches that of the instrument itself, otherwise it will attempt to upload the non-serialized ancc file.

Use the following steps to copy the ancc file onto the USB memory stick:

1. Plug the USB memory stick into the USB slot of the computer. A message displays indicating that the operating system recognizes the drive and it is ready to use.
2. From the **Start** menu, click **Computer** > **Downloads**.
3. In the displayed list, find the filename.ancc file and right click on it.
4. Click **Send to:** ***drive name*** and press **Enter**. This loads the file onto the memory stick.
5. Repeat steps 3 and 4 for each ancc file to be copied.

AlinIQ NCi - Upload an NC (ancc) file to an instrument

To upload an NC (ancc) file, an i-STAT Alinity base station and a USB memory stick that the NC (ancc) file resides on are needed.

Note: Some preformatted USB flash drives may not work with the Alinity system. To avoid issues, reformat the drive using a Windows PC before using the USB flash drive with the Alinity system.

Follow these steps:

1. Plug the USB memory stick into the USB slot of the base station.
2. Place the i-STAT Alinity instrument in the base station.
3. Touch **More Options**
4. Touch **Instrument Options**
5. Touch **Network Settings**
6. Install **Network Settings**
7. Enter Operator ID, touch **Next**
8. Follow instructions on the i-STAT Alinity screen.

AlinIQ NCi - Customization and Connectivity

After creating the NC (ancc) file, refer to the section in this document for *AlinIQ Customization Workspace for i-STAT* (AlinIQ CWi). Connectivity features in the CWi enable the instrument to transmit to and receive information from remote systems.

AlinIQ NCi - Determining Success or Failure

After you have used NCi to configure connectivity, you can test the connection. Follow the steps shown here:

- To check a wired network connection, place the i-STAT Alinity instrument in the base station that is connected to the facility's network and power on the instrument. On the instrument screen, in the upper right corner, the ethernet symbol  displays indicating an active connection.
- To check a wireless network connection, remove the i-STAT Alinity instrument from the base station. On the instrument screen, in the upper right corner, the wireless internet symbol displays. This symbol  represents a strong signal. Some or all of the bars in the signal should be filled in, depending upon the signal strength in the location. A location that displays the symbol with all bars empty represents no signal. If the symbol displays with all bars empty, move the instrument to a location closer to the wireless access point.

This page intentionally left blank.

Network Connectivity for i-STAT Alinity Worksheet

1A - The configuration will be used for: Multiple instruments

Enter a name for configuration (maximum 53 characters)

1D Configuration Name: _____

2A - Using a Proxy Server to Access Internet

2B Select either HTTP or Socks

HTTP	Yes/No
Socks	Yes/No

Enter IP address and port of the proxy server

2C Proxy Server Address: _____ Port: _____

2D Proxy Server User Name: _____

2E Proxy Server Password: _____

If connection to a Wireless Network is required, complete information below

3A - Connect to Wireless

Enter Name of the wireless local area network (WLAN)

3B Network Name (SSID): _____

If connection to a single access point is required, Enter BSSID

3C Connect to a specific Access Point (BSSID): _____

3D Authentication Type: _____

For Personal Authentication, select one of the following options

PERSONAL

WPA Personal	Yes/No
WPA2 Personal	Yes/No
WPA2/WPA Personal	Yes/No

Enter PSK Passphrase (8 to 63 characters), or 64-digit HEX key

3E Network Security Key: _____

Select either Automatic (DHCP) or Static IP Address Option

3F IP Address Mode:

Automatic (DHCP)	Yes/No
Static IP Address	Yes/No

If Static IP Address Option is selected, enter IP Address, Subnet Mask and Optional Default Gateway

3G IP Address: _____

3H Subnet Mask: _____

3I Default Gateway: _____

Select either Automatic (DHCP) or Static IP Address Option

3F IP Address Mode:

Automatic (DHCP)	Yes/No
Static IP Address	Yes/No

If Static IP Address Option is selected, enter IP Address, Subnet Mask and Optional Default Gateway

3G IP Address: _____

3H Subnet Mask: _____

3I Default Gateway: _____

Select either Automatic (DHCP) or Static IP Address Option

3J DNS Server Address Mode:

Automatic (DHCP)	Yes/No
Static IP Address	Yes/No

If Static IP Address Option is selected, enter Preferred and Alternate DNS

3K Preferred DNS: _____

3L Alternate DNS: _____

If operation in a single Wi-Fi Frequency band is required, select one of the frequency bands

3M Wi-Fi Frequency Bands:

2.4 GHz	Yes/No
5 GHz	Yes/No

Network Connectivity for i-STAT Alinity Worksheet

For Enterprise Authentication, select one of the following options

Enterprise

WPA Personal	Yes/No
WPA2 Personal	Yes/No
WPA2/WPA Personal	Yes/No

Select one of three EAP Methods and complete security credential information for selected option

3N EAP Method

TLS	TTLS/MSCHAPv2	PEAPv0/EAP-MSCHAPv2
3O Server Name:	Server Name:	Server Name:
3P CA Certificate File:	CA Certificate File:	CA Certificate File:
3Q Client Certificate File:	Client Certificate File:	Username/Identity:
3R Client Key File:	Client Key File:	Password:
3S Client Key Password:	Client Key Password:	Anonymous ID: anonymous
3T Username/Identity:	Username/Identity:	
	Password:	
	Anonymous ID: anonymous	

If connection to a Wired Network is required, complete information below

4A - Connect to Wired

4B Authentication Type:	open

4C IP Address Mode:

Automatic (DHCP)	Yes/No
Static IP Address	Yes/No

If Static IP Address Option is selected, enter IP Address, Subnet Mask and Optional Default Gateway

4D IP Address: _____

4E Subnet Mask:

4F Default Gateway: _____

Select either Automatic (DHCP) or Static IP Address Option

4G DNS Server Address Mode:

Automatic (DHCP)	Yes/No
Static IP Address	Yes/No

If Static IP Address Option is selected, enter Preferred and Alternate DNS

3K Preferred DNS: _____

3L Alternate DNS: _____

Customization Workspace

This page intentionally left blank.

3.1 - AlinIQ CWi - Customization Workspace for i-STAT

This section contains a general description of the CWi (Customization Workspace for i-STAT). i-STAT Alinity instruments can be customized for use in a variety of healthcare settings. Abbott Point of Care recommends that you read this document in its entirety before logging in to CWi. Specifics on the functions and features are outlined in the following sections.

CWi is a web-based software application that enables healthcare professionals to manage customization settings for the i-STAT Alinity instrument. Customization settings allow the HCO to change the user experience at the individual instrument level. CWi also manages users that maintain the customization of the i-STAT Alinity.

Out-of-the-box, the i-STAT Alinity is a fully-functioning instrument whose workflow contains no customization. Customization allows the healthcare organization to change the operating characteristics of each instrument. For example, the instrument, out-of-the-box, has no reference ranges defined. To define these ranges and upload them to the instrument(s), a profile must be created.

A profile is a collection of customization options found in categories. Each instrument within a healthcare organization (HCO) can have a different profile. The specifics of the profile are determined by the needs of the operating location. As an example, for an instrument used in the NICU it may be necessary to turn off the instrument's sound to avoid disturbing the infants or to prompt operators to perform required quality control testing.

Customization also enables the administrator or POCC to establish action ranges based on sample type, age, and sex or cutoffs for certain analytes based on the patient's sex. In addition, an administrator or POCC may establish actions to be taken when results fall outside of the reference range. Customization may be used to require operators to record critical callback documentation on the instrument.

Workspaces

CWi is a collection of three workspaces. The workspaces are:

Manage and Assemble Profiles

Use this workspace to define the instrument's settings for options such as data entry format, inactivity time interval allowed before powering off, and action to take when the memory is full. Most of the customization of the i-STAT Alinity is accomplished using the options in the Profile workspace.

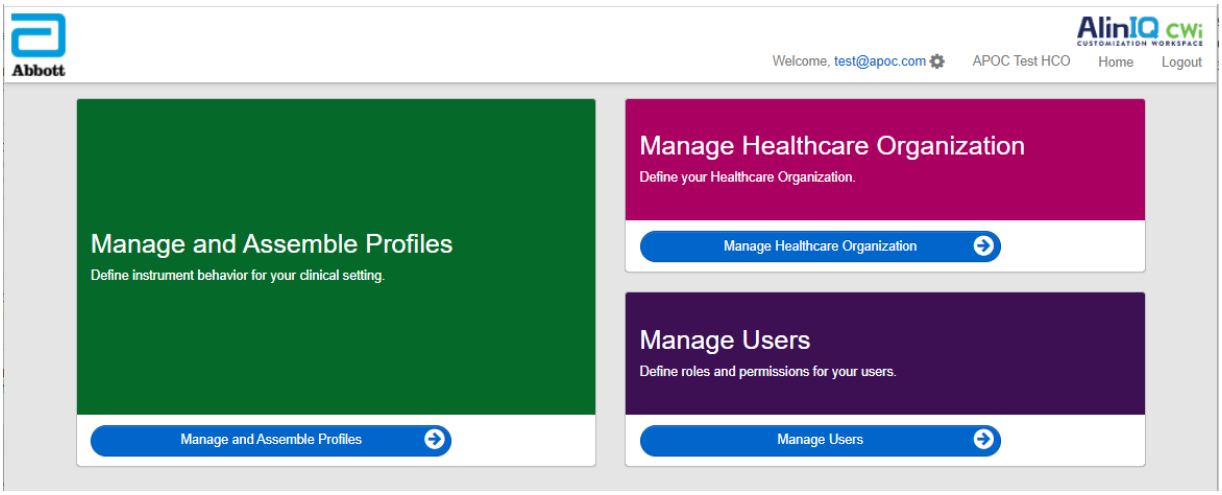
Manage Users

In this workspace create a list of CWi users, their contact information, and their CWi role (POCC, POC Super User, HCO Manager).

Manage Healthcare Organization

This workspace displays the name of the customer's healthcare organization.

Details and information for all options are included in the section for each workspace. The workspaces are shown on the **Home** page:



Best Practices

There are references to best practices throughout this guide. These represent the options used by the majority of Abbott Point of Care established customers in creating their current i-STAT customization profiles. Those options, along with features available only on the i-STAT Alinity system were assembled and titled “best practices”. They are intended only as examples. Each HCO should establish its own best practices.

How to Proceed

Begin by contacting Abbott Point of Care and establishing your Healthcare Organization (HCO) (refer to the next section, *Getting Started*). Next, define the primary CWi user (refer to the section *Manage Users*).

Note:

- Abbott Point of Care strongly encourages a healthcare organization (HCO) to establish more than one HCO manager. Then, in the event that one HCO manager is unavailable, other HCO managers can use the system.
- One HCO manager only is specified as the “primary”.
- Only a primary HCO manager can assign the role of healthcare organization manager to another CWi user.

Getting Started

The function of CWi is to customize the i-STAT Alinity instrument. Users of CWi may wish to verify information for their site, edit user information, or add instruments. Abbott Point of Care strongly recommends that you read this section in its entirety before logging in to CWi.

Note: The computer used to access CWi should reside behind the healthcare facility’s IT firewall and have antivirus software installed.

If you have an established HCO and you are logging in to CWi, you can skip the information below and log in as usual. The following information is provided for users who will be logging in to CWi for the first time.

In order to ensure the security of users' customizations, profiles and other data, Abbott Point of Care establishes the healthcare organization (HCO). This is done once. At the time the HCO is created, an HCO primary manager must be identified. The HCO primary manager is the person responsible for the CWi. An HCO must always have an HCO primary manager. If the HCO primary manager needs to be replaced, contact Abbott Point of Care.

Abbott Point of Care is responsible for establishing:

- the healthcare organization within the CWi
- the primary Health Care Organization manager. One HCO manager only is specified as the "primary". The primary HCO manager has permission to access all functions of the CWi including creating other CWi users.

Prerequisites

The healthcare organization information required by Abbott Point of Care includes:

- name of the healthcare organization
- facilities
- city
- postal code
- country
- language

For the primary HCO manager, specify:

- email address
- first and last name
- contact information

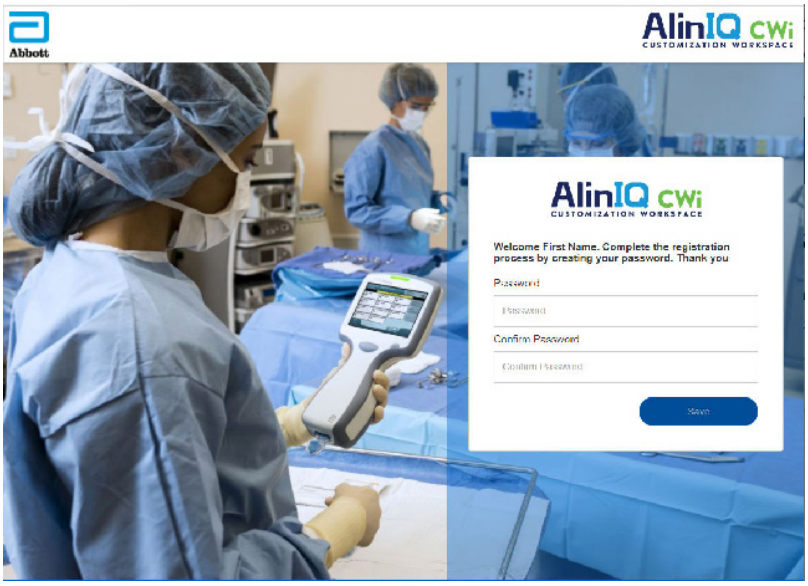
Note: For all features of the software to work properly, use CWi with the Internet Explorer® , Google Chrome™ or Microsoft Edge web browsers.

For New User of CWi, log in as follows:

1. Check user email for Registration email. Click on the link to Complete Registration.

Note: If link is expired or email is never received, the email can be resent via the Forgot Password? function on the AlinIQ CWi log in screen.

2.Create and confirm password.



AlinIQ CWi imposes password requirements. They are as follows:

Must be 8 to 20 characters long and contain 3 of the 4 (example: Pr86h22h):

uppercase character low-

ercase character number

special character

Cannot contain:

ampersand (&)

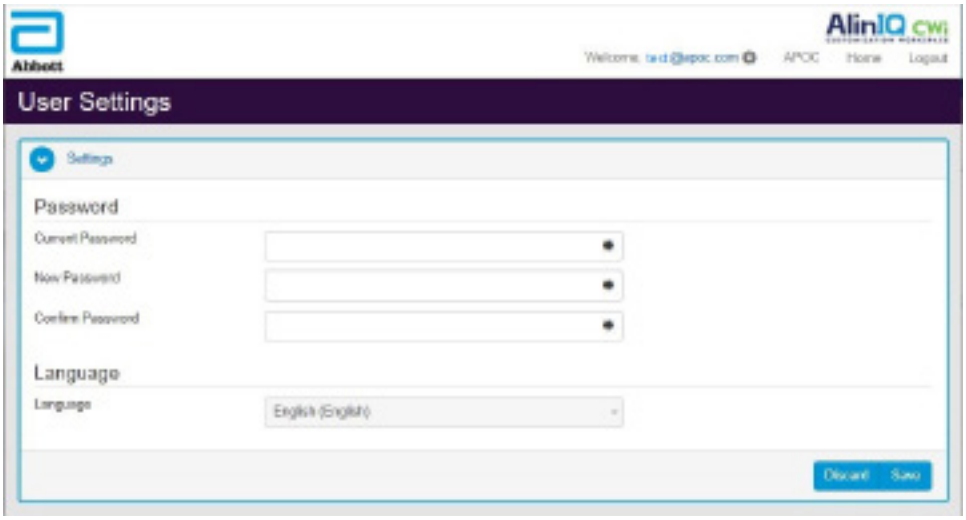
blank space

less than symbol (<)

control character

May not reuse last 10 passwords.

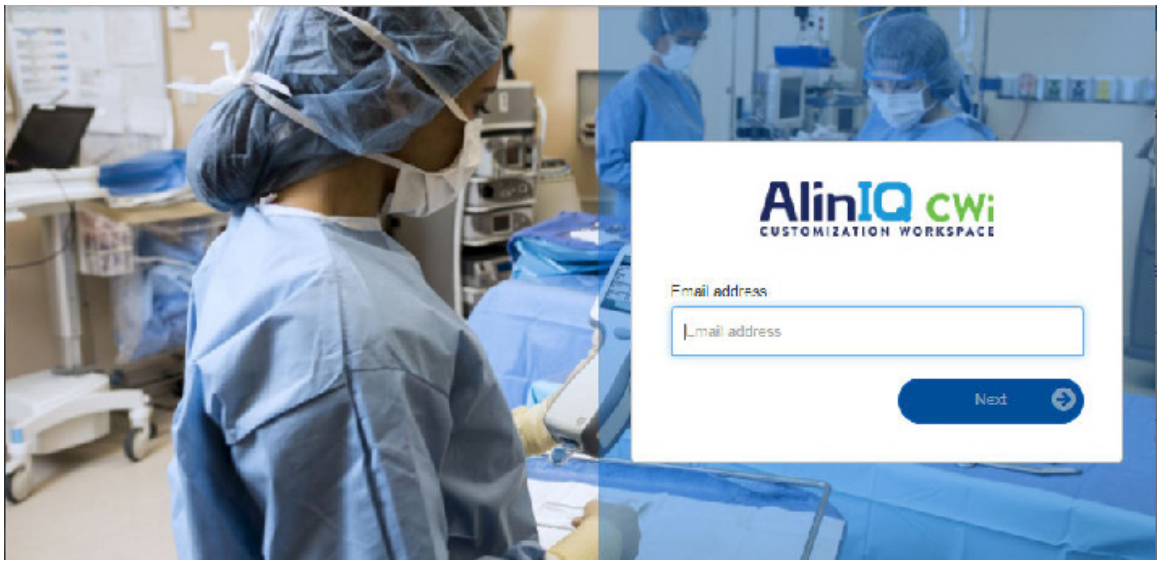
On the **Home** page, next to the 'Welcome' is the email address of the user who is logged on. Next to the email address is a " " gear icon. Click on the icon to open the User Settings screen. The password and language settigns can be adjusted from this page.



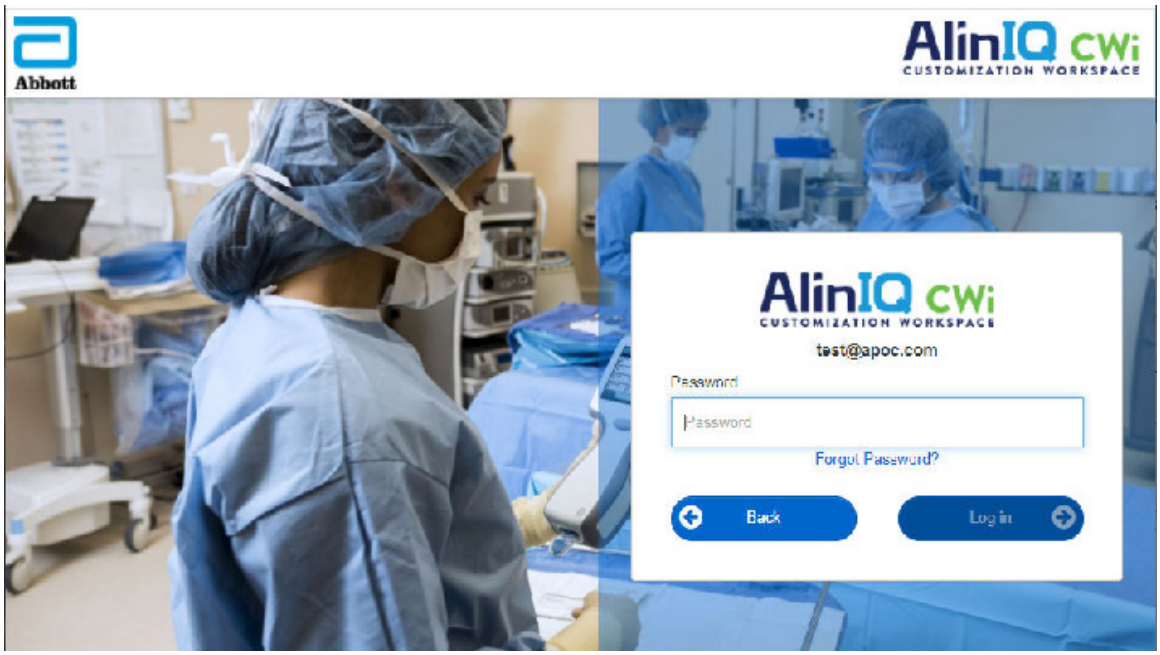
To change the user password or language settings, enter the new password or select a language from the drop down menu and click the “Save” button.

For Existing User of CWi, log in as follows:

1. Using a compatible web browser, navigate to *https://aliniqcwi.abbott.com*
2. Click on the link for **AlinIQ CWi**
3. Log in with the user’s email address and click the “Next” button.



4. Enter the password created by the user and click the “Log in” button. If 5 failed attempts are made, the system will lock out the user. The lockout will last for one hour, unless the user resets their password.

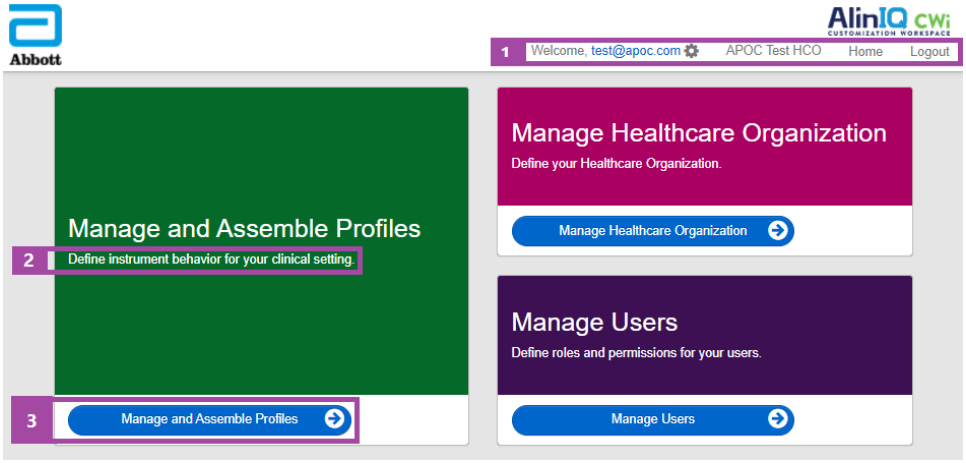


Note:

- If the link to AlinIQ CWi found on *https://aliniqcwi.abbott.com* does not open the application, contact Technical Support for further assistance.

CWi - Home page

The **Home** page is the first screen displayed after you log in to CWi.



The **CWi Home page** consists of the following:

1 **Command Line**	Welcome Email address of user HCO Name as assigned by Abbott Point of Care	Displays the email address of the user who is logged on and the name of the Healthcare Organization only
	User Settings 	Provides link for password to be changed and language chosen.
	Home	Link to the home page
	Logout	Logs out of CWi
2 **Work Area Description**	Define instrument behavior for your clinical setting.	
	Define your Healthcare Organization.	
	Define roles and permissions for AlinIQ CWi users.	
3 **Link to Work Area**	Manage and Assemble Profiles	Link to the workspace where customization options are defined.
	Manage Healthcare Organization	
	Manage Users	

Details about each workspace and its features are discussed in following sections.

This page intentionally left blank.

3.2 - Manage Healthcare Organization

Overview - Healthcare Organization

The Healthcare Organization is the unique identifier assigned to an organization by Abbott Point of Care. Information that you supply to Abbott Point of Care for your healthcare organization on the CWi form will be used during the initial setup of the CWi program. You can view the **Manage Healthcare Organization** workspace to ensure that the information for your healthcare organization is correct.

In order to ensure the security of profiles and other data, Abbott Point of Care establishes a unique identifier for each healthcare organization. This is done once. At the time the healthcare organization is created, the Primary Healthcare Organization manager must be identified. The Primary Healthcare Organization manager is the person responsible for the CWi. A healthcare organization must always have one Primary Healthcare Organization manager. If the Primary Healthcare Organization manager needs to be replaced, contact Technical Support.

Abbott Point of Care is responsible for establishing:

- the healthcare organization within the CWi
- the primary healthcare organization manager. One healthcare organization manager only is specified as the "primary" and indicated in the Manage User list with a check mark (✓). The primary healthcare organization manager has permission to access all functions of the CWi during the initial setup and creation of other CWi users.

The **Manage Healthcare Organization** workspace displays this information:

- name
- city
- postal code
- country
- language
- date format*
- decimal character*

*Click "Change" in the **Manage Healthcare Organization** workspace to change **Date Format** and **Decimal Character** settings.

Best Practices

There are references to best practices throughout this guide. Manage healthcare organization information needed for the initial setup includes: name of healthcare organization, city, postal code, country, and language. Each healthcare organization should establish its own best practices.

Getting Started

The healthcare organization information required by Abbott Point of Care includes:

- name of the healthcare organization
- city
- postal code
- country
- language

For the primary healthcare organization manager, specify:

- email address
- first and last names
- contact information

3.3 - Manage Users

This workspace is used to identify all users of the CWi, and specify the level of access for each. Operators of the i-STAT Alinity instrument may be identified in the data management system.

Overview

Within the healthcare organization, all users who are authorized to access CWi must be defined. The type of role assigned to a user determines which actions can be performed.

- **Primary Healthcare Organization Manager** One healthcare organization manager only is specified as the "primary" and is indicated in the **Manage Users** list with a check mark (✓). The primary healthcare organization manager has permission to access all functions of the CWi including creating the healthcare organization and creating other CWi users.
  - Only the primary healthcare organization manager can assign the role of healthcare organization manager to another user.
  - It is important to keep the primary healthcare organization manager current. Should the assigned primary healthcare organization manager need to be changed or password need to be reset, contact technical support by email: oustechsvc@apoc.abbott.com.
- **Healthcare Organization Manager** has permission to access all functions of the CWi including creating other CWi users, except for the primary healthcare organization manager.
  - Other healthcare organization managers can only assign the roles of Point of Care Super User and Point of Care Coordinator.
- **Point of Care Coordinator** (POCC) has permission to access all functions of the CWi program, but is limited to assigning the role of Point of Care Super User when creating other users.
- **Point of Care Super User** has limited permission to CWi program, including ability to view profiles and categories, view instruments with profiles, and view healthcare organization information.

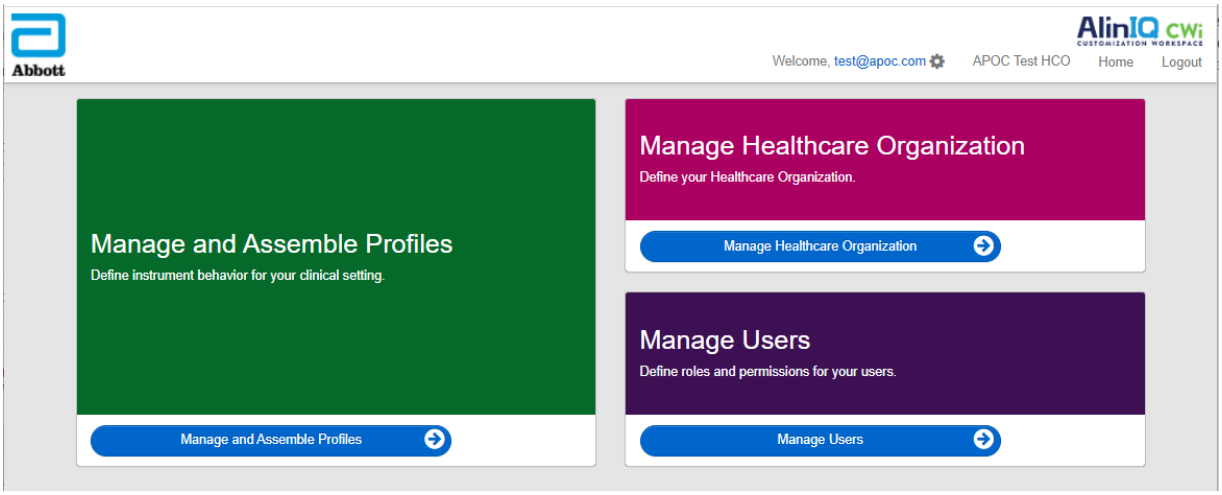
Best Practices

When defining users:

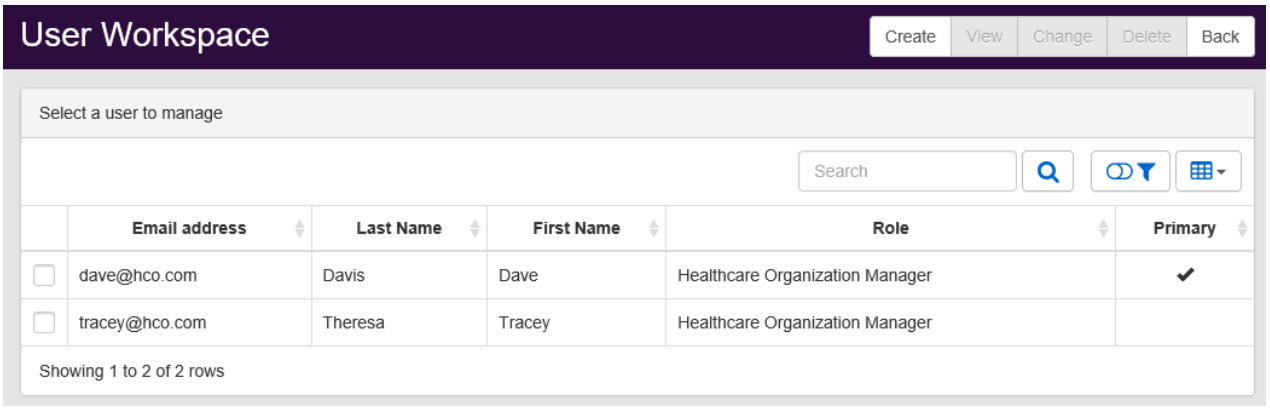
- Abbott Point of Care strongly encourages healthcare organizations to establish more than one healthcare organization manager for the CWi. Then, in the event that one of the healthcare organization managers is unavailable, any other healthcare organization manager can use the system.
- One healthcare organization manager is specified as the "primary" and indicated in the Manage User list with a check mark (✓). To change the primary healthcare organization manager, contact Abbott Point of Care technical support by email: oustechsvc@apoc.abbott.com.

Getting Started

To access this workspace, from the **Home** page, in the lower right corner, click **Manage Users**.



This screen displays:



The name of the Healthcare Organization is at the top of the screen. Note that this name is assigned by Abbott Point of Care.

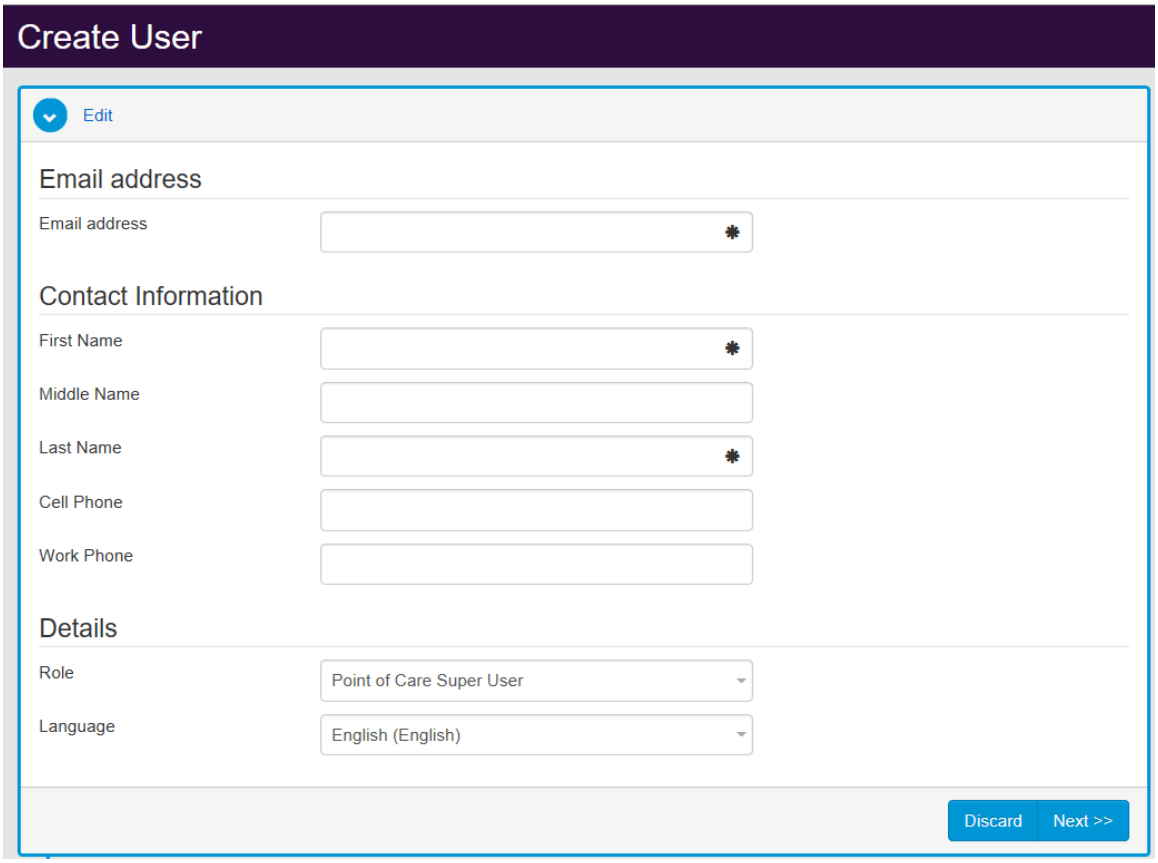
Command Line Actions

On the upper right corner of the screen, in addition to **Create**, the command line includes these actions:

- **View** - CWi user can be viewed
- **Change** - Change information for a CWi user
- **Delete** - Delete a CWi user
- **Back** - Go back to previous page

To create a user, in the upper right corner of the screen, click **Create**.

This screen displays:



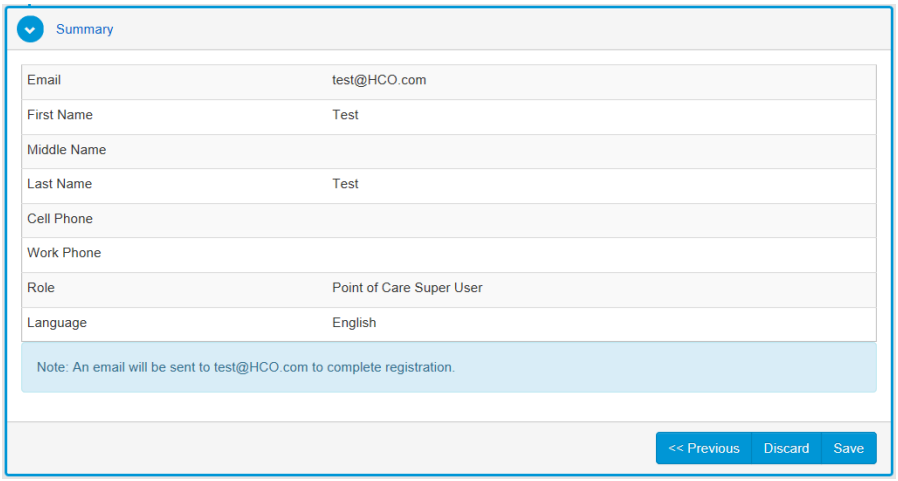
On this screen any field marked with an asterisk (*) requires a value to be provided. To create a user, the **required fields** are:

- **Email address** - User's email address. Enter up to 40 characters.
- **First name**
- **Last name**
- **Language** - Select a language from the drop down list.
- **Role** - Select one of the following from the drop down list:

  Healthcare Organization Manager
  Point of Care Super User
  Point of Care Coordinator

To delete these specifications, click **Discard**.

To save them, Click **Next** and the **Summary** tab displays.



At the bottom of the screen these options display:

- **Previous** - displays the **Create User** screen allowing you to edit any specifications
- **Discard** - deletes these specifications
- **Save** - saves the user as defined

The Search field is used to find free-field text (i.e. email addresses or user names) in the User Workspace table.

The Filter option is used to limit what is displayed in the User Workspace table.

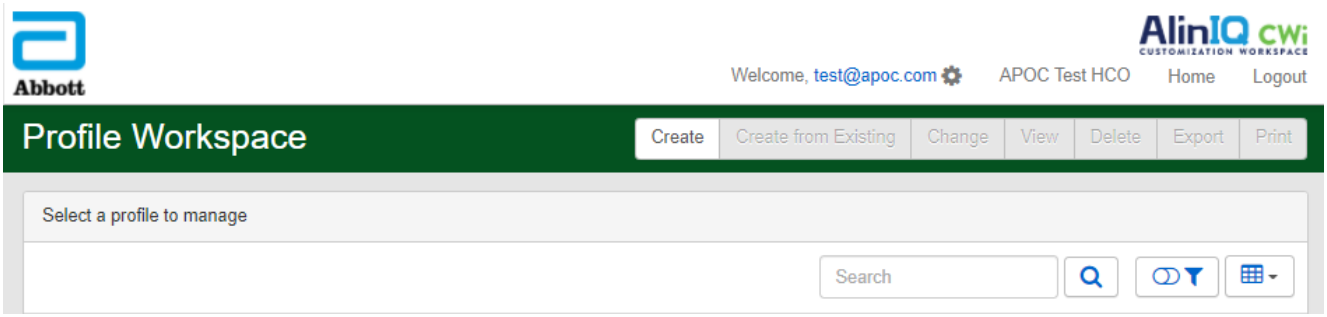
3.4 - Manage and Assemble Profiles

Customization of instruments is controlled by profiles built in the CWi. A profile is a set of categories. A group of features makes up a category.

Building categories and assembling them into profiles allows each instrument to behave differently than an instrument used ‘out of the box’.

Instruction on building categories and profiles is discussed in this section.

The following screen is an example:



The commands shown on the upper right can be used to perform these actions:

Create	Create a profile or category.
Create from Existing	Manage Profile and all Categories have a **Create from Existing** capability. The purpose of this action is to allow a user the ability toselect and copy an existing Profile or Category so modifications can bemade easily. When using this action the user will be required to rename the Profile or Category and then make the desired changes to the features.
Change	Manage Profile and all Categories can be changed without renaming.
View	Select a Profile or Category for viewing to determine the enabled features.
Delete	Remove a Profile or Category from the Manage and Assemble Profile Workspace. Assigned Profiles or Categories cannot be deleted.
Export	Export a package file to a USB device or storage device.
Print	Select a Profile or Category to print a hard copy.

The Search field is used to find free-field text in the Workspace table.

The Filter option is used to limit what is displayed in the Workspace table. These functions are available for all categories in the Manage and Assemble Profiles Workspace.

Best Practices

For ease of use, Abbott Point of Care recommends these guidelines when using the Manage and Assemble Profiles Workspace.

- **Profile and Category Naming** - Name the Profile with the area where the i-STAT Alinity instrument will be used, for example: NICU, Emergency Department, Respiratory Care.

  Name Categories by specifying their use for all areas or for specific areas, such as: Hospital-wide General Settings, ICU Operator Settings, NICU Analyte Settings, Emergency Department Quality Settings.
- **Print the APOC Profile or all APOC Categories individually** - prior to creating categories and profiles. After printing, review and identify the desired changes to each Category by marking the changes on the printout. Use the printout when creating the categories and assembling the profile.
- **Print the Laboratory Reference and Action (Critical) ranges** - including units of measure for each analyte that will be used on the i-STAT Alinity. This can minimize the time needed to build the Analyte Settings Unit and Range feature.
- **Enable Age and Gender in Patient Settings** - if the Analyte Settings Ranges are created with Age and Gender applied. If eGFR is being used, this feature is required.
- **If Liquid QC and/or Cal Ver Schedules are used** - A list of the site's areas and the cartridges used in each area can be helpful when creating the Quality Settings Category.
- **Contact the IT department or patient registration** - If using barcoded patient armbands or labels. Ensure that the type of barcode on the armband or label is enabled in the Patient Settings Category.
- **Contact Human Resources or Employee Services** - If using barcoded employee badges. Ensure that the type of barcode on the badge is enabled in the Operator Settings Category.
- **Contact Laboratory Information System administrator** - If using an accession/specimen ID entry. It will be necessary to find out which barcode type will be scanned and to determine where the barcoded labels will be printed. Printing functions in the LIS may need to be changed in order for accession number labels to be printed on the testing floor.

  Note: Selections made in categories and profiles change screen content and sequencing. Best practice would be to evaluate all selections made when building the profile by:
  - uploading the profile
  - performing testing in the patient and control pathways
  - evaluating the outcome to ensure that results and behavior are as expected.

Creating a Category

To create a category, navigate to the **Home** page and click **Manage and Assemble Profiles**. The ten categories are shown on the right side of the screen.

The categories used to build a profile are shown below. You can choose the categories in any order. The asterisk (*) indicates that these are required categories:

- *General Settings
- *Operator Settings
- *Quality Settings
- *Patient Settings
- *Analyte Settings

In addition to the required categories, there are optional categories that can be included in a profile:

- User Defined Message
- Training Settings
- STATNotes
- Result Notes
- Connectivity Settings

Note: Profiles are created by assembling categories. When creating profiles for the first time, it is necessary to create categories first. Details on each category are in the following sections.

Category Index

* General Settings

- Basic Functions
  - Sound
  - Volume Levels
  - Inactivity
  - Software Updates
  - Decimal Character
  - Memory Full Action
- Date
  - Date Entry
  - Date Display
- Communications
  - Result Auto Transmit
  - Power Down Communications
  - Wireless Communications
- Operator Actions
  - Accept or Reject Results
  - Test Cancellation
  - Test Selection
  - Accession/Specimen ID Entry
- Critical Callback
  - Critical Callback Documentation
- Print
  - Test Result Printout
  - i-STAT Printing

* Operator Settings

- ID Entry
- List Actions
  - Search for Operator ID on Operator List
  - Operator ID on Operator List-Certification Expired Action
  - Operator ID not on Operator List Action
- Operator Expiration
  - Operator Certification Expiration Notification

* **Patient Settings**

- ID Entry
- Patient Information and Positive Identification (PPID)
  - Age and Sex
  - Patient List
- Basic Functions
  - Patient Age/Gender Entry

* **Analyte Settings**

- Units
- Sample Types
  - Default Sample Types
  - Custom Sample Types
  - Sample Type Entry Options
- Ranges
- Enable/Disable Analyte
  - Apply Globally
  - Apply by Panel
- Hematocrit
  - Hematocrit Setting (Calibration by Laboratory Hematology Analyzer)
  - Apply CPB Protein Algorithm to Hematocrit Setting
- Adjustments
  - BE Equation
  - eGFR Equation
  - eGFR Variants
- ACT
  - ACTk Mode
  - Stop ACT Test
- Critical Tests

***Quality Settings**

- Electronic Simulator
  - Simulator Testing Schedule
- QC Notifications
  - Control Test Settings
  - Control Test Out of Range Settings (Manual Pass/Fail Determination Only)
  - Cal Ver Test Settings
  - Cal Ver Test Out of Range Settings (Manual Pass/Fail Determination Only)
  - eVAS Type
  - Cartridge Lot QC Settings
- Liquid QC Schedules
  - Frequency
- Cal Ver Schedules
  - Frequency

User Defined Message

- User Defined Message

Training Settings

- Basic Functions
  - Training Mode
  - Training Pathway Cartridges
  - Operator Direct Observation Checklist
  - Training Scenarios

STATNotes

- STATNotes
  - Manage Items
  - Manage Sets

Result Notes

- Result Notes
  - Manage Items
  - Manage Sets

Connectivity Settings

- Connectivity Map
  - Test Records
  - Device Events
  - Operator List
  - Patient List
  - Cartridge List
  - Log Events

*General Settings Category

This section contains features to customize the general settings for the i-STAT Alinity, such as volume, date, and printing. The General Settings Category can be created or modified with the following steps.

Click **General Settings,** then select `APOCGeneralSettings` and click **View**. The screen displays the default name `APOCGeneralSettings`, and default values for each feature. Scan through the `APOCGeneralSettings` and determine if the selections work for the profile being assembled. If they do then no additional work is needed in this category. The `APOCGeneralSettings` category will be available in the **Manage Profiles** section. Use it to assemble the new profile. If the `APOCGeneralSettings` do not work for the profile being assembled, click **Finish** to stop viewing. Click **Create** and follow the instructions below.

Note: All required categories have a default setting named with the APOC prefix. In addition, the settings are populated with default values.

You are prompted to specify a name for the settings and an optional description:

General Settings

Name	Required. Specify a name that is from 4 to 40 characters long and: • consists only of the following characters: ○ 0 through 9 ○ A through Z or alphabet appropriate for language (in upper or lower case) ○ blank space ○ underscore (_) • does not begin with the characters APOC (in upper or lower case) • is a unique name within this healthcare organization
Description	Optional. Provide any information that helps the user know how or why the category was named or created.

When finished, choose from the actions shown at the bottom of the screen:

- **Discard** - to undo changes
- **Next** - to open the next tab

Basic Functions

The **Basic Functions** tab includes settings such as volume, action taken when the i-STAT memory is full, and transmitting results.

On **Basic Functions** screen you can define settings for these features:

Sound	
Enable Sound	Unselect the checkbox to turn sound off. This will disable all sounds.
Volume Levels	With sound enabled, you can set the volume for these functions. From the drop down box, select a value from 0 to 100%. Selecting 0 turns sound off. The default is 100%. You can also adjust the sound using the slider bar. Click and drag the dot left or right along the “ruler” to raise or lower the volume. **Basic Functions** **Transmitting** **Touch Screen** **Barcoding** **Results Display**

Inactivity	
Results Present, Data Entry Complete	The instrument will power down after the chosen number of seconds have elapsed.
Results Present, Data Entry Pending	The instrument will power down after the chosen number of seconds have elapsed.
Training Mode Active	The instrument will power down after the chosen number of seconds have elapsed.

Software Updates	

Software Expiration Warning	Number of days prior to the expiration of the instrument software to display a warning message on the screen. Allowable values are 0 through 30. The default is 15 days. The following is an example of the message displayed:
	`Software expires on:`
	`31DEC2020`
	`Testing will be disabled on that date.`
	`Contact the system administrator`

Require Electronic Simulator test after software installation	After the software update, select this option to lock out the instrument to prevent it from being used until the electronic simulator test is performed and passed.
Update and install software from Server	After the software update is downloaded from the Abbott Managed Server, or the SDi, the instrument will install the software without requiring the installation confirmation.

Decimal Character	
	Select the decimal point or comma for the display of results on the instrument. Decimal point is the default.

Memory Full Action		
The instrument can store 500 results (including Patient, QC, Training esults). This setting controls the action taken when the memory is full:		
	Overwrite the oldest record without notification	New records overwrite old records. The oldest record is overwritten first, the next oldest record is overwritten next, and so on. This is the default.
	Memory full notification at instrument start-up	When the instrument is powered up a start up alert will display indicating the memory is full. The operator is prompted to clear the memory, otherwise old records may be overwritten.
	Lockout all Testing Pathways until memory is cleared	Testing will be suspended until the memory is cleared. Lockout message displays on the instrument at start up.

When finished, choose from the options shown at the bottom of the screen:

- **Previous** to go back to the previous screen
- **Discard** to undo changes
- **Finish Later** to create a draft
- **Next** to open the next tab

Date

These settings control the format of the date when it is entered and displayed on the i-STAT Alinity.

Date Entry	Select one of these options for the format to be used when entering the date into the instrument. The default is **mm/dd/yy**: mm/dd/yy dd/mm/yy
Date Display	Select one of these options for the format of the date as it is displayed on the instrument. The default is **dd/mm/yyyy**: dd/mm/yyyy mm/dd/yyyy ddMMMyyyy

When finished, choose from the options shown at the bottom of the screen:

- **Previous** to go back to the previous screen
- **Discard** to undo changes
- **Finish Later** to create a draft
- **Next** to open the next tab

Communications

These settings control the communication method and action taken if upload fails or is delayed.

Result Auto Transmit	Transmit all result or results to data manager once displayed on the instrument and after all required entries are completed or after the inactivity time is reached.	
Power Down Communications	Select the action to be taken for data transmission when the instrument powers down:	
	None	No data will be communicated or transmitted from instrument to data management system or network service when the instrument powers down.
	Unsent Results	Unsent results will be transmitted to the data management system when the instrument powers down.
	All (Unsent Results, Lists,eVAS)	All unsent results, Operator/Patient/Cartridge Lists, if enabled, and eVAS, if new version available, will be communicated and transmitted to or from the data management system and network service when the instrument powers down.
Wireless Communications	Enables wireless communication for the i-STAT Alinity instrument. The default setting is enabled. Uncheck the box to disable. Wireless communication is not fully enabled until the instrument is configured using the NCi application. See the NCi section of this manual for additional instruction.	

When finished, choose from the options shown at the bottom of the screen:

- **Previous** to go back to the previous screen
- **Discard** to undo changes
- **Finish Later** to create a draft
- **Next** to open the next tab

Operator Actions

The features in this section determine the actions for Operators when working in the patient test pathway or training mode pathway.

Operator Actions		
Accept or Reject Results	Determines whether the operator has the ability to accept or reject results after they are displayed on the instrument.	
	Enable Accept or Reject Results	Select the check box to allow operators to accept or reject test results after results display on the instrument. If results are rejected no patient treatment should be performed from the rejected results. Unselect the checkbox and operators will not have the option of rejecting or accepting results after they display on the instrument. If results are transmitted to the data management system, only those that are accepted will go through to the LIS/EMR. Rejected results will not be sent tothe LIS/EMR.
Rejection Comment	Select either option:	
	Optional	The operator is prompted to enter a comment for rejecting test results.
	Mandatory	The operator is prompted to enter aman-datory comment for rejecting test results.
Rejection Comment Style	Controls display of comments on the i-STAT Alinity. Select either:	
	Comment List	Only comments chosen from the selection list will be displayed and available for attaching to a rejected result.
	Comment List with text box	Comments chosen from the comment list along with a text box that will accept 20 characters will be displayed and available for attaching to a rejected result. A maximum of 6 comments can be displayed with a text box.

Operator Actions	
Rejection Comments	At least one comment is required when the Accept/Reject feature is enabled. The comment list is created by the CWi user. The comments will display on the instrument screen when a result is rejected. Operator selects the most appropriate. Rejection comments will be attached to the test record and can be viewed under the **Review Results** > **Patient Results** > **Rejected Patient Results**

Test Cancellation

Enable Test Cancellation	Allows the operator to cancel a test during testing. Select the check box to enable test cancellation. The default is disabled. Canceled tests can be viewed by going to **Review Results** > **Canceled Results.**

Test Selection	Requires the operator to select analytes to be reported from all of the analytes available on the cartridge scanned. Select the checkbox to require tests to be selected. Unselect the check box if you do not want to require tests to be selected.	
Accession/Specimen ID entry	Accession or Specimen ID number generated from facility LIS when a test is ordered:	
	Enable	Select the check box to enable prompting for an entry. If you select the check box to enable prompting, choose one of these options:
		Optional Prompt the operator for entry of the accession/ specimen ID number. The operator may skip this prompt.
		Mandatory with Override Prompt the operator for a mandatory entry. If the override feature is chosen by the operator no further action is required and the instrument will advance to the next screen.
		Mandatory Prompt the operator for a mandatory entry. Cartridge testing cannot continue until information is entered.

Data Entry Format	Determine the format used to enter data. Select either:	
	Numeric Only	Data will be entered only as numbers.
	Alphanumeric	Data will be entered as either letters or numbers.
Entry Type	Determine how the data will be entered into the i-STAT Alinity Instrument. Select one of the following:	
	Allow Scan and Manual Entry	Allow barcode scan or manual data entry.
	Scan Only	Allow barcode scan data entry only.
	Manual Entry Only	Allow manual data entry only.

Manual Entry

Do Not Repeat Manual Entry	Deselect this option if double entry is required when manually entering data into this field.
Minimum Length	Enter the minimum data characters allowed.
Maximum Length	Enter the maximum data characters allowed.

Scan Mask	Barcode scanning setting that allows for the selection of specific character positions to be retained. • The first position (the position farthest to the left) is numbered position “1”. • The scanmask field will accept a text input consisting of numbers 1-9, commas (‘,’), and hyphens (‘-’) to identify the scanmask selection. • If, for example, the barcode reads “abcdefghi1234567890” and the selection pattern is “2,5-8,11-14” then the barcode will be interpreted as “befgh2345”. If the selection pattern is “3-4”, then the barcode will be “cd”. • Individual position selections that are separated by a comma such as “2,4,7,8,19” cannot be duplicated. • In each number range, the starting number must be smaller than the ending number. For example, “3-5” is a valid range, but “5-3” is not. • Selection ranges cannot overlap. The end of each number range must be smaller than the beginning of the next number range. For example, “3-6,7-9” is a valid selection, but “3-6,6-9” is not. • Entering consecutive commas or hyphens is invalid. For example, “2--5”, “2-5,,7-10”, and “2,-5” are all invalid ranges.

Manual Check Digit Method	If a facility uses a supported check digit algorithm when creating operator or patient IDs, the i-STAT Alinity can verify the entered ID format by calculating the check digit and comparing it to the entered ID number. If the check digits do not match, the ID is rejected. **Note:** The i-STAT Alinity System supports the Mod 10 and Mod 11 check digit algorithms described in the HL7 Table 0061 (Check Digit Scheme) in the HL7 Specification (Rev 1.4). Contact your LIS/HIS or IT departments to determine if your facility uses check digits in the creation of operator and/or patient ID numbers, and if so, which algorithm is used. Allowable values are:	
	No check digit on manual entry	Do not use a check digit when creating operator or patient IDs.
	Mod 11 check digit on manual entry	Use the Mod 11 algorithm when creating operator or patient IDs.
	Mod 10 check digit on manual entry	Use the Mod 10 algorithm when creating operator or patient IDs.
Scan Entry Check Digit Method	Whether to use a check digit when scanning a value to create an operator or patient ID.	
	No check digit on scan entry	Do not use a check digit when creating operator or patient IDs.
	Mod 11 check digit on scan entry	Use the Mod 11 algorithm when creating operator or patient IDs.
	Mod 10 check digit on scan entry	Use the Mod 10 algorithm when creating operator or patient IDs.

Barcode Type	Select all that apply.

When finished, choose from the options shown at the bottom of the screen:

- **Previous** to go back to the previous screen
- **Discard** to undo changes
- **Finish Later** to create a draft
- **Next** to open the next tab

Critical Callback

This section describes the critical callback feature. This feature requires that action ranges are defined in the Analyte Settings Category.

Critical Callback Documentation

Enable Critical Callback Documentation	Select this check box to enable the Critical Callback documentation feature.	
	Mandatory with Override	Prompt the operator for a mandatory entry. If the override feature is chosen by the operator no further action is required and the instrument will advance to the next screen.
	Mandatory	Prompt the operator for a mandatory entry. Cartridge testing cannot continue until information is entered.

Patient Last Name	Operator enters the patient's last name for confirmation when a critical callback is read to the caregiver. Refer to the options below. If Positive Patient Identification (PPID) is enabled, this information is automatically populated.

Options

Enable	Select this check box to enable comments. If comments are enabled, select one of these options:	
	Optional	Comment is optional.
	Mandatory	Comment is required.

Format	Determine the format used to enter data. Select either:	
	Numeric Only	Data will be entered only as numbers.
	Alphanumeric	Data will be entered as either letters or numbers.

Entry Type	Determine how the data will be entered into the i-STAT Alinity instrument. Select one of the following:	
	Allow Scan and Manual Entry	Allow barcode scan or manual data entry.
	Scan Only	Allow barcode scan data entry only.
	Manual Entry Only	Allow manual data entry only.
	Minimum Length	Enter the minimum data characters allowed.

	Maximum Length	Enter the maximum data characters allowed.
Scan Mask	Barcode scanning setting that allows for the selection of specific character positions to be retained. • The first position (the position farthest to the left) is numbered position “1”. • The scanmask field will accept a text input consisting of numbers 1-9, commas (‘,’), and hyphens (‘-’) to identify the scanmask selection. • If, for example, the barcode reads “abcdefghi1234567890” and the selection pattern is “2,5-8,11-14” then the barcode will be interpreted as “befgh2345”. If the selection pattern is “3-4”, then the barcode will be “cd”. • Individual position selections that are separated by a comma such as “2,4,7,8,19” cannot be duplicated. • In each number range, the starting number must be smaller than the ending number. For example, “3-5” is a valid range, but “5-3” is not. • Selection ranges cannot overlap. The end of each number range must be smaller than the beginning of the next number range. For example, “3-6,7-9” is a valid selection, but “3-6,6-9” is not. • Entering consecutive commas or hyphens is invalid. For example, “2--5”, “2-5,,7-10”, and “2,-5” are all invalid ranges.	

Manual Check Digit Method	If a facility uses a supported check digit algorithm when creating operator or patient IDs, the i-STAT Alinity can verify the entered ID format by calculating the check digit and comparing it to the entered ID number. If the check digits do not match, the ID is rejected. **Note:** The i-STAT Alinity System supports the Mod 10 and Mod11check digit algorithms described in the HL7 Table 0061 (Check Digit Scheme) in the HL7 Specification (Rev 1.4). Contact your LIS/HIS or IT departments to determine if your facility use check digits in the creation of operator and/or patient ID numbers, and if so, which algorithm is used. Allowable values are:	
	No check digit on manual entry	Do not use a check digit when creating operator or patient IDs.
	Mod 11 check digit on manual entry	Use the Mod 11 algorithm when creating operator or patient IDs.
	Mod 10 check digit on manual entry	Use the Mod 10 algorithm when creating operator or patient IDs.

Scan Entry Check Digit Method	Whether to use a check digit when scanning a value to create an operator or patient ID.	
	No check digit on scan entry	Do not use a check digit when creating operator or patient IDs.
	Mod 11 check digit on scanen-try	Use the Mod 11 algorithm when creating operator or patient IDs.
	Mod 10 check digit on scan entry	Use the Mod 10 algorithm when creating operator or patient IDs.

Barcode Type	Select all that apply.

Patient First Name	Operator enters the patient's first name for confirmation when a critical callback is read to the caregiver. If Positive Patient Identification (PPID) is enabled, this information is automatically populated. **Note:** For **Patient First Name** options see the section for **Patient Last Name** Options. Options are the same for both.

Caregiver ID	Operator enters the caregiver's last name or ID for confirmation when a critical callback is read to the caregiver.

Format	**Note: Caregiver ID** options for **Format, Entry Type, Minimum Length, Maximum Length, Scan Mask, Manual Check Digit Method, Scan Entry Check Digit Method** and **Barcode Type** are the same as those for **Patient Last Name.** See the information shown earlier in this section.
Entry Type	
Minimum Length	
Maximum Length	
Scan Mask	
Manual Check Digit Method	
Scan Entry Check Digit Method	
Barcode Type	

Comments

Options

Enable	Select this check box to prompt the operator to enter a comment. If you enable this feature, choose one of the following options:	
	Optional	Prompts the operator to enter an optional comment.
	Mandatory	Prompts the operator to enter a mandatory comment.
Comment Style	Determines the type of information that can be entered as a comment:	
	Comment List	Comments must be chosen from a list.
	Comment List with text box	Comments can be chosen from a comment list or entered into a text box that accepts up to 20 characters. A comment will be displayed and available for attaching to a result.
	Comments	A list of comments created by the CWi user. Operator selects the most appropriate. The comment will be attached to the test record. Each comment can be 17 characters in length including spaces.
	Comment Field Prompt	Specify the text, up to 17 characters, to display on the instrument, as a prefix to a comment. **Note:** The prefix specified as Comment Field Prompt will display with a comment. For example, if the Comment Field Prompt built is `Critical Result` and the operator chooses `Repeat per MD` from the comment list on the instrument, the full comment will appear as `Critical Result Repeat per MD`.

When finished, choose from the options shown at the bottom of the screen:

- **Previous** to go back to the previous screen
- **Discard** to undo changes
- **Finish Later** to create a draft
- **Next** to open the next tab

Print

This section describes settings for printing from the instrument to the i-STAT Alinity printer.

Test Result Printout	Includes or excludes information that will be printed:	
	Show Reference Ranges	Print reference ranges with the results on the printout. **Note:** Reference Ranges must be defined in Analyte Settings in order for the reference ranges to be displayed and available to print.
	Show Patient Name, Gender, and Age	Print the patient name, gender and age on the printout. **Note:** If PPID is enabled in Patient Settings the patient name, gender and age will be available for print. If prompts for the Patient Name, gender and age are displayed and entered on the instrument the information will be available for print.
	Print Operator ID as per the Operator ID Presentation setting	When checked, printouts will contain Operator ID as per the Operator ID Presentation settings (see Operator Settings category). When not checked, printouts will contain the entire Operator ID.
	Print Operator Name as per the Operator Name Presentation setting	When checked, printouts will contain Operator Name as per the Operator Name Presentation settings (see Operator Settings category). When not checked, printouts will contain the entire Operator Name. **Note:** Operator list must be enabled in Operator Settings in order for the operator name to be displayed and available for print.

i-STAT Printing

Enable i-STAT printing	Unselect the check box if printing is not allowed or if there are no i-STAT Alinity printers available.

When finished, choose from the options shown at the bottom of the screen:

- **Previous** to go back to the previous screen
- **Discard** to undo changes
- **Finish Later** to create a draft
- **Publish** to make settings available to use in a Profile

i-STAT Reserved

For Abbott Point of Care use only and to be used only at the direction of Abbott Point of Care.

Summary

The Summary is a collapsed view of the settings that can be expanded to provide a complete display. The Summary should be reviewed prior to Publish. Once the settings are confirmed, click on the Publish button to finalize them. A Category can be added to a Profile only when the publish status is completed.

When finished, choose from the options shown at the bottom of the screen:

- **Previous** to go back to the previous screen
- **Discard** to undo changes
- **Finish Later** to create a draft
- **Publish** to make settings available to use in a Profile

*Operator Settings Category

This section contains features for identifying operators, such as, method for entering the operator's ID, enhancing security by utilizing an operator list, and giving notification when an operator's certification is due to expire. The Operator Settings category can be created using the following steps.

Click **Operator Settings**, then select `APOCOperatorSettings` and click **View**. The screen displays the default name `APOCOperatorSettings`, and default values for each feature. Scan through the `APOCOperatorSettings` and determine if the selections work for the profile being assembled. If they do then no additional work is needed in this category. The `APOCOperatorSettings` category will be available in the **Manage Profiles** section. Use it to assemble the new profile. If the `APOCOperatorSettings` do not work for the profile being assembled, click **Finish** to stop viewing. Click **Create** and follow the instructions below.

Note: All required categories have a default setting named with the APOC prefix. In addition, the settings are populated with default values.

You are prompted to specify a name for the settings and an optional description:

Operator Settings

Name	Required. Specify a name that is from 4 to 40 characters long and: • consists only of the following characters: ○ 0 through 9 ○A through Z or alphabet appropriate for language (in upper or lower case) ○blank space ○underscore (_) • does not begin with the characters APOC (in upper or lower case) • is a unique name within this healthcare organization
Description	Optional. Provide any information that helps the user know how or why the category was named or created.

When finished, choose from the actions shown at the bottom of the screen:

- **Discard** - to undo changes
- **Next** - to open the next tab

ID Entry

Options	Select either of these options:	
	Optional	Enables optional ID entry.
	Mandatory	Enables required ID entry.

Manual Entry		
	Do Not Repeat Manual Entry	Deselect this option if double entry is required when manually entering data into this field.

Format	Determine the format used to enter data. Select either:	
	Numeric Only	Data will be entered only as numbers.
	Alphanumeric	Data will be entered as either letters or numbers.

Entry Type	Determine how the data will be entered into the i-STAT Alinity instrument. Select one of the following:	
	Allow Scan and Manual Entry	Allow barcode scan or manual data entry.
	Scan Only	Allow barcode scan data entry only.
	Manual Entry Only	Allow manual data entry only.
	Minimum Length	Enter the minimum data characters allowed.
	Maximum Length	Enter the maximum data characters allowed.
Scan Mask	Barcode scanning setting that allows for the selection of specific character positions to be retained. • The first position (the position farthest to the left) is numbered position “1”. • The scanmask field will accept a text input consisting of numbers 1-9, commas (‘,’), and hyphens (‘-’) to identify the scanmask selection. • If, for example, the barcode reads “abcdefghi1234567890” and the selection pattern is “2,5-8,11-14” then the barcode will be interpreted as “befgh2345”. If the selection pattern is “3-4”, then the barcode will be “cd”. • Individual position selections that are separated by a comma such as “2,4,7,8,19” cannot be duplicated. • In each number range, the starting number must be smaller than the ending number. For example, “3-5” is a valid range, but “5-3” is not. • Selection ranges cannot overlap. The end of each number range must be smaller than the beginning of the next number range. For example, “3-6,7-9” is a valid selection, but “3-6,6-9” is not. • Entering consecutive commas or hyphens is invalid. For example, “2--5”, “2-5,,7-10”, and “2,-5” are all invalid ranges.	

Manual Check Digit Method	If a facility uses a supported check digit algorithm when creating operator or patient IDs, the i-STAT Alinity can verify the entered ID format by calculating the check digit and comparing it to the entered ID number. If the check digits do not match, the ID is rejected. **Note:** The i-STAT Alinity System supports the Mod 10 and Mod 11 check digit algorithms described in the HL7 Table 0061 (Check Digit Scheme) in the HL7 Specification (Rev 1.4). Contact your LIS/HIS or IT departments to determine if your facility uses check digits in the creation of operator and/or patient ID numbers, and if so, which algorithm is used. Allowable values are:	
	No check digit on manual entry	Do not use a check digit when creating operator or patient IDs.
	Mod 11 check digit on manual entry	Use the Mod 11 algorithm when creating operator or patient IDs.
	Mod 10 check digit on manual entry	Use the Mod 10 algorithm when creating operator or patient IDs.

Scan Entry Check Digit Method	Whether to use a check digit when scanning a value to create an operator or patient ID.	
	No check digit on scan entry	Do not use a check digit when creating operator or patient IDs.
	Mod 11 check digit on scan entry	Use the Mod 11 algorithm when creating operator or patient IDs.
	Mod 10 check digit on scan entry	Use the Mod 10 algorithm when creating operator or patient IDs.

Barcode Type	Select all that apply.

Operator ID Presentation	Determine how the operator ID will be displayed on the i-STAT Alinity. Select from the following options:	
	Display Operator ID	Display the entire operator ID.
	Partially Display Operator ID	Display only the last 3 digits of the operator ID.
	Hide Operator ID	Display none of the operator ID.

Operator Name Presentation	Determine how the operator name will be displayed on the i-STAT Alinity. Select from the following options:	
	Partially Display Operator Name	Display the operator's first name and last initial.

Cartridge Insert Help

Enable Cartridge Insert Help	Graphics displayed on the instrument screen after all required fields are complete but before the cartridge is inserted. The cartridge help screens include the 'collect and mix sample' and 'fill cartridge' graphics.

When finished, choose from the options shown at the bottom of the screen:

- **Previous** to go back to the screen displayed previous to this screen
- **Discard** to undo changes
- **Finish Later** to create a draft
- **Next** to open the next tab

List Actions

List Actions determine how the i-STAT Alinity responds when accessing the Operator List. Additionally, these options control the action taken in different situations, such as access to testing pathways if an operator's certification is expired. Enabling these selections requires connectivity to a data management system, LIS and/or an HIS depending on the facilities set up.

Operator Settings - List Actions		
Search for Operator ID on Operator List	Select this check box to search the Operator List for the operator ID when entering any of the testing pathways. In order to search the Operator List for Operator ID, the Operator List must be enabled and configured in Connectivity Settings.	
Operator ID on Operator List —Certification Expired Action	Determine an operator's access to the test pathway if the operator ID is expired.	
	Unscheduled QC Test Pathway	Choose one of these options:
		Warn user and prompt to continue Display a warning message to the operator that certification has expired and provide a **Continue** tab to allow access to the test pathway for testing to be performed.
		Lockout user Deny access if an operator's certification is expired.
	Training Test Pathway	Determine an operator's access to the test pathway if the operator's ID is expired.
		Warn user and prompt to continue Display a warning message to the operator that certification has expired and provide a **Continue** tab to allow access to the test pathway so that testing can be performed.
		Lockout user Deny access if an operator's certification is expired.
	Test Pathways other than Training or Unscheduled QC	Determine an operator's access if the operator's certification has expired.

Operator Settings - List Actions		
		Warn user and prompt to continue Display a message to the operator warning that certification has expired and allow access to the test pathway so that testing can be performed.
		Lockout user Deny access if an operator's certification is expired.
Operator ID not on Operator List Action	Determine what access an operator will have in the test pathways when the operator ID is not on the Operator List.	
	Unscheduled QC Test Pathway	Choose one of these options:
		Warn user and prompt to continue Display a warning message to the operator stating that the operator's ID is not on the Operator List and allow access to the test pathway for testing to be performed.
		Lockout user Deny access if an operator's ID is not on the Operator List.
	Training Test Pathway	Determine an operator's access to the test pathway if the operator's ID is expired.
		Warn user and prompt to continue Display a warning message to the operator stating that the operator's ID is not on the Operator List and allow access to the test pathway for testing to be performed.
		Lockout user Deny access if an operator's ID is not on the Operator List.

Operator Settings - List Actions		
	Test Pathways other than Training or Unscheduled QC	Determine an operator's access to the test pathway if the operator's ID is expired.
		Warn user and prompt to continue Display a warning message stating that the operator's ID is not on the Operator List and allow access to the test pathway for testing to be performed.
		Lockout user Deny access if an operator's ID is not on the Operator List.

When finished, choose from the options shown at the bottom of the screen:

- **Previous** to go back to the previous screen
- **Discard** to undo changes
- **Finish Later** to create a draft
- **Next** to open the next tab

Operator Expiration

Operator Certification Expiration Notification	Display a message on the i-STAT Alinity prior to the date of the operator's certification expiration	
	Show notification *n* days before certification expires	Specify the number of days (0 - 365) before the operator's certification expires to display the message. The default is 0, which disables notification.
	Notification to display	Create a customized message of up to 5 lines and a maximum of 40 characters per line.

When finished, choose from the options shown at the bottom of the screen:

- **Previous** to go back to the previous screen
- **Discard** to undo changes
- **Finish Later** to create a draft
- **Next** to open the next tab

Summary

The Summary is a collapsed view of the settings that can be expanded to provide a complete display. The Summary should be reviewed prior to **Publish**. Once the settings are confirmed, click on the **Publish** button to finalize them. A **Category** can be added to a Profile only when the publish status is completed.

When finished, choose from the options shown at the bottom of the screen:

- **Previous** to go back to the previous screen
- **Discard** to undo changes
- **Finish Later** to create a draft
- **Publish** to make settings available to use in a Profile

*Patient Settings Category

This section contains features to customize the patient settings for the i-STAT Alinity. The Patient Settings category can be created with the following steps.

Click **Patient Settings**, then select `APOCPatientSettings` and click **View**. The screen displays the default name `APOCPatientSettings`, and default values for each feature. Scan through the `APOCPatientSettings` and determine if the selections work for the profile being assembled. If they do then no additional work is needed in this category. The `APOCPatientSettings` category will be available in the **Manage Profiles** section. Use it to assemble the new profile. If the `APOCPatientSettings` do not work for the profile being assembled, click **Finish** to stop viewing. Click **Create** and follow the instructions below.

Note: All required categories have a default setting named with the APOC prefix. In addition, the settings are populated with default values.

You are prompted to specify a name for the settings and an optional description:

Patient Settings Name	Required. Specify a name that is from 4 to 40 characters long and: • consists only of the following characters: ○ 0 through 9 ○ A through Z or alphabet appropriate for language (in upper or lower case) ○ blank space ○ underscore (_) • does not begin with the characters APOC (in upper or lower case) • is a unique name within this healthcare organization
Description	Optional. Provide any information that helps the user know how or why the category was named or created.

When finished, choose from the options shown at the bottom of the screen:

- **Discard** to undo changes
- **Next** to open the next tab

ID Entry

Options	Select either of these options:	
	Optional	Enables optional ID entry.
	Mandatory	Enables required ID entry.

Manual Entry		
	Do Not Repeat Manual Entry	Deselect this option if double entry is required when manually entering data into this field.

Format	Determine the format used to enter data. Select either:	
	Numeric Only	Data will be entered only as numbers.
	Alphanumeric	Data will be entered as either letters or numbers.

Entry Type	Determine how the data will be entered into the i-STAT Alinity instrument. Select one of the following:	
	Allow Scan and Manual Entry	Allow barcode scan or manual data entry.
	Scan Only	Allow barcode scan data entry only.
	Manual Entry Only	Allow manual data entry only.
	Minimum Length	Enter the minimum data characters allowed.
	Maximum Length	Enter the maximum data characters allowed.

Scan Mask	Barcode scanning setting that allows for the selection of specific character positions to be retained. • The first position (the position farthest to the left) is numbered position “1”. • The scanmask field will accept a text input consisting of numbers 1-9, commas (‘,’), and hyphens (‘-’) to identify the scanmask selection. • If, for example, the barcode reads “abcdefghi1234567890” and the selection pattern is “2,5-8,11-14” then the barcode will be interpreted as “befgh2345”. If the selection pattern is “3-4”, then the barcode will be “cd”. • Individual position selections that are separated by a comma such as “2,4,7,8,19” cannot be duplicated. • In each number range, the starting number must be smaller than the ending number. For example, “3-5” is a valid range, but “5-3” is not. • Selection ranges cannot overlap. The end of each number range must be smaller than the beginning of the next number range. For example, “3-6,7-9” is a valid selection, but “3-6,6-9” is not. • Entering consecutive commas or hyphens is invalid. For example, “2--5”, “2-5,,7-10”, and “2,-5” are all invalid ranges.

Manual Check Digit Method	If a facility uses a supported check digit algorithm when creating operator or patient IDs, the i-STAT Alinity can verify the entered ID format by calculating the check digit and comparing it to the entered ID number. If the check digits do not match, the ID is rejected.  **Note:** The i-STAT Alinity System supports the Mod 10 and Mod 11 check digit algorithms described in the HL7 Table 0061 (Check Digit Scheme) in the HL7 Specification (Rev 1.4). Contact your LIS/HIS or IT departments to determine if your facility uses check digits in the creation of operator and/or patient ID numbers, and if so, which algorithm is used. Allowable values are:	
	No check digit on manual entry	Do not use a check digit when creating operator or patient IDs.
	Mod 11 check digit on manual entry	Use the Mod 11 algorithm when creating operator or patient IDs.
	Mod 10 check digit on manual entry	Use the Mod 10 algorithm when creating operator or patient IDs.

Scan Entry Check Digit Method	Whether to use a check digit when scanning a value to create an operator or patient ID.	
	No check digit on scan entry	Do not use a check digit when creating operator or patient IDs.

	Mod 11 check digit on scan entry	Use the Mod 11 algorithm when creating operator or patient IDs.
	Mod 10 check digit on scan entry	Use the Mod 10 algorithm when creating operator or patient IDs.

Barcode Type	Select all that apply.

When finished, choose from the options shown at the bottom of the screen:

- **Previous** to go back to the previous screen
- **Discard** to undo changes
- **Finish Later** to create a draft
- **Next** to open the next tab

Patient Information and Positive Patient Identification (PPID)

Patient Information customization features control prompting for patient age and sex, and whether patient gender obtained from the patient list is to be used as the patient sex. The Positive Patient Identification (PPID) feature enables the i-STAT Alinity to present secondary patient identifiers (patient's name, birth date, and gender) obtained from the hospital's Admission, Discharge, and Transfer (ADT) data based upon the entered patient identification number. Using these secondary identifiers, the operator can confirm the patient's identity. The PPID feature helps hospitals improve the accuracy of patient identification by obtaining at least two forms of patient identification prior to diagnostic testing.

Age and Sex		
Prompt for age and sex if Patient List is Not Enabled or information is not in the Patient List	Patient age and sex prompt is required if reference and action ranges are built with age and sex applied in **Analyte Settings**. In order to display results for eGFR, the **Prompt for age and sex if Patient List is Not Enabled or information is not in the Patient List** option must be enabled. **Note:** Sex types displayed on the instrument for manual entry of Age and Sex are **Male**, **Female**, and **Unknown**. If a sex type is selected from the list, but a reference and action range are not set for that sex type, no reference or action range will display with the results.	
Use Patient List	Select this check box to search the patient list for this patient ID. If you enable this feature, the following options are available:	
	Patient ID not on List	Choose one of these options for the action to take if the patient ID is not on the patient list:
		Allow testing Default is to display a message to warn the user and prompt them to continue.
		Require repeat ID entry to allow testing Select this option to require user to repeat patient ID entry in order to proceed with patient testing.
		Prohibit testing Select this option to prohibit patient testing.

Age and Sex		
Confirm Patient Displayed on Instrument	Determines the method used to confirm the patient ID. Select one of the following:	
	Confirm	The operator confirms the patient ID.
	Replicate Year of Birth	The operator is prompted to enter the four digits of the patient's year of birth. The year of birth, from the ADT feed, is displayed on the instrument screen.
	Enter Year of Birth	The operator is prompted to enter the four digits of the patient's year of birth.
Mapping Gender to Sex		
Gender in list may NOT be equivalent to Sex at Birth: Do not allow mapping	Select this option if the Gender contained in the patient list **is not** equivalent to the patient's sex at birth. This is the default option.	
Gender in list is equivalent to Sex at Birth: Allow mapping	Select this option if the Gender contained in the patient list **is** equivalent to the patient's sex at birth. When this option is selected, if Gender is available from the patient list, patient gender will be used for items that require patient sex (reference ranges, action ranges, cutoffs and eGFR) and the operator will not be prompted to enter patient sex.	

When finished, choose from the options shown at the bottom of the screen:

- **Previous** to go back to the previous screen
- **Discard** to undo changes
- **Finish Later** to create a draft
- **Next** to open the next tab

Summary

The Summary is a collapsed view of the settings that can be expanded to provide a complete display. The Summary should be reviewed prior to Publish. Once the settings are confirmed, click on the Publish button to finalize them. A Category can be added to a Profile only when the publish status is completed.

When finished, choose from the options shown at the bottom of the screen:

- **Previous** to go back to the previous screen
- **Discard** to undo changes
- **Finish Later** to create a draft
- **Publish** to make settings available to use in a Profile

*Analyte Settings Category

This section contains features to customize the analyte settings for the i-STAT Alinity, such as units, reference and action ranges. The Analyte Settings category can be created or modified with the following steps.

Click **Analyte Settings**, then select `APOCAnalyteSettings` and click **View**. The screen displays the default name `APOCAnalyteSettings`, and default values for each feature. Scan through the `APOCAnalyteSettings` and determine if the selections work for the profile being assembled. If they do then no additional work is needed in this category. The `APOCAnalyteSettings` category will be available in the **Manage Profiles** section. Use it to assemble the new profile. If the `APOCAnalyteSettings` do not work for the profile being assembled, click **Finish** to stop viewing. Click **Create** and follow the instructions below.

Note: All required categories have a default setting named with the APOC prefix. In addition, the settings are populated with default values.

You are prompted to specify a name for the settings and an optional description:

Analyte Settings

Name	Required. Specify a name that is from 4 to 40 characters long and: • consists only of the following characters: ○ 0 through 9 ○ A through Z or alphabet appropriate for language (in upper or lower case) ○ blank space ○ underscore (_) • does not begin with the characters APOC (in upper or lower case) • is a unique name within this healthcare organization
Description	Optional. Provide any information that helps the user know how or why the category was named or created.

When finished, choose from the options shown at the bottom of the screen:

- **Discard** to undo changes
- **Next** to open the next tab

Units

Specify the measurement unit to be used for an analyte. In addition, for some analytes you can select the analyte name. For example, BUN or Urea. To change a value, click the drop down list and select an option.

Note: If you change units for an analyte, you may also need to adjust reference ranges, action ranges, cutoffs and custom reportable ranges for that analyte.

When finished, choose from the options shown at the bottom of the screen:

- **Previous** to go back to the previous screen
- **Discard** to undo changes
- **Finish Later** to create a draft
- **Next** to open the next tab

Sample Types

Sample Types		
Use Default Sample Types	Unselect this check box to use Custom Sample Types. Default sample types are: **Arterial** **Venous** **Capillary** **Unspecified**	
Custom Sample Types	Define a name for each custom sample type. Specify a name up to 20 characters long. A maximum of 6 sample types can be defined. In the drop down box next to the name, select the sample type: other, arterial, venous, or capillary. The default sample type that is selected from the drop down box will provide the graphics help displays on the instrument while the operator is using the patient testing pathway.	
Sample Type Entry Options	Determine whether the operator is prompted to enter the type of sample used.	
	Enable	Unselect the check box if you do not want to prompt the operator for the sample type.
		Optional User is prompted to enter optional sample type.
		Mandatory with override User is prompted to enter mandatory sample type. If the override feature is chosen by the operator no further action is required and the instrument will advance to the next screen.
		Mandatory User is required to enter sample type.

When finished, choose from the options shown at the bottom of the screen:

- **Previous** to go back to the previous screen
- **Discard** to undo changes
- **Finish Later** to create a draft
- **Next** to open the next tab

Ranges

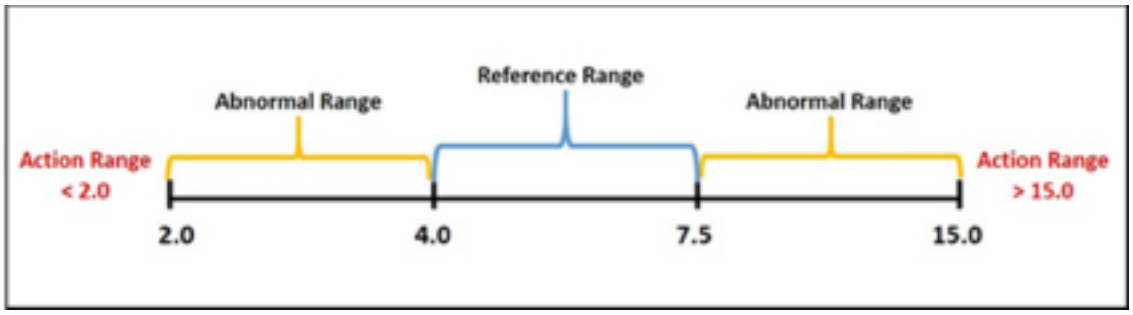
This section allows for the setting of ranges. Range options are reportable, reference and action or cutoff as applicable to the analyte. If a reference and reportable range are set for an analyte, the system defines the area in between these as abnormal. Setting ranges changes the appearance of the result screen on the instrument. Results that fall in the reference range have no color or arrows associated with that result (in the result bubble).
Results that fall in the action range (critical range) or above a critical cutoff will have a red tip and a solid arrow in the result bubble. Arrow direction indicates if the result is out of range high or low. Results that fall outside of the reference range, but not yet in the action range are abnormal. The result bubble will have a yellow tip and hollow arrows indicating whether the result is high or low.

Range

Range opens to a list of analytes and the custom reportable range display. To begin editing:

1. Click on the *+* icon found in far left hand column.
2. Click on the **Edit** button.
3. To customize reference range(s), click on **Add Range** under the Reference Range section. This area allows for ranges to be set based on sample type and/or age and/or sex. It is also possible to enter only the low and high range independent of sample type, age, or sex.
   - To make reference ranges sample type dependent, check the box in the **Apply** column and choose the sample types applicable by clicking the down arrow in the **Sample Type** column. The sample types displayed are either the default types or the types customized in the **Sample Types** section of the **Analyte Settings** category.
   - Reference ranges are age dependent by default. Up to six different sets of ranges can be age dependent. Enter the low and high age limits and units; or, to disable age dependent reference ranges, click to un-check the box in the **Apply** column. To use this feature, another customization item must be added to the profile: **Patient Settings** > **Patient Information and Positive Patient Identification** > **Age and Sex**
   - To make reference ranges sex dependent, check the box in the **Apply** column and choose the sex applicable by clicking the down arrow in the **Sex** column. To use this feature, another customization item must be added to the profile: **Patient Settings** > **Patient Information and Positive Patient Identification** > **Age and Sex**
4. To customize action range(s), click on **Add Range** under the **Action Range** section. The same structure is in place for changing action range as it is for reference range.
5. To customize cutoffs, click on **Apply Single Cutoff** or **Apply Sex Specific Cutoff** depending on your health systems policies, and enter the cutoff value(s).

Below is an example of reference, abnormal and action ranges. In this example, the reference range was set as 4.0-7.5. The low action range was set at 2.0 and the high action range was set at 15.0. The instrument calculates the abnormal range. When ranges are set and the profile is loaded onto the instrument, the result screen will reflect these changes. An example of a result screen displaying range customization can be found in *Interpreting Results with customization features applied*.



Note: Never enter reference, action or custom reportable ranges outside of the manufacturers reportable range.

Custom Reportable Ranges

Restrict the display range to custom values. For example, healthcare organization managers may wish to limit the display ranges to values that have been verified using calibration verification materials. Set the low and high values. Narrowing the reportable range of certain tests may affect the presentation of other dependent test results. In the table below, if any of the results in the first column are outside the reportable range, the dependent test results listed in the second column will be suppressed (displayed as <>).

Note: Never enter a null (blank) value for the Custom Reportable range for Low or High. The values can be left as -99999.9 for Low or 99999.9 for High.

Note: Range customization may not apply to all cartridge types.

Table 3–1: Reportable Range Limitations

Test (Outside the Reportable Range)	Dependent Suppressed Tests (displayed as <>)
Na	K, Cl, BUN, Anion Gap, Hgb, Hct
Hct	Cl, Bun, Anion Gap, Hgb
PCO_2	TCO_2, Anion Gap, Base Excess, HCO_3, sO_2
pH	TCO_2, Anion Gap, Base Excess, HCO_3, sO_2
HCO_3	TCO_2, Anion Gap, Base Excess, sO_2
Cl	Anion Gap
K	Anion Gap
TCO_2	Anion Gap
PO_2	sO_2

Click **Update** to save changes to analyte or click **Cancel** to discard. Repeat this process for all analytes needed.

When finished selecting all ranges for all desired analytes, choose from the options shown at the bottom of the screen:

- **Previous** to go back to the previous screen
- **Discard** to undo changes
- **Finish Later** to create a draft
- **Next** to open the next tab

Analyte Cutoff Feature

Background and Explanation:

A cutoff is a value at which a test result is flagged for action. Two types of action cutoff flags are supported on the i-STAT Alinity: ‘warning’ or ‘critical’. An i-STAT Alinity system administrator (e.g., Point of Care Coordinator or Laboratory Administrator) can define a threshold above which the test result is ‘flagged for action’ for analytes that support critical cutoffs.

The i-STAT Alinity System supports cutoffs for the following analytes: GFAP, UCH-L1, and hs-TnI. Cutoffs for GFAP and UCH-L1 are fixed, not customizable, and are ‘warning’ type cutoffs; refer to the TBI and TBI Plasma cartridge IFUs for details on cutoffs for GFAP and UCH-L1. hs-TnI cutoffs must be customized by the system administrator and are ‘critical’ type cutoffs. This section details how to customize instruments for critical cutoffs.

The default setting for the i-STAT Alinity instrument critical cutoff feature is ‘Do Not Apply Cutoffs’. This means when the i-STAT Alinity instrument is shipped, there are no critical cutoffs defined. Additionally, within the AlinIQ CWi software (the customization tool used to configure the i-STAT Alinity) there are no critical cutoffs configured by default. Critical cutoffs on the instrument can only be configured through AlinIQ CWi customization https://aliniqcwi.abbott.com. Direct customization via the i-STAT Alinity instrument’s user interface screens is not available.

When critical cutoff values are configured for the i-STAT Alinity instrument, values above the critical cutoff are indicated with an “up arrow”. There is no “down arrow” indicator for values below the cutoff. There is no indicator arrow displayed when a cutoff is not set (e.g., for the ‘Do Not Apply Cutoffs’ selection). For analytes which support cutoffs, analyte Reference Ranges and Action Ranges are not available for customization.

Examples pictured in this section are for reference only and show test results related to ‘critical’ type cutoffs.

Figure 3.4.1: No Cutoff Defined

Figure 3.4.2: Above Single Cutoff

Figure 3.4.3: Above Sex Specific Cutoff

Customization options:

i-STAT Alinity supports two critical cutoff options; a Single Cutoff or a Sex Specific Cutoff:

1. **Single Cutoff:**
   - Cutoff will be applied to all patients, regardless of sex.
   - When “Apply Single Cutoff” is selected cutoff value must be entered.

2. **Sex Specific Cutoff:**
   - Cutoff will be applied to patients depending on the sex identified on the instrument via the patient list feature or via operator prompt on the analyzer screen at test time.
   - When “Apply Sex Specific Cutoffs” is selected cutoff values must be entered for all three sex types: Female, Male, Unknown.
   - ‘Unknown’ sex option is provided for cases where the patient’s biological sex is not known, or indeterminate.

Note: Understanding Gender vs. Sex
By default, the i-STAT Alinity instrument does not map the ADT patient gender information to patient sex. If a patient ADT list is in effect, and the patient list gender field is populated with patient’s biological sex via the ADT system, the POCC may customize the instrument to use the value in the patient list gender field as the patient’s sex for purposes of test result interpretation. See section Mapping Gender to Sex in this manual for instructions.

- When Sex Specific Cutoffs are enabled and patient is found on the ADT list, testing will continue with the appropriate prompt based on cartridge scanned, Figure 3.4.4 below:

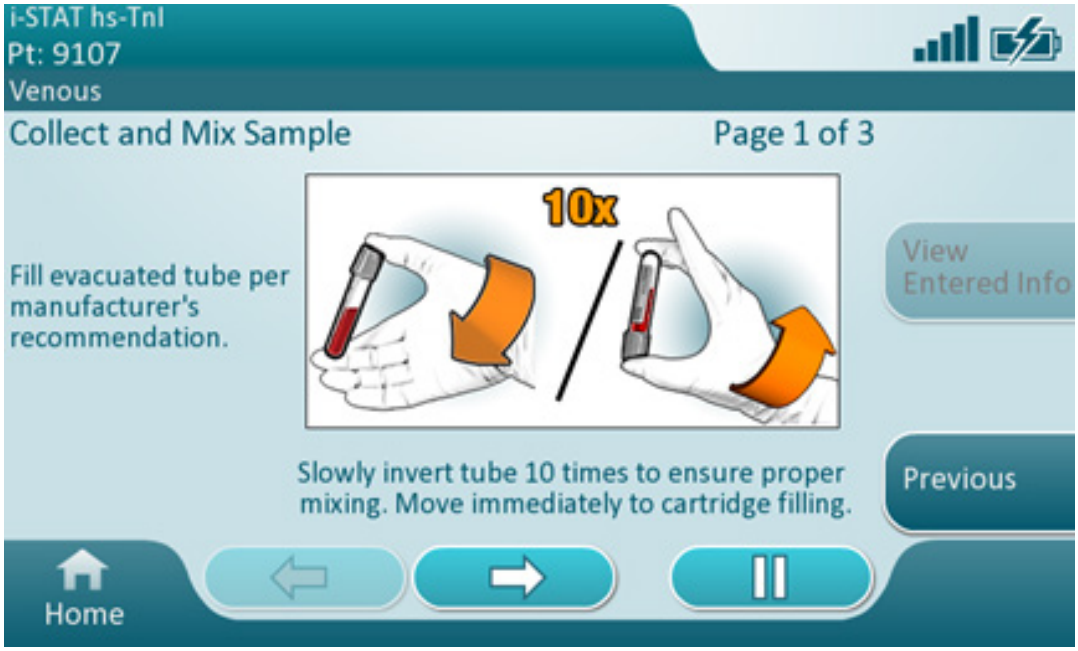


Figure 3.4.4

- When Sex Specific Cutoffs are enabled and the patient's sex is not available from the patient ADT list, the user will be required to select the 'PATIENT SEX' during the testing process after the cartridge is scanned, Figure 3.4.5 below:

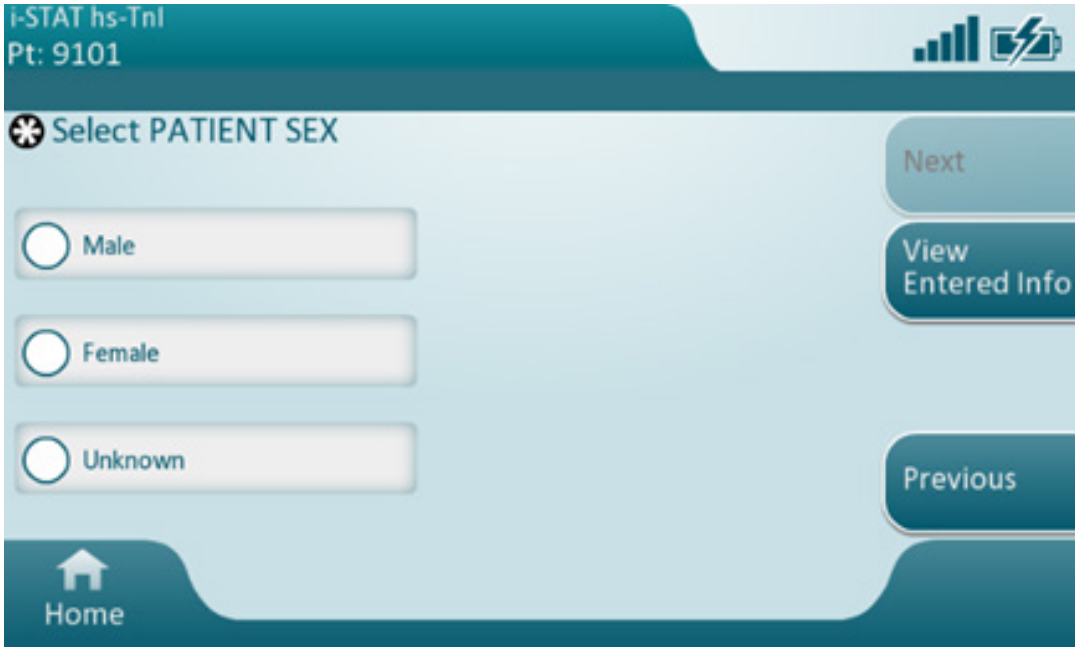
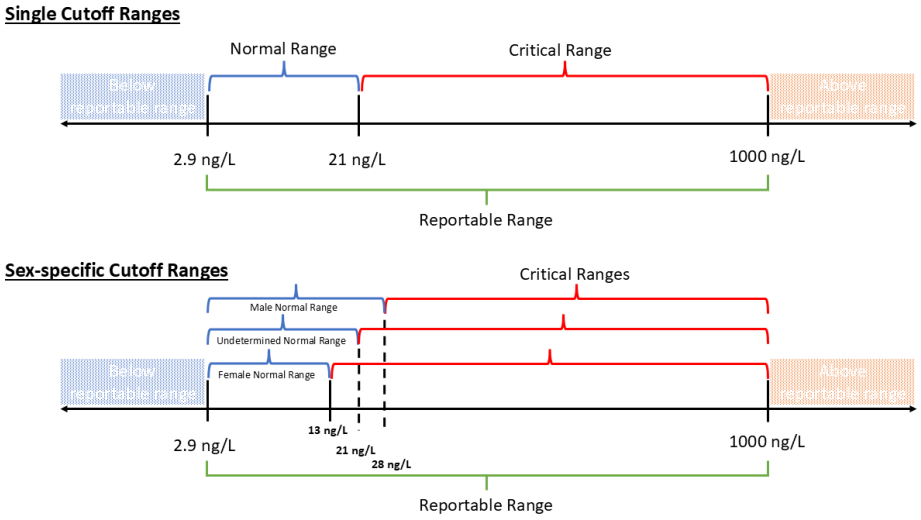


Figure 3.4.5

Notes & Caution(s):

1. Results greater than the 'critical' type cutoff (> for hs-TnI) or equal to/or greater than the 'warning' type cutoff (=/> TBI cartridges) will be flagged on the i-STAT Alinity instrument results display and results printout with an indicator arrow.
2. Cutoff values in effect at time of patient test, and patient sex (if Sex Specific Cutoffs are in effect) will be shown on the instrument's result displays and results printouts.
3. When instrument is customized for more than one cutoff for an analyte (i.e. hs-TnI Sex Specific Cutoffs), but one or more of the cutoff values is outside the reportable range (either below lower reportable range limit or above upper reportable range limit), the analyzer will ignore all cutoffs associated with the analyte.
4. Follow your facility's policies and procedures for interpreting test results.

Below is a diagram that helps explain the i-STAT Alinity cutoff behavior for i-STAT hs-TnI:



Enable/Disable Analyte

This section is used to disable analytes. The system default is all analytes are enabled, except for eGFR.

Apply Globally	Analytes can be disabled for all cartridge types. Example, if glucose is disabled, no cartridge that performs glucose will display a glucose result.
Apply by Panel	Analytes can be disabled on select cartridge types except BhCG. Example, glucose is available on CHEM8+ and EC8+. If glucose is not to be reported when an EC8+ is tested, disable the glucose by panel (cartridge type). The glucose would display when the CHEM8+ cartridge is tested, because it was not disabled on the CHEM8+ cartridge.

When finished, choose from the options shown at the bottom of the screen:

- **Previous** to go back to the previous screen
- **Discard** to undo changes
- **Finish Later** to create a draft
- **Next** to open the next tab

Hematocrit

On this tab, select settings for testing Hematocrit.

Hematocrit Setting (Calibration by Laboratory Hematology Analyzer)	Specify the anticoagulant used to calculate hematocrit result. For best agreement of i-STAT Alinity and hematology analyzer hematocrit results, the i-STAT Alinity customization setting is selected according to the calibration of the comparative hematology ana-lyzer (MH-K_2EDTA or MH-K_3EDTA). Since most clinical hematology analyzers are calibrated by the microhematocrit method using K_3EDTA anticoagulant, the i-STAT Alinity System default customization is K_3EDTA. Select either: **K2EDTA** **K3EDTA** The default is K3EDTA.
Apply CPB Protein Algorithm to Hematocrit	The Apply CPB option is intended for use when samples are collected from patients on cardiopulmonary bypass. The CPB function adjusts hematocrit and hemoglobin results for the dilutional effect of pump fluid during cardiopulmonary bypass surgery. However, the facility may validate its use for other patient populations known to have protein levels significantly lower than the normal adult population. **Note:** If an instrument customized as “CPB, always apply” is used for patients who are not on the pump, it is possible that the hematocrit results will be reported falsely high. If an instrument customized as “CPB, never apply” is used for patients who are on the pump or have decreased levels of protein, the hematocrit results maybe reported falsely low. An instrument that is customized to prompt for CPB requires the operator to answer Yes or No. Yes indicates that the CPB correction should be applied. No indicates that the CPB correction should not be applied. Select one of the following:
	CPB, Prompt Prompts the operator to apply CPB correction when the cartridge has a hematocrit sensor.
	CPB, always apply Apply CPB correction every time a cartridge with a hematocrit sensor is used.
	CPB, never apply Do not apply CPB correction when running a cartridge with a hematocrit sensor.

When finished, choose from the options shown at the bottom of the screen:

- **Previous** to go back to the previous screen
- **Discard** to undo changes
- **Finish Later** to create a draft
- **Next** to open the next tab

Adjustments

The settings for result displays of base excess and eGFR (Estimated Glomerular Filtration Rate) are determined in this tab.

BE Equation	Base excess of the extracellular fluid or standard base excess is the concentration of titratable base minus the concentration of titratable acid when titrating the average intracellular fluid (plasma plus interstitial fluid) to an arterial plasma pH of 7.40 at PCO_2 of 40 mmHg at 37°C. Excess concentration of base in the average ECF remains virtually constant during acute changes in the PCO_2 and reflects only nonrespiratory component of pH disturbances. Select either option:
	Extra Cellular Fluid Base Excess of Extracellular Fluid (BEecf) $BEecf = HCO_3 - 24.8 + 16.2\ (pH - 7.4)$ This is the default.
	Blood Base Excess of Blood (BEb) $BEb = (1 - 0.014*Hb) * [HCO_3 - 24.8 + (1.43 * Hb + 7.7) * (pH - 7.4)]$
eGFR Equation	**MDRD (default)**
	CKD-EPI 2009
eGFR Variants	Select one of these options:
	Display both eGFR and Black/African American eGFR
	Display only eGFR
	Display only Black/African American eGFR **Note:** Black/African American eGFR displays as eGFR-a on the instrument screen.

When finished, choose from the options shown at the bottom of the screen:

- **Previous** to go back to the previous screen
- **Discard** to undo changes
- **Finish Later** to create a draft
- **Next** to open the next tab

ACT (Activated Clotting Time)

This screen allows you to customize the setting for ACT testing with Kaolin activator. You can select between the current 37° (Pre-warm) result calibration and an ambient temperature (Non-warm) result calibration.

Options on the screen are:

ACTk Mode	For ACT-K (Kaolin ACT) cartridges, select either:
	Pre-warm 37°C result calibration applies to patient test pathway only pre-warm is the default
	Non-warm ambient temperature result calibration
Stop ACT Test	Determines whether an operator can stop an ACT test while it is being performed. Select the check box to enable stopping a test. This is the default. Unselect the check box to prevent an operator from stopping a test.

When finished, choose from the options shown at the bottom of the screen:

- **Previous** to go back to the previous screen
- **Discard** to undo changes
- **Finish Later** to create a draft
- **Next** to open the next tab

Critical Tests

Critical tests can be selected by the customer.

When finished, choose from the options shown at the bottom of the screen:

- **Previous** to go back to the previous screen
- **Discard** to undo changes
- **Finish Later** to create a draft
- **Next** to open the next tab

Summary

The Summary is a collapsed view of the settings that can be expanded to provide a complete display. The Summary should be reviewed prior to Publish. Once the settings are confirmed, click on the Publish button to finalize them. A Category can be added to a Profile only when the publish status is completed.

When finished, choose from the options shown at the bottom of the screen:

- **Previous** to go back to the previous screen
- **Discard** to undo changes
- **Finish Later** to create a draft
- **Publish** to make settings available to use in a Profile

*Quality Settings Category

This section contains features to customize the quality settings for the i-STAT Alinity, such as liquid QC pass/fail determination, Cal Ver pass/fail determination, and cartridge lot QC. The Quality Settings category can be created or modified with the following steps.

Click **Quality Settings**, then select `APOCQualitySettings` and click **View**. The screen displays the default name `APOCQualitySettings`, and default values for each feature. Scan through the `APOCQualitySettings` and determine if the selections work for the profile being assembled. If they do then no additional work is needed in this category. The `APOCQualitySettings` category will be available in the **Manage Profiles** section. Use it to assemble the new profile. If the `APOCQualitySettings` do not work for the profile being assembled, click **Finish** to stop viewing. Click **Create** and follow the instructions below.

Note: All required categories have a default setting named with the APOC prefix. In addition, the settings are populated with default values.

You are prompted to specify a name for the settings and an optional description:

Quality Settings

Name	Required. Specify a name that is from 4 to 40 characters long and: • consists only of the following characters: ○ 0 through 9 ○A through Z or alphabet appropriate for language (in upper or lower case) ○blank space ○underscore (_) • does not begin with the characters APOC (in upper or lower case) • is a unique name within this healthcare organization
Description	Optional. Provide any information that helps the user know how or why the category was named or created.

When finished, choose from the actions shown at the bottom of the screen:

- **Discard** to undo changes
- **Next** to open the next tab

Electronic Simulator

Testing for the external Electronic Simulator can be scheduled to be performed based on an interval of a number of days. This setting is usually determined by compliance with regulatory agencies.

Note: Internal Electronic Simulator testing is performed every time a cartridge is tested on the i-STAT Alinity.

Simulator Testing Schedule	
Run Electronic Simulator every *n* days	Determines how frequently the external electronic simulator is tested. Specify a number of days in the range 0 - 365. The default is 0, which turns off testing. **Note:** Abbott Point of Care manufacturer's requirement is for the electronic simulator to be tested every 6 months (182 days).

When finished, choose from the options shown at the bottom of the screen:

- **Previous** to go back to the previous screen
- **Discard** to undo changes
- **Finish Later** to create a draft
- **Next** to open the next tab

QC Notifications

Control Test Settings		
	Use the control test settings to determine the i-STAT Alinity response or behavior when quality control testing is performed. These settings may aid in accomplishing regulatory compliance, and ease of use for the operator.	
Pass/Fail Determination	Describes the method used to determine the acceptability of liquid QC results. Select one of these options:	
	None	QC Pass/Fail determination is not applied.
	Auto via eVAS	Automatically determine if the results of a liquid QC test passed or failed, based on QC ranges from an electronic Value Assignment Sheet (eVAS or ReVAS) file downloaded to the instrument. It is recommended that the instruments are wirelessly connected to the CWi for automatic eVAS updates. If the instruments are not connected to CWi, the eVAS must be loaded onto each instrument using the USB port on the Base Station.
	Manual	The operator manually compares the liquid QC results to a Value Assignment Sheet downloaded or printed from the Support area of the Abbott Point of Care website at: www.globalpointofcare.abbott and indicates on the instrument whether the QC test passed or failed.
Results Display Format	Determines whether Quality Control results displayed on the instrument are either:	
	Numeric	Display Liquid QC results in numeric format.
	Suppressed	The following symbol <> is displayed next to each Liquid QC test name in place of the quantitative (numeric) results. Do not select this option if manual pass/fail determination is selected.

Fluid Settings	
Only allow APOC fluids	Unselect the check box if non-APOC control fluids are used.

Cartridge Help	
Display Insert Cartridge Help	Graphics displayed on the instrument screen after all required fields are complete but before the cartridge is inserted. The cartridge help screens include the 'collect and mix sample' and 'fill cartridge' graphics.

Control Test Out of Range Settings (Manual Pass/Fail Determination Only)	
	These settings determine the operator action when Liquid Quality Control results are outside of the acceptable range and Pass/Fail Determination is set to Manual.

Comments		
Comment Code	**Enable**	Select this check box to prompt the operator to enter a comment code when results are out of range. Choose one of the following options:
		Optional Prompt the operator for an optional entry.
		Mandatory Prompt the operator for a mandatory entry. Cartridge testing cannot continue until information is entered.
Comment Style	Determines how comments are displayed on the instrument when a Liquid Quality Control result is out of acceptable range. Choose either of these options:	
	Comment List	Comments must be chosen from a selection list. See below for creating comments that will display.
	Comment List with Text Box	Operator will be prompted to choose a comment or to type a comment into the text box provided. It is a one or the other selection by the operator. A maximum of 6 comments can be displayed with a text box.
Comments	A list of comments created by the CWi user. Operator selects the most appropriate. The comment will be attached to the test record. Each comment can be 20 characters in length including spaces.	

Cal Ver Test Settings

Calibration Verification (Cal Ver) test settings can assist the operator and support compliance with regulatory agencies.

Cal Ver Test Settings		
Pass/Fail Determination	Describes the method used to determine the acceptability of Cal Ver results. Select one of these options:	
	None	Cal Ver Pass/Fail determination is not applied.
	Auto via eVAS	Automatically determine if the results of a Cal Ver test passed or failed, based on Cal Ver ranges from an electronic Value Assignment Sheet (eVAS or ReVAS) file downloaded to the instrument. It is recommended that the instruments are wirelessly connected to the CWi for automatic eVAS updates. If the instruments are not connected to CWi, the eVAS must be loaded onto each instrument using the USB port on the Base Station.
	Manual	The operator manually compares the Cal Ver results to a Value Assignment Sheet downloaded or printed from the Support area of the Abbott Point of Care website at: www.globalpointofcare.abbott and indicates on the instrument whether the Cal Ver test passed or failed.
Results Display Format	Determines whether the Cal Ver results displayed on the instrument are either:	
	Numeric	Cal Ver results are displayed in numeric format.
	Suppressed	The following symbol <> is displayed next to each Cal Ver test name in place of the quantitative (numeric) results. Do not select this option if manual pass/fail determination is selected.
Fluid Settings		
Only Allow APOC fluids	Unselect the check bo x if non-APOC Cal Ver fluids will be used.	
Cartridge Help		
Display Insert Cartridge Help	Graphics displayed on the instrument screen after all required fields are complete but before the cartridge is inserted. The cartridge help screens include the ‘collect and mix sample’ and ‘fill cartridge’ graphics.	

Cal Ver Test Out of Range Settings (Manual Pass/Fail Determination Only)		
	The settings in this section determine the operator action when a Cal Ver result falls outside of the acceptable range and Pass/Fail Determination is set to Manual.	
Comment Code		
Enable	Select this check box to prompt the operator to enter a comment code when results are out of range. If you select this check box to enable prompting, choose one of the following options:	
	Optional	Operator is prompted to enter an optional comment code.
	Mandatory	Operator is prompted to enter a mandatory comment code.
Comment Style	Determines whether comments must be chosen from a selection list or can be entered as text. Choose either of these options:	
	Comment List	Comments can only be chosen from the selection list.
	Comment List with text-box	Operator will be prompted to choose a comment or to type a comment into the text box provided. It is a one or the other selection by the operator. A maximum of 6 comments can be displayed with a text box.
	Comments	A list of comments created by the CWi user. Operator selects the most appropriate. The comment will be attached to the test record. Each comment can be 20 characters in length including spaces.
eVAS Type	The file type uploaded onto the i-STAT Alinity for the use of the Pass/Fail Determination feature. Select either:	
	eVAS	Select for all countries except Germany.
	ReVAS	Select only if you are in Germany.

Cartridge Lot QC Settings		
	User-defined cartridge QC settings to aid in compliance with regulatory agency requirements or recommendations. Do not select the options below if the data management system in use does not support cartridge lot QC. The data management system must be able to accept cartridge lot numbers and change the status so that cartridges are available for use.	
Search Cartridge List for Cartridge Lot Number		
Enable	Select this check box to search for the lot number in a list of cartridges in use or ready for use.	
	Lot Number not on List -- QC Tests	Determine the action to be taken if the lot number is not on the list:
		Warn Display a warning to the operator and allow the test to be run in the QC test pathway only. Patient and proficiency testing is disabled until the cartridge lot number is available in the cartridge list.
		Lockout Do not allow the test to be run until the lot number has been added to the list of cartridges.

Cartridge QC Warning Screen		
Enable Cartridge QC Warning Screen	Select this check box to display a warning screen on the instrument when the i-STAT cartridge QC is due. If you select this feature, the following option is available:	
	Show warning *n* days in advance	Specify the number of days in advance of the QC deadline when the warning message will be displayed. Allowable values range from 1 through 365. The default is 1.

When finished, choose from the options shown at the bottom of the screen:

- **Previous** to go back to the previous screen
- **Discard** to undo changes
- **Finish Later** to create a draft
- **Next** to open the next tab

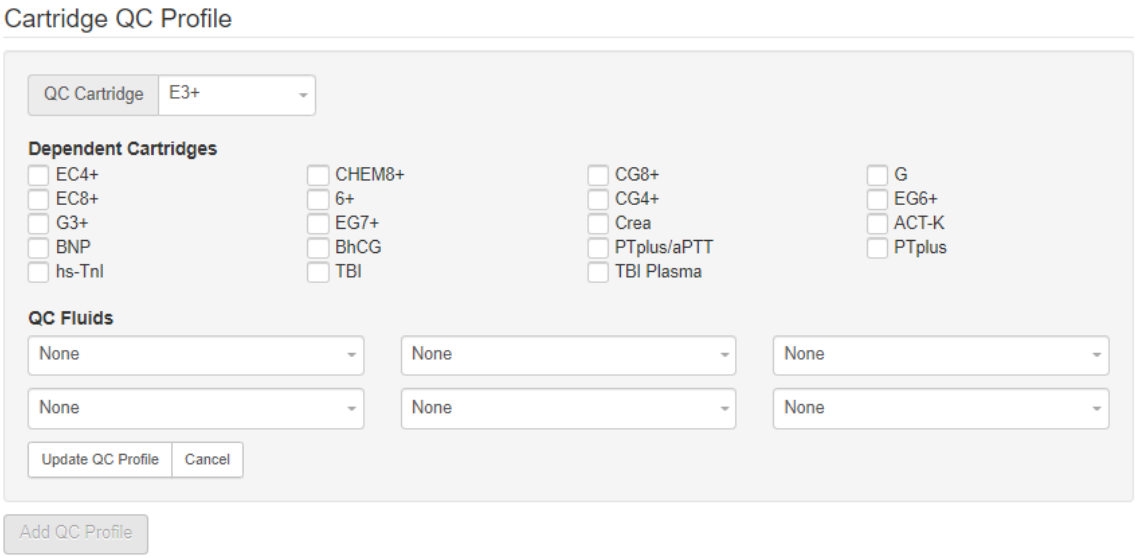
Liquid QC (Quality Control) Schedules

This feature is used to define a liquid quality control (QC) plan for the i-STAT Alinity instruments. A customized QC testing schedule can include: the cartridge types and liquid QC fluids to be used, the cartridge types that are enabled by running the liquid QC, and the schedule for performing liquid QC. Up to 3 liquid quality control schedules can be defined. The options for liquid QC schedules are shown here once, since the options are identical for all three.

Note: Not all products are available in all regions. Check with your local representative for availability in specific markets.

Frequency	Select one of the following:	
	Off	This is the default.
	Daily	Run liquid QC every day.
	Every_____	Blank is filled in with a day of the week selection from the drop down list.
	Every_____ _____ ofeach month	The first blank is filled in with first, second, third, fourth or last chosen from drop down list. The second blank is filled in with day of the week chosen from the drop down list. Example - Every 2nd Thursday of the month.
	Every *n* days starting on *mmddyy*	Schedule liquid QC to run according to a time interval and a start date. The time interval is a number of days in the range 1 to 99. Select the start date from the pop-up calendar.
	Time	This option is enabled only when a value other than Off has been specified for Frequency.
	Testing due at *HH:mm*	Time of day when liquid QC testing is due to be done. Specify a value for hours and minutes in the range 00:00 to 23:59. Default is 00:00 (midnight).
	Grace period	Additional amount of time allowed before and after testing due time to perform liquid QC testing if testing is not done at the scheduled time. After this amount of time elapses, patient testing is disabled. Grace period also determines when the alert message for scheduled QC will display on the instrument.
		***n* hours** Number of hours. 8 hours is default. Range is 0 to 255.
	Apply Schedule to	Select which months to perform testing. Any or all months of the year can be selected.
	Cartridge QC Profile	If Frequency is specified, define at least one Cartridge QC Profile.

	Add QC Profile	Click **Add QC Profile**. This panel displays:



QC Cartridge	Click the arrow to display a drop down list of cartridges. From the list, select the cartridge for this profile. This is the parent cartridge.

Dependent Cartridges	When more than one type of cartridge can test for the same analyte, one cartridge can be the dependent of the other. When testing is performed, the result for an analyte common to both cartridges then applies to both the cartridge that was tested as well as its dependent. For example, a CHEM8+ cartridge tests for creatinine. A Crea cartridge also tests for creatinine. If CHEM8+ is selected from the drop down list titled "QC Cartridge", then a Crea cartridge can be selected as its dependent. The CHEM8+ is the parent and the Crea is the dependent. When QC testing is done for the CHEM8+ cartridge and the result is a 'pass' for creatinine, then the Crea cartridge is also considered as having passed the test for creatinine. Option to select one or more cartridges as dependents. Choose a dependent by selecting the check box next to the cartridge name. **Note:** All analytes used within the facility should be included in liquid QC and Cal Ver testing schedules. **Note:** A QC cartridge that is selected as a parent cartridge in one Cartridge QC Profile cannot be a dependent cartridge in another Cartridge QC Profile within the same schedule. It can be a dependent cartridge in a Cartridge QC Profile belonging to a different schedule.

Measured Cartridges and Analytes

	CHEM8+	EC8+	Crea	G	CG8+	EG7+	EGC+	CG4+	G3+	ACT-K	TBI Plasma	TBI	hs-TnI
Sodium (Na)	X	X			X	X	X						
Potassium (K)	X	X			X	X	X						
Chloride (Cl)	X	X											
Ionized Calcium (iCa)	X				X	X							
Glucose (Glu)	X	X		X	X								
Urea Nitrogen (BUN)/Urea	X	X											
Creatinine	X		X										
TCO2	X												
Hematocrit	X	X			X	X	X						
Lactate								X					
pH					X	X	X	X	X				
PCO2					X	X	X	X	X				
PO2					X	X	X	X	X				
ACT										X			
GFAP											X	X	
UCH-Ll											X	X	
hs-Tnl													X

QC Fluids	Select up to 6 different fluids in 1 QC schedule. Selections must not be duplicated. **Note:** Only APOC controls will work with Auto Pass/Fail Determination with eVAS. After fluids have been selected, click **Update QC Profile**.

When finished, choose from the options shown at the bottom of the screen:

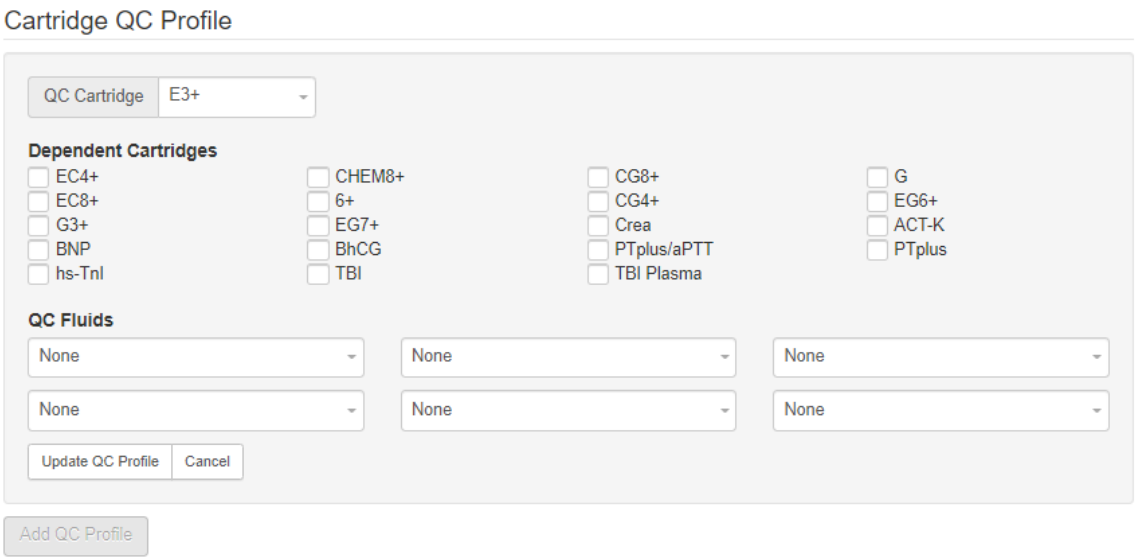
- **Previous** to go back to the previous screen
- **Discard** to undo changes
- **Finish Later** to create a draft
- **Next** to open the next tab

Cal Ver Schedules

This feature is used to define a Cal Ver testing schedule for the i-STAT Alinity instruments. A customized Cal Ver testing schedule can include: the cartridge types and Cal Ver fluids to be used, the cartridge types that are enabled by running the Cal Ver fluids, and the schedule for performing Cal Ver testing. Up to 3 Cal Ver testing schedules can be defined. The options for schedules are shown here once, since the options are identical for all three.

Note: Not all products are available in all regions. Check with your local representative for availability in specific markets.

Frequency	Select one of the following:	
	Off	This is the default.
	Every_____ _____ ofeach month	The first blank is filled in with first, second, third, fourth or last chosen from drop down list. The second blank is filled in with day of the week chosen from the drop down list. Example - Every 2nd Thursday of the month.
	Time	This option is enabled only when a value other than Off has been specified for Frequency.
	Testing due at *HH:mm*	Time of day when Cal Ver is due to be done. Specify a value for hours and minutes in the range 00:00 to 23:59. Default is 00:00 (midnight).
	Grace period	Additional amount of time allowed before and after testing due time to perform Cal Ver testing if testing is not done at the scheduled time. After this amount of time elapses, patient testing is disabled. Grace period also determines when the alert message for scheduled Cal Ver will display on the instrument.
		***n* hours** Number of hours. 8 hours is default. Range is 0 to 255.
	Apply Schedule to	Select which months to perform testing. Any or all months of the year can be selected.
	Cartridge QC Profile	If Frequency is specified, define at least one Cartridge QC Profile.
	Add QC Profile	Click **Add QC Profile**. This panel displays:



QC Cartridge	Click the arrow to display a drop down list of cartridges. From the list, select the cartridge for this profile. This is the parent cartridge.

Dependent Cartridges	When more than one type of cartridge can test for the same analyte, one cartridge can be the dependent of the other. When testing is performed, the result for an analyte common to both cartridges then applies to both the cartridge that was tested as well as its dependent. For example, a CHEM8+ cartridge tests for creatinine. A Crea cartridge also tests for creatinine. If CHEM8+ is selected from the drop down list titled “QC Cartridge”, then a Crea cartridge can be selected as its dependent. The CHEM8+ is the parent and the Crea is the dependent. When QC testing is done for the CHEM8+ cartridge and the result is a ‘pass’ for creatinine, then the Crea cartridge is also considered as having passed the test for creatinine. Option to select one or more cartridges as dependents. Choose a dependent by selecting the check box next to the cartridge name. **Note:** All analytes used within the facility should be included in liquid QC and Cal Ver testing schedules. **Note:** A QC cartridge that is selected as a parent cartridge in one Cartridge QC Profile cannot be a dependent cartridge in another Cartridge QC Profile within the same schedule. It can be a dependent cartridge in a Cartridge QC Profile belonging to a different schedule.

QC Fluids	Select up to 6 different fluids in 1 QC schedule. Selections must not be duplicated. After fluids have been selected, click **Update QC Profile**.

When finished, choose from the options shown at the bottom of the screen:

- **Previous** to go back to the previous screen
- **Discard** to undo changes
- **Finish Later** to create a draft
- **Next** to open the next tab

Summary

The Summary is a collapsed view of the settings that can be expanded to provide a complete display. The Summary should be reviewed prior to Publish. Once the settings are confirmed, click on the Publish button to finalize them. A Category can be added to a Profile only when the publish status is completed.

When finished, choose from the options shown at the bottom of the screen:

- **Previous** to go back to the previous screen
- **Discard** to undo changes
- **Finish Later** to create a draft
- **Publish** to make settings available to use in a Profile

User Defined Message Category

This category enables creation of a user-defined message that will display on the i-STAT Alinity instrument prior to cartridge insertion in testing pathways. This category is optional.

To create new user-defined messages, click on **Create**. The screen displays the default name `TemporaryName`. Change the name, using the specifications shown below:

User Defined Message

Name	Required. Specify a name that is from 4 to 40 characters long and: • consists only of the following characters: ○ 0 through 9 ○A through Z or alphabet appropriate for language (in upper or lower case) ○blank space ○underscore (_) • does not begin with the characters APOC (in upper or lower case) • is a unique name within this healthcare organization
Description	Optional. Provide any information that helps the user know how or why the category was named or created.

When finished, choose from the options shown at the bottom of the screen:

- **Discard** to undo changes
- **Next** to open the next tab

User Defined Message	The screen for entry of the user-defined message content displays. A maximum of 40 characters per line, and a maximum of 10 lines can be specified.

After entering the user-defined message, choose from the options shown at the bottom of the screen:

- **Previous** to go back to the screen displayed previous to this screen
- **Discard** to undo changes
- **Finish Later** to create a draft
- **Next** to open the next tab

Summary

The Summary is a collapsed view of the settings that can be expanded to provide a complete display. The Summary should be reviewed prior to **Publish**. Once the settings are confirmed, click on the **Publish** button to finalize them. A **Category** can be added to a Profile only when the publish status is completed.

When finished, choose from the options shown at the bottom of the screen:

- **Previous** to go back to the previous screen
- **Discard** to undo changes
- **Finish Later** to create a draft
- **Publish** to make settings available to use in a Profile

Training Settings Category

In the Training Settings Category you can create user-defined training scenarios, to provide a consistent learning experience for all operators. Every operator will view the same patient information and results, created in the training scenarios. This will provide standardized training material for the individual overseeing point of care testing.

To create new category settings, click on Create. The screen displays the default name, TemporaryName. Change the name, using the specifications shown below:

Training Settings

Name	Required. Specify a name that is from 4 to 40 characters long and: • consists only of the following characters: ○ 0 through 9 ○A through Z or alphabet appropriate for language (in upper or lower case) ○ blank space ○underscore (_) • does not begin with the characters APOC (in upper or lower case) • is a unique name within this healthcare organization
Description	Optional. Provide any information that helps the user know how or why the category was named or created.

When finished, choose from the options shown at the bottom of the screen:

- **Discard** to undo changes
- **Next** to open the next tab

Basic Functions

Options on this tab control access to training mode and provide a workspace to create training scenarios.

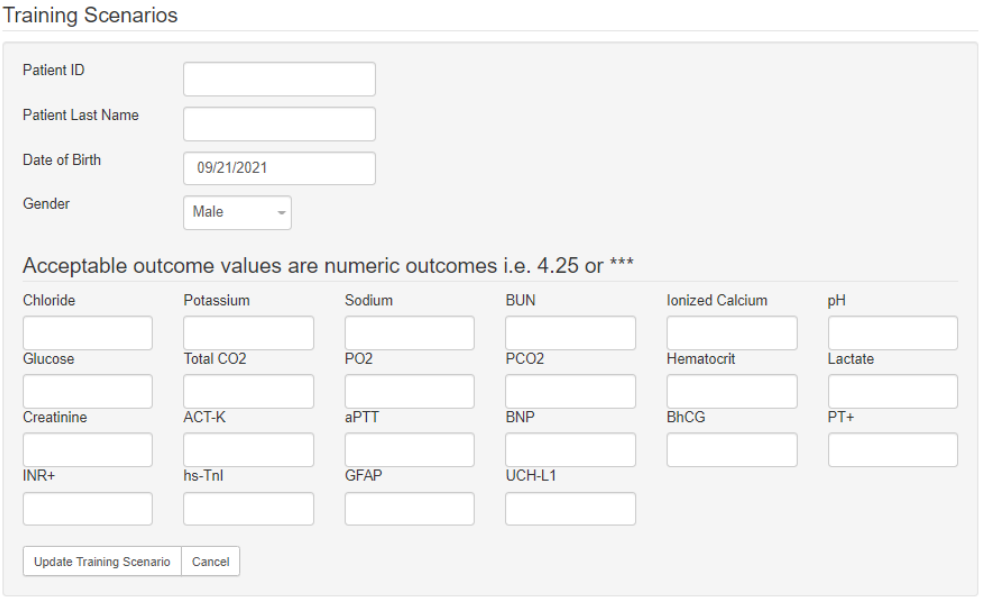
Training Mode		
Allow Instrument to Enter Training Mode	To deny access to the training path, unselect the check box. If access to the training path is enabled, choose one of these options:	
	Require permissions	This is the default.
	No permissions required	Select to allow access to the training path regardless of permissions.

Training Pathway Cartridges	
Allow Expired Cartridges in Training Pathway	Select this check box to allow expired cartridges to be used in the training path.

Operator Direct Observation Checklist	
Edit Observation Checklist	Select this option to create a checklist of items to display on the i-STAT Alinity instrument. Observation checklist is intended to be used as a location on the instrument where a super user (trainer) and an operator can see a comprehensive list of the skills needed to remain competent. The super user (trainer) observes the operator performing the skills and communicates to the POCC (administrator) that the operator successfully completed the list. A text box displays and up to 40 characters can be entered. To save, click **Add Observation**. This will display another text box for an additional item. When all items have been entered, specify an identifier for the revision in the **Checklist Revision** text box.
Update Observation Checklist	Select this option after all the checklist items have been created and a **Checklist Revision** value was supplied. The checklist items and checklist revision information will display.

Training Scenarios	
Add Training Scenario	Select this option to open a workspace to create training scenarios. Be aware of the following: • For the patient information to be displayed on the i-STAT Alinity instrument, the **PPID** feature in **Patient Settings** must be enabled. • For analyte values to display as critical, abnormal, or normal values, reference and action ranges or cutoffs in **Analyte Settings** are required.

On the screen that displays, enter values for the scenario you are creating.



When all information has been entered, click **Update Training Scenario**. The scenario that was created displays on a screen similar to the one shown here:

You can select:

- **Edit Training Scenario** to make changes
- **Delete Training Scenario** to discard
- **Add Training Scenario** to create another scenario

When finished, choose from the options shown at the bottom of the screen:

- **Previous** to go back to the previous screen
- **Discard** to undo changes
- **Finish Later** to create a draft
- **Next** to open the next tab

Summary

The Summary is a collapsed view of the settings that can be expanded to provide a complete display. The Summary should be reviewed prior to **Publish**. Once the settings are confirmed, click on the **Publish** button to finalize them. A **Category** can be added to a Profile only when the publish status is completed.

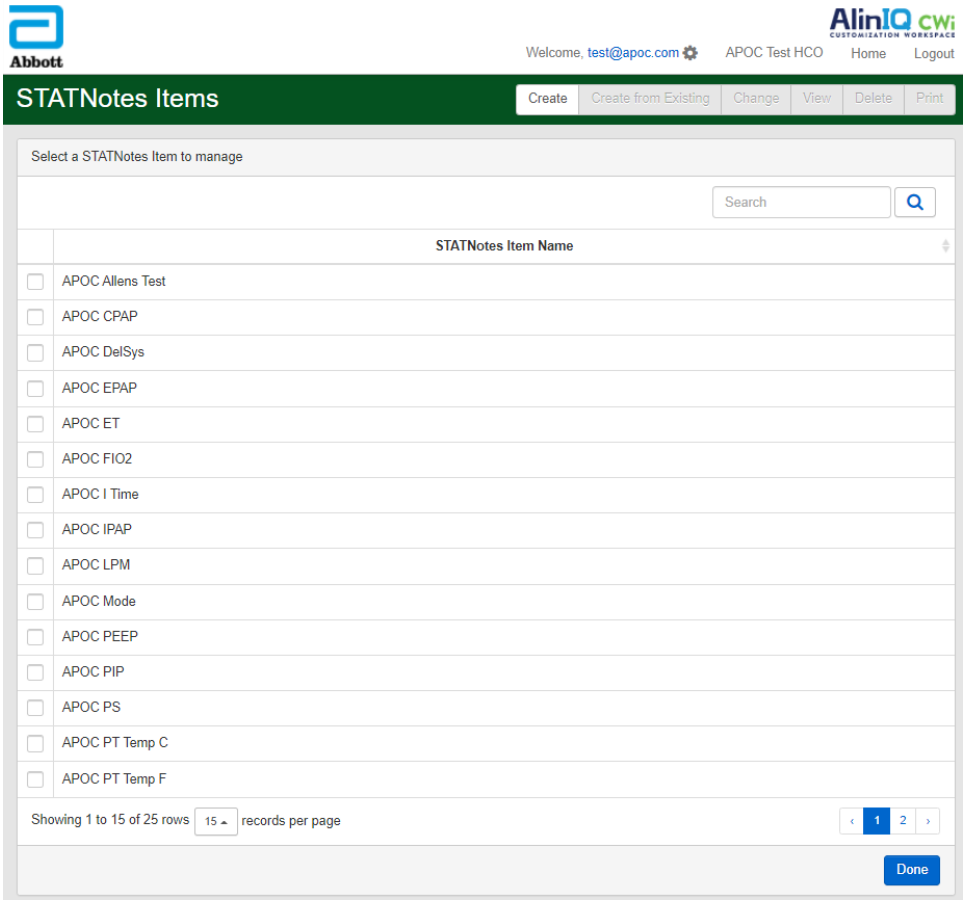
When finished, choose from the options shown at the bottom of the screen:

- **Previous** to go back to the previous screen
- **Discard** to undo changes
- **Finish Later** to create a draft
- **Publish** to make settings available to use in a Profile

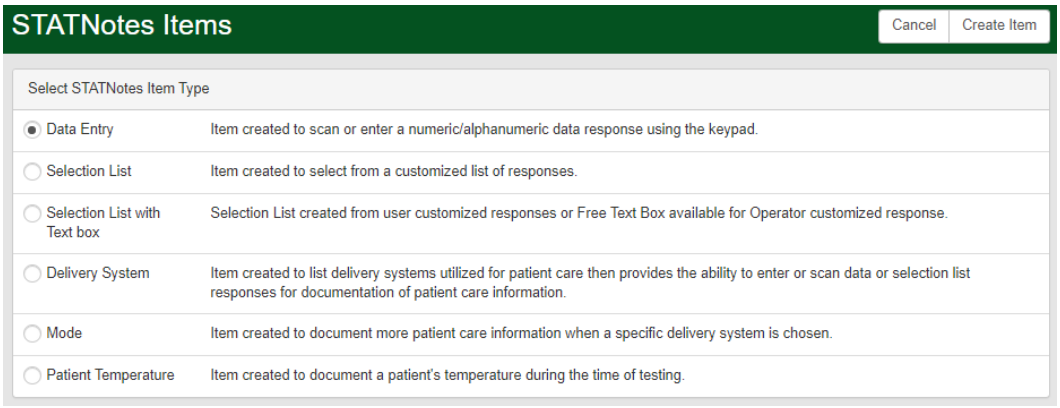
STATNotes Category

STATNotes are used to obtain relevant patient information, such as respiratory parameters, at the time of a test. Much like profiles that are built with categories, STATNotes are built using sets. Additionally, sets are built with items. Items are what the operator sees on the instrument. Items require responses. Items are assigned to a set. This is performed in the Manage Set section. Continue through the process until the set is published. Once a set is published it is available for assigning to a cartridge type when building a STATNote. The information below will explain the process in detail.

Items listed with names that begin with “APOC” are predefined. Details of each APOC predefined item can be viewed by clicking on the item and then clicking on **View**. If the predefined item satisfies the needs of the customer, no further action is required and the item is ready to be added to a set. If changes to the APOC predefined item are required, follow the instructions for **Create from Existing** in the General Settings section of this document.

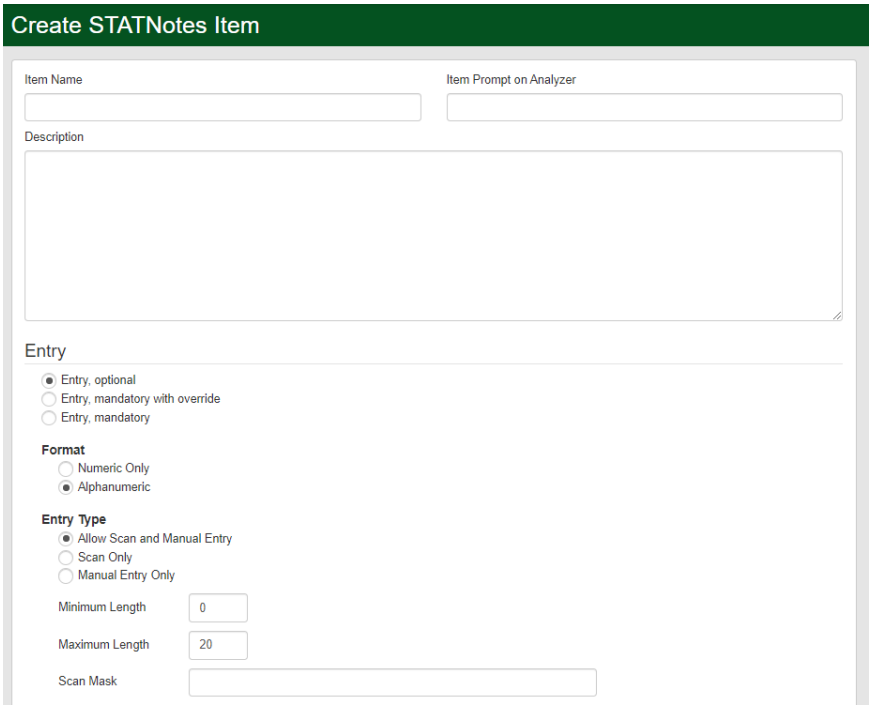


Begin building an item. Click on **Manage and Assemble Profiles** > **STATNotes** > **Manage Items** > **Create**. The following item types are available: Data Entry, Selection List, Selection List with text box, Delivery System, Mode and Patient Temperature. Each of these choices is detailed below.


STATNotes Items
Cancel
Create Item
Select STATNotes Item Type
Data Entry
Item created to scan or enter a numeric/alphanumeric data response using the keypad.
Selection List
Item created to select from a customized list of responses.
Selection List with Text box
Selection List created from user customized responses or Free Text Box available for Operator customized response.
Delivery System
Item created to list delivery systems utilized for patient care then provides the ability to enter or scan data or selection list responses for documentation of patient care information.
Mode
Item created to document more patient care information when a specific delivery system is chosen.
Patient Temperature
Item created to document a patient's temperature during the time of testing.

Data Entry

This section describes creating a Data Entry item that will prompt the operator to supply information, either using the keypad or by scanning.



On this screen, define the following:

Item Name	Required. Specify a name that is from 1 to 20 characters long and: • does not begin with the characters APOC (in upper or lower case) • is a unique name within this healthcare organization.	
Item Prompt on Analyzer	Required. Specify a prompt that is from 1 to 20 characters long and: • does not begin with the characters APOC (in upper or lower case) • is a unique name within this healthcare organization.	
Description	Optional.	
Entry	Select one of the following:	
	Entry, optional	Prompt the operator for an optional entry.
	Entry, mandatory with override	Prompt the operator for a mandatory entry. If the override feature is chosen by the operator no further action is required and the instrument will advance to the next screen.
	Entry, mandatory	Prompt the operator for a mandatory entry. Cartridge testing cannot continue until information is entered.

Format	Determine the format used to enter data. Select either:	
	Numeric Only	Data will be entered only as numbers.
	Alphanumeric	Data will be entered as either letters or numbers.

Entry Type	Determine how the data will be entered into the i-STAT Alinity instrument. Select one of the following:	
	Allow Scan and Manual Entry	Allow barcode scan or manual data entry.
	Scan Only	Allow barcode scan data entry only.
	Manual Entry Only	Allow manual data entry only.
	Minimum Length	Enter the minimum data characters allowed.
	Maximum Length	Enter the maximum data characters allowed.
Scan Mask	Barcode scanning setting that allows for the selection of specific character positions to be retained. • The first position (the position farthest to the left) is numbered position “1”. • The scanmask field will accept a text input consisting of numbers 1-9, commas (‘,’), and hyphens (‘-’) to identify the scanmask selection. • If, for example, the barcode reads “abcdefghi1234567890” and the selection pattern is “2,5-8,11-14” then the barcode will be interpreted as “befgh2345”. If the selection pattern is “3-4”, then the barcode will be “cd”. • Individual position selections that are separated by a comma such as “2,4,7,8,19” cannot be duplicated. • In each number range, the starting number must be smaller than the ending number. For example, “3-5” is a valid range, but “5-3” is not. • Selection ranges cannot overlap. The end of each number range must be smaller than the beginning of the next number range. For example, “3-6,7-9” is a valid selection, but “3-6,6-9” is not. • Entering consecutive commas or hyphens is invalid. For example, “2--5”, “2-5,,7-10”, and “2,-5” are all invalid ranges.	

Manual Check Digit Method	If a facility uses a supported check digit algorithm when creating operator orpatient IDs, the i-STAT Alinity can verify the entered ID format by calculating the check digit and comparing it to the entered ID number. If the check digits do not match, the ID is rejected.  **Note:** The i-STAT Alinity System supports the Mod 10 and Mod 11 check digit algorithms described in the HL7 Table 0061 (Check Digit Scheme) in the HL7 Specification (Rev 1.4). Contact your LIS/HIS or IT departments to determine if your facility uses check digits in the creation of operator and/or patient ID numbers, and if so, which algorithm is used. Allowable values are:	
	No check digit on manual entry	Do not use a check digit when creating operator or patient IDs.

	Mod 11 check digit on manual entry	Use the Mod 11 algorithm when creating operator or patient IDs.
	Mod 10 check digit on manual entry	Use the Mod 10 algorithm when creating operator or patient IDs.

Scan Entry Check Digit Method	Whether to use a check digit when scanning a value to create an operator or patient ID.	
	No check digit on scan entry	Do not use a check digit when creating operator or patient IDs.
	Mod 11 check digit on scanen-try	Use the Mod 11 algorithm when creating operator or patient IDs.
	Mod 10 check digit on scanen-try	Use the Mod 10 algorithm when creating operator or patient IDs.

Barcode Type	Select all that apply.

When the specifications for this item are complete, in the lower right corner of the screen:

- Click **Publish** to complete the item so it will appear on the Manage Items list
- Click **Discard** to delete the item

Selection List

Use Selection List to create a list of items that the operator can select from.

Item Name	Required. Specify a name that is from 1 to 20 characters long and: • does not begin with the characters APOC (in upper or lower case) • is a unique name within this healthcare organization.

Item Prompt on Analyzer	Required. Specify a prompt that is from 1 to 20 characters long and: • does not begin with the characters APOC (in upper or lower case) • is a unique name within this healthcare organization.

Description	Optional.

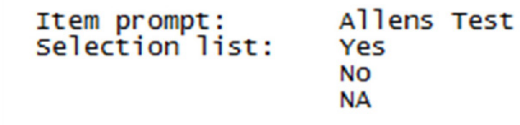
Entry Prompt	Select one of the following:
	Entry, optional Prompt the operator for an optional entry.
	Entry, mandatory with override Prompt the operator for a mandatory entry. If the override feature is chosen by the operator no further action is required and the instrument will advance to the next screen.
	Entry, mandatory Prompt the operator for a mandatory entry. Cartridge testing cannot continue until information is entered.

Each item for the selection list is defined next.

Click **Edit Selection List**. A text box displays.

Enter up to 20 characters in the text box. This will be the first item in the selection list.
To create additional items, click **Add Item.**

Example of selection list item displayed on the i-STAT Alinity:



The operator is prompted to choose one of the selection list responses.

After all selection list items have been created, click **Update Selection List** or **Cancel**.

- Click **Publish** to complete the item so it will appear on the Manage Items list
- Click **Discard** to delete the item

Selection List with Text box

This is nearly identical to the Selection List item with one important difference. With a Selection List item, the operator can choose from a list of items. In a Selection List with text box, the operator can choose from a list of items or type a customized response into a text box.

Item Name	Required. Specify a name that is from 1 to 20 characters long and: • does not begin with the characters APOC (in upper or lower case) • is a unique name within this healthcare organization.

Item Prompt on Analyzer	Required. Specify a prompt that is from 1 to 20 characters long and: • does not begin with the characters APOC (in upper or lower case) • is a unique name within this healthcare organization.

Description	Optional.

Entry Prompt	Select one of the following:
	Entry, optional Prompt the operator for an optional entry.
	Entry, mandatory with override Prompt the operator for a mandatory entry. If the override feature is chosen by the operator no further action is required and the instrument will advance to the next screen.
	Entry, mandatory Prompt the operator for a mandatory entry. Cartridge testing cannot continue until information is entered.

Each item for the selection list is defined next.

Click **Edit Selection List**. A text box displays.

Enter up to 20 characters in the text box. This will be the first item in the selection list.
To create additional items, click **Add Item**.

After all selection list items have been created, click **Update Selection List** or **Cancel**.

- Click **Publish** to complete the item so it will appear on the Manage Items list
- Click **Discard** to delete the item

Mode

Use the Mode item to document more detailed patient care information when a specific delivery system is chosen. “Mode” refers to ventilator modes. There are many different ventilator modes. Each mode has different settings. Each setting is created as a STATNote item. See the Table below for examples.

Note: All STATNotes items must be available before a Mode item can be created.

Example, the table below shows the various ventilator modes and the corresponding STATNotes items.

Table 3–2: Modes (Examples Only)

Mode	STATNotes Items
A/C	Set Rate Vt FIO2 PEEP PS Heliox
CMV	Set Rate Vt FIO2 PEEP PS Heliox N
CPAP	Vt PIP FIO2 PEEP PS iNO Heliox N
HFOV	HZ AMP Delta P Bias Flow FIO2

Mode	STATNotes Items
NIV	Set Rate Vt FIO2 PEEP PS

In the table above, A/C mode requires 6 STATNotes items. To check whether these STATNotes items exist: Click **Manage and Assemble Profiles** > **STATNotes** > **Manage Items**.

The screen displays all existing items.

If all of the STATNotes items needed for mode A/C are included in the list, this means that the A/C Mode item can be built. It is also important to note, when checking the STATNotes list for an item, the item may exist under the "APOC" name. For example, if you are searching the list for the **Set Rate** item, it may be listed as **APOC set rate**.

If any of the STATNotes items do not exist, create them.

When creating a Mode item, the following steps will be completed:

Item Name	Required. Specify a name that is from 1 to 20 characters long and: • does not begin with the characters APOC (in upper or lower case) • is a unique name within this healthcare organization.

Item Prompt on Analyzer	Required. Specify a prompt that is from 1 to 20 characters long and: • does not begin with the characters APOC (in upper or lower case) • is a unique name within this healthcare organization.

Description	Optional.

For this example, do not specify a Description.

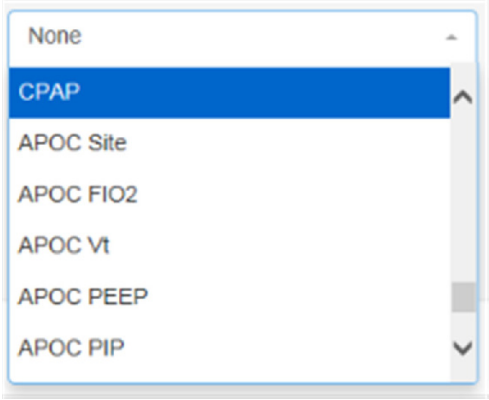
Entry Prompt	Select one of the following:
	Entry, optional Prompt the operator for an optional entry.
	Entry, mandatory with override Prompt the operator for a mandatory entry. If the override feature is chosen by the operator no further action is required and the instrument will advance to the next screen.

	Entry, mandatory Prompt the operator for a mandatory entry. Cartridge testing cannot continue until information is entered.

Selection List

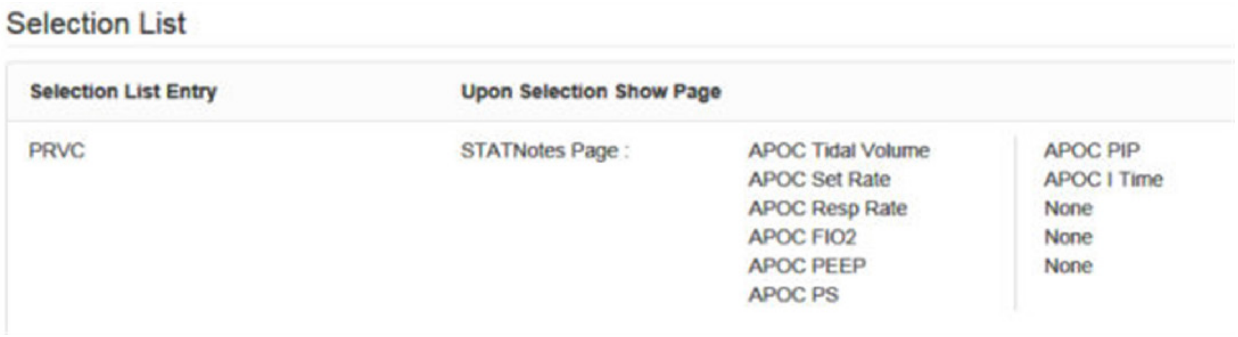
Click **Edit Selection List**. This displays the next part of the screen:

Selection List Entry	Enter the name of the ventilator mode. An example of a ventilator mode is AC. If no STATNotes items will be assigned to the page select: **No Page**. If STATNotes Items are to be assigned to the page select: **STATNotes Page**.
STATNotes Items	In the box directly below **STATNotes Items** click the arrow to dis-playthe drop down list. Select all items that should be used on the instrument to prompt for responses for the ventilator mode being-built. Items must be unique and chosen only once.



Repeat this process for all STATNotes items that will be needed for the ventilator mode that is being built. Once all STATNotes items have been selected for the ventilator mode click **Save**.

The screen display will be similar to:



Note: The STATNotes items displayed in the example above may not be the prompt displayed on the i-STAT Alinity. Example: APOC PIP will display on the instrument as PIP. Also the STATNotes Item shown as None will not display on the instrument.

Follow the same steps as described above for every mode.

When finished, choose from the options shown at the bottom of the screen:

- Click **Publish** to complete the item so it will appear on the Manage Items list
- Click **Discard** to delete the item

Delivery System

The Delivery System item is created to document how oxygen is delivered. Various oxygen delivery systems have settings or measurements that should be documented. The settings and/or measurements are created as STATNote items. Items must be created and available in the Manage Items section before building the Delivery System. See Table below for examples of delivery systems.

Note: All STATNotes items must be available before a Delivery System item can be created.

Example, the table below shows various delivery systems and the corresponding STATNotes items and modes.

Table 3–3: Delivery System table

Delivery System	STATNotes Items and Modes
Vent	Mode (*custom-built mode*)
Room Air	None
BNC	LPM FIO2 iNO
VentiMask	FIO2
CPAP	FIO2 CPAP LPM

In the table above, BNC delivery system requires 3 STATNotes items. To check whether these STATNotes items exist: Click **Manage and Assemble Profiles** > **STATNotes** > **Manage Items**

The screen displays all existing items. If all of the STATNotes items needed for delivery system BNC are included in the list, this means that the delivery system item can be built. It is also important to note, when checking the STATNotes list for an item, the item may exist under the “APOC” name. For example, if you are searching the list for the **Set Rate** item, it may be listed as **APOC set rate**.

If any of the STATNotes items do not exist, create them.

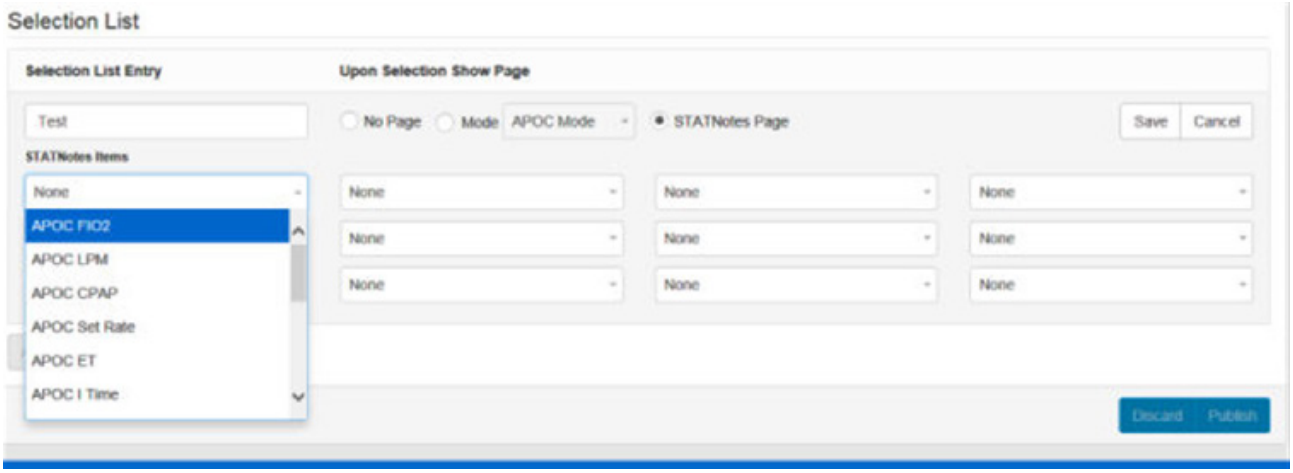
When creating a Delivery System item, the following steps will be completed:

Item Name	Required. Specify a name that is from 1 to 20 characters long and: • does not begin with the characters APOC (in upper or lower case) • is a unique name within this healthcare organization.

Item Prompt on Analyzer	Required. Specify a prompt that is from 1 to 20 characters long and: • does not begin with the characters APOC (in upper or lower case) • is a unique name within this healthcare organization.

Description	Optional.

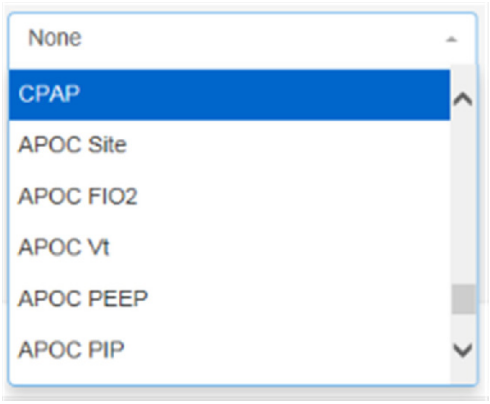
Entry Prompt	Select one of the following:
	Entry, optional Prompt the operator for an optional entry.
	Entry, mandatory with override Prompt the operator for a mandatory entry. If the override feature is chosen by the operator no further action is required and the instrument will advance to the next screen.
	Entry, mandatory Prompt the operator for a mandatory entry. Cartridge testing cannot continue until information is entered.



The fields on this screen are:

Selection List	A list of oxygen delivery systems identified with a page name. Each-delivery system will have `No Items`, `Mode` or `STATNotes Page`-applied.
Selection List Entry	Name of the page for the delivery system. Example: **BNC**. Select **STATNotes Items**.
No Page	The delivery system does not have settings or measurements. Example: Room Air. Once **No Page** is selected, click **Save**.
Mode	The delivery system has various modes. Example: Ventilator. Once **Mode** is selected, click **Save**.

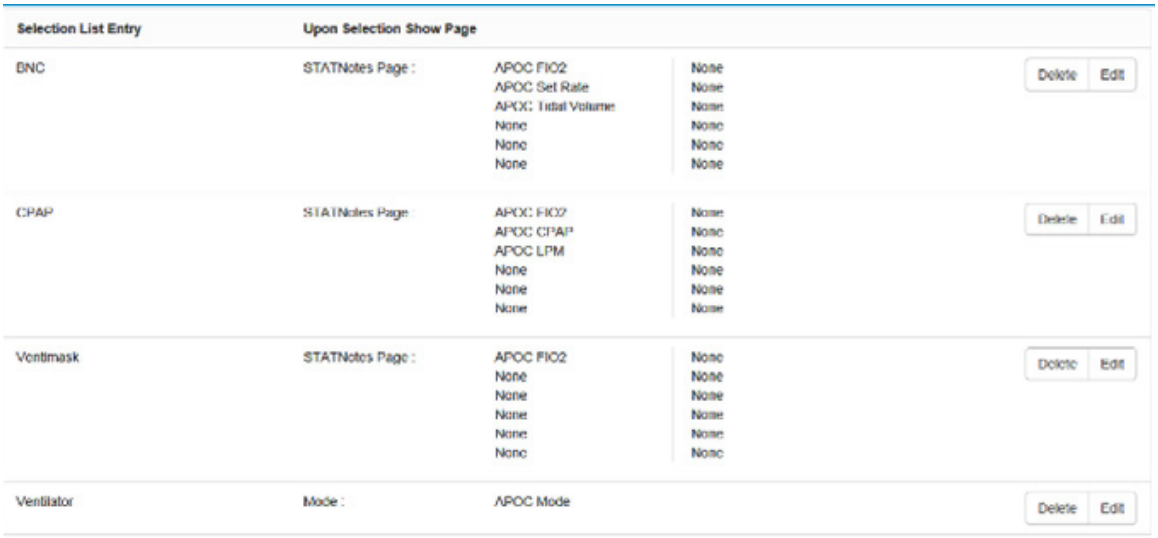
STATNotes Page	The delivery system has various settings and measurements. Example: **BNC**, STATNotes items: **FIO2**, **LPM**, **iNO**. In the box directly below **STATNotes Items** click the arrow to display the drop down list. Select all items that should be prompted for responses on the instrument for the delivery system being built.



Repeat this process for all STATNotes items that will be needed for the delivery system that is being built. Once all STATNotes items have been selected for the delivery system click **Save**.

For all Delivery Systems Pages being built, click **Add Selection List Entry**, then repeat all steps from Selection List Entry through STATNotes Page instruction.

Below is an example of a Delivery System with 4 Selection List entries:



Note: The STATNotes Items shown in the examples above may not match the prompt displayed on the i-STAT Alinity. Example: **APOC FIO2** will display on the instrument as **FIO2**. Also the STATNotes Items shown as **None** will not display on the instrument.

When finished, choose from the options shown at the bottom of the screen:

- Click **Publish** to complete the item so it will appear on the Manage Items list
- Click **Discard** to delete the item

Patient Temperature

Use this item to prompt the operator to record the patient temperature at the time of testing.

To create a STATNotes Patient Temperature item, enter the following information on the screen:

Item Name	Required. Specify a name that is from 1 to 20 characters long and: • does not begin with the characters APOC (in upper or lower case) • is a unique name within this healthcare organization.

Item Prompt on Analyzer	Required. Specify a prompt that is from 1 to 20 characters long and: • does not begin with the characters APOC (in upper or lower case) • is a unique name within this healthcare organization.

Description	Optional.

Entry Prompt	Select one of the following:
	Entry, optional Prompt the operator for an optional entry.
	Entry, mandatory with override Prompt the operator for a mandatory entry. If the override feature is chosen by the operator no further action is required and the instrument will advance to the next screen.
	Entry, mandatory Prompt the operator for a mandatory entry. Cartridge testing cannot continue until information is entered.

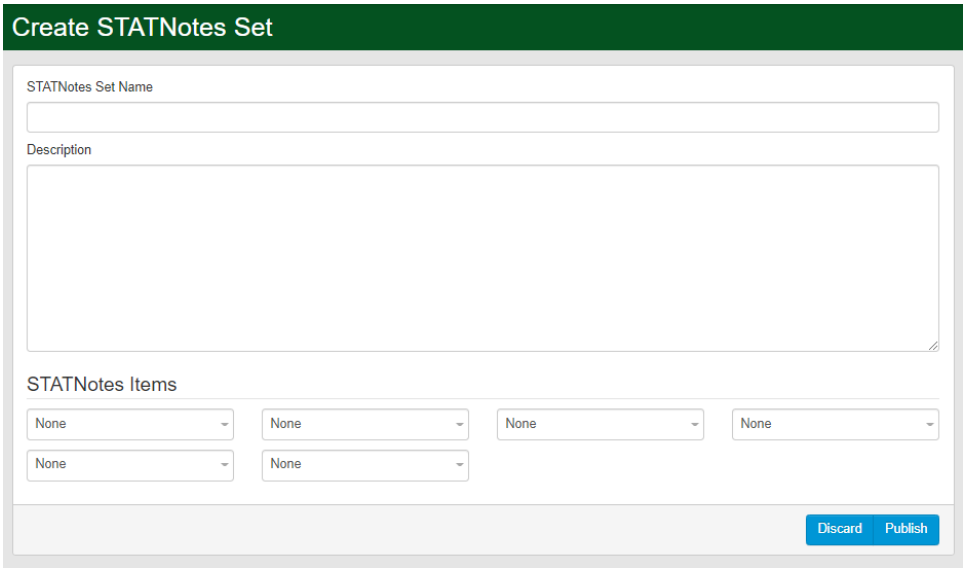
Unit	The temperature scale used. Select one of these values:	
	Fahrenheit	This is the default.
	Celsius	

When finished, choose from the options shown at the bottom of the screen:
- Click **Publish** to complete the item so it will appear on the Manage Items list
- Click **Discard** to delete the item

Manage Sets

A STATNotes set is a collection of STATNotes items. Use **Manage Items** to display a list of all available items. Items must be created and available in the Manage items section before a Manage Set can be built. After verifying that all items exist, a STATNotes set can be created. Once a set is created, it can be applied to cartridges. When patient testing is performed using a cartridge that has a STATNotes set applied, the STATNotes items will be displayed on the instrument.

Click on **Manage Sets** > **Create**. This screen displays:



On this screen, specify:

STATNotes Set Name	Required. Specify a name that is from 1 to 20 characters long and: • does not begin with the characters APOC (in upper or lower case) • is a unique name within this healthcare organization.

Description	Optional.

STATNotes Items	Select up to 6 items from the drop down boxes to create the set. Do not duplicate.

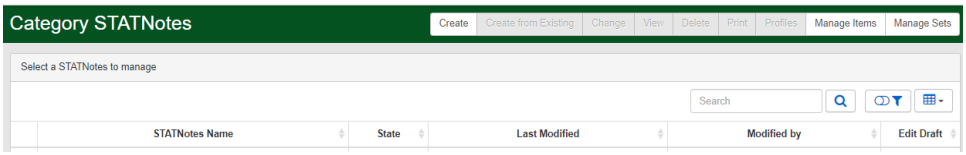
When finished, choose from the options shown at the bottom of the screen:

- Click **Publish** to create the set
- Click **Discard** to delete the set

After a STATNotes set has been published, click **Done**.

Create STATNotes

On the command line, click **Create**.



The following prompts will display on the screen:

STATNotes Name

Name	Required. Specify a name that is from 4 to 40 characters long and: • consists only of the following characters: ○ 0 through 9 ○ A through Z or alphabet appropriate for language (in upper or lower case)○blank space○underscore (_) • does not begin with the characters APOC (in upper or lower case) • is a unique name within this healthcare organization
Description	Optional. Provide any information that helps the user know how or why the category was named or created.

When finished, choose from the options shown at the bottom of the screen:

- **Next** to open the next tab for this Category
- **Discard** to undo changes

Applying STATNotes to a Cartridge

To apply STATNotes to a cartridge, click the drop down box next to the cartridge, and highlight the name of the set.

When you have finished, choose from the options shown at the bottom of the screen:

- **Previous** to go back to the previous screen
- **Discard** to undo changes
- **Finish Later** to create a draft
- **Next** to open the next tab

Summary

The Summary is a collapsed view of the settings that can be expanded to provide a complete display. The Summary should be reviewed prior to **Publish**. Once the settings are confirmed, click on the **Publish** button to finalize them. A **Category** can be added to a Profile only when the publish status is completed.

When finished, choose from the options shown at the bottom of the screen:

- **Previous** to go back to the previous screen
- **Discard** to undo changes
- **Finish Later** to create a draft
- **Publish** to make settings available to use in a Profile

Result Notes Category

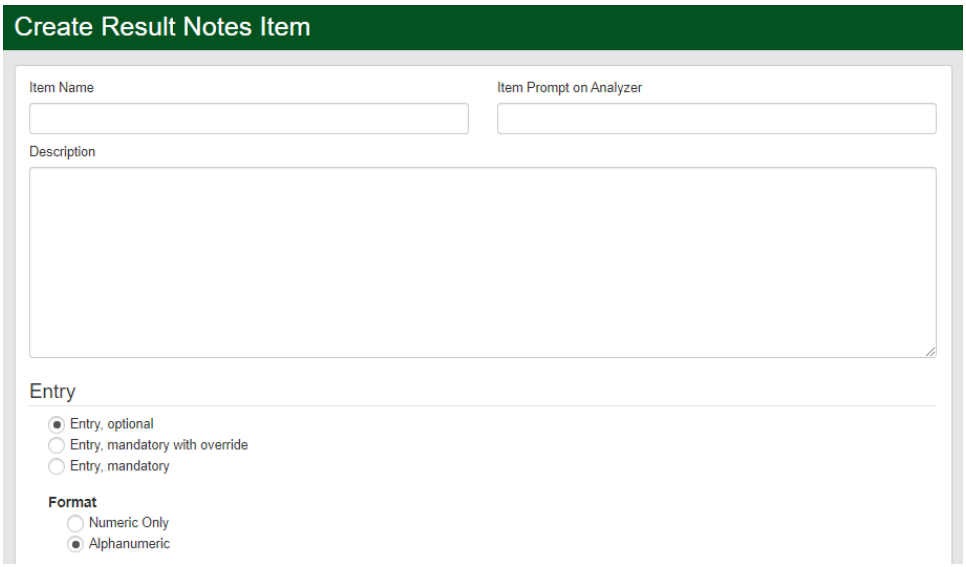
Result Notes are used to prompt the operator for additional information after the display of patient results or quality results. Much like profiles that are built with categories, Result Notes are built using sets. Additionally, sets are built with items. Items are what the operator sees on the instrument. Items require responses. Items are assigned to a set. This is performed in the **Manage Set** section.

When building a set, it will be necessary to choose whether the set will display in the Patient pathway or the Control and Cal Ver pathway. Continue through the process until the set is published. Once a set is published it is available for assigning to a cartridge type when building a Result Note. The information below will explain the process in detail.

Begin building an item. Click on **Manage and Assemble Profile** > **Result Notes** > **Manage Items** > **Create**. The following item types are available: **Data Entry**, **Selection List**, **Selection List with text box**, **Repeat Test**, **Action Range Comment** and **QC Auto Fail Comment**. Each of these choices is detailed below.

Data Entry

This section describes creating a Data Entry item that will prompt the operator to supply information, either using the keypad or by scanning.



On this screen, define the following:

Item Name	Required. Specify a name that is from 1 to 20 characters long and: • does not begin with the characters APOC (in upper or lower case) • is a unique name within this healthcare organization.

Item Prompt on Analyzer	Required. Specify a prompt that is from 1 to 20 characters long and: • does not begin with the characters APOC (in upper or lower case) • is a unique name within this healthcare organization.

Description	Optional.

Entry Prompt	Select one of the following:
	Entry, optional Prompt the operator for an optional entry.
	Entry, mandatory with override Prompt the operator for a mandatory entry. If the override feature is chosen by the operator no further action is required and the instrument will advance to the next screen.

	Entry, mandatory Prompt the operator for a mandatory entry. Cartridge testing cannot continue until information is entered.

Format	Determine the format used to enter data. Select either:	
	Numeric Only	Data will be entered only as numbers.
	Alphanumeric	Data will be entered as either letters or numbers.

Entry Type	Determine how the data will be entered into the i-STAT Alinity instrument. Select one of the following:	
	Allow Scan and Manual Entry	Allow barcode scan or manual data entry.
	Scan Only	Allow barcode scan data entry only.
	Manual Entry Only	Allow manual data entry only.
	Minimum Length	Enter the minimum data characters allowed.
	Maximum Length	Enter the maximum data characters allowed.
Scan Mask	Barcode scanning setting that allows for the selection of specific character positions to be retained. • The first position (the position farthest to the left) is numbered position “1”. • The scanmask field will accept a text input consisting of numbers 1-9, commas (‘,’), and hyphens (‘-’) to identify the scanmask selection. • If, for example, the barcode reads “abcdefghi1234567890” and the selection pattern is “2,5-8,11-14” then the barcode will be interpreted as “befgh2345”. If the selection pattern is “3-4”, then the barcode will be “cd”. • Individual position selections that are separated by a comma such as “2,4,7,8,19” cannot be duplicated. • In each number range, the starting number must be smaller than the ending number. For example, “3-5” is a valid range, but “5-3” is not. • Selection ranges cannot overlap. The end of each number range must be smaller than the beginning of the next number range. For example, “3-6,7-9” is a valid selection, but “3-6,6-9” is not. • Entering consecutive commas or hyphens is invalid. For example, “2--5”, “2-5,,7-10”, and “2,-5” are all invalid ranges.	

Manual Check Digit Method	If a facility uses a supported check digit algorithm when creating operator or patient IDs, the i-STAT Alinity can verify the entered ID format by calculating the check digit and comparing it to the entered ID number. If the check digits do not match, the ID is rejected. **Note:** The i-STAT Alinity System supports the Mod 10 and Mod 11 check digit algorithms described in the HL7 Table 0061 (Check Digit Scheme) in the HL7 Specification (Rev 1.4). Contact your LIS/HIS or IT departments to determine if your facility uses check digits in the creation of operator and/or patient ID numbers, and if so, which algorithm is used. Allowable values are:	
	No check digit on manual entry	Do not use a check digit when creating operator or patient IDs.
	Mod 11 check digit on manual entry	Use the Mod 11 algorithm when creating operator or patient IDs.
	Mod 10 check digit on manual entry	Use the Mod 10 algorithm when creating operator or patient IDs.

Scan Entry Check Digit Method	Whether to use a check digit when scanning a value to create an operator or patient ID.	
	No check digit on scan entry	Do not use a check digit when creating operator or patient IDs.
	Mod 11 check digit on scan entry	Use the Mod 11 algorithm when creating operator or patient IDs.
	Mod 10 check digit on scan entry	Use the Mod 10 algorithm when creating operator or patient IDs.

Barcode Type	Select all that apply.

When the specifications for this item are complete, choose from the options in the lower right corner of the screen:

- Click **Publish** to complete the item so it will appear on the Manage Items list
- Click **Discard** to delete the item

Selection List

Use Selection List to create a list of items that the operator can select from.

Item Name	Required. Specify a name that is from 1 to 20 characters long and: • does not begin with the characters APOC (in upper or lower case) • is a unique name within this healthcare organization.

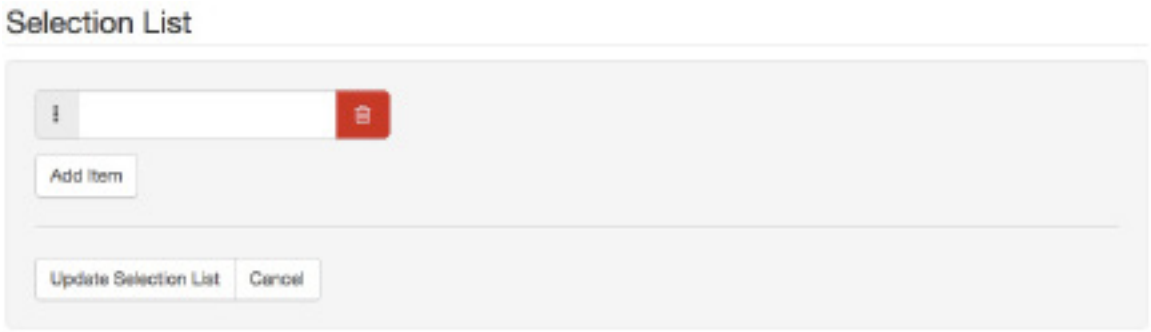
Item Prompt on Analyzer	Required. Specify a prompt that is from 1 to 20 characters long and: • does not begin with the characters APOC (in upper or lower case) • is a unique name within this healthcare organization.

Description	Optional.

Entry	Select one of the following:
	Entry, optional Prompt the operator for an optional entry.
	Entry, mandatory with override Prompt the operator for a mandatory entry. If the override feature is chosen by the operator no further action is required and the instrument will advance to the next screen.
	Entry, mandatory Prompt the operator for a mandatory entry. Cartridge testing cannot continue until information is entered.

Each item for the selection list is defined next.

Click **Edit Selection List**. A text box displays:



Enter up to 20 characters in the text box. This will be the first item in the selection list. To create additional items, click **Add Item**.

After all selection list items have been created, click **Update Selection List** or **Cancel**.

- Click **Publish** to complete the item so it will appear on the Manage Items list
- Click **Discard** to delete the item

The **Result Notes Item Name** list displays and now includes the Selection List item that was just created.

Selection List with Text box

This is nearly identical to the Selection List item with one important difference. With a Selection List item, the operator can choose from a list of items. In a Selection List with Text box, the operator is prompted to choose their response either from the selection list or to type a customized response into a text box.

Item Name	Required. Specify a name that is from 1 to 20 characters long and: • does not begin with the characters APOC (in upper or lower case) • is a unique name within this healthcare organization.

Item Prompt on Analyzer	Required. Specify a prompt that is from 1 to 20 characters long and: • does not begin with the characters APOC (in upper or lower case) • is a unique name within this healthcare organization.

Description	Optional.

Entry Prompt	Select one of the following:
	Entry, optional Prompt the operator for an optional entry.
	Entry, mandatory with override Prompt the operator for a mandatory entry. If the override feature is chosen by the operator no further action is required and the instrument will advance to the next screen.
	Entry, mandatory Prompt the operator for a mandatory entry. Cartridge testing cannot continue until information is entered.

Each item for the selection list is defined next.

Click **Edit Selection List**. A text box displays.

Enter up to 20 characters in the text box. This will be the first item in the selection list. To create additional items, click **Add Item**.

After all selection list items have been created, click **Update Selection List** or **Cancel**.

- Click **Publish** to complete the item so it will appear on the Manage Items list
- Click **Discard** to delete the item

Repeat Test Item

Use the Repeat Test Item to prompt the operator to answer “Yes” or “No” if a repeat test is needed.

On the screen that displays, enter values for:

Item Name	Required. Specify a name that is from 1 to 20 characters long and: • does not begin with the characters APOC (in upper or lower case) • is a unique name within this healthcare organization.

Item Prompt on Analyzer	Required. Specify a prompt that is from 1 to 20 characters long and: • does not begin with the characters APOC (in upper or lower case) • is a unique name within this healthcare organization.

Description	Optional.

Entry	Select one of the following:
	Entry, optional Prompt the operator for an optional entry.
	Entry, mandatory with override Prompt the operator for a mandatory entry. If the override feature is chosen by the operator no further action is required and the instrument will advance to the next screen.
	Entry, mandatory Prompt the operator for a mandatory entry. Cartridge testing cannot continue until information is entered.

Under **Selection List** the values **Yes** and **No** are shown. These are the only possible responses displayed on the instrument.

- Click **Publish** to complete the item so it will appear on the Manage Items list
- Click **Discard** to delete the item

Action Range Comment

The **Action Range Comment** item prompts the operator to select a comment for any patient result that is within the action range.

Item Name	Required. Specify a name that is from 1 to 20 characters long and: • does not begin with the characters APOC (in upper or lower case) • is a unique name within this healthcare organization.

Item Prompt on Analyzer	Required. Specify a prompt that is from 1 to 20 characters long and: • does not begin with the characters APOC (in upper or lower case) • is a unique name within this healthcare organization.

Description	Optional.

Entry Prompt	Select one of the following:
	Entry, optional Prompt the operator for an optional entry.
	Entry, mandatory with override Prompt the operator for a mandatory entry. If the override feature is chosen by the operator no further action is required and the instrument will advance to the next screen.
	Entry, mandatory Prompt the operator for a mandatory entry. Cartridge testing cannot continue until information is entered.

Each item for the selection list is defined next.

Click **Edit Selection List**. A text box displays:

Enter up to 20 characters in the text box. This will be the first item in the selection list. To create additional items, click **Add Item**.

After all selection list items have been created, click **Update Selection List** or **Cancel**.

- Click **Publish** to complete the item so it will appear on the Manage Items list
- Click **Discard** to delete the item

QC Auto Fail Comment

The Result Notes QC Auto Fail Comment is only applied when QC Pass/Fail determination is set to Auto via eVAS (refer to Quality Settings Category).

Item Name	Required. Specify a name that is from 1 to 20 characters long and: • does not begin with the characters APOC (in upper or lower case) • is a unique name within this healthcare organization.

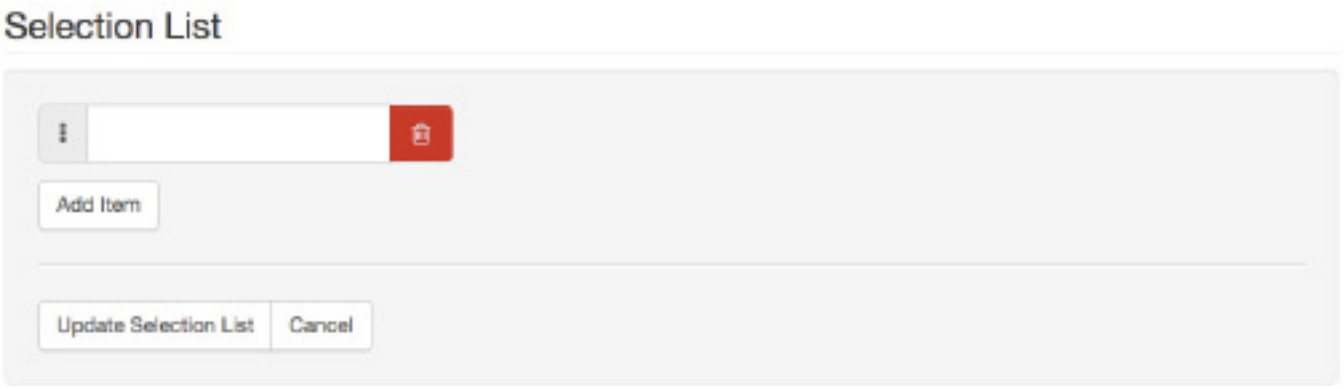
Item Prompt on Analyzer	Required. Specify a prompt that is from 1 to 20 characters long and: • does not begin with the characters APOC (in upper or lower case) • is a unique name within this healthcare organization.

Description	Optional.

Entry Prompt	Select one of the following:
	Entry, optional Prompt the operator for an optional entry.
	Entry, mandatory with override Prompt the operator for a mandatory entry. If the override feature is chosen by the operator no further action is required and the instrument will advance to the next screen.
	Entry, mandatory Prompt the operator for a mandatory entry. Cartridge testing cannot continue until information is entered.

Each item for the selection list is defined next.

Click **Edit Selection List**. A text box displays:



Enter up to 20 characters in the text box. This will be the first item in the selection list. To create additional items, click **Add Item**.

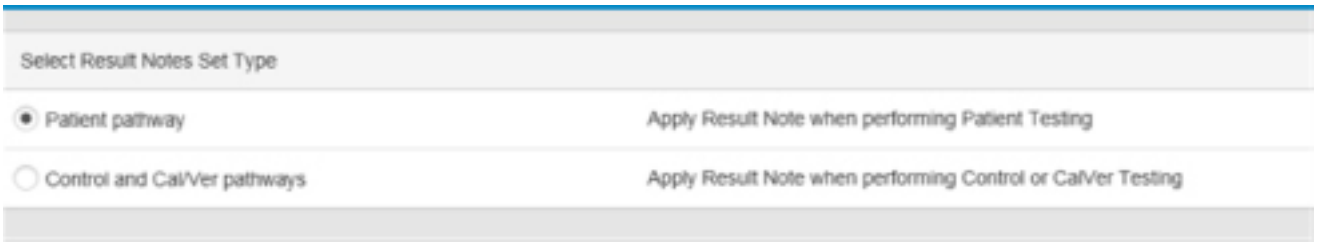
After all selection list items have been created, click **Update Selection List** or **Cancel**.

- Click **Publish** to complete the item so it will appear on the Manage Items list
- Click **Discard** to delete the item

Manage Sets

A Result Notes set is a collection of Result Notes items. Use **Manage Items** to display a list of all available items. Items must be created and available in the Manage items section before a Manage Set can be built. After verifying that all items exist, a Result Notes set can be created. When creating a Result Notes set, the patient or control and Cal Ver testing pathway needs to be determined for the Result Notes Set. Once a set is created, it can be applied to cartridges. After patient testing or control and Cal Ver testing is performed using a cartridge, the Result Notes item will be displayed on the instrument.

Use **Manage Sets** > **Create**. This screen displays:



On the screen shown above, select either:

Patient pathway	Apply Result Notes when performing patient testing.
Control and Cal Ver pathways	Apply Result Notes when performing Control or Cal Ver testing.

Next, in the upper right corner of the screen, click **Create Set**.

Result Notes Set

Name	Required. Specify a name that is from 4 to 40 characters long and: • consists only of the following characters: ○ 0 through 9 ○A through Z or alphabet appropriate for language (in upper or lower case) ○blank space ○underscore (_) • does not begin with the characters APOC (in upper or lower case) • is a unique name within this healthcare organization

Description	Optional.

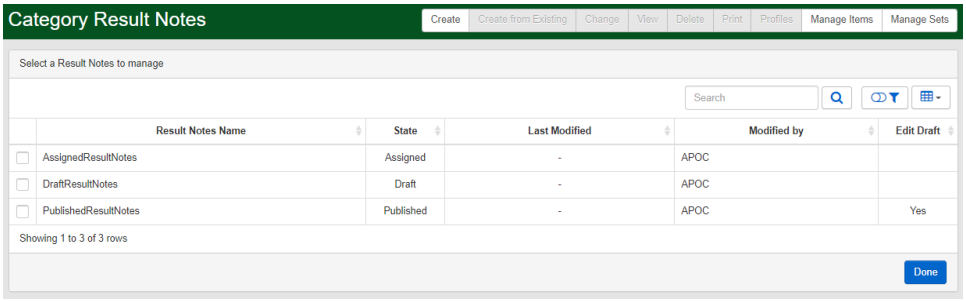
Result Notes Items	Select up to 6 items from the drop down boxes to create the set. Do not duplicate.

When finished, choose from the options shown at the bottom of the screen:
- **Discard** to undo changes
- **Publish** to create the set

After a Result Notes set has been published, click **Done**.

Create Result Notes

On the command line, click **Create**.



Result Notes

Name	Required. Specify a name that is from 4 to 40 characters long and: • consists only of the following characters: ○ 0 through 9 ○A through Z or alphabet appropriate for language (in upper or lower case) ○blank space ○underscore (_) • does not begin with the characters APOC (in upper or lower case) • is a unique name within this healthcare organization

Description	Optional.

When finished, choose from the options shown below:

- **Next** to open the next tab for this Category
- **Discard** to undo changes.

Applying a Result Notes Set to a Cartridge

To apply a Result Notes set to a cartridge, click the drop down box next to the cartridge, and highlight the name of the set. Patient pathway Result Notes Sets can be applied to cartridges. Control and Cal Ver pathways Result Notes Sets can only be applied to Control/CalVer Sets.

When finished, choose from the options shown at the bottom of the screen:

- **Previous** to go back to the previous screen
- **Discard** to undo changes
- **Finish Later** to create a draft
- **Next** to open the next tab

Summary

The Summary is a collapsed view of the settings that can be expanded to provide a complete display. The Summary should be reviewed prior to **Publish**. Once the settings are confirmed, click on the **Publish** button to finalize them. A **Category** can be added to a Profile only when the publish status is completed.

When finished, choose from the options shown at the bottom of the screen:

- **Previous** to go back to the previous screen
- **Discard** to undo changes
- **Finish Later** to create a draft
- **Publish** to make settings available to use in a Profile

Connectivity Settings Category

This section contains features to customize the connectivity settings for the i-STAT Alinity to transmit to and receive from remote systems, such as operator, cartridge, and patient lists.

To create connectivity settings, click on **Create**. The screen displays the default name `TemporaryName`. Change the name, using the specifications shown below:

Connectivity Settings

Name	Required. Specify a name that is from 4 to 40 characters long and: • consists only of the following characters: ○ 0 through 9 ○A through Z or alphabet appropriate for language (in upper or lower case) ○ blank space ○underscore (_) • does not begin with the characters APOC (in upper or lower case) • is a unique name within this healthcare organization
Description	Provide any information that helps the user know how or why the category was named or created.

When finished selecting values, choose from the options shown below:

- **Next** to open the next tab for this Category
- **Discard** to undo changes.

Connectivity Map

To enable the sending and receiving of data to and from the i-STAT Alinity instrument, configure the connections to the remote systems listed in the Connectivity Map.

The Connectivity Map includes:

Test Records
Device Events
Operator List
Patient List
Cartridge List
Log Events

For each remote system mapped, the following information is needed:

- Reviewer Name - information system name, for example, InfoHQ
- Vendor Name - for example, Abbott Point of Care
- IP Address
- Network Port

Instrument Clock Date/Time Synchronization

When the Connectivity Map settings are enabled for Test Records, Operator List, Patient List or Cartridge List and the instrument is connected to a network via wired or wireless interface, the instrument will automatically synchronize the date and time of its clock with the data manager's time. This feature may be disabled via the instrument Set Clock flow. See *Instrument Clock Date/Time Synchronization* in section 1.2 i-STAT Alinity Instrument for details.

If all the IP addresses in the Connectivity Map are the same, the instrument may synchronize time during any of the data manager communication sessions (for example, transmitting results or receiving lists).

If the IP addresses in the Connectivity Map are not all the same, the instrument will synchronize time with only one data manager. In this case, the instrument will select the one data manager according to the first enabled IP address in the Connectivity Map in the following order: Test Records, Operator List, Cartridge List, Patient List.

Note: Instruments can be set to initiate communication with internal sources each time they power down. See the section *Communications* for details on **Power Down Communications**.

When finished, choose from the options shown at the bottom of the screen:

- **Previous** to go back to the previous screen
- **Discard** to undo changes
- **Finish Later** to create a draft
- **Next** to open the next tab

Summary

The Summary is a collapsed view of the settings that can be expanded to provide a complete display. The Summary should be reviewed prior to **Publish**. Once the settings are confirmed, click on the **Publish** button to finalize them. A **Category** can be added to a Profile only when the publish status is completed.

When finished, choose from the options shown at the bottom of the screen:

- **Previous** to go back to the previous screen
- **Discard** to undo changes
- **Finish Later** to create a draft
- **Publish** to make settings available to use in a Profile

Assemble a Profile

An i-STAT Alinity profile is a collection of categories. There are five categories (indicated with an asterisk*) required to build a profile and five optional categories, all listed below.

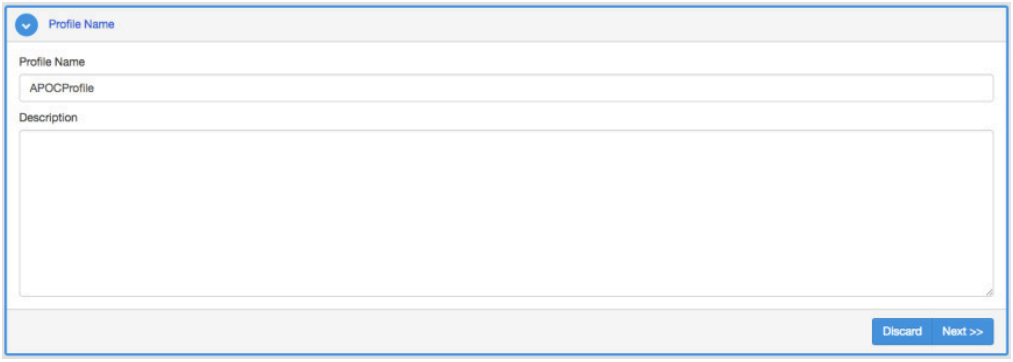
These categories are **required** (indicated with an asterisk *) to build a profile:

- *General Settings
- *Operator Settings
- *Quality Settings
- *Patient Settings
- *Analyte Settings

In addition to the required categories, there are optional categories that can be included in a profile:

- User Defined Message
- Training Settings
- STATNotes
- Result Notes
- Connectivity Settings

To begin defining a profile, from the **Home** page: click **Manage and Assemble Profiles** > **Profile** > **Create**. This screen displays:



This screen has the following options:

Profile

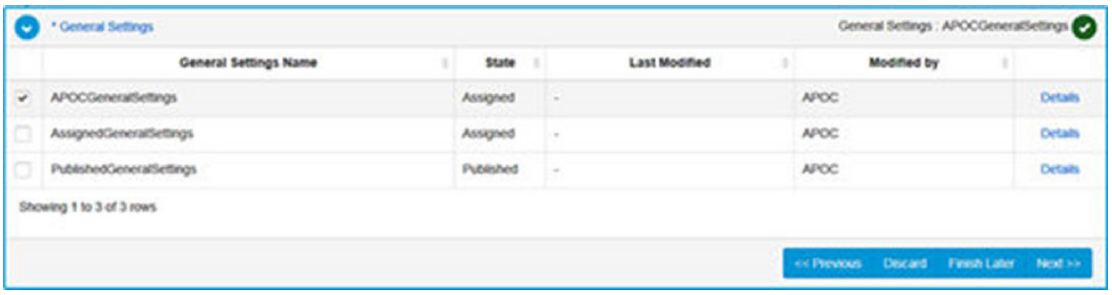
Name	Required. Specify a name that is from 4 to 40 characters long and: • consists only of the following characters: ○ 0 through 9 ○A through Z or alphabet appropriate for language (in upper or lower case) ○blank space ○underscore (_) • does not begin with the characters APOC (in upper or lower case) • is a unique name within this healthcare organization
Description	Provide any information that helps the user know how or why the profile was named or created.

In the bottom right corner of the screen, click either:

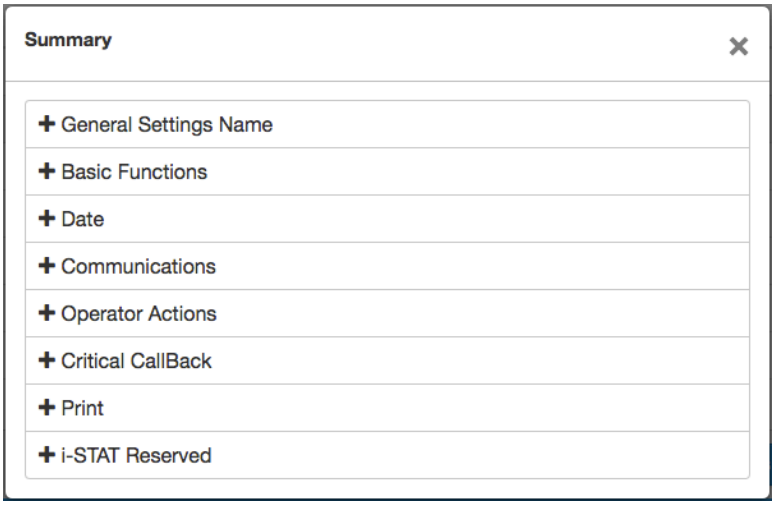
- **Discard** to discard the information, or
- **Next** to open the next tab

Select Pre-defined or customized categories for a Profile

Clicking **Next** after specifying a Profile name opens the **General Settings** list. This is a list of all the existing General Settings categories:



General Settings is a required category for a profile. Select a General Settings category by clicking the check box next to the name. To display the contents of the category, click **Details**. A Summary screen opens:



The Summary screen shows all the tabs for that category. Click any tab name to display the options for that tab. After reviewing the details of the category, exit the Summary screen by clicking the **X**.

When finished selecting categories, choose from the options shown at the bottom of the screen:

- **Previous** to go back to the previous screen
- **Discard** to undo changes
- **Finish Later** to create a draft
- **Next** to open the next tab

To select all the categories for a profile, follow the same steps as described for General Settings. Select one category for each of the required categories: General Settings, Operator Settings, Quality Settings, Patient Settings, and Analyte Settings. If a required category is not selected, the pre-defined category will be applied to the profile. Optional categories may also be selected for the profile.

When selections are complete, choose from the options shown at the bottom of the screen:

- **Previous** to go back to the previous screen
- **Discard** to undo changes
- **Finish Later** to create a draft
- **Publish** to make the Profile available to use

The **Profile Name** list displays and now includes the Profile that was just created.

Save and Export a Profile

After a profile is published it can be saved and exported. To save a profile, on the **Profile Name** list, select the check box next to the name of the profile to be saved. In the upper right corner of the screen, click **Export**. At the bottom of the screen a prompt similar to the one shown below displays:

Select:

Open	(Not recommended)	
Save	To save the file. Click the down arrow and select:	
	Save as	To save the file to a specific destination (USB).
	Save and open	(Not recommended)
Cancel	To not save the file.	

Install a Profile from a USB

1. Ensure that the correct profile.apkg file has been loaded onto the USB.
2. Locate the USB port on the side of the Base Station and insert the USB.
3. Place the instrument on the Base Station. Power on the instrument.
4. Navigate to **More Options** > **Administrative Options** > **Profile Management** > **Install Profile from USB**
5. Follow the prompts on the screen to begin the installation process.
6. The **Activate USB Drive** screen displays 2 check boxes. Both boxes must display a green check mark (✔) for the installation to proceed. If necessary, troubleshooting steps are listed below.
7. Confirm that the profile has been uploaded to the instrument by navigating to **More Options** > **In-strument Status** then use **Page** key to advance to page 2. The profile name and date of install will be displayed. If the correct information is not displayed, repeat the installation procedure.

Troubleshooting

If the instrument does not detect the Base Station, try the following:
- remove the instrument and re-seat it on the Base Station
- check to ensure the Base Station is getting power (blue light illuminated)

If the instrument does not detect the USB drive, try the following:
- remove the USB and reinsert
- make sure the USB is formatted

This page intentionally left blank.

3.5 - AlinIQ CWi – Customization Workspace for i-STAT Troubleshooting

Issue	Solution
Category Name or Profile Name displays an error message	The following characters are not allowed when naming categories or profiles: < (less than) : (colon) / (forward slash) | (vertical bar or pipe) * (asterisk) > (greater than) ” (double quote) \ (backslash) ? (question mark)
Forgot AlinIQ CWi Password	Launch CWi and enter Email address. Click the **Forgot Password?** link. Check your email for a message received from **pointofcare_services@noreply.abbott.com** Follow the instructions in the message to reset your password.
No sound on i-STAT Alinity	Check **General Settings Category** to confirm that sound is enabled on the profile assigned to the instrument. Follow CWi instructions in this manual to make necessary changes.
Date display is incorrect on i-STAT Alinity	Check **General Settings Category** for **Date Display**. Follow CWi instructions in this manual to make necessary changes.
i-STAT Alinity wireless function does not work	Check **General Settings Category** to confirm the check box has a check enabling the Wireless Communication. Check the NCi settings for wireless connectivity.
Operator barcode will not scan	Check Barcode settings in the **Operator Settings ID Entry** feature on the profile assigned to the instrument. Follow CWi instructions in this manual to change the barcode type.

Issue	Solution
i-STAT Alinity only displays the last 3 numbers or letters of the Operator ID or No Operator ID. The entire Operator ID should display.	Check the **Operator ID Presentation** feature in the **Operator ID Entry** feature on the profile assigned to the instrument. Follow CWi instructions in this manual to change the display.
i-STAT Alinity only displays the operator's first name and last initial. The entire name should display.	Check the **Operator Name Presentation** in the **Operator ID Entry** feature on the profile assigned to the instrument. If the check box is marked for **Partially Display Operator Name**, uncheck it to display entire name. Follow CWi instructions in this manual.
i-STAT Alinity will not upload operator list	Check and confirm that the **Search for Operator ID on Operator List** feature in the **Operator Settings Category** is checked on the profile assigned to the instrument. If not checked, follow CWi instructions in this manual to change the profile and enable the instrument to load the operator list from the data management system. Check the **Connectivity Settings Category** to confirm the IP address is programmed for operator list.
i-STAT Alinity will not upload cartridge lot list	Check to confirm **Search Cartridge List for Cartridge Lot Number** is enabled in the **Quality Settings Category** on the profile assigned to the instrument. If not enabled, follow CWi instructions in this manual to enable **Search Cartridge List for Cartridge Lot Number** to load the cartridge list from the data management system. Check the **Connectivity Settings Category** to confirm the IP address is programmed for cartridge list.
Patient armband barcode will not scan	Check Barcode settings in the **Patient Settings ID Entry** feature on the profile assigned to the instrument. Follow CWi instructions in this manual to change the barcode type.
Patient list will not upload onto the i-STAT Alinity	Check and confirm that the **Search Patient List for Patient ID** feature is enabled in the **Patient Settings Category** on the profile assigned to the instrument. If it is not, follow the CWi instructions in this manual to change the profile and enable the instrument to load the Patient List from the data management system. Check the **Connectivity Settings Category** to confirm the IP address is programmed for Patient List.

Issue	Solution
Analyte ranges were created with age and gender applied but no reference ranges or action ranges will display on the i-STAT Alinity. The display shows no color.	Check to confirm in **Patient Settings**, **Basic Functions** that **Patient Age/Gender Entry** has been enabled. If not, follow the directions in this manual to change setting and upload profile with correction.
STATNotes set does not display when clicking on the drop down arrow beside the cartridge.	A STATNotes set must be created and published under the **Manage Set** tab before the set will appear as available for application to a cartridge. Follow the instructions in this manual to create a STATNotes set.
Category created does not appear in the list of available categories when creating a profile	Categories must be in the **Published** status to appear as available when creating a profile.
Cartridge QC Lot List is applied and defined in CWi and data management system but QC or Cal Ver results are not being displayed in the data management system.	CWi Pass/Fail determination for QC or Cal Ver is required. If set to **None** the data management system will not recognize the test performed. Follow the instructions in this manual to set **Auto via eVAS or Manual**.

Issue	Solution
Instrument time does not agree with data manager time	**1.** Power on the instrument and allow it sufficient time on the Home screen to connect to the network and communicate with the data manager. **2.** Check the network status icon on the instrument screen. If icon appears but indicates no connection: **For Wired connection:** - Ensure instrument is properly seated in the base station. - Confirm the base station has a wired connection to the network. **For Wireless connection:** - Ensure Wireless is Enabled via the Enable/Disable Wireless workflow. - Check Wireless Communication is Enabled in the customization profile, General Settings Category. Follow CWi instructions in this manual to make necessary changes. **3.** Check that the network status icon on the instrument screen shows instrument has a network connection. If not, then use NCi to verify the NC settings within the NC file installed on the instrument are correct. Follow NCi instructions in this manual to make necessary changes to network settings. **4.** Check Connectivity Map in customization profile to confirm at least one of the following is Enabled and has the correct IP Address and Port of the data manager: Test Results, Operator List, Cartridge List, Patient List. Follow CWi instructions in this manual to make necessary changes. **5.** Check the data manager to ensure it is operational and supports communication with i-STAT Alinity instruments.

Additional Information

AlinIQ CWi is a web-based application and therefore may experience periods of downtime. Scheduled downtime will be noted when logging in. Unscheduled downtime, although never desired, may happen from time to time. (For example: security patches and application updates.)

Best practice would be to save all assigned profiles in a file on a healthcare organization manager's computer. If a profile needs to be loaded onto an instrument while the system is down, upload can be

performed from USB. Temporary loss of user access to AlinIQ CWi will not affect profiles already loaded onto instruments.

This page intentionally left blank.