

**i-STAT 1 System Individualized Quality Control Plan (IQCP) Risk Assessment Template**

**Directions for Use**

To facilitate completion of a Risk Assessment (RA) and adherence with the Individualized Quality Control Plan (IQCP) option included in some laboratory survey organization’s requirements, Abbott Point of Care has developed a tool that helps identify the risk-mitigation features and control methods associated with the *i-STAT 1 System* for the *i-STAT* testing process the laboratory utilizes. This tool presents potential risks in the testing process, potential failures, and related failure causes that laboratories may want to include in the RA and related Quality Control Plan (QCP). This tool directs laboratories to suggested documents to review specific risk-related information in the *i-STAT 1 System Manual* and/or other documents. **Other steps in the testing process, potential failures, and failure causes may need to be considered; therefore, additional sections of the *i-STAT 1 System Manual* and related documents may need to be referenced.** This tool is not a manufacturer’s requirement and must be used with approval from the Laboratory Director.

This tool can be modified as needed to eliminate and add any potential failures and potential causes for those failures specific to the lab’s testing process. A blank line has been left in each of the 5 sections of this template for the Risk Assessment tool so the addition of a process step can be included; more lines can be added as needed. Steps that are included in this tool that are not performed by the lab should be removed. Once the selected *i-STAT* information is reviewed, this output document can serve as evidence of regulatory compliance with the review of the manufacturer’s risk-related information for the potential failures and potential causes that can lead to errors in patient test results.

Laboratories should review the information sections suggested for each of the potential failures and potential causes related to the Sample, Operator, Reagents, Laboratory Environment, and Measuring System (Test System) that are applicable to their laboratory. This template includes instructions for answering the question “Risk with Acceptable Frequency and Impact?”

While reviewing each line of the risk-related information suggested in this template, the acceptability of the risk frequency and impact for each failure/cause combination can be assessed for the testing process. A “Yes” or “No” (or “Y” or “N”) can be added based on the lab’s determination of risk acceptability with the testing process. When the answer to the question “Risk with Acceptable Frequency and Impact?” is “No” (or “N”) for a potential failure/potential cause combination, the space provided in this column may be used to record additional steps for inclusion in the QCP approach.

For many *i-STAT* cartridges, the lab may determine that the risks will be the same for potential failures and potential causes for all analytes on that cartridge. Where there are differences in the assessment of the acceptability of risk for one or more specific analytes, there should be a recording of “N” or “No” for those specific analytes and additional steps for these significant unmitigated risks should be added.

The use of the “IQCP Guide” can be used for additional details or resources and assets that could provide more direction for the Risk Assessment and QCP.

Acronyms found throughout the worksheet:

CTI: Cartridge and Test Information Sheets

IFU: Instructions for Use (*i-STAT* cartridge)

TB: *i-STAT 1 System* Technical Bulletin

| **i-STAT 1 System Individualized Quality Control Plan (IQCP) Risk Assessment Template** |
| --- |
| **Facility:****Locations Used:** **Cartridge:**  | **Risk Assessment** |
| **Step Where Potential Failure Could Occur** | **Potential Failure** | **Potential Cause** | **Risk Information Location** | **Risk w/ Acceptable Frequency and Impact? Yes (Y) No (N)****If "N", Identify Analyte(s) with Unacceptable Risk and Add Additional Steps for Significant Unacceptable Risks** |
| **Sample Collection Preparation** | **Sample Integrity - Contaminated** | **Contaminated with Alcohol** | *i-STAT 1 System Manual -*  Section “Sample Collection“ |  |
| **Sample Collection Preparation** | **Sample Integrity - Contaminated** | **Contaminated with Other Cleansing Agents** | *CTI sheet:* *PT/ INR*  |  |
| **Sample Collection Preparation** | **Sample Integrity - Contaminated** | **Anticoagulants in Intravenous (IV) Line Fluids**  | *i-STAT 1 System Manual -*  Section “Sample Collection“ |  |
| **Sample Collection Preparation** | **Sample Integrity - Contaminated** | **Intravenous (IV) Fluids** | *i-STAT 1 System Manual -*  Section “Sample Collection“ |  |
| **Sample Collection Preparation** | **Sample Integrity - Contaminated** | **Admixture with Other Fluids/ Materials** | *i-STAT 1 System Manual -*  Section “Sample Collection“CTI & IFUs |  |
| **Sample Collection** | **Sample Integrity - Inadequate Sample** | **Poor Circulation at Sample Site** | *i-STAT 1 System Manual -*  Section “Sample Collection“ |  |
| **Sample Collection** | **Sample Integrity - Inadequate Sample** | **Poor Vascular Access** | *i-STAT 1 System Manual -*  Section “Sample Collection“ |  |
| **Sample Collection** | **Sample Integrity - Inadequate Sample** | **Inadequate Sample Volume** | *i-STAT 1 System Manual -*  Section “Sample Collection“CTI & IFUs |  |
| **Sample Collection** | **Sample Integrity - Inadequate Sample** | **Poor Technique** | *i-STAT 1 System Manual -*  Section “Sample Collection“ |  |
| **Sample Collection** | **Sample Integrity - Inadequate Sample** | **Hemolysis** | *i-STAT 1 System Manual -*  Section “Sample Collection“CTI & IFUs |  |
| **Sample Collection** | **Sample Integrity - Inappropriate Sample** | **Sample Collected on Wrong Patient** | ***i-STAT/DE* *User Guide***  |  |
| **Sample Collection** | **Sample Integrity - Inappropriate Sample** | **Incorrect Sample Type** | *i-STAT 1 System Manual -*  Section “Sample Collection“*TB: Sample Type Customization on the i-STAT 1 Analyzer*CTI & IFUs |  |
| **Sample Collection** | **Sample Integrity - Inappropriate Sample** | **Sample Collected in Wrong Tube or Syringe/Wrong Additives** | *i-STAT 1 System Manual -*  Section “Sample Collection“*i-STAT 1 System Manual -*Section ”Cartridge and Test Information” |  |
| **Sample Collection** | **Sample Integrity - Inappropriate Sample** | **Sample Clots/Has Clots** | *i-STAT 1 System Manual -*  Section “Sample Collection“*i-STAT 1 System Manual –* Section “Troubleshooting the Analyzer”*TB: Analyzer Coded Messages*CTI & IFUs  |  |
| **Sample Collection** | **Sample Integrity - Inappropriate Sample** | **Technique - Air in Syringe/Sample Exposed to Air**  | *i-STAT 1 System Manual -*  Section “Sample Collection“IFUs |  |
| **Sample Collection** | **Sample Integrity- Patient Condition Inappropriate for Testing Method** | **Hematocrit (HCT), Interference – Patient Undergoing CPB** | *i-STAT/DE User Guide* IFUs |  |
| **Sample Collection** | **Sample Integrity- Patient Condition Inappropriate for Testing Method** | **Medications Interfere with Method** | *i-STAT 1 System Manual -*  Section “Sample Collection“*i-STAT 1 System Manual –* Section “Procedure for Cartridge Testing”CTI & IFUs |  |
| **Sample Collection** | **Sample Integrity- Patient Condition Inappropriate for Testing Method** | **Lipemia**  | IFUs |  |
| **Sample Testing** | **Sample Integrity- Incorrect Procedure/ Technique** | **Incorrect Procedure/ Technique - Iced Samples** | *i-STAT 1 System Manual -*  Section “Sample Collection“IFUs |  |
| **Sample Testing** | **Sample Integrity- Incorrect Procedure/ Technique** | **Incorrect Time Before Testing/ Time to Transport Sample** | *i-STAT 1 System Manual -*Section ”Cartridge and Test Information”CTI & IFUs |  |
| **Sample Testing** | **Sample Integrity- Incorrect Procedure/ Technique** | **Sample Inadequately Mixed** | *i-STAT 1 System Manual -*  Section “Sample Collection” CTI & IFUs |  |
| **Sample Testing** | **Sample Integrity- Incorrect Procedure/ Technique** | **Incorrect Patient Identification Information Entered Into Instrument** | *i-STAT 1 System Manual –* Section “Customization”***i-STAT/DE User Guide*** |  |
| **Sample Testing**  | **Sample Integrity- Incorrect Procedure/ Technique**  | **Sample Mislabeled/Not Labeled** | Not applicable with immediate testing  |  |
| **Sample Testing** | **Sample Integrity- Incorrect Procedure/ Technique** | **Improper Handling of Cartridge** | *i-STAT 1 System Manual –* **Section “**Procedure for Handling Cartridges”*i-STAT 1 System Manual -*Section “Troubleshooting the Analyzer”*TB: Analyzer Coded Messages*  |  |
| **Sample Testing** | **Sample Integrity - Inappropriate Amount of Sample Presented** | **Cartridge Underfill** | *i-STAT 1 System Manual –* **Section “**Procedure for Handling Cartridges” *i-STAT 1 System Manual -*Section “Troubleshooting the Analyzer”*TB: Analyzer Coded Messages*  |  |
| **Sample Testing** | **Sample Integrity - Inappropriate Amount of Sample Presented** | **Cartridge Overfill** | *i-STAT 1 System Manual –* **Section “**Procedure for Handling Cartridges”*i-STAT 1 System Manual –* Section “Troubleshooting the Analyzer” *TB: Analyzer Coded Messages* |  |
| **Sample Testing** | **Sample Integrity - Inappropriate Amount of Sample Presented** | **Introduction of Air Bubbles** | *i-STAT 1 System Manual –* Section “Sample Collection”*i-STAT 1 System Manual –* Section “Procedure for Handling Cartridges” *i-STAT 1 System Manual -*Section “Troubleshooting the Analyzer”*TB: Analyzer Coded Messages* |  |
| **Sample Testing** | **Sample Integrity - Inappropriate Amount of Sample Presented** | **Clot in Cartridge** | *i-STAT 1 System Manual –* Section “Troubleshooting the Analyzer”*TB: Analyzer Coded Messages*  |  |
| **Sample Testing** | **Introduction of Cartridge to Test Device** | **Cartridge Type Scanned Does Not Match Cartridge Type Inserted into Analyzer** | *i-STAT 1 System Manual –* Section “Procedure for Cartridge Testing”*TB: Analyzer Coded Messages* |  |
| **Sample Testing** | **Introduction of Cartridge to Test Device** | **Cartridge Not Inserted Properly** | *i-STAT 1 System Manual –* **Section “**Procedure for Handling Cartridges” *i-STAT 1 System Manual –* Section “Troubleshooting the Analyzer”*TB: Analyzer Coded Messages* |  |
| **Sample Testing** | **Introduction of Cartridge to Test Device** | **Removal of Cartridge Before Completion of Test** | *i-STAT 1 System Manual -* **Section “i-STAT 1 Analyzer”***i-STAT 1 System Manual -* **Section “**Procedure for Handling Cartridges” |  |
| **Sample Testing** |  |  |  |  |
|  |  |  |  |  |
| **Operator Training and Capacity** | **Capacity** | **Lack of Training** | *i-STAT 1 System Manual -* Section “i-STAT 1 Analyzer” *i-STAT 1 System Manual -* Section “Sample Collection”*i-STAT 1 System Manual -* Section “Procedure for Cartridge Handling” *i-STAT 1 System Manual –* Section “Procedure for Cartridge Testing” *i-STAT 1 System Manual –* Section “Quality Control”*i-STAT 1 System Manual –* **Section “**Theory” ***i-STAT/DE User Guide*** ***TB:*** *Analyzer Coded Messages*CTI & IFUs |  |
| **Operator Training and Capacity** | **Capacity** | **Incompetency** | ***i-STAT/DE User Guide*** ***TB:*** *Analyzer Coded Messages* CTI & IFUs |  |
| **Operator Training and Capacity** | **Capacity** | **Untrained Operator** | ***i-STAT/DE User Guide***  |  |
| **Operator Training and Capacity** | **Staffing** | **Inadequate Staffing** | **Not Applicable** |  |
| **Operator Training and Capacity** |  |  |  |  |
|  |  |  |  |  |
| **Reagents** | **Cartridge Reagent Degradation** | **Improper Shipping** | *i-STAT 1 System Manual –* Section “Quality Control” |  |
| **Reagents** | **Cartridge Reagent Degradation** | **Improper Storage** | *i-STAT 1 System Manual –* **Section “**i‑STATCartridge” *i-STAT 1 System Manual –* Section “Quality Control” |  |
| **Reagents** | **Cartridge Reagent Degradation** | **Used Past Expiration** | *i-STAT 1 System Manual –* **Section “**i‑STATCartridge”*i-STAT 1 System Manual –* **Section “Quality Control**”***TB:*** *Analyzer Coded Messages*  |  |
| **Reagents** | **Quality Control Material Degradation** | **Improper Shipping** | *i-STAT 1 System Manual –* **Section “**Quality Control” |  |
| **Reagents** | **Quality Control Material Degradation** | **Improper Storage** | *i-STAT 1 System Manual –* **Section “**Quality Control”  |  |
| **Reagents** | **Quality Control Material Degradation** | **Used Past Expiration** | *i-STAT 1 System Manual –* **Section “**Quality Control” |  |
| **Reagents** | **Quality Control Material - Inaccurate Preparation and Use** | **Procedure not followed for Preparation, Mixing, Use; Wrong VAS Used** | *i-STAT 1 System Manual –* **Section “**Quality Control”*i-STAT/DE User Guide*Value Assignment Sheets www.globalpointofcare.abbott |  |
| **Reagents** | **Calibration Verification Material Degradation** | **Improper Shipping** | *i-STAT 1 System Manual –* Section “Quality Control” |  |
| **Reagents** | **Calibration Verification Material Degradation** | **Improper Storage** | *i-STAT 1 System Manual –* **Section “**Calibration Verification” |  |
| **Reagents** | **Calibration Verification Material Degradation** | **Used Past Expiration** | ***i-STAT 1 System Manual -*  Section “**Calibration Verification”  |  |
| **Reagents** | **Calibration Verification Material - Inaccurate Preparation and Use** | **Procedure Not Followed for Preparation, Mixing, Use/ Wrong VAS Used** | ***i-STAT 1 System Manual -*  Section “**Calibration Verification”*TB:* i‑STAT ***Celite ACT and*** i‑STAT ***Kaolin ACT Heparin Linearity Procedure***Value Assignment Sheets www.globalpointofcare.abbott |  |
| **Reagents** |  |  |  |  |
|  |  |  |  |  |
| **Laboratory Environment** | **Atmospheric Environment** | **Improper Temperature** | ***i-STAT 1 System Manual -*  Section “**i‑STAT 1 Analyzer” ***i-STAT 1 System Manual -*  Section “**i‑STAT Cartridge”***i-STAT 1 System Manual -*  Section “**Electronic Simulator”***i-STAT 1 System Manual -***  Section “Quality Control”*i-STAT 1 System Manual –* Section “Troubleshooting the Analyzer”*TB: Analyzer Coded Messages* |  |
| **Laboratory Environment** | **Atmospheric Environment** | **Improper Humidity** | ***i-STAT 1 System Manual -*  Section “**i‑STAT 1 Analyzer”***i-STAT 1 System Manual -***   **Section “**Electronic Simulator”*TB: Analyzer Coded Messages* |  |
| **Laboratory Environment** | **Atmospheric Environment** | **Improper Barometric Pressure/ Altitude** | ***i-STAT 1 System Manual -*  Section “**i‑STAT 1 Analyzer” ***i-STAT 1 System Manual -***  Section “Quality Control” ***i-STAT 1 System Manual -***  Section “Calibration Verification” i-STAT 1 System Manual – Section “Proficiency or External Quality Control”*TB: Analyzer Coded Messages* |  |
| **Laboratory Environment** | **Atmospheric Environment** | **Dust and Debris** | ***i-STAT 1 System Manual -*  Section “**Procedure for Handling Cartridges”*i*-*STAT 1 System Manual –* Section “Troubleshooting the Analyzer”*TB: Analyzer Coded Messages* |  |
| **Laboratory Environment** | **Utility Environment** | **Inadequate Electrical Availability** | ***i-STAT 1 System Manual -*  Section “i-STAT 1 Analyzer”*****i-STAT 1 System Manual -*  Section “**i‑STAT 1 Downloader”*i-STAT 1 System Manual –* Section “Portable Printer” |  |
| **Laboratory Environment** | **Utility Environment** | **Radio Frequency Interference/ Electromagnetic Interference** | ***i-STAT 1 System Manual –* Section “Troubleshooting the Analyzer:*****TB:*** i‑STAT 1 Wireless Analyzer *Specifications**TB: Analyzer Coded Messages* |  |
| **Laboratory Environment** | **Utility Environment** | **Vibration/Motion**  | ***i-STAT 1 System Manual -*  Section “Procedure for Handling Cartridges”*****i-STAT 1 System Manual -*  Section “Procedure for Cartridge Testing”**CTI |  |
| **Laboratory Environment** | **Utility Environment** | **Not Testing on Flat/Level Surface** | ***i-STAT 1 System Manual –* Section “Procedure for Handling Cartridges”** ***i-STAT 1 System Manual -***  Section “Procedure for Cartridge Testing” *i-STAT 1 System Manual –* Section “Quality Control”*i-STAT 1 System Manual –* Section “Calibration Verification” *i-STAT 1 System Manual –* Section “Proficiency or External Quality Control”  |   |
| **Laboratory Environment** | **General Environment** | **Inadequate Airflow/ Ventilation** | *i-STAT 1 System Manual*: Section “i-STAT 1 Downloader/Recharger”*i-STAT 1 System Manual:* Section “Troubleshooting the Analyzer”*TB: Analyzer Coded Messages* |  |
| **Laboratory Environment** |  |  |  |  |
|  |  |  |  |  |
| **Measuring System** | **Sample Analysis/ Analytical Process**  | **Poor Precision** | CTI & IFUs | [-Type Natriuretic Peptide / BNP](https://www.abbottpointofcare.com/download?docUri=/static-assets/technical-documentation/716969-00L.pdf) [BUN/Urea](https://www.abbottpointofcare.com/download?docUri=/static-assets/technical-documentation/714176-00O.pdf) [Cardiac Troponin I/cTnI](https://www.abbottpointofcare.com/download?docUri=/static-assets/technical-documentation/715595-00U.pdf) [Celite ACT](https://www.abbottpointofcare.com/download?docUri=/static-assets/technical-documentation/714185-00P.pdf) [Chloride](https://www.abbottpointofcare.com/download?docUri=/static-assets/technical-documentation/714175-00N.pdf) [Creatine Kinase MB/CK-MB](https://www.abbottpointofcare.com/download?docUri=/static-assets/technical-documentation/716675-00N.pdf) [Creatinine](https://www.abbottpointofcare.com/download?docUri=/static-assets/technical-documentation/714183-00X.pdf) [Glucose](https://www.abbottpointofcare.com/download?docUri=/static-assets/technical-documentation/714177-00S.pdf) [Hematocrit](https://www.abbottpointofcare.com/download?docUri=/static-assets/technical-documentation/714178-00P.pdf) [Ionized Calcium](https://www.abbottpointofcare.com/download?docUri=/static-assets/technical-documentation/714179-00O.pdf) [Kaolin ACT](https://www.abbottpointofcare.com/download?docUri=/static-assets/technical-documentation/715878-00N.pdf) [Lactate](https://www.abbottpointofcare.com/download?docUri=/static-assets/technical-documentation/714184-00N.pdf) [PCO2](https://www.abbottpointofcare.com/download?docUri=/static-assets/technical-documentation/714182-00U.pdf) [PH](https://www.abbottpointofcare.com/download?docUri=/static-assets/technical-documentation/714181-00M.pdf) [PO2](https://www.abbottpointofcare.com/download?docUri=/static-assets/technical-documentation/714180-00L.pdf) [Potassium](https://www.abbottpointofcare.com/download?docUri=/static-assets/technical-documentation/714174-00M.pdf) [Prothrombin Time PT/INR](https://www.abbottpointofcare.com/download?docUri=/static-assets/technical-documentation/715236-00R.pdf) [Sodium](https://www.abbottpointofcare.com/download?docUri=/static-assets/technical-documentation/714173-00O.pdf) [Total Beta-Human Chorionic Gonadotropin (b-hCG)](https://www.abbottpointofcare.com/download?docUri=/static-assets/technical-documentation/730474-00_A.pdf) [Total Carbon Dioxide/TC02](https://www.abbottpointofcare.com/download?docUri=/static-assets/technical-documentation/716661-00G.pdf) [-Type Natriuretic Peptide / BNP](https://www.abbottpointofcare.com/download?docUri=/static-assets/technical-documentation/716969-00L.pdf) [BUN/Urea](https://www.abbottpointofcare.com/download?docUri=/static-assets/technical-documentation/714176-00O.pdf) [Cardiac Troponin I/cTnI](https://www.abbottpointofcare.com/download?docUri=/static-assets/technical-documentation/715595-00U.pdf) [Celite ACT](https://www.abbottpointofcare.com/download?docUri=/static-assets/technical-documentation/714185-00P.pdf) [Chloride](https://www.abbottpointofcare.com/download?docUri=/static-assets/technical-documentation/714175-00N.pdf) [Creatine Kinase MB/CK-MB](https://www.abbottpointofcare.com/download?docUri=/static-assets/technical-documentation/716675-00N.pdf) [Creatinine](https://www.abbottpointofcare.com/download?docUri=/static-assets/technical-documentation/714183-00X.pdf) [Glucose](https://www.abbottpointofcare.com/download?docUri=/static-assets/technical-documentation/714177-00S.pdf) [Hematocrit](https://www.abbottpointofcare.com/download?docUri=/static-assets/technical-documentation/714178-00P.pdf) [Ionized Calcium](https://www.abbottpointofcare.com/download?docUri=/static-assets/technical-documentation/714179-00O.pdf) [Kaolin ACT](https://www.abbottpointofcare.com/download?docUri=/static-assets/technical-documentation/715878-00N.pdf) [Lactate](https://www.abbottpointofcare.com/download?docUri=/static-assets/technical-documentation/714184-00N.pdf) [PCO2](https://www.abbottpointofcare.com/download?docUri=/static-assets/technical-documentation/714182-00U.pdf) [PH](https://www.abbottpointofcare.com/download?docUri=/static-assets/technical-documentation/714181-00M.pdf) [PO2](https://www.abbottpointofcare.com/download?docUri=/static-assets/technical-documentation/714180-00L.pdf) [Potassium](https://www.abbottpointofcare.com/download?docUri=/static-assets/technical-documentation/714174-00M.pdf) [Prothrombin Time PT/INR](https://www.abbottpointofcare.com/download?docUri=/static-assets/technical-documentation/715236-00R.pdf) [Sodium](https://www.abbottpointofcare.com/download?docUri=/static-assets/technical-documentation/714173-00O.pdf) [Total Beta-Human Chorionic Gonadotropin (b-hCG)](https://www.abbottpointofcare.com/download?docUri=/static-assets/technical-documentation/730474-00_A.pdf) [Total Carbon Dioxide/TC02](https://www.abbottpointofcare.com/download?docUri=/static-assets/technical-documentation/716661-00G.pdf)  |
| **Measuring System** | **Sample Analysis/ Analytical Process**  | **Poor Trueness/ Correlation with Laboratory Method** | ***i-STAT 1 System Manual -*  Section “Calibration Verification”*****i-STAT 1 System Manual -*  Section “Proficiency or External Quality Control”**CTI & IFUs |  |
| **Measuring System** | **Sample Analysis/ Analytical Process**  | **Interferences** | CTI & IFUs |  |
| **Measuring System** | **Sample Analysis/ Analytical Process**  | **Used Beyond Intended Use** | CTI & IFUs |  |
| **Measuring System** | **Sample Analysis/ Analytical Process**  | **Used Beyond Limitations for Use** | CTI & IFUs |  |
| **Measuring System** | **Sample Analysis/ Analytical Process**  | **Incorrect Analysis Mode** | ***i-STAT 1 System Manual -*  Section “**i‑STAT 1 Analyzer”***i-STAT 1 System Manual -***  Section “Calibration Verification”***i-STAT 1 System Manual -***  Section “Proficiency or External Quality Control |  |
| **Measuring System** | **Sample Analysis/ Analytical Process**  | **Incorrect Analyte Selected** | ***i-STAT 1 System Manual –* Section “**Customization”*i-STAT/DE* *Customization Workspace Guide*  |  |
| **Measuring System** | **Sample Analysis/ Analytical Process**  | **Incorrectly Programming Parameters** | ***i-STAT 1 System Manual -*  Section “**Customization”*i-STAT/DE* *Customization Workspace Guide* |  |
| **Measuring System** | **Sample Analysis/ Analytical Process**  | **Instrument Error**  | ***i-STAT 1 System Manual -*  Section “Troubleshooting the Analyzer”*****TB:*** *Analyzer Coded Messages*  |  |
| **Measuring System** | **Instrument Failure/ Analytical Process** | **Readout Device Failure** | ***i-STAT 1 System Manual -*  Section “Procedure for Cartridge Testing”** ***i-STAT 1 System Manual -*  Section “Routine Care of the Analyzer and Downloader”*****i-STAT 1 System Manual –* Section “**Troubleshooting the Analyzer” |  |
| **Measuring System** | **Instrument Failure/ Analytical Process** | **Loss/ Corruption of Data** | ***i-STAT 1 System Manual -*  Section “**i‑STAT 1 Analyzer”***i-STAT 1 System Manual -***   **Section “**Portable Printer”*i-STAT/DE User Guide* |  |
| **Measuring System** | **Instrument Failure/ Analytical Process** | **Electronic Components Failure**  | ***i-STAT 1 System Manual -***  Section “Electronic Simulator”***i-STAT 1 System Manual***  Section “Customization”***i-STAT 1 System Manual -***  Section “Quality Control”*i-STAT 1 System Manual –* Section “Troubleshooting the Analyzer”***TB:*** *Analyzer Coded Messages*  |  |
| **Measuring System** | **Instrument Failure/ Analytical Process** | **Electronic Components Failure - Dropped Device** | ***i-STAT 1 System Manual -*  Section “**Procedure for Cartridge Testing” ***i-STAT 1 System Manual -*  Section “**Quality Control”*i-STAT 1 System Manual –* Section “Troubleshooting the Analyzer”***TB:*** *Analyzer Coded Messages* |  |
| **Measuring System** | **Instrument Failure/ Analytical Process** | **Inadequate Battery Charge** | *i-STAT 1 System Manual -* **Section “i-STAT 1 Analyzer”** *i-STAT 1 System Manual -*  **Section “i-STAT Downloader/Recharger”*****i-STAT 1 System Manual –* Section “**Routine Care of the Analyzer and Downloader” ***i-STAT 1 System Manual –* Section “**Troubleshooting the Analyzer” ***TB:*** *Analyzer Coded Messages* |  |
| **Measuring System** | **Instrument Failure/ Analytical Process** | **Expired Software / Software Corruption** | ***i-STAT 1 System Manual –* Section “**Updating the Software”***i-STAT 1 System Manual –*** Section “Troubleshooting the Analyzer” ***TB:*** *Analyzer Coded Messages* |  |
| **Measuring System** | **Instrument Failure/ Analytical Process** | **Connectivity Software Failure** | ***i-STAT 1 System Manual -* Section “i-STAT 1 Analyzer”*****i-STAT 1 System Manual –* Section *“***i‑STAT 1 Downloader/Recharger” *TB: Procedure for using the i-STAT 1 Wireless Analyzer**i-STAT/DE User Guide*  |  |
| **Measuring System** | **Instrument Maintenance** | **Dirty Optics** | ***i-STAT 1 System Manual –* Section “**Routine Care of the Analyzer and Downloader” |  |
| **Measuring System** | **Instrument Maintenance** | **Contamination** | ***i-STAT 1 System Manual –* Section “**Routine Care of the Analyzer and Downloader” |   |
| **Measuring System** | **Instrument Maintenance** | **Scratches** | N/A |  |
| **Printer System** | **Instrument Failure** | **Inadequate Battery Charge** | ***i-STAT 1 System Manual –* Section “**Portable Printer” |  |
| **Downloader** | **Instrument Failure** | **Inadequate Result Transmission**  | ***i-STAT 1 System Manual –* Section *“***i‑STAT Downloader/Recharger”***i-STAT 1 System Manual –* Section “**Routine Care of the Analyzer and Downloader” *TB: Procedure for using the i-STAT 1 Wireless Analyzer**i-STAT DE User Guide*Refer to [www.globalpointofcare.abbott](http://www.globalpointofcare.abbott) for connectivity and data management options |  |
|  |  |  |  |  |

The material discussed within this document is for informational purposes only and not for the purpose of providing legal or regulatory advice.

Use of the information provided in this document is at your own discretion. Please contact your attorney and regulatory experts to determine the best approach for your lab.

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