



i-STAT® TECHNICAL BULLETIN

i-STAT 1 DOWNLOADERS CAUTION STATEMENTS

Introduction

This Technical Bulletin provides guidance on Caution statements provided in the i-STAT 1 System Manual as to where i-STAT 1 Downloaders and Downloader/Rechargers may be placed and what may be connected to them.

The specific Caution statements being addressed are:

- a) The Downloader and Downloader/Recharger are not intended for use in the patient environment (within 1.5 meters of the physical location of the patient) and
- b) Users should not connect the Downloader or Downloader/Recharger to a medical electrical system.

The information in this Technical Bulletin supersedes the information provided for these two Caution statements in the following sections of the i-STAT System Manual:

- 1) Section 6 – i-STAT Downloader (Art:714368-00F, Rev. Date: 03/03/2008)
- 2) Section 21 – Downloader Programming and Wiring (Art: 714383-00E Rev. Date: 03/03/2008)

Note: In this document, the phrase “i-STAT 1 Downloaders” applies to the following: the i-STAT 1 Serial Downloader, the i-STAT 1 Serial Downloader/Recharger, the i-STAT 1 Network Downloader, and the i-STAT 1 Network Downloader/Recharger.

Location of i-STAT 1 Downloaders

The i-STAT 1 Downloaders should not be installed within 1.5 meters of a patient environment¹ as defined in International Electrotechnical Commission 60601-1². The i-STAT 1 Downloaders should not be installed in such a way that it is possible for a healthcare provider to make physical contact with both the i-STAT 1 Downloader and a patient simultaneously or in such a way that a patient may make physical contact directly with an i-STAT 1 Downloader while connected to a medical electrical system³ as defined in International Electrotechnical Commission 60601-1.

Connection of i-STAT 1 Downloaders

The i-STAT 1 Downloaders should not be connected to a medical electrical system.

The i-STAT 1 Downloader’s network connection and serial port should not be connected simultaneously, except under the following circumstances:

- An i-STAT 1 Serial Downloader or i-STAT 1 Serial Downloader/Recharger may be connected to the serial port of an i-STAT 1 Network Downloader or an i-STAT 1 Network Downloader/Recharger.
- An Abbott Diabetes Care docking station used with the Precision PCx™ and/or Precision XceedPro™ hospital glucose instrument may be connected to the serial port of an i-STAT 1 Network Downloader or an i-STAT 1 Network Downloader/Recharger, provided the docking station is not connected to anything other than the i-STAT 1 Downloader.

¹From IEC 60601:

PATIENT ENVIRONMENT: any volume in which intentional or unintentional contact can occur between a patient and parts of the ME EQUIPMENT or ME SYSTEM or between a patient and other persons touching parts of the ME EQUIPMENT or ME SYSTEM.

²Complete title: International Standard 60601 Third Edition 2005-12– Medical Electrical Equipment Part 1: General requirements for basic safety and essential performance.

³ MEDICAL ELECTRICAL SYSTEM (ME SYSTEM): combination, as specified by its manufacturer, of items of equipment, at least one of which is MEDICAL ELECTRICAL EQUIPMENT to be inter-connected by functional connection or by use of a power outlet.

MEDICAL ELECTRICAL EQUIPMENT (ME EQUIPMENT): electrical equipment having a part that is intended to come into physical contact with a patient.

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