

Instructions for Use Addendum - English

This document is an addendum to your Flex Cardio Physiomonitring System *Instructions for Use*. Keep this document with your *Instructions for Use*.

- The following warnings related to the Flex Cardio have been added to the general safety section of your *Instructions for Use*.

WARNINGS: Do not turn the Flex Cardio device on and/or off while a patient case is open. Close the patient case prior to powering down. Open a patient case after the device is fully powered on. Failure to do so can result in a synchronization issue between the Flex Cardio device and the host system, resulting in a failure of system alarms.

The Flex Cardio device must communicate with its host system via an isolated, dedicated Ethernet port. When using the XDS host computer, ensure the Flex Cardio is connected to XDS computer's Ethernet port LAN 1. If the connection to the host computer is not an isolated, dedicated Ethernet port, communication issues can result in alarm and vital sign data delays.

- The following specifications related to ECG Signal Amplitude have been added to the Specifications section of your *Instructions for Use*.

Gain Settings

On Monitor Display:

Size: 19 in; Resolution: 1280 x 1024; Aspect Ratio: 5:4

Gain Setting	ECG Signal Amplitude (mm/mV)	Gain Setting	ECG Signal Amplitude (mm/mV)	Gain Setting	ECG Signal Amplitude (mm/mV)
50	9	1100	200	2100	380
100	18	1200	218	2200	396
200	35	1300	236	2300	418
300	54	1400	254	2400	436
400	72	1500	272	2500	452
500	89	1600	290	2600	470
600	108	1700	309	2700	485
700	127	1800	324	2800	508
800	146	1900	345	2900	526
900	163	2000	362	3000	545
1000	181				

In Print: At a 100 Gain Setting, a printed ECG waveform has an ECG Signal Amplitude of 10mm/mV $\pm 20\%$.

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