Deltex Medical
Terminus Road, Chichester
West Sussex, PO19 8TX
United Kingdom

Head Office: +44 (0)1243 774 837
Facsimile: +44 (0)1243 532 534
Customer Service: 0845 085 0001

Date: July 8, 2013
FSCA ID: 001

URGENT FIELD SAFETY NOTICE

Customer Name:
Facility:
Address:
Post Code:

Product: CardioQ-ODM/CardioQ-ODM+ Cardiac Function and Fluid Status Monitoring Systems

Product Sales Codes: 9051-7103, 9051-7104.

Concerns: Updated method for cleaning exterior surface of system monitor and accessories to ensure compatibility (MHRA Medical Device Alert MDA/2013/019).

Dear Customer,

Deltex Medical wishes to bring your attention to the following information, which has also been communicated to the Competent Authorities of your country.

Problem: The current method for cleaning the exterior surface of the CardioQ-ODM system monitor and accessories as described in the Operating Handbook is not a validated disinfection method.

Actions: To guarantee that you receive sufficient information to determine compatibility with our product Deltex Medical recommends the following cleaning method:

Monitor Cleaning

Deltex Medical recommends that CardioQ-ODM system monitors are cleaned at least once a month. It may be appropriate to clean the monitor more frequently depending on the environment in which it is used. The monitor must be switched off, and the power cord disconnected, before cleaning.

Deltex Medical recommends that the CardioQ-ODM system is cleaned with 1% Sodium Hypochlorite (Milton – 10,000ppm) solution. A damp soft cloth should be used.

The display window should be cleaned with a soft cloth dampened with the solution to avoid scratching the screen. Do not use solvents, or cleaners containing solvents. Care must be taken to avoid liquid cleaning solution entering the monitor.

The monitor case, including the rear panel, knobs and buttons, may be cleaned with a soft cloth dampened with the solution. Solvents must not be used. Care must be taken when cleaning the air vents to prevent fluid entering the unit. Care must be taken to avoid liquid entering the connector sockets.
As with any electronic equipment the monitor must not be immersed in liquid nor should any liquid be allowed to enter the unit.

The Patient Interface Cable may be cleaned using a soft cloth dampened with the cleaning solution. Under no circumstances should the ends of the cable be immersed in the solution. Deltex Medical does not recommend sterilization of the monitor or cable.

Please distribute this information within your facility to all those who need to be aware of it.

Please complete the feedback form as soon as possible and return it to us.

Should the above information not apply to your facility or should the device have been transferred to another hospital, please be so kind as to indicate this on the attached feedback form and pass this Field Safety Notice to the hospital where the device has been transferred.

We apologise for the inconvenience we have caused and we thank you for your careful attention to this issue and your continued support.

If you have any questions about this matter, please contact me.

Sincerely,

Lawrence Brookfield
Regulatory Affairs Manager
Tel. No. +44 (0) 1243 774837.

URGENT SAFETY NOTICE

We kindly ask you to fax or email back the attached information as soon as possible.
Thank you for your co-operation.

Deltex Medical
Terminus Road, Chichester
West Sussex, PO19 8TX
United Kingdom

Head Office: +44 (0)1243 774 837
Facsimile: +44 (0)1243 532 534
Customer Service: 0845 085 0001

Customer/Facility Name:	<Customer _Name_Facility_Site>
Address:	<Street_Address>
	<City_State>
Post Code:	<Post Code_Zip Code>

Notice Reference: Previously recommended method of cleaning system monitor and accessories in Operating Handbook updated to fully meet the requirements of MHRA Medical Device Alert (MDA/2013/019).

Product Reference: CardioQ-ODM/CardioQ-ODM+ Cardiac Function and Fluid Status Monitoring System, Product Sales Codes: 9051-7103, 9051-7104

☐ I confirm that I have received and understand the attached notice.

☐ This notice does not apply to my facility.

☐ The system has been transferred to another hospital.

Customer:

Name:	
Position:	
Signature:	
Date:	
Tel. Number:	

☐ Please correct our contact information as follows:

Customer/Facility Name:	
Address:	

Fax this completed form to <fax no.>
or email us on < email address> indication the reference code above in the subject line