

Safety information Failure of acoustic alarm for deltastream MDC, i-cor and iLA active consoles

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To all users of the deltastream MDC, i-cor and iLA active consoles.

In this letter we would like to draw your attention to a problem, which may occur with the drive consoles listed below. At the same time, we also want to inform you about our planned corrective measures.

Affected consoles

Product number Designation Series numbers

ME MDC 0001	deltastream MDC console	from SN MDC001-MDC207
4000104	iLA active console	from SN iLA001-ILA192
5000001	i-cor console	from SN ICOR001-ICOR020

Description of problem

The loudspeaker of the aforementioned consoles may fail upon activation of the alarm as a result of a technical fault with the diaphragms (cones). In this case no acoustic alarm is emitted. The simultaneous visual alarm display is output and is not affected by the fault. The fault may occur during system start-up (self-test), but also during therapy.

In this context, we would like to draw your attention once again to the safety notices in the instruction manual:

- The user is responsible for checking the visual and acoustic signalling device during the start-up test.
- In the case of notices and alarm signals on the console, the corresponding display must always be checked and assessed and the patient must be monitored.
- During therapy with an extracorporeal circulation machine, the vital parameters of the patient must be monitored.
- The operating position is in front of the console. The console must be positioned so that the user has access to the operating elements at all times and can see the display elements. Ensure that you can see the visual alarm displays at all times.
- The condition of the pump and the extracorporeal circulation machine must be monitored constantly.
- The product may only be used upon instruction from a physician and under medical supervision and only by suitably qualified and trained personnel (e.g. perfusionist/specialist nurses and critical care staff). For patient safety reasons the operation of the product requires continuous monitoring by the aforementioned personnel.

Non-intended use of the device:

- Improper commissioning
- Operating the equipment with faulty safety devices.

In order to ensure safe handling of the console, the user must observe the aforementioned safety notices, as well as perform the following additional checks.

Necessary measure for checking the loudspeaker

Proceed as follows:

- Start the console.
- Remove the left battery according to the instruction manual.
- Wait 3 seconds. An alarm message appears "Error 304 Left battery not detected" and a short acoustic signal is emitted.
- Repeat this test daily for clinical applications in order to check the loudspeaker.

In the event of a **malfunction** with the console during the start-up of the system, the console **cannot be put into operation**. Please direct any questions you may have to our Customer Service department:

Customer Service +49 7131 2706 133

Notice!

Please do not hesitate to contact us should you have any other questions in relation to this safety information and the recommended measure.

Please ensure that all affected individuals within your organisation or other related organisations are informed about this safety information.

In any event, the Technical Service department of Xenios AG will contact you promptly in order to discuss a replacement or repair of the respective loudspeaker.

Please confirm receipt of this safety information by returning the completed Enclosure A of this safety information.

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Heilbronn, 09.02.2016



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