

Field Safety Notice

Battery packs for deltastream MDC console and iLA active console

Manufacturer: MEDOS Medizintechnik AG
Obere Steinfurt 8-10
52222 Stolberg
Germany

To all Users of deltastream MDC console and iLA active console

We are writing to inform you on a specific problem which may affect the battery packs of our consoles. At the same time we would like to provide you an adequate corrective measure.

Concerned Battery Packs

Ref. No.	Description	Serial No. Battery Packs
ME MDC 0008	Battery Pack deltastream MDC	SN 00030 until SN 00381
4000216	Battery Pack iLA active	SN 00030 until SN 00381

Problem Description

The battery packs of the deltastream MDC console and iLA active console with above named serial numbers might have been exposed to a temperature of 0 °C or lower during transportation to your hospital. In consequence the battery packs might have been locked due to unsuitable temperature conditions. When switching to battery power supply, this could result in a breakdown of the console even though fully charged battery packs have been displayed and without prior warning by the console.

In order to ensure a safe application of your console, the proper function of all concerned battery packs must be tested immediately. Make sure that during transportation and storage the temperature range (5 °C to 40 °C) as indicated in the Instructions For Use is always guaranteed.

Required Measure: Testing of the Battery Pack

The procedure is as follows:

- The backup drive has to be directly connected to the battery pack.



Picture 1:

The backup drive directly connected to the battery.

- Start the backup drive
- Adjust speed to 3000 rpm

The battery is functional when the backup drive is working properly and the set speed is reached.

In case of any **malfunction** of the battery pack(s) **do not use** the console.
In this case please contact immediately the respective hotline:

Medos +49 700 666699 – 66

Novalung +49 700 6682 5864

Important Note!

A check of the battery by pressing the status bar indicator is **NOT** sufficient to check the battery pack for proper function.

The battery packs of consoles in operation likewise have to be tested and, if applicable, to be changed against fully functioning battery packs. For testing during operation an effective main power supply is an indispensable precondition.

Please contact us in case you have any further question to this field safety notice or the suggested measure.

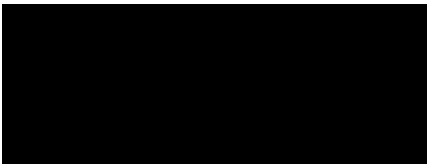
However, for exchange or repair of the battery packs our Technical Service will contact you timely in order to coordinate either exchange or repair of the affected battery packs.

This field safety notice needs to be passed on all those who need to be aware about the above described problem within your organization or any other concerned organization.

Please confirm the receipt of this field safety notice by returning the filled in attachment A until **Dec. 18th, 2014** to the contact named below.

Contact: Dr. Torsten Rinne
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Stolberg, December 12th, 2014



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