

FIELD SAFETY NOTICE

(date)

REMINDER:

Recommended replacement cycles of consumable parts of Merivaara beds, specifically batteries

Dear Customer,

We would like to remind you that the maintenance of health care equipment is very important. We have been made aware of two incidents where neglecting recommended replacement cycles of consumable parts have led to malfunctions that compromise the safety of the beds.

The incidents have been associated with the battery that reached the end of its useful life. Both incidents have happened with Carena hospital bed. Recommended replacement cycle for the battery is four years in normal use, and three years for machine washable Carena bed. As indicated in warranty terms, Merivaara gives one year warranty for batteries.

The incidents we have been made aware of, have been associated with the battery unit (TBB) manufactured by TiMotion. TBB was used in Carena hospital beds manufactured before September 2013.

In both cases the malfunction has caused internal burning inside the battery unit. This was noticed as smell of smoke in a room. Fire brigade was called to investigate the root cause in both cases. As materials used in battery are incombustible, internal burning of the battery was not visible (no flames or smoke), but battery unit was heated. In both cases, the source of smell was not detected visibly. When room was investigated with heat sensor gun, battery of the bed was detected to be heated.

If the internal burning would continue inside the battery, there would finally be deformation of battery covers due to melting and carbonizing.

When defected battery was investigated by the component manufacturer, it appeared that battery cell leaked to PCB (Printed Circuit Board) causing short-circuit inside the battery. This was possible in battery model TBB manufactured before 9/2013, as components (battery cells and PCB) inside the battery were not isolated from each other.

TiMotion improved the battery unit properties and launched TBB4 -battery in 2013. In TBB4, the new design fully separates battery from the PCB and prevents short-circuit due to liquid leaking in any circumstances. Merivaara has not received information of similar defects with the new type of battery (TBB4).

Merivaara started to use TBB4 from serial number 130927-114852 onwards.

We kindly ask you to pay attention to recommended replacement cycles of consuming parts, and appropriately carrying out the service activities defined by the manufacturer. If malfunctions are noticed, units must be repaired without delay in order to ensure operation and patient safety.

If spare parts are needed during your service activities, our Service Department will gladly assist with selecting and recommending the correct spare parts. For new batteries, please contact your local Merivaara representative for an offer.

For more information:
service@merivaara.com

With kind regards

Jyrki Nieminen
Director of R&D
Merivaara Corp.

Emilia Lempiäinen
Quality Manager
Merivaara Corp.

FIELD SAFETY NOTICE, ATTACHMENT 1

Confirmation of receipt

We kindly ask you to return filled form to service@merivaara.com:

Name of the hospital / clinic:	
Name of the contact person:	
Title:	
Phone:	
E-mail:	
Address:	

I confirm the receipt of Field Safety Notice

Date

Name and signature