

Urgent Field Safety Notice (FSN)

Replacing the power supply unit
for care beds in the Ecofit Xtra range

17.06.2024

Responsible for implementation on the manufacturer side: Robin Knabe (Managing Director)

1. Information on Affected Devices

Product name	Sizes	Catalogue numbers	Serial numbers
Ecofit Xtra 120	120x200cm	BE 28005 or 00400	All serial numbers from 21 0000000000 to 23 9999999999
Ecofit Xtra 140	140x200cm	BE 29006 or 00401	

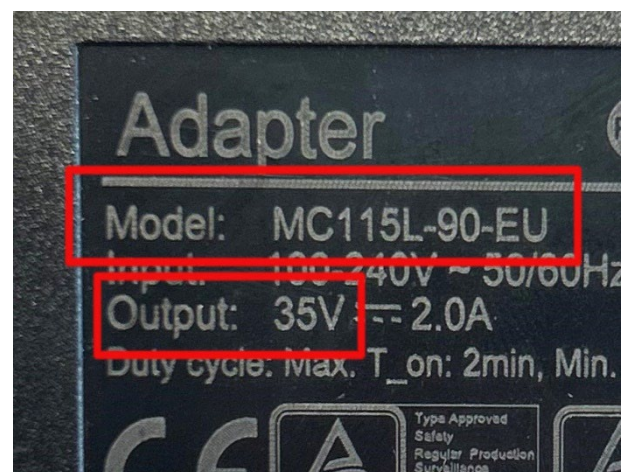
2. Reason for Field Safety Corrective Action

Dear Customer

As part of our ongoing commitment to quality and safety, we would like to inform you of an important preventative measure we are taking with regard to our care beds in the Ecofit Xtra range.

Identification of the medical devices concerned:

This only applies to Ecofit Xtra care beds with the built-in power supply unit **MC 115L-90-EU** (manufacturer limoss GmbH) and an output voltage of **35V**. The attached list shows the serial numbers of all products (see cover sheet) for which the power supply unit needs to be replaced.



Description of the product problem including the identified cause:

In ongoing tests by an external test institute, it was determined that there is a possibility of exceeding the standardized limit value for conducted emissions. This can occur in load scenarios of a high load in the range of the maximum patient weight.

To date, we have not received any reports from our customers that problems have occurred during the use of our beds.

However, risks that could be triggered by conducted emissions cannot be completely ruled out. The recommended measures are therefore taken as a precautionary measure to rule out any risks.

The risks mentioned could be malfunctions of neighbouring electronic devices / systems during the vertical movement of the mattress base under high load.

In order to fully ensure that the limit values are complied with at a safe working load, we have developed a new power supply unit in collaboration with our supplier. We have switched the production of current beds to the new power supply unit in the meantime and have only been supplying you with new products in an updated design since 15th of April 2024.

3. Type of Action to mitigate the risk***Measures to be taken by the customer:***

Please replace the MC115L-90-EU power supply unit with the PS1102 power supply unit provided free of charge by tecfor care for care beds from the Ecofit Xtra range in your inventory or during the next maintenance. Instructions for replacement can be found in the appendix to this letter.

There have been no incidents with a care bed from the Ecofit Xtra-serie in conjunction with the MC115L-90-EU power supply unit. If you have used an Ecofit Xtra care bed in combination with an invasive ventilator and the invasive ventilator is not equipped with an emergency battery or alarm system, the power supply unit must be replaced immediately.

Due to the very low risk of injury, there is no need to replace the care bed immediately for all other combinations between the care bed and other electrical devices. However, the deadline for implementing the measure is 30th April of 2026.

Measures taken by the manufacturer:

- 1) We are issuing this safety information as a precautionary measure to draw the attention of users and operators of our heavy-duty care beds in the Ecofit Xtra range to the fact that, if the care bed is subjected to a high load in the range of the permissible patient weight, conducted emissions above the standardised limit values could occur, which could affect other electrical appliances.
- 2) We have identified the cause. A modified power supply unit (model PS1102 (35V)) is installed in new care beds. Together with the care bed and a load of 390kg, it has been tested several times by an accredited test laboratory under the most unfavourable conditions and does not exceed the limit values.

Transmission of this Field Safety Notice

Please ensure that all users of the above-mentioned products within your organization and other necessary persons are made aware of this Urgent Field Safety Notice. If you have supplied the products to third parties, please forward a copy of this information or inform the contact person specified below.

Please keep this information until the action has been completed.

The Federal Institute for Drugs and Medical Devices has received a copy of this "Urgent Field Safety Information".

Contact person:

Mr. J. Feer

Quality management representative of tecfor care GmbH

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Place, date: Gummersbach, 17.06.2024



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ANNEX:**Instructions: Replacing the power supply unit**Scope of delivery:Description:

Plug-in power supply SMPS - PS1102
200-240V, 50-60Hz, 2,4A, IPX6
Model number: 503605

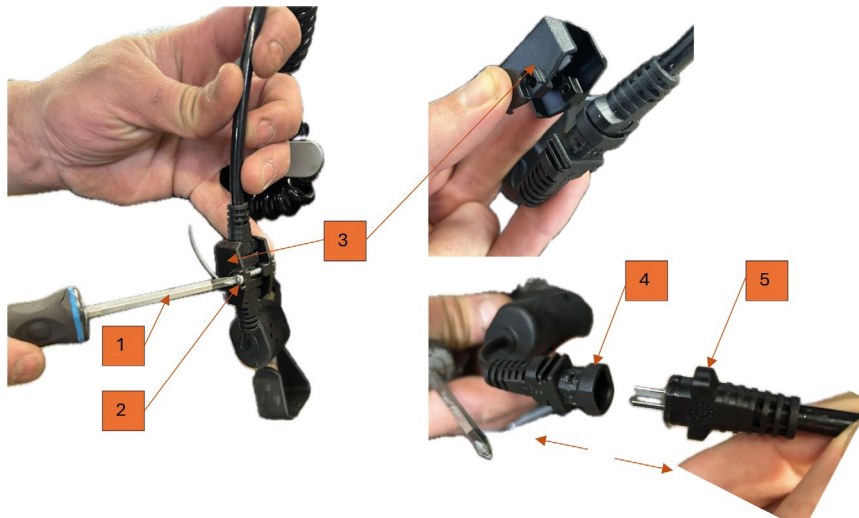
To replace the power supply unit, please follow the instructions below:

Dismantling:

Disconnect the power supply unit from the mains before replacing it.



1. To remove the previously installed power supply unit, use a screwdriver (1) to loosen the screw (2) on the safety cap of the plug connection.
2. You can then remove the protective cap (3) with little effort.
3. Now release the plug connection (4+5) by pulling in the opposite direction.

Assembly:

1. Take the new plug from the scope of delivery and fit it in the opposite direction as described in the "Disassembly" section.
2. Once steps 3-1 have been carried out, the power supply unit is ready for use and can be reconnected to the mains supply.