

Urgent Field Safety Notice (FSN)

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

17.06.2024

Responsible for [REDACTED] (Managing Director)
implementation on the
manufacturer side:

1. Information on Affected Devices

Product name	Sizes	Catalogue numbers		Serial numbers
Ecofit S	80x200cm, 90x200cm 100x200cm 120x200cm	00100 00102 00105 00106 00108 00109 00110 00111 00113 00116 00117 00120 00123 00125 00126	BE 30001 BE 30006 BE 30120 BE 30122 BE 30017 BE 30018 BE 30010 BE 30022 BE 30004 BE 30011 BE 30012 BE 30121 BE 32000 BE 32002 BE 32003	All serial numbers from 21 0000000000 to 23 9999999999
Ecofit S Low	80x200cm, 90x200cm 100x200cm 120x200cm	00200 00207 00210 00212	BE 30200 BE 30209 BE 30208 BE 30206	
Ecofit S Plus	90x200cm	00124 00903 00918	BE 32001 BE 30100 BE 30111	
Ecofit S Low Plus	80x200cm, 90x200cm	00203 00907 00908	BE 30102 BE 30103 BE 30104	
Ecofit Plus	90x200cm	00900 00916 00922	BE 20002 BE20000 CN BE 20001	
Ecofit Plus Low	90x200cm	00912 00920	BE 20010 BE 26005	
Ecofit S Comfort	90x200cm	00103 00115	BE 30015 BE 30008	

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 range.

Identification of the medical devices concerned:

This only applies to Ecofit 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 test by an external test institute, it was determined that there is a possibility of exceeding the standardised limit value for conducted emissions. This can occur in load scenarios over 185kg. 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 full load.

Our tests have shown that with a load below 185kg, the products comply to the required limit values.

In order to fully ensure that the limit values are also complied with at a safe working load of 220kg, we have developed a new power supply unit in co-operation 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 1st March 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 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-serie in conjunction with the MC115L-90-EU power supply unit. If you have used an Ecofit S care bed on a patient weighing over 150kg 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 care beds in the Ecofit range to the fact that if the care bed is loaded with 185kg or more, conducted emissions above the normative 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 220kg, it has been tested several times by an accredited test laboratory under the most unfavourable conditions to be assumed 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 Notice".

Contact person:

Mr. J. Feer

Quality management representative of tecfor care GmbH

Telephone: +49 2261 50186 – 29

Mail: jfeer@tecfor-care.com

Place, date: Gummersbach, 17.06.2024

ANNEX:**Instructions: Replacing the power supply unit**Scope of delivery:Description:**Plug-in power supply SMPS - PS1102**

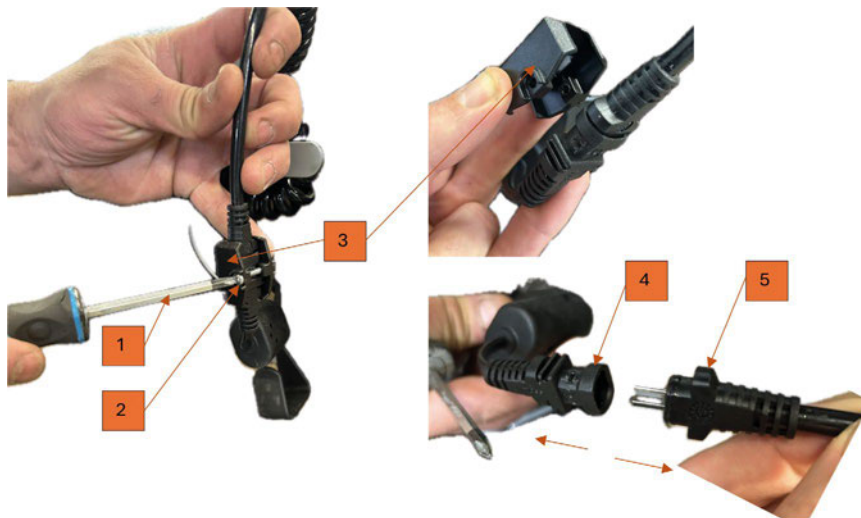
200-240V, 50-60Hz, 2,4A, IPX6

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.