

Bad Ems, 03. November 2014

Important safety notice: Field Safety Corrective Action

LeoniPlus: replacement of the membrane keypad

Dear Sir or Madam,

Quality and safety are our utmost priorities. That is why it is important to us to implement the following field safety corrective action for the LeoniPlus ventilator

Sender:

Heinen + Löwenstein GmbH & Co. KG, Arzbacher Strasse 80, 56130 Bad Ems

Addressees:

Users and operators of LeoniPlus ventilators

Identification of the medical devices concerned:

Article number	Name	Serial numbers
0217004	LeoniPlus with HFO	Up to 0217004hul4450 1179
0217001	LeoniPlus	Up to 0217001hul30200 368

Description of the problem including the cause identified:

In rare occasions, where contrary to the instruction for use the display is cleaned with liquids instead of wiping with an approved cleaning agent, ingress of such liquids may lead to malfunction of the keypad. The malfunction can be identified as a permanent or a missing function of the keys.

Measure for customers / operators:

In order to ensure the greatest possible degree of patient safety, devices which are used for life-support ventilation among critical patients have priority and will be corrected as quickly as possible.

- Please verify prior to every use of the LeoniPlus ventilator the proper function of the keys on the keypad. In case of a malfunction of the keypad the LeoniPlus must not be used, please inform the technical service promptly. The replacement is free of charge. For further information please refer to annex C.
- In general, remove any residual moisture from the device.
- During the annual service, all LeoniPlus devices must be equipped with a sealed keypad which prevents the ingress of moisture. The replacement of the keypad must be confirmed by the service technician using the form given in annex B. The keypad is integral part of the service kit at no additional charges.

- Please ensure that this safety information is brought to the attention of all users of the above-mentioned products and other people to be informed in your organization. If you have passed these products on to third parties, please forward a copy of this information on to them or inform the point of contact given below.
- Please confirm receipt of this correspondence by returning the enclosed reply form annex A.

Contact:

Please don't hesitate to contact us directly; of course we are at your disposal for any questions. If necessary, contact your Area Manager or our local technical service.
For general technical support in Germany use-mail: customerservice@hul.de

Yours sincerely,

Heinen + Löwenstein GmbH & Co. KG



Jens Schmidt
Quality Management and Regulatory Affairs

Annex A

Reply to Heinen + Löwenstein GmbH & Co. KG
Regarding the FSCA "LeoniPlus keypad"

Annex B

Reply to Heinen + Löwenstein GmbH & Co. KG
Replacement „LeoniPlus keypad“ during annual service

Annex C

Check keypad

Reply to Heinen + Löwenstein GmbH & Co. KG Regarding the FSCA "LeoniPlus keypad" dated 24.10.2014

The original letter was sent to:

Please return this completed reply form by fax, e-mail or post to:

Fax: +49 2603 96 00 1890
e-mail: vigilance@hul.de

Heinen + Löwenstein GmbH & Co. KG
Qualitätsmanagement
Arzbacher Strasse 80
56130 Bad Ems
Germany

Please complete in block capitals:

- Company details are the same as the above address field
- Company details are different from the above address field. The company details are as follows:

Your customer number: _____

Company and address: _____

- I hereby confirm receipt of this safety information further confirm that I have read and understood its content. This letter has been brought to the attention of all users of the product and other people to be informed in my organization. Where we have passed on these products to third parties, a copy of this letter has been forwarded to them.

Date, signature

Name (in BLOCK CAPITALS)

Position (in BLOCK CAPITALS)

e-mail (in BLOCK CAPITALS)

Annex B

**Reply to Heinen + Löwenstein GmbH & Co. KG
Replacement „LeoniPlus keypad“ during annual service**

Heinen + Löwenstein GmbH & Co. KG · Arzbacher Str. 80 · D-56130 Bad Ems
(Fax back the completed form to: +49 2603 9600 1890 or confirm online via
www.hul.de/FSN1)

In my responsibility as qualified service technician, I herewith confirm the completion of the corrective measure replacement of the keypad as indicated in the instructions for the following device:

Device: LEONI PLUS, Serial Number: _____

Replacement date: _____

Location of the device: _____

Name of the technician: _____

Country: _____

The signee confirms the replacement of the keypad and that the device did not show any abnormalities during test run.













Date


Signature

Verify the proper functioning of the keypad



Use hard keys on keypad to verify the following functions:

Hard key		Expected response
	ON/OFF	<ul style="list-style-type: none"> ▪ Switch on the device
	START	<ul style="list-style-type: none"> ▪ Open the start screen
	Mode	<ul style="list-style-type: none"> ▪ Position the selection frame on the ventilation mode IPPV
	START	<ul style="list-style-type: none"> ▪ Start ventilation
	Manual breath	<ul style="list-style-type: none"> ▪ Trigger a manual breath by holding the hard key pressed until it stops automatically ▪ Stop a manual breath by releasing the button
	Pause	<ul style="list-style-type: none"> ▪ Start a ventilation pause
	START	<ul style="list-style-type: none"> ▪ Stop a ventilation pause early
	Loops	<ul style="list-style-type: none"> ▪ Open the loop window ▪ Place a selection frame in the loop window ▪ Close the loop window
	Charts	<ul style="list-style-type: none"> ▪ Open the charts window resp. place a selection frame in the charts window
	Alarm limit values	<ul style="list-style-type: none"> ▪ Open the alarm limit values window ▪ Place a selection frame in the alarm limit values window ▪ Close the alarm limit values window
	Monitoring	<ul style="list-style-type: none"> ▪ Toggle to the second numeric table ▪ Toggle to the first numeric table
	Alarm mute	<ul style="list-style-type: none"> ▪ Switch alarm sound to mute ▪ Switch alarm sound on

 *The device may not be put into operation if any hard key does not respond as expected! Pay special attention to a sustained activation of a pressed hard key when only short time pressed. In this case contact Heinen + Löwenstein Service.*