

FIELD SAFETY CORRECTIVE ACTION

Laerdal Medical FSCO Number: 2016-R-01

Date: 27 September 2016

Laerdal Suction Unit

Actions to ensure continued compliance with ISO 10079-1

In order to ensure that your Laerdal Suction Unit (LSU) is in compliance with ISO 10079-1¹, one of the following actions described as Option 1 and Option 2 below must be taken.

Please read the below information carefully and report back to Laerdal on the attached *Customer Response Form* within three weeks.

Option 1: Where the LSU is Not Stored or Installed in Cold Temperatures - Re-label the LSU with revised conditions at which the LSU can be stored and installed before operation

Choose this option if your LSU is NOT stored or installed in conditions where the core temperature of the NiMH battery may cool to below 12 °C (54 °F) immediately before use.

Examples of such use includes hospitals, home healthcare, heated ambulances etc.

If this is the case, you may continue to use the LSU without any changes to the unit. In order to inform end-users of the LSU about the limitation in operating conditions, we ask you to re-label your LSU with the revised operating conditions 12 °C to 40 °C (54 °F to 104 °F).

To re-label your LSU, a new Operating Conditions label provided by Laerdal Medical is required. When labelled according to these instructions, the LSU complies with ISO 10079-1 without need of any further actions.

If you decide to re-label your LSU with revised operating conditions – please complete Section 1 of the Customer Response Form.

In the response form, we ask you to specify the number of LSU units that are currently in use, so that Laerdal Medical may provide you with a suitable number of labels.

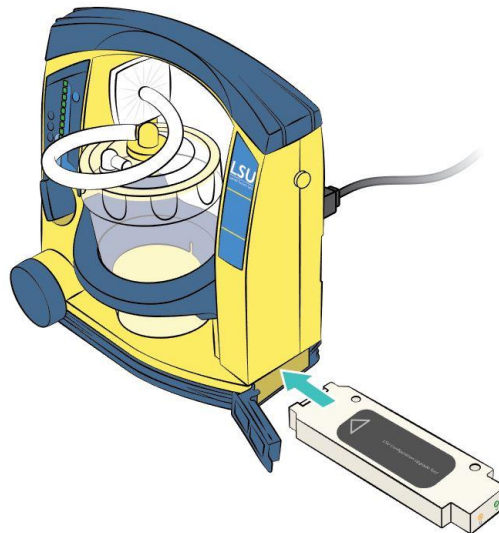
¹ ISO 10079-1 Medical suction equipment — Part 1: Electrically powered suction equipment — Safety requirements

Option 2: Where the LSU May Be Stored or Installed in Cold Temperatures - Change LSU configuration setting to ensure use in the full temperature operating range

Choose this option if your LSU is stored or installed at low temperatures at prolonged periods, i.e., in conditions where the core temperature of the battery is likely to be between 0 °C and 12 °C (32 °F to 54 °F).

If this is the case, the configuration of the LSU should be changed so that it can be used in the full operating range of 0 °C to 40 °C (32 °F to 104 °F).

To change the LSU configuration setting, a tool from Laerdal Medical is required. This is a 'do-it yourself' tool that is simple and intuitive to use, can be used to change the configuration of multiple units, and will be provided free of charge. The configuration change will take less than a minute.



If you decide to change the configuration of your LSU, please complete Section 2 of the Customer Response Form.

In the response form, we kindly ask you to specify the number of LSU units that are currently in use, so that Laerdal Medical may provide you with a suitable number of Configuration Change Kits.

After Laerdal Medical has received the completed Customer Response Form, you will receive a Configuration Change Kits, including instructions on how to use the tool, and copies of the revised Directions for Use. You will be asked to report to Laerdal to confirm that the configuration has been changed.

When the configuration is changed, LSU is in compliance with ISO 10079-1.