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PACIFIC MEDICO

URGENT - Field Safety Notice

PMH7000 series Heated humidifiers
Reference of FSCA: DT026-2017
Reference of FSN: PMFSN0002

To the attention of:	Intensive Care Unit Managers and Staff, Electrical Medical Equipment Technicians
Date of issue:	19 January 2018
Product Codes:	7000000, 7000002, 7000003, 7000007, 517106, 517115, 517146, 517152, 517154, 517158
Serial Numbers:	All Serial Numbers

Reason for this Field Safety Corrective Action:
The humidifier model PMH7000 series are not equipped with a water deficiency detection alarm. We have received two case reports from one hospital in Germany where the devices were used after the water in the chamber had been used up and the chamber was empty for a long period of time. Although the incidents did not result in any harm to the patients, in order to minimise potential hazard for patient health due to exposure to dry air, Pacific Medico have decided to take the following action.

Description of Corrective Action:

- Our local Distributor will arrange an urgent visit to distribute this FSN form and replace the existing IFU with a revised version which includes details of the requirement for the regular checking of the water levels in the humidification chamber.
  The IFU (page 5-6) will be modified to include the warning:

  *" ***NEW*** ● **WARNING !** Please keep watching and checking the water level in the humidification chamber."*

- If you are prepared to use the device under the guidance of the updated IFU, continue using the device. Please contact the local Distributor for software update. The new software will enable water deficiency detection alarm and will be available in 6 months.
- Tentative version of software with restriction can be offered in 1.5 months. This will be limited to therapies that use flows of 30l/min and above. If the restricted software limits your use of the humidifier and you are prepared

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to continue using the device whilst regularly monitoring the water levels as per the above warning, please indicate this on the response form.

- If you are not prepared to use the device under the guidance of the updated IFU, please stop using the device. Please contact the local Distributor who will either collect it from you and arrange a full credit or will provide a replacement device with the alarm detection function, once this updated version is available.
- Please make sure all users of the PMH7000 Humidifier in your facility are made aware of the updated instructions, and specifically with the requirement to regularly check and maintain the water levels within the humidification chamber.
- Please confirm receipt of this FSN by completing the attached response form with details of the serial numbers of any affected units in your facility.

Transmission of this Field Safety Notice

Please distribute this notice to any potential users of the PMH7000 Humidifiers in your facility.

The undersigned confirms that the appropriate Regulatory Agency has been notified of this action.

Yours sincerely,

Yuichiro Hayashi
General Manager, Quality Assurance
Pacific Medico Co., Ltd.

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URGENT - Field Safety Notice
Customer Response Form

PMH7000 series Heated humidifiers
Reference of FSCA: DT026-2017
Reference of FSN: PMFSN0002
Product Codes: 7000000, 7000002, 7000003, 7000007, 517106, 517115, 517146, 517152, 517154, 517158

Please complete the feedback form as relevant and fax or email it back to Mr. Satoshi Amano, Satoshi.Amano@pacific-medico.com

Customer /Facility Information:
Hospital Name:
Hospital Address:
Quantity of Affected Devices:
Serial Number(s):

Confirmation of Field Safety Notice:

☐ I confirm that this facility has received updated IFU and agree to one of the following options:

- ☐ I will use the device under the updated IFU guidance and agree to one of the following options:
  - ☐ I do require the limited software
  - ☐ I do not require the limited software option and will wait for the final software
- ☐ I will stop using the device

☐ I confirm that no devices are in use at our facility

Name:
Position:
Signature:
Date (yyyy-mm-dd):
Phone number / e-mail address: