

Field Safety Notice

PMH7000 series Heated humidifiers

Reference of FSCA: DT026-2017

Reference of FSN: PMFSN0004

To the attention of: Intensive Care Unit Managers and Staff, Electrical
Medical Equipment Technicians

Date of issue: November 24th, 2020

Product Codes: 7000000, 7000002, 7000003, 7000007, 517106,
517115, 517146, 517152, 517154, 517158

Serial Numbers: All serial numbers

Reason for this Field Safety Corrective Action:

Pacific Medico had been working for this corrective action since 2018. Pacific Medico was merged by a Japanese company IMI Co., Ltd. on 1st October 2020, and the corrective action was taken over by IMI Co., Ltd.

Company Profile

Company Name	IMI Co., Ltd.
Date of Establishment	May 16, 1974
Representative	Hideki Yokoyama, President & CEO
Head Office	3-3-12 Ryutsu-danchi, Koshigaya-shi, Saitama, Japan
Zip code	343-0824
Person in charge	Satoshi Amano
Email	amanos.qlo@imimed.co.jp

This Field Safety Corrective Action update has been raised to inform users that due to time and regulatory limitations, IMI Co., Ltd. is unable to further develop a water-out alarm for the PMH7000. This update is intended to close the FSCA DT026-2017.

The corrective action detailed below is intended to amend and supersede the preceding corrective actions DT026-2017 (Field Safety Notices PMFSN0002 and PMFSN0003).

Description of Corrective Action:

As described above, IMI Co., Ltd. no longer intend to offer a water-out alarm upgrade to the users.

If you purchased a PMH7000 humidifier before November 2018, your facility has already received FSN (PMFSN0002) informing you of the risks of not checking and maintaining the water level in the humidification chamber during use. If you have responded to this FSN, you have also previously confirmed that your facility is prepared to continue to use the humidifier in line with this guidance.

In addition, IMI Co., Ltd. and the local distributors confirmed that most of the users have been using PMH7000 with Firmware version 1.63 by regularly checking the water levels in the humidification chamber for more than two years, including during the recent COVID-19 pandemic. We and our local distributors have not received any complaints regarding the missing water-out alarm with Firmware version 1.63.

Some of the users have also been using PMH7000 with Firmware version 1.70 for over 6 months without issue and with an understanding of the risk of the false positive error.

Our local distributor will arrange a contact with the users to distribute this FSN and collect the Customers Response Form.

IMI Co., Ltd. will ask the users to respond to this FSN by filling out the Customers Response Form to confirm:

- Which version of the firmware the users are using, version 1.70, or the previous version 1.63.
- If the users will accept the risk of false positive alarms with version 1.70, or if the users will accept that the water in the humidification chamber will require regular visual monitoring with the version 1.63

User Actions:

- Please confirm receipt of this latest FSN by completing the attached response form with details of the serial numbers and current software version of any affected units in your facility.

Note: The software version of your device is displayed on start-up. Please see humidifier IFU for details.

If you are aware of any incidents related to this issue or if you have any questions, please contact IMI Co., Ltd. immediately at the below e-mail:

amanos.qlo@imimed.co.jp

Thank you for your continued support and we apologise for any inconvenience caused.

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,



Kaoru Nihei
Executive Officer
International Trade & Logistics
IMI Co., LTD

URGENT - Field Safety Notice Customer Response Form

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Reference of FSN: PMFSN0004
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517152, 517154, 517158

Please complete the feedback form as relevant and fax or email it back to Mr. Satoshi Amano,
amanos.qlo@imimed.co.jp

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 the attached FSN and that our humidifier(s) have the following firmware version(s) installed:

- Firmware version 1.70 (including water out alarm)
- Firmware version 1.63 or below (with no water-out alarm included)

I agree to one of the following options:

- I continue using our humidifier(s) with current firmware version and I acknowledge one of the following:
 - I continue using our humidifier(s) with firmware version 1.70 and I acknowledge that this version of the firmware has the risk of false positive alarm
 - I continue using our humidifier(s) with firmware version 1.63 and I acknowledge that this version of the firmware does not include a water-out alarm and will require regular visual monitoring of the water level
- I will stop using our humidifier(s)

NOTE: If you wish to stop using the humidifier, IMI or your local distributor will contact you on further actions

Name:

Position:

Signature:

Date (yyyy-mm-dd):

Phone number / e-mail address: