
Urgent Field Safety Notice

Product name of the affected product : Bubble Humidifier

FSCA ID : FSCA-202606-01

Type of action : Instruction for Use (IFU) Update

Date: 27th July, 2026

Attention:

This Field Safety Notice (FSN) has been established in accordance with Regulation (EU) 2017/745 (MDR) Articles 87–90 following consultation with the National Competent Authority (AFMPS, Belgium). This action targets risks occurring during both clinical and home-use environments.

Details on affected devices:

Basic UDI-DI	UDI-DI	Model No.	Model name	Batch number	Description
471268805000072 58OTASV	N/A	HAB01-916E	125mL Bubble Humidifier	20240308073	Oxygen Therapy and Accessories - Bubble Humidifier
	N/A	HAB01-916E	125mL Bubble Humidifier	20231016046	Oxygen Therapy and Accessories - Bubble Humidifier
	N/A	HAB01-916E	125mL Bubble Humidifier	20240221071	Oxygen Therapy and Accessories - Bubble Humidifier
	N/A	HAB01-916E	125mL Bubble Humidifier	20240329037	Oxygen Therapy and Accessories - Bubble Humidifier
	N/A	HAB01-916E	125mL Bubble Humidifier	20240709030	Oxygen Therapy and Accessories - Bubble Humidifier
	N/A	HAB01-916E	125mL Bubble Humidifier	20250217106	Oxygen Therapy and Accessories - Bubble Humidifier
	N/A	HAB01-916E	125mL Bubble Humidifier	20250529054	Oxygen Therapy and Accessories - Bubble Humidifier

**Description of the problem:**

Hsiner Co., Ltd. received a serious vigilance notification regarding an isolated incident in a home-care environment in Belgium (AFMPS Report No: 44631). The bubble humidifier bottle experienced an internal flow blockage, which indirectly led to an insufficient oxygen supply to the patient.

Investigation Findings & Technical Root Cause: A rigorous technical assessment of the manufacturing retained samples from batch 20240308073 was conducted. The samples underwent 100% full production control inspection, confirming zero air leakage and full compliance with mechanical parameters at release.

However, further assessment of the device interaction within home-use conditions reveals that local water hard-mineral contents and individual extended usage profiles directly accelerate the rate of subsequent calcification and scale buildup inside the humidifier core. In home-care environments, if cleaning intervals are insufficient, this rapid mineral calcification can result in sudden flow resistance or cross-sectional blockage. Hsiner Co., Ltd. has thus decided to specify cleaning instructions in the device instructions for use (IFU) in order to mitigate the risk for similar incidents occurring.

Advise on action to be taken by the user:

If you have devices from the above listed batch numbers in your stock, please carry out the following steps immediately:

1. **QUARANTINE AFFECTED DEVICES:** Immediately identify, stop using, and isolate any remaining inventory of the list of details on affected devices from active clinical or home care areas to prevent accidental misallocation.
2. **ADHERE TO REVISED IFU (Rev.06):** For all subsequent shipments and ongoing device handling, strictly enforce the new homecare maintenance schedules (3-day wash, 30-day replacement cap).

Please note that the device is released for use once the IFU (Rev.06) is affixed as instructed under point 3. below.

3. **DISTRIBUTE THIS NOTICE:** Pass this Field Safety Notice immediately to all operational units, home nursing coordinators, sub-distributors, and relevant caregivers within your organization who need to be aware of this action. Maintain a transmission log.

3.1 For authorized distributor:

- a. Provision of the new IFU: Hsiner will print the new IFU, pack it in a self-adhesive PE bag, and then send it to the distributor/importer.

- b. Providing new instruction manual to cover over the old version: Upon receiving the new instruction manual, the distributor/importer is requested to affix it to the outer bag of the moisture bottle inventory.
- c. Once the IFU is replaced as instructed above, the devices are released for use.

3.2 For end users and operators:

- a. Send back the quarantined products to our distributor in EU.
- b. Our EU distributor will then proceed the re-labelling following steps mentioned above.

4. COMPLETE AND RETURN THE ATTACHED CONFIRMATION FORM: Complete, sign, and return the enclosed Customer Response/Return Slip to your European representative or regional distributor immediately, even if your inventory of the affected batch is currently zero.

EU Representative information as below:

mdi Europa GmbH
Langenhagener Str. 71,
30855 Langenhagen, Germany
Tel: +49 511 3908 9530
Fax: +49 511 3908 9539
<http://www.mdi-europa.com>

Transmission of this Field Safety Notice:

In fulfillment of our manufacturer risk management responsibilities under ISO 14971, Hsiner Co., Ltd. is executing a systematic correction to mitigate all foreseeable home-use misuse scenarios:

- 1. Instruction for Use (IFU) Revision (Rev.06):** The IFU has been revised to enforce explicit risk control barriers for non-professional home users.
 - 2. Home Cleaning Protocols:** Enforced mandatory cleaning every 3 days using warm soapy water to actively eliminate mineral deposit precursors. Do not use bleach or ammonia.
 - 3. Strict Lifetime Limitation:** Mandated a strict maximum 30-day product replacement interval, or immediate disposal if scale residues cannot be removed.
 - 4. Water Quality Guidance:** Setting restriction to use distilled water only in order to reduce mineral buildup across critical geographical hard-water regions.
 - 5.** This notice needs to be passed on to all those who need to be aware within your organization or to any organization where the potentially affected products have been transferred.
 - 6.** It is important to maintain awareness on this notice and resulting action for an appropriate period to
- QRQC-0071(Rev.01)

ensure effectiveness of the corrective action.

6.1 On receiving the FSN, the action is expected to be conducted within one month.

7. The competent authority affected has received a copy of this Field Safety Notice and was informed regarding this matter.



Contact reference person:

Organization : HSINER Co., Ltd.

Address : 312, Jhongshan Rd., Shengang Dist, Taichung City 429, Taiwan

Contact details :

Tel: 886-4-25152480 Fax: 886-4-25152482

Email: robert@hsiner.com; kevin@hsiner.com

Web Site:<http://www.hsiner.com>

Signature:

Quality Assurance Manager

HSINER Co., Ltd.



Response Form

Exchange of the instructions for use **list of *Details on affected devices.***

Please fill out this reply form and send it to us by e-mail, fax or post to:

E-Mail: robert@hsiner.com ; kevin@hsiner.com

Fax: 886-4-25152482

Post: 312, Jhongshan Rd., Shengang Dist, Taichung City 429, Taiwan

☐ We hereby confirm receipt of the letter. We have read and understood the content and will implement all measures immediately. All users and operators of the product and other persons to be informed have received the letter.

Please fill out completely in block letters:

- Sender: _____
- Address: _____
- Contact person: _____
- Telephone No: _____ Fax No: _____
- Date/Signature: _____

☐ We still have the device in stock:

The device, Model No. _____, quantity: _____ pcs, for 125mL Bubble Humidifier

☐ We no longer have this product in stock.