December 28, 2023

URGENT MEDICAL DEVICE – CORRECTION
FSCA 3009507273-12/28/2023-001-C
Bubble Sensor BS 3/8x3/32 L1.7

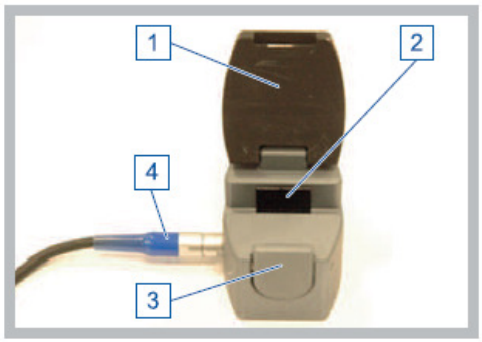
Product REF Number	Product Name				UDI DI
70105.5720	Bubble Sensor BS 3/8x3/32 L1.7				Correct UDI DI: 04037691816432 *Incorrect UDI DI (as labeled, see below):* ***04058863025148***
Distributed Affected Serial Numbers:	90041799	90041816	90041938	90042009	90042069
	90041802	90041817	90041939	90042011	90042070
	90041804	90041818	90041940	90042036	90042071
	90041805	90041821	90041943	90042037	90042074
	90041806	90041822	90041957	90042038	90042076
	90041807	90041823	90041963	90042042	90042079
	90041808	90041826	90041966	90042049	90042083
	90041809	90041836	90041974	90042050	90042085
	90041810	90041898	90041983	90042054	90042089
	90041811	90041905	90041993	90042056	90042090
	90041812	90041907	90041994	90042058	90042092
	90041813	90041921	90041995	90042060	90042093
	90041814	90041925	90041997	90042063	90042094
	90041815	90041930	90042005	90042066	90042097
Manufacturing Dates:	August 4, 2021, through February 4, 2022				
Distribution Dates:	October 27, 2021, through February 28, 2022				

Dear Risk Manager,

Getinge / Maquet Cardiopulmonary GmbH is initiating a voluntary Medical Device Correction for the above referenced serial numbers of Bubble Sensor BS 3/8x3/32 L1.7 (Product Code / REF: 70105.5720) (the “Bubble Sensor”) due to an incorrect Unique Device Identifier (UDI) on the product label.

The Bubble Sensor, shown in Figure 1 below, is an optional accessory to the CARDIOHELP-i extracorporeal life support system. It is used for detection of bubbles and air in the venous tubing. If a bubble or air is detected, the CARDIOHELP-i generates an audible alarm and can also automatically stop the pump (if the default setting for this intervention has not been disabled by a user). CARDIOHELP-i also includes a non-optional flow/bubble

sensor (FBS 3/8” x 3/32” L0.9), used on the arterial tubing, which is not affected by this labeling issue and is not a part of this Medical Device Correction.



1 Cover
2 Tube retainer
3 Locking device
4 Connecting cable

Figure 1: Bubble sensor, 70105.5720, BS 3/8x3/32 L1.7

Identification of the Issue:

The Bubble Sensor has a label attached to its cable (the “type label”). A change to this type label went into effect on July 22, 2021 that included an incorrect UDI (**04058863025148**) instead of the correct UDI for the product (**04037691816432**) (See Figure 2, Figure 3).

Figure 2: Type label with correct UDI 04037691816432

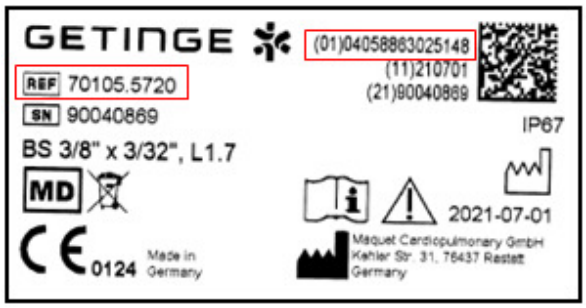


Figure 3: Type label with incorrect UDI 04058863025148

However, the outer packaging label of the affected sensors included the correct UDI (**04037691816432**). We therefore do not expect that any incorrect product was shipped when Bubble Sensors were ordered.

Risk to Health:

The company’s Health Hazard Evaluation (HHE) determined that an incorrect type label could cause the following hazardous situations and resulting harms:

- A user may delay or not provide treatment with CARDIOHELP-i, which could expose the patient to inappropriate low blood flow and result in Ischemia.
- A user may decide not to use the Bubble Sensor, potentially introducing air to the patient and resulting in ischemia. (As noted above the *arterial* flow/bubble sensor is unaffected by the labeling issue described in this notification).
- A user may have to exchange an incorrectly selected device, which could inconvenience the user.

Getinge has not identified any complaints or reports of adverse events related to the issue described in this notification.

Actions to be taken by the Customer:

Our records indicate that you have received a Bubble Sensor with a serial number that is affected by this voluntary Medical Device Correction (see Page 1).

- Please examine your inventory immediately to determine if you have any affected product in your inventory.
- Whether or not your facility has affected product(s) listed in this notice, please complete and sign the attached MEDICAL DEVICE - CORRECTION RESPONSE FORM (Page 4) to acknowledge that you have received this notification. Return the completed form to Getinge by e-mailing a scanned copy to BubbleSensorUDI2023.cp@getinge.com or by faxing the form to 1-866-416-5299.
- **Affected Bubble Sensors do not need to be returned and can be used as-is.**
- **Please forward this information to all current and potential Bubble Sensor users within your hospital / facility.**
- **If you are a distributor who has shipped any affected products to customers, please forward this document to their attention for appropriate action.**

Action by Getinge:

Getinge is informing all customers to whom the affected products have been distributed via this Medical Device Correction notification of this labeling non-conformity.

This Medical Device Correction only affects the products listed on page 1; no other products are affected.

Adverse reactions or quality problems experienced with the use of any of the products identified on page 1 may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax using the following:

- **Online**: www.accessdata.fda.gov/scripts/medwatch/
- **Regular Mail**: Download form at www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form
- **Fax**: 1-800-FDA-0178 (1-800-332-0178)

If you have any questions, please contact your Getinge representative or call Getinge Customer Support at (888) 943-8872 (press option 2), Monday through Friday, between the hours of 8:00 a.m. and 6:00 p.m. (Eastern Time Zone).

This Medical Device Correction is being made with the knowledge of the U.S. Food and Drug Administration.

Sincerely,

Charles Ryan
Senior Manager, Regulatory Affairs and Field Action Compliance