

2024-01-18

URGENT FIELD SAFETY NOTICE

Manufacturer SRN: DE-MF-000020091
FSCA Reference: 782698 Bubble Sensor - Incorrect labelling of Bubble Sensor
Field Safety Notice (FSN) Type: New
Affected Product: Bubble Sensor BS 3/8x3/32 L1.7 (Article no. 701055720)
Unique Device Identifier(s) (UDI-DI): 04037691816432
Affected Serial No.: 90041745 - 90042097 (274 pcs.), see also Annex I
For Attention of: Customers and users of the medical device listed below

Dear valued customer,

Maquet Cardiopulmonary GmbH would like to inform you with this letter about the incorrect labelling on the Bubble Sensor BS 3/8x3/32 L1.7 (Article no. 701055720).

The Bubble Sensor BS 3/8x3/32 L1.7 (Article no. 701055720) is used for detection of bubbles and air intervention in tubes of extracorporeal life support systems. If an air bubble is detected with active intervention, the sensor generates an electric signal which causes a pump stop to protect the patient from unintended air entering the body. The bubble sensor under investigation can be used with the following extracorporeal life support systems: CARDIOHELP -i and Rotaflow II.

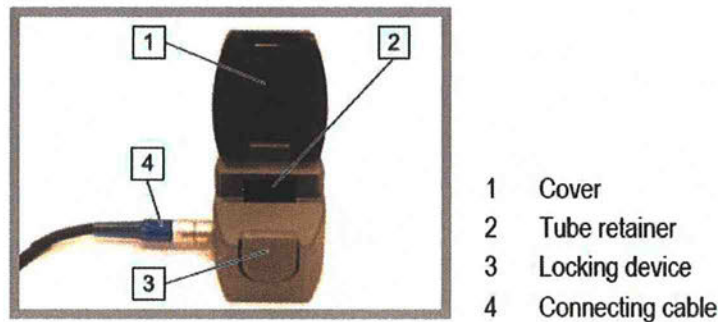


Figure 1: Bubble Sensor BS 3/8x3/32 L1.7 (Article no. 701055720)

Problem description

Since a label change in 2021, a label template with a Unique Device Identifier (UDI) was used for the type label attached to the Bubble Sensor BS 3/8x3/32 L1.7 (Article no. 701055720) itself. The affected labels refers to UDI **04058863025148** instead of **04037691816432** (Figure 2, Figure 3).



Figure 2: Type label with correct UDI 04037691816432



Figure 3: Type label with incorrect UDI 04058863025148

In fact, UDI **04058863025148** belongs to HL40 Flow Bubble Sensor FBS 3/8"x3/32" L2.0 (Article no. 701065317) (Table 1).

Table 1: Overview correct UDI and related products

UDI	Article number	Item Description	Device
04037691816432	701055720	BS 3/8x3/32 L1.7	CARDIOHELP-i, RotaFlow II
04058863025148	701065317	FBS 3/8"x3/32" L2.0	HL 40

Despite the error on the type label, the outer packaging label of the affected sensors are according to specification and reference the correct UDI **04037691816432**. Therefore, incorrect deliveries of Bubble Sensors due to the issue can be ruled out. Further, a cross-functional use of the two Bubble Sensor is not possible due to a difference in design (Figure 4, Figure 5).



Figure 4: Connector of CARDIOHELP-i/ RotaFlow II Bubble Sensor (Article no. 701055720)



Figure 5: Connector of HL 40 Bubble Sensor (Article no. 701065317)

Hazardous situation

A wrong UDI possibly leads to a hazardous situation as a clinician might not find / locate a bubble sensor for an emergency situation if relying on the UDI number while preparing a device. In course of a Health Hazard Evaluation (HHE), Maquet Cardiopulmonary GmbH determined the following hazardous situations for the incorrect labelling

- The patient is exposed to inappropriate low blood flow
- The user decides to forgo use of the venous bubble sensor altogether resulting in air introduction to the patient
- Product/device exchange

Potential Harm

The possible immediate and/or long-range health consequences and risk levels of the nonconformance include the following (for more information refer to Annex II):

- Ischemia

Maquet Cardiopulmonary GmbH has not identified any complaints of patient harm, serious injuries, or deaths due to the failure modes described above.

Action to be taken by the user:

- | | |
|---|--|
| <input checked="" type="checkbox"/> Identify Device | <input type="checkbox"/> Quarantine Device |
| <input type="checkbox"/> Return Device | <input type="checkbox"/> Destroy Device |

Details of the further actions:

- According to our post-market surveillance documentation, you may have products affected by this action. Please examine your inventory immediately to determine, if you have any affected Bubble Sensors in your inventory.
- Please **always** report any adverse events in regard to the affected products to your Getinge Representative.
- If you have an affected bubble sensor, please duly complete and sign the enclosed customer response form and send it back to your local Getinge representative, at the latest by **February 16, 2024**. Please give **FSCA-782698** as reference in the subject line of your email.

Action to be taken by the Manufacturer:

- | | |
|---|--|
| <input type="checkbox"/> Product Removal | <input type="checkbox"/> On-site device modification/ inspection |
| <input type="checkbox"/> Software upgrade | <input type="checkbox"/> IFU or labelling change |
| <input checked="" type="checkbox"/> Other | <input type="checkbox"/> None |

- Inform all customers possessing the affected products promptly about this Field Action by sending the Field Safety Notice for Customers

Enclosed documents:

- Customer response form
- Annex I List of affected products
- Annex II Further information regarding Hazardous situation, Harms and Risk Levels

Transmission of the Field Safety Notice

- Please ensure in your organization that all users of the above-mentioned products and other persons to be informed are made aware of this Urgent Field Safety Notice.
- Please transfer this notice to other organizations on which the action has an impact.
- If you have given the products to third parties, please forward a copy of this information or inform the contact person indicated below.
- Please maintain awareness on the notice and resulting actions for an appropriate period to ensure effectiveness of the corrective action.

We sincerely apologize for any inconvenience this may cause you and will do our utmost to carry through this action as swiftly as possible.

As required, we have provided this notification to the necessary Regulatory Agencies.

Should you have questions or require additional information, please contact your local Getinge representative, or send an e-mail to FSCA.cp@getinge.com.

Sincerely,

[Redacted]

Signature:

[Redacted]

Email:

[Redacted]

[Redacted]

Signature:

[Redacted]

Email:

[Redacted]

Contact details of manufacturer

[Redacted]

CUSTOMER RESPONSE FORM

FSCA Reference: 782698 Bubble Sensor - Incorrect labelling of Bubble Sensor

Affected Product: Bubble Sensor BS 3/8x3/32 L1.7 (Article no. 701055720)

Affected Serial No.: 90041745 - 90042097 (274 pcs.), see also Annex I

Please send this form to your local Getinge representative at the latest by **February 16, 2024**.

By completing this document and signing it, I acknowledge that I have read and understand the following associated points:

- I have read and understand this Field Safety Notice for affected products Bubble Sensor BS 3/8x3/32 L1.7 (Article no. 701055720). We will take action as soon as possible according to given instructions.
- I confirm that I have distributed this Field Safety Notice to the affected personal.

Following affected products are in our inventory:

Article Number	Description	Serial Number	Quantity

Your Comments:

Country

Hospital / Clinic (full address)

Date

Name (Function)

Signature

Please return the completed form to your local Getinge representative by email FSCA.cp@getinge.com.

Annex I – List of affected serial numbers

This Annex I List of affected products is considered a supplementary attachment to the 782698 Field Safety Notice.

COUNTRY	ITEM	ITEM DESCRIPTION	LOT OR SERIAL #
Australia	701055720	BS 3/8x3/32 L1.7	90041968
Australia	701055720	BS 3/8x3/32 L1.7	90041972
Australia	701055720	BS 3/8x3/32 L1.7	90041976
Australia	701055720	BS 3/8x3/32 L1.7	90041979
Australia	701055720	BS 3/8x3/32 L1.7	90041980
Australia	701055720	BS 3/8x3/32 L1.7	90041982
Australia	701055720	BS 3/8x3/32 L1.7	90041984
Australia	701055720	BS 3/8x3/32 L1.7	90041985
Australia	701055720	BS 3/8x3/32 L1.7	90041986
Australia	701055720	BS 3/8x3/32 L1.7	90041989
Belgium	701055720	BS 3/8x3/32 L1.7	90041833
Belgium	701055720	BS 3/8x3/32 L1.7	90041845
Belgium	701055720	BS 3/8x3/32 L1.7	90041889
Belgium	701055720	BS 3/8x3/32 L1.7	90041911
Bosnia and Herzegovina	701055720	BS 3/8x3/32 L1.7	90041854
Bosnia and Herzegovina	701055720	BS 3/8x3/32 L1.7	90041886
Bulgaria	701055720	BS 3/8x3/32 L1.7	90041945
Chile	701055720	BS 3/8x3/32 L1.7	90042012
Chile	701055720	BS 3/8x3/32 L1.7	90042013
Chile	701055720	BS 3/8x3/32 L1.7	90042014
Costa Rica	701055720	BS 3/8x3/32 L1.7	90041803
Czech Republic	701055720	BS 3/8x3/32 L1.7	90041903
Denmark	701055720	BS 3/8x3/32 L1.7	90041975
France	701055720	BS 3/8x3/32 L1.7	90041754
France	701055720	BS 3/8x3/32 L1.7	90041785
France	701055720	BS 3/8x3/32 L1.7	90041801
France	701055720	BS 3/8x3/32 L1.7	90041825
France	701055720	BS 3/8x3/32 L1.7	90041827
France	701055720	BS 3/8x3/32 L1.7	90041839
France	701055720	BS 3/8x3/32 L1.7	90041922
France	701055720	BS 3/8x3/32 L1.7	90041934
France	701055720	BS 3/8x3/32 L1.7	90041947
France	701055720	BS 3/8x3/32 L1.7	90042064
Germany	701055720	BS 3/8x3/32 L1.7	90041749
Germany	701055720	BS 3/8x3/32 L1.7	90041776
Germany	701055720	BS 3/8x3/32 L1.7	90041782
Germany	701055720	BS 3/8x3/32 L1.7	90041783
Germany	701055720	BS 3/8x3/32 L1.7	90041828
Germany	701055720	BS 3/8x3/32 L1.7	90041829
Germany	701055720	BS 3/8x3/32 L1.7	90041830
Germany	701055720	BS 3/8x3/32 L1.7	90041831
Germany	701055720	BS 3/8x3/32 L1.7	90041832
Germany	701055720	BS 3/8x3/32 L1.7	90041834
Germany	701055720	BS 3/8x3/32 L1.7	90041837
Germany	701055720	BS 3/8x3/32 L1.7	90041838
Germany	701055720	BS 3/8x3/32 L1.7	90041841
Germany	701055720	BS 3/8x3/32 L1.7	90041842

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Germany	701055720	BS 3/8x3/32 L1.7	90041843
Germany	701055720	BS 3/8x3/32 L1.7	90041863
Germany	701055720	BS 3/8x3/32 L1.7	90041869
Germany	701055720	BS 3/8x3/32 L1.7	90041870
Germany	701055720	BS 3/8x3/32 L1.7	90041878
Germany	701055720	BS 3/8x3/32 L1.7	90041883
Germany	701055720	BS 3/8x3/32 L1.7	90041899
Germany	701055720	BS 3/8x3/32 L1.7	90041909
Germany	701055720	BS 3/8x3/32 L1.7	90041915
Germany	701055720	BS 3/8x3/32 L1.7	90041927
Germany	701055720	BS 3/8x3/32 L1.7	90041933
Germany	701055720	BS 3/8x3/32 L1.7	90041956
Germany	701055720	BS 3/8x3/32 L1.7	90041958
Germany	701055720	BS 3/8x3/32 L1.7	90041960
Germany	701055720	BS 3/8x3/32 L1.7	90041961
Germany	701055720	BS 3/8x3/32 L1.7	90041962
Germany	701055720	BS 3/8x3/32 L1.7	90041967
Germany	701055720	BS 3/8x3/32 L1.7	90041987
Germany	701055720	BS 3/8x3/32 L1.7	90041988
Germany	701055720	BS 3/8x3/32 L1.7	90041990
Germany	701055720	BS 3/8x3/32 L1.7	90041991
Germany	701055720	BS 3/8x3/32 L1.7	90042039
Germany	701055720	BS 3/8x3/32 L1.7	90042052
Hungary	701055720	BS 3/8x3/32 L1.7	90041851
Hungary	701055720	BS 3/8x3/32 L1.7	90041861
India	701055720	BS 3/8x3/32 L1.7	90041745
India	701055720	BS 3/8x3/32 L1.7	90041746
India	701055720	BS 3/8x3/32 L1.7	90041748
India	701055720	BS 3/8x3/32 L1.7	90041751
India	701055720	BS 3/8x3/32 L1.7	90041753
India	701055720	BS 3/8x3/32 L1.7	90041756
India	701055720	BS 3/8x3/32 L1.7	90041758
India	701055720	BS 3/8x3/32 L1.7	90041766
India	701055720	BS 3/8x3/32 L1.7	90041767
India	701055720	BS 3/8x3/32 L1.7	90041768
India	701055720	BS 3/8x3/32 L1.7	90041772
India	701055720	BS 3/8x3/32 L1.7	90041779
India	701055720	BS 3/8x3/32 L1.7	90041780
India	701055720	BS 3/8x3/32 L1.7	90041788
India	701055720	BS 3/8x3/32 L1.7	90041792
India	701055720	BS 3/8x3/32 L1.7	90041793
India	701055720	BS 3/8x3/32 L1.7	90041795
India	701055720	BS 3/8x3/32 L1.7	90041900
India	701055720	BS 3/8x3/32 L1.7	90041904
India	701055720	BS 3/8x3/32 L1.7	90041908
India	701055720	BS 3/8x3/32 L1.7	90041910
India	701055720	BS 3/8x3/32 L1.7	90041912
India	701055720	BS 3/8x3/32 L1.7	90041919
India	701055720	BS 3/8x3/32 L1.7	90041923
India	701055720	BS 3/8x3/32 L1.7	90041924
India	701055720	BS 3/8x3/32 L1.7	90041926
India	701055720	BS 3/8x3/32 L1.7	90041928
India	701055720	BS 3/8x3/32 L1.7	90041929

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India	701055720	BS 3/8x3/32 L1.7	90041937
India	701055720	BS 3/8x3/32 L1.7	90041942
India	701055720	BS 3/8x3/32 L1.7	90041944
India	701055720	BS 3/8x3/32 L1.7	90041946
India	701055720	BS 3/8x3/32 L1.7	90041949
India	701055720	BS 3/8x3/32 L1.7	90041950
India	701055720	BS 3/8x3/32 L1.7	90041951
India	701055720	BS 3/8x3/32 L1.7	90041952
India	701055720	BS 3/8x3/32 L1.7	90041954
India	701055720	BS 3/8x3/32 L1.7	90041955
India	701055720	BS 3/8x3/32 L1.7	90041964
India	701055720	BS 3/8x3/32 L1.7	90041965
India	701055720	BS 3/8x3/32 L1.7	90041970
India	701055720	BS 3/8x3/32 L1.7	90041978
India	701055720	BS 3/8x3/32 L1.7	90041981
India	701055720	BS 3/8x3/32 L1.7	90042002
India	701055720	BS 3/8x3/32 L1.7	90042010
India	701055720	BS 3/8x3/32 L1.7	90042017
India	701055720	BS 3/8x3/32 L1.7	90042065
India	701055720	BS 3/8x3/32 L1.7	90042067
India	701055720	BS 3/8x3/32 L1.7	90042080
India	701055720	BS 3/8x3/32 L1.7	90042082
India	701055720	BS 3/8x3/32 L1.7	90042091
Israel	701055720	BS 3/8x3/32 L1.7	90042046
Israel	701055720	BS 3/8x3/32 L1.7	90042051
Israel	701055720	BS 3/8x3/32 L1.7	90042055
Italy	701055720	BS 3/8x3/32 L1.7	90041757
Italy	701055720	BS 3/8x3/32 L1.7	90041760
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Italy	701055720	BS 3/8x3/32 L1.7	90041992
Italy	701055720	BS 3/8x3/32 L1.7	90041996
Italy	701055720	BS 3/8x3/32 L1.7	90042001
Italy	701055720	BS 3/8x3/32 L1.7	90042003
Italy	701055720	BS 3/8x3/32 L1.7	90042007
Italy	701055720	BS 3/8x3/32 L1.7	90042008
Japan	701055720	BS 3/8x3/32 L1.7	90041857
Japan	701055720	BS 3/8x3/32 L1.7	90041873
Japan	701055720	BS 3/8x3/32 L1.7	90041874
Mexico	701055720	BS 3/8x3/32 L1.7	90041747
Mexico	701055720	BS 3/8x3/32 L1.7	90041819
Mexico	701055720	BS 3/8x3/32 L1.7	90041824
Mexico	701055720	BS 3/8x3/32 L1.7	90041835
Mexico	701055720	BS 3/8x3/32 L1.7	90041885
Mexico	701055720	BS 3/8x3/32 L1.7	90041999
Mexico	701055720	BS 3/8x3/32 L1.7	90042019
Mexico	701055720	BS 3/8x3/32 L1.7	90042020
Mexico	701055720	BS 3/8x3/32 L1.7	90042031
Netherlands	701055720	BS 3/8x3/32 L1.7	90041914
Norway	701055720	BS 3/8x3/32 L1.7	90041850
Norway	701055720	BS 3/8x3/32 L1.7	90041862
Norway	701055720	BS 3/8x3/32 L1.7	90041895
Norway	701055720	BS 3/8x3/32 L1.7	90042043
Norway	701055720	BS 3/8x3/32 L1.7	90042059

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Pakistan	701055720	BS 3/8x3/32 L1.7	90042006
Philippines	701055720	BS 3/8x3/32 L1.7	90041820
Poland	701055720	BS 3/8x3/32 L1.7	90041852
Poland	701055720	BS 3/8x3/32 L1.7	90041920
Poland	701055720	BS 3/8x3/32 L1.7	90041935
Poland	701055720	BS 3/8x3/32 L1.7	90042033
Romania	701055720	BS 3/8x3/32 L1.7	90041752
Romania	701055720	BS 3/8x3/32 L1.7	90041859
Romania	701055720	BS 3/8x3/32 L1.7	90041860
Romania	701055720	BS 3/8x3/32 L1.7	90041931
Romania	701055720	BS 3/8x3/32 L1.7	90041936
Saudi Arabia	701055720	BS 3/8x3/32 L1.7	90042040
Slovakia	701055720	BS 3/8x3/32 L1.7	90041846
South Africa	701055720	BS 3/8x3/32 L1.7	90041858
South Africa	701055720	BS 3/8x3/32 L1.7	90041865
South Africa	701055720	BS 3/8x3/32 L1.7	90041868
South Africa	701055720	BS 3/8x3/32 L1.7	90041880
South Africa	701055720	BS 3/8x3/32 L1.7	90041893
South Africa	701055720	BS 3/8x3/32 L1.7	90041894
South Africa	701055720	BS 3/8x3/32 L1.7	90041913
South Korea	701055720	BS 3/8x3/32 L1.7	90041849
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South Korea	701055720	BS 3/8x3/32 L1.7	90041856
South Korea	701055720	BS 3/8x3/32 L1.7	90041864
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South Korea	701055720	BS 3/8x3/32 L1.7	90041871
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South Korea	701055720	BS 3/8x3/32 L1.7	90041876
South Korea	701055720	BS 3/8x3/32 L1.7	90041876
South Korea	701055720	BS 3/8x3/32 L1.7	90041877
South Korea	701055720	BS 3/8x3/32 L1.7	90041879
South Korea	701055720	BS 3/8x3/32 L1.7	90041882
South Korea	701055720	BS 3/8x3/32 L1.7	90041884
South Korea	701055720	BS 3/8x3/32 L1.7	90041887
South Korea	701055720	BS 3/8x3/32 L1.7	90041890
South Korea	701055720	BS 3/8x3/32 L1.7	90041891
South Korea	701055720	BS 3/8x3/32 L1.7	90041892
South Korea	701055720	BS 3/8x3/32 L1.7	90041897
South Korea	701055720	BS 3/8x3/32 L1.7	90041916
South Korea	701055720	BS 3/8x3/32 L1.7	90041917
South Korea	701055720	BS 3/8x3/32 L1.7	90041918
South Korea	701055720	BS 3/8x3/32 L1.7	90042034
South Korea	701055720	BS 3/8x3/32 L1.7	90042035
Switzerland	701055720	BS 3/8x3/32 L1.7	90041790
Thailand	701055720	BS 3/8x3/32 L1.7	90041902
Turkey	701055720	BS 3/8x3/32 L1.7	90042016
United Arab Emirates	701055720	BS 3/8x3/32 L1.7	90042004
United Kingdom	701055720	BS 3/8x3/32 L1.7	90042047
United Kingdom	701055720	BS 3/8x3/32 L1.7	90042061
United States	701055720	BS 3/8x3/32 L1.7	90041799
United States	701055720	BS 3/8x3/32 L1.7	90041802

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United States	701055720	BS 3/8x3/32 L1.7	90041804
United States	701055720	BS 3/8x3/32 L1.7	90041805
United States	701055720	BS 3/8x3/32 L1.7	90041806
United States	701055720	BS 3/8x3/32 L1.7	90041807
United States	701055720	BS 3/8x3/32 L1.7	90041808
United States	701055720	BS 3/8x3/32 L1.7	90041809
United States	701055720	BS 3/8x3/32 L1.7	90041810
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United States	701055720	BS 3/8x3/32 L1.7	90041812
United States	701055720	BS 3/8x3/32 L1.7	90041813
United States	701055720	BS 3/8x3/32 L1.7	90041814
United States	701055720	BS 3/8x3/32 L1.7	90041815
United States	701055720	BS 3/8x3/32 L1.7	90041816
United States	701055720	BS 3/8x3/32 L1.7	90041817
United States	701055720	BS 3/8x3/32 L1.7	90041818
United States	701055720	BS 3/8x3/32 L1.7	90041821
United States	701055720	BS 3/8x3/32 L1.7	90041822
United States	701055720	BS 3/8x3/32 L1.7	90041823
United States	701055720	BS 3/8x3/32 L1.7	90041826
United States	701055720	BS 3/8x3/32 L1.7	90041836
United States	701055720	BS 3/8x3/32 L1.7	90041898
United States	701055720	BS 3/8x3/32 L1.7	90041905
United States	701055720	BS 3/8x3/32 L1.7	90041907
United States	701055720	BS 3/8x3/32 L1.7	90041921
United States	701055720	BS 3/8x3/32 L1.7	90041925
United States	701055720	BS 3/8x3/32 L1.7	90041930
United States	701055720	BS 3/8x3/32 L1.7	90041938
United States	701055720	BS 3/8x3/32 L1.7	90041939
United States	701055720	BS 3/8x3/32 L1.7	90041940
United States	701055720	BS 3/8x3/32 L1.7	90041943
United States	701055720	BS 3/8x3/32 L1.7	90041957
United States	701055720	BS 3/8x3/32 L1.7	90041963
United States	701055720	BS 3/8x3/32 L1.7	90041966
United States	701055720	BS 3/8x3/32 L1.7	90041974
United States	701055720	BS 3/8x3/32 L1.7	90041983
United States	701055720	BS 3/8x3/32 L1.7	90041993
United States	701055720	BS 3/8x3/32 L1.7	90041994
United States	701055720	BS 3/8x3/32 L1.7	90041995
United States	701055720	BS 3/8x3/32 L1.7	90041997
United States	701055720	BS 3/8x3/32 L1.7	90042005
United States	701055720	BS 3/8x3/32 L1.7	90042009
United States	701055720	BS 3/8x3/32 L1.7	90042011
United States	701055720	BS 3/8x3/32 L1.7	90042036
United States	701055720	BS 3/8x3/32 L1.7	90042037
United States	701055720	BS 3/8x3/32 L1.7	90042038
United States	701055720	BS 3/8x3/32 L1.7	90042042
United States	701055720	BS 3/8x3/32 L1.7	90042049
United States	701055720	BS 3/8x3/32 L1.7	90042050
United States	701055720	BS 3/8x3/32 L1.7	90042054
United States	701055720	BS 3/8x3/32 L1.7	90042056
United States	701055720	BS 3/8x3/32 L1.7	90042058
United States	701055720	BS 3/8x3/32 L1.7	90042060
United States	701055720	BS 3/8x3/32 L1.7	90042063

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United States	701055720	BS 3/8x3/32 L1.7	90042066
United States	701055720	BS 3/8x3/32 L1.7	90042069
United States	701055720	BS 3/8x3/32 L1.7	90042070
United States	701055720	BS 3/8x3/32 L1.7	90042071
United States	701055720	BS 3/8x3/32 L1.7	90042074
United States	701055720	BS 3/8x3/32 L1.7	90042076
United States	701055720	BS 3/8x3/32 L1.7	90042079
United States	701055720	BS 3/8x3/32 L1.7	90042083
United States	701055720	BS 3/8x3/32 L1.7	90042085
United States	701055720	BS 3/8x3/32 L1.7	90042089
United States	701055720	BS 3/8x3/32 L1.7	90042090
United States	701055720	BS 3/8x3/32 L1.7	90042092
United States	701055720	BS 3/8x3/32 L1.7	90042093
United States	701055720	BS 3/8x3/32 L1.7	90042094
United States	701055720	BS 3/8x3/32 L1.7	90042097

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Annex II – Further information regarding Hazardous situation, Harms and Risk Levels

This Annex II Further information regarding Hazardous situation, Harms and Risk Levels is considered a supplementary attachment to the 782698 Field Safety Notice.

Hazardous situation	Harm	S from part III	P from above	Risk		
				Low	Med	High
The patient is exposed to inappropriate low blood flow	Ischemia	4	1	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
The user decides to forgo use of the venous bubble sensor altogether resulting in air introduction to the patient	Ischemia	4	1	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Product/device exchange	User inconvenience	2	1	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Severity Definitions:

Negligible (1) Inconvenience or temporary discomfort of patient, user or third party. No medical intervention or follow-up treatment is required

Low (2) Temporary injury or disability of patients, users or third parties. No medical intervention or follow up treatment is required.

Critical (3) Temporary injury or disability of patients, users or third parties. Medical intervention or follow-up treatment is required.

Catastrophic (4) Permanent injury or disability (e.g., loss of a body part), a life-threatening situation or death of patients, users or third parties

Probability Definitions:

Improbable (1) Harm is not likely.

Remote (2) Harm occurs infrequently

Occasional (3) Harm may occur occasionally / intermittent

Probable (4) Harm may occur often

Frequent (5) Harm will occur repeatedly