

Urgent !

Field Safety Notice (FSN)
Signapore specific FSN



Version
(Version)
V 01

Gültig ab
(valid from)
See last signature

Page 1 of 4

2019-08-01

FSCA Number: FSCA-2019-07-15

FSCA Title: Heater Unit HU 35 – Potentially incorrect software version

Affected product: Heater Unit HU 35

Affected product details: Serial number range and material number of potentially affected products produced within the timeframe September, 2017 until October, 2018:

1.) 70107.2162 Heater Unit HU 35, 230 V
➔ S/N: 90031802 – 90032235

2.) 70107.2163 Heater Unit HU 35, 110-115V
➔ S/N: 90034502 – 90034539

Please refer to the Annex I for details. Not all serial numbers within the range above are affected. If your serial number is within this range, but is not on the list in Annex I, then your device is not affected by this FSCA.

Description of the problem: Dear valued colleagues and business partners,
cc to the Chairman Medical Board and relevant Head-of-Department

Maquet Cardiopulmonary GmbH has determined that the above listed HU 35 Heater Units produced within the timeframe September, 2017 until October, 2018 might have been delivered with an incorrect software version – not in correspondence with the set point temperature range described in the Instructions for Use for these devices. The affected units potentially have received the software version 1.01 instead of the correct software version 1.02.

In version 1.01 of the HU 35 software, the set point water temperature can be set between 33°C and 39°C, while in the correct software version 1.02 for the above listed units the set point temperature range is limited between 35°C and 39°C.

Urgent !

Field Safety Notice (FSN)
Signapore specific FSN

Furthermore in software version 1.01 a high priority alarm (visual and acoustic alarm) is triggered if the water temperature falls to 32°C or below while in the new correct software version 1.02 a high priority alarm is already triggered if the water temperature drops to 34°C or below in order to avoid unintended hypothermia of a patient connected.

According to the intended use for the affected Heater-Units HU 35, the device acts as a heat supply in order to maintain the patient's body temperature via a heat exchanger of a PLS Oxygenator or HLS Module or other oxygenator-heat exchangers as part of an extracorporeal circuits. The HU 35 is not indicated for cooling a patient.

To check whether the unit you have in place is affected by the incorrect software version, please compare first if the serial number of your unit is listed in Annex I.

- If the serial number is not listed in Annex 1, the device is not affected by this field action. No further action is required.
- If the serial number is listed in Annex 1, set the lowest possible set point temperature, when the device is not clinically in use.
- If the set point temperature cannot be set below 35°C, you do not have an affected device. Please complete the Letter of Acknowledgement for Customers and return it as soon as possible to your local Getinge representative by mentioning FSCA-2019-07-15 as reference. No further action is required.
- If the set point temperature can be set below 35°C, you have an affected device with the incorrect software version 1.01. Please follow the further instructions below.

The customer can further use affected HU 35 units with the incorrect software version 1.01 before the corrective action has been implemented by not setting the set point temperature below 35°C as a precaution to prevent unintended hypothermia of the patient.

As described in the Instructions for Use for HU 35, monitor the patient's body temperature and electrocardiography using an external independent monitoring system during the application, and monitor the blood temperature at the oxygenator.

Maquet Cardiopulmonary GmbH has not received any complaints associated with hypothermia or following serious injuries or deaths due to the potentially incorrect software version 1.01 installed on affected HU 35.

Urgent !

Field Safety Notice (FSN)
Singapore specific FSN



Version
(Version)
V 01

Gültig ab
(valid from)
See last signature

Page 3 of 4

Corrective Action:

**Advice on action
to be taken by the
User:**

- Replacement of the HU 35 control board for all HU 35 units with the S/N listed in Annex I, which have been delivered with the incorrect software version 1.01
- According to our post-market surveillance documentation, your current stock may include products affected by this action.
- The replacement of the HU 35 control board of the affected HU 35 systems must be performed by authorized Getinge service personnel.
- If you have an affected product in place listed on Annex I, please identify the software version on the device by:
 - Setting the lowest possible set point temperature, when the device is not clinically in use.
 - If the set point temperature can be set below 35°C, you have an affected device with the incorrect software version 1.01.
- Duly fill out the enclosed Letter of Acknowledgement for Customers and return it as soon as possible to your local Getinge representative by mentioning FSCA-2019-07-15 as reference.

**Referenced
documents/attach
ments:**

- Letter of Acknowledgement Customer
- Annex I: List of affected products

Urgent !

Field Safety Notice (FSN)

Singapore specific FSN

GETINGE 

Version
(Version)
V 01

Gültig ab
(valid from)
See last signature

Page 4 of 4

Transmission of the Field Safety Notice:

- 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 devices have been transferred.
- Please transfer this notice to other organizations on which the action has an impact.
- Please maintain awareness on the notice and resulting actions for an appropriate period to ensure effectiveness of the corrective action.

After the feedback to your local Getinge representative, whether you have a HU 35 unit(s) with incorrect software in place you will be contacted for planning and performing the replacement of the HU 35 control board for your HU 35 unit(s).

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

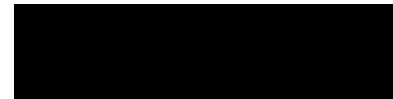
As required, we have provided this notification to the necessary Regulatory Agencies.

Should you have questions or require additional information, please contact your local Maquet representative.

Sincerely,

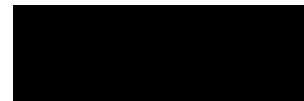
Managing Director `sig,bio=1`

*2019-08-01
Senior Director of
Quality Improvement Programs*



Safety Officer `sig,bio=1`

2019-08-01



Maquet Cardiopulmonary GmbH
Kehler Str. 31
76437 Rastatt
Germany

Urgent!

Field Safety Notice (FSN)

-Annex I-

List of affected products country-/ region-specific



This Annex I is considered as a supplementary attachment to the Field Safety Notice of FSCA-2019-07-15

2019-08-01

FSCA Number: FSCA-2019-07-15

FSCA Title: Heater Unit HU 35 – Potentially incorrect software version

Affected Products: Serial number range and material number of potentially affected products produced within the timeframe September, 2017 until October, 2018:

1.) 70107.2162 Heater Unit HU 35, 230 V

➔ S/N: 90031802 – 90032235

2.) 70107.2163 Heater Unit HU 35, 110-115V

➔ S/N: 90034520 – 90034538

List of affected products			
Country	Material No.	Material Description	Serial No.
Australia	70107.2162	Heater Unit HU 35, 230V	90031811
Australia	70107.2162	Heater Unit HU 35, 230V	90031855
Australia	70107.2162	Heater Unit HU 35, 230V	90031858
Australia	70107.2162	Heater Unit HU 35, 230V	90031859
Australia	70107.2162	Heater Unit HU 35, 230V	90031860
Australia	70107.2162	Heater Unit HU 35, 230V	90031871
Australia	70107.2162	Heater Unit HU 35, 230V	90031873
Australia	70107.2162	Heater Unit HU 35, 230V	90031877
Australia	70107.2162	Heater Unit HU 35, 230V	90031881
Australia	70107.2162	Heater Unit HU 35, 230V	90031894
Australia	70107.2162	Heater Unit HU 35, 230V	90031898
Australia	70107.2162	Heater Unit HU 35, 230V	90031910
Australia	70107.2162	Heater Unit HU 35, 230V	90031932
Australia	70107.2162	Heater Unit HU 35, 230V	90031940
Australia	70107.2162	Heater Unit HU 35, 230V	90031995
Australia	70107.2162	Heater Unit HU 35, 230V	90031996
Australia	70107.2162	Heater Unit HU 35, 230V	90032038
Australia	70107.2162	Heater Unit HU 35, 230V	90032043

Urgent!

Field Safety Notice (FSN)



-Annex I-

List of affected products country-/ region-specific

Australia	70107.2162	Heater Unit HU 35, 230V	90032045
Australia	70107.2162	Heater Unit HU 35, 230V	90032050
Australia	70107.2162	Heater Unit HU 35, 230V	90032052
Australia	70107.2162	Heater Unit HU 35, 230V	90032058
Australia	70107.2162	Heater Unit HU 35, 230V	90032099
Australia	70107.2162	Heater Unit HU 35, 230V	90032101
Australia	70107.2162	Heater Unit HU 35, 230V	90032114
Australia	70107.2162	Heater Unit HU 35, 230V	90032117
Australia	70107.2162	Heater Unit HU 35, 230V	90032121
Australia	70107.2162	Heater Unit HU 35, 230V	90032170
Australia	70107.2162	Heater Unit HU 35, 230V	90032184
Australia	70107.2162	Heater Unit HU 35, 230V	90032207
Australia	70107.2162	Heater Unit HU 35, 230V	90032214
Australia	70107.2162	Heater Unit HU 35, 230V	90032215
Australia	70107.2162	Heater Unit HU 35, 230V	90032216
Australia	70107.2162	Heater Unit HU 35, 230V	90032217
Australia	70107.2162	Heater Unit HU 35, 230V	90032219
Belgium	70107.2162	Heater Unit HU 35, 230V	90031900
Canada	70107.2163	Heater Unit HU 35, 115V	90034520
Canada	70107.2163	Heater Unit HU 35, 115V	90034521
Canada	70107.2163	Heater Unit HU 35, 115V	90034536
Canada	70107.2163	Heater Unit HU 35, 115V	90034537
Canada	70107.2163	Heater Unit HU 35, 115V	90034539
Chile	70107.2162	Heater Unit HU 35, 230V	90032091
Chile	70107.2162	Heater Unit HU 35, 230V	90032092
Chile	70107.2162	Heater Unit HU 35, 230V	90032093
Czech Republic	70107.2162	Heater Unit HU 35, 230V	90031875
Czech Republic	70107.2162	Heater Unit HU 35, 230V	90031987
Czech Republic	70107.2162	Heater Unit HU 35, 230V	90032053
Czech Republic	70107.2162	Heater Unit HU 35, 230V	90032056
Czech Republic	70107.2162	Heater Unit HU 35, 230V	90032124
Czech Republic	70107.2162	Heater Unit HU 35, 230V	90032163

Urgent!

Field Safety Notice (FSN)



-Annex I-

List of affected products country-/ region-specific

Czech Republic	70107.2162	Heater Unit HU 35, 230V	90032191
Czech Republic	70107.2162	Heater Unit HU 35, 230V	90032194
Finland	70107.2162	Heater Unit HU 35, 230V	90031802
Finland	70107.2162	Heater Unit HU 35, 230V	90031832
Finland	70107.2162	Heater Unit HU 35, 230V	90032141
Finland	70107.2162	Heater Unit HU 35, 230V	90032143
France	70107.2162	Heater Unit HU 35, 230V	90031803
France	70107.2162	Heater Unit HU 35, 230V	90031809
France	70107.2162	Heater Unit HU 35, 230V	90031831
France	70107.2162	Heater Unit HU 35, 230V	90031833
France	70107.2162	Heater Unit HU 35, 230V	90031836
France	70107.2162	Heater Unit HU 35, 230V	90031839
France	70107.2162	Heater Unit HU 35, 230V	90031843
France	70107.2162	Heater Unit HU 35, 230V	90031852
France	70107.2162	Heater Unit HU 35, 230V	90031867
France	70107.2162	Heater Unit HU 35, 230V	90031868
France	70107.2162	Heater Unit HU 35, 230V	90031903
France	70107.2162	Heater Unit HU 35, 230V	90031933
France	70107.2162	Heater Unit HU 35, 230V	90031945
France	70107.2162	Heater Unit HU 35, 230V	90031948
France	70107.2162	Heater Unit HU 35, 230V	90031960
France	70107.2162	Heater Unit HU 35, 230V	90031961
France	70107.2162	Heater Unit HU 35, 230V	90031984
France	70107.2162	Heater Unit HU 35, 230V	90032000
France	70107.2162	Heater Unit HU 35, 230V	90032007
France	70107.2162	Heater Unit HU 35, 230V	90032009
France	70107.2162	Heater Unit HU 35, 230V	90032016
France	70107.2162	Heater Unit HU 35, 230V	90032017
France	70107.2162	Heater Unit HU 35, 230V	90032074
France	70107.2162	Heater Unit HU 35, 230V	90032077
France	70107.2162	Heater Unit HU 35, 230V	90032082
France	70107.2162	Heater Unit HU 35, 230V	90032088

Urgent!

Field Safety Notice (FSN)



-Annex I-

List of affected products country-/ region-specific

France	70107.2162	Heater Unit HU 35, 230V	90032089
France	70107.2162	Heater Unit HU 35, 230V	90032098
France	70107.2162	Heater Unit HU 35, 230V	90032104
France	70107.2162	Heater Unit HU 35, 230V	90032105
France	70107.2162	Heater Unit HU 35, 230V	90032106
France	70107.2162	Heater Unit HU 35, 230V	90032108
France	70107.2162	Heater Unit HU 35, 230V	90032162
France	70107.2162	Heater Unit HU 35, 230V	90032182
France	70107.2162	Heater Unit HU 35, 230V	90032203
France	70107.2162	Heater Unit HU 35, 230V	90032208
France	70107.2162	Heater Unit HU 35, 230V	90032223
France	70107.2162	Heater Unit HU 35, 230V	90032231
Germany	70107.2162	Heater Unit HU 35, 230V	90031808
Germany	70107.2162	Heater Unit HU 35, 230V	90031813
Germany	70107.2162	Heater Unit HU 35, 230V	90031814
Germany	70107.2162	Heater Unit HU 35, 230V	90031816
Germany	70107.2162	Heater Unit HU 35, 230V	90031824
Germany	70107.2162	Heater Unit HU 35, 230V	90031826
Germany	70107.2162	Heater Unit HU 35, 230V	90031829
Germany	70107.2162	Heater Unit HU 35, 230V	90031837
Germany	70107.2162	Heater Unit HU 35, 230V	90031838
Germany	70107.2162	Heater Unit HU 35, 230V	90031841
Germany	70107.2162	Heater Unit HU 35, 230V	90031842
Germany	70107.2162	Heater Unit HU 35, 230V	90031844
Germany	70107.2162	Heater Unit HU 35, 230V	90031846
Germany	70107.2162	Heater Unit HU 35, 230V	90031847
Germany	70107.2162	Heater Unit HU 35, 230V	90031848
Germany	70107.2162	Heater Unit HU 35, 230V	90031850
Germany	70107.2162	Heater Unit HU 35, 230V	90031853
Germany	70107.2162	Heater Unit HU 35, 230V	90031854
Germany	70107.2162	Heater Unit HU 35, 230V	90031874
Germany	70107.2162	Heater Unit HU 35, 230V	90031876

Urgent!

Field Safety Notice (FSN)



-Annex I-

List of affected products country-/ region-specific

Germany	70107.2162	Heater Unit HU 35, 230V	90031878
Germany	70107.2162	Heater Unit HU 35, 230V	90031879
Germany	70107.2162	Heater Unit HU 35, 230V	90031880
Germany	70107.2162	Heater Unit HU 35, 230V	90031882
Germany	70107.2162	Heater Unit HU 35, 230V	90031883
Germany	70107.2162	Heater Unit HU 35, 230V	90031884
Germany	70107.2162	Heater Unit HU 35, 230V	90031885
Germany	70107.2162	Heater Unit HU 35, 230V	90031887
Germany	70107.2162	Heater Unit HU 35, 230V	90031888
Germany	70107.2162	Heater Unit HU 35, 230V	90031890
Germany	70107.2162	Heater Unit HU 35, 230V	90031891
Germany	70107.2162	Heater Unit HU 35, 230V	90031892
Germany	70107.2162	Heater Unit HU 35, 230V	90031893
Germany	70107.2162	Heater Unit HU 35, 230V	90031901
Germany	70107.2162	Heater Unit HU 35, 230V	90031902
Germany	70107.2162	Heater Unit HU 35, 230V	90031908
Germany	70107.2162	Heater Unit HU 35, 230V	90031918
Germany	70107.2162	Heater Unit HU 35, 230V	90031919
Germany	70107.2162	Heater Unit HU 35, 230V	90031920
Germany	70107.2162	Heater Unit HU 35, 230V	90031921
Germany	70107.2162	Heater Unit HU 35, 230V	90031922
Germany	70107.2162	Heater Unit HU 35, 230V	90031923
Germany	70107.2162	Heater Unit HU 35, 230V	90031924
Germany	70107.2162	Heater Unit HU 35, 230V	90031925
Germany	70107.2162	Heater Unit HU 35, 230V	90031928
Germany	70107.2162	Heater Unit HU 35, 230V	90031929
Germany	70107.2162	Heater Unit HU 35, 230V	90031934
Germany	70107.2162	Heater Unit HU 35, 230V	90031935
Germany	70107.2162	Heater Unit HU 35, 230V	90031950
Germany	70107.2162	Heater Unit HU 35, 230V	90031951
Germany	70107.2162	Heater Unit HU 35, 230V	90031954
Germany	70107.2162	Heater Unit HU 35, 230V	90031955

Urgent!

Field Safety Notice (FSN)



-Annex I-

List of affected products country-/ region-specific

Germany	70107.2162	Heater Unit HU 35, 230V	90031956
Germany	70107.2162	Heater Unit HU 35, 230V	90031958
Germany	70107.2162	Heater Unit HU 35, 230V	90031966
Germany	70107.2162	Heater Unit HU 35, 230V	90031968
Germany	70107.2162	Heater Unit HU 35, 230V	90031969
Germany	70107.2162	Heater Unit HU 35, 230V	90031970
Germany	70107.2162	Heater Unit HU 35, 230V	90031974
Germany	70107.2162	Heater Unit HU 35, 230V	90031978
Germany	70107.2162	Heater Unit HU 35, 230V	90031979
Germany	70107.2162	Heater Unit HU 35, 230V	90031980
Germany	70107.2162	Heater Unit HU 35, 230V	90031982
Germany	70107.2162	Heater Unit HU 35, 230V	90031983
Germany	70107.2162	Heater Unit HU 35, 230V	90031989
Germany	70107.2162	Heater Unit HU 35, 230V	90031990
Germany	70107.2162	Heater Unit HU 35, 230V	90031993
Germany	70107.2162	Heater Unit HU 35, 230V	90031994
Germany	70107.2162	Heater Unit HU 35, 230V	90032012
Germany	70107.2162	Heater Unit HU 35, 230V	90032014
Germany	70107.2162	Heater Unit HU 35, 230V	90032015
Germany	70107.2162	Heater Unit HU 35, 230V	90032019
Germany	70107.2162	Heater Unit HU 35, 230V	90032035
Germany	70107.2162	Heater Unit HU 35, 230V	90032044
Germany	70107.2162	Heater Unit HU 35, 230V	90032046
Germany	70107.2162	Heater Unit HU 35, 230V	90032047
Germany	70107.2162	Heater Unit HU 35, 230V	90032051
Germany	70107.2162	Heater Unit HU 35, 230V	90032061
Germany	70107.2162	Heater Unit HU 35, 230V	90032080
Germany	70107.2162	Heater Unit HU 35, 230V	90032083
Germany	70107.2162	Heater Unit HU 35, 230V	90032090
Germany	70107.2162	Heater Unit HU 35, 230V	90032102
Germany	70107.2162	Heater Unit HU 35, 230V	90032110
Germany	70107.2162	Heater Unit HU 35, 230V	90032116

Urgent!

Field Safety Notice (FSN)



-Annex I-

List of affected products country-/ region-specific

Germany	70107.2162	Heater Unit HU 35, 230V	90032119
Germany	70107.2162	Heater Unit HU 35, 230V	90032135
Germany	70107.2162	Heater Unit HU 35, 230V	90032136
Germany	70107.2162	Heater Unit HU 35, 230V	90032148
Germany	70107.2162	Heater Unit HU 35, 230V	90032160
Germany	70107.2162	Heater Unit HU 35, 230V	90032166
Germany	70107.2162	Heater Unit HU 35, 230V	90032186
Germany	70107.2162	Heater Unit HU 35, 230V	90032193
Germany	70107.2162	Heater Unit HU 35, 230V	90032195
Germany	70107.2162	Heater Unit HU 35, 230V	90032198
Germany	70107.2162	Heater Unit HU 35, 230V	90032201
Germany	70107.2162	Heater Unit HU 35, 230V	90032205
Germany	70107.2162	Heater Unit HU 35, 230V	90032210
Germany	70107.2162	Heater Unit HU 35, 230V	90032213
Germany	70107.2162	Heater Unit HU 35, 230V	90032220
Germany	70107.2162	Heater Unit HU 35, 230V	90032221
Germany	70107.2162	Heater Unit HU 35, 230V	90032222
Germany	70107.2162	Heater Unit HU 35, 230V	90032234
Germany	70107.2162	Heater Unit HU 35, 230V	90032235
Hong Kong	70107.2162	Heater Unit HU 35, 230V	90031861
Hong Kong	70107.2162	Heater Unit HU 35, 230V	90031865
Hong Kong	70107.2162	Heater Unit HU 35, 230V	90032145
India	70107.2162	Heater Unit HU 35, 230V	90031909
India	70107.2162	Heater Unit HU 35, 230V	90031914
India	70107.2162	Heater Unit HU 35, 230V	90031915
India	70107.2162	Heater Unit HU 35, 230V	90031938
India	70107.2162	Heater Unit HU 35, 230V	90031941
India	70107.2162	Heater Unit HU 35, 230V	90031971
India	70107.2162	Heater Unit HU 35, 230V	90031975
India	70107.2162	Heater Unit HU 35, 230V	90031999
India	70107.2162	Heater Unit HU 35, 230V	90032001
India	70107.2162	Heater Unit HU 35, 230V	90032022

Urgent!

Field Safety Notice (FSN)



-Annex I-

List of affected products country-/ region-specific

India	70107.2162	Heater Unit HU 35, 230V	90032023
India	70107.2162	Heater Unit HU 35, 230V	90032024
India	70107.2162	Heater Unit HU 35, 230V	90032025
India	70107.2162	Heater Unit HU 35, 230V	90032026
India	70107.2162	Heater Unit HU 35, 230V	90032029
India	70107.2162	Heater Unit HU 35, 230V	90032032
India	70107.2162	Heater Unit HU 35, 230V	90032033
India	70107.2162	Heater Unit HU 35, 230V	90032037
India	70107.2162	Heater Unit HU 35, 230V	90032122
India	70107.2162	Heater Unit HU 35, 230V	90032123
India	70107.2162	Heater Unit HU 35, 230V	90032125
India	70107.2162	Heater Unit HU 35, 230V	90032126
India	70107.2162	Heater Unit HU 35, 230V	90032127
India	70107.2162	Heater Unit HU 35, 230V	90032128
India	70107.2162	Heater Unit HU 35, 230V	90032130
India	70107.2162	Heater Unit HU 35, 230V	90032132
Ireland	70107.2162	Heater Unit HU 35, 230V	90031805
Ireland	70107.2162	Heater Unit HU 35, 230V	90031810
Italy	70107.2162	Heater Unit HU 35, 230V	90031856
Italy	70107.2162	Heater Unit HU 35, 230V	90031937
Italy	70107.2162	Heater Unit HU 35, 230V	90031946
Italy	70107.2162	Heater Unit HU 35, 230V	90031947
Italy	70107.2162	Heater Unit HU 35, 230V	90031949
Italy	70107.2162	Heater Unit HU 35, 230V	90032018
Italy	70107.2162	Heater Unit HU 35, 230V	90032039
Italy	70107.2162	Heater Unit HU 35, 230V	90032040
Italy	70107.2162	Heater Unit HU 35, 230V	90032041
Italy	70107.2162	Heater Unit HU 35, 230V	90032042
Italy	70107.2162	Heater Unit HU 35, 230V	90032065
Italy	70107.2162	Heater Unit HU 35, 230V	90032066
Italy	70107.2162	Heater Unit HU 35, 230V	90032067
Italy	70107.2162	Heater Unit HU 35, 230V	90032068

Urgent!

Field Safety Notice (FSN)



-Annex I-

List of affected products country-/ region-specific

Italy	70107.2162	Heater Unit HU 35, 230V	90032069
Italy	70107.2162	Heater Unit HU 35, 230V	90032070
Italy	70107.2162	Heater Unit HU 35, 230V	90032071
Italy	70107.2162	Heater Unit HU 35, 230V	90032072
Italy	70107.2162	Heater Unit HU 35, 230V	90032073
Italy	70107.2162	Heater Unit HU 35, 230V	90032081
Italy	70107.2162	Heater Unit HU 35, 230V	90032146
Mexico	70107.2163	Heater Unit HU 35, 115V	90034502
Mexico	70107.2163	Heater Unit HU 35, 115V	90034503
Mexico	70107.2163	Heater Unit HU 35, 115V	90034507
Mexico	70107.2163	Heater Unit HU 35, 115V	90034510
Mexico	70107.2163	Heater Unit HU 35, 115V	90034538
Netherlands	70107.2162	Heater Unit HU 35, 230V	90032149
Netherlands	70107.2162	Heater Unit HU 35, 230V	90032151
Netherlands	70107.2162	Heater Unit HU 35, 230V	90032152
Netherlands	70107.2162	Heater Unit HU 35, 230V	90032153
New Zealand	70107.2162	Heater Unit HU 35, 230V	90031822
Norway	70107.2162	Heater Unit HU 35, 230V	90032013
Poland	70107.2162	Heater Unit HU 35, 230V	90031827
Portugal	70107.2162	Heater Unit HU 35, 230V	90031812
Portugal	70107.2162	Heater Unit HU 35, 230V	90031821
Portugal	70107.2162	Heater Unit HU 35, 230V	90031916
Portugal	70107.2162	Heater Unit HU 35, 230V	90031943
Portugal	70107.2162	Heater Unit HU 35, 230V	90031944
Russia	70107.2162	Heater Unit HU 35, 230V	90031896
Russia	70107.2162	Heater Unit HU 35, 230V	90031897
Serbia	70107.2162	Heater Unit HU 35, 230V	90032005
Singapore	70107.2162	Heater Unit HU 35, 230V	90031866
Singapore	70107.2162	Heater Unit HU 35, 230V	90031869
Singapore	70107.2162	Heater Unit HU 35, 230V	90031911
Singapore	70107.2162	Heater Unit HU 35, 230V	90031912
Singapore	70107.2162	Heater Unit HU 35, 230V	90031913

Urgent!

Field Safety Notice (FSN)



-Annex I-

List of affected products country-/ region-specific

Singapore	70107.2162	Heater Unit HU 35, 230V	90031917
Singapore	70107.2162	Heater Unit HU 35, 230V	90032006
Singapore	70107.2162	Heater Unit HU 35, 230V	90032062
Singapore	70107.2162	Heater Unit HU 35, 230V	90032133
Singapore	70107.2162	Heater Unit HU 35, 230V	90032140
Singapore	70107.2162	Heater Unit HU 35, 230V	90032158
Singapore	70107.2162	Heater Unit HU 35, 230V	90032175
Singapore	70107.2162	Heater Unit HU 35, 230V	90032190
Singapore	70107.2162	Heater Unit HU 35, 230V	90032228
Singapore	70107.2162	Heater Unit HU 35, 230V	90032232
Slovakia	70107.2162	Heater Unit HU 35, 230V	90032159
Slovakia	70107.2162	Heater Unit HU 35, 230V	90032161
South Africa	70107.2162	Heater Unit HU 35, 230V	90032120
South Africa	70107.2162	Heater Unit HU 35, 230V	90032147
South Africa	70107.2162	Heater Unit HU 35, 230V	90032150
South Africa	70107.2162	Heater Unit HU 35, 230V	90032155
South Africa	70107.2162	Heater Unit HU 35, 230V	90032172
South Africa	70107.2162	Heater Unit HU 35, 230V	90032177
South Africa	70107.2162	Heater Unit HU 35, 230V	90032178
South Africa	70107.2162	Heater Unit HU 35, 230V	90032180
South Africa	70107.2162	Heater Unit HU 35, 230V	90032181
South Korea	70107.2162	Heater Unit HU 35, 230V	90031834
South Korea	70107.2162	Heater Unit HU 35, 230V	90031845
South Korea	70107.2162	Heater Unit HU 35, 230V	90031992
South Korea	70107.2162	Heater Unit HU 35, 230V	90032002
South Korea	70107.2162	Heater Unit HU 35, 230V	90032008
South Korea	70107.2162	Heater Unit HU 35, 230V	90032027
South Korea	70107.2162	Heater Unit HU 35, 230V	90032030
South Korea	70107.2162	Heater Unit HU 35, 230V	90032156
South Korea	70107.2162	Heater Unit HU 35, 230V	90032197
Spain	70107.2162	Heater Unit HU 35, 230V	90031815
Spain	70107.2162	Heater Unit HU 35, 230V	90031825

Urgent!

Field Safety Notice (FSN)



-Annex I-

List of affected products country-/ region-specific

Spain	70107.2162	Heater Unit HU 35, 230V	90031962
Spain	70107.2162	Heater Unit HU 35, 230V	90031963
Spain	70107.2162	Heater Unit HU 35, 230V	90031964
Spain	70107.2162	Heater Unit HU 35, 230V	90031965
Spain	70107.2162	Heater Unit HU 35, 230V	90031967
Spain	70107.2162	Heater Unit HU 35, 230V	90031998
Spain	70107.2162	Heater Unit HU 35, 230V	90032034
Spain	70107.2162	Heater Unit HU 35, 230V	90032036
Spain	70107.2162	Heater Unit HU 35, 230V	90032055
Spain	70107.2162	Heater Unit HU 35, 230V	90032078
Spain	70107.2162	Heater Unit HU 35, 230V	90032118
Spain	70107.2162	Heater Unit HU 35, 230V	90032137
Spain	70107.2162	Heater Unit HU 35, 230V	90032142
Spain	70107.2162	Heater Unit HU 35, 230V	90032144
Spain	70107.2162	Heater Unit HU 35, 230V	90032183
Switzerland	70107.2162	Heater Unit HU 35, 230V	90031904
Switzerland	70107.2162	Heater Unit HU 35, 230V	90031905
Switzerland	70107.2162	Heater Unit HU 35, 230V	90032164
Switzerland	70107.2162	Heater Unit HU 35, 230V	90032167
Switzerland	70107.2162	Heater Unit HU 35, 230V	90032179
Thailand	70107.2162	Heater Unit HU 35, 230V	90032075
Thailand	70107.2162	Heater Unit HU 35, 230V	90032076
Thailand	70107.2162	Heater Unit HU 35, 230V	90032094
Thailand	70107.2162	Heater Unit HU 35, 230V	90032095
Thailand	70107.2162	Heater Unit HU 35, 230V	90032097
Thailand	70107.2162	Heater Unit HU 35, 230V	90032107
Thailand	70107.2162	Heater Unit HU 35, 230V	90032112
Thailand	70107.2162	Heater Unit HU 35, 230V	90032138
Thailand	70107.2162	Heater Unit HU 35, 230V	90032204
Turkey	70107.2162	Heater Unit HU 35, 230V	90031942
Turkey	70107.2162	Heater Unit HU 35, 230V	90031981
Turkey	70107.2162	Heater Unit HU 35, 230V	90031986

Urgent!

Field Safety Notice (FSN)



-Annex I-

List of affected products country-/ region-specific

Turkey	70107.2162	Heater Unit HU 35, 230V	90031988
Turkey	70107.2162	Heater Unit HU 35, 230V	90032010
Turkey	70107.2162	Heater Unit HU 35, 230V	90032011
Turkey	70107.2162	Heater Unit HU 35, 230V	90032109
Turkey	70107.2162	Heater Unit HU 35, 230V	90032169
Turkey	70107.2162	Heater Unit HU 35, 230V	90032188
Turkey	70107.2162	Heater Unit HU 35, 230V	90032192
United Arab Emirates	70107.2162	Heater Unit HU 35, 230V	90031828
United Arab Emirates	70107.2162	Heater Unit HU 35, 230V	90031830
United Arab Emirates	70107.2162	Heater Unit HU 35, 230V	90031849
United Arab Emirates	70107.2162	Heater Unit HU 35, 230V	90031851
United Arab Emirates	70107.2162	Heater Unit HU 35, 230V	90031862
United Arab Emirates	70107.2162	Heater Unit HU 35, 230V	90031936
United Arab Emirates	70107.2162	Heater Unit HU 35, 230V	90031939
United Arab Emirates	70107.2162	Heater Unit HU 35, 230V	90031976
United Arab Emirates	70107.2162	Heater Unit HU 35, 230V	90032054
United Arab Emirates	70107.2162	Heater Unit HU 35, 230V	90032057
United Arab Emirates	70107.2162	Heater Unit HU 35, 230V	90032079
United Arab Emirates	70107.2162	Heater Unit HU 35, 230V	90032111
United Arab Emirates	70107.2162	Heater Unit HU 35, 230V	90032206
United Kingdom	70107.2162	Heater Unit HU 35, 230V	90031804
United Kingdom	70107.2162	Heater Unit HU 35, 230V	90031806
United Kingdom	70107.2162	Heater Unit HU 35, 230V	90032096
United Kingdom	70107.2162	Heater Unit HU 35, 230V	90032173
United Kingdom	70107.2162	Heater Unit HU 35, 230V	90032174

Please note: SSUs are called to actively find out whether the listed devices have been forwarded or sold into any other country. That country where the unit is currently located is also an affected country. Please send any information about forwarding and selling to other countries to: FSCA.cp@getinge.com.

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

For follow up actions, please contact us on FSCA.cp@getinge.com.

Sincerely,

Maquet Cardiopulmonary GmbH
Kehler Str. 31

Urgent!

Field Safety Notice (FSN)

-Annex I-

List of affected products country-/ region-specific



76437 Rastatt
Germany