Urgent Field Safety Notice

YYYY-MMM-DD | FSCA 2026-015 – OT 1555113 | Rev 03

Update: Getinge Poladus 150 H1/H2

Products affected:

This Field Safety Notice applies to all Getinge Poladus 150 H1/H2 devices manufactured under the item numbers listed below.
Our records indicate that at least one (1) of the below listed products was delivered to your location. Please verify if you have any of the listed products and follow the information in this notification.

Item number	UDI	Item name
6034510000	04053275000226	Getinge Poladus 150 H1
6034510001	04053275000233	Getinge Poladus 150 H1
6034510002	04053275000240	Getinge Poladus 150 H2
6034510003	04053275000257	Getinge Poladus 150 H2
6034510004	04053275000264	Getinge Poladus 150 H2
6034510005	04053275000271	Getinge Poladus 150 H2

Description of the issue

Getinge is informing you that the use of the Poladus 150 H1/H2 may resume.

The supporting tests that led to the initial Field Safety Notice were reassessed and repeated following identified limitations in the original test methodology and documentation. The repeated testing has been successfully completed.

Potential hazards

Based on the completed investigation and updated Health Hazard Evaluation, Getinge has not identified a safety risk requiring continued suspension of use of the Poladus 150 H1/H2 when the device is used in accordance with the instructions for use.

No modification to the device or sterilization cycles is required as a result of this field safety corrective action.

Precautions - Important information concerning validation and compatibility of goods to sterilize

The following information clarifies the respective responsibilities of Getinge as legal manufacturer of the sterilizer, the sterilization facility and the relevant manufacturer of the goods to sterilize.

Getinge has verified the sterilization performance of the Poladus 150 using defined representative test loads, including test loads representative of rigid and flexible endoscopes, in accordance with the applicable verification approach reflected in Annex D of ISO 14937 and ISO 22441. This verification does not constitute validation, compatibility confirmation or approval of any individual medical device or customer-specific load configuration.

Reprocessing compatibility and sterilization suitability of each medical device remain the responsibility of the manufacturer of the goods to sterilize.

Users must verify that the relevant reprocessing instructions of manufacturer of the goods to sterilize or manufactures of robotic instruments authorize VH2O2 sterilization and must comply with any limitations specified in those instructions, including those relating to material compatibility. Each sterilization facility remains ultimately responsible for validating its specific load configurations and sterilization process in accordance with an international standard such as ISO 14937 and ISO 22441.

Customer Actions

1. Please ensure that this notice is forwarded to all relevant persons within your organization and to any organization to which an affected device has been transferred.
2. For traceability purposes, please complete and return the Customer Reply Form to your local Getinge representative before resuming use of the device. Please send it to @<insert local Getinge representative email>.

Attachments

- FSCA 2026-015 - OT 1555113 Reply Form

We sincerely apologize for any inconvenience this may have caused you.

Getinge is communicating this information to the appropriate regulatory agencies.

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

Sincerely,

Diana Gutekunst
Local Quality Manager, PRRC,
Maquet GmbH
Kehler Str. 31, 76437 Rastatt
Germany

Digital unterschrieben
von Simon Burkart
Grund: Confirmed
Datum: 2026.10.20
16:49:58 +02'00'

Contact details of your local Getinge representative

Contact Name
Contact e-mail
Contact phone
Contact office address

GETINGE

Reply Form

MMM-DD-YYYY | FSCA 2026-015 – OT 1555113 | Rev 03

Update: Getinge Poladus 150 H1/H2

Products affected:

Our records indicate that the below listed products were delivered to your location. Please verify if you have any of the listed products and complete the information below.

Getinge order no.	Item number	Serial number
X	X	XXXX
Y	Y	YYYY
Z	Z	ZZZZ

Record the total number of affected products currently located at your facility here please → ___.

Confirmation:

Please check the boxes below as appropriate. Make sure to tick the first box. Should you not understand the communication please reach us for guidance. Your organization's reply is the evidence we need to monitor the progress of this Field Safety Notice.

- ☐ We have read the Field Safety Notice and understand the communication and required actions.
- ☐ The listed device(s) are in our use and located at the address to which this communication was sent.
- ☐ The listed device(s) are in our use but located at a different location. Please complete the "New device location" section below.
- ☐ We have sold, moved, transferred, or otherwise provided the listed device(s) to another facility. Please complete the "New device location" section below.
- ☐ The listed device(s) are no longer in use at our facility.

* New device location (if applicable)

Serial number(s) at this new location: _____ _____		
New Facility Name	Contact name / title	e-Mail address
New Address (no PO box)	City, State, ZIP/Postal code	Phone number (Fax number)

For device distributors only:

- ☐ We have checked our stock and quarantined inventory and reviewed the list of devices to identify any affected downstream customers.
- ☐ We will share the list of devices, updated with customer details, with Getinge to support Field Safety Notice tracking and authority reporting, where required.
- ☐ We will share the list of devices with Getinge after finalizing the field action and identify the state of each device in the list.

Please return your completed form to:

Getinge market organization	Contact name / title	e-Mail address
XYZ	XYZ	XYZ
Address (no PO box)	City, State, ZIP/Postal code	Phone number (Fax number)
XYZ	XYZ	XYZ

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