

URGENT - FIELD SAFETY NOTICE**GETINGE VOLISTA StandOP and TRIOP
Field Action MSA-2017-001-IU**

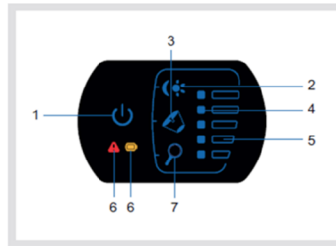
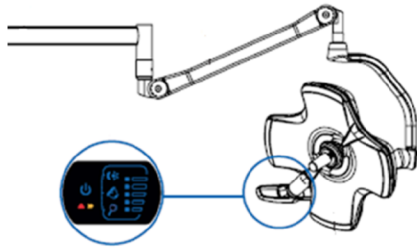
Date:	March 15, 2018
Product Issue:	Potential keypad failure on VOLISTA StandOP and TRIOP Surgical Lights
Affected Product:	All Getinge VOLISTA cupolas of model StandOP and TRIOP made until June 2017 equipped with keypad ARD568801560. The complete list of affected serial numbers for your market are listed in a separate document (Annex 1).
Resolution:	Maquet SAS proposes to replace the keypads ARD568801560 on the devices with keypads of a different design ARD568805501 to make sure all devices present in the market are working effectively and safely
Affected Serial Nos.:	See Annex 1 (consignee list)
Field Correction Notice:	MSA/2017/001/IU
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Dear Customer:

Our records indicate that you bought at least one cupola VOLISTA StandOP or TRIOP with a serial number listed in the consignee list.

This letter is to inform you of a corrective action that will be performed on the cupolas to prevent a possible failure of a device.

The issue we found can cause a failure of the control keypad. This can result in the cupola not turning on or off. We have received numerous complaints where this problem happened on 3 different keypad versions. From our investigation which includes our evaluation of worst-case scenarios it was concluded that there is only a remote chance that the problem may cause injury. However it is possible.



- 1 On/Off button
- 2 Standard lighting / ambient lighting button
- 3 Light field variation button
- 4 Level display for the selected function
- 5 Button to reduce / increase the selected function level
- 6 Status indicators
- 7 Camera zoom mode setting key

This potential for malfunction is caused by an internal frequency issue of a component on keypads version 1, and by the touch-sensitive technology that was not sensitive enough on versions 2 and 3 . The keypads at fault are no longer produced. We have implemented a more robust keypad using a different technology. Although the probability of occurrence of harm is low, we want to prevent any related event from occurring with our customers.

This action is to replace the potentially defective keypads with the new ones. The devices involved at your facility are listed in the consignee list file you received for this field action.

Next Steps

1. Please make sure that all caregivers and users of the VOLISTA StandOP and TRIOP cupolas referenced on the consignee list are made aware of this Field Notice and all listed devices at your facility are available to be replaced by an authorised Getinge service technician.
2. Complete and sign the enclosed Customer Response Form and return this form to the local Getinge office.
Note: A Getinge Sales or Service person will contact the person you listed on the Customer Response Form to schedule service to replace your device, free of charge

Transmission of this Field Notice:

This Getinge VOLISTA StandOP and TRIOP Field Notice needs to be distributed to those individuals who need to be aware within your organization - or to any organization where the potentially affected devices have been transferred.

Please maintain awareness of this notice and resulting action for the use period of the device to ensure effectiveness of the corrective action.

In cases where you as customer choose not to proceed with completion of the corrective action requirements described above, Getinge cannot accept any responsibility for safety related issues or legal liabilities caused by the failure to respond to this Field Safety Notice.

Additional Comment

We deeply regret this inconvenience, but we greatly appreciate your understanding as we take actions to ensure correct product performance. If you have any further questions or require assistance completing the Customer Response Form, please contact Getinge.

Yours sincerely

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