“Urgent Safety Information”

Urgent Medical Device - Corrective Action

INNOVA - E4 with 20.000.45 Pressure Chamber Rack

15/12/2014

Preface and reason for the corrective action:	Dear BHT Customer, We are writing to inform you of the corrective action to be taken in relation to a possible error in the performance and effectiveness of the BHT INNOVA – E4 washer-disinfector unit in connection with the 20 000.45 pressure chamber rack accessory. During maintenance work, it was determined by a customer that the fitting pipe between the rack and the water channel for the water supply to the lower level of the washing rack was no longer present. From when and for what reason the fitting pipe was no longer present at the time of the maintenance work has not yet been able to be clarified, an external mechanical influence cannot be ruled out. No further cases could be determined in a precautionary investigation of 11 additional machines at different operators. In its delivery condition, the component is attached in a force-locked manner and is secured additionally by two locking screws that are glued in. The fitting pipe has a double function: it bridges the distance from the rack to the water channel and at the same time, it opens the water channel to the machine as a result. 
Health Risks	As a result of a missing connection fitting pipe, it is anticipated that the pressure chamber was not supplied with a sufficient amount of processing water for the treatment of flexible endoscopes that are located in the rack. As a result, the safe processing of an endoscope in the affected pressure chamber cannot be guaranteed. For patients who were investigated or who are investigated with an endoscope that had been treated in a rack with such a fault, there is a risk of an infection with possible health hazards.
Affected products:	All INNOVA - E4

	In connection with the 20000.45 pressure chamber rack accessory
Affected countries	Germany, Poland, Lithuania, Denmark, Finland, The Russian Federation, Canada
Measures that must be taken by the customer/user:	1. Inform the affected users and their service personnel 2. Check the pressure chamber rack for completeness and check the functioning of the water supply. If this fault should have occurred, then the device must not be used any further for treatment until the device has been returned to its original condition. 3. Instruct the users that they have to check the functioning of the water supply between the water channel and the rack for every loading of the machine with the pressure chamber rack in the future. Document this instruction in the machine logbook. 4. We would like to ask you to reply to this letter in accordance with the attachment. 5. Amend your machine documentation with the appendices that we have supplied and add them to your operating instructions and technician's handbook.
Measures made by BHT-Hygienetechnik	Representatives of BHT-Hygienetechnik are available to you while implementing the measures or for questions by telephone or by e-mail.
Additional information and assistance	If you require any additional information or support regarding these corrective actions, please contact your respective representative for medicinal products or the service department of BHT-Hygienetechnik at the telephone numbers listed. ☐ Europe and the Russian Federation (07:00-17:00 CET) +49 82127890 E-mail QM@bht.de ☐ Canada (08:00 a.m. – 5:00 p.m.) + 1 800 667 7733 Fax: 416 445 2727
Forwarding of the information described here	• Please ensure that all users who operate the above-named products and any other people who should be informed have been made aware of this "Urgent Safety Information". If you have passed the product on to any third parties, then please pass on a copy of this information or inform the department that is named in "*Additional information and assistance*". • Please retain this information at least until the corrective action has been completed. • The German Federal Institute for Drugs and Medical Devices (Das Bundesinstitut für Arzneimittel und Medizinprodukte) has received a copy of this "Urgent Safety Information".

Yours faithfully,

[redacted]

Safety Office for Medical Devices and QM

Feedback Form

Safety Instructions

Urgent Medical Device - Corrective Action

"INNOVA E4 Missing Fitting Pipe Accessory 20000.45 Pressure Chamber Rack"

Name of Hospital / Dealer:	
Address:	
Post code, city:	
For the attention of:	

1. I have received and read this notice
2. I have ensured that all relevant staff members have been completely informed about the safety information
3. I will contact BHT-Hygienetechnik with any questions.

Name: (Block capitals)		**Position**
Signature:		☐ Department manager
Hospital / company name:		☐ User
Telephone number:		☐ Building Services
E-mail:		☐ Dealer
Date:		☐ Service partner

PLEASE SEND THIS FEEDBACK FORM TO:

BHT-Hygienetechnik GmbH
For the attention of the QM
Subject: E4 - Pressure Chamber Rack
Europe and the Russian Federation (07:00-17:00h CET) +49 82127890
E-mail QM@bht.de
Canada (08:00 a.m. – 5:00 p.m.) + 1 800 667 7733
Fax 416 445 2727