

URGENT: MEDICAL DEVICE RECALL

26.03.2012

Dear Sir/ Madam,

This is to inform you of a product recall involving:

Leica ASP6025, Tissue Processor, Serial number: 162 / 163 / 168-171 / 182-184 / 200-267.

This recall has been initiated due to a potential malfunction with the device in autorotation mode, which can lead to incorrect reagent handling of the device. The end-result may lead to damage or to loss of tissue specimens.

If you are receiving this letter you have received product that is subject to this recall. In this letter, we have included instructions on what you the customer should do with the recalled product. Please follow these steps:

1. Remove and dispose all reagents including Paraffin and clean all bottles and Paraffin bathes
2. Conduct a "Smart Clean" (IFU, chapter 6.1.4)
3. In Submenu "System Setup", here at "Program options", respectively "Station sequence", customer shall switch from "Concentration" to "Auto by RMS"
4. Prestored Xylene protocols shall be used instead of autorotation protocols (IFU, chapter 5.6.2 "Time - optimized Xylene infiltration programs"). Here you find the five validated programs which need to be copied to Favourite programs (IFU, chapter 5.5.3)
5. Use the Reagents, bottle set up from "Time optimized Xylene programs" (IFU, chapter 5.6.2., page 134) and implement them into submenu "Reagents" (IFU, chapter 5.2. following pages)

6. In submenu "The RMS system adjusting warning thresholds rules" (IFU, chapter 5.2.2) the validated reagent thresholds need to be implemented into Submenu "Reagents" (IFU, chapter 5.2).
7. Current Reagent management values are visible within Submenu "Reagent Status" (IFU, chapter 5.2.3)

This recall should be carried out to the end-user level. Your assistance is appreciated and necessary to prevent patient harm.

Please complete and return the enclosed response form within ten working days and send it to
Fax : 0049/(0)6224/143 5345

If you have any questions, please contact:

Robert Gropp

Tel.: 0049/(0)6224 143 345

Email: Robert.Gropp@leica-microsystems.com

This recall is being made with the knowledge of the relevant Health Authorities.

We are sincerely sorry to any inconvenience caused by this.

Best regards,



Robert Gropp

RA/QA Manager

Leica Biosystems Nussloch GmbH