

SAFETY ADVISORY NOTICE

GETINGE

Place
Getinge Disinfection AB, Växjö
Date
2007-04-04
Issued by
QA/RA Peter Carlsson
Subject:
CPU/Relay boards

Our identity mark
AN07-0002
Revision
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Distribution:
Getinge & Arjo Sales Companies

Dear Sir/Madam

Getinge Disinfection AB (GDSE) has found that there can be a problem with CPU/Relay board with part numbers 5004052-00 and 5004052-01. The problem has been found on 46-Series and 86-Series Washer Disinfectors and 600-Series and SP-1000/2000 (Arjo – Tornado) Flusher Disinfectors delivered from December 9th 2004 until January 22nd 2007.

Background

A premature failure of an electronic component may cause the Washer Disinfector (WD) to perform in an abnormal manner. Symptoms of the problems that have been reported include:

- Does not progress to the next phase, e.g. lengthened washing phase.
- Unintended parameter changes without operator intervention
- Button functions do not work properly when pressed.
- The backup battery on the board becomes drained and is lacking the available power necessary for holding the program in power failure mode or equipment off-mode.

Actions to Take

If you notice any of the above listed symptoms with your Washer or Flusher Disinfector, we recommend that you do not use the equipment until the CPU/Relay Board has been replaced by a trained Getinge or Arjo representative.

If none have been exhibited, the user can continue using the device until the CPU/Relay board will be exchanged. We recommend that the CPU/Relay board must be exchanged at normal service or at latest within 12 months.

Order CPU/Relay boards from GDSE together with the serial number of the machine (SEV0XXXXXX).
Christina Bergström +46 470 77 98 59
christina.bergstrom@getinge.com

Report with serial numbers and date of exchange of CPU/relay boards must be sent to QA/RA Peter Carlsson Getinge Disinfection AB every month.

All Sales and service organizations will have following documentation from GDSE;

1. Customer letter
2. List of machines with Serial Nos. and Purchase order Nos.
3. Instruction for Service Technicians
4. Flow chart of actions.

Thank you for your kind co-operation.

Should you need further information, do not hesitate to contact me at:

☎ +46 470 77 98 88 Fax +46 470 295 66 or E-mail: peter.carlsson@getinge.com

Yours sincerely

GETINGE DISINFECTION AB

(Signature on File) _____

Peter Carlsson
QA/RA Manager

DEVICE CORRECTION NOTICE

GETINGE WASHER DISINFECTORS

Date: 5th.July , 2007

Summary

This notice is to report an issue that involves the Getinge Models 8666, 8668, 46-2, 46-4, 46-5 Washer Disinfectors, and S-607, S-608, S-617, S-618 and SP1000 Flusher Disinfectors. A premature failure of an electronic component may cause the Washer and Flusher Disinfector (WD) to perform in an abnormal manner. Symptoms of the problems that have been reported include:

- Does not progress to the next phase, e.g. lengthened washing phase.
- Unintended parameter changes without operator intervention
- Button functions do not work properly when pressed.
- The backup battery on the board becomes drained and is lacking the available power necessary for holding the program in power failure mode or equipment off-mode.

If you notice any of the above listed symptoms with your Washer or Flusher Disinfector, we recommend that you do not use the equipment until the CPU/Relay Board has been replaced by a trained Getinge representative.

If none have been exhibited, the user can continue using the device until the CPU/Relay board will be exchanged. We recommend that the CPU/Relay board must be exchanged at normal service or at latest within 12 months.

Manepa Ltd. is taking action to replace the CPU/Relay Board component to prevent the possibility of a malfunction during a process cycle. This action is being done voluntarily in the interest of continued safety, reliability and customer satisfaction, and will be done at no cost to you.

Affected Units

This action only affects

- **Getinge Models 8666, 8668, 46-2, 46-4, 46-5 Washer Disinfectors, and S-607, S-608, S-617, S-618 and SP1000 Flusher Disinfectors**
- **Units with serial number from SEV0442290 to SEV0701036**

You can check the type and serial number of your unit by looking at the label with "Getinge Disinfection AB" at the top. The model is indicated in the box to the right of the letters "TYP," and the serial number is indicated in the box to the right of the letters "NO." Serial numbers are all structured SEVYYWWXXX, where

- YY = the last two digits of the year,
- WW = the two digits of the production week, and
- XXX = the sequential number the unit was in production that week



- Example: SEV0519225 = the 225th unit produced in week 19 of 2005.

If the serial number on your unit falls into the range above, it is likely affected by this notification.

Instructions

- If any of the symptoms listed in the Summary section above have occurred, please contact Manepa Ltd on 01 2959191 . Manepa will order a pre programmed replacement CPU card from from Getinge Disinfection and arrange for immediate CPU exchange. A Manepa representative will contact you to schedule an appointment to install a replacement CPU/Relay board. If you have any questions regarding the status of your service appointment, please Manepa on 01 2959191

• Enclosed is a Customer Response Form that we request being completed, to ensure for our records, that you received this notification. Please complete the form and fax it to 01 2959152 We appreciate your patience as we work to quickly resolve this matter. Manepa & Getinge regrets any inconvenience that this may cause. Your satisfaction with Manepa's service & Getinge products is of the utmost importance to us. If you should have any questions, please call Michael O Brien on 086 3847836

Sincerely

Michael O Brien
Manepa Ltd.