



URGENT: PRODUCT CORRECTION
Automatic Endoscope Reprocessor (AER)

January 13, 2012

Dear Valued Customer:

The Minntech Corporation (“Minntech”) as the manufacturer of the ASP AER, and Advanced Sterilization Products (“ASP”) have addressed the elevated high-level disinfectant solution temperature issue associated with the ASP Automatic Endoscope Reprocessor (“AER”). Minntech has developed a long-term solution in the form of a software upgrade and it is now available as an option for you.

Installing this software upgrade requires a physical change of the CPU card located on the controller board. This board is located inside of the unit. Installation of this new CPU with the new software fix will ensure that the temperature of high-level disinfectant used in the ASP AER will remain at the correct level for optimum product efficacy and user safety once the ASP AER’s heater is reconnected. There are two options to complete this installation activity.

For either installation option, you are required to order the software upgrade. To place an order for the software upgrade kit, please call 1-866-677-8668 M-F between 7:00AM and 6:00PM (CST).

Below are options for installing the new Minntech software upgrade:

1. Install it yourself. Included in the upgrade kit will be PARTS and INSTRUCTIONS on how to install the software upgrade. You must order the software upgrade no later than March 31, 2012.
2. Utilize ASP’s contracted service provider, Universal Hospital Supply (UHS). This is a courtesy service provided at no charge.
 - Call UHS to order the parts and schedule an appointment no later than March 31, 2012.
 - Actual dates to perform the upgrade will be based on service availability and the upgrade needs to be performed no later than June 30, 2012.
 - You **MUST** have the upgrade kit at your facility. The service provider will **NOT** have the upgrade kits on hand.

The deadline for ordering the upgrade kit and/or making an installation appointment is March 31, 2012.

Please continue to follow the Instructions for Use for the high-level disinfectant being used in the ASP AER.



Should You Choose NOT to Install the Software Upgrade

If you desire to keep the ASP AER heater disconnected and **not** install the software upgrade, please complete the attached form and send it to ASP via facsimile (facsimile number: 1-866-912-8417) as soon as possible.

You can continue to operate the ASP AER with the heater disconnected in accordance with the precautionary steps outlined below. This will ensure continued safe operation of the ASP AER and avoid the potential for elevated high-level disinfectant temperatures.

- **CIDEX[®] OPA Solution Users:** If you are using CIDEX[®] OPA Solution, and the ASP AER heater remains disconnected, you must use the CIDEX[®] OPA Solution in accordance with its label directions of 12 minute immersion time at 20° C. ASP recommends that the user check the solution temperature in the basin on a regular basis per institutional guidelines.
- **Users of Other High-Level Disinfectants:** If you are currently using a disinfectant that must be used at 25° C or higher and the ASP AER heater remains disconnected, you must immediately discontinue using the ASP AER with that disinfectant. Instead, you must process your endoscopes by another method in accordance with the Instructions for Use (“IFU”) for that particular disinfectant.

If you plan to continue to use the ASP AER, with the heater disconnected, you must obtain a high-level disinfectant that does not require heating above room temperature. Information on high-level disinfectants cleared for use by the FDA can be obtained from the website:

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/ReprocessingofSingle-UseDevices/UCM133514>.

ASP and Minntech appreciate your patience and regret any inconvenience this situation may cause you. If you have any questions or need assistance, please contact ASP at 1-888-783-7723.

Sincerely,

Richard J. Alberti
Vice President, Quality, Regulatory, & PE
Advanced Sterilization Products



**URGENT: ASP AUTOMATED ENDOSCOPE REPROCESSOR (AER)
SOFTWARE UPGRADE ORDER FORM
RESPONSE REQUIRED BY MARCH 31, 2012**

Our records indicate that you have one or more ASP AERs operating in your facility.
Please fill out the table below and return via fax to 1-866-912-8417.

1. **I wish to install the software upgrade myself:** Mark X in this column
2. **I wish to Utilize ASP's contracted service provider:** Mark X in this column
3. **I am not interested in the software upgrade:** Mark X in this column
4. **ASP AER unit is no longer in service/at location:** Mark X in this column
5. **Facility name and address of new location, if applicable:** Please supply information, if known, where the unit is now located.
6. Add any additional ASP AER serial numbers you may have in your facility and follow steps above.

ASP AER SERIAL NUMBER*	I WISH TO INSTALL THE SOFTWARE MYSELF	I WISH TO UTILIZE ASP'S CONTRACTED SERVICE PROVIDER	NOT INTERESTED IN SOFTWARE UPGRADE	ASP AER UNIT IS NO LONGER IN SERVICE/AT LOCATION	NAME AND ADDRESS OF NEW ASP AER LOCATION

Information to be completed by the contact filling out the form:

Name: _____ Title: _____

Signature: _____ Date: _____ Phone: _____

*The ASP AER serial number can be found on the label placed on the inside of the system front door.