

PRIMUS STERILIZER LABELING

Overview

PRIMUS is required by the US Food and Drug Administration (FDA), Underwriters Laboratories (UL), ASME Code, Canadian Medical Device Regulations (CMDR), ISO 9001 and ISO 13485 laws, regulations, and requirements to affix a variety of labels to all steam sterilizers prior to shipment to end user customers.

Detailed information about these agencies and organizations can be found in previously published PRIMUS Did You Know? bulletins or on the Internet. All previously published Did You Know? bulletins can be found on the PRIMUS website www.primus-sterilizer.com.

In addition to the labels discussed below, PRIMUS also provides an electrical diagram with each sterilizer. The electrical diagram is adhered to the inside of the control box. Operator Manuals are provided on CDs. One copy is located in the control box. The second copy is located in the chamber in an envelope labeled "Please Save! Operator CD Manual." The respective PRIMUS Job Number is also written on the envelope. This process may vary if special shipping is required by the customer.

An Uncrating work instruction is affixed to the door of the sterilizer. Inside every chamber is a "PRIMUS Care Kit" containing two (2) extra rolls of printer paper, a can of stainless steel polish and one replacement gasket.

Labels

Examples of the labels on each sterilizer are:

- ASME Name Plate**
- UL Listing Label**
- Serial Number Plate**
- Control Cover Shock Hazard Warning Label**

The following describe the purpose of each label and where each is normally located for ease of visibility.



NO: 215

JUNE 12, 2013

PRIMUS STERILIZER LABELING (CONTINUED)

ASME Name Plate



All sterilizers have an ASME name plate identifying PRIMUS Sterilizer Company, LLC as the manufacturer. The label includes the Manufacturer's Location, Jacket and Chamber Maximum Working Pressure rating, Minimum Design Temperature, Serial Number for the vessel, Year Built, and the Canadian Registration Number (C.R.N.)

Location: On vertical door units, the name plate is located above the door. If the door is a double door unit with a bio-seal, the name plate is located on the non-bio-seal side.

On horizontal door units, the name plate is located on the service side of the chamber.

If an end user customer does not know a sterilizer's respective Job Number, the customer should look on the name plate for the serial number. Having the serial number when contacting PRIMUS is very important, for it will help the company quickly locate the sterilizer's Device History Record (DHR).



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PRIMUS STERILIZER LABELING (CONTINUED)

Steam Sterilizer Serial Number Label with UL Listing Label



Label Legend

Rating: Indicates the electrical service requirements

Model #: **PSS8** identifies the control system - **X** Size of the chamber (e.g., AA = 16x16x26 chamber) - **M** Type of vessel (M=Multifunctional), **X** Steam source (E = Electric Boiler; S= House Steam) and **XX** Door Configuration (SD=Single Door, DD=Double Door)

Loc. Iden.: Manufacturing location and address

Serial #: Manufacturer Serial Number (vessel specific)

Nat. Bd: ASME Inspection Number (vessel specific)

UL Listing Label

- Clear over-lay
- Located next to (left) of the Serial Number Label as indicated above

Location: Service side, located on the electrical service box or upper left corner of the frame

Visibility: From service access area

UL Listing Number: UL Listing E234703



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PRIMUS STERILIZER LABELING (CONTINUED)

Control Cover Shock Hazard Warning Label



Location(s):

- A. Top (lid) of NEMA rated computer control box.
- B. On the cover of electrical service supply terminal strip box.
Top right, rear corner of frame.
- C. Boiler control, if applicable

Visibility:

From the area of the label application. In the case of the label (B.) it is visible to anyone removing the protective cover of the electrical service supply terminal box.



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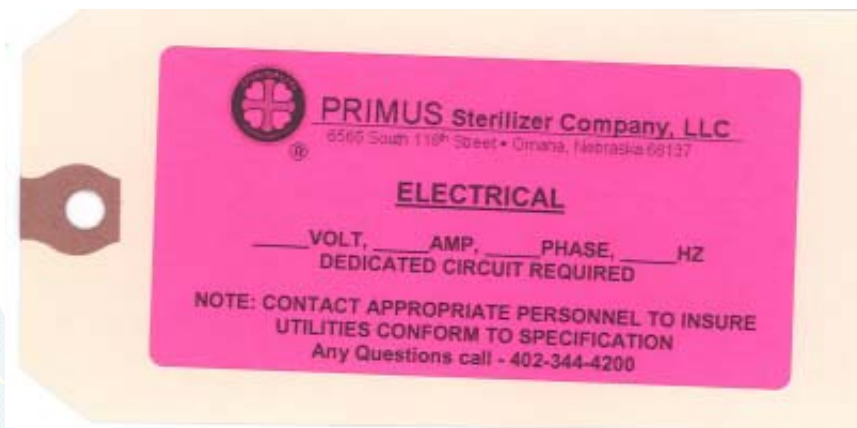
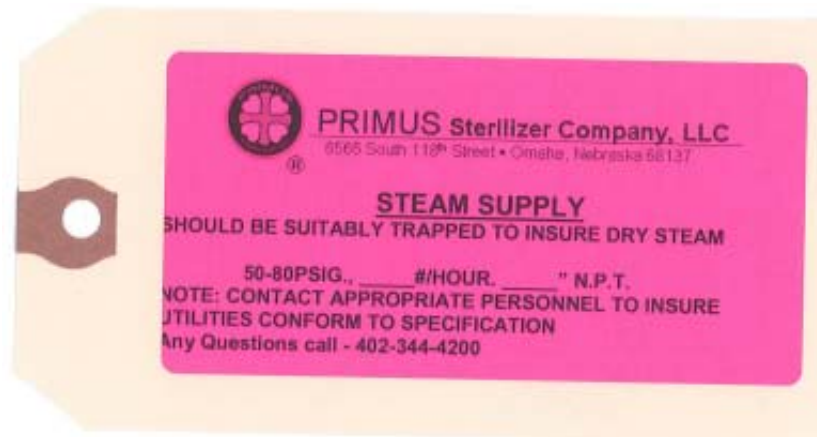
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PRIMUS STERILIZER LABELING (CONTINUED)

Sterilizer Installation Labels



Location: At the connection point of the utility

Visibility: From the area of the label application



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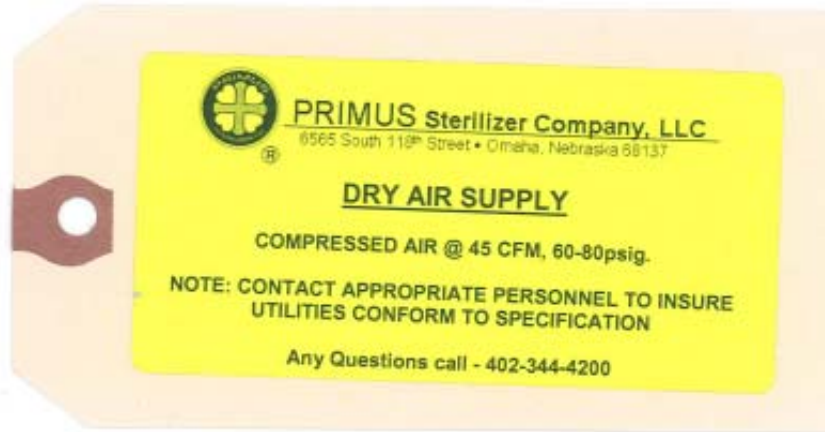
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PRIMUS STERILIZER LABELING (CONTINUED)

Sterilizer Installation Labels (Continued)



Location: At the connection point of the utility

Visibility: From the area of the label application



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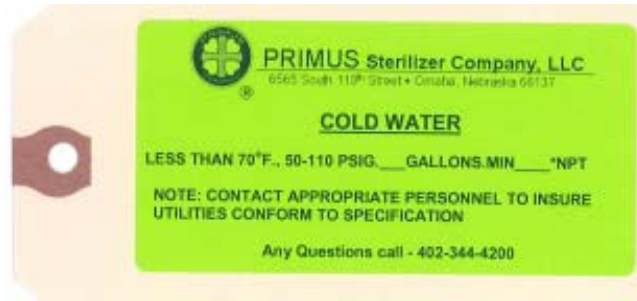
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PRIMUS STERILIZER LABELING (CONTINUED)

Sterilizer Installation Labels (Continued)



PRIMUS Sterilizer Company, LLC
6565 S. 118th Street, Omaha NE 68137
Vacuum Pump Storage & Installation

Pump filled with vegetable oil on _____ (Date)
Rotate shaft of pump monthly during storage. Prior to startup,
drain vegetable oil down to center point of pump (shaft level).
Follow all procedures & precautions in the SIHI Pump IOM Manual.

Read IOM Manual fully prior to installation or storage.

**For any questions call PRIMUS Service:
402-344-4200 Ext 8**

Location: At the connection point of the utility

Visibility: From the area of the label application

The above labels provide the information needed to properly install sterilizer utilities. Additionally, the labels will allow operator and maintenance technicians to safely and effectively operate and maintain the sterilizer.



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