

DID YOU KNOW?

NO: 27

NOVEMBER 2, 2009

FACTORY ACCEPTANCE TEST (FAT)

PRIMUS performs a Factory Acceptance Test (FAT) on every unit before it leaves the factory. The FAT record is stored in the Device History Record (DHR) file (see DYK #23) and a copy is provided to the customer in the Operator Manual.

The FAT test is subject to review during ISO and FDA audits.

The purpose of the FAT is to evaluate and document the sterilizer following assembly and verify its operations are in accordance with design specifications. Sterilizer system components and software are confirmed in this testing phase. Functionality of the sterilizer is qualified, verified and documented. The FAT is followed in accordance with FDA regulatory codes that govern medical devices.

The FAT contains the following specific information for each sterilizer tested:

Customer, Model Number, Job Number, Sterilizer Serial Number, Computer Serial Number, Printer Serial Number, Touchpad Serial Number, Software Serial Number, Software Revision Number, National Board Number

Detailed Inspections Conducted

Controller assembly

Vessel set-up

Door assembly

Electrical inspection

Plumbing inspection

Sterilizer devices

These highly detailed visual and tactile tests are performed to certify cleanliness, correct component usage, conformance to customer specifications, no inadvertent component damage, components mounted properly and securely, noise levels, alarms audible, no leakage of any type, etc.

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PRIMUS

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FACTORY ACCPETANCE TEST (FAT)

Operational Tests Performed

Sterilizer alarm verification tests

Vacuum cycle (134°C/273°F for 15 minutes, 3 minute dry time with 3 pre-vacs)

Gravity cycle (122.8°C/253°F for 15 minutes, 3 minute dry time)

Liquids cycles (122.8°C/253°F for 15 minutes, 4 minute cool time)

Non-healthcare units run a vacuum leak test (pull chamber to 20 inches of vacuum. The unit must not lose more than .7 hg over 20 minutes). The vacuum leak test is already integrated into the healthcare software.

Hi-Pot test (must withstand a test potential of 1000 volts for 60 seconds)

General Information

All testing runs are performed at the factory

FAT results are verified by a second party independently of the first tester. Final results are reviewed and signed off by a member of PRIMUS management.

Any problems encountered during the FAT are documented in writing and corrected before proceeding with the testing.

Controllers are set-up with specific cycles and parameters

A checklist is performed to ensure all labels, brackets, crating, etc. are proper to ensure a quality final product

The customer and/or ASA is/are always welcome to visit the facility and watch the FAT test run on their respective unit(s). While attending the FAT is free, all travel, lodging, and meal expenses are covered by the customer.

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