THE RULES HAVE CHANGED. WHAT DO WE DO NOW?

Recent changes to the standards for performing preventive maintenance have raised a lot of questions. The majority of these questions come from the fact that the governing bodies have deferred to the OEM for the preventive maintenance schedule. Not a big deal, right? Not really, as long as you are only responsible for one model with the most current software/hardware version and the most up to date service manual.

For the other 99.9%, this will effect you greatly. CMS (Centers for Medicare & Medicaid Services)**1 and ACR (American College of Radiology)**2 have both suggested that preventive maintenance schedules should be done in accordance with the OEM specifications. There in lies the problem. If you look at the current offerings from the OEMs, you will be surprised to find out that there are more than 70 ultrasound equipment offerings. When you have the free-time, like we all do, find and download the service manuals for the equipment that you are responsible for. Once you have each up-to-date service manual, read over the preventive maintenance procedures. You will notice, very quickly, that they differ from OEM to OEM and even model to model. That being said, some OEMs don’t require preventive maintenance on the ultrasound system, transducers or accessories. What are the safety concerns for your patients when the OEM’s recommendation is to not service the system, transducers or accessories?

The question remains, how do I perform a preventive maintenance on my ultrasound equipment? When do I perform a preventive maintenance and what are the standards?

Use this document to have a better understanding of what needs to be done during a preventive maintenance, standards for pass/fail and submission for accreditation. You can also use the attached Ultrasound Certification Report to develop and document your own maintenance program that supersedes the OEM recommendation. GMI recommends performing preventive maintenance every 6 months. This schedule will increase the lifespan of your system and will ensure the safety of your patients and operators. You will also see the benefit of regular maintenance in your budget and bottomline.

INTRODUCTION

- When possible introduce yourself to the user
- Inquire as to the current functionality of the equipment
- Inquire as to the current Network configuration
- Ask if there are any items that need to be addressed during the PM.
  - Software updates
  - Options
  - Peripherals
  - Backups
2 VISUAL INSPECTION

SYSTEM
- Inspect the monitor for obvious signs of damage and wear
- Inspect the monitor arm/mechanism; insure that it can support the monitor in a fixed location. Make sure the arm/mechanism can be secured via locking mechanism
- Inspect the screen for missing pixels, burn-in
- Verify operation of brightness/contrast controls
- Verify focus of the monitor

SYSTEM
- Inspect the entire control panel for obvious signs of damage/wear
- Closely inspect all keys, buttons, knobs, LEDs for and slide pots for functionality and missing cosmetic pieces
- Inspect touch screens/LEDs for missing pixels, focus and proper touch calibration
- Inspect trackball for proper operation (up, down, left, right)
- Inspect QWERTY keyboard for function of all keys
- Inspect down-lighting assembly for proper illumination
- Inspect control panel arm/mechanism

SYSTEM
- Inspect all cosmetic panels/cover for obvious damage wear
- Closely inspect all panels for missing screws

SYSTEM
- Inspect the electrical cord/plug for obvious damage/wear

SYSTEM
- Inspect all casters for obvious damage/wear
- Inspect each caster for proper operation
- Inspect brake assembly for proper operation
- Make sure brake assembly can securely hold the system in place
**VISUAL INSPECTION**

**TRANSDUCER**
- Check the plastic housing for damage, separation, cracks, stains or discoloration
- Check the scanhead strain relief for separation, tearing, deterioration or discoloration
- Check the rubber membrane for holes, cuts, tears, separation from housing, delamination (adhesive separation from crystal), discoloration or stains

Any damage to the transducer that would allow fluid to infiltrate the transducers internal components is an **AUTOMATIC FAILURE**. The transducer should be removed immediately from service.

**CABLE**
- Check the cable sheath for cuts, tears, holes, discoloration, stains and showing braid or wires
- Check that the cable is attached at both strain reliefs (Connector & Scanhead)

**SCANHEAD**

**TRANSFORMER**
- Check the connector housing for damage, missing screws and damaged locking mechanism
- Check the connector for bent, broke, missing or damaged pins
- Check connector strain relief for separation, tearing, deterioration or discoloration
3 SYSTEM DIAGNOSTICS

- Perform on-board user level diagnostics to verify system hardware and software
- Note any and all failures

4 SYSTEM CLEANING

Use a gentle cleaning agent (SonoWipes or warm water & mild soap) and wipe down all surfaces of the equipment to include:
- Monitor/LCDs
- Control Panel
- Handles
- Cosmetic Panels
- Transducers
5 SYSTEM DISASSEMBLY

- Remove all filters and clean; clean with a vacuum or warm water
- Remove cosmetic panels
- Remove card cage shields
- Remove circuit boards from card cage (use ESD safe mat or bags)
- Use an ESD safe vacuum to gently clean the card cage and assemblies

NOTE:
Shut down the equipment and unplug

6 SYSTEM REASSEMBLY

- Reinstall all circuit boards in to the card cage
- Replace the card cage shields
- Replace cosmetic panels
- Reinstall all air filters once cleaning is complete
• Power up the system and note any boot-up failures
• Enter “Test” Patient Demographics
• Select a transducer
• Select a factory default preset according to probe type
• Acquire/Save an image in each mode of operation

**IMAGING MODE**

*Use 2D Gain Control and TGC Control*
- Acquire an even gray-scale image both vertically and horizontally
- Look for signs of weak or dead elements within the scan field
- Once the image is acquired, select a set of targets to perform measurements with and freeze the image
- Select calipers and measure both horizontal and vertical targets. (Horizontal Expected Distance = 2.00 cm, Vertical Expected Distance = 1.00 cm)

**IMAGE UNIFORMITY CHECKS**
- Average brightness at the edge of the scan field is the same as in the middle
- No signs of shadowing vertically or horizontally in the scan-field
- No brightness transitions between focal zones

**PENETRATION**
- What is the maximum depth you are able to successfully visualize the Ecographic pattern on the phantom

**TRANSUDER FAILURE CRITERIA**
- No more than 2 dead elements within the scan field
- No more than 4 weak elements within the scan field
IMAGING MODE

M-MODE

(Use 2D/M-MODE Gain Control and TGCs)
• Acquire an even gray-scale image both vertically and horizontally (Image Uniformity Checks)
• Select a target on the phantom within the scan field
• Engage the M-MODE sample line and adjust to the selected target
• Ensure the scrolling graphics display is working properly

COLOR DOPPLER

(Use 2D Gain, Doppler Gain and TGCs)
• Acquire an even gray-scale image both vertically and horizontally (Image Uniformity Checks)
• Acquire an anatomical image based on the transducer and preset selected
• Engage the Color Doppler function
• Adjust the ROI (Region of Interest) using the trackball
• Select an area with measurable blood-flow
• Adjust the Color Doppler Gain, Doppler Scale and Baseline to show proper blood-flow in the selected area
**IMAGING MODE**

**SPECTRAL DOPPLER**

(Pulsed & Continuous Wave)
- Acquire an even gray-scale image both vertically and horizontally (Image Uniformity Checks)
- Acquire an anatomical image based on the transducer and preset selected
- Engage PW or CW function (CW is only available for Cardiac functions)
- Select an area with measurable blood-flow
- Adjust the Gate or Sample Line using the trackball
- Adjust the Doppler Gain, Doppler Scale and baseline to display the correct spectral waveform for the area of interest

**IMAGING MODE**

**3D/4D**
- Acquire an even gray-scale image both vertically and horizontally (Image Uniformity Checks)
- Acquire an anatomical image based on the transducer and preset selected
- Engage the 3D function
- Adjust the ROI (Region of Interest) using the trackball
- Freeze the image or engage 3D/4D rendering
MEDIA

- Select the “Test” patient from the Patient Archive/Hard Drive
- Designate Storage Location: CD/DVD/USB
- Send patient file to specified storage location
- Verify successful write to removable media

NETWORKING

- Select the “Test” patient from the Patient Archive/Hard Drive
- Designate DICOM Server destination
- Send “Test” patient file to DICOM Server
- Verify successful transmission either by successful send message on the machine or physical verification on the server
1. **CUSTOMER INFORMATION**
   - Site Name:
   - Department:
   - Contact:
   - Address:
   - Phone:
   - Fax:
   - E-mail:
   - WorkOrder Number:

2. **EQUIPMENT INFORMATION**
   - System Type:
   - System Manufacturer:
   - System Serial Number:
   - Software Level/Version:
   - Build/Cart Level:

3. **EQUIPMENT EVALUATION**
   - Chassis/Panels
     - Look for obvious signs of damage and or missing cosmetic panels
     - Look for damage to the chassis/frame and or missing screws
   - Caster/Brakes
     - Check to insure that all casters roll freely in the un-locked position
     - Check the integrity of the rubber wheels, make sure the wheel is intact and secure
     - Check to ensure that the casters hold the system in place when the brake is applied
   - AC Plug
     - Check to make sure the AC plug is seated and secured to the system
   - Fans/Air Filters
     - Check the cable for any signs of damage or wear
     - Ensure that all air filters have been cleaned
     - Ensure that all air filters are present
   - Monitor/LCD
     - Make sure that all system fans are operational
     - Inspect the monitor for signs of damage and wear
     - Inspect the monitor arm/mechanism; ensure that it can support the monitor in a fixed location
     - Make sure the arm/mechanism can be secured via locking mechanism
     - Inspect the screen for missing pixels and burnt-in pixels
     - Verify operation of brightness/contrast controls
     - Verify focus of the monitor
   - Control Panel
     - Inspect the entire control panel for signs of damage and wear
     - Closely inspect all keys, buttons, knob, LEDs and slide pots for functionality and missing cosmetic pieces
     - Inspect touch screens, LEDs, LCDs for missing pixels, focus and proper touch calibration
     - Inspect trackball for proper operation (up, down, left, right)
     - Inspect QWERTY keyboard for function of all keys
     - Inspect down-lighting assembly for proper illumination
     - Inspect control panel arm/mechanism
CD/DVD
Verify operation of removable media device by storing digital images to the device and review

DICOM Ping/Verify
Ping the DICOM storage device to verify connectivity
Verify DICOM operation by sending DICOM packet to the storage server

2D Scan
Verify 2D mode of operation based on Section 7
Color Doppler
Verify Color Doppler mode of operation based on Section 7

PW/CW Scan
Verify Spectral Doppler mode of operation based on Section 7

3D/4D Scan
Verify 3D/4D mode of operation based on Section 7

On-Board Diagnostics
Perform user level system diagnostics

4. TRANSDUCER INFORMATION
Model - This is the model as designated on the transducer
Part Number - This is the actual part number for reorder or replacement
Select Pass or Fail in reference to physical and diagnostic condition of the transducer.
Once the probe has been cleaned, check the Cleaned box
Serial Number - Each probe has a unique serial number and should be documented as such
For any Fail items, make notes in the comments field

Measurements
Select 2 different types of probes to perform the selected measurements.
Enter the probe model number
Enter the probe serial number
Perform measurements in accordance with Imaging Mode 2D section, input the measurements for both horizontal and vertical parameters. (Tolerance +/- 10%)
Select Pass if measurements meet the tolerance allowance, select Fail if the tolerance is exceeded

5. PERIPHERAL INFORMATION
Model - The is the model as designated on the peripheral device
Type: VCR/DVR/BW Printer / Color Printer
Serial Number - Each peripheral device has a unique serial number and should be documented as such
Select Pass or Fail
For any Fail items, make notes in the comment field

6. CREATE SYSTEM/PRESETS BACKUP
Create a backup on removable media to be stored off-site or secure location
Backup should consist of all systems settings to include:
  - Software Version
  - User Settings
  - Network Settings
  - Custom Presets
  - Options

7. DOCUMENT ALL BOARD AND SOFTWARE PART NUMBERS
Create a hard copy or digital copy of all software and hardware part numbers. Generally accessible under user service menus.

8. LEAKAGE EVALUATION
System
Verify Chassis/Enclosure Leakage with the use of a leakage tester. (SA-2010S / Dale 601)
Chassis/Enclosure Leakage Limit = 0.3mA

ECG
Verify ECG/Patient Lead Leakage with the use of a leakage tester. (SA2010S / Dale 601)
ECG/Patient Lead Leakage Limit = 0.01mA

9. TRANSDUCER EVALUATION
Model - This is the model as designated on the transducer

Type
  - CA-Curved Array
  - LA-Linear Array
  - PA-Phased Array
  - TEE-Transesophageal Echo Transducer

Serial Number - Each transducer has a unique serial number and should be documented as such

Parameter
Pass/Fail based on Visual Inspection - Transducers
Once the transducer has been cleaned, check the Cleaned box
For any Fail items, make notes in the comment field

Penetration
What is the maximum depth you are able to successfully visualize the Ecographic pattern on the phantom, record.

Image Uniformity
Average brightness at the edge of the scan field is the same as in the middle
No signs of shadowing vertically or horizontally in the scan field
No brightness transitions between focal zones

Comments
Freeform comments field for any notes or suggestions
PASS/FAIL CRITERIA

TRANSDUCERS

• IMAGE
  • 2 or more dead elements within the scan field
  • 4 or more weak elements within the scan field
  • Excessive Color Noise (Noise present at minimal gain)
  • Excessive PW/CW Doppler Noise (Noise present at minimal gain)
  • Inability to perform 3D/4D scan

• COSMETIC
  • Any damage that would allow liquid to infiltrate the transducer’s internal components.
10 LEAKAGE TESTING

TRANSDUCERS
- SAFETY/LEAKAGE TESTING
  TEE Transducer (Type CF) **MUST BE PERFORMED BEFORE EACH USE**
  > 0.01mA (10 microamperes) under Normal Conditions
  > 0.05mA (50 microamperes) under Single Fault Conditions
  GENERAL Transducer (Type BF)
  > 0.1mA (100 microamperes) under Normal Conditions
  > 0.5mA (500 microamperes) under Single Fault Conditions

TEE TESTING PROCEDURE
We recommend the BC Biomedical Group ULT-2020 Ultrasound Transducer Leakage Tester. The ULT-2020 is simple to use, with OEM specific adapters that ensure the transducer is connected properly, one button bath test and transducer leakage test and the ability to print reports directly from the device. Easy to read pass/fail test message eliminating confusion about leakage limits.

1. Saline Bath should consist of 27g salt per 3 liters of water.

2. Once the ULT-2020 is powered up and passed it’s power up self test, the unit is ready for testing.

3. Connect the dual connectivity probe to the Chassis port of the ULT-2020 and attach it to the test basin.

4. Press the Select Button and use the Up & Down buttons to select the OEM, then use the Up & Down buttons to select the transducer model.

5. Connect the OEM probe adapter to the External port of the ULT-2020 and plug in the transducer for testing.

6. Press the Bath Test button. If the Bath test passes, proceed to the next step. If the Bath test fails, discontinue the test.

7. Insert the probe into the test basin, at least 50cm.

8. Press the Full Test button. If the Full test passes, proceed to the next step. If the Full Test fails, the transducer should be retested and removed from service after a second failure.

9. Remove the transducer from the basin and wipe off any excess water.

10. Record or Print the test results for record keeping.
REFERENCES

1. Centers for Medicare & Medicaid Services; Center for Clinical Standards and Quality & Certification Group. Ref: S&C: 14-07-Hospital

2. American College of Radiology: Ultrasound Accreditation Program Requirements: Quality Control; Preventative Maintenance