ENERGY STAR® Program Requirements Product Specification for Medical Imaging Equipment

Final Draft Test Method For Determining Medical Imaging Equipment Energy Use Rev. Aug - 2014

1 OVERVIEW

The following test method shall be used for determining product compliance with requirements in the ENERGY STAR Eligibility Criteria for Medical Imaging Equipment (MIE).

2 APPLICABILITY

The proposed test method shall be used to determine the energy efficiency of all products under the ENERGY STAR Product Specification for Medical Imaging Equipment. Medical Imaging Equipment and all products identified below are defined in this test method in Section 3.B).

Note: A proposed Scope is included in this document for completeness. Upon development of the Version 1.0 Draft 1 specification and eligibility criteria, the U.S. Environmental Protection Agency (EPA) will further refine and define the scope of included products for the program.

2.1 Products Included in Scope

A) Computed Tomography (CT)

B) General Radiography (X-ray)

C) Magnetic Resonance Imaging (MRI)

D) Mammography Equipment

E) Nuclear Imaging

F) Ultrasound Imaging/Sonography

2.2 Products excluded from scope

A) Endoscopy

B) Photoacoustic Imaging

C) Thermography

3 DEFINITIONS

Note: For completeness, the acronyms and definitions below have been included in the test method. The entire definitions section will be moved to the eligibility criteria upon development of the Version 1.0 Draft 1 specification.

A) Acronyms and Units:

1) ac: Alternating Current

2) CT: Computed Tomography

3) dc: Direct Current

4) IEC: International Electrotechnical Commission

5) MIE: Medical Imaging Equipment

6) MRI: Magnetic Resonance Imaging

7) PET: Positron Emission Tomography

8) PSU: Power Supply Unit

9) RF: Radio Frequency

10) SPECT: Single Proton Emission Computed Tomography

11) UPS: Uninterruptible Power Supply

12) UUT: Unit Under Test

13) W: Watts

B) Definitions:

1) Computed Tomography: Technology that creates a computer-generated 3D image from a large series of two-dimensional X-ray images taken around a single axis of rotation. Computed Tomography (CT) scans use X-rays to produce precise cross-sectional images of anatomical structures and spaces within objects.

2) Cyberknife: Frameless robotic radiosurgery system composed of (1) a linear accelerator and, (2) a robotic arm that directs the X-ray. The X-ray is used to destroy cancer cells.

3) Endoscopy: Use of small camera directly inserted into the body to examine the interior of a hollow organ or cavity in the body.

4) Fluoroscope: Device that obtains real time images of internal structures. The fluoroscope employs an X-ray source and a fluorescent screen that go on either side of a patient.

5) General Radiography (X-ray): An X-ray image is produced when a small amount of ionizing radiation passes through the body. The ability of X-rays to penetrate tissues and bones varies according to the tissue's composition and mass. Examples of devices using general radiography include a cyberknife, fluoroscope, and linear accelerator.

6) Linear Accelerator: Device that delivers a uniform dose of high energy X-ray to a tumor or other cancerous cells. The X-rays can destroy cancer cells while sparing the normal tissue surrounding a tumor.

7) Low power mode: This mode represents the minimum energy consumption state that the user can select according to the user manual. The power consumption is lower than Ready-to-scan and higher than Off mode (e.g., sleep mode, service/evaluation mode).

8) Magnetic Resonance Imaging: Technology used to obtain highly refined images of the body's interior. It employs magnets that polarize and excite hydrogen nuclei in water molecules within tissues and creates 2D images.

9) Mammography Equipment: Equipment that uses low-dose X-rays to examine the human breast for tumors and cysts. Mammography equipment can be either analog, projecting low-dose X-rays on film, or digital, converting X-rays into electrical signals that produce digital images.

10) Medical Imaging Equipment: Medical imaging equipment employs technologies, such as radiology and sonography, to create images of the human body. This type of equipment is used to reveal, diagnose, and examine patients for clinical purposes, or to study human anatomy and physiology for the purposes of medical science.

11) Nuclear Imaging: A patient consumes short-lived isotopes which emit radiation that is measured, commonly with the use of a gamma camera. Scintigraphy, single proton emission computed tomography (SPECT), and positron emission tomography (PET) are types of nuclear imaging technologies. Scintigraphy produces 2D images, while SPECT and PET technologies produce 3D images.

12) Off mode: The system is shut down with ac mains off, according to the user manual. The system consumes no energy.

13) Photoacoustic Imaging: A non-ionizing technique that uses low-energy lasers with an infrared wavelength. The wavelength can penetrate deep into the body with sensitive ultrasonic detectors capturing 2D and 3D images from the way the light is absorbed by various tissues.

14) Ready-to-scan mode: This mode represents the state of the system between individual scans, where no scan has been prescribed (e.g., during patient handling, data archiving, examination planning, or contrast agent injection). This mode does not include potential mechanical movements such as X-ray tube rotor or gantry rotation.

15) Scan mode: The system is actively scanning the patient to generate images. The computing system interprets the data and generates the image. This mode also includes any potential mechanical movements such as X-ray tube rotor or gantry rotation.

16) Thermography: A diagnostic technique where an infrared camera is used to capture temperature variations on the surface of the body, revealing sites of abnormal tissue growth below the skin.

17) Ultrasound Imaging/Sonography: Technology that exposes a body part to high-frequency sound waves that are reflected by tissues in the body to produce real-time 2D and 3D images.

4 TEST SETUP

A) General Testing Conditions: General testing conditions shall be as specified in Section 9 of International Electrotechnical Commission (IEC) 62354 Ed. 2.0.

B) Input Power: Input power shall be as specified in Section 10 of IEC 62354 Ed 2.0.

C) Ambient Temperature: Ambient temperature shall be within 23 °C ± 5 °C over the duration of the test.

D) Relative Humidity: Relative humidity shall be within 20% and 80%.

Note: The minimum acceptable relative humidity has been revised from 15% to 20% from the preliminary test method.

E) Power Meter: General requirements for power meters shall be as specified in Section 11.1 of IEC 62354 Ed. 2.0.

1) Accuracy: The accuracy of power meters shall be as specified in Section 11.2 of IEC 62354 Ed. 2.0.

2) Calibration: Power meter calibration shall be as specified in Section 11.4 of IEC 62354 Ed. 2.0.

3) Polyphase: Power meters shall be capable of measuring either single phase or polyphase voltage and current.

5 TEST CONDUCT

A) As-shipped Condition: Products shall be tested in their “as-shipped” configuration, which includes both hardware configuration and system settings, unless otherwise specified in this test method.

B) Measurement Location: All power measurements shall be taken at a point between the ac or dc power source and the Unit Under Test (UUT). For MIE devices that do not simply plug into a wall outlet, the power meter shall be installed onto the input to the main disconnect panel of the system to ensure that all energy consumption of the MIE is captured (e.g., cooling equipment, cryogen compressor, water heat exchanger, peripheral computer terminal).

C) Air Flow Management: Any air flow directly surrounding the UUT during testing shall only be generated by fans or cooling devices that are standard components of the UUT. The use of external fans or cooling devices to purposefully direct air at, or away from, the UUT during testing is prohibited.

Note: The Air Flow Management requirement is included to clarify that external cooling equipment, such as localized air fans directed at the UUT, are not permitted. However, DOE recognizes that large medical imaging equipment is generally cooled to avoid overheating the components and imaging room. DOE has therefore specified an ambient temperature requirement during testing (Section **4**.C)).

D) Power Supplies: All power supply units (PSUs) must be connected and operational.

E) Power Management: All power management and/or power-saving features available on the UUT shall be disabled during testing

1) The entire Medical Imaging Equipment Test Method may be voluntarily repeated with power management and/or power-saving features enabled.

6 TEST PROCEDURES FOR ALL PRODUCTS

6.1 UUT Preparation

A) Record the UUT manufacturer, model name, and system configuration details.

B) The MIE system shall be installed and calibrated according to its specification, including all system-critical items needed to perform a basic scan (e.g., gradient amplifiers, Radio Frequency (RF) unit, reconstruction engine(s), gantry, X-ray generator and tube, power supplies, controllers, console/computer, cryogen compressor, water heat exchanger, patient table, etc.).

Any equipment and accessories beyond the basic product offering that is not required for a basic scan (e.g., customer-provided equipment, optional supplier equipment, patient vital signs accessories, facility-provided cooling water equipment, hardware for advanced medical applications, etc.) shall not be included in the measurements below.

C) Connect the UUT to an appropriate ac or dc voltage source using the following guidelines:

1) No uninterruptible power supply (UPS) units shall be connected between the power meter and the UUT;

2) The power meter shall remain connected until all testing is complete;

3) Power values shall be recorded from the power meter in a way that is consistent with the requirements in Section 4.E) of this document.

D) Verify that the UUT is configured in its as-shipped configuration.

E) Power on the UUT, either by switching it on or connecting it to mains power.

F) Let the UUT stabilize for 15 minutes

6.2 Ready-to-scan Mode Testing

A) Ensure that the power meter is on and functioning.

B) Prescribe a patient and execute any scan to ensure that the UUT is functioning.

C) After the scan completes, wait 5 minutes, and then record the average power draw (rate of energy consumption), for a period of 12 minutes. Record this value, in kW.

Note: The preliminary test method has been revised to include a waiting period of 5 minutes after completing a scan and before beginning the measurement of average power. This waiting period is included to allow any data processing that may occur after the scan to complete.

6.3 Low-power Mode Testing

A) Ensure that the power meter is on and functioning.

B) Select the Low-power mode as specified in the user manual.

C) Wait to ensure that all applicable system elements of the UUT have adapted to this mode.

D) Measure the average power draw (rate of energy consumption), for a period of at least 10 minutes. If the system has a variable power usage in this mode, the measurement duration shall be amended to one complete power usage cycle, which shall be taken to be the cycle from minimum to maximum usage.

E) Record this value, in kW.

Note: The test methods for Ready-to-scan and Low-power modes are primarily based on COCIR *Computed Tomography Measurement of Energy Consumption (Revision 0)*, and COCIR *Magnetic Resonance Equipment Measurement of Energy Consumption (Revision 1)*.

This test method only includes test methods for Ready-to-scan and Low-power modes. DOE and EPA realize that there are many complexities associated with testing in Scan (active) mode, such as setting proper scan protocols (for abdomen, chest, head, etc.) and specifying phantom materials to use. Furthermore, energy consumption in Low-power and Ready-to-scan modes can represent the majority of total annual energy consumption.

7 REFERENCES

A) IEC 62354 Ed. 2.0 (2009) – General testing procedures for medical electrical equipment.