May 29, 2014

Dear Mr. Kent,

The Medical Imaging & Technology Alliance (MITA) thanks you for your time on March 19 2014. At that meeting, you requested power modes and energy use data for medical imaging equipment.

Due to the medical use of our products, and their regulation by the Food and Drug Administration (FDA), we do not believe ENERGY STAR is the appropriate vehicle for highlighting energy improvements of medical devices. However, we would like to learn from EPA which providers have contacted the Agency with recommendations for additional information on energy savings for medical devices, along with their specific concerns and requests. This will help our industry better understand the needs of providers and tailor our designs and communications to help them achieve increased energy efficiency while preserving high-quality operation and safety, in addition to the best images and diagnostics available. It may also help us to make our energy-saving features more user-friendly.

As we note above, our devices are regulated by the FDA. Specifically, the FDA’s Center for Devices and Radiological Health regulates MITA member company devices at all stages of the product lifecycle – from regular audits of the facilities where devices are designed and manufactured, to monitoring performance and safety of devices while in a clinical setting, all the way through de-installation and possible remanufacture. The FDA has traditionally been reserved the privilege of regulating medical electrical equipment, due to the significance of the patient safety and public health concerns FDA is responsible for. Under this logic, medical electrical equipment has been exempted from EPA’s Toxic Substances Control Act, and the FCC’s electromagnetic field safety regulations.

Medical imaging and radiation therapy devices are unique among industry sectors in that not only are there limited numbers of models on the market (especially among the larger modalities), but that one device can affect people in ways that no other electrical equipment can: saving lives through detection and intervention.

You asked us to provide energy use settings by power mode setting and by modality. Depending on the technology, power settings vary. There are some similar settings across all modalities, but each has distinct power needs based on how it operates. Below are some power settings for the technology in which EPA has expressed interest:

**MRI**

**Off mode**: The system moves to its minimum energy consumption state that the user is allowed to access, through selection of off or shutdown, at the operator console.
**Ready-to-scan mode:** This mode represents the state of the system between individual scans (e.g. during patient handling, data archiving, examination planning or contrast agent injection).

**Scan mode:** The MRI is actively scanning the patient to generate images by sending and receiving RF energy and switching the magnetic field gradients. The computing system interprets the data and generates the image.

**Low power mode:** This operator selected mode represents a state of the system with power consumption lower than ready-to-scan and higher than off mode. (i.e., sleep mode, service/evaluation mode)

**CT**

**Off:** The system is shut down, AC mains off, according to the user manual. The system consumes no energy.

**Low-power:** The system moves to its minimum energy consumption state that the user is allowed to select according to the user manual.

**Idle mode:** A state of the system when fully powered, but when no scan has been prescribed. This mode does NOT include x-ray tube rotor or gantry rotation.

**Scan mode:** A state of the system between individual scans and during scans (e.g. during patient handling, examination planning, contrast agent injection and active scanning with x-ray generation). This mode includes tube rotor rotation, gantry rotation and generation of image, and any possible idle between scans.

**X-RAY**

**Off mode:** The system is shut down, AC mains off, according to the user manual. The system consumes no energy.

**Low-power:** The system moves to its minimum energy consumption state that the user can select according to the user manual.

**Ready-to-scan:** A state of the system when fully powered and ready to acquire an image.

**Scan mode:** A state of the system during scans. This mode includes tube rotor rotation, x-ray generation and generation of image.

**ULTRASOUND**

**Scanning / ready to scan:** System is already booted up. This is the average power consumption for a system which is actively scanning or ready to scan in any scanning mode.

**Standby:** Need to boot up the system. System is ready to boot up/resume operation from a reduced power consumption standby state. A Standby mode may not be supported by all products.

**Off/hibernation:** System off, plugged into mains, circuit breaker on.

MITA is eager to continue our dialogue with EPA, and understand how we can work together to identify methods to inform customers of energy saving functions without ENERGY STAR. As the COCIR Self-Regulatory Initiative shows, the medical imaging and radiation therapy industry gives high priority to sustainability, and we look forward to understanding how our efforts can assist the EPA’s mission to build awareness of energy consumption. We offer the selected data on the two modalities on which we have already completed studies below, excerpted from the COCIR SRI:

<table>
<thead>
<tr>
<th>MRI</th>
<th>MODE</th>
<th>Average Power Consumption (kW)</th>
<th>Average distribution of daily energy consumption %</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Off</td>
<td>9.3</td>
<td>34</td>
</tr>
<tr>
<td></td>
<td>Ready to scan</td>
<td>14.6</td>
<td>34</td>
</tr>
<tr>
<td></td>
<td>Scan</td>
<td>22.3</td>
<td>32</td>
</tr>
</tbody>
</table>
The medical imaging and radiation therapy industry has taken a proactive approach, and already demonstrated successful self-regulation in terms of energy efficiency and sustainability. The COCIR SRI, which is regarded as the industry standard and accepted by the European Union, sets forth guidance for energy-saving features and how to implement them in a clinical setting to maximize their impact. Individual companies have gone further, investing considerable time and resources in communicating with customers on proper use to maximize energy saving features of devices.

MITA member companies represent 90 percent of the global market for medical imaging and radiation therapy equipment. We are well-positioned to build consensus that will drive impacts on voluntary and mandatory regulations and programs that affect our products and their use.

Please let us know if there is any further information we can provide you, as well as your availability for another opportunity to discuss.

Sincerely,

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