**Draft EU GPP Criteria for Health Care EEE**

Green Public Procurement (GPP) is a voluntary instrument. This document provides the EU GPP criteria developed for electrical and electronic equipment used in the health care sector (health care EEE).

The accompanying Technical Background Report provides full details on the reasons for selecting these criteria and references for further information.

It is proposed to set core and comprehensive criteria for health care EEE:

* The core criteria are those suitable for use by any contracting authority across the Member States and address the key environmental impacts. They are designed to be used with minimum additional verification effort or cost increases.
* The comprehensive criteria are for those who wish to purchase the best products available on the market. These may require additional verification effort or a slight increase in cost compared to other products with the same functionality.

Detailed information about the health care EEE product group, including the information about related legislation and other sources can be found in the Technical Background Report.

1. **Definition and Scope**

This document covers procurement actions for health care EEE. For the purposes of these criteria, health care EEE includes both high and low voltage equipment. It covers the complete care cycle (prevention, diagnostic, therapy and care). According to the standards 60601-1 ISBN 0-762 9-0 8 4 8-3 medical electrical equipment is defined as:

Medical Electrical Equipment provided with not more than one connection to a particular supply mains and intended to diagnose, treat, or monitor the patient under medical supervision and which makes physical or electrical contact with the patient and/or transfers energy to or from the patient and/or detects such energy transfer to or from the patient. The equipment includes those accessories as defined by the manufacturer which are necessary to enable the normal use of the equipment.

Mobile Medical Electrical Equipment is transportable Equipment intended to be moved from one location to another between periods of use while supported by its own wheels or equivalent means.

Regarding product groups excluded from the scope, se the Technical background report.

The procurement criteria in this document are intended to be used in the procurement of the following products:

* Anaesthesia equipment- ventilator
* Autoclave
* Washer disinfector
* Flusher disinfector
* Computed Tomography (CT)
* Dialysis equipment
* Diathermy equipment
* Electrocardiographic (ECG) equipment (diagnostic)
* Endoscopic equipment
* Incubators for babies (permanent)
* Infusion pumps- volumetric and syringe pumps
* Intensive care equipment – active respiratory gas humidifier
* Laser instruments for surgery
* Medical freezers
* Medical lighting- operation lamps
* Monitoring equipment
* Magnetic Resonance Imaging (MRI)
* Patient warming systems
* Ultrasound
* X-ray
1. **Key environmental impacts**

The proposed GPP criteria are designed to reflect the key environmental impacts. This approach is summarised as follows:

|  |  |  |
| --- | --- | --- |
| **Key Environmental Impacts** |  | **GPP Approach** |
| * Energy usage in the use phase (Ex. Global warming)
* Water consumption in the use phase, dialysis, disinfectors (Water scarcity)
* Gas consumption in the use phase, anaesthesia equipment

(Ex. Global warming)* GWP of refrigerants in medical freezers (Global warming, ozone depletion)
* Use of materials

(Scarcity of resources)* Content of hazardous chemicals

(Ex. Carcinogenic properties)* Social and ethical impacts such as workers’ conditions etc.
 |  | * Award energy efficient equipment
* Award automatic low power mode
* Purchase equipment supplied with green performance management instructions
* Award water efficient dialysis and disinfectant equipment
* Award low-flow, leak-tested anaesthesia equipment
* Award medical freezers containing refrigerants with low GWP
* Award material conscious designed equipment
* Purchase eco designed equipment
* Award refurbishment
* Award phase out of hazardous substances
* Purchase equipment that in production phase fulfills social requirements regarding working conditions, health and safety and decent work standards
 |

The order of impacts does not necessarily reflect their importance.

1. **EU GPP Criteria for Indoor Lighting**

The below proposed EU GPP criteria for health care EEE are based on data and information in the Technical Background Report.

|  |
| --- |
| 3.1 EU GPP criteria for health care EEE |
| **Core criteria** |
| **SUBJECT MATTER** |
| Purchase of green/sustainable electrical and electronic equipment used in the health care sector |
| **TECHNICAL SPECIFICATIONS** |
| * 1. **1. User instructions for green performance management (General criteria for all equipment)**

A guide shall be provided with instructions on how to maximise the environmental performance of the particular medical equipment, in accordance with the standard IEC 60601-1-9, in written form as a specific part of the user manual and in digital form accessible via the manufacturer’s website, on a CD, or in paper format. The instruction manual shall be delivered together with the equipment.The documentation shall, as a minimum requirement, include the following:* Instructions for users regarding how to use the equipment to minimize the environmental impact during installation, use, service and recycling/disposal.
* Instructions for users regarding how to minimize consumption of energy, water, consumable materials/parts, emissions etc.

**Verification:**A copy of the instruction manual shall be supplied to the authority. This manual shall be available for access on the manufacturer’s website, on a CD, or in paper format. A statement from the manufacturer demonstrating that these requirements have been met shall also be provided.  |
| **AWARD CRITERIA** |
| * 1. **2. Content of substances on the Candidate List (General criteria for all equipment)**

Points will be awarded if the equipment is free from substances listed on the REACH Candidate List, i.e. the equipment does not contain more than 0.1 % weight of Candidate List substance/ weight of article[[1]](#footnote-1). The less candidate list substances present in the equipment the more points will be awarded.**Verification:**If the equipment contains Candidate List substances:A written statement naming (including CAS number) any Candidate List substances present in the product at a concentration ≥ 0.1% weight of Candidate List substance/ weight of article1.If the equipment does not contain Candidate List substances: A written statement guaranteeing that the equipment contains maximum 0.1 % weight of Candidate List substance/ weight of article1.  |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| * 1. **3. Energy performance of health care EEE**

**To participants in open consultation:** should use scenario be specified – i.e. estimated averages of hrs/day are predetermined to be able to simplify for the procurer?Points will be awarded for the equipment which has reported the **lowest Energy usage, E (kwh)/day**, according to the table and the test conditions below. Please, fill in the table for the relevant medical equipment:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Equipment** | **Mode** | **Use scenario***Stated by procurer* | **Energy in use phase***Stated by tenderer* | **The Energy usage (E) calculation:**  |
| **Active Respiratory Gas Humidifier** | Active  | T1 | P1  | (T1\*P1) + (T2\*P2) = **E (kWh) per day** |
| Off  | T2  | P2  |
| *Definitions of modes according to appendix 1.* | *T=time, number of hours in the current mode per day* | *P= power (kW), Power measurements according to test conditions in appendix12* |
| **Autoclave** | Active  | N= Number of specified cycles per day *(Specify: L= load per cycle (kg),M= material type (metal or textile), T=Type of cycle (sterilizing Tº))* | E1 = Energy usage (kWh) per cycle based on the specified cycle stated by the procurer | [∑ (N1\*E1)] + (T2\*P2) + (T3\*P3) = **E (kWh) per day** |
| Standby  | T2  | P2  |
| Off  | T3  | P3  |
| *Definitions of modes according to appendix 1.* | *T=time, number of hours in the current mode per day* | *P= power (kW), Power and Energy usage measurements according to test conditions in appendix 4.* |
| **Computed Tomography** | Scan  | T1 | P1  | (T1\*P1) + (T2\*P2) + (T3\*P3) + (T4\*P4) = **E (kWh) per day**  |
| Ready- to- scan  | T2  | P2  |
| Service/diagnostic  | T3  | P3  |
| Off  | T4 | P4 |
| *Definitions of modes according to appendix 2.* | *T=time, number of hours in the current mode per day* | *P= power (kW), Power measurements according to test conditions in appendix 5.* |

**To participants in open consultation:** Due to lack of time, no criteria regarding heat dissipation from MRI and CT were developed. According to report, cooling of equipment rather than the room is recommended. Do you have suggestions?

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Equipment** | **Mode** | **Use scenario***Stated by procurer* | **Energy in use phase***Stated by tenderer* | **The Energy usage (E) calculation:**  |
| **Dialysis (haemo) equipment** | *Dialysis phase* | (T1\*P1) + (T2\*P2) = **E (kWh) per day** |
| Active  | T1 | P1  |
| Off  | T2  | P2  |
| *Definitions of modes according to appendix 1.* | *T=time, number of hours in the current mode per day* | *P= power (kW), Power measurements according to test conditions in appendix 6.* |
| *Disinfection phase (heat)* | (T1\*P1) + (T2\*P2) + (T3\*P3) = **E (kWh) per day** |
| Active  | T1 | P1  |
| Standby  | T2  | P2  |
| Off  | T3  | P3  |
| *Definitions of modes according to appendix 1.* | *T=time, number of hours in the current mode per day* | *P= power (kW), Power measurements according to test conditions in appendix 6.* |
| *Disinfection phase (chemicals)* | (T1\*P1) + (T2\*P2) + (T3\*P3) = **E (kWh) per day** |
| Active  | T1 | P1  |
| Standby  | T2  | P2  |
| Off  | T3  | P3  |
| *Definitions of modes according to appendix 1.* | *T=time, number of hours in the current mode per day* | *P= power (kW), Power measurements according to test conditions in appendix 6.* |
| **Diathermy equipment** | Active  | T1 = 20 % of operation hours per day  | P1  = (measured with load 500 Ω for mono polar and 50 Ω for bipolar with duration time 30 seconds) | (T1\*P1) + (T2\*P2) = **E (kWh) per day** |
| Off  | T2 = 80 % of operation hours per day | P2  |
| *Definitions of modes according to appendix 1.* |  | *P= power (kW), Power measurements according to test conditions in appendix 7.* |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Equipment** | **Mode** | **Use scenario***Stated by procurer* | **Energy in use phase***Stated by tenderer* | **The Energy usage (E) calculation:**  |
| **ECG** (Electro-cardio- graphic) **equipment (diagnostic)** | Active  | T1 | P1  | (T1\*P1) + (T2\*P2) + (T3\*P3) = **E (kWh) per day** |
| Standby *(for those which have this mode)* | T2  | P2  |
| Off  | T3  | P3  |
| *Definitions of modes according to appendix 1.* | *T=time, number of hours in the current mode per day* | *P= power (kW), Power measurements according to test conditions in appendix 8.* |
| **Endoscopic equipment** | Active  | T1 | P1  | (T1\*P1) + (T2\*P2) = **E (kWh) per day** |
| Off  | T2  | P2  |
| *Definitions of modes according to appendix 1.* | *T=time, number of hours in the current mode per day* | *P= power (kW), Power measurements according to test conditions in appendix 9.* |
| **Flusher Disinfector** | Active  |  N= number of specified cycles per day, (Specify: *T=Type of cycle*) | E1 = Energy usage (kWh) per cycle, measured with no load  |  [∑ (N1\*E1)] + (T2\*P2) + (T3\*P3) = **E (kWh) per day** |
| Standby  | T2  | P2  |
| Off  | T3  | P3  |
| *Definitions of modes according to appendix 1.* | *T=time, number of hours in the current mode per day* | *P= power (kW), measured with no load. Power and energy usage measurements according to test conditions in appendix 4.* |
| **Incubator for babies (permanent)** | Active  | T1 | P1  | (T1\*P1) + (T2\*P2) = **E (kWh) per day** |
| Off  | T2  | P2  |
| *Definitions of modes according to appendix 1.* | *T=time, number of hours in the current mode per day* | *P= power (kW), Power measurements according to test conditions in appendix10.* |
| **Infusion pumps (volumetric and syringe)** | Active  | T1 | P1  | (T1\*P1) + (T2\*P2) = **E (kWh) per day** |
| Off  | T2  | P2  |
| *Definitions of modes according to appendix 1.* | *T=time, number of hours in the current mode per day* | *P= power (kW), Power measurements according to test conditions in appendix11.* |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Equipment** | **Mode** | **Use scenario***Stated by procurer* | **Energy in use phase***Stated by tenderer* | **The Energy usage (E) calculation:**  |
| **Laser instruments for surgery** | Active mode = Ready condition  | T1 | P1  | (T1\*P1) + (T2\*P2) = **E (kWh) per day** |
| Off  | T2  | P2  |
| *Definitions of modes according to appendix 1 and the active mode is defined according to the definition in the standard SS-EN 60 601-2-22, 2.1.117 – ready condition.* | *T=time, number of hours in the current mode per day* | *P= power (kW), Power measurements according to test conditions in appendix13* |
| **Magnetic Resonance Imaging (MRI) equipment** | Scan | T1 | P1  | (T1\*P1) + (T2\*P2) + (T3\*P3) + (T4\*P4) = **E (kWh) per day**  |
| Ready- to- scan  | T2  | P2  |
| Service/diagnostic  | T3  | P3  |
| Off  | T4 | P4 |
| *Definitions of modes according to appendix 2.* | *T=time, number of hours in the current mode per day* | *P= power (kW), Power measurements according to test conditions in appendix 15.* |
| **Medical freezers** | Active  | T1 = 24 hrs. Specify: Useful capacity, the length, the width and the height of the inner volume of the freezer, as well as requested temperature. | P1, measured during the following conditions: the freezer shall be empty, with no interior/fittings during the test and according to specified useful capacity, inner volume and requested temperature over en period of 24 hours. No freezer door openings shall occur during the measurement. | (T1\*P1) = **E (kWh) per day** |
| *Definitions of modes according to appendix 1.* | *T=time* | *P= power (kW), Power measurements according to test conditions in appendix 3.* |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Equipment** | **Mode** | **Use scenario***Stated by procurer* | **Energy in use phase***Stated by tenderer* | **The Energy usage (E) calculation:**  |
| **Medical lighting (surgical lamps)** | Active | T1= number of hours in this mode per day, with the following conditions specified by procurer:Lux= Light intensity Ra= Colour rendering index T°= Colour temperature (Kelvin) Life span in hours | P1 = measured for lamp type fulfilling the conditions specified by the procurer | (T1\*P1) + (T2\*P2) = **E (kWh) per day** |
| Off | T2 | P2 |
| *Definitions of modes according to appendix 1.* | *T=time, number of hours in the current mode per day* | *P= power (kW), Power measurements according to test conditions in appendix 17.* |
| **Monitoring equipment** | Active | T1 | P1 | (T1\*P1) + (T2\*P2) + (T3\*P3) = **E (kWh) per day** |
| Standby | T2 | P2 |
| Off | T3 | P3 |
| *Definitions of modes according to appendix 1.* | *T=time, number of hours in the current mode per day* | *P= power (kW), Power measurements according to test conditions in appendix 14.* |
| **Patient warming systems (excl. forced air devices)** | Active | T1 | P1 | (T1\*P1) + (T2\*P2) = **E (kWh) per day** |
| Off  | T2 | P2 |
| *Definitions of modes according to appendix 1.* | *T=time, number of hours in the current mode per day* | *P= power (kW), Power measurements according to test conditions in appendix 18.* |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Equipment** | **Mode** | **Use scenario***Stated by procurer* | **Energy in use phase***Stated by tenderer* | **The Energy usage (E) calculation:**  |
| **Ultrasound equipment** | Active  | T1 | P1  | (T1\*P1) + (T2\*P2) + (T3\*P3) + (T4\*P4) = **E (kWh) per day** |
| Standby *(for those which have this mode)* | T2  | P2  |
| Off  | T3  | P3  |
| *Definitions of modes according to appendix 1* |  |  |
| Ready-to-scan: *The ultrasound unit is on and ready to acquire the image. All modules except the ones needed for the scan are on (the transducer is not activated).* | T4 | P4 |
|  | *T=time, number of hours in the current mode per day* | *P= power (kW), Power measurements according to test conditions in appendix 16.* |
| **Ventilator** | Active  | T1 | P1  | (T1\*P1) + (T2\*P2) + (T3\*P3) = **E (kWh) per day** |
| Standby | T2  | P2  |
| Off  | T3  | P3  |
| *Definitions of modes according to appendix 1.* | *T=time, number of hours in the current mode per day* | *P= power (kW), Power measurements according to test conditions in appendix 3.* |
| **Washer Disinfector** | Active  |  N= number of specified cycles per day, (Specify: *T=Type of cycle*)  | E1 = Energy usage (kWh) per cycle, measured with no load  |  [∑ (N1\*E1)] + (T2\*P2) + (T3\*P3) = **E (kWh) per day** |
| Standby  | T2  | P2  |
| Off  | T3  | P3  |
| *Definitions of modes according to appendix 1.* | *T=time, number of hours in the current mode per day* | *P= power (kW), measured with no load. Power and energy usage measurements according to test conditions in appendix 4.* |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Equipment** | **Mode** | **Use scenario***Stated by procurer* | **Energy in use phase***Stated by tenderer* | **The Energy usage (E) calculation:**  |
| **X-ray** | Standby  | T1 | P1 | (T1\*P1) + (T2\*P2) = **E (kWh) per day** |
| Off  | T2  | P2  |
| *Definitions of modes according to appendix 1.* | *T=time, number of hours in the current mode per day* | *P= power (kW), Power measurements according to test conditions in appendix 3.* |

Contracting authorities will have to indicate in the contract notice and tender documents how many points will be awarded for each award criterion.**Verification:**For all other equipment:Tenderers must provide appropriate technical documentation, i. e. test report according to standard EN 50564:2011 (6.1, 6.2, 6.3, 6.4) or equivalent, with included energy performance data for the offered equipment, also demonstrating that the above standards and test conditions or equivalent are met. For Computed Tomography:Tenderers must provide appropriate technical documentation (ACCOMPANYING DOCUMENTS and the MANUFACTURERS test results (see appendix 5)) for the offered equipment demonstrating that the test conditions above or equivalent are met.The above verifications shall be independent third party verified type III declarations according to ISO 17025 or equivalent. |
| **4. Automatic low power mode for autoclave, CT, ECG diagnostic, MRI, and ultrasound**Points will be awarded if the offered equipment is being able to be configured to go automatically into a low power or off mode after a certain period of inactivity or after a predetermined schedule, according to below pattern:

|  |  |  |
| --- | --- | --- |
| **Equipment** | **From mode** | **To mode** |
| Autoclave | Standby mode | Off mode |
| CT | Ready-to-scan mode | Service/diagnostic mode |
| ECG, diagnostic | Active or standby mode | Off mode |
| MRI | Ready-to-scan mode | Service/diagnostic mode |
| Ultrasound | Ready-to-scan mode (The ultrasound unit is on and ready to acquire the image. All modules except the ones needed for the scan are on (the transducer is not activated). | Standby mode |

Describe the function of the automatic low power or off mode according to the above pattern and the available configuration options. Points will be awarded if the offered equipment has a short and automated start up to full functionality after its automatic function according to above has activated. Specify the time in seconds and the active efforts required of staff. The less seconds and active efforts needed, the more points will be awarded. Definitions of modes are according to appendix 2 for CT and MRI and according to appendix 1 for the remaining equipment above.**Verification:**A copy of the instruction manual, describing the required automatic low power mode and start up time with its required active efforts of staff, shall be supplied to the authority. This manual shall be available for access on the manufacturer’s website, on a CD, or in paper format. A statement from the manufacturer demonstrating that these requirements have been met shall also be provided.  |
| **5. Water consumption for haemodialysis equipment**What is the water consumption for the offered dialysis equipment in the **dialysis phase and disinfection phase** in accordance with the process of validation the manufacturer has for the equipment. Please, fill in the table:

|  |  |  |  |
| --- | --- | --- | --- |
| **Mode** | **Use scenario (hrs/day)***Stated by procurer* | **Water consumption per mode***Stated by tenderer* |   |
|   |
| *Dialysis phase* |   |
| Active mode  | T1= number of hours in this mode per day | W1 = Liters/ hour |   |
| *Disinfection phase (heat)* |   |
| Active mode  | N heat= number of treatments per day | V heat = Liters/ treatment |   |
| *Disinfection phase (chemicals)* |   |
| Active mode  | N chemicals= number of treatments per day | V chemicals = Liters/ treatment |   |

 The water consumption (W) will be calculated by using the following formula:T1\*W1 + N heat\* V heat + N chemicals\* V chemicals = W (liters/ day)     The mode is defined according to appendix 1.Points will be awarded for the equipment which has reported the lowest water consumption according to the table above and the test conditions in appendix 6. Additional points will be awarded for the equipment which is equipped with a low/no water consumption mode in order to lower the water consumption in the standby mode. Contracting authorities will have to indicate in the contract notice and tender documents how many additional points will be awarded for each award criterion.**Verification:**Tenderers must provide appropriate technical documentation, i. e. test report according to standard EN 50564:2011 (6.1, 6.2, 6.3, 6.4) or equivalent, with included energy performance data for the offered equipment, also demonstrating that the above standards and test conditions or equivalent are met. The above verifications shall be independent third party verified type III declarations according to ISO 17025 or equivalent. |
| **6. Water consumption for flusher and washer disinfectant equipment**What is the water consumption for the offered equipment according to the use scenario specified below? Please, fill in the table:

|  |  |  |
| --- | --- | --- |
| **Mode2** | **Use scenario per day***Stated by procurer* | **Volume (liters/cycle)***Stated by tenderer* |
|
| Active mode  | N= number of cycles, measured with no load, per day | V  |

Definitions of modes are according to appendix 1.The water consumption (W) will be calculated by the following formula:∑ ((N\*V)/day) = W (liter/ day) Additional points will be awarded for the equipment which has reported the lowest water consumption according to the table above and the test conditions in appendix 4. Contracting authorities will have to indicate in the contract notice and tender documents how many additional points will be awarded. **Verification:**Tenderers must provide appropriate technical documentation, i. e. test report according to standard EN 50564:2011 (6.1, 6.2, 6.3, 6.4) or equivalent, with included energy performance data for the offered equipment, also demonstrating that the above standards and test conditions or equivalent are met. The above verifications shall be independent third party verified type III declarations according to ISO 17025 or equivalent. |
| **CONTRACT PERFORMANCE CLAUSES** |
| **7. Social responsible production (General criteria for all equipment) - Will only be available in swedish version**PLEASE NOTE that this contract performance clause only is appropriate to use if it concerns a framework agreement or procurement with a contract period. In situations where the procurement only concerns a one time delivery, or if it concerns goods which have already been produced, it is not appropriate to use contract performance clauses. The supplier must have ***procedures*** in place to ensure that production of the goods supplied during the contract period takes place throughout the supply chain under conditions consistent with fundamental working conditions. In the event there is a discrepancy between national and international regulations, the highest standard shall apply not clear. The procedures must ensure that goods delivered have been produced under conditions that are consistent with:* ILO core conventions on forced labour, child labour, discrimination, freedom of association and right to organize (numbers 29, 87, 98, 100, 105, 111, 138 and 182)[[2]](#footnote-2),
* The United Nations Convention on the Rights of the Child, Article 32,
* the working environment legislation that is applicable in the country of production,
* *and* the labour laws, including legislation on minimum wage and social insurance in force in the country of production.

During the contract period, the client is entitled to inspect, monitor and report on the supplier’s compliance with the social requirements.The supplier must *without prompting* submit procedures and answers to the enclosed questionnaire concerning compliance with social requirements in the supply chain within [specify time period] of the commencement of the agreement [enclose questionnaire]. **The procedures must at least contain:**1. Division of responsibility at the supplier company concerning social responsibility in the supply chain.
2. A description of how new suppliers are evaluated from a social perspective in production.
3. What social requirements are placed on the supply chain. These must at least correspond to the requirements we set for you.
4. A description of how check controls and discussion are conducted with the supply chain. The issues that are checked and discussed must be relevant for the requirements set.
5. Schedule for check controls and discussion with supply chain.
6. How non-conformances are handled.

If non-conformances are detected during follow-up by the procuring authority, the supplier must, within a time period to be will agree upon, implement measures for improvement according to a plan of action. If measures are not taken within the stipulated period of time, this will be regarded as a gross breach of contract on the part of the supplier, and the client may terminate the contract.**Verification during follow-up:**Reporting according to questionnaire in appendix.**Questionnaire** can be found [here](http://offentlig.csr-kompassen.se/doc/msr_csr_exempel_frageformular_EN.pdf).**Text explaining the questionnaire** can be found [here](http://offentlig.csr-kompassen.se/doc/msr_csr_exempel_forklaringstexter_EN.pdf).For more information, visit the CSR Compass, [www.csrkompassen.se](http://www.csrkompassen.se) (in Swedish only). References can be given to possible SA 8000 certification, Fairtrade certification or working in accordance with Business Social Compliance Initiative (BSCI), ISO 26000 or similar. |
| **Comprehensive criteria** |
| **AWARD CRITERIA** |
| **8. Material conscious design (General criteria for all equipment)**Points will be awarded if the equipment is manufactured according to material conscious design routines in order to fulfil the targets to minimize the environmental impacts due to the usage of materials, with maintained or improved functionality of the equipment. **Verification:**Documentation shall be provided from the manufacturer regarding material conscious design routines for the offered equipment, proving that the above criteria are fulfilled. These can be from for example IEC 60601-1-9, IEC 62430, ISO 14006:2011 or equivalent. The routines include:* Product development guidelines for the offered equipment, providing environmental profiles on materials for a conscious choice of materials with the least environmental impacts and guidance regarding reduction of weight/ amount of materials
* Checklists in the product development procedure for the offered equipment such as overview of materials not preferred
* Or likewise documentation for the offered equipment that helped product development professionals to know which materials to choose and prevent using materials that cannot be changed later in the process
 |
| **9. Equipment part of refurbishment system (General criteria for all equipment)**Points will be awarded if the equipment is part of a refurbishment system. To be awarded points, the refurbishment system that the equipment is part of shall comprise of at least the following (or equivalent): * A selection process of old models to refurbish which comprise the equipment
* A de-installation process of the offered equipment and transport procedure
* A refurbishing procedure of the offered equipment including the following:
	+ Cleaning procedure
	+ Parts replacement procedure
	+ Components and possible subsystems tests /checks
	+ Software updates
	+ Customer configuration
	+ System check procedures
* An installation procedure of the offered equipment

**Verification:**To be awarded points, the tender must contain a description of the refurbishment system, preferably containing momentums mentioned above.  |
| **10. Refrigerants in medical freezers**Points will be awarded if the equipment contains refrigerants with GWP100 (Global Warming Potential) < 10.**Verification:**Documentation stating the refrigerants used in the medical freezer and their GWP100, proving that the above criterion is fulfilled. |
| **11. Gas consumption for anaesthesia equipment***Low-flow equipment*Anaesthesia equipment for long and medium term treatment shall be equipped with back pressure compensated low-flow adjustment.**Verification:**A copy of the instruction manual, describing the required low-flow adjustment, shall be supplied to the authority. This manual shall be available for access on the manufacturer’s website, on a CD, or in paper format. A statement from the manufacturer demonstrating that these requirements have been met shall also be provided. *Gas leakage*Points will be awarded if the equipment has been tested for leaks. The value shall not exceed 150 ml/minute with 30 cm water/3 kPa overpressure according to leak test method in ISO 8835-2:2007 or equivalent.**Verification:**Independent third party verification: test protocol following ISO 8835-2:2007 or equivalent. |
| **12. Content of beryllium substances in X-ray and computed tomography equipment**Points will be awarded if the equipment is free from the following substances:* Beryllium, CAS 7440-41-7
* Beryllium oxide, CAS 1304-56-9

I.e. the equipment does not contain more than 0.1 % weight of above listed substance/ weight of article1.**Verification:**A written statement guaranteeing that the equipment contains maximum 0.1 % weight of above listed substance/ weight of article1.  |
| **CONTRACT PERFORMANCE CLAUSES** |
| **13. Environmental conscious design for leasing or service contract (General criteria for all equipment)**Equipment provided during leasing or service contract must be manufactured according to standards or guidelines on Eco design or environmental conscious design such as IEC 60601-1-9, IEC 62430, ISO 14006:2011 or equivalent. This means that:* Relevant environmental aspects of the equipment across all life cycle phases are identified
* The significant environmental impacts of the equipment are determined, on a qualitative or quantitative basis, and documented
* Suppliers that contribute to the significant environmental aspects of the equipment are identified and documentation necessary to assist in identifying and assessing the environmental aspects (see above) is obtained
* Targets to minimize the environmental impact of the equipment with maintained or improved functionality of the equipment are determined, documented and fulfilled

**Verification during follow-up:**Information on the used standard or guidelines and internal documented procedures on the process, or where available, certificates released by competent bodies or information from the manufacturer proving that the above criteria are fulfilled. |

1. **Explanatory notes**

**Award Criteria**

Contracting authorities will have to indicate in the contract notice and tender documents how many additional points will be awarded for each award criterion. Environmental award criteria should, altogether, account for at least 15% of the total points available.

1. **Cost considerations**

**Life cycle costing**

The results of the energy performance and water consumption award criteria can be used in Life cycle costs (LCC) which are cradle to grave costs summarized as an economics model of evaluating alternatives for equipment. Usually the cost of operation, maintenance, and disposal costs exceed all other first costs many times over (supporting costs are often 2-20 times greater than the initial procurement costs).

1. **Appendixes**

***Appendix 1***

The modes are defined as follows:

**‘active mode(s)’** means a condition in which the equipment is connected to the mains power source and at least one of the main function(s) providing the intended service of the equipment has been activated;

**‘standby mode(s)’** means a condition where the equipment is connected to the mains power source, depends on energy input from the mains power source to work as intended and provides only the following functions, which may persist for an indefinite time: reactivation function, or reactivation function and only an indication of enabled reactivation function, and/or information or status display;

**‘off mode’** means a condition in which the equipment is connected to the mains power source and is not providing any function; the following shall also be considered as off mode:

(a) conditions providing only an indication of off-mode condition;

(b) conditions providing only functionalities intended to ensure electromagnetic compatibility pursuant to Directive 2004/108/EC of the European Parliament and of the Council (1);

***Appendix 2***

The modes are defined according to the SRI report, Self-Regulatory Initiative for Medical Imaging Equipment, Ecodesign target for MRI.

CT

 **‘scan mode’** is actively scanning the patient to generate the image. The computing system interprets the data and generates the image.

 **‘ready- to- scan- mode’** the equipment is on and ready to acquire the image. All modules except the ones needed for the scan are on. This mode represents the state of the system during patient handling and/or archiving, between individual scans.

**‘service/diagnostic mode’** during the course of a typical day, a system may go into a lower power state where it is available for service access, such as remote diagnostics, but not necessarily in a ready-to-scan state. The power draw of the system is to be measured in this state.

**‘off mode’** the equipment is in a low power state. The system functions into the minimum energy use state that the typical user can access, through selection of off or shutdown, at the operator console.

MRI

 **‘scan mode’** the MRI is actively scanning the patient to generate the image by sending high frequency waves and reading the resulting variations in the magnetic field. The computing system interprets the data and generates the image. The is actively scanning the patient to generate the image by sending high frequency waves and reading the resulting variations in the magnetic field. The computing system interprets the data and generates the image.

 **‘ready- to- scan- mode’** the MRI is on and ready to acquire the image. All modules except the ones needed for the scan are on (gradient amplifiers and RF senders and receivers). This mode represents the state of the system during patient handling and/or archiving, between individual scans.

**‘service/diagnostic mode’** during the course of a typical day, a system may go into a lower power state where it is available for service access, such as remote diagnostics, but not necessarily in a ready-to-scan state. The power draw of the system is to be measured in this state.

**‘off mode’** the MRI is in a low power state. In superconductive cylindrical MRIs the magnet and the cry-cooler can never be switched off so the energy consumption is determined by those two modules. The system functions into the minimum energy consumption state that the typical user can access, through selection of off or shutdown, at the operator console.

***Appendix 3***

Ventilator, Medical freezer, X-ray

Test conditions

The tests shall be carried out according to thestandard EN 50564:2011 or equivalent, the sampling method, see 5.3.2.

According to thestandard EN 50564:2011;4.2 Test room:The tests shall be carried out in a room that has an air speed close to the product under test of ≤0,5 m/s. The ambient temperature shall be maintained at (23 ± 5) °C throughout the test.

The power measurement device shall be calibrated with traceability document, i.e. a document which describes the method of calibration which shows that the measuring device is calibrated according to prevailing standards and that the calibration can be traced.

***Appendix 4***

Autoclave, Washer Disinfector, Flusher Disinfector

Test conditions

The tests shall be carried out according to thestandard EN 50564:2011 or equivalent, the sampling method, see 5.3.2.

According to thestandard EN 50564:2011;4.2 Test room:The tests shall be carried out in a room that has an air speed close to the product under test of ≤0,5 m/s. The ambient temperature shall be maintained at (23 ± 5) °C throughout the test.

The power measurement device shall be calibrated with traceability document, i.e. a document which describes the method of calibration which shows that the measuring device is calibrated according to prevailing standards and that the calibration can be traced.

Other conditions

During the tests the temperature of incoming water shall be 15 degrees according to EN 285:2006 or equivalent. The sterilization/ disinfection result shall comply with prevailing standards.

***Appendix 5***

Computed tomography

Test conditions

**Environmental Conditions**: The measurements are to be taken at a steady-state operating temperature, and within ambient temperature at (23 ± 5) °C.

**Measurement**: Prior to each mode’s measurement, the equipment shall remain in that mode for sufficient time to allow temperature and other pertinent transient conditions to stabilize.

**Power measurement device:** A certificated device according to the ISO-9001 requirements or equivalent capable of measuring 3-phase voltage and current and calculating the integral of power with respect to time (energy) or a calibrated power meter able to sample average power ratings.

Examples of power measurement equipment:

Hioki 3197 or 3198 Power Quality Analyzer

Hioki 9660 CAT III Clamp on Sensor (100A)

**Energy usage measurement method:**

The energy performance could normally be calculated by summing the energy performance in each mode, these being calculated by multiplying the power draw in each mode with the time duration of each mode:

Energy performance per day = Toff\*Poff + Tready-to-scan\* Pready-to-scan+Tscan\*Pscan + Pservicing\*Tservicing (In the criteria this formula is (T1\*P1) + (T2\*P2) + (T3\*P3) + (T4\*P4) = E (kWh) per day)

The power draws in off mode, servicing mode and ready-to-scan mode can be easily measured.

For the scan mode, the following applies:

Tscan : Duration of scan mode is stated by the procurer

Pscan : Power draw in scan mode is measured according to the following:

To attain Pscan, we need according to the formula P= U\*I, Uscan and Iscan, where U is the voltage and U is the current. These are the Tube Voltage and the Tube Current, which shall be measured according to 60601-2-44, 203.109.1.

**203.109 Dose statements**

**203.109.1 *CTDI*100**

The following dose information shall be obtained by using the dosimetry PHANTOM for COMPUTED TOMOGRAPHY. For any CT SCANNER separate dose information shall be provided for each application (e.g. head, body, cardiac, etc.) in the ACCOMPANYING DOCUMENTS. All dose measurements shall be performed with the PHANTOM specified in 203.108 placed on the PATIENT SUPPORT without additional attenuating material present. The dosimetry PHANTOM appropriate for the application shall be centred in the scan field and on the axis of rotation of the CT SCANNER. The following information shall be given in the ACCOMPANYING DOCUMENTS for each application. a) The *CTDI*100 and the corresponding CT CONDITIONS OF OPERATION at the following locations in the dosimetry PHANTOM specified in 203.108. The CT CONDITIONS OF OPERATION shall be the typical values suggested by the MANUFACTURER.

1) Along the axis of rotation of the PHANTOM (*CTDI*100(centre)).

2) Along a line parallel to the axis of rotation and 10 mm interior to the surface of the PHANTOM, with the PHANTOM positioned so that the *CTDI*100 is the maximum obtainable at this depth.

3) Along a line parallel to the axis of rotation and 10 mm interior to the surface of the PHANTOM at positions 90°, 180° and 270° from the position in item a) 2) of this subclause. The location of the position where the *CTDI*100 is maximum as specified in item a) 2) of this subclause shall be given by the MANUFACTURER with respect to the gantry or other readily identifiable part of the CT SCANNER in such a manner as to permit placement of the dosimetry PHANTOM in this orientation.

4) *CTDI*100 (peripheral) as the average of the four values of *CTDI*100 measured around the dosimetry PHANTOM periphery according to 203.109.1 a) 2) and 3) above.

b) The *CTDI*100 in the centre location of the dosimetry PHANTOM for each selectable CT CONDITION OF OPERATION that varies the *CTDI*100(centre) value. This *CTDI*100(centre) shall be presented as a value that is normalized to the *CTDI*100 in the centre location of the dosimetry PHANTOM from item a) of this subclause, with the *CTDI*100(centre) of item a) of this subclause having a value of 1. As a single CT CONDITION OF OPERATION is changed, all other independent CT CONDITIONS OF OPERATION shall be maintained at the typical values described in item a) of this subclause. These data shall encompass the range of each CT CONDITION OF OPERATION stated by the MANUFACTURER as appropriate. When more than three selections of a CT CONDITION OF OPERATION are available, the normalized *CTDI*100 shall be provided, at least for the minimum, maximum and one mid-range value of the CT CONDITION OF OPERATION.

c) The *CTDI*100 (peripheral) average for each selectable CT CONDITION OF OPERATION that varies this *CTDI*100 (peripheral) average value. This *CTDI*100 (peripheral) average shall be presented as a value that is normalized to the *CTDI*100 (peripheral) average from item a) of this subclause, with the *CTDI*100 (peripheral) average of item a) of this paragraph having a value of 1. As a single CT CONDITION OF OPERATION is changed, all other independent CT CONDITIONS OF OPERATION shall be maintained at the typical values described in item a) of this subclause. These data shall encompass the range of each CT CONDITION OF OPERATION stated by the MANUFACTURER as appropriate. When more than three selections of a CT CONDITION OF OPERATION are available, the normalized *CTDI*100 (peripheral) average shall be provided, at least for the minimum, maximum and one mid-range value of the CT CONDITION OF OPERATION.

 d) A statement of the maximum deviation from the values given according to items a), b) and c). Deviation of values shall not exceed these limits.

*Compliance is checked by inspection of the ACCOMPANYING DOCUMENTS and by inspection of* *the MANUFACTURERS test results.*

The power measurement device shall be calibrated with traceability document, i.e. a document which describes the method of calibration which shows that the measuring device is calibrated according to prevailing standards and that the calibration can be traced.

***Appendix 6***

Dialysis equipment

Test conditions

The tests shall be carried out according to thestandard EN 50564:2011 or equivalent, the sampling method, see 5.3.2.

According to thestandard EN 50564:2011;4.2 Test room:The tests shall be carried out in a room that has an air speed close to the product under test of ≤0,5 m/s. The ambient temperature shall be maintained at (23 ± 5) °C throughout the test.

The power measurement device shall be calibrated with traceability document, i.e. a document which describes the method of calibration which shows that the measuring device is calibrated according to prevailing standards and that the calibration can be traced.

Other conditions

During the tests the temperature of incoming water shall be 15 degrees.

Other conditions regarding the dialysis phase

The operating conditions during measurement of energy performance of the haemodialysis equipment in the dialysis phase shall be according to the standard IEC 60601-2-16:2008 or equivalent:

DIALYSING FLUID flow: 500 ml/min;

blood flow: 300 ml/min;

ULTRAFILTRATION flow: 0,5 l/h;

DIALYSING FLUID temperature: 37 °C

***Appendix 7***

Diathermy equipment

Test conditions

The tests shall be carried out according to thestandard EN 50564:2011 or equivalent, the sampling method, see 5.3.2.

According to thestandard EN 50564:2011;4.2 Test room:The tests shall be carried out in a room that has an air speed close to the product under test of ≤0,5 m/s. The ambient temperature shall be maintained at (23 ± 5) °C throughout the test.

The power measurement device shall be calibrated with traceability document, i.e. a document which describes the method of calibration which shows that the measuring device is calibrated according to prevailing standards and that the calibration can be traced.

Other conditions

According to the standard EN 60601-2-2:

201.11.1.1 \* Maximum temperature during NORMAL USE Addition Duty cycle: HF SURGICAL EQUIPMENT, set up to deliver its RATED OUTPUT POWER into a resistive load using the electrode cable, is operated for 1 h with a DUTY CYCLE as specified by the manufacturer but with operating times of at least 10 s alternating with a resting time of not more than 30 s.

Max load 500 Ω for mono polar and 50 Ω for bipolar with a duration of 30 seconds.

According to the standard EN 50564:2011, (5.2 Preparation of product), steps below shall be followed:

 – determine if the product contains a battery and whether the product contains circuitry for recharging a rechargeable battery. Reference shall be made to determine whether there is a legal provision which specifies the conditions to be applied, otherwise the following shall apply. For products containing a recharging circuit, the power consumed in – off mode and standby mode shall be measured after precautions have been taken to ensure that the battery is not being charged during the test, e.g. by removing the battery where this is possible, or ensuring that the battery is kept fully charged if the battery is not removable;

– a maintenance mode shall be measured with the batteries installed and fully charged before any measurements are undertaken.

***Appendix 8***

ECG equipment

Test conditions

The tests shall be carried out according to thestandard EN 50564:2011 or equivalent, the sampling method, see 5.3.2.

According to thestandard EN 50564:2011;4.2 Test room:The tests shall be carried out in a room that has an air speed close to the product under test of ≤0,5 m/s. The ambient temperature shall be maintained at (23 ± 5) °C throughout the test.

The power measurement device shall be calibrated with traceability document, i.e. a document which describes the method of calibration which shows that the measuring device is calibrated according to prevailing standards and that the calibration can be traced.

Other conditions

The test shall be carried out during a measurement cycle over en period of 15 minutes and the following values shall be achieved and recorded during the test.

Sinusrytm: 60 BPM

ECG-amplitudes: 1 mV

***Appendix 9***

Endoscopic equipment

Test conditions

The tests shall be carried out according to thestandard EN 50564:2011 or equivalent, the sampling method, see 5.3.2.

According to thestandard EN 50564:2011;4.2 Test room:The tests shall be carried out in a room that has an air speed close to the product under test of ≤0,5 m/s. The ambient temperature shall be maintained at (23 ± 5) °C throughout the test.

The power measurement device shall be calibrated with traceability document, i.e. a document which describes the method of calibration which shows that the measuring device is calibrated according to prevailing standards and that the calibration can be traced.

The test object/product: The endoscopic equipment shall be consisting of lamp (on max power), camera, insufflator and monitor during the test.

***Appendix 10***

Incubator for babies (permanent)

Test conditions

According to the standard for infant incubator EN 60601-2-19; 201.5.3 Ambient temperature, humidity, atmospheric pressure:

If not otherwise specified in this particular standard, all tests shall be carried out at an ambient temperature within the range of 21 °C to 26 °C.

The test shall be carried out at an ambient temperature of 21 °C to 26 °C with an operating time one hour and the CONTROL TEMPERATURE (temperature selected at the temperature control) shall be 36 °C. See further information in Clause 201.12.1.101 Stability of INCUBATOR TEMPERATURE

According to the standard EN 50564:2011, (5.2 Preparation of product), steps below shall be followed:

 – determine if the product contains a battery and whether the product contains circuitry for recharging a rechargeable battery. Reference shall be made to determine whether there is a legal provision which specifies the conditions to be applied, otherwise the following shall apply. For products containing a recharging circuit, the power consumed in

– off mode and standby mode shall be measured after precautions have been taken to ensure that the battery is not being charged during the test, e.g. by removing the battery where this is possible, or ensuring that the battery is kept fully charged if the battery is not removable;

– a maintenance mode shall be measured with the batteries installed and fully charged before any measurements are undertaken.

The power measurement device shall be calibrated with traceability document, i.e. a document which describes the method of calibration which shows that the measuring device is calibrated according to prevailing standards and that the calibration can be traced.

***Appendix 11***

Infusion pumps

Test conditions

The tests shall be carried out according to thestandard EN 50564:2011 or equivalent, the sampling method, see 5.3.2.

According to thestandard EN 50564:2011; 4.2 Test room: The tests shall be carried out in a room that has an air speed close to the product under test of ≤0,5 m/s. The ambient temperature shall be maintained at (23 ± 5) °C throughout the test.

The power measurement device shall be calibrated with traceability document, i.e. a document which describes the method of calibration which shows that the measuring device is calibrated according to prevailing standards and that the calibration can be traced.

Other conditions

The test shall be achieved and recorded at the INTERMEDIATE RATE for a period of 120 minutes at back pressures of ± 13, 33 kPa (± 100 Hg), according to the standard SS-EN 60601-2-24 or equivalent.

***Appendix 12***

Active respiratory gas humidifier

Test conditions

The tests shall be carried out according to thestandard EN 50564:2011 or equivalent, the sampling method, see 5.3.2.

According to thestandard EN 50564:2011; 4.2 Test room: The tests shall be carried out in a room that has an air speed close to the product under test of ≤0,5 m/s. The ambient temperature shall be maintained at (23 ± 5) °C throughout the test.

The power measurement device shall be calibrated with traceability document, i.e. a document which describes the method of calibration which shows that the measuring device is calibrated according to prevailing standards and that the calibration can be traced.

Other conditions

Performance data and safety-related requirements for active respiratory gas humidifiers are specified by the standard ISO 8185:2007. According to this standard, the minimum water content of inspired respiratory gas is ca. 33 mg/dm³ and the maximum respiratory gas temperature is ca. 42 °C

The test shall be carried out without heating coil.

***Appendix 13***

Laser instruments

Test conditions

The tests shall be carried out according to thestandard EN 50564:2011 or equivalent, the sampling method, see 5.3.2.

According to thestandard EN 50564:2011; 4.2 Test room: The tests shall be carried out in a room that has an air speed close to the product under test of ≤0,5 m/s. The ambient temperature shall be maintained at (23 ± 5) °C throughout the test.

The power measurement device shall be calibrated with traceability document, i.e. a document which describes the method of calibration which shows that the measuring device is calibrated according to prevailing standards and that the calibration can be traced.

Other conditions

The laser shall be in ready condition according to the definition in the standard EN 60 601-2-22 or equivalent at 15 minutes during measurement of energy consumption.

***Appendix 14***

Monitoring equipment

Test conditions

The tests shall be carried out according to thestandard EN 50564:2011 or equivalent, the sampling method, see 5.3.2.

According to thestandard EN 50564:2011; 4.2 Test room: The tests shall be carried out in a room that has an air speed close to the product under test of ≤0,5 m/s. The ambient temperature shall be maintained at (23 ± 5) °C throughout the test.

According to the standard EN 50564:2011, (5.2 Preparation of product), steps below shall be followed:

 – determine if the product contains a battery and whether the product contains circuitry for recharging a rechargeable battery. Reference shall be made to determine whether there is a legal provision which specifies the conditions to be applied, otherwise the following shall apply. For products containing a recharging circuit, the power consumed in

– off mode and standby mode shall be measured after precautions have been taken to ensure that the battery is not being charged during the test, e.g. by removing the battery where this is possible, or ensuring that the battery is kept fully charged if the battery is not removable;

– a maintenance mode shall be measured with the batteries installed and fully charged before any measurements are undertaken.

The power measurement device shall be calibrated with traceability document, i.e. a document which describes the method of calibration which shows that the measuring device is calibrated according to prevailing standards and that the calibration can be traced.

***Appendix 15***

MRI

Test conditions according to the SRI report, Self-Regulatory Initiative for Medical Imaging Equipment, Ecodesign target for MRI.

Test conditions

**Unit Under Test (UUT)**

**System Configuration**: System configuration should be recorded and configured to perform the set of specified procedures with an appropriate surface coil.

**Installation**: The 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, RF unit, MR coils needed for the specific measurements, reconstruction engine(s), required electronics such power supplies, controllers, console/computer, cryogen compressor, water heat exchanger (facility cooled water is provided), patient table, magnet and helium-conservation equipment.

Any equipment and accessories beyond basic product offering and not required for a basic scan, or customer-provided equipment, e.g. optional MR coils, patient vital signs accessories, facility-provided cooling water equipment and hardware for advanced medical applications shall not be included in the measurement.

**Environmental Conditions**: The measurements are to be taken at a steady-state operating temperature, and within ambient temperature at (23 ± 5) °C.

**Measurement**: Prior to each mode’s measurement, the equipment shall remain in that mode for sufficient time to allow temperature and other pertinent transient conditions to stabilize.

**Emulated System**: For sequence duration determination, it is permissible to use a device that emulates the hardware capabilities of the system, and uses the product software, to ensure the same prescription restrictions as a full system.

**Power measurement device**

A certificated device according to the ISO- 9001 requirements or equivalent capable of measuring 3-phase voltage and current and calculating the integral of power with respect to time (energy) or a calibrated power meter able to sample average power ratings.

Examples of power measurement equipment:

Hioki 3197 or 3198 Power Quality Analyzer

Hioki 9660 CAT III Clamp on Sensor (100A)

**Energy Performance measurement method**

The energy consumption could normally be calculated by summing the energy consumption in each mode, calculated multiplying the power consumption for each mode for the relative duration:

Energy consumption per day = Toff \* Poff + Tready-to-scan \* Pready-to-scan + Tscan \* Pscan + Pservicing \* Tservicing (I e (T1\*P1) + (T2\*P2) + (T3\*P3) + (T4\*P4) = E (kWh) per day)

The power consumption in off mode, servicing mode and ready-to-scan mode can be easily measured. For MRI the following elements are unknown:

Tscan : Duration of scan mode (but this is stated by the procurer)

Pscan : Power consumption in scan mode

The table 4 (Appendix I in SRI) (abstract of the configuration parameters table), in the SRI report, Self-Regulatory Initiative for Medical Imaging Equipment- Ecodesign target for MRI, shall be used and all sequence/program has to be followed for measuring of energy consumption in scan mode.

The power measurement device shall be calibrated with traceability document, i.e. a document which describes the method of calibration which shows that the measuring device is calibrated according to prevailing standards and that the calibration can be traced.

***Appendix 16***

Ultrasound equipment

Test conditions

According to the standard EN 60601-2-37; 201.11.1.3.1.1.1 Test methods

b) Test criteria based upon temperature rise measurements

The ambient temperature shall be 23 °C ± 3 °C. For TRANSDUCER ASSEMBLIES intended for **external use**, the initial temperature of the surface of the test object at the object transducer interface shall be between 20° C and 33° C, and the surface temperature rise of the APPLIED PART shall not exceed 10 °C.

**201.11.1.3.3 Test duration**

Standard probe/ transducer using 5 MHz or most equivalent probe shall be used over a period of 30 minutes continuously during the test.

The power measurement device shall be calibrated with traceability document, i.e. a document which describes the method of calibration which shows that the measuring device is calibrated according to prevailing standards and that the calibration can be traced.

***Appendix 17***

Medical lighting – surgical lamps

Test conditions

The tests shall be carried out according to thestandard EN 50564:2011, the sampling method, see 5.3.2.

According to thestandard EN 50564:2011; 4.2 Test room: The tests shall be carried out in a room that has an air speed close to the product under test of ≤0,5 m/s. The ambient temperature shall be maintained at (23 ± 5) °C throughout the test.

Other conditions

According to the standard SS- EN 60601-2-41, 201.5.4 other conditions:

In order to measure stabilized performances, the output values shall be measured after a pre-ageing period, depending on the light source technology, at RATED VOLTAGE under NORMAL CONDITIONS.

This pre-aging period is:

3 h for halogen lamp and LED;

50 h for discharge lamp;

for other light sources, the pre-aging period after which the performances variation does not exceed 1% per 100 h.

***Appendix 18***

Patient warming systems

Test conditions

The tests shall be carried out according to thestandard EN 50564:2011 or equivalent, the sampling method, see 5.3.2.

The power measurement device shall be calibrated with traceability document, i.e. a document which describes the method of calibration which shows that the measuring device is calibrated according to prevailing standards and that the calibration can be traced.

*Other test conditions:*

The test object/product: The blanket without forced air device

According to EN 80601-2-35 Annex CC, test room conditions are: ambient temperature at 23 °C +/-2 °C in a room with an air velocity of less than 0,1m/s.

For active mode:

Operate the HEATING DEVICE, as specified in 201.11.1.2.1.101.1, until a steady CONTACT

SURFACE TEMPERATURE of 36 °C is attained. In addition to section 201.11.1.2.1.101.1, section 201.12.4 desribes further the measurement procedure:

Four temperature sensors conductively attached to copper plates 65 mm\*65 mm\*0,5 mm, are placed on the contact surface at the midpoints of the four rectangles formed by bisecting the length and the width of the contact. The temperature control is set so that the CONTACT SURFACE TEMPERATURE reaches 36 °C. Temperature readings are taken at least every 10 min for 60 min. From these the values of the individual average temperatures at T1 to T4 are calculated and compared with the average values of the CONTACT SURFACE TEMPERATURE.

From annex CC, the procedure uses the temperature rise after 1 h in a water-filled plastic bag under

stated conditions, as an indicator of the heat transfer from the HEATING DEVICE to the PATIENT. Heat transfer should be kept att 115 W/m2, which corresponds to an increase of the temperature of 2 l of water in a plastic bag by 1 °C in 1 h, when an area of 200 cm2 of the bag is in contact with the surface of the HEATING DEVICE.

***Appendix 19***

**1. Child labour in violation of national legislation and international conventions is prohibited (ILO 138, ILO 182 and the UN’s Convention on the Rights of the Child)**

*“Child labour” refers to all financial activity conducted by a person of compulsory school age or younger.*

a. Children under 18 years of age shall not perform any type of work that puts the child’s safety and/or physical or psychological health in danger.

b. Children under 15 years of age (or the age specified in national legislation) shall not perform any type of work that obstructs or damages their potential for development.

**2. Forced labour is prohibited (ILO core conventions 29 and 105)**

*“Forced labour” refers to labour or services that are performed under the threat of punishment or similar, and which are not performed on a voluntary basis.*

a. Forced labour or non-voluntary labour of any form is prohibited,

b. Employees are free to terminate their employment under a reasonable period of notice.

**3. Discrimination is prohibited (ILO core conventions 100 and 111)**

*“Discrimination” refers to distinctions made by employers that are not based on merits or qualities, but are instead based on special treatment on non-objective grounds.*

a. Employees shall not be discriminated against due to gender, ethnicity, religious or political views, sexual orientation or disability.

**4. Freedom of association and collective bargaining rights must be respected (ILO core conventions 87 and 98)**

*“Freedom of association” and “collective bargaining rights” refer to formalized and/or non-formalized cooperations to promote and defend one’s own interests in working life and in relations between employees and employers.*

a. Employees and employers have the right to organize and join organizations they themselves wish to participate in, and to conduct collective bargaining.

b. All participation in such organizations shall be entirely without reprisal and shall not entail any other form of disadvantage for the employee.

**5. Working conditions must be safe and hygienic (ILO 155 and 164 and the UN’s Universal Declaration of Human Rights, Article 23)**

*A “safe and hygienic working environment” refers to the right of the employee, when he or she is in a place that the employer has direct or indirect control over, to be guaranteed freedom or protection from conditions that can pose a risk to the employee’s physical and/or mental health.*

a. The employer shall ensure, as far as possible, that the use of chemical, physical and biological agents and substances under their control do not present health risks, and that appropriate safety measures are taken.

b. The employer shall, as far as possible, ensure that workplaces, machinery, equipment and processes under their control are safe and without health risks, and that the employees have free access to protective clothing and equipment in those work situations in which such equipment can prevent accidents or adverse health effects.

c. The employer shall have procedures for handling emergency situations and accidents, including unrestricted emergency exits, fire safety equipment and first aid supplies.

d. Employees and their representatives shall receive regular training in health and safety and the use of protective clothing and equipment that is relevant to their work. This training must be documented.

e. Employees shall have access to clean sanitation, clean water, sufficient space and ventilation, and hygienic storage areas for food, if this is necessary. This applies even if the employer provides accommodation.

**6. Secure employment conditions (ILO 158)**

a. Employees have the right to written employment contracts, which establish the employee’s wages and working conditions in accordance with national laws, where these exist.

b. The employer shall not require a deposit from workers or have control of the workers’ identification papers.

c. Employment cannot be terminated unless there are valid reasons related to the employee’s capacity or behaviour, or which are based on relevant requirements for the operation of the business.

d. Employees shall not receive disciplinary reactions or suffer dismissal on grounds of temporary absence due to illness, injury, parental leave, or claims directed against the employer for violation of legislation or regulations.

e. The employer shall not evade obligations by making use of temporary contracts, subcontracts and the like.

**7. Wages shall cover basic needs and shall be paid in periods not longer than specified in national legislation (ILO 95 and the UN’s Universal Declaration of Human Rights, Article 23)**

a. Wages shall be paid regularly and in accordance with national legislation. Wages shall always cover basic needs.

b. All employees shall receive written and understandable information on their wages and working conditions before employment commences, and shall receive information on the wages for the period and on each payment period.

c. Deductions from wages as a disciplinary action or punishment shall not occur. Deductions that are not specified in legislation shall not occur without special permission from the employee. All such adjustments shall be made in writing.

**8. Regular and reasonable working hours (ILO 1, 14 and 116, and the UN’s Universal Declaration of Human Rights, Article 24)**

a. Working hours shall be in accordance with national legislation. Normal working hours shall under all conditions not exceed 48 hours a week.

b. Work beyond normal and agreed working hours shall be counted as working hours. Overtime shall be limited to a maximum of 12 hours a week.

c. Overtime compensation shall be paid, at a minimum of what is specified in applicable legislation.

d. Employees shall have at least 24 consecutive hours free from work each week.

1. According to the definition of an article in Article 3.3 REACH Regulation (EC) No 1907/2006 [↑](#footnote-ref-1)
2. See Appendix 19. [↑](#footnote-ref-2)