**Final 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 standard 60601-1 medical electrical equipment is defined as:

- Medical Electrical Equipment provided with not more than one connection to a particular supply mains (immobile equipment) 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 which 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, see the Technical Background Report.

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

* CPV 33157000-5: Anaesthesia equipment- ventilator ( intensive care ventilator excl. transport ventilator, anaesthesia ventilator excl. home ventilators)
* CPV 33195100-4: Bed side monitoring equipment
* CPV 33115100-0: Computed Tomography (CT)
* CPV 33123200-0: Electrocardiographic (ECG) equipment, diagnostic
* CPV 33168000-5, 33168100-6: Endoscopic equipment (camera unit, endoscope, light, air pump)
* CPV 39330000-4: Flusher disinfector
* CPV 33181100-3: Hemodialysis equipment
* CPV 33161000-6: HF Surgery, diathermy equipment, bipolar, mono polar
* CPV 33152000-0: Incubators for babies, permanent
* CPV 33194110-0: Infusion pumps and syringe pumps
* CPV 33157400-9: Intensive care equipment – active respiratory gas humidifier
* CPV 33169100-3: Laser instruments for surgery
* CPV 33111610-0: Magnetic Resonance Imaging (MRI)
* CPV 39711120-6: Medical freezers
* CPV 31524110-9: Medical lighting- surgical lamps
* CPV 33191110-9: Medical sterilizer
* CPV 33160000-9, 33162000-3: Patient warming systems (blankets, pads, mattresses)
* CPV 33112200-0: Ultrasound, excl. therapeutic
* CPV 33191000-5: Washer disinfector
* CPV 33111000-1, 33111650-2: X-ray (including Mammography, excl. osteporos)

The safety and welfare of patients as well as that of medical staff, technicians and maintenance personnel remains the paramount objective, and has been the basis for the development of these criteria. Electrical and electronic equipment used in the health sector should be purchased and operated in accordance with these criteria,

Acronyms can be found in appendix 22.

1. **Key environmental impacts**

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

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| **Key Environmental Impacts** |  | | **GPP Approach** |
| * Energy usage in the use phase (e.g. emission of GHG emissions and air pollution in energy production) * Water consumption in the use phase, dialysis, disinfectors (Water scarcity) * Gas consumption in the use phase, anaesthesia equipment   (e.g. emission of greenhouse gases)   * 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. |  | * Purchase energy efficient equipment * Purchase equipment with low power mode * Purchase equipment supplied with green performance management instructions * Purchase equipment with a metering device * Purchase equipment with offered education and installation for energy efficiency optimization purposes * Purchase water efficient dialysis and disinfectant equipment * Purchase low-flow anaesthesia equipment * Purchase medical freezers containing refrigerants with low GWP * Purchase equipment part of a refurbishment system and with high recycling and recovery rate * Purchase equipment information on the presence of hazardous substances with low levels of hazardous substances and equipment from suppliers with chemicals managements systems * Purchase equipment that in production phase fulfills social requirements regarding working conditions, health and safety and decent work standards[[1]](#footnote-1) | |

The order of impacts does not necessarily reflect their importance.

1. **Draft EU GPP Criteria for health care EEE**

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

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| 3.1 Draft EU GPP criteria for health care EEE |
| **Core criteria** |
| **SUBJECT MATTER** |
| Purchase of electrical and electronic equipment used in the health care sector with reduced environmental impact. |
| **SELECTION CRITERIA** |
| **1. Chemicals management system(General criteria for all equipment)**  The tenderer shall have a chemicals management system in place with dedicated resources, the necessary expertise and with documented routines and instructions in order to ensure that the tenderer is aware of the presence of substances in the product(s) purchased under this contract which have been included in the Candidate List of Substances of Very High Concern (SVHC) identified under Article 57 of Regulation (EC) No 1907/2006 (REACH regulation), including possible additions to the Candidate List. This includes:   * that information about the presence of the listed substances have been requested to suppliers, including new additions to the list (within 1 month after the publication of a revised list by ECHA); * a systematic collection and archiving of received information on SVHC in the REACH Candidate List in the products purchased under this contract ; i.e. record-keeping and monitoring procedures (for example, regular inspections of documentation regarding content of Candidate List Substances in the product and spot checks of chemical content (laboratory analysis reports), in order to evaluate collected information to spot inconsistencies;   Verification: Tenderers shall confirm that they have above described routines and instructions in place and describe the system for documentation, monitoring and following-up and the resources allocated (time, personnel and their expertise). Spot checks of the reports described in the requirement above can be carried out[[2]](#footnote-2). |

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| **TECHNICAL SPECIFICATIONS** |
| **2. 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 written form as a specific part of the user manual, in digital form accessible via the manufacturer’s website, on a CD, or in paper format on the packaging and/or on documentation accompanying the product. The instruction manual shall be delivered together with the equipment. The documentation shall, as a minimum requirement and without detriment to the clinical performance of the equipment, include the following:   * Instructions for users how to use the equipment to minimize the environmental impact during installation, use, service and recycling/disposal (included stated recycling rate), including instructions how to minimize consumption of energy, water, consumable materials/parts, emissions etc. * Recommendations on the proper maintenance of the product, including information on which spare parts can be replaced, cleaning advice, etc. * Information on the content in the product(s) purchased under this contract of Candidate List Substances of Very High Concern (SVHC) identified under Article 57 of Regulation (EC) No 1907/2006 (REACH regulation) in order for the procurement authority to take appropriate precautionary measures, i.e. so that they can ensure that users of the product receive the information and can act accordingly   **Verification:**  A copy of the relevant pages 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.  A list of the substances present in the product(s) purchased under this contract, which are included in the Candidate List of Substances of Very High Concern (SVHC) identified under Article 57 of Regulation (EC) No 1907/2006 (REACH regulation), and complementary information according to article 33 in REACH, in order for the procurement authority to take appropriate precautionary measures, i.e. so that they can ensure that users of the product receive the information and can act accordingly. |
| **3. Product longevity and warranty**  Repair or replacement of the product shall be covered by the warranty terms for minimum five years. The tenderer shall further ensure that genuine or equivalent spare parts are available (direct or via other nominated agents) for the expected service life of the equipment in question where this exceeds the stated warranty period, at least for 5 years over warranty.  Verification:  Products holding a relevant Type 1 Eco-label fulfilling the listed requirements will be deemed to comply. Other appropriate means of proof will also be accepted, such as a self- declaration from the manufacturer stating that the above clause is met. |

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| **4. 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 function.  **Verification:**  A copy of the relevant pages of the instruction manual, describing the required low-flow function, 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. Information on content of Candidate List Substances of Very High Concern (General criteria for all equipment)**  Within 5 years following the delivery of the product, the procurement authority shall be notified of the content of new Candidate List Substances of Very High Concern (SVHC) identified under Article 57 of Regulation (EC) No 1907/2006 (REACH regulation) within 6 months of the ECHA publishing a revised list for all products within the contract, also in regards to the results of the risk management file review, in order for them to take appropriate precautionary measures, i.e. so that they can ensure that users of the product receive the information and can act accordingly.  **Verification:**  Declaration of the tenderer that this requirement will be met. |

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| **AWARD CRITERIA** |
| **6. Content and release of BPA (Incubators, ventilators, dialysis equipment, infusion pumps)**  Points will be awarded if parts in incubators, ventilators, dialysis equipment and infusion pumps, where there is potential oral, dermal or inhalation exposure during their intended use, do neither contain (Total Amount) nor release (Specific Migration) Bisphenol-A (BPA), CAS registry number 80-05-7, of more than 10 PPM. For parts in contact with nutrition flow to babies, the limit is 0,6 PPM.  The following is guidance regarding examples of parts in which there is potential oral, dermal or inhalation exposure:   * Incubators: hood, pad, tubing and connectors * Ventilators: connectors, tubing * Dialysis equipment: membrane * Infusion pumps: connectors   Note that these are examples of parts with content of bisphenol compounds in health care EEE, this is not an exhaustive list.  **Verification:**  Tenderers shall provide appropriate technical documentation, i. e. laboratory analysis results, showing that the material of the product part does neither contain (Total Amount) nor release (Specific Migration) more than 10 PPM of Bisphenol-A (BPA), CAS registry number 80-05-7. For parts in contact with nutrition flow to babies, the limit is 0,6 PPM. The laboratory analysis shall be according to methods specified in prevailing standards or regulations or as common laboratory practice, with a for the material of the product part appropriate extraction medium regarding the migration analysis and with a for the material of the product part appropriate dissolvent regarding the content analysis. Examples of such standards and regulations are regulation 10/2011, standard EN 12673-F15, standard EN 13130. |

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| **7. Energy performance of health care EEE**  Points will be awarded for the equipment based on how low the reported daily Energy usage is, **E (kwh)/day)**, according to the table and the test conditions below. Please, fill in the table for the relevant medical equipment: (the lower daily Energy usage, the more points will be awarded)  Definitions of modes are according to Appendix 1. Verification description can be viewed below the table. Energy performance criteria for CT, hemodialysis equipment, MRI, medical sterilizers and disinfectors can be found in separate criteria.  Contracting authorities will have to indicate in the contract notice and tender documents how many points will be awarded for each award criterion.   |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | | **Equipment** | **Mode** | **Customised scenario**  *Stated by procurer* | **Pre-determined use scenario**  *Guidance* | **Energy in use phase**  *Stated by tenderer* | **The Energy usage (E) calculation:** | | **Active Respiratory Gas Humidifier** | Active | T1 | T1 =24 | P1 | (T1\*P1) = **E (kWh) per day** | | *Definitions of modes according to appendix 1.* | *T=time, number of hours in the current mode per day* | *Recommended use scenario.* | *P= power (kW), Power measurements according to test conditions in appendix12* | | **Bed side monitoring equipment** | Active | T1 = 24 hrs. | T1 = 24 | P1 | (T1\*P1)= **E (kWh) per day** | | *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.* |  | | **ECG** (Electro-cardio- graphic) **equipment (diagnostic)** | Active | T1 | T1 = 2 | P1 | (T1\*P1) + (T2\*P2) + (T3\*P3) = **E (kWh) per day** | | Standby *(for those which have this mode)* | T2 | T2 = 2 | P2 |  | | Off | T3 | T3 = 20 | 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.* |  | | **Equipment** | **Mode** | **Customised scenario**  *Stated by procurer* | **Pre-determined use scenario**  *Guidance* | **Energy in use phase**  *Stated by tenderer* | **The Energy usage (E) calculation:** | | **Endoscopic equipment (camera unit, endoscope, light, air pump)** | Active | T1 =number of hours in this mode per day, with the following conditions specified for the light source by procurer:  Lux= Light intensity  Ra= Colour rendering index  T°= Colour temperature (Kelvin)  Life span in hours | T1 = 5 | P1 | (T1\*P1) + (T2\*P2) = **E (kWh) per day** | | Off | T2 | T2 = 19 | 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.* |  | | **HF surgery, diathermy equipment** | Active | T1 = 20 % of operation hours per day | T1 = 5 | 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 | T2 = 19 | P2 | | *Definitions of modes according to appendix 1.* |  |  | *P= power (kW), Power measurements according to test conditions in appendix 7.* |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | | **Equipment** | **Mode** | | | **Customised scenario**  *Stated by procurer* | **Pre-determined use scenario**  *Guidance* | **Energy in use phase**  *Stated by tenderer* | **The Energy usage (E) calculation:** | | **Incubator for babies (permanent)** | Active | | | T1 = 24  Specify: space for patients, i.e. space for patients up to 6 kg and length of 60 cm | T1 = 24, incubator shall fit patients up to 6 kg and length of 60 cm | E1= (T1\*P1) per V | (T1\*P1)/ V = **E (kWh) per day and m3 of incubator** | | *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. V= volume(m3) of incubator fulfilling the conditions specified by the procurer* | | **Infusion pumps and syringe pumps** | Active | | | T1 | T1 = 14 | P1 | (T1\*P1) + (T2\*P2) = **E (kWh) per day** | | Off | | | T2 | T2 = 10 | 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.* | | **Laser instruments for surgery, Continuous lasers** | Active mode = Ready condition | | | T1 | T1 = 5 | P1 | (T1\*P1) + (T2\*P2) + (T3\*P3) = **E (kWh) per day** | | Standby = laser standby | | | T2 | T2 = 4 | P2 | | Off | | | T3 | T3 = 15 | P3 | | *Definitions of modes according to appendix 1 and the active mode and standby mode are defined according to the definition in the standard SS-EN 60 601-2-22, 2.1.117 – stand-by/ready condition.* | | | *T=time, number of hours in the current mode per day* |  | *P= power (kW), Power measurements according to test conditions in appendix13* | | **Equipment** | | **Mode** | **Customised scenario**  *Stated by procurer* | | **Pre-determined use scenario**  *Guidance* | **Energy in use phase**  *Stated by tenderer* | **The Energy usage (E) calculation:** | | **Medical freezers** | | Active | T1 = 24 hrs. Specify: Useful capacity, the length, the width and the height of the inner volume = V, volume (m3) of the freezer, as well as requested temperature. | | T1 = 24 | P1 | (T1\*P1)/ V = **E (kWh) per day and m3 of freezer** | | *Definitions of modes according to appendix 1.* | *T=time*  *V= volume* | |  | *P= power (kW), Power measurements according to test conditions in appendix 19.* | | **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 | | T1= 8 | P1 = measured for lamp type fulfilling the conditions specified by the procurer | (T1\*P1) + (T2\*P2) = **E (kWh) per day** | | Off | T2 | | T2= 16 | 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.* |  |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | | **Equipment** | **Mode** | **Customised scenario**  *Stated by procurer* | | **Pre-determined use scenario**  *Guidance* | | **Energy in use phase**  *Stated by tenderer* | | **The Energy usage (E) calculation:** | | **Patient warming systems (blankets, pads, mattresses))** | Active | T1 | | T1 = 9 | | P1 | | (T1\*P1) + (T2\*P2) = **E (kWh) per day** | | Off | T2 | | T2= 15 | | 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.* | | | With forced air device | Active | T1 | | T1 = 9 | | P1+ PF | | (T1\*(P1+ PF)) + (T2\*P2) = **E (kWh) per day** | | Off | T2 | | T2= 15 | | 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.*  *PF = power of the forced air device* | |  | | **Ultrasound equipment, excl. therapeutic** | Scan / ready-to-scan | T1 | | T1= 6 | | P1 | | (T1\*P1) + (T2\*P2) + (T3\*P3) = **E (kWh) per day** | | Standby | T2 | | T2= 6 | | P2 | | | Off | T3 | | T3= 12 | | P3 | | | *Definitions of modes according to COCIR SRI v1 (2009)* | *T=time, number of hours in the current mode per day* | | *Recommended use scenario.* | | *P= power (kW), Power measurements according to test conditions in appendix 16.* | | | For battery powered U/S equipment:  Energy consumption (kWh) to fully charge the battery: Echarge  Daily Consumption for battery powered models: Echarge\*3 | | | | | | |  | | **Equipment** | **Mode** | | **Customised scenario**  *Stated by procurer* | | **Pre-determined use scenario**  *Guidance* | | **Energy in use phase**  *Stated by tenderer* | **The Energy usage (E) calculation:** | | **Ventilator , intensive care ventilator excl. transport ventilator, anaesthesia ventilator excl. home ventilators** | Active | | T1 = 24 hrs. | | T1 = 24 | | P1 | (T1\*P1) = **E (kWh) per day** | | *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 20.* | | **X-ray incl. mammo-graphy, excl. osteporos** | Standby | | T1 | | T1 = 15 | | P1 | (T1\*P1) + (T2\*P2) = **E (kWh) per day** | | Off | | T2 | | T2= 9 | | 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.* |   **Verification:**  Tenderers shall provide appropriate technical documentation, i. e. a test report according to the standard EN 50564:2011 (6.1, 6.2, 6.3, and 6.4) or equivalent. The test report shall include energy performance data for the offered equipment. The data shall be measured in the modes and according to the test conditions and use scenarios stated above.  The testing shall be performed by laboratories according to the general requirements of EN ISO 17025, or equivalent such as U.S. 21 CFR Part 820 or ISO 13485, according to the test conditions stated above. |
| **8. Energy performance for Computed Tomography (CT)**  Points will be awarded for the equipment based on how low the reported daily Energy usage is, **E (kwh)/day)**, according to the table and the test conditions below. (the lower daily Energy usage, the more points will be awarded)  Definitions of modes are according to Appendix 2.  **Predetermined use scenario** (to be used as the reference to compare CTs)  Tenderers deliver the daily energy consumption for 3 scenarios[[3]](#footnote-4) according to the methodology and test conditions in the COCIR SRI for Computed Tomography Equipment, see [www.cocir.org](http://www.cocir.org):   * Scenario Off: energy consumption according to COCIR use (20 scans per day) with 12h in Off mode overnight * Scenario Idle: energy consumption according to COCIR use (20 scans per day) with 12h in Idle mode overnight * Scenario Lowpower: energy consumption according to COCIR use (20 scans per day) with 12h in LowPower mode overnight   Contracting authorities will have to indicate in the contract notice and tender documents how many points will be awarded for each award criterion.  **Customised use scenario**  Tenderers deliver the following values according to the methodology and test conditions in the COCIR SRI for Computed Tomography Equipment, see [www.cocir.org](http://www.cocir.org):  Poff :Power consumption (kW) in Off mode  PIdle : Power consumption (kW) in Idle mode  Plow: Power consumption (kW) in LowPower mode  Escan: Energy consumption during abdomen scan  Tscan: duration of abdomen scan (from prescription to power back in idle mode)  The daily energy consumption can be calculated with the following formula (in blue values to be determined by the purchaser, in black declared by the supplier)  kWh/d = Poff x **Toff** + Plow x **Tlow** + **N.scan** x Escan + Pidle x (24h - **Toff** - **TLow** - **N.scan** x Tscan)  Where:  N.scan is the number of scans per day.  Considering the little influence of energy used in scan mode over 24 hours, results from the COCIR methodology have shown that energy usage for scan mode can be approximated very well by using the abdomen scan only.  Tlow,off is time in hours per day for each mode.  Tscan is time duration for each scan (stated by the tenderer).  **Verification:**  For CT: Tenderers shall provide appropriate technical documentation, i. e. a test report according to the COCIR SRI for Imaging Equipment, see [www.cocir.org](http://www.cocir.org), showing the energy performance data for the offered equipment.  The testing shall be performed by laboratories according to the general requirements of EN ISO 17025, or equivalent such as U.S. 21 CFR Part 820 or ISO 13485, according to the test conditions stated above. |
| **9. Energy performance for hemodialysis equipment:**  Points will be awarded for the equipment based on how low the reported Energy usage per treatment is, E(kwh)/ treatment, according to the test conditions below. (the lower Energy usage per treatment, the more points will be awarded).  The treatment cycle shall follow:   * Test - depending on machine * Filling/Rinsing - 10 Minutes * Pre-Circulation - 15 Minutes * Dialysis- 4h * Heat/Chemical Disinfection - depending on machine *Preference of type of disinfection is stated by the procurer.*   The energy usage per treatment shall be measured according to test conditions specified in Appendix 6.  Additional points will be awarded if the dialysis equipment is equipped with an automatic function to reduce the dialysis flow during the time between priming and dialysis phase. State the reduced dialysis flow.  Additional points will be awarded if the dialysis equipment turns itself off when not in use for 10 minutes after the disinfection.  Contracting authorities will have to indicate in the contract notice and tender documents how many points will be awarded for each award criterion.  **Verification:**  Tenderers shall provide appropriate technical documentation, i. e. a test report according to the standard EN 50564:2011 (6.1, 6.2, 6.3, and 6.4) or equivalent. The test report shall include energy performance data for the offered equipment. The data shall be measured in the modes and according to the test conditions and use scenarios stated above.  The testing shall be performed by laboratories according to the general requirements of EN ISO 17025, or equivalent such as U.S. 21 CFR Part 820 or ISO 13485, according to the test conditions stated above. |
| **10. Energy performance for Magnetic Resonance Imaging (MRI)**  Points will be awarded for the equipment based on how low the reported daily Energy usage is, **E (kwh)/day)**, according to the table and the test conditions below. (the lower daily Energy usage, the more points will be awarded)  Definitions of modes are according to Appendix 2.  **Predetermined use scenario** (to be used as the reference to compare MRIs)  Tenderers deliver the daily energy consumption according to the methodology and test conditions in the COCIR SRI for Magnetic Resonance Imaging Equipment, see www.cocir.org.  **Customised use scenario**  Tenderers deliver the following values according to the methodology and test conditions in the COCIR SRI for Magnetic Resonance Imaging Equipment, see [www.cocir.org](http://www.cocir.org) :  Poff :Power consumption (kW) in Off mode  Plow: Power consumption (kW) in LowPower mode  Pready: Power consumption (kW) in Ready-to-scan mode  Escan: Energy consumption during scan for 5 body regions (head, spine, abdomen, knee, angio)  Tscan: duration of scan (including sequences scan time and a fixed ready-to-scan time defined in the COCIR methodology)  The daily energy consumption can be calculated with the following formula (in blue values to be determined by the purchaser, in black declared by the tenderer)  kWh/d = Poff x **Toff** + Plow x **Tlow** + **N.scan** x Escan + Pready x (24h - **Toff** - **TLow** - **N.scan** x Tscan)  Where:  N.scan is the number of scan for each body region: **N.scan** x Tscan = **Nhead** x Thead + **Nabdomen** x Tabdomen + **Nspine** x Tspine + **Nknee** x Tknee + **Nangio** x Tangio.  Tlow,off is time in hours per day for each mode.  Tscan is time duration for each scan (stated by the tenderer).  **Verification:**  For MRI: Tenderers shall provide appropriate technical documentation, i. e. a test report according to the COCIR SRI for Imaging Equipment, see [www.cocir.org](http://www.cocir.org), showing the energy performance data for the offered equipment.  The testing shall be performed by laboratories according to the general requirements of EN ISO 17025, or equivalent such as U.S. 21 CFR Part 820 or ISO 13485, according to the test conditions stated above.. |
| **11. Energy performance for medical sterilizers**  **Pre-determined use scenario**  The capacity and the loading of a sterilizer both have an impact on the energy performance depending on the usage of the available capacity. The more goods that are sterilized with one single cycle, the lower the energy consumption per goods. The energy consumption of sterilizers can be either rated based on the usable chamber volume in litres or on the maximum load capacity in kg. The tenderer shall state both criteria in numbers to give the contracting authority an average impression of energy consumption.  The procurer can weight a single criterion more than the other by awarding more points for it. Points will be awarded for the equipment based on how low the reported energy usage per cycle is, i.e.:   * how low the reported energy usage per liter is, **EV (Wh/l)**, according to the test conditions in appendix 4. * how low the reported energy usage per load is, **EW (Wh/kg)**, according to the test conditions in appendix 4.   The lower the Energy usage per cycle, the more points will be awarded.  Contracting authorities will have to indicate in the contract notice and tender documents how many points will be awarded for each award criterion.  The tenderer specifies the below:   * energy usage:   EV for empty chamber  EW for maximum load as specified in Appendix 4   * the usable chamber volume (in liters) * the applied product standard (EN 13060 or EN 285)   Definitions of modes are according to Appendix 1.  The measurements shall be carried out according to the test conditions specified in Appendix 4.  **Verification:**  Tenderers shall provide appropriate technical documentation, i. e. energy performance data, EV and EW for the offered equipment, based on test protocols according to the standard EN 50564:2011 (6.1, 6.2, 6.3, and 6.4) or equivalent. The data from the test protocols shall be valid for the modes and according to the test conditions in appendix 4. The testing shall be performed by laboratories according to the general requirements of EN ISO 17025, or equivalent such as U.S. 21 CFR Part 820 or ISO 13485, according to the test conditions stated above.  **Customised use scenario**  Points will be awarded for the equipment based on how low the reported daily Energy usage is, **E (kwh)/day)**, according to the table and the test conditions below. Please, fill in the table: (the lower daily Energy usage, the more points will be awarded)  Definitions of modes are according to Appendix 1. Verification description can be viewed below the table.   |  |  |  |  |  | | --- | --- | --- | --- | --- | | **Equipment** | **Mode** | **Customised use scenario**  *Stated by procurer* | **Energy in use phase**  *Stated by tenderer* | **The Energy usage (E) calculation:** | | **Medical sterilizer** | 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), drying stage used (yes/no))* | 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** | | Ready | T2 | P2 | | Standby | 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.* |   The measurements shall be carried out according to the test conditions specified in Appendix 4.  **Verification:**  Tenderers shall provide appropriate technical documentation, i. e. a test report according to the standard EN 50564:2011 (6.1, 6.2, 6.3, and 6.4) or equivalent. The test report shall include energy performance data EV or and EW for the offered equipment. The data shall be valid for the modes and according to the test conditions in appendix 4 and use scenarios stated by the procurer. The testing shall be performed by laboratories according to the general requirements of EN ISO 17025, or equivalent such as U.S. 21 CFR Part 820 or ISO 13485, according to the test conditions stated above |
| **12. Energy performance and water consumption for flusher and washer disinfectant equipment**  Points will be awarded for the equipment based on how low the reported Energy usage per cycle is, E(kwh)/ cycle, according to the test conditions below. (the lower Energy usage per treatment, the more points will be awarded).  Points will also be awarded based on how low the reported water consumption per cycle is, according to test conditions below. (the lower the water consumption, the more points will be awarded)  The procurer states which type of disinfector that will be procured:   * Disinfector for flexible endoscopes * Disinfector for all other instruments (General surgical instruments, MIS, Anathaetics, Orthopaedics, etc.) * Disinfector for bulky goods like Sterile Containers, Trolleys, OP-Theater-Shoes, etc. * Disinfector for human waste containers   The procurer specifies the below:   * Specific required  load (amount of load) * Draying stage used (Yes/No) * HW (Hot Water) (Yes/No) * Treated Water in Final rinse (Yes/No) * Heating methods (Steam or Electrical) * Voltage   Measurements shall be carried out by manufacturer according to   * A0 Value   + Disinfector for surgical and analytical instruments: A0 3000   + Disinfector for Instruments and bulky goods: A0 600   + Disinfector for human waste containers: A0 60 * CW (Cold Water) Max temperature 20°C * HW (Hot Water) Max temperature 60°C * Treated Water Max temperature 20°C * Steam Max 500 kPa   Additional test conditions for energy performance measurements are found in Appendix 3.  The manufacturer states what acceptance criteria is for cleaning, disinfection and drying performance in accordance to ISO 15883  The tenderer states the energy performance and water consumption per cycle, based on above parameters.  Contracting authorities will have to indicate in the contract notice and tender documents how many points will be awarded for each award criterion.  **Verification:**  Tenderers must provide appropriate technical documentation, i. e. test report with included water consumption data and energy performance for the offered equipment, also demonstrating that the above standards and test conditions or equivalent are met.  The testing shall be performed by laboratories according to the general requirements of EN ISO 17025, or equivalent such as U.S. 21 CFR Part 820 or ISO 13485, according to the test conditions stated above. |
| **13. Automatic low power mode for medical sterilizer, disinfector, CT, ECG diagnostic, MRI, and ultrasound**  Points will be awarded if the offered equipment can be configured to go automatically into a standby or off mode after a certain period of inactivity or after a predetermined schedule, according to below pattern**.** For CT and MRI points will be awarded if the scanner is equipped with a low power mode which can be activated by the operator:   |  |  |  | | --- | --- | --- | | **Equipment** | **From mode** | **To mode** | | Medical sterilizer and disinfector | Ready mode | Standby mode | | CT | Idle | Low power mode | | ECG, diagnostic | Active or standby mode | Off mode | | MRI | Ready-to-scan mode | Low power 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 |   Points will also be awarded if the offered equipment has a short and automated startup 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 shorter time and active efforts needed, the more points will be awarded.  Contracting authorities will have to indicate in the contract notice and tender documents how many points will be awarded for each award criterion.  Definitions of modes are according to appendix 2 for CT and MRI and according to appendix 1 for the remaining equipment above.  **Verification:**  Tenderers shall provide documentation such as a copy of the instruction manual, describing:   * the required automatic low power or off mode according to the above pattern, how it can be activated by the operator and the available configuration options, including individualized automatic behavior and functions or description on how to best use low power modes to save energy, and   the startup time with its required active efforts of the staff This documentation 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. |
| **14. Water consumption for haemodialysis equipment**  Points will be awarded based on how low the reported water consumption of dialysis equipment per treatment is, according to test conditions specified in IEC 60601-2-16:2008. (the lower the water consumption, the more points will be awarded)  The treatment cycle shall follow:   * Test - depending on machine * Filling/Rinsing - 10 Minutes * Pre-Circulation - 15 Minutes * Dialysis- 4h * Heat/Chemical Disinfection - depending on machine *Preference of type of disinfection is stated by the procurer.*   Additional points will be awarded for the equipment which is equipped with a low (at least 50 % reduction in saving mode) water consumption function in order to lower the water consumption during pre-circulation. Additional points will be awarded for the equipment which is equipped with a no water consumption function during standby (100 % reduction in saving mode).  Contracting authorities will have to indicate in the contract notice and tender documents how many points will be awarded for each award criterion.  **Verification:**  Tenderers must provide appropriate technical documentation, i. e. test report with included water consumption data and relevant pages of or link to instruction manual covering the low and no water consumption functions for the offered equipment, also demonstrating that the above standards and test conditions or equivalent are met.  The testing shall be performed by laboratories according to the general requirements of EN ISO 17025, or equivalent such as U.S. 21 CFR Part 820 or ISO 13485, according to the test conditions stated above. |
| **15. Equipment equipped with metering device**  Points will be awarded if the equipment has or can be equipped with a metering device, so that a log of the current consumption (of electricity, water (if relevant for the offered equipment), gas (relevant for an/iva (anaesthesia and intensive care) equipment)) can be observed and registered. The user should also be able to take out statistics from historic consumption in report form. State the conditions for consumption metering, as well as if additional cost will be applied to connect the metering device. Restrictions regarding what or how the staff can measure with the metering device shall be stated. Points will also be awarded if the acquired data can automatically be sent to a central.  **Verification:**  Tenderers shall provide documentation such as a copy of the instruction manual, describing the metering device and its functions, conditions and restrictions. |

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| --- |
| **CONTRACT PERFORMANCE CLAUSES** |
| **16. 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)[[4]](#footnote-5), * 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 21.  **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. |
| **17. Education for energy efficiency optimisation (General criteria for all equipment)**  Offered clinical education and technical education must include elements regarding adjustment and fine-tuning of the offered equipment’s electricity using parameters in order to optimise the electricity use. Describe to what extent this can be provided for.  **Verification during follow-up:**  Curriculum of offered clinical education. |
| **18. Installation with energy efficiency optimisation (General criteria for all equipment)**  In the installation procedure of the offered equipment, a needs analysis of the user (i.e. the ward) must be done (i.e. frequency of use, type of examinations etc) and on the basis of the analysis the optimisation of the offered equipment’s electricity using parameters shall be documented and informed about. This process shall then be repeated and revised at every preventive maintenance of the equipment done by the supplier.  **Verification during follow-up:**  Description of the installation procedure and preventive maintenance procedure. |
| **Comprehensive criteria (proposed for use in addition to core criteria)** |
| **AWARD CRITERIA** |
| **19. Re-use**[[5]](#footnote-6) **and recovery of equipment**  **Refurbishment system**  Points will be awarded if the equipment is part of a refurbishment[[6]](#footnote-7) system  To be awarded points, the refurbishment system that the equipment is part of shall include at least the following (or equivalent):   * A selection process of used equipment * A de-installation process and transport procedure * A refurbishing procedure including the following: * Cleaning & Disinfection * Refurbishment Planning * Cosmetic Refurbishment * Mechanical and Electrical Refurbishment and System Configuration (incl. Parts replacement, Software updates) * Customer configuration * System Testing (including Components and possible subsystems tests /checks) * Refurbishment Declaration * Packing & Shipment * An installation process of the refurbished equipment as for new equipment   **Refurbished parts**  Additional points will be awarded if the equipment contains refurbished parts.  **Recycled equipment**  Additional points will be awarded if the equipment has a minimum of 95% of recovery[[7]](#footnote-8) and 85% of recycling[[8]](#footnote-9) by an average weight per product.  Recycling rate: the sum of the materials potentially recyclable divided by the weight of the product.  Recovery rate: the sum of materials potentially recoverable divided by the weight of the product.  **Verification:**  *Refurbishment*  To be awarded points, the tender must provide a description of the refurbishment system, preferably containing the dashed items mentioned above. Quality shall be guaranteed by compliance to standard ISO 13485 or equivalent[[9]](#footnote-10) and by a confirmation that the system does meet the specification of an EU declaration of conformity relevant for the type of system that was refurbished.  *Refurbished parts*  Product declaration showing the bar code or rfid tag of the refurbished component. Refurbished components should be marked (bar coded / rfid tagged) to identify that they have been refurbished and the number of times they have been through a refurbishment process.  *Recovery and recycling*  Self-declaration demonstrating the total composition (bill of material) of his products in grams (or 100%) showing the following categories:   * Metals (ferrous / non ferrous) * Strategic raw materials[[10]](#footnote-11) * Glas * Plastics * Organic * Others |
| **20. 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. |
| **21. Gas consumption for anaesthesia equipment**  Points will be awarded for equipment with features which automatically drive to low flow or provide informational tools which aid the clinician in achieving low flow.  Low Flow: A flow rate that gives adequate O2 and agent to the patient with a good response time to changes; typically around 2 liters per minute in clinical studies.  **Verification:**  A copy of the relevant pages of the instruction manual, describing the required low-flow adjustment and features for automatic low flow or informational tools, 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. |
| **22. 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 article[[11]](#footnote-12).  **Verification:**  A written statement guaranteeing that the equipment contains maximum 0.1 % weight of above listed substance/ weight of article4. |

1. **Explanatory notes**

**Award Criteria**

Contracting authorities will have to indicate in the contract notice and tender documents how many 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, according to EN 50564:2011 and EC 1275/2008:

**‘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;

**‘ready mode(s)’** means a condition in which the equipment is connected to the mains power source and provides (immediate) activation of all available functions.

**‘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***

CT

The modes, test conditions and procedures are defined according to the COCIR SRI document: “CT measurement on energy consumption methodology”

Link: [www.cocir.org](http://www.cocir.org)

MRI

The modes, test conditions and procedures are defined according to the COCIR SRI document: “MRI measurement on energy consumption methodology”

Link: [www.cocir.org](http://www.cocir.org)

***Appendix 3***

X-ray, Washer Disinfector, Flusher Disinfector

Test conditions

The methodology for measuring the energy performance shall be according to the sampling method 5.3.2. in standard EN 50564:2011 or equivalent. According to thestandard EN 50564:2011; 4.2 Test room, or equivalent, 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***

Medical sterilizers

**Pre-determined use scenario, test conditions**

The type of cycle to be used shall comply with either EN 285 or EN 13060, according to the volume stated by the procurer.

EV definition for EN 13060 or EN 285 compliant sterilizer

EV=E/V (kWh/liter)

E=Energy consumption in kWh per cycle run with empty chamber

V=Maximum usable volume of sterilizer in liter.

EW definition for EN 13060 or EN 285 compliant sterilizer:

EW=EM/M (kwh/kg)

EM=Energy consumption in kWh per cycle with test load M (kg)

M=Test metal load as stated by the supplier (kg)

For EN 13060 compliant sterilizer the test load is the maximum metal load stated by the supplier (kg).

For EN 285 compliant sterilizer the test load is 15 kg metal load x STE (while STE is the maximum usable volume stated by the manufacturer)

Note: The metal used in the test load shall be stainless steel according to EN 10088-1.

Note: The energy performance data are valid for a 134 oC wrapped goods cycle

The sterilizer shall be pre-heated and ready to use.

The test shall be performed with active drying.

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, according to the standard EN 50564:2011; 4.2 Test room, or equivalent. The ambient temperature shall be maintained at (23 ± 2) °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.

**Customised use scenario, test conditions**

The sterilizer shall be pre-heated and ready to use.

The energy performance shall be measured according to the procurer’s specified conditions such as if active drying is included, load per cycle, material type, type of cycle.

The methodology for measuring the energy performance shall be according to the sampling method 5.3.2. in standard EN 50564:2011 or equivalent. According to thestandard EN 50564:2011; 4.2 Test room, or equivalent, 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

The modes, test conditions and procedures are defined according to the COCIR SRI document: “CT measurement on energy consumption methodology”

Link: [www.cocir.org](http://www.cocir.org)

***Appendix 6***

Dialysis equipment

Test conditions

According to thestandard EN 50564:2011; 4.2 Test room, or equivalent, 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 ± 2) °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.

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

Other test 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***

HF Surgery, diathermy equipment

Test conditions

The methodology for measuring the energy performance shall be according to the sampling method 5.3.2. in standard EN 50564:2011 or equivalent. According to thestandard EN 50564:2011; 4.2 Test room, or equivalent, 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 test conditions for active mode

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 OUTPUT POWER of 50 W 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 methodology for measuring the energy performance shall be according to the sampling method 5.3.2. in standard EN 50564:2011 or equivalent. According to thestandard EN 50564:2011; 4.2 Test room, or equivalent, 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 test conditions for active mode

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 methodology for measuring the energy performance shall be according to the sampling method 5.3.2. in standard EN 50564:2011 or equivalent. According to thestandard EN 50564:2011; 4.2 Test room, or equivalent, 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 light source (on max power), camera unit, endoscope, and air pump during the test. The light source must have reached working temperature before start of 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. Temperature shall have stabilized before the test starts.

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 methodology for measuring the energy performance shall be according to the sampling method 5.3.2. in standard EN 50564:2011 or equivalent. According to thestandard EN 50564:2011; 4.2 Test room, or equivalent, 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 methodology for measuring the energy performance shall be according to the sampling method 5.3.2. in standard EN 50564:2011 or equivalent According to thestandard EN 50564:2011; 4.2 Test room, or equivalent, 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 test 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 respired 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.

The flow shall be 10 liters/ minute. ~~The test duration shall be 100 minutes, giving 1 m3 air and 33 g of water.~~

The ventilator connected with the active respiratory gas humidifier shall be adjusted to tidale volume 500 ml and breathing frequency of 14/min and air, i.e. 21 % oxygene volume controlled mode.

Är detta enligt standarden ISO 80601-2-12, 201.12.1.101

***Appendix 13***

Laser instruments

Test conditions

The methodology for measuring the energy performance shall be according to the sampling method 5.3.2. in standard EN 50564:2011 or equivalent. According to thestandard EN 50564:2011; 4.2 Test room, or equivalent, 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 laser shall be in standby mode according to the definition in the standard EN 60 601-2-22 or equivalent during measurement of the energy consumption in the standby 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.

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 in the active mode.

Modes definitions from IEC 60601-2-22:

STAND-BY condition: The mains cable is connected and the mains switch activated. The LASER is not capable of emitting the WORKING BEAM even if the LASER control switch is activated. READY condition: The LASER EQUIPMENT is capable of emitting LASER OUTPUT when the control switch is activated.

***Appendix 14***

Bed side monitoring equipment

Test conditions

The methodology for measuring the energy performance shall be according to the sampling method 5.3.2., in standard EN 50564:2011 or equivalent. According to thestandard EN 50564:2011; 4.2 Test room, or equivalent, 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.

Other test conditions

During the measurement of energy performance in the active mode, the Input signals in the range of ± 5 mV, varying at a rate to 125 mV/s, shall be reproduced on the output, this according to IEC 60601-2-27, 201.12.1.101.1 or equivalent.

The monitor must have reached working temperature before start of test.

***Appendix 15***

MRI

The modes, test conditions and procedures are defined according to the COCIR SRI document: “MRI measurement on energy consumption methodology”

Link: [www.cocir.org](http://www.cocir.org)

***Appendix 16***

Ultrasound equipment

Test conditions

The methodology for measuring the energy performance shall be according to the sampling method 5.3.2., in standard EN 50564:2011 or equivalent. According to thestandard EN 50564:2011; 4.2 Test room, or equivalent, 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 test conditions

The ultrasound system shall be equipped with a standard 5 MHz probe or equal.

Use a standard test phantom like RMI403GS or likewise.

Scan the phantom with 2D scanning mode using a sending frequency as close as possible to 5 MHz. Adjust an appropriate image on 10cm depth.

Measure the energy consumption during 30 min of continues scanning with parameters above.

***Appendix 17***

Medical lighting – surgical lamps

Test conditions

The methodology for measuring the energy performance shall be according to the sampling method 5.3.2. in standard EN 50564:2011 or equivalent. According to thestandard EN 50564:2011; 4.2 Test room, or equivalent, 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.

The light source must have reached working temperature before start of test.

***Appendix 18***

Patient warming systems

Test conditions

The methodology for power measurements shall be according to the sampling method 5.3.2., in standard EN 50564:2011 or equivalent. According to thestandard EN 50564:2011; 4.2 Test room, or equivalent, 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 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 describes 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 at 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.

For active mode for forced air device:

During the power measurement in the active mode of a forced air device, the forced air device shall be connected to a torso blanket that has reached a stabilized temperature of 38°C and the test duration shall be 1 hour.

***Appendix 19***

Medical freezer

Test conditions

The methodology for measuring the energy performance shall be according to the sampling method 5.3.2. in standard EN 50564:2011 or equivalent. According to thestandard EN 50564:2011; 4.2 Test room, or equivalent, 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.

Temperature shall have stabilized before the test starts.

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.

***Appendix 20***

Ventilator

Test conditions

The methodology for measuring the energy performance shall be according to the sampling method 5.3.2. in standard EN 50564:2011 or equivalent. According to thestandard EN 50564:2011; 4.2 Test room, or equivalent, 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 equipment shall be pre-heated and ready for use, and adjusted according to the standard ISO 80601-2-12 or equivalent, 201.12.1.101 Volume-controlled breath type.

The measurement’s duration shall be 15 minutes and the average power shall be registered.

***Appendix 21***

**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.

***Appendix 22***

BPA: Bisphenol-A

CAS: Chemical Abstracts Service

COCIR: European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry

CT: Computer Tomography

ECG: Electrocardiographic

EEE: Electrical and electronic equipment

GHG: Green House Gas

GPP: Green Public Procurement

GWP: Global Warming Potential

HF: High frequency

LCC: Life Cycle Costing

LED: Light-Emitting Diode

MRI: Magnetic Resonance Imaging

REACH: Registration, Evaluation, Authorisation and Restriction of Chemicals

RF: Radio frequency

SRI: Self Regulatory Initiative

1. Social and ethical impacts will only be part of the Swedish criteria, [www.msr.se](http://www.msr.se), not the EU criteria, since they are limited to green procurement. Social considerations can be included according to the "Buying Social Guide" http://ec.europa.eu/social/main.jsp?langId=en&catId=89&newsId=978&furtherNews=yes [↑](#footnote-ref-1)
2. For further guidance, see the ECHA Guidance to substances in article, [http://echa.europa.eu/](http://echa.europa.eu/" \t "_blank) or similar guidance e.g. [www.cocir.org](http://www.cocir.org), or other industry guidance on REACH. [↑](#footnote-ref-2)
3. This provides the purchaser a good overview of the energy usage and how much can be saved by using the equipped Off and LowPower modes [↑](#footnote-ref-4)
4. See Appendix 19. [↑](#footnote-ref-5)
5. According to Directive 2008/98/EC: "re-use" means any operation by which products or components that  are not waste are used again for the same purpose for which they were

   conceived; [↑](#footnote-ref-6)
6. Definitions of re-use, refurbishment, remanufacturing are available in BS8887-2 (2009) [↑](#footnote-ref-7)
7. According to Directive 2008/98/EC: "recovery" means any operation the principal result of which is waste serving a useful purpose by replacing other materials which would otherwise have been used to fulfil a particular function, or  waste being prepared to fulfil that function, in the plant or in the wider economy. Annex II sets out a non-exhaustive list of recovery operations; [↑](#footnote-ref-8)
8. "recycling" means any recovery operation by which waste materials are reprocessed into products, materials or substances whether for the original or other purposes. It includes the reprocessing of organic material but does not include energy recovery and the reprocessing into materials that are to be used as fuels or for backfilling operations; [↑](#footnote-ref-9)
9. i.e. for example Good Refurbishment Practice (GRP) issued by COCIR 2010 [↑](#footnote-ref-10)
10. Economically important raw materials defined by the EC, <http://ec.europa.eu/enterprise/policies/raw-materials/critical/> [↑](#footnote-ref-11)
11. According to the definition of an article in Article 3.3 REACH Regulation (EC) No 1907/2006 [↑](#footnote-ref-12)