## ΕΝΤΥΠΟ 1Α

# ΠΙΝΑΚΑΣ ΠΡΟΣΦΟΡΑΣ ΚΑΙ ΣΥΜΜΟΡΦΩΣΗΣ ΜΕ ΤΙΣ ΤΕΧΝΙΚΕΣ ΠΡΟΔΙΑΓΡΑΦΕΣ

# TECHNICAL SPECIFICATIONS AND STATEMENT OF CONFORMITY WITH SPECIFICATIONS

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| **Package Outline of Specifications** |
| A fully automated ceiling suspended digital X ray unit to be used at the Bank of Cyprus oncology Centre to acquire high quality X ray images.All the system components offered must be of the latest State-of-the-art design and be compatible with each other, in order to form an ergonomic x ray system. The system to be based on an advanced technology platform for speedy, noiseless, free of vibration and precise executions of all studies with consistently high resolution and high performance for X ray imaging. In addition, the system must have the following qualities:1. Be ergonomic and user friendly
2. System must be installed in the existing X ray room. It is imperative that the system must be able to perform all radiographic examinations.
3. Microprocessor Controlled High Frequency X-ray generator
4. Provide high Image Quality with the lowest possible dose to the patients using digital flat panel technology of at least 35x43cm flat panel detector, based on CsI(Tl) technology.
5. Able to acquire and display images in real time and able to automatically save these images.
6. At least one 21“TFT/LCD viewing monitor must be provided, with a maximum brightness of at least 400cd/m2
7. Advanced Image processing
8. Connectivity / Upgradeability: The system to be DICOM 3.0 compliant. It should be able to connect to the Hospital’s DICOM 3.0 / HL7 compliant network and, PACS / RIS system. DICOM 3.0 conformance statement to be submitted with the offer.
9. Able to produce Dicom Structured reports.
10. Able to store at least 10000 uncompressed images
11. Able to export RAW (Unprocessed) images via CD/DVD or USB
12. System must be secure and password/or key protected.
13. The user must be able to disable X rays.
14. Installation, Acceptance Testing and Training of the Centre’s Staff
15. System operations, Reliability, Maintenance Contract, Spare Parts.
16. Manufacturer Support, software and hardware releases during the warranty and the 8 year maintenance period
17. Regulatory compliance with relative IEC standards, European CE Mark 2017 or later (Certificates to be provided with the offer)
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Tenderer Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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| **Radiographic digital X ray Unit**  |
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| **Essential Information** | (To be completed by Tenderer) |  |
| Name of Manufacturer |   |  |
| Model |   |  |
| Country of origin |   |  |
| Year on which model was launched to the market |   |  |
| Year on which model was last upgraded |   |  |
| Indicate if there is next planned upgrade and date of release |   |  |

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|  Installations conditions |
| **No** | **Specification Requirements** | **REQUIREMENT** | **Statement of Conformity(To be completed by Tenderer)** | **Reference to Product Literature (Page & Paragraph)** |
| 1.1 | Please state temperature and humidity requirements of the unit. This should conform to the current room conditions.  | YES |   |   |
| 1.2 | Please state power requirements of the scanner and that it is compatible with current supply. | YES |   |   |
| 1.3 | Please state the minimum room dimensions needed for the installation of the scanner. Scanner must be installed in the existing room. | YES |   |   |
| 1.4 | Interference suppression must be in compliance to CYS EN 60601-1-2 | YES |  |  |
| 1.5 | State Power consumption | YES |  |  |
| 1.6 | Positioning of the system in the existing room must be agreed with the head of the radiology department prior installation. The current lead shield can be reused.  | YES |  |  |
| 1.7 | Additional installation cables, normal construction works for installation, such as ceiling or floor rails, base plates, cables boxes, cable ducts or any other special installation requirements must be provided by the manufacturer prior to installation of the System. **A visit from the installations/service engineer to the BOCOC is required for inspection of the room and verification of the above**. Please state the date of the visit | YES |  |  |

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| X Ray generation (Generator and tube) requirements |
| **No** | **Specification Requirements** | **REQUIREMENT** | **Statement of Conformity(To be completed by Tenderer)** | **Reference to Product Literature (Page & Paragraph)** |
| 2.1 | The X-ray generator to be microprocessor controlled, high frequency and with a nominal power, such as to be able to perform all examinations. Overload protection to be included.Nominal output to comply with EN60336 standard | YES |  |  |
| 2.2 | State the output power of the generator (min 80kW IEC 60601-2-54). | YES |  |  |
| 2.3 | mAs range 0.5 to 800mAsmA range 1mA to 1000mAexp times 0.001 to 3s | YES |  |  |
| 2.4 | State housing 2500kHU) and anode (min 800kHU) heat capacity. | YES |  |  |
| 2.5 | State anode heat dissipation rate (min 160kHU)  |  |  |  |
| 2.6 | State KV range (Range: 40kV or less -150kV or more)Accuracy (±10%) | YES |  |  |
| 2.7 | kV ripple less than 5% | YES |  |  |
| 2.8 | State Exposure time Accuracy (±5%) | YES |  |  |
| 2.9 | State total filtration (min 2.5mmAl @80kV, IEC 60601-1-3) | YES |  |  |
| 2.10 | Leakage radiation (IEC 60601-1-3) <1mGy @1m |  |  |  |
| 2.11 | State Nominal focal spot sizes Should comply withIEC 60336 or IEC 336Min 2 selectable focal spots (small and large) required | YES |  |  |
| 2.12 | State built auto filter selection, 0.1 mm, 0.2 mm, 0.3 mm Cu. Programmable into clinical protocols. | YES |  |  |
| 2.13 | Load to indicator that will display limits and message to forbid x-ray when needed and display of availiable heat units in % | YES |  |  |
| 2.14 | 4 axis auto and manual blade collimatorState minimum and maximum field sizesRotation ± 45° | YES |  |  |
| 2.15 | Light indication (LED) state power of said LED | YES |  |  |
| 2.16 | SID laser light alignment | YES |  |  |
| 2.17 | Manual SID indication, tape measure | YES |  |  |
| 2.18 | Integrated Dose Area Product meter (DAP) with light transparency more than 70%Reporting in units of μGym2 (or equivalent). Software option for DAP display is also accepted. | YES |  |  |
| 2.19 | At least 10” multifunction touch screen display on the X ray head and physical buttons with the capability of user modification of the following parameters:kV, mAs, ms, focal spotAEC selection, detector dose/sensitivityCollimation/head movement in all directionsSelection of exposure (Table/Bucky/Free exposure)Display of patient and examination dataAutomatic display of detector angle andCollimation size | YES |  |  |

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| Detectors requirements |
| **No** | **Specification Requirements** | **REQUIREMENT** | **Statement of Conformity(To be completed by Tenderer)** | **Reference to Product Literature (Page & Paragraph)** |
| 3.1 | Wireless Flat panel detector must be provided which is fully compatible with the provided X-RAY System. Compliant with IEC 60601. WLAN Standard (802.11 2.4GhZ/5GHz). The detector must be the most recent model within specifications of the manufacturer based on Caesium iodide scintillator coupled to TFT matrix with amorphous silicon technology with Lithium-ion rechargeable battery. | YES |   |  |
| 3.2 | Active detector area of at least 40cm x 40 cm  | YES |  |  |
| 3.3 | Wireless detector must have in-tray charging support for table and Bucky acquisitions. | YES |  |  |
| 3.4 | Please state additional cost for second detector of similar size | optional |  |  |
| 3.5 | State pixel size (max 150μm) matrix and active-matrix size | YES |   |  |
| 3.6 | State A/D conversion depth (min 14bit) | YES |   |  |
| 3.7 | State DQE for the detector (RQA5 values 2μGy, IEC 62220):DQE(1lp/mm) (min 50%)DQE(2lp/mm) (min 40%) DQE(3lp/mm) (min 35%)  | YES |  |  |
| 3.8 | State MTF for the detector (RQA5 values, IEC 62220):MTF(1lp/mm) (min 65%)MTF(2lp/mm) (min 40%)MTF(3lp/mm) (min 25%) | YES |  |  |
| 3.9 | State image spatial resolution (min 4.1lp/mm) | YES |  |  |
| 3.10 | 1x Removable anti scatter grid of at least 40 lines/cm, fo=115-150cm1x Removable anti scatter grid of at least 90 lines/cm, fo=180cm | YES |  |  |
| 3.11 | Charge system where the detector can be charged in a docking station.  | YES |  |  |
| 3.12 | Battery charge time of less than 5 hours (0-100%)Operation time no less than 6h in standard modeElectromagnetic compatibility: compliance with IEC 60601-1-2 | YES |  |  |
| 3.13 | Mass of detector (43X43) incl. battery 3.2kg or less | YES |  |  |
| 3.14 | Max load capacity 300kg or more –distributed weight on detector100kg or more point | YES |  |  |

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| General Unit requirements |
| **No** | **Specification Requirements** | **REQUIREMENT** | **Statement of Conformity(To be completed by Tenderer)** | **Reference to Product Literature (Page & Paragraph)** |
| 4.1 | Hand switch for x ray activation with button from the control panel and wireless remote control | YES |   |  |
| 4.2 | User must be able to prevent X ray exposure.  | YES |  |  |
| 4.3 | X ray tube movementHorizontal travel: min 340cmTransverse: min 200cm (3m trolley)Vertical: min 108cmSpeed: min 0.3m/sX ray tube rotation Manual/motorized: min ±150o, (Vertical axis)Manual/motorized: min ±135o (Horizontal axis)Speed min 40o/s |  |  |  |
| 4.4 | SID out of Bucky exposure range of 55cm to 200cm | YES |  |  |
| 4.5 | Movement of X ray tube, vertical bucky and table must be motorized and synchronized in all directions. | YES |  |  |
| 4.6 | Vertical BuckyVertical travel range from 32 to 175 cm. Tilting +90° to -20° Table top made of X ray transparent material ≤0.65mm Al at 100keV |  |  |  |
| 4.7 | TableTable height: from 52 to 95 cm Max. patient weight: 300 kg Longitudinal tabletop travel: ± 48 cm Table top width min 80cmTable top length min 246cmTable top made of X ray transparent material ≤0.65mm Al at 100keVSwitches to control height and float of table must be provided. | YES |  |  |
| 4.8 | Automatic tube tracking for table and vertical Bucky. Must be programmable up to 10 preset positions initiated by a user with wireless remote control.  | YES |  |  |
| 4.9 | AEC for dose management with dose and sensitivity modification. The AEC system must include at least 3 ion chambers two lateral and one central and active chambers must be independently selected by the user.  | YES |  |  |
| 4.10 | Tube parking and tube centering | YES |  |  |
| 4.11 | AI-assisted Smart Collimation/Positioning | YES |  |  |

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| Control panel requirments |
| **No** | **Specification Requirements** | **REQUIREMENT** | **Statement of Conformity(To be completed by Tenderer)** | **Reference to Product Literature (Page & Paragraph)** |
| 5.1 | Images must be displayed on an LCD or TFT monitor (21” or more)  | YES |   |  |
| 5.2 | High resolution monitors (at least 1600\*1200 pixels HD)  | YES |  |  |
| 5.3 | Monitor must have a maximum brightness of up to 400 cd/m2 or more | YES |  |  |
| 5.4 | State of the art modern multi-core processor Intel Core i5 GHz 4-Core or better (min 3 GHz) with at least 16GB RAM and 500GB storage (store at least 10000 images) | YES |  |  |
| 5.5 | Raw (unprocessed) images to be exported via DVD/CD or USB  | YES |  |  |
| 5.6 | User-friendly control panel with digital display of all parameters (e.g. kV, mAs) and audiovisual indication of exposure with no noticeable delay. This can be performed via separate control panel or via the provided touch screen see (5.1). | YES |  |  |

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| Software and image processing |
| **No** | **Specification Requirements** | **REQUIREMENT** | **Statement of Conformity(To be completed by Tenderer)** | **Reference to Product Literature (Page & Paragraph)** |
| 6.1 | The system to be ready of being connected to a Radiology Information System, Hospital Information System and PACS | YES |   |  |
| 6.2 | Image Communication through Ethernet interface in DICOM 3 format to support:a) Sendb) Printc) Query/Retrieved) Storagee) Modality Work Listf) MPPSg) Dose structured report Other DICOM 3 statements to be stated | YES |  |  |
| 6.3 | Emergency Patient registration | YES |  |  |
| 6.4 | System to display and dose area product (DAP) and exposure index (EI) | YES |  |  |
| 6.5 | Study and image data administration | YES |   |  |
| 6.6 | Application manager | YES |   |  |
| 6.7 | System must have advanced user management including individual password management and user authorization | YES |  |  |
| 6.8 | Remote access tools | YES |  |  |
| 6.9 | Image measurements and annotations e.g. distance, angle measurement, annotation, ROI (rectangle, ellipse), arrow, mean and standard deviation  | YES |  |  |
| 6.10 | Post processing tools:At least Contrast and Brightness / Zoom / Flip / Rotate / Invert / Shutter | YES |  |  |
| 6.11 | System battery status display and low battery indication for wireless detectors | YES |  |  |
| 6.12 | Grid line removal software  | YES |  |  |
| 6.13 | Advanced protocol/anatomy based imaging processing, use of sharp and blur spatial filters etc  | YES |  |  |
| 6.14 | Clinical assurance program for repeat/reject analysis | YES |  |  |
| 6.15 | Pre programming techniques  | YES |  |  |
| 6.16 | Protocol assist to match procedure codes from anatomy | YES |  |  |
| 6.17 | Setting of parameters for imagepreprocessing (e.g. amplification, harmonization, edge enhancement andLUT) | YES |  |  |
| 6.18 | Hard disk encryption | YES |  |  |
| 6.19 | System must provide RAW (unprocessed) images according to IEC 62220-1  | YES |  |  |
| 6.20 | Describe any other software/imaging applications offered and state any extra cost (if any) |  |  |  |
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| Accesories |
| **No** | **Specification Requirements** | **REQUIREMENT** | **Statement of Conformity(To be completed by Tenderer)** | **Reference to Product Literature (Page & Paragraph)** |
| 7.1 | Hand grips for patient table and Bucky wall standHand grips for patient table and Bucky wall stand | YES |  |  |
| 7.2 | Compression beltFootswitch for table height adjustment and tabletop float releaseMobile detector holderPatient positioning mattressTable and vertical bucky paper holderWall holder for 2 gridsWall charger for wireless detector | YES |  |  |
| 7.3 | UPS to protect console/PC from power failures. Enough time should be provided to shut down the system.  | YES |  |  |

**ΣΗΜΕΙΩΣΕΙΣ:**

* 1. **Είναι υποχρεωτική η απάντηση σε όλα τα σημεία του Πίνακα. Σε περίπτωση που δεν έχει απαντηθεί οποιοδήποτε σημείο, η απάντηση θεωρείται αρνητική.**
	2. Στη Στήλη «Specification Requirements», περιγράφονται αναλυτικά οι αντίστοιχοι τεχνικοί όροι, υποχρεώσεις ή επεξηγήσεις για τα οποία θα πρέπει να δοθούν αντίστοιχες απαντήσεις.
	3. Στη στήλη «Statement of Conformity» σημειώνεται η απάντηση του Προσφέροντα που, είτε είναι το συγκεκριμένο προϊόν που προσφέρει, είτε έχει τη μορφή ΝΑΙ/ΟΧΙ εάν η αντίστοιχη προδιαγραφή πληρούται ή όχι από την Προσφορά ή ένα αριθμητικό μέγεθος που δηλώνει την ποσότητα του αντίστοιχου χαρακτηριστικού στην Προσφορά.
	4. Στη στήλη «Reference to Product Literature (Page & Paragraph)» θα καταγραφεί η σαφής παραπομπή σε Παράρτημα της Τεχνικής Προσφοράς το οποίο θα περιλαμβάνει αριθμημένα Τεχνικά Φυλλάδια κατασκευαστών, ή αναλυτικές τεχνικές περιγραφές των προσφερόμενων προϊόντων, που κατά την κρίση του Προσφέροντα τεκμηριώνουν τα δηλούμενα στον Πίνακα Στοιχεία. Οι παραπομπές πρέπει να είναι συγκεκριμένες (π.χ. Τεχνικό Φυλλάδιο 3, Σελ. 4 Παράγραφος 4, κ.λ.π.), ενώ αντίστοιχα στο τεχνικό φυλλάδιο ή την αναφορά θα υπογραμμίζεται το σημείο τεκμηρίωσης και θα σημειώνεται η αντίστοιχη παράγραφος του Πίνακα στην οποία καταγράφεται το ζητούμενο χαρακτηριστικό.