## **CLARIFICATIONS No. 2 to the TENDER DOSSIER**

Contract Title:Supply of Electrical and Medical Equipment, Furniture and ConsumablesPublication Reference:SIHHAT/2025/SUP/INT/03

Doc: Document

ITT: Instructions to Tenderers

TD: Tender Dossier

TS: Annex II + III: Technical Specifications + Technical Offer / c4f\_annexiitechspeciiitechoffer\_en

Further to the requests received from the tenderers, the following clarifications are provided.

#	DOC.	LOT/ITEM	CLAUSE	QUESTION / REQUEST	ANSWER
1	TS	6.3.	The device shall have a thermal printer that uses z-folded or roll paper with a width of $210\pm10$ (two hundred ten plus minus ten) mm and a length of $297\pm20$ (two hundred ninety-seven plus minus twenty) mm.	Requested Version: The device shall have a thermal printer that uses z-folded or roll paper with a width of $210\pm10$ (two hundred ten plus minus ten) mm and a length of $150\pm10$ (one hundred and fifty plus or minus ten) mm.	This item will remain as it was stated in TS.
2	TS	6.7.	The device shall take minimum 30 (thirty) ECGs with a fully charged battery.	Requested Version: The device shall take minimum 30 (thirty) ECGs with a fully charged battery and have a battery life of 3 hours.	This item will remain as it was stated in TS.
3	TS	6.9.	The device must have an AC mains interference filter, DFT isoline filter and EMG filter.	Requested Version: The device shall include an AC mains interference filter, a DFT baseline filter, or an EMG filter.	This item will remain as it was stated in TS.
4	TS	6.11.	The filter settings on the device must meet minimum 3 of the 20 Hz, 25 Hz, 35 Hz, 40 Hz, 45 Hz and 300 Hz options.	Requested Version: The filter settings on the device must meet minimum 3 of the following options: 20 Hz, 25 Hz, 35 Hz, 40 Hz, 45 Hz, or 75 Hz, or 300 Hz.	Please see Changes to the Tender Dossier.
5	TS	6.19.	The ECG printouts to be taken from the device shall include the minimum open filter values, pulse, time, date, patient name, age, height, weight and gender information.	Requested Version: The ECG printouts obtained from the device shall include, at a minimum, the active filter settings, heart rate, time, date, patient name, age or height or weight, and gender information.	Please see Changes to the Tender Dossier.
6	TS	6.22.	The printer sensitivity of the device shall be adjustable to minimum 3 (three) steps as 5 (five) mm/mV, 10 (ten) mm/mV or 12.5 (twelve and a half) and 20 (twenty) mm/mV.	Requested Version: The printer sensitivity of the device shall be adjustable in at least 3 (three) levels among the following: 5 mm/mV, 10 mm/mV, 12.5 mm/mV, 20 mm/mV, or 25 (twenty-five) mm/mV.	Please see Changes to the Tender Dossier.

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7	TS	6.24.	The device must have the DXL ECG algorithm or Marquette 12SL ECG algorithm or ECAPS12C or Culprit Coronary Artery Algorithm analysis or Bionet algorithm or Minnesota algorithm feature as standard.	Requested Version: The device must have by default with the CardioPro ECG Analysis Program.	This item will remain as it was stated in TS.
8	TS	7.1.6.	The frequency bandwidth of the device must cover the range of 1.5-17.5 MHz as minimum.	Requested Version: 7.1.6. The frequency bandwidth of the device must cover the range of 1.8- 17.5 MHz as minimum. Justification: Our probe does not support the frequency range specified in the original specification. This limitation is also applicable to other device manufacturers. Since this change does not impose any clinical or functional constraints, we request that the relevant modification be made to ensure fair competition.	This item will remain as it was stated in TS.
9	TS	7.1.7.	The maximum frame rate of the device must be minimum 1200 frames/sec in B-Mode.	Requested Version: 7.1.7. The maximum frame rate of the device must be minimum 450 frames/sec in B-Mode with an appropriate probe Justification: The proposed system supports a frame rate of 450 frames per second when used with a suitable probe. Since this meets the intended performance, we respectfully request that the phrase "with an appropriate probe" be added to the technical specification to prevent any misunderstandings during the procurement process. This amendment does not introduce any clinical or functional limitations. We respectfully request this amendment in order to foster a competitive procurement environment.	This item will remain as it was stated in TS.
10	TS	7.1.11.	All probes provided must have multi-frequency and/or wide-band technology. The system must have one of the following written probes. It must be possible to connect the device to one of the IDMS or Purewave or ComboWave or IQ linear probes; systems that do not allow connection shall not be accepted. The probe of the above-mentioned technology shall be shown on the original catalog. Minimum 1 of the probes to be proposed must have one of these technologies.	Requested Version 7.1.11. All probes provided must have multi-frequency and/or wide-band technology. The system must have one of the following written probes. It must be possible to connect the device to one of the IDMS or Purewave or C-Probe linear probes; systems that do not allow connection shall not be accepted. The probe of the above-mentioned technology shall be shown on the original catalog. Minimum 1 of the probes to be proposed must have one of these technologies.	This item will remain as it was stated in TS.

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11	TS	7.1.12.	It must be possible to connect one of the abdominal probes to the device with one of the IDMS or Purewave or IQ or 3T Single Crystal probe technologies. The probe of the above-mentioned technology shall be shown on the original catalog. Minimum 1 of the probes to be proposed must have one of these technologies. The probes written below must be provided with the systems:	Justification: Our device includes linear probes equipped with C-Probe technology, which is equivalent to the technologies defined in the specification. These probes offer enhanced image quality with reduced artifacts due to improved sensitivity. Thanks to their broadband capability, they deliver high-level spatial resolution, excellent penetration, and precise Doppler imaging. We respectfully request this amendment in order to foster a competitive procurement environment. Requested Version: 7.1.12. It must be possible to connect one of the abdominal probes to the device with one of the IDMS or Purewave or C-Probe probe technologies. The probe of the above-mentioned technology shall be shown on the original catalog. Minimum 1 of the probes to be proposed must have one of these technologies. The probes written below must be provided with the systems. Justification: Our device includes convex probes equipped with C-Probe technology, which is equivalent to the technologies defined in the specification. These probes provide enhanced image quality by minimizing artifacts through improved sensitivity. Their broadband features allow for high spatial resolution, excellent penetration, and precise Doppler imaging. We respectfully request this amendment in order to foster a competitive procurement environment.	This item will remain as it was stated in TS.
12	TS	7.1.12.a.	Convex Probe min. 1.0 / 6.0 MHz bandwidth	Requested Version: 7.1.12.a. Convex Probe: Minimum frequency bandwidth of 1.8 / 6.0 MHz Justification: Our probe does not support the frequency range specified in the original clause. This limitation is also applicable to other device manufacturers. Since this modification does not impose any clinical or functional restrictions, we respectfully request the change to ensure fair competition.	This item will remain as it was stated in TS.
13	TS	7.1.12.b.	Linear Probe min. 4.0 / 13.0 MHz bandwidth	Requested Version: 7.1.12.b. Linear Probe: Minimum frequency bandwidth of 5.0 / 14.0 MHz	This item will remain as it was stated in TS.

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				Justification: Our probe does not support the frequency range specified in the original clause. This situation applies to other device manufacturers as well. As the requested change does not introduce any clinical or functional limitations, we respectfully request this amendment to support a competitive procurement environment.	
14	TS	7.1.12.c.	Endocavitary Probe min. 4.0 / 9.0 MHz bandwidth and 190-degree Field of View	Requested Version: 7.1.12.c. Endocavitary Probe: Minimum frequency bandwidth of 4.0/9.0 MHz and 180-degree Field of View Justification: Our available probe does not support the field of view specified in the original clause. This situation applies to other device manufacturers as well. As the requested change does not introduce any clinical or functional limitations, we respectfully request this amendment to support a competitive procurement environment.	This item will remain as it was stated in TS.
15	TS	7.1.22.	The system must have an integrated minimum 250GB Hard Disk and an integrated CD or DVD Writer for archiving purposes. The system must be able to record frozen images in JPEG or TIFF format and clips/cine images in MPEG or AVI format. It must be possible to open all recordings of frozen images and clips on any computer (Windows environment) without additional software. Measurements must be available in all these recordings.	Requested Version: 7.1.22. The system must have an integrated minimum 250GB Hard Disk and an integrated CD or DVD Writer for archiving purposes. The system must be able to record frozen images in JPEG or TIFF or similar formats. format and clips/cine images in MPEG or AVI or similar format. It must be possible to open all recordings of frozen images and clips on any computer (Windows environment) without additional software. Measurements must be available in all these recordings. Justification: The cine loop feature of the proposed system operates using the WMV9 format, which does not restrict image accessibility in any way. To avoid any confusion after the procurement process, we kindly request that the inclusion of alternative formats and USB port options be accepted and that our system's commercial name be noted in the technical specification. As the requested change does not introduce any clinical or functional limitations, we respectfully request this amendment to support a competitive procurement environment.	This item will remain as it was stated in TS.

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16	TS	7.2.2.	Before signing the contract, the contractor must submit a price list in the tender dossier, of all spare parts, accessories, auxiliary equipment, peripheral equipment and consumable parts, without exception, including life- limited parts, not to exceed 120% of the device unit price. All the parts, which are not specified in the price schedule whether inadvertently or on purpose and subsequently required for the operation of the device, shall be covered by the contractor free of charge. However, if the manufacturer declares that the product/device in question can only be repaired in a factory environment or replaced through repair, the participant must provide the replacement repair cost not exceeding 120% of the device unit price. If the manufacturer stops producing the spare parts, the relevant products/devices shall be replaced with the same model or a higher model, priced as replacement within the scope of repair, and workmanship, assembly, transportation etc. shall be covered by the contractor free of charge. Along with the identification code of the products, both English and Turkish names must be included in the price list.	Requested Version: 7.2.2. Before signing the contract, the contractor must submit a price list in the tender dossier, of all spare parts, accessories, auxiliary equipment, peripheral equipment and consumable parts, without exception, including life-limited parts, not to exceed 150% of the device unit price. All the parts, which are not specified in the price schedule whether inadvertently or on purpose and subsequently required for the operation of the device, shall be covered by the contractor free of charge. However, if the manufacturer declares that the product/device in question can only be repaired in a factory environment or replaced through repair, the participant must provide the replacement repair cost not exceeding 150% of the device unit price. If the manufacturer stops producing the spare parts, the relevant products/devices shall be replaced with the same model or a higher model, priced as replacement within the scope of repair, and workmanship, assembly, transportation etc. shall be covered by the contractor free of charge. Along with the identification code of the products, both English and Turkish names must be included in the price list.	This item will remain as it was stated in TS.
17	TS	7.2.19.b.	In case of a request for a maintenance and repair contract including all spare parts required for the operation of the device and the equipment (probe, etc.) delivered with the device, this ratio shall be maximum 5% of the device unit price. The contractor shall comply with this request unconditionally upon receiving the maintenance and repair request.	Requested Version: 7.2.19.b. In case of a request for a maintenance and repair contract including all spare parts required for the operation of the device and the equipment (probe, etc.) delivered with the device, this ratio shall be maximum 8% of the device unit price. The contractor shall comply with this request unconditionally upon receiving the maintenance and repair request. Justification: We respectfully request the proposed revision to be made.	This item will remain as it was stated in TS.
18	TD	Lot 9		Financed by the European Union (EU) and implemented by the Turkish Ministry of Health, the "Support for Migrant Health Services in Türkiye (SIHHAT III) Project" will conduct an international open tender procedure for the procurement of "Electrical and Medical Equipment, Furniture, and	All documents in the tender dossier will remain as it was stated in TS.

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				Consumables" in accordance with EU procurement regulations (PRAG). However, we would like to submit a bid for the cleaning materials and equipment listed under LOT9 in the relevant tender. Our review indicates that the procurement will be conducted together with medical materials, which prevents companies specializing in cleaning materials from participating in the tender. As a company, we would like to participate in the tender; however, we request that cleaning materials be categorized separately as "cleaning" and "medical." This adjustment will reduce costs for the tender, increase the number of participants, and enhance competition to its highest level. Furthermore, making necessary corrections to the technical specifications will encourage more manufacturers and distributors to participate in your tender. We respectfully request the categorization of the relevant materials into groups.	
19	TS	Lot 9/ 9.27.1	Disinfectant must contain minimum 88% ethyl alcohol by volume (v/v) in 100 g of ready-to-use solution.	The statement "Disinfectant must contain minimum 88% ethyl alcohol by volume $(v/v)$ in 100 g of ready- to-use solution." should be amended to "Disinfectant must contain minimum 70% ethyl alcohol by volume $(v/v)$ in 100 g of ready-to-use solution."	Please see Changes No.2 to the Tender Dossier.
20	TS	9.28.17.	The manufacturer must have a GMP (Good Manufacturing Practices) certificate approved by the TSI (TSI EN ISO 22716) and submit this certificate in the tender dossier.	Correction request: The manufacturer must be approved by TSE or possess a (Good Manufacturing Practices) certificate issued by the Turkish Medicines and Medical Devices Agency (TS EN ISO 22716) and must submit this document in the tender dossier.	Please see Changes to the Tender Dossier.
21	TS	9.37.1.	The product must be made of 100% bleached chemical cellulose. There must be an analysis report from an accredited laboratory and it must be submitted in the tender dossier.	Correction request: The TSE 12385 Class-1, Category-3, Type-1, Species-1, Form-1 certificate indicates at least 90%. Therefore, the term "100%" must be corrected to "at least 90%".	This item will remain as it was stated in TS.

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22	TS	9.37.2.	The manufacturer must have a letter of undertaking stating that the product is made of 100% cellulose and submit this document in the tender dossier.	Correction request: The TSE 12385 certificate indicates at least 90%. Therefore, the term "100%" must be corrected to "at least 90%".	This item will remain as it was stated in TS.
23	TS	9.37.3.	The manufacturer must have an FSC certificate and submit this certificate in the tender dossier. As proof that the product has FSC, the FSC logo must be on the packaging according to the specified standards and the submitted document must be verifiable from the original FSC website.	Correction request: The FSC application applies to cellulose manufacturers, and only one company in Türkiye (Hayat Kimya A.Ş.) possesses this certificate. Since requiring this document restricts competition, it must be removed. Other technical specifications regarding thickness, density, dimensions, color, packaging, and certification remain unchanged.	This item will remain as it was stated in TS.
24	TS	9.39.1.	The product must be made of 100% bleached chemical cellulose. There must be an analysis report from an accredited laboratory and it must be submitted in the tender dossier.	Correction request: The term "100%" must be corrected to "at least 90%".	This item will remain as it was stated in TS.
25	TS	9.39.2.	The manufacturer must have a letter of undertaking stating that the product is made of 100% cellulose and submit this document in the tender dossier.	Correction request: The term "100%" must be corrected to "at least 90%".	This item will remain as it was stated in TS.
26	TS	9.39.3.	The manufacturer must have an FSC certificate and submit this certificate in the tender dossier.	Correction request: The FSC application applies to cellulose manufacturers, and only one company in Türkiye (Hayat Kimya A.Ş.) possesses this certificate. Since requiring this document restricts competition, it must be removed. Other technical specifications regarding thickness, density, dimensions, color, packaging, and certification remain unchanged.	This item will remain as it was stated in TS.
27	TS	9.39.9.	The double ply paper density must be minimum 40 $g/m^2$ .	Correction request: The double-layer paper density must be adjusted from "at least 40 g/m <sup>2</sup> " to "at least $34 \text{ g/m}^{2}$ ".	This item will remain as it was stated in TS.
28	TS	9.40.4.	The waste bag must have the medical waste logo and a warning description on a red background.	Correction request: The bag must include a medical waste logo and warning label.	This item will remain as it was stated in TS.
29	TS	9.40.6.		New item request: The product must have a TS 13819 certificate and bidders must provide it in the tender dossier.	This item will not be added to TS. The items will remain as it.

#	DOC.	LOT/ITEM	CLAUSE	QUESTION / REQUEST	ANSWER
30	TS	9.48.3.	The manufacturer must have a Good Manufacturing Practices (GMP) Certificate issued by the Turkish Medicines and Medical Devices Agency and must submit it in the tender dossier.		Please see Changes to the Tender Dossier.
31	TS	9.48.12.	The product must have a biocidal certificate and it must be submitted in the tender dossier.	Correction request: The product must possess a biocidal certificate or a TSE 5682 certificate.	This item will remain as it was stated in TS.