CLARIFICATIONS No: 1 to TENDER DOSSIER

Contract Title **:** Supply of Medical Equipment, Devices and Consumables

Publication Reference **:** SIHHAT/2019/SUP/INT/15

CN: Contract Notice
TD: Tender Dossier
DOC: Document
ART: Article
ITT: c4b_itt_en [Instructions to Tenderers]*
DC: Draft Contract
TS: c4f_annexiitechspeciiitechoffer_en [Annex II + III: Technical Specifications + Technical Offer]*
GC: General Conditions
SC: c4d_specialconditions_en [Special Conditions]*
PG: c4h_perfguarantee_en [Performance Guarantee]
TG: c4n_tenderguarantee_en [Tender Guarantee]
App B: Appendix B to Annex II - Training Proposal [Appendix B to Annex II+III Training Proposal]*
Ann V: Annex V - Warranty Proposal [Annex V - Warranty Obligations Form]*
* *In-parenthesis parts show the title inside the documents.*

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

#	DOC	ART / ITEM	CLAUSE	QUESTION	ANSWER
1	CN	16.1	The average annual turnover of the tenderer in the last three years must be equal or exceed the 25% tenderer's financial offer.	In the case of bidding for all lots, the average turnover for the last three years must be exceed the total amount of the proposed lots or will be evaluated on one lot basis?	Tendering for more than one lot, the average annual turnover of the tenderer in the last three financial years must exceed the cumulative amount of the financial offers of all the lots for which the tenderer

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					submitted tenders.
2	CN	16.1	The average annual turnover of the tenderer in the last three years must be equal or exceed the 25% tenderer's financial offer.	Our company was established on 1 June 2016. Is it mandatory to submit 2016 year in full year as the financial data of the last three years is requested in the tender document? Or is the 2016 half year financial data sufficient?	Economic operators that have been operational for less than three years will have to demonstrate an operational cash flow, which must exceed their financial proposal for the years in which they have been operational.
3	CN	16.2	The tenderer shall provide written evidence of his, or manufacture's, if the tenderer is not the manufacturer, current and valid certificate for the Quality Management System.	In the Selection and Award Criteria as stated in Article 2- Our company is not manufacturer for the tender items and according to this situation only our company's quality document is enough or is it mandatory to give manufacturer's quality documents?	If the tenderer is not the manufacturer, current and valid certificate for the Quality Management System.
4	CN	16.3.a	For Lot 1, Lot 2 The tenderer has delivered supplies under at most three contracts with a budget of at least one-fourth (¼) of the financial offer of the lot being tendered in supply of medical consumable(s).	In the Selection and Award Criteria as stated in Article 3- Technical Capacity of tenderer section, Is it mandatory to provide only medical consumables supply references for LOT 1 and LOT 2.? The references with consumables supplied with the device acceptable or medical equipment references adequate?	Considering the volume and the nature of the tender and the risk assessment of the Contracting Authority, the existing requirement assessed to be sufficient.
5	ITT	1.1.	… in 4 lots to the points at the provinces of Turkey (please refer to the Appendix A - Delivery Points List), within 90 (ninety) calendar days for all lots as also stated in Special Conditions, DDP[1], in accordance with point 15 of the Contract Notice. Please	Since there are 9 items, totally 3605 pieces to be delivered to 179 healtcare premises and to 29 different locations (cities) in LOT 7-MEDICAL DEVICES in order to be on the safe side we request the delivery time to be extended to 120 days after the contract signature. The production, device verification, delivery,	Considering the volume and the nature of the tender and the risk assessment of the Contracting Authority, the existing requirement assessed to be sufficient.

[1] DDP (Delivered Duty Paid) — Incoterms 2010 International Chamber of Commerce http://www.iccwbo.org/products-and-services/trade-facilitation/incoterms-2010/the-incoterms-rules/.

<table>
<tr><th>#</th><th>DOC</th><th>ART / ITEM</th><th>CLAUSE</th><th>QUESTION</th><th>ANSWER</th></tr>
<tr><td></td><td></td><td></td><td>be aware that the Contracting Authority reserves the right to update the quantities per delivery point at any time based on the possible fluctuations on the number of migrants.</td><td>importation of the manufactured items and their provisional acceptance will certainly take so much time.</td><td></td></tr>
<tr><td>6</td><td>ITT</td><td>2.</td><td>
<table>
<tr><th></th><th>DATE</th><th>TIME*</th></tr>
<tr><td>Clarification meeting / site visit (if any)</td><td>Not applicable</td><td>Not applicable</td></tr>
<tr><td>Deadline for requesting clarifications from the contracting authority</td><td>21.05.2019</td><td>18:00</td></tr>
<tr><td>Last date on which clarifications are issued by the contracting authority</td><td>31.05.2019</td><td>-</td></tr>
<tr><td>Deadline for submission of tenders</td><td>11.06.2019</td><td>12:00</td></tr>
<tr><td>Tender opening session</td><td>11.06.2019</td><td>14:30</td></tr>
<tr><td>Notification of award to the successful tenderer</td><td>July 2019**</td><td>-</td></tr>
<tr><td>Signature of the contract</td><td>July 2019**</td><td>-</td></tr>
</table>
* All times are in the time zone of the country of the contracting authority provisional date
</td><td>Accoring to the time table when the clarifications are to be issued on May 31, 2019 there remains no sufficient time to make the necessary changes in technical specifications even there may not be enough time to change the device that has been already decided to be offered.

In the remaining time, that is, from the clarification date to the deadline for submission of tenders it will not be possible to prepare and to complete exactly the required documents for the tender dosier.

In this period of time there is also a holiday from June 4 to June 6. Therefore one and a half day remains for the tenderers to adapt the new technical specifications, even to find a new device which wil meet the new specifications or to register this new device for UTS, etc., if applicable.

So to maintain the competitiveness, to enable the tenderers to prepare well for the tender we kindly request you to shift the tender submisision date by at least 21 days for giving enough time to the tenderers for tender dosier preparation.</td><td>Considering the current official deadline of the project under which this tender is being funded (SIHHAT), there is no possibility to extend the period as requested.</td></tr>
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#	DOC	ART / ITEM	CLAUSE	QUESTION	ANSWER
			**** Provisional date**		
7	ITT	4.1.	Unless otherwise provided in the contract or below, all goods purchased under the contract must originate in a Member State of the European Union or in a country or territory of the regions covered and/or authorised by the specific instruments applicable to the programme specified in clause 3.1 above. For these purposes, 'origin' means the place where the goods are mined, grown, produced or manufactured and/or from which services are provided. The origin of the goods must be determined according to the relevant international agreements (notably WTO agreements), which are reflected in EU legislation on rules of origin for customs purposes: the Customs Code (Council Regulation (EEC) No 2913/92) in particular its Articles 22 to 246 thereof, and the Code's implementing provisions (Commission Regulation (EEC) No 2454/93. All supplies under this contract must originate in one or more of the above countries. Tenderers must provide an undertaking signed by their representative certifying compliance with this requirement. The tenderer is obliged to verify that the provided information is correct. Otherwise, the tenderer risks to be excluded because of	We kindly request you to change the content of the article as; "4.1. Unless otherwise provided in the contract or below, …….. All supplies EXCEPT -LOT 3 MEDICAL EQUIPMENT 3.7 PULSE OXIMETER -LOT 3 MEDICAL EQUIPMENT 3.3. MEASURING TAPE under this contract must originate in one or more of the above countries. Tenderers must provide an undertaking signed by their representative certifying compliance with this requirement. The tenderer is obliged to verify that the provided information is correct. Otherwise, the tenderer risks to be excluded because of negligently misrepresenting information. For more details, see Section 2.3.5. of the practical guide."	Considering the Market Research of the tender, there is no need to change the existing requirement.

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			negligently misrepresenting information. For more details, see Section 2.3.5. of the practical guide.”		
8	ITT & Annex V	11. & 6.	… o a proposal for after-sales service over 2 years for Lot 3 and Lot 4; … & … • All equipment must have at least 5 years of commercial warranty (for Lot 3 and Lot 4). …	There is a discrepancy about warranty; At the document c4b_itt_en, [A. INSTRUCTIONS TO TENDERERS], 11.Content of tenders, Part 1: Technical offer: a proposal for after-sales service over 2 years for Lot 3 and Lot 4. On the other hand, at the document Warranty Proposal, [ANNEX V: WARRANTY OBLIGATIONS FORM], 6th item, All equipment must have at least 5 years of commercial warranty (for Lot 3 and Lot 4). What should be the duration of commercial warranty, 2 or 5 years?	Annex V item 6 has been revised as: … • All equipment must have at least 2 years of commercial warranty (for Lot 3 and Lot 4). … Please also refer to Changes No: 1 to TD.
9	TS	1.6.4	The mask should be in pediatric sizes, transparent and disposable; it should fit on the face and should not stink. The mask should cover the mouth and nose.	We think it’s a translation-related error The mask should be in adult sizes, transparent and disposable; it should fit on the face and should not stink. The mask should cover the mouth and nose.	The item has been revised as: The mask should be in adult sizes, transparent and disposable; it should fit on the face and should not stink. The mask should cover the mouth and nose. Please also refer to Changes No: 1 to TD.
10	TS	1.9	ECG CABLE END GRABBER ADAPTER ECG Devices Brand/Model	ECG Cable and Grabber Adapter for which brand, model device is required to be used and the type of device is not specified. Can you give details about this?	The item remains unchanged considering the needs of the Contracting Authority.
11	TS	1.23.6	1 roll should be 15 meters at least.	In order to strengthen the competition, we kindly request the Contracting Authority to change mentioned specification as follows; 1 roll should be 15 meters **(±2 m) at least.**	The item has been revised as: 1 roll should be 15 meters (±2 m) at least. Please also refer to Changes No: 1 to TD.

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12	TS	1.23.7	The roll weight should be 400 grams at least.	In order to strengthen the competition, we kindly request the Contracting Authority to change mentioned specification as follows; The roll weight should be 400 grams **(±5 gr)** at least.	The item has been revised as: The roll weight should be 400 grams (±5 gr) at least. Please also refer to Changes No: 1 to TD.
13	TS	1.23.6 & 1.23.7	1 roll should be 15 meters at least. & The roll weight should be 400 grams at least.	Article 1.23.6 "1 roll should be 15 meters at least." and Article 1.23.7 "The roll weight should be 400 grams at least." We were unable to determine which feature to offer. Because of the inconsistency between the two article. Is roll meter or roll weight important? At least 400 gram request equals much more than 15 meters and this increases the costs. We kindly request removal of 1.23.7 article from the technical statement.	Please see the answer to clarification number 11 and 12 above.
14	TS	1.23.8	The width of a leaf should be 10 cm.	In order to strengthen the competition, we kindly request the Contracting Authority to change mentioned specification as follows; The width of a leaf should be 10 cm **(±2 cm)**	The item has been revised as: The width of a leaf should be 10 cm (±2 cm). Please also refer to Changes No: 1 to TD.
15	TS	1.23.9	Breaking strength should be N/m 30 at least.	In order to strengthen the competition, we kindly request the Contracting Authority to change mentioned specification as follows; Breaking strength should be N/m 30 **(±2 n/m)** at least	The item has been revised as: Breaking strength should be N/m 30 (±2 N/m) at least. Please also refer to Changes No: 1 to TD.
16	TS	1.23.10	Extension rate % should be 10-35 cm at least.	In order to strengthen the competition, we kindly request the Contracting Authority to change mentioned specification as follows;	The item has been revised as: Extension rate % should be 10-35 cm (±2 cm) at least.

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				Extension rate % should be 10-35 cm **(±2 cm)** at least.	Please also refer to Changes No: 1 to TD.
17	TS	1.25.5	The fiber dimensions should be 21.5x24 cm.	In order to strengthen the competition, we kindly request the Contracting Authority to change mentioned specification as follows; The fiber dimensions should be 21.5x24 cm **(±2cm)**	The item has been revised as: The fiber dimensions should be 21.5 x 24 cm (±2 cm). Please also refer to Changes No: 1 to TD.
18	TS	1.25.5	The fiber dimensions should be 21.5x24 cm.	We kindly request the following modification in the article: The fiber dimensions should be 21.5x24 cm ± 0,5 cm	Please see the answer to clarification number 17 above.
19	TS	1.25.6	The pack should include 12 packages and package weight should be 400 grams at least.	In order to strengthen the competition, we kindly request the Contracting Authority to change mentioned specification as follows; The pack should include 12 packages and package weight should be 400 grams **(±40 gr)** at least.	The item has been revised as: The pack should include 12 packages and package weight should be 400 grams (±40 gr) at least. Please also refer to Changes No: 1 to TD.
20	TS	2.4.4	No should be 3/0 25±3 mm 3/8, sharp, 45 cm.	In order to strengthen the competition, we kindly request the Contracting Authority to change mentioned specification as follows; No Shoud be 3/0 25±3 mm 3/8, sharp, **at least** 45 cm**.**	The item has been revised as: No Should be 3/0 25±3 mm 3/8, sharp, at least 45 cm. Please also refer to Changes No: 1 to TD.
21	TS	2.8.4	No should be 5/0 16±3 mm 3/8, sharp, 75 cm.	In order to strengthen the competition, we kindly request the Contracting Authority to change mentioned specification as follows; No should be 5/0 **16±5** mm 3/8, sharp, 75 cm.	The item has been revised as: No should be 5/0 16±5 mm 3/8, sharp, 75 cm. Please also refer to Changes No: 1 to TD.
22	TS	2.9.4	No should be 6/0 13±3 mm 3/8, sharp, 75	In order to strengthen the competition, we kindly	The item has been revised as:

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			cm.	request the Contracting Authority to change mentioned specification as follows; No should be 6/0 **13±5** mm 3/8, sharp, **at least 45 cm**	No should be 6/0 13±5 mm 3/8, sharp, at least 45 cm. Please also refer to Changes No: 1 to TD.
23	TS	2.E	Common features of products 2.21, 2.22 and 2.23.	3 pieces injector (without gasket) is not available in any manufacturer. It is not current production. The 3-piece injector has a gasket structure. If the injector is 2-part, it can be produced without gasket. For this reason, we kindly request that all these article be reviewed and the 3-pieces or non-gasket statement shall be removed from the technical statement.	Considering the Market Research of the tender, there is no need to change the existing requirement.
24	TS	2.20.7	It should be sterilized by gamma beams and sterilization method should be specified on the packages.	In order to strengthen the competition, we kindly request the Contracting Authority to change mentioned specification as follows; It should be sterilized by gamma beams **or ethylene oxide** and sterilization method should be specified on the packages.	The item has been revised as: It should be sterilized by gamma beams or ethylene oxide and sterilization method should be specified on the packages. Please also refer to Changes No: 1 to TD.
25	TS	2.24	HYPOALLERGENIC PLASTER	The dimensions should be 10 cm x 10 m. We request the addition of the substance.	The item 2.24.8 has been revised as: Adhesive should be polymeric acrylate. Back side should be made of non-woven polyester fabric. The dimensions should be 10 cm x 10 m. Please also refer to Changes No: 1 to TD.
26	TS	2.F.8	The manufacturer company should have ISO 9001 or ISO 9002 and EN 46001 quality certificates.	In order to strengthen the competition, we kindly request the Contracting Authority to change mentioned specification as follows;	The item has been revised as: The manufacturer company should have ISO 9001 or ISO 9002 or EN 46001

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				The manufacturer company should have ISO 9001 or ISO 9002 **or** EN 46001 quality certificates.	quality certificates. Please also refer to Changes No: 1 to TD.
27	TS	2.27.10	Dimensions should be 7 x9 cm.	In order to strengthen the competition, we kindly request the Contracting Authority to change mentioned specification as follows; Dimensions should be 7 x9 cm **(±1 cm)**	The item has been revised as: Dimensions should be 7 x 9 cm (±1 cm). Please also refer to Changes No: 1 to TD.
28	TS	2.40.12	The manufacturing company should have CE certificate, ISO 13485:2003 Quality Management System certificates.	In order to strengthen the competition, we kindly request the Contracting Authority to change mentioned specification as follows; The manufacturing company should have CE certificate, ISO 13485:2003 Quality Management System certificates or ISO 13485:2016 Quality Management System certificates	The item has been revised as: The manufacturing company should have CE certificate, ISO 13485:2003 Quality Management System certificates or ISO 13485:2016 Quality Management System certificates. Please also refer to Changes No: 1 to TD.
29	TS	2.41	IV INFUSION FILTER SET 2.41.4 IV infusion filter set should have 1 bacteria trapping filter and this filter should be 0.2 micron. 2.41.5 The filter set should have a hydrophobic air discharge membrane. 2.41.6 Inner diameter of the filter set tube should be 3 to 4.1 mm. 2.41.7 A latex-free injection port aqnd luer lock connector should exist on the set for additional dose administrations. 2.41.8 The manufacturer company should have ISO 9001 or ISO 9002 and EN 46001	We think that the technical specification of I.V Infusion Filter Set in the 2.41nd Item of the tender was written by mistake. The istems specified in the technical specification mostly describe the materials used for chemotherapy patients. The products to be purchased are npt suitable for use in immigrant health centers. Also, the cost of products is quite expensive compared to the serum sets purchased by your instution las year. We therefore request that the specification be changed to the serum set. Manufactured from medical grade PVC. Shall be packed single and sterile. Shall have a air inlet puncture hole.	The items has been revised as: 2.41.4 Manufactured from medical grade PVC. 2.41.5 Shall be packed single and sterile. 2.41.6 Shall have a air inlet puncture hole. 2.41.7 The drop adjuster shall be large enough to be easily gripped by finger and to facilitate movement of the roller in the desired direction. 2.41.8 Shall have an injection port. 2.41.9 Tube length shall be at least 1,5 m and shall not king

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			quality certificates.	The drop adjuster shall be large enough to be easily gripped by finger and to facilitate movement of the roller in the desired direction. Shall have an injection port. Tube length shall be at least 1,5 m and shall not king Shall have 20 drops = 1 ml The tank shall be soft and easily filled and must be at least 12 ± 2 cc in volume The tank shall have a fixed 15 micron liquid filter at its base The tank shall have a fixed 15 micron liquid filter at its base Shall be designed to be opened without contaminating its sterileness.	2.41.10 Shall have 20 drops = 1 ml 2.41.11 The tank shall be soft and easily filled and must be at least 12 ± 2 cc in volume 2.41.12 The tank shall have a fixed 15 micron liquid filter at its base 2.41.13 The tank shall have a fixed 15 micron liquid filter at its base Please also refer to Changes No: 1 to TD.
30	TS	2.45.6	It should be provided in 5-liter cans and the cans should have a gasket and a locked cap to prevent leak.	We think it's a translation-related error. Because products such as ethyl alcohol will erode the tin can not be kept in cans. We request clarification from you about the article.	The item has been revised as: It should be provided in 5-liter plastic barrels and the barrels should have a gasket and a locked cap to prevent leak. Please also refer to Changes No: 1 to TD.
31	TS	2.47.4	100 g disinfecting solution should contain 42 g Ethyl Alcohol and 0.05 g didecylmethylamoniumchloride.	Request: It is a unique formulation of a company. To achieve the most profitable cost and obtain fair competition in tender, we recommend to change the specificaions as:" 100 g disinfecting solution should contain minimum 48 g alcohol content (Ethyl Alcohol or isopropyl alcohol) and minimum 0.05 g Didecyldimethylamoniumchlo ride"	The item has been revised as: 100 g disinfecting solution should contain minimum 42 g Ethyl Alcohol and minimum 0.05 g didecylmethylamoniumchloride. Please also refer to Changes No: 1 to TD.

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32	TS	2.47.4	100 g disinfecting solutionshould contain 42 g Ethyl Alcohol and 0.05 g didecylmethylamoniumchloride.	We kindly request the following modification in the article: "100 g disinfecting solution should contain minimum 50 gr ethanol, 10 gr-2 propanol and 0,05 gr didecylmethylamoniumchloride."	Please see the answer to clarification number 31 above.
33	TS	2.47.8	Disinfectant should be bactericid (including Tbc, MRSA), fungucid, yeasticid and virus inactivator (HBV/HIV/HCV/BVDV/FCV/ Vaccinia, Adeno, Rota, Noro-norwalk, Influenza viruses.	Request: "Rota" is not a standart test virus. According to EN14476 standart a product is stated as "virucidal", inactivitaing all viruses if all EN14476 test on Adeno, Polio and Noro virus is succesfull. To achieve the most profittable cost and obtain fair competition with CEN standarts in tender, we recommend to change the specificaions as below: "Disinfectant should be bactericid (including Tbc, MRSA, VRE), fungucid, yeasticid and virus inactivator (HBV/HIV/HCV/BVDV/FCV/Vaccinia, Adeno, Polio, Noro, Influenza viruses)	The item remains unchanged considering the needs of the Contracting Authority.
34	TS	2.47.9	CONTACT PRIOD: In accordnace with DGHM/VAH/EN 13727/EN 13624/EN 1276/EN 1650/EN 13697, EN 16615; Surface Disinfection; bactericid, yeasticid 2 min. DGHM/VAH, 5 min. Tuberculocid (M. Terrae) (clean conditions as per EN 14348) 1 min. Virucid (Vaccinia, Influenza, BVDV, HBV, HIV,HCV dahil) 30 sec.	It is stated that "Disinfectant should be bactericid (including Tbc, MRSA), fungucid, yeasticid and virus inactivator (HBV/HIV /HCV/BVDV/FCV/ Vaccinia, Adeno, Rota, Noronorwalk, Influenza viruses). Request: According to EN 14476 standart a product is stated as" virucidal", inactivitaing all viruses if all EN14476 test on Adeno, Polio and Noro virus is succesfull. Hence HBV/HIV/HCV /BVDV/FCV/ Vaccinia, Rota tests are not necessary as scientific data. To achieve the most profittable cost and obtain fair competition in tender, we recommend to change the specificaions as below: Disinfectant should be	The item has been revised as: CONTACT PRIOD: In accordance with EN 13727/EN 13624/EN 1276/EN 1650/EN 13697, EN 16615; Surface Disinfection; bactericid, yeasticid 2 min. DGHM/VAH, 5 min. Tuberculocid (M. Terrae) (clean conditions as per EN 14348) 1 min. Virucid (Vaccinia, Influenza) 30 sec. Rota 1 min. Noro virus (MNV) (as per EN 14476) 5

#	DOC	ART / ITEM	CLAUSE	QUESTION	ANSWER
			Rota 1 min. Noro virus (MNV) (as per EN 14476) 5 min.	bactericid (including Tbc), fungucidal, yeasticidal and virus inactivator (Polio, Adeno, Noro viruses)	min. Please also refer to Changes No: 1 to TD.
35	TS	2.47.9	CONTACT PRIOD: In accordnace with DGHM/VAH/EN 13727/EN 13624/EN 1276/EN 1650/EN 13697, EN 16615; Surface Disinfection; bactericid, yeasticid 2 min. DGHM/VAH, 5 min. Tuberculocid (M. Terrae) (clean conditions as per EN 14348) 1 min. Virucid (Vaccinia, Influenza, BVDV, HBV, HIV,HCV dahil) 30 sec. Rota 1 min. Noro virus (MNV) (as per EN 14476) 5 min.	CONTACT PRIOD: In accordnace with DGHM/VAH/EN 13727 / EN 13624 / EN 1276 / EN 1650 / EN 13697, EN 16615; Surface Disinfection; bactericid, yeasticid 2 min Request: DGHM/VAH, 5 min. DGHM/VAH is for German products only, futhermore to these part is written with technical mistakes and old unvalid standarts. To achieve the most profittable cost and obtain fair competition with CEN standarts in tender, we recommend to change the specificaions as below: CONTACT PERIOD: 5 minutes The product should have scientific test reports as proof of microbiological activity: EN 13727 / EN 13624 / EN 14561 / EN 14562 / EN 14348 and EN 14476 (Adeno, Polio, Noro viruses)	Please see the answer to clarification number 34 above.
36	TS	2.47.10	It should be dermatologically tested.	Request: The described product use area is not skin, so this item should be excluded	The specification has been removed from the Technical Specifications.
37	TS	2.47.13	Disinfectant should be included in DGHM/VAH list.	Request: DGHM/VAH list is for disinfectants only for Germany, this item is should be excluded because the tender is not in Germany.	The item remains unchanged considering the needs of the Contracting Authority.
38	TS	2.48.4	100 g ready for use disinfectant should contain; 64.4 g ethanol, 1,3-Butandiol, glycerin, perfume and pure water.	Request: It is a unique formulation of a company. To achieve the most profittable cost and obtain fair competition in tender, we recommend to change the specificaions as below: “100 g ready for use disinfectant should	The item has been revised as: 100 g ready for use disinfectant should contain; minimum 63 g ethanol, maximum 1,3-Butandiol, glycerin,

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				contain; min 63 g ethanol, 1,3- Butandiol, lanoline, glycerin and pure water.	perfume and pure water. Please also refer to Changes No: 1 to TD.
39	TS	2.48.4	100 g ready for use disinfectant should contain; 64.4 g ethanol, 1,3-Butandiol, glycerin, perfume and pure water.	We kindly request the following modification in the article: "100 g ready for use disinfectant should contain; 65.9 g 2 ethanol (%70 v/v) , 0,12 % butlydiglycol and 0,5 % lanolin"	Please see the answer to clarification number 38 above.
40	TS	2.48.12	Hygenic hand disinfectation (as per EN 1500) 3 ml- 30 sec. Surgical hand disinfectation (as per EN 12791), 3x3 ml- 1.5 min.	Request: EN 12791 standart "Surgical Hand Disinfection" application method is 3 minutes for ethanol based hand disinfectants. So some part of the technical specification should be changed as "Surgical hand disinfectation (as per EN 12791), 3 ml-3 min". To achieve the most profittable cost and obtain fair competition in tender, we recommend to change the specificaions as below: Hygenic hand disinfection (as per EN 1500) 3 ml- 30 sec. And Surgical hand disinfection (as per EN 12791), 3 ml- 3 min.	The item has been revised as: Hygenic hand disinfectation (as per EN 1500) 3 ml - 30 sec. Surgical hand disinfectation (as per EN 12791) 3 ml - 3 min. Please also refer to Changes No: 1 to TD.
41	TS	2.49.5	The product should include quarterner ammonium compounds (Alkyldimethylbenzyl ammonium chloride, Alkyldimethylbenzyl ammonium chloride, alkyl didesil dimethyl ammmonium chloride, dialkyl dimetil ammonium chloride etc.), non-ionic surfactant and anti-corosive agents.	We kindly request the following modification in the article: The product should include quarterner ammonium compounds minimum 9,9 gr didecylmethylamoniumchloride.''	The item has been revised as: The product should include quarterner ammonium compounds (Alkyldimethylbenzyl ammonium chloride, alkyl didesil dimethyl ammmonium chloride, dialkyl dimetil ammonium chloride etc.), non-ionic surfactant and anti-corosive agents. Please also refer to Changes No: 1 to TD.
42	TS	2.49.8	When diluted by 0.3% (1/300); bactericide, fungucide, virucide and tuberculocide effect	We kindly request the following modification in the article: "When diluted concentration product	The item remains unchanged considering the needs of the Contracting Authority.

#	DOC	ART / ITEM	CLAUSE	QUESTION	ANSWER
			should be achieved in 5 minutes.	has bactericide, fungucide, virucide effect (Adeno, Polio, MNV) in 15 minutes 0.25%"	
43	TS	2.49.8	When diluted by 0.3% (1/300); bactericide, fungucide, virucide and tuberculocide effect should be achieved in 5 minutes.	Request: To achieve the most profittable cost and obtain fair competition in tender, we recommend to change the specificaions as below: When diluted by 0.5% (1/200); bactericide, fungucide, virucide and tuberculocide effect should be achieved in 5- minutes	The item remains unchanged considering the needs of the Contracting Authority.
44	TS	2.49.9	In accordance with Biocidal Product regulation dated on 22.6.2015; the product should be effective against the following; • Bactericide as per EN 13727 standard (Pseudomanas aeruginosa, Staphylococcus aureus, Enterococcus hirae), • Mycobactericide as per EN 14348 standard (M. terrae, M. avium) • Fungucide as per EN13624 standard (Candida albicans ATCC 10231, Aspergillus brasiliensis, Aspergillus niger ATCC 16404) • Virucide as per EN14476 standard (Human Adenovirus Type 5 Strain ,Poliovirus Type 1- LSc-2ab, • Adenoid 75, HBV, HCV, HIV, Polio, Papova, Adeno, Vaccina Parvovirüs). • Reports obtained from accredited organizations referred by Ministry of Health as a prrof of such effect.	Request: These tests Show a unique product. If a products has Biocidal lycience of MOH, there is no need to specify the tests, MOH has standarts on biocidal products. To achieve the most profittable cost and obtain fair competition in tender, we recommend to change the specificaions as below: In accordance with Biocidal Product regulation dated on 22.6.2015; the product should have the Biocidal Lycience of MOH in Turkey.	The item has been revised as: In accordance with Biocidal Product regulation dated on 22.6.2015, the product should have the Biocidal Licence of MOH in Turkey. Please also refer to Changes No: 1 to TD.

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45	TS	2.49.9	In accordance with Biocidal Product regulation dated on 22.6.2015; the product should be effective against the following; • Bactericide as per EN 13727 standard (Pseudomanas aeruginosa, Staphylococcus aureus, Enterococcus hirae), • Mycobactericide as per EN 14348 standard (M. terrae, M. avium) • Fungucide as per EN13624 standard (Candida albicans ATCC 10231, Aspergillus brasiliensis, Aspergillus niger ATCC 16404) • Virucide as per EN14476 standard (Human Adenovirus Type 5 Strain ,Poliovirus Type 1- LSc-2ab, • Adenoid 75, HBV, HCV, HIV, Polio, Papova, Adeno, Vaccina Parvovirüs). • Reports obtained from accredited organizations referred by Ministry of Health as a prrof of such effect.	We kindly request the following modification in the article: In accordance with Biocidal Product regulation dated on 22.6.2015; the product should be effective against the following; • Bactericide as per EN 13727 standard (Pseudomanas aeruginosa, Staphylococcus aureus, Enterococcus hirae),) • Fungucide as per EN13624 standard (Candida albicans ATCC 10231, Aspergillus brasiliensis, Aspergillus niger ATCC 16404) • Virucide as per EN14476 standard (Human Adenovirus Type 5 Strain ,Poliovirus Type 1-LSc-2ab, • Adenoid 75, HBV, HCV, HIV, Polio, Papova, Adeno, Vaccina Parvovirüs). • Reports obtained from accredited organizations referred by Ministry of Health as a prrof of such effect.	Please see the answer to clarification number 44 above.
46	TS	2.49.10	The product should be licensed by Turkish Public Health Organization of TR Ministry of Health and included in Biocidal Inventory List. The manufacturer company should have TSE and ISO quality certificates.	Request: There is no TSE certificate for disinfectants. This should be changed with CE/ISO 13485 certificate. To achieve the most profittable cost and obtain fair competition in tender, we recommend to change the specificaions as below : The manufacturer company should have CE, ISO9001, ISO 13485, GMP, ISO 14001 quality certificates	The item has been revised as: The product should be licensed by Republic of Turkey Ministry of Health, Directorate General of Public Health and included in Biocidal Inventory List. Please also refer to Changes No: 1 to TD.
47	TS	2.50.5	The bleacher should be clear and viscous.	In order to strengthen the competition, we kindly request the Contracting Authority to change mentioned specification as follows;	The item has been revised as: The bleacher should be clear. Please also refer to Changes No: 1 to TD.

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				The bleacher should be clear.	
48	TS	2.51.10	It should be clear, liquid and nacrous white.	In order to strengthen the competition, we kindly request the Contracting Authority to change mentioned specification as follows; **It should be liquid and consistent**	The item has been revised as: It should be viscous and liquid. Please also refer to Changes No: 1 to TD.
49	TS	3.1	GLUCOMETER	According to our research in the market, following branded products, which are the best well-known brands, are made in outside of eligible countries. We kindly present the necessary links to prove that, and kindly ask the commission to give "derogation" for this specific item or remove the item from the context of the tender;	Considering the Market Research of the tender, there is no need to change the existing requirement.
50	TS	3.1.5	The measuring range shall be 20-500 mg/dl.	We kindly request the following modification in the article: "3.1.5. The measuring range shall be at least in the range 20-500 mg/dl or 10-600 mg/dl."	The measuring range shall be 20-500 mg/dl. The requirement in these specification is presented as a minimum value which the offered goods must meet. Your offer value "10-600 mg/dl" covers "20-500 mg/dl" and there is no need to change the existing requirement.
51	TS	3.1.6	The device to be given with the strips shall be able to measure sugar in at most 20 seconds.	Measuring up to 20 seconds can cause blood clotting, for this reason, the item should be changed to "The device to be given with the strips shall be able to measure sugar in at most 10 seconds."	The item remains unchanged considering the needs of the Contracting Authority.
52	TS	3.1.7	The device to be given with the strips shall be able to produce results at 10 to 40 degrees.	The item should be changed to "The device to be given with the strips shall be able to produce results at 10 to 40 or 4 to 32 degrees."	The item has been revised as: The device to be given with the strips shall be able to produce results at least

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					between 10 to 32 degrees. Please also refer to Changes No: 1 to TD.
53	TS	3.1.7	The device to be given with the strips shall be able to produce results at 10 to 40 degrees.	We kindly request the following changes to be made in the article: "3.1.7 The device to be given with the strips shall be able to produce results at least in the range 10 to 40 degrees or 8-42 degrees centigrade."	Please see the answer to clarification number 52 above.
54	TS	3.1.8	At least 20 devices shall be given with the strips.	Claim: Due to the tender documentation, it is already for 800 pieces of Glucometer Devices (not to buy strips). Therefore, we kindly require you to make amendment of the mentioned article 3.1.8.as follows. Request: At least, 20 box (50 strips/box) of strips shall be given with the each devices.	The item has been revised as: At least 1000 strips shall be given with each device. Please also refer to Changes No: 1 to TD.
55	TS	3.1.8	At least 20 devices shall be given with the strips.	Due to misspelling, the item should be changed to "1000 strips shall be given with each device."	Please see the answer to clarification number 54 above.
56	TS	3.1.8	At least 20 devices shall be given with the strips.	It is not clear the number of strips to be given for each devices. We understand that we shall supply glucometer strips for at least 20 devices. Please clarify the number of strips to be given for each glucometer devices.	Please see the answer to clarification number 54 above.
57	TS	3.1.8	At least 20 devices shall be given with the strips.	We understand that we shall supply glucometer strips for at least 20 devices. But it is not clear the number of strips to be given for each of 20 devices. Therefore, 520 out of 540 devices do	Please see the answer to clarification number 54 above.

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				not have any strips and cannot be used immediately by the users. Would you specify the number of strips to be given for each of at least 20 devices? On the other hand, a more specific and reasonable article may be written as follows: "At least 10 strips shall be supplied for each glucometer" This type of articles are generally written when strip supply is the main subject of the tender. But notably herein the main subject is the glucometer supply itself.	
58	TS	3.1.11	The company shall do a demo and receive approval before the tender.	Claim: The Glucometer devices we will offer meets the System Accuracy according to EN ISO:15197:2013 Request: We kindly require you to remove this article 3.1.11 from Glucometer Technical Condition.	The specification has been removed from the Technical Specifications. Please also refer to Changes No: 1 to TD.
59	TS	3.1.11	The company shall do a demo and receive approval before the tender.	We kindly request the following changes to be made in the article: "3.1.11 The company shall do a demo and receive approval after it is awarded the contract." Furthermore, during provisional acceptance all devices shall be tested functionally before the approval given to them. Otherwise, if demo is deemed to be compulsory and necessary then; a. The healthcare premise name & address, b. Demo date,	Please see the answer to clarification number 58 above.

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				c. The related laboratory and d. The personnel in charge of assessment, e. The number of devices to be delivered, should be determined and published well before the tender submission date.	
60	TS	3.1.13	The measurement strip shall be able to measure at the 20-70% hematocrit range.	The item should be changed to "The measurement strip shall be able to measure at least 20-60% hematocrit range and this specification shall be seen obviously in the prospectus and catalog."	The item has been revised as: The measurement strip shall be able to measure at the 20-60% hematocrit range. Please also refer to Changes No: 1 to TD.
61	TS	3.1.13	The measurement strip shall be able to measure at the 20-70% hematocrit range.	There two modes of operation at our device. Thus we would like you to add this feature to the article to avoid misinterpretation during usage; 3.1.13 The measurement strip shall be able to measure at the 20-70% hematocrit range or 20-70% hematocrit range in outside meter-mode or at least 30-55 %.	Please see the answer to clarification number 60 above.
62	TS	3.1.13	The measurement strip shall be able to measure at the 20-70% hematocrit range.	Our change request is "The measurement strip shall be able to measure at the 20-60% hematocrit range."	Please see the answer to clarification number 60 above.
63	TS	3.1.14	Each strip shall be covered in aluminum foil and shall not be affected from moisture, heat and light.	New technology strips are not so much sensitive to heat, moister and Light. They are stored in a vial with secure lid. So we kindly request you to change the article as follows; "3.1.14 Each strip shall be covered in aluminum foil and shall not be affected from moisture, heat and light or strips are stored in a cylinderical vial with tightly closing lid"	The item has been revised as: Strips shall be in a box and shall not be affected from moisture, heat and light. Please also refer to Changes No: 1 to TD.

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64	TS	3.1.14	Each strip shall be covered in aluminum foil and shall not be affected from moisture, heat and light.	Our change request is “The strips shall not be affected from moisture, heat and light.” Because, there is only one manufacturer that producing aluminum foil covered strips.	Please see the answer to clarification number 63 above.
65	TS	3.1.14	Each strip shall be covered in aluminum foil and shall not be affected from moisture, heat and light.	Claim: There is only one company which is producing actively of the Glucometer Strips covered in aluminium foil in the world. It is fully obstructive of competition between the companies who will intent to participate the tender due to the article indicates only one product in the world. In addition to this, currently Glucose Strips are common use in a Box (prevented heat, light and moisture) in Turkey. Therefore, we kindly require you to make amendment of the mentioned article 3.1.14.as follows. Request: Strips shall be in a box to prevent from heat, light and moisture.	Please see the answer to clarification number 63 above.
66	TS	3.1.14	Each strip shall be covered in aluminum foil and shall not be affected from moisture, heat and light.	”Each strip shall be covered in aluminum foil and shall not be affected from moisture, heat and light.” The specifications that is mentioned at the above is just available for one brand, so we kindly request the removal of this mentioned Article because fair competition is not possible because of the opportunity to offer a device for a certain brand and equal opportunity for all tenderers.	Please see the answer to clarification number 63 above.
67	TS	3.1.15	The system shall use biosensor technology or amperometric, capillary sensor	With the advances in biochemistry science the cutting-edge sensor technology is now	The item has been revised as: The system shall use; biosensor

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			technology.	fotometric. So we would like you to add this new sensor technology to the existing ones in the article; "3.1.15 The system shall use biosensor technology or amperometric, capillary sensor technology or photometric sensor technology."	technology or amperometric, capillary sensor technology or photometric sensor technology or GDH - FAD enzyme. Please also refer to Changes No: 1 to TD.
68	TS	3.1.15	The system shall use biosensor technology or amperometric, capillary sensor technology.	"The system shall use biosensor technology or amperometric, capillary sensor technology." We kindly request removal of 3.9.10 article from the technical statement.	Please see the answer to clarification number 67 above.
69	TS	3.1.15	The system shall use biosensor technology or amperometric, capillary sensor technology.	The item should be changed to "The system shall use biosensor technology or amperometric, capillary sensor technology. The strips shall not be affected by maltose, galactose and xylose. For this reason, the strips shall be use GDH - FAD enzyme. Reason: The strips shall not be affected by drug interference, and shall not give erroneous glucose results for patients who use extraneal (icodextrin 7.5%) for peritoneal dialysis treatment. therefore; the strips shall not be affected by maltose, galactose and xylose. Due to these reasons, the strips shall be use GDH - FAD enzyme which is recommended by the World Health Organization.	Please see the answer to clarification number 67 above.
70	TS	3.1.16	In the event of the device malfunctioning, the company shall cover kit expenditure free of charge.	Claim: It is not possible to determine how much number of the kit expenditure quantities in case of device malfunctioning before the tender.	The item remains unchanged considering the needs of the Contracting Authority and the public interest.

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				Therefore, we kindly require you to make amendment of the mentioned article 3.1.16 as follows. Request: In case of any device malfunctioning, the company shall provide a new one instead of the device which is out of order.	
71	TS	3.1.17	The company shall provide batteries for the devices, shall supply the control serum till the end of the year free of charge.	Claim: It is not possible to determine the batteries and Control Serum expenditure before the tender. Therefore, we kindly require you to make amendment of the mentioned article 3.1.17.as follows. Request: The company shall provide 2 (two) pieces of batteries and 2 ml Control Serum with per devices.	The item has been revised as: The company shall provide at least 2 (two) pieces of batteries and at least 2 (two) pieces 2 ml Control Serum with per devices. Please also refer to Changes No: 1 to TD.
72	TS	3.1.17	The company shall provide batteries for the devices, shall supply the control serum till the end of the year free of charge.	In this article, there is some ambiquity in the statement, namely “till the end of the year”. Please kindly specify which year is meant herein.	Please see the answer to clarification number 71 above.
73	TS	3.1.18	The company shall bring samples to our laboratories for approval (at least 20 illnesses)	Will you please clarify what is meant by “at least 20 illnesses” and when we will bring those materials, during demo or durin provisional acceptance procedures? It would be better to write down the article by indicating those issues such as; 1. The number of glucometer devices, 2. The amount of control solutions, 3. The number of strips, 4. The time they are to be delivered.	The specification has been removed from the Technical Specifications. Please also refer to Changes No: 1 to TD.

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				to be delivered to the laboratory for approval.	
74	TS	3.2.6	The tape shall show both cm and inches.	For not using the inches in Turkey, our change request is "The tape shall show only cm."	The item has been revised as: The tape shall show centimeter. Please also refer to Changes No: 1 to TD.
75	TS	3.3.6	Electrical characteristics of the device: 220V/50Hz - not more than 0.4 Amp/70Watt.	Without causing any performance degradation we request you to change the article as follows; "3.3.6 Electrical characteristics of the device: 220V/50 Hz- not more than 0.4 Amp/70Watt or 220 V +/- 10%, 50 Hz and maximum 170 VA."	The item has been revised as: Electrical characteristics of the device: 220V/50 Hz (± 10%) - not more than 0.4 Amp / 70 Watt or maximum 170 VA. Please also refer to Changes No: 1 to TD.
76	TS	3.3.7	The devices compressor air flow in a minute shall be at least 6.5 liters and the outlet pressure must be at least 3.0 bar.	The air flow of devices on the market starts from 6.0 liters in a minute. Our change request is "The devices compressor air flow in a minute shall be at least 6 liters and the outlet pressure must be at least 2.4 bar."	The item has been revised as: The devices compressor air flow in a minute shall be at least 6 liters and the outlet pressure must be at least 2.4 bar. Please also refer to Changes No: 1 to TD.
77	TS	3.3.7	The devices compressor air flow in a minute shall be at least 6.5 liters and the outlet pressure must be at least 3.0 bar.	Since the design characteristics may differ from company to company sometimes with some smaller values of the same parameter we can get the same or better performance Here we attain a flow of 6,5 liter/min at maksimum 2.5 bar. Thus we request you to change the article as follows; "3.3.7 The device's compressor air flow in a minute shall be at least 6.5 liters and the outlet pressure must be at least 2.5 bar."	Please see the answer to clarification number 76 above.
78	TS	3.3.7	The devices compressor air flow in a	The devices compressor air flow in a minute	Please see the answer to clarification

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			minute shall be at least 6.5 liters and the outlet pressure must be at least 3.0 bar.	shall be at least 6.5 liters per second and the outlet pressure must be at least 3.0 bar. " We kindly request you to update the specification as given below in order to increase the competition among different leading systems without having no change in pe1fo1mance or user experience in tenns of lowest detection limit and selectivity. The devices compressor air flow in a minute shall be at least 6.5 liters per second and the outlet pressure must be at least 2.5 bar.	number 76 above.
79	TS	3.3.10	The noise level of the device shall not exceed 56 decibels.	Our change request is "The noise level of the device shall not exceed 60 decibels."	The item has been revised as: The noise level of the device shall not exceed 60 decibels. Please also refer to Changes No: 1 to TD.
80	TS	3.3.11	The aerosol particles formed by the device shall have a diameter (MMAD) of 0.30 micron to 6 microns. Atomizer capacity shall be 6 ml	Atomizer capacity is given once more in the Article 3.3.12. Therefore, the article may be changed as; "3.3.11 The aerosol particles formed by the device shall have a diameter (MMAD) of 0.30 micron to 6 microns. "	The item has been revised as: The aerosol particles formed by the device shall have a diameter (MMAD) of 0.30 micron to 6 microns. Please also refer to Changes No: 1 to TD.
81	TS	3.4.4	The weighing capacity of the device shall be 20 kg (+5)	Since only babies are being planned to be weighed on this scale so we request you to change the article as follows: "3.4.4 The weighing capacity of the device shall be 20 kg +/-5 kg."	The specification remains unchanged considering the needs of the Ministry.
82	TS	3.4.5	The device shall have a sensitivity of 5 gr up to 10 kg and 15 gr over 10 kg.	Our change request is "The device shall have a maximum sensitivity of 5 gr up to 10 kg and a	The item has been revised as: The device shall have a maximum

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				maximum sensitivity of 15 gr for above 10 kg."	sensitivity of 5 gr up to 10 kg and a maximum sensitivity of 15 gr for above 10 kg. Please also refer to Changes No: 1 to TD.
83	TS	3.4.5	The device shall have a sensitivity of 5 gr up to 10 kg and 15 gr over 10 kg.	We propose a much more sensitive device to track the changes in the weight of the babies. "3.4.5 The device shall have a sensitivity of 5 gr up to 10 kg and 15 gr over 10 kg or 2 gr up to 6 kg and 5 gr up to 15 kg." If a weighing capacity of 20 kg is mandatory necessity then we request the article to be rewritten as "3.4.5 The device shall have a sensitivity of 10 gr up to 20 kg."	Please see the answer to clarification number 82 above.
84	TS	3.4.9	The device shall be battery operated.	The device operates from mains to reduce and avoid battery consumption costs so we request you to change the article as follows: "3.4.9 The device shall be battery operated or the device shall operate from the mains."	The specification remains unchanged considering the needs of the Ministry.
85	TS	3.4.10	Shall be able to weigh gross weight, gross weighing shall be possible automatically done by pressing a button.	Article 3.4.10 "Shall be able to weigh gross weight, gross weighing shall be possible automatically done by pressing a button." The device we want to offer has a superior feature "...gross weighing shall be possible automatically done without pressing a button" Could you please make an evaluation for this button because we have problems with the devices we delivered as a superior feature in our previous delivery?	The item has been revised as: Shall be able to weigh gross weight, gross weighing shall be possible automatically done with/without pressing a button. Please also refer to Changes No: 1 to TD.

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86	TS	3.5.5	It shall be able to work with storage battery or cell battery.	The device operates from mains to reduce and avoid battery consumption costs so we request you to add these fetaures to the article: "3.5.5 It shall be able to work with storage battery or cell battery or from mains or built-in rechargeable battery."	The item has been revised as: It shall be able to work with storage battery or cell battery or built-in rechargeable battery. Please also refer to Changes No: 1 to TD.
87	TS	3.5.6	It shall have a digital (LCD) indicator and shall be waterproof.	For a bright and easily readable display the scale uses LED technology. And "water-proof" feature requires to be indicated as IPXY (ingress protection number) So we request you to add LED fetaure to the article and extract "water-proof" feature if IP XY number is not available. Those scales are clinically tested and approved as medical devices and are suitable for use use in hospitals and healthcare premises. They have CE Certificate, also. "3.5.6. It shall have a digital (LCD or LED) indicator."	The item has been revised as: It shall have a digital (LCD or LED) indicator and shall be waterproof. Please also refer to Changes No: 1 to TD.
88	TS	3.5.8	Batteries shall be supplied with the scale.	The device operates from mains and has a rechargeable battery inside it. Therefore we kindly request you to include this feature in the article:" "3.5.8 Batteries or built-in rechargeable batteries shall be supplied with the scale."	The item has been revised as: Batteries or built-in rechargeable batteries shall be supplied with the scale. Please also refer to Changes No: 1 to TD.
89	TS	3.6	Automatic Tourniquet	We kindly would like to inform Contracting Authority that, all manufacturers of this item are located in non-eligible countries, because of the production material and its cheap unit price. We kindly request Contracting Authority to derogate this item from the rule of origin or remove the	Considering the Market Research of the tender, there is no need to change the existing requirement.

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				item from the context of the tender.	
90	TS	3.7	Pulse Oximeter	We kindly would like to inform Contracting Authority that, all manufacturers of this item are located in non-eligible countries, because of the production material and its cheap unit price. We kindly request Contracting Authority to derogate this item from the rule of origin or remove the item from the context of the tender.	Considering the Market Research of the tender, there is no need to change the existing requirement.
91	TS	3.7.6	The device should work with 16 bit Q-Chip technology to minimize artefacts caused by motion.	This feature belongs to an ancient pulse oximeter and its production has been discontinued. We kindly request you to cancel this article since it defines a specific brand and an extinct medical device.	The specification has been removed from the Technical Specifications. Please also refer to Changes No: 1 to TD.
92	TS	3.7.6	The device should work with 16 bit Q-Chip technology to minimize artefacts caused by motion.	16 bit Q-Chip technology is patented technology by a manufacturer and the manufacturer is not manufacturing the related device anymore. Therefore, this item should be removed.	Please see the answer to clarification number 91 above.
93	TS	3.7.6	The device should work with 16 bit Q-Chip technology to minimize artefacts caused by motion.	This shall be deleted because this is a unique specification for one device and that device is no more produced by the factory.	Please see the answer to clarification number 91 above.
94	TS	3.7.6	The device should work with 16 bit Q-Chip technology to minimize artefacts caused by motion.	**Claim:** There is only one company producing Finger Type Pulse Oximeter working with 16 bit Q-Chip Technology. It is fully obstructive of competition between the companies who will intent to participate the tender since the article point out only one product in the world.	Please see the answer to clarification number 91 above.

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				Request: We kindly require you to remove this article 3.7.6 from the Technical Conditions.	
95	TS	3.7.7	The measuring range of the device shall be 20-300 bpm and the measurement accuracy shall be ± 1.	We kindly request you change the article as follows," 3.7.7 The measuring range of the device shall be 20-300 bpm or 30-250 bpm ± 2bpm or 2%."	The item has been revised as: The measuring range of the device shall be 30 – 250 bpm and the measurement accuracy shall be ±2. Please also refer to Changes No: 1 to TD.
96	TS	3.7.7	The measuring range of the device shall be 20-300 bpm and the measurement accuracy shall be ± 1.	**Claim:** The device we will offer the measuring range is 30 – 250 bpm and the measurement accuracy is ± 1. Therefore, we kindly require you to make amendment of the mentioned article 3.7.7.as follows. **Request:** The measuring range of the device shall be 30 - 250 bpm and the measurement accuracy shall be ± 1.	Please see the answer to clarification number 95 above.
97	TS	3.7.7	The measuring range of the device shall be 20-300 bpm and the measurement accuracy shall be ± 1.	This shall be changed as "The measuring range of the device shall be 30 – 250 bpm and the measurement accuracy shall be ±2 or 2%. "	Please see the answer to clarification number 95 above.
98	TS	3.7.7	The measuring range of the device shall be 20-300 bpm and the measurement accuracy shall be ± 1.	We kindly request to revise the item as "The measuring range of the device shall be 20 – 300 bpm or 30 – 250 bpm and the measurement accuracy shall be ±2 or 2%." Reason: The most common range for the pulse	Please see the answer to clarification number 95 above.

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				oximeters are between 30-250 bpm.	
99	TS	3.7.8	The saturation measurement range of the device shall be between 0-100% and the measurement accuracy shall be ± 2 between 70% - 100%.	We kindly request you change the article as follows," "3.7.8 The saturation measurement range of the device shall be between 0-100% and the measurement accuracy shall be ± 2 between 70% - 100% or measurement range shall be 35-100% and measurement accuracy shall be ± 3% between 70-99% and no definition for <69%."	The item has been revised as: The saturation measurement range of the device shall be between at least 35-100% and the measurement accuracy shall be ± %3 between 70% - 99%. Please also refer to Changes No: 1 to TD.
100	TS	3.7.8	The saturation measurement range of the device shall be between 0-100% and the measurement accuracy shall be ± 2 between 70% - 100%.	This shall be changed as "The saturation measurement range of the device shall be between 35%-100% and the measurement accuracy shall be ± %3 between 70% - 99%."	Please see the answer to clarification number 99 above.
101	TS	3.7.8	The saturation measurement range of the device shall be between 0-100% and the measurement accuracy shall be ± 2 between 70% - 100%.	We kindly request to revise the item as "The saturation measurement range of the device shall be between at least 35-100% and the measurement accuracy shall be ± %3 between 70% - 99%."	Please see the answer to clarification number 99 above.
102	TS	3.7.9	The device shall be able to operate continuously for at least 50 hours with 2 AAA alkaline batteries.	We kindly request you change the article as follows," "3.7.9 The device shall be able to operate continuously for at least 20 hours with 2 AAA alkaline batteries."	The item has been revised as: The device shall be able to operate continuously for at least 15 hours with 2 AAA alkaline batteries. Please also refer to Changes No: 1 to TD.

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103	TS	3.7.9	The device shall be able to operate continuously for at least 50 hours with 2 AAA alkaline batteries.	We kindly request to revise the item as "The device shall be able to operate continuously for at least 15 hours with 2 AAA alkaline batteries."	Please see the answer to clarification number 102 above.
104	TS	3.7.10	The dimensions of the device shall be 57 mm x 35 mm x 27 mm.	We kindly request you to make the following changes in the article:" "The dimensions of the device shall be 57 mm x 35 mm x 27 mm +/- 5 mm."	The item has been revised as: The dimensions of the device shall be 57 mm x 35 mm x 27 mm (±5 mm). Please also refer to Changes No: 1 to TD.
105	TS	3.7.10	The dimensions of the device shall be 57 mm x 35 mm x 27 mm.	We kindly request to revise the item as "The dimensions of the device shall be 57 mm x 35 mm x 27 mm (±5)."	Please see the answer to clarification number 104 above.
106	TS	3.7.10	The dimensions of the device shall be 57 mm x 35 mm x 27 mm.	**Claim:** The device we will offer has the dimensions are 58,5 mm x 31 mm x 32 mm **Request:** We kindly require you to arrange this 3.7.10 article as we can participate the tender.	Please see the answer to clarification number 104 above.
107	TS	3.7.11	The weight of the device shall not exceed 50 grams including the battery.	3.7.11 We kindly request you to make the following changes in the article: "3.7.11 The weight of the device shall not exceed 50 +/- 5 grams including the battery."	The item has been revised as: The weight of the device shall not exceed 60 grams including the battery. Please also refer to Changes No: 1 to TD.
108	TS	3.7.11	The weight of the device shall not exceed 50 grams including the battery.	We kindly request to revise the item as "The weight of the device shall not exceed 60 grams including the battery."	Please see the answer to clarification number 107 above.
109	TS	3.7.14	Carrying case and hanger shall be provided	Although carrying case protects the device it	The specification remains unchanged

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			with the device.	cause to increase its unit price. With a land-yard (hanger) it is safe to be used in a hospital by the healtcare professionals safely. So we kindly request you to make the following changes in the article: "3.7.14 Carrying case and/or hanger shall be provided with the device."	considering the needs of the Ministry.
110	TS	3.7.15	The device shall be capable of doing 3,000 spot checks.	Please kindly clarify whether it indicates the battery capacity or durabilitiy of the device for the number of spot checks that can be performed. This parameter depends on the time it takes for a single measurement we kindly request to cancel this article.	The specification remains unchanged considering the needs of the Ministry.
111	TS	3.7.15	The device shall be capable of doing 3,000 spot checks.	**Claim:** The device we will offer is practically capable of doing approximately 3,000 spot checks. But, we have not any written document to prove our claim at the moment. **Request:** We kindly require you to remove this 3.7.15 article from the Technical Conditions.	The specification remains unchanged considering the needs of the Ministry.
112	TS	3.7.15	The device shall be capable of doing 3,000 spot checks.	We demand removal of this item.	The specification remains unchanged considering the needs of the Ministry.
113	TS	3.7.17	The device shall be able to operate at -20-50 °C.	We kindly request you to make the following changes in the article: "3.7.17 The device shall be able to operate at -20-50 °C or 5-40 °C."	The item has been revised as: The device shall be able to operate at 10-40 °C. Please also refer to Changes No: 1 to TD.

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114	TS	3.7.17	The device shall be able to operate at -20-50 °C.	**Claim:** The device we will offer can operate between at +10 - +40 °C. Therefore, we kindly require you to make amenmend of the mentioned article 3.7.17.as follows. **Request:** The device shall be able to operate at +10 - +40 °C.	Please see the answer to clarification number 113 above.
115	TS	3.7.17	The device shall be able to operate at -20-50 °C.	We kindly request to revise the item as "The device shall be able to storage at -20-50 °C." Reason: Due to misspelling, it should be changed.	Please see the answer to clarification number 113 above.
116	TS	3.7.19	If required, the charging unit and the vehicle charge shall be provided in exchange for a fee.	**Claim:** The device we will offer has not charging unit and the vehicle charge. **Request:** We kindly require you to remove this article 3.7.19 from the Technical Conditions.	The specification has been removed from the Technical Specifications. Please also refer to Changes No: 1 to TD.
117	TS	3.7.22	The importer or seller company shall have a TSE Service Location Qualification Certificate and the name and brand of this document should be indicated.	It is unnecessary to request the TSE certificate for the finger type pulse oximeter. It will bring the limit on the participation of the tender. We kindly request removal of 3.7.22 article from the technical statement.	The specification has been removed from the Technical Specifications. Please also refer to Changes No: 1 to TD.
118	TS	3.7.22	The importer or seller company shall have a TSE Service Location Qualification Certificate and the name and brand of this document should be indicated.	**Claim:** This "TSE Service Location Qualification Certificate" is requested to assure Technical Service After Sales if the requested device is needed service. Those kind of Devices are not	The specification has been removed from the Technical Specifications. Please also refer to Changes No: 1 to TD.

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				needed Technical Service like Finger Type Pulse Oximeter. In addition to this, 3.7.21 article in the same group is pointed out for the device "No service or calibration other than battery replacement shall be required" **Request:** We kindly require you to remove this article 3.7.22 from the Technical Condition.	
119	TS	3.8	BINOCULAR MICROSCOPE	The manufacturer of the microscope product we wish to offer declares that it is not covered by the medical device and it is out of scope. Is UBB / ÜTS registration mandatory for binocular microscope?	UBB / ÜTS registration is not mandatory for binocular microscope.
120	TS	3.8.6	Microscope objective, ocular and observation tubeshall be anti-microbial to prevent fungus and germ repulsion and this should be documented.	All optical parts are anti-microbal and anti-fungus treated and germ repulsion. Nowadays it is a standard in professional microscopy. We can not provide a document related for this specs. Also we have just requested from the manufacturer. We would like to request the article change such as: "Microscope objective, ocular and observation tubeshall be anti-microbial to prevent fungus and germ repulsion."	All supplies must be supplied with appropriate documentation (i.e. original set of operating and users' manuals developed by the vendor, instructions for routine use and maintenance procedure) in English and in Turkish (if commercially available). If manuals are not in Turkish, a "Quick Guide" in Turkish shall be supplied together with the manual where applicable. Manuals should also be supplied as electronic copy.
121	TS	3.8.6	Microscope objective, ocular and observation tubeshall be anti-microbial to prevent fungus and germ repulsion and this should be documented.	Objective, ocular and observation tubes can be covered with anti-fungus treatment. In order to prove that manufacturer's declaration or brochures or data sheet can be submitted with the offer. But, we would like to inform contracting authority that there is no other	All supplies must be supplied with appropriate documentation (i.e. original set of operating and users' manuals developed by the vendor, instructions for routine use and maintenance procedure) in English and in Turkish (if commercially

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				documentation is present except we have just specified. Therefore, please confirm that no other documentation will be requested during evaluation or provisional acceptance procedures. Otherwise, please cancel this specification from TS.	available). If manuals are not in Turkish, a "Quick Guide" in Turkish shall be supplied together with the manual where applicable. Manuals should also be supplied as electronic copy.
122	TS	3.8.10	Microscope's resolution settings shall be provided by a coaxill macro micro double button control. A full turn of fine division shall be at least 0.004 mm.	There is a misspelling about the value of a full turn of fine division, for this reason, this shall be changed as "Microscope's resolution settings shall be provided by a coaxill macro micro double button control. A full turn of fine division shall be at least 0.004 mm or 0.3 mm."	Fine division value shall be at least 0.004 mm. The requirement in these specification is presented as a minimum value which the offered goods must meet. Your offer value 0.3 mm is higher than 0.004 and there is no need to change the existing requirement.
123	TS	3.8.10	Microscope's resolution settings shall be provided by a coaxill macro micro double button control. A full turn of fine division shall be at least 0.004 mm.	We would like to offer the microscope model: a full turn of fine division is 0.002 mm is a more superior feature. Could you please make an evaluation for these values in the microscope because we have problems with the devices we delivered as a superior feature in our previous delivery?	Fine division value shall be at least 0.004 mm. The requirement in these specification is presented as a minimum value which the offered goods must meet. Your offer value 0.002 mm is higher than 0.004 and there is no need to change the existing requirement.
124	TS	3.8.12	Microscope's standard Abbé nA 1.20 shall be standard condenser.	We kindly request the following modification in the article: "Microscope's standard Abbé nA 1.20 or 1.25 shall be standard condenser."	The item has been revised as: Microscope's standard Abbé nA 1.20 or 1.25 shall be standard condenser. Please also refer to Changes No: 1 to TD.
125	TS	3.8.12	Microscope's standard Abbé nA 1.20 shall be standard condenser.	We would like to inform contracting authority that above mentioned specification is mistyped. In the market, generally, abbe N.A. 1.25, standard condenser is used. Therefore, please correct the specification as, "Microscope's standard Abbé N.A. 1.25 shall be standard	Please see the answer to clarification number 124 above.

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				condenser"	
126	TS	3.8.17	Microscope's lighting shall be provided with 3W LED lighting system.	For more powerful illumination we kindly request you to change the article as: " "3.8.17 Microscope's lighting shall be provided with at least 3W LED lighting system."	The item has been revised as: Microscope's lighting shall be provided with at least 3W LED lighting system. Please also refer to Changes No: 1 to TD.
127	TS	3.9.4	The device shall be portable and shall have a 2 MHz probe with a monoblock body and a minimum diameter of 20 mm.	The performance of the probe is not directly related to the diameter of the distal end of the probe so we kindly request you to make the following changes in the article as. "3.9.4. The device shall be portable and shall have a 2 MHz probe with a monoblock body."	The item remains unchanged considering the needs of the Contracting Authority.
128	TS	3.9.6	The device ultrasonic density should be below 9 mW / cm. The heart rate shall be within the range of 60-240 bpm.	We kindly request you to make the following changes in the article as." "3.9.6. The device ultrasonic density should be below or equal 10 mW/cm2. The heart rate shall be within the range of 60-240 bpm or 50-210 bpm."	The item has been revised as: The device ultrasonic density should be below or equal 10 mW/cm2. The heart rate shall be within the range of 60-240 bpm or 50-210 bpm. Please also refer to Changes No: 1 to TD.
129	TS	3.9.6	The device ultrasonic density should be below 9 mW / cm. The heart rate shall be within the range of 60-240 bpm.	"The device ultrasonic density should be below 9 mW / cm. The heart rate shall be within the range of 60-240 bpm." Ultrasound density is required as 9 mW / cm2. However, no fetal hand doppler on the world does not meet this criterion. With the expression ultrasound density "we could not understand clearly what was requested. However, we estimate that there may be ISPTA or ISATA parameters. The FDA limit for ISPTA is 94 mW / cm2 and for ISATA it is 20 mW / cm2. In our	Please see the answer to clarification number 128 above.

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				(2 Mhz obstetric probe) probe, the ISPTA is less than 40 mW / cm2, whereas the manufacturer does not measure ISATA but it is not possible to exceed 20 mW / cm2. So, We kindly request the following modification in the article: "The device ultrasonic density should be below 40 mW / cm2. The heart rate shall be within the range of 60-210 bpm."	
130	TS	3.9.7	Clips shall be provided on the device to fit into a pocket or attached to a belt.	With clips the device may be damaged or broken in case it is in user's pocket and the user is leaning forward or when it is attached to the user's belt. We recommend the Healthcare professionals to use a soft carrying case. So we kindly request you to make the following changes in the article as." "3.9.7 Clips shall be provided on the device to fit into a pocket or attached to a belt or the device shall have a soft carrying case."	The item has been revised as: Clips shall be provided on the device to fit into a pocket or attached to a belt or the device shall have a soft carrying case. Please also refer to Changes No: 1 to TD.
131	TS	3.9.9	The device shall have a tape or external speaker connection and an alternate audio output that can be used in the recording.	This shall be changed as "The device shall have a tape or external speaker connection or internal speaker and an alternate audio output that can be used in the recording or for earphones."	The item has been revised as: The device shall have a tape or external speaker connection or internal speaker and an alternate audio output that can be used in the recording or for earphones. Please also refer to Changes No: 1 to TD.
132	TS	3.9.9	The device shall have a tape or external speaker connection and an alternate audio output that can be used in the recording.	Claim: It has not any "Tape or External Speaker Connection" but it has own Speaker and Audio Output that can be used for recording on the device we will offer. In addition to this, there is	Please see the answer to clarification number 131 above.

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				not any device which has a tape or external speaker connection on Fatal Doppler body in the market. Therefore, we kindly require you to make amendment of the mentioned article 3.9.9 as follows. Request: The device shall have own speaker and audio output that can be used for recording.	
133	TS	3.9.10	A ON/OFF switch, volume knob shall be found on the device.	"Clips shall be provided on the device to fit into a pocket or attached to a belt." The device we want to offer does not have a clip. But any doctor, nurse, physician is already holding these devices in his pocket or belt or anywhere else. So no such use of the fetal hand doppler device anymore. So, We kindly request the following modification in the article: "Clips shall be provided on the device to fit into a pocket or attached to a belt or the bag can be attached to a belt" or we kindly request removal from the technical statement of 3.9.10 article.	The item remains unchanged considering the needs of the Contracting Authority.
134	TS	3.9.15	The device shall be able to produce results even in the case of sufficient IFS.	We kindly request you to clarify the article especially the abbreviation IFS or to cancel the article.	The specification has been removed from the Technical Specifications.
135	TS	4.3.10	The maximum frame rate of the device shall be able to increase to at least 490 frame/second level at B-Mod.	Requested version: In Abdomen application, with curve transducer at 35 cm depth the maximum frame rate of the device shall be able to increase to at least 50 frame/second in B-Mode	The item remains unchanged considering the needs of the Contracting Authority.

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136	TS	4.3.34	As an option, it shall be possible to add 3 Dimension (3D) B Mode imaging or 3 Dimension (3D) Coloured Doppler imaging option to the proposed device. 3D imaging function must be possible to be made by at least two different probes that are usable in the system. The price of this optional function cannot exceed 3% of the unit price acquired by updating the tender unit price cost over the Turkish Statistical Institute's Price Index on the date of tender.	Requested version: As an option, it shall be possible to add 3 Dimension (3D) B Mode imaging or 3 Dimension (3D) Coloured Doppler imaging option to the proposed device. The price of this optional function cannot exceed 3% of the unit price acquired by updating the tender unit price cost over the Turkish Statistical Institute's Price Index on the date of tender.	The item remains unchanged considering the needs of the Contracting Authority.
137	TS	4.3.35	In the proposed device, it shall be possible to add volume probes and Real Time 3D (4D) imaging function as software and hardware against a fee. As an option, it shall be possible to connect 4D probes to the device. In 4D applications, Tomographic Ultrasound Imaging, Thick Slice Imaging, Multi Slice Display and similar functions shall be present to be used in post process actions. The 4D frame rate value of the device shall go up to at least 30 volume / second. The price of this optional function cannot exceed 10% of the unit price acquired by updating the tender unit price cost over the Turkish Statistical Institute's Price Index on the date of tender.	Requested version: In the proposed device, it shall be possible to add volume linear and vaginal probes or Real Time 3D (4D) imaging function as software and hardware against a fee. As an option, it shall be possible to connect 3D probes to the device. In 3D applications, Tomographic Ultrasound Imaging, Thick Slice Imaging, Multi Slice Display and similar functions shall be present to be used in post process actions. The 4D frame rate value of the device shall go up to at least 30 volume / second or it should be possible for Linear volume transducers to support Intuitive 3D navigation and save as 3D volume loops that can support review package with advanced 3D realtime post-processing in 3D B-mode and sharwave Eastography volume measurements. The price of this optional function cannot exceed 10% of the unit price acquired by updating the tender unit price cost over the Turkish Statistical Institute's Price Index on the date of tender.	The item has been revised as: In the proposed device, it shall be possible to add volume linear and vaginal probes or Real Time 3D (4D) imaging function as software and hardware against a fee. As an option, it shall be possible to connect 3D probes to the device. In 3D applications, Tomographic Ultrasound Imaging, Thick Slice Imaging, Multi Slice Display and similar functions shall be present to be used in post process actions. The 4D frame rate value of the device shall go up to at least 30 volume / second or it should be possible for Linear volume transducers to support Intuitive 3D navigation and save as 3D volume loops that can support review package with advanced 3D realtime post-processing in 3D B-mode and sharwave Eastography volume measurements. The price of this optional function cannot exceed 10% of

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					the unit price acquired by updating the tender unit price cost over the Turkish Statistical Institute's Price Index on the date of tender. Please also refer to Changes No: 1 to TD.
138	TS	4.3.40	The device shall have the ability to perform strain elastography. Elastography function must be usable by convex and/or micro-convex and/or linear probes. As well as the visual analysis (colour codes indicating the hardness level of the lesion), elastography Imaging mode shall also contain a Quantification analysis program or Strain ratio measurement program. With the Quantification analysis program, it shall be possible to perform real time or post processing actions. With strain ratio measurement, it shall be possible to measure the ratio of the pixels changing places in the selected area, or in other words, the ratio of the tissue. This way, it shall be possible to relatively specify the hardness level between the two selected tissue areas and also monitor on the screen.	Requested version: The device shall have the ability to perform strain or shearwave elastography. Elastography function must be usable by convex and/or micro-convex and/or linear probes. As well as the visual analysis (colour codes indicating the hardness level of the lesion), elastography Imaging mode shall also contain a Quantification analysis program or Strain or shearwave ratio measurement program. With the Quantification analysis program, it shall be possible to perform real time or post processing actions. With strain or shearwave ratio measurement, it shall be possible to measure the ratio of the pixels changing places in the selected area, or in other words, the ratio of the tissue. This way, it shall be possible to relatively specify the hardness level between the two selected tissue areas and also monitor on the screen.	The item remains unchanged considering the needs of the Contracting Authority.
139	TS	4.3.47	For the volume probe, biplane probes, and Matrix or XMatrix or IQ probe technologies this price cannot exceed 12% of the unit price acquired by updating the tender unit price cost over the Turkish Statistical Institute's Price Index on the date of tender. These ratios do not include laparoscopic, pen, TEE probes. Applicant	Requested version: For the volume probes, this price cannot exceed 12% of the unit price acquired by updating the tender unit price cost over the Turkish Statistical Institute's Price Index on the date of tender. These ratios do not include laparoscopic, pen, TEE probes. Applicant company shall provide a list of all probes conforming to the device during the	The item remains unchanged considering the needs of the Contracting Authority.

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			company shall provide a list of all probes conforming to the device during the contract phase.	contract phase.	