CLARIFICATIONS No: 1
to the
TENDER DOSSIER

Publication Reference **:** SIHHAT/2019/SUP/INT/21
Subject **:** Supply of Defibrillator for Migrant Health Centres
Location **:** Turkey/EU

TD: Tender Dossier
DOC: Document
ART: Article
TS: c4f_annexiitechspeciiitechoffer_en [Annex II + III: Technical Specifications + Technical Offer]*
GR: General Requirements
PC: Particular Conditions
** 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 (page #)	CLAUSE	QUESTION	ANSWER
1	**TS GR PC**	**3.7 (2)**	The tender shall submit along with their bids the originals or notarized copies of the following documents, which certify that they are actually engaged in the business that is covered by the tender and pertain to the year in which the tender is conducted. Capacity Report, Industry Ministry after Sales Service Qualification Certificate, Industry	This article (3.7) of Annex II+III is limiter and prohibitive to submit the bids. It is prohibitive because of Capacity Report and It is limiter because of Industry Ministry after Sales Service Qualification Certificate, Industry Ministry Authorized Service Certificate. Capacity Report can be only submitted by manufacturers, so it means only manufacturers can join the tender.	Please see the Corrigendum No: 1 to the TD.

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			Ministry Authorized Service Certificate, ISO 9001 Certificate.	Moreover, certificates for defibrillator (medical devices) mentioned above are taken by only a few companies. Many companies take service adequacy certificate (SAC) from Turkish Standard Institution (TSE) instead of mentioned certificates. Because, Turkish Pharmaceuticals and Medical Devices Agency (TİTCK) as authorized institution about Medical Devices in Turkey says that Medical Device Companies for their after-sales services must take TS 12426 or TS 13703 SAC from TSE (Circular letter no of TİTCK: 2019/1). As a result of our remarks to increase competition and to correct tender documents to comply with the formal regulations: We think that capacity report must be removed from Article 3.7. We think that for this tender Industry Ministry after Sales Service Qualification Certificate, Industry Ministry Authorized Service Certificate must be removed from Article 3.7, and instead of these TSE service adequacy certificate related with medical devices (TS 12426 / TS 13703) must be added to Article 3.7, as said in	

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				circular letter of authorized institution (TİTCK).	
2	**TS**	**1.1.4 (5)**	The subject of these technical specifications includes the technical properties, examination methods and other related topics related to defibrillators that can be used for 12-channel ECG measurement and 12-channel ECG presentation on the monitor.	We kindly request above item to be changed as below so that specifications shall be competitive. 1.1.4 The subject of these technical specifications includes the technical properties, examination methods and other related topics related to defibrillators that can be used for 12-channel ECG measurement and any channel can be chosen and presented on the monitor.	Please see the Corrigendum No: 1 to the TD.
3	**TS**	**1.1.4 (5)**	The subject of these technical specifications includes the technical properties, examination methods and other related topics related to defibrillators that can be used for 12-channel ECG measurement and 12-channel ECG presentation on the monitor.	Can the 12-channel EKG measurement and 12-channel EKG presentation requirements be removed from the monitor?	Please see the answer to clarification number 2 above.
4	**TS**	**1.1.5 (5)**	1.1.5 Definition: Defibrillator, the medical device that can be used for defibrillation, monitoring, 12-channel ECG measurement and recording, 12-channel ECG presentation on the monitor and SPO2, EtCO2 and pacing	We kindly request above item to be changed as below considering Covid-19 Supply Chain Breakage in the world and also in order to increase competition. Definition: Defibrillator, the medical device that can be used for defibrillation, monitoring, 12-channel ECG measurement	Please see the Corrigendum No: 1 to the TD.

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			measurement, meeting the requirements set out in the technical specifications.	and recording, ECG presentation on the monitor and meeting the requirements set out in the technical specifications.	
5	**TS**	**1.1.5 (5)**	1.1.5 Definition: Defibrillator, the medical device that can be used for defibrillation, monitoring, 12-channel ECG measurement and recording, 12-channel ECG presentation on the monitor and SPO2, EtCO2 and pacing measurement, meeting the requirements set out in the technical specifications.	Our request is removing SPO2, EtCO2, PACING features from specs.	Please see the answer to clarification number 4 above.
6	**TS**	**1.1.6 (5)**	The device should be suitable for being used for ambulance and bed-side defibrillation, monitoring and pacing.	We kindly request change on above item as below; The device should be suitable for being used for ambulance and bed-side defibrillation and monitoring.	The item remains unchanged considering the needs of the Contracting Authority.
7	**TS**	**1.1.6 (5)**	The device should be suitable for being used for ambulance and bed-side defibrillation, monitoring and pacing.	Our request is removing pacing.	Please see the answer to clarification number 6 above.
8	**TS**	**1.1.8 (5)**	The device should have at least 7-inches colour LCD or TFT screen and it should be capable to provide a clear view in a sunny day or the device setting should allow the same.	We kindly request change of above item as below as sunny day clear view is relatively subjective. The device should have at least 7-inches colour LCD or TFT screen and it should be capable to provide a clear view.	Please see the Corrigendum No: 1 to the TD.

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9	**TS**	**1.1.8 (5)**	The device should have at least 7-inches colour LCD or TFT screen and it should be capable to provide a clear view in a sunny day or the device setting should allow the same.	In order to strengthen the competition, we kindly request the Contracting Authority to change mentioned specification as follows; The device should have at least ***6,5*** -inches colour LCD or TFT screen and it should be capable to provide a clear view in a sunny day or the device setting should allow the same.	Please see the answer to clarification number 8 above.
10	**TS**	**1.1.9 (5)**	At least 2 waveforms, should be displayed on the device screen at the same time.	As we asked removal of additional sensors in item 1.1.5 we kindly request above item to be changed as below. Single channel ECG waveform should be displayed on the device screen.	The item remains unchanged considering the needs of the Contracting Authority.
11	**TS**	**1.1.9 (5)**	At least 2 waveforms, should be displayed on the device screen at the same time.	Our request is 1 (one) waveform display on the screen	Please see the answer to clarification number 10 above.
12	**TS**	**1.1.13 (6)**	Devices operating with single battery should be capable to perform at least 100 defibrillations at the highest energy level, while Devices operating with multiple batteries should be capable to perform at least 200 defibrillations at the highest energy level.	In order to strengthen the competition, we kindly request the Contracting Authority to change mentioned specification as follows; Devices operating with single battery should be capable to perform at least 90 defibrillations at the highest energy level, while Devices operating with multiple batteries should be capable to perform at least 200 defibrillations at the highest energy level.	Please see the Corrigendum No: 1 to the TD.

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13	**TS**	**1.1.15 (6)**	The device should have the external PACER feature as a standard feature in at least the demand and fixed (non-demand) modes. Pacer speed should be adjustable between at least 40 and 150 ppm and pace current should be adjustable between at least 10 and 140 mA in certain intervals.	We kindly request removal of this item from tender specifications as we asked removal of pacer in item 1.1.6.	Please see the Corrigendum No: 1 to the TD.
14	**TS**	**1.1.15 (6)**	The device should have the external PACER feature as a standard feature in at least the demand and fixed (non-demand) modes. Pacer speed should be adjustable between at least 40 and 150 ppm and pace current should be adjustable between at least 10 and 140 mA in certain intervals.	This item is describing PACER. Our request is removing this item from specs.	Please see the answer to clarification number 13 above.
15	**TS**	**1.1.15 (6)**	The device should have the external PACER feature as a standard feature in at least the demand and fixed (non-demand) modes. Pacer speed should be adjustable between at least 40 and 150 ppm and pace current should be adjustable between at least 10 and 140 mA in certain intervals.	In these Articles of Technical Specifications, pacer speed has been wanted as between at least 10-140 mA for both entry level and medium level defibrillators. Accepted International Articles show that there is no sense to measure under 35 mA. Ambulance tender made by your Institution at the date of 31.03.2020, defibrillator technical specs of ambulance was *"… at least between 35 mA and 140 mA…*" We, all, know that ambulances work the hardest conditions, in	Please see the answer to clarification number 13 above.

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				other words, it is more possible that a defibrillator in ambulance can be used on different kinds of patients. While 35 mA is enough even for this device, why 10 mA (although this value does not make any sense) is wanted for the device for Migrant Health Centres? Even though for the ambulance carrying patient to Migrant Health Services is enough 35 mA, Why Device at Migrant Health Centres MUST measure below 10 mA, it looks like to decrease competition for this tender. Because of these reasons, we would like to ask this article can be changed for both Lot 1 (Article 1.1.15) and Lot 2 (2.1.15.) as *"The device should have the external PACER feature as a standard feature in at least the demand and fixed (non-demand) modes. Pacer speed should be adjustable between at least 40 and 150 ppm and pace current should be adjustable between at least 35 and 140 mA in certain intervals."*	
16	**TS**	**1.1.15 (6)**	The device should have the external PACER feature as a standard feature in at least the demand and fixed (non-demand) modes. Pacer speed should be adjustable between at least 40 and 150 ppm and pace current should be	Our device specification is 20-200 mA. According to our engineers comments "It is absolutely will not be problem to stimulate the heart from 20mA since then the doctor will adjust it to the heart rhythm." Could you please clarify is it acceptable or not?	Please see the answer to clarification number 13 above.

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			adjustable between at least 10 and 140 mA in certain intervals.		
17	**TS**	**1.1.15 (6)**	The device should have the external PACER feature as a standard feature in at least the demand and fixed (non-demand) modes. Pacer speed should be adjustable between at least 40 and 150 ppm and pace current should be adjustable between at least 10 and 140 mA in certain intervals.	Can the current range be 210 Ma instead of 140 Ma? (is + - 10 value change a problem?)	Please see the answer to clarification number 13 above.
18	**TS**	**1.1.16 (6)**	The device should be capable to perform 12 lead/ECG measurements simultaneously by use of a cable harness of 10 cables, and it should be possible to view chest derivations on the screen.	We kindly request above item to be changed as below because measurements can be made simultaneously but presentation of 12 measurements simultaneously is not possible. The device should be capable to perform 12 lead/ECG measurements simultaneously by use of a cable harness of 10 cables, and it should be possible to view any chosen chest derivations on the screen.	The item remains unchanged considering the needs of the Contracting Authority.
19	**TS**	**1.1.17 (6)**	The device should have SPO2 and EtCo2 measurement sensors and finger probes that are compatible with the device and do detect accurate values even when moving and in low perfusion.	As we asked removal of additional sensors in item 1.1.5 we kindly request above item to be removed from tender specifications.	The item remains unchanged considering the needs of the Contracting Authority.

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20	**TS**	**1.1.17 (6)**	The device should have SPO2 and EtCo2 measurement sensors and finger probes that are compatible with the device and do detect accurate values even when moving and in low perfusion.	This item is describing SPO2, EtCO2 related with 1.1.5 and we request removing from tender specs	Please see the answer to clarification number 19 above.
21	**TS**	**1.1.20 (7)**	The device should have a thermal recorder with at least 2 channels. In order for the measurements received from the device to be easily read, width of the thermal paper should be at least 50 mm.	The device should have a thermal recorder with 1 channels. In order for the measurements received from the device to be easily read, width of the thermal paper should be at least 50 mm.	Please see the Corrigendum No: 1 to the TD.
22	**TS**	**1.1.20 (7)**	The device should have a thermal recorder with at least 2 channels. In order for the measurements received from the device to be easily read, width of the thermal paper should be at least 50 mm.	Our request for thermal recorder is to be revised as 1 (one) channel.	Please see the answer to clarification number 21 above.
23	**TS**	**1.1.20 (7)**	The device should have a thermal recorder with at least 2 channels. In order for the measurements received from the device to be easily read, width of the thermal paper should be at least 50 mm.	Is the single channel thermal recorder acceptable in the device?	Please see the answer to clarification number 21 above.
24	**TS**	**1.1.20 (7)**	The device should have a thermal recorder with at least 2 channels. In order for the measurements received from the device to be easily read, width	We kindly request change of above item as below ;	Please see the answer to clarification number 21 above.

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			of the thermal paper should be at least 50 mm.	The device must be equipped with a single channel thermal recorder. The width of the thermal paper must be at least 50 mm for easy reading of the measurements taken from the device.	
25	**TS**	**1.1.23 (7)**	The device should allow both wired and wireless transfer of the data obtained or transfer of the same to a USB driver or Transfer to SD card or it should be possible to review and print out the past data on the device at any time.	We kindly request change on above item as below as "past data" was not defined. We assume past data as past defibrillation data. The device should allow both wired and wireless transfer of the data obtained or transfer of the same to a USB driver or Transfer to SD card or it should be possible to review and print out the past defibrillation data on the device at any time.	The item remains unchanged considering the needs of the Contracting Authority.
26	**TS**	**1.1.26 (7)**	It should be possible to perform charging, discharging and turning on and off operations easily on the paddles.	In order to strengthen the competition, we kindly request the Contracting Authority to change mentioned specification as follows; It should be possible to perform charging, discharging ***or*** turning on and off operations easily on the paddles.	Please see the Corrigendum No: 1 to the TD.
27	**TS**	**1.1.26 (7)**	It should be possible to perform charging, discharging and turning on and off operations easily on the paddles.	Most of the devices have turn on and off from main body of the device. Our request is for the change of this item.	Please see the answer to clarification number 26 above.
28	**TS**	**1.1.26 (7)**	It should be possible to perform charging, discharging and turning on and off operations easily on the paddles.	Can this feature be completely cancelled?	Please see the answer to clarification number 26 above.

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29	**TS**	**1.1.26 (7)**	It should be possible to perform charging, discharging and turning on and off operations easily on the paddles.	From the first published date of defibrillator tender (including cancelled tenders), we are searching specs of defibrillator devices, making comparison between devices and published technical specifications. We examined the all best-known devices in the market. During this stage there is a spec which is changed never: "It should be possible to perform charging, discharging and turning on and off operations easily on the paddles." We really wonder that which device(s) have specs to perform turning on and off on the paddles? Because we did not find devices (for entry and medium levels) capable of turning on and off on its paddles. Quite the contrary, turning on and off operations are never operated from paddles of defibrillator (to prevent the irremediable process), it is contradictory to manufacturing and using purposes of defibrillator. We also searched AHA and ERC guidelines and we could not see a such kind of advice in those guidelines. Because of these reasons, we ask to remove Article 1.1.26 of Lot 1 and 2.1.26 of Lot 2 or change as "It should be possible to perform charging, discharging on the paddles."	Please see the answer to clarification number 26 above.

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30	**TS**	**1.1.26 (7)**	It should be possible to perform charging, discharging and turning on and off operations easily on the paddles.	Turn on and off can be done on main unit so we kindly request change on above unit as below It should be possible to charge and discharge on the paddles.	Please see the answer to clarification number 26 above.
31	**TS**	**1.1.26 (7)**	It should be possible to perform charging, discharging and turning on and off operations easily on the paddles.	According to the our engineers advices we do not recommend you to prefer this feature because it will effect as for "turning off" from paddles, it can be dangerous and life risk if by chance this button is pushed during shocking. So we kindly ask you to consider above advices for this annex.	Please see the answer to clarification number 26 above.
32	**TS**	**1.1.26 (7)**	It should be possible to perform charging, discharging and turning on and off operations easily on the paddles.	It should be possible to perform charging, discharging on the paddles.	Please see the answer to clarification number 26 above.
33	**TS**	**1.1.27 (7)**	Defibrillator paddles should have hand protection and they should be resistant to breakage and durable. In addition, paddles should be left and right side compatible.	Defibrillator paddles should be flexible. Also, the paddles must have a separation of sternum and Apex.	Please see the Corrigendum No: 1 to the TD.
34	**TS**	**1.1.27 (7)**	Defibrillator paddles should have hand protection and they should be resistant to breakage and durable. In addition, paddles should be left and right side compatible.	Most of the manufacturers does now use close loop hand protectors as different hands may easily fit in it so we kindly request above item to be changed as below; Defibrillator paddles should be resistant to breakage and durable. In addition, paddles	Please see the answer to clarification number 33 above.

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				should be left and right side compatible or Apex and sternum must be visually shown on the pedals.	
35	**TS**	**1.1.29 (7)**	The device should be resistant to demanding conditions. In this context, monitoring, ECG, defibrillation and pacer modes should be operable after waiting for 1 hour at most in ambient temperature between 5°C and (+40)°C.	In order to strengthen the competition, we kindly request the Contracting Authority to change mentioned specification as follows; The device should be resistant to demanding conditions. In this context, monitoring, ECG, defibrillation and pacer modes should be operable after waiting for 1 hour at most in ambient temperature between 5°C and (+40)°C ***or 10°C and (+30)°C***	The item remains unchanged considering the needs of the Contracting Authority.
36	**TS**	**1.1.29 (7)**	The device should be resistant to demanding conditions. In this context, monitoring, ECG, defibrillation and pacer modes should be operable after waiting for 1 hour at most in ambient temperature between 5°C and (+40)°C.	Our request is removing Pacer mode from this item	Please see the answer to clarification number 35 above.
37	**TS**	**1.1.29 (7)**	The device should be resistant to demanding conditions. In this context, monitoring, ECG, defibrillation and pacer modes should be operable after waiting for 1 hour at most in ambient temperature between 5°C and (+40)°C.	We kindly request removal of pacer modes from above description as we asked removal of this feature at item 1.1.6 1.1.29 The device should be resistant to demanding conditions. In this context, monitoring, ECG and defibrillation should be operable after waiting for 1 hour at most	Please see the answer to clarification number 35 above.

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				in ambient temperature between 5°C and (+40)°C.	
38	**TS**	**1.1.30 (7)**	The device's IP (Ingress Protection) class should be at least 44.	In order to strengthen the competition, we kindly request the Contracting Authority to change mentioned specification as follows; The device's IP (Ingress Protection) class should be at least ***IPX0***.	Please see the Corrigendum No: 1 to the TD.
39	**TS**	**1.1.30 (7)**	The device's IP (Ingress Protection) class should be at least 44.	IP class being 44 will decrease product diversity, there will be no competitive environment. For this reason, Is it possible to accept IP class to be 30 and to be presented with an extra cover for IP44 (bag etc.)?	Please see the answer to clarification number 38 above.
40	**TS**	**1.1.30 (7)**	The device's IP (Ingress Protection) class should be at least 44.	We kindly request change of IP 44 to IP X4 1.1.30 The device's IP (Ingress Protection) class should be at least X4.	Please see the answer to clarification number 38 above.
41	**TS**	**1.1.30 (7)**	The device's IP (Ingress Protection) class should be at least 44.	Our device has 32 IP as standard use for hospitals and you do not need 44 IP in hospital. We already providing you carrying bag with our Defibrillator for ambulances use and with carrying bag IP standards become to 44 IP Standards. Could you please clarify is it acceptable or not?	Please see the answer to clarification number 38 above.
42	**TS**	**1.1.30 (7)**	The device's IP (Ingress Protection) class should be at least 44.	From the first published date of defibrillator tender including cancelled tenders, many of specs has not been changed but this IP	Please see the answer to clarification number 38 above.

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				(Ingress Protection) specs has been changed suddenly with these tender specifications. With this change, our defibrillators happened out of tender procedure and our company has been unable to bid for the tender. Older specs for IP class are IPX1 and IP1X for both medium and entry level defibrillators. As we mentioned above, a defibrillator using in ambulance has to meet harder conditions than a defibrillator using in Migrant Health Centres. So, a defibrillator is already working in ambulances for years but that defibrillator will not join to tender because of these specs, we think that this situation is really decreasing competition. Moreover these devices are devices using with their protective/carrying cases. Also this requirement is already wanted in this tender, too (Please see Article 1.1.43 and 2.1.43). These bags are already increasing devices' IP class naturally. Because of this reason why is IP class wanted too high as 44. Can a defibrillator with protective case using in a Center be exposed to what kinds of hard conditions; heavy rain, storm, snowstorm etc.? We think that being wanted high level of IP class for these	

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				devices are for really decreasing competition. To be able to bid to tender we want to ask for Articles 1.1.30 & 2.1.30 of Lot 1 and Lot 2 to be changed as "The device's IP (Ingress Protection) class should be at least 22."	
43	**TS**	**1.1.40 (8)**	One (1) SPO2 connecting cable and one adult and one paediatric multiuse SPO2 probe should be supplied on the device. For devices on which the connecting cable and probe are not separated, single cable should be supplied.	As we asked removal of additional sensors in item 1.1.5 we kindly request above item to be removed from tender specifications.	The item remains unchanged considering the needs of the Contracting Authority.
44	**TS**	**1.1.40 (8)**	One (1) SPO2 connecting cable and one adult and one paediatric multiuse SPO2 probe should be supplied on the device. For devices on which the connecting cable and probe are not separated, single cable should be supplied.	Our request is removing SPO2 from spare part list	Please see the answer to clarification number 43 above.
45	**TS**	**1.1.41 (8)**	One (1) EtCO2 connecting cable and one adult and one paediatric multiuse EtCO2 probe should be supplied on the device. For devices on which the connecting cable and probe are not separated, single cable should be supplied.	As we asked removal of additional sensors in item 1.1.5 we kindly request above item to be removed from tender specifications.	The item remains unchanged considering the needs of the Contracting Authority.

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46	**TS**	**1.1.41 (8)**	One (1) EtCO2 connecting cable and one adult and one paediatric multiuse EtCO2 probe should be supplied on the device. For devices on which the connecting cable and probe are not separated, single cable should be supplied.	Our request is removing EtCO2 from spare part list	Please see the answer to clarification number 45 above.
47	**TS**	**2.1.4 (10)**	The subject of these technical specifications includes the technical properties, examination methods and other related topics related to defibrillators that can be used for 12-channel ECG measurement and 12-channel ECG presentation on the monitor.	Can the 12-channel EKG measurement and 12-channel EKG presentation requirements be removed from the monitor?	The item remains unchanged considering the needs of the Contracting Authority.
48	**TS**	**2.1.8 (10)**	The device should have at least 7-inches colour LCD or TFT screen and it should be capable to provide a clear view in a sunny day or the device setting should allow the same.	In order to strengthen the competition, we kindly request the Contracting Authority to change mentioned specification as follows; The device should have at least ***6,5*** -inches colour LCD or TFT screen and it should be capable to provide a clear view in a sunny day or the device setting should allow the same.	The item remains unchanged considering the needs of the Contracting Authority.
49	**TS**	**2.1.13 (11)**	Devices operating with single battery should be capable to perform at least 100 defibrillations at the highest energy level, while Devices operating with	In order to strengthen the competition, we kindly request the Contracting Authority to change mentioned specification as follows; Devices operating with single	Please see the Corrigendum No: 1 to the TD.

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			multiple batteries should be should be capable to perform at least 200 defibrillations at the highest energy level.	In order to strengthen the competition, we kindly request the Contracting Authority to change mentioned specification as follows; battery should be capable to perform at least ***90*** defibrillations at the highest energy level, while Devices operating with multiple batteries should be should be capable to perform at least 200 defibrillations at the highest energy level.	
50	**TS**	**2.1.15 (11)**	The device should have the external PACER feature as a standard feature in at least the demand and fixed (non-demand) modes. Pacer speed should be adjustable between at least 40 and 150 ppm and pace current should be adjustable between at least 10 and 140 mA in certain intervals.	Our device specification is 20-200 mA. According to our engineers comments "It is absolutely will not be problem to stimulate the heart from 20mA since then the doctor will adjust it to the heart rhythm." Could you please clarify is it acceptable or not?	Please see the Corrigendum No: 1 to the TD.
51	**TS**	**2.1.15 (11)**	The device should have the external PACER feature as a standard feature in at least the demand and fixed (non-demand) modes. Pacer speed should be adjustable between at least 40 and 150 ppm and pace current should be adjustable between at least 10 and 140 mA in certain intervals.	Can the current range be 210 Ma instead of 140 Ma? (is + - 10 value change a problem?)	Please see the answer to clarification number 50 above.
52	**TS**	**2.1.15 (11)**	The device should have the external PACER feature as a standard feature in	In these Articles of Technical Specifications, pacer speed has been	Please see the answer to clarification number 50 above.

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			at least the demand and fixed (non-demand) modes. Pacer speed should be adjustable between at least 40 and 150 ppm and pace current should be adjustable between at least 10 and 140 mA in certain intervals.	wanted as between at least 10-140 mA for both entry level and medium level defibrillators. Accepted International Articles show that there is no sense to measure under 35 mA. Ambulance tender made by your Institution at the date of 31.03.2020, defibrillator technical specs of ambulance was "… at least between 35 mA and 140 mA…" We, all, know that ambulances work the hardest conditions, in other words, it is more possible that a defibrillator in ambulance can be used on different kinds of patients. While 35 mA is enough even for this device, why 10 mA (although this value does not make any sense) is wanted for the device for Migrant Health Centres? Even though for the ambulance carrying patient to Migrant Health Services is enough 35 mA, Why Device at Migrant Health Centres MUST measure below 10 mA, it looks like to decrease competition for this tender. Because of these reasons, we would like to ask this article can be changed for both Lot 1 (Article 1.1.15) and Lot 2 (2.1.15.) as "The device should have the external PACER feature as a standard feature in at least the demand and fixed (non-demand) modes. Pacer speed should be adjustable	

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				between at least 40 and 150 ppm and pace current should be adjustable between at least 35 and 140 mA in certain intervals.”	
53	**TS**	**2.1.20 (11-12)**	The device should have a thermal recorder with at least 2 channels. In order for the measurements received from the device to be easily read, width of the thermal paper should be at least 50 mm.	Is the single channel thermal recorder acceptable in the device?	Please see the Corrigendum No: 1 to the TD.
54	**TS**	**2.1.26 (12)**	It should be possible to perform charging, discharging and turning on and off operations easily on the paddles.	In order to strengthen the competition, we kindly request the Contracting Authority to change mentioned specification as follows; It should be possible to perform charging, discharging ***or*** turning on and off operations easily on the paddles.	Please see the Corrigendum No: 1 to the TD.
55	**TS**	**2.1.26 (12)**	It should be possible to perform charging, discharging and turning on and off operations easily on the paddles.	According to the our engineers advices we do not recommend you to prefer this feature because it will effect as for "turning off" from paddles, it can be dangerous and life risk if by chance this button is pushed during shocking. So we kindly ask you to consider above advices for this annex.	Please see the answer to clarification number 54 above.
56	**TS**	**2.1.26 (12)**	It should be possible to perform charging, discharging and turning on and off operations easily on the paddles.	From the first published date of defibrillator tender (including cancelled tenders), we are searching specs of defibrillator devices, making comparison between devices and published technical specifications. We	Please see the answer to clarification number 54 above.

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				examined the all best-known devices in the market. During this stage there is a spec which is changed never: “It should be possible to perform charging, discharging and turning on and off operations easily on the paddles.” We really wonder that which device(s) have specs to perform turning on and off on the paddles? Because we did not find devices (for entry and medium levels) capable of turning on and off on its paddles. Quite the contrary, turning on and off operations are never operated from paddles of defibrillator (to prevent the irremediable process), it is contradictory to manufacturing and using purposes of defibrillator. We also searched AHA and ERC guidelines and we could not see a such kind of advice in those guidelines. Because of these reasons, we ask to remove Article 1.1.26 of Lot 1 and 2.1.26 of Lot 2 or change as “It should be possible to perform charging, discharging on the paddles.”	
57	**TS**	**2.1.26 (12)**	It should be possible to perform charging, discharging and turning on and off operations easily on the paddles.	Can this feature be completely cancelled?	Please see the answer to clarification number 54 above.

#	DOC	ART / ITEM (page #)	CLAUSE	QUESTION	ANSWER
58	**TS**	**2.1.29 (12)**	The device should be resistant to demanding conditions. In this context, monitoring, ECG, defibrillation and pacer modes should be operable after waiting for 1 hour at most in ambient temperature between 5°C and 40°C.	In order to strengthen the competition, we kindly request the Contracting Authority to change mentioned specification as follows; The device should be resistant to demanding conditions. In this context, monitoring, ECG, defibrillation and pacer modes should be operable after waiting for 1 hour at most in ambient temperature between 5°C and (+40)°C ***or 10°C and (+30)°C***	The item remains unchanged considering the needs of the Contracting Authority.
59	**TS**	**2.1.30 (12)**	The device must have an IP (Ingress Protection) class of at least 44.	In order to strengthen the competition, we kindly request the Contracting Authority to change mentioned specification as follows; The device's IP (Ingress Protection) class should be at least ***IPX0***.	Please see the Corrigendum No: 1 to the TD.
60	**TS**	**2.1.30 (12)**	The device must have an IP (Ingress Protection) class of at least 44.	Our device has 32 IP as standard use for hospitals and you do not need 44 IP in hospital. We already providing you carrying bag with our Defibrillator for ambulances use and with carrying bag IP standards become to 44 IP Standards. Could you please clarify is it acceptable or not?	Please see the answer to clarification number 59 above.
61	**TS**	**2.1.30 (12)**	The device must have an IP (Ingress Protection) class of at least 44.	IP class being 44 will decrease product diversity, there will be no competitive environment. For this reason, Is it possible to accept IP class to be 30 and to be	Please see the answer to clarification number 59 above.

#	DOC	ART / ITEM (page #)	CLAUSE	QUESTION	ANSWER
				presented with an extra cover for IP44 (bag etc.)?	
62	**TS**	**2.1.30 (12)**	The device must have an IP (Ingress Protection) class of at least 44.	From the first published date of defibrillator tender including cancelled tenders, many of specs has not been changed but this IP (Ingress Protection) specs has been changed suddenly with these tender specifications. With this change, our defibrillators happened out of tender procedure and our company has been unable to bid for the tender. Older specs for IP class are IPX1 and IP1X for both medium and entry level defibrillators. As we mentioned above, a defibrillator using in ambulance has to meet harder conditions than a defibrillator using in Migrant Health Centres. So, a defibrillator is already working in ambulances for years but that defibrillator will not join to tender because of these specs, we think that this situation is really decreasing competition. Moreover these devices are devices using with their protective/carrying cases. Also this requirement is already wanted in this tender, too (Please see Article 1.1.43 and 2.1.43). These bags are already increasing devices' IP class naturally. Because of this reason why is IP class wanted too high as 44.	Please see the answer to clarification number 59 above.

#	DOC	ART / ITEM (page #)	CLAUSE	QUESTION	ANSWER
				Can a defibrillator with protective case using in a Center be exposed to what kinds of hard conditions; heavy rain, storm, snowstorm etc.? We think that being wanted high level of IP class for these devices are for really decreasing competition. To be able to bid to tender we want to ask for Articles 1.1.30. & 2.1.30. of Lot 1 and Lot 2 to be changed as "*The device's IP (Ingress Protection) class should be at least 22."*	