CHANGES NO: 1 TO TENDER DOSSIER

Contract Title **: Supply of Medical Equipment for the Secondary Healthcare Premises - Relaunch**

Publication Reference **:** SIHHAT/2018/SUP/INT/10-BIS

CN: Contract Notice
TD: Tender Dossier
DOC: Document
ART: Article
ITT: c4b_itt_en [Instructions to Tenderers]*
TS: c4f_annexiitechspeciiitechoffer_en [Annex II + III: Technical Specifications + Technical Offer]*
SC: c4d_specialconditions_en [Special Conditions]*
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]*
Ann IV: Annex IV - Budget breakdown (Model financial offer)
** In-parenthesis parts show the title inside the documents.*

#	DOC	ART / ITEM	FORMER TEXT	SHALL READ AS NEW TEXT
1	TS – General Requirements	3.8.4	The manufacturer and representative and, if any, authorized dealer shall provide service for a fee for at least 10 years after the end of the commercial warranty. Supplier should give all spare parts list of all of required items including price information of each of the items in euros. Supplier should guarantee by a declaration letter that, all spare parts of the required items shall be supplied by the supplier for 10 years period after the warranty period.	**DELETED**
2	TS – General Requirements	3.9	Unless otherwise stated, the contractor at least 2 (two) days free training of at least 2 (two) staff to determine the use, maintenance, calibration, care and possible defects of the device with their trained staff. These trainings will be repeated up to 3 times for each device if requested during the warranty	Unless otherwise stated **(please see technical specifications for each Lot for the specific requirements of each Lot)**, the contractor at least 2 (two) days free training of at least 2 (two) staff to determine the use, maintenance, calibration, care and possible defects of the

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			period. This requirement will be certified by the contractor in the tender file. The date and place which will be determined by the center. Documents and equipment's required for training shall be met by the Contractor.	device with their trained staff. These trainings will be repeated up to 3 times for each device if requested during the warranty period. This requirement will be certified by the contractor in the tender file. The date and place which will be determined by the center. Documents and equipment's required for training shall be met by the Contractor.
3	TS – General Requirements	4	**4. Definitions** Ultrafiltration: Liquid removal from the body Device: Hemodialysis Machine ml / min: milliliter per minute mS / cm: milliemens per centimeter TMP: Transmembrane pressure UF: Ultrafiltrasyon	**DELETED**
4	TS – General Requirements	5.4		

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5	TS	1.1	The device should be a still produced model designed for the newborn patient group (babies between 500 gr-1 kg). Adult devices with uploaded newborn software or devices which can also work for adults shall not be accepted. If demanded in the future, HFO/HFOV/HFV feature software and/or hardware shall be uploaded in the device without a change in the brand and model. The companies shall present the manufacturer document with apostille approval indicating that this is possible in their tender files.	The device should be a still produced model designed for the newborn patient group (babies between 500 gr-**10** kg). Adult devices with uploaded newborn software or devices which can also work for adults shall not be accepted. If demanded in the future, HFO/HFOV/HFV feature software and/or hardware shall be uploaded in the device without a change in the brand and model. The companies shall present the manufacturer document with apostille approval indicating that this is possible in their tender files.
6	TS	1.4	The device should work in the ventilation modes defined below. Modes should be present in every device as standard. All modes should work for newborn patient group and they should be pressure controlled suitable for newborn ventilation and/or they should work with the volume limit principle.	The device should work in the ventilation modes defined below. Modes should be present in every device as standard. All modes should work for newborn patient group and they should **work with pressure control suitable** for newborn ventilation and/or they should work with the volume limit principle.
7	TS	1.6	Freeze and save buttons should be present on the device, wave forms and loops should be frozen or saved as instant images.	There should be freeze or save button on the device and wave forms **or** loops should be frozen or saved as instant images.
8	TS	1.10	The concentration of the oxygen going to the patient should be adjusted from %21-%100 on the device and the adjusted value and the actual value read by the sensor should be monitored separately from the device's integrated monitor.	The **oxygen concentration that** going to the patient should be adjusted between %21-%100 on the device and the adjusted value and the actual value read by the sensor should be monitored separately from the device's integrated monitor.
9	TS	1.11	The "Flow Sensor" of the device should be mounted on the Y-part. Thus, the measurements should indicate the exact values going to the patient. Differences resulting from the patient circuit shouldn't affect the measurement results and apnea, tube obstruction or disconnection situations should be detected.	The "Flow Sensor" of the device should be mounted on the Y-part. Thus, the measurements should **display** the exact values going to the patient. Differences resulting from the patient circuit shouldn't affect the measurement results and apnea, tube obstruction or disconnection situations should be detected.

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10	TS	1.12	The inspiration line of the device, through which clean gas mixture passes, should be stable, the expiration line should be easily removable for sterilization or inspiration and expiration line should be on a separate sterilizable block on which moisturizing jar can be placed.	The inspiration line of the device, through which clean gas mixture passes, should be stable; the expiration line should be easily removable for sterilization or on the same sterilizable block where inspiration and expiration line moisturizing jar can be installed.
11	TS	1.13	The device has a fixed key for manual ventilation on the device or a touch key on the display and the keypad must not contain any other functions for easy operation.	There should befixed key on the device for manual ventilation or a touch key on the display and the keypad must not contain any other functions for the sake of easy operation.
12	TS	1.16	3 (three) waveforms and 2 breathing cycles or 4 waveforms should be monitored at the same time in the internal screen of the device. In addition, respiratory cycles (P / F, P / V, V / F) should be monitored.	3 (three) waveforms and 2 breathing cycles or 4 waveforms should be monitored at the same time **on** the internal screen of the device. In addition, respiratory cycles (P / F, P / V, V / F) should be monitored.
13	TS	1.17.1	The humidifier unit of the device should be designed for use in neonatal patients. If the heated humidification unit to be supplied has an automatic (servo) operating principle, the control panel should operate with no additional adjustment, except the patient being intubated or masked by ventilation. The moisture performance of the device should be at least 33 mg / liter in intubation mode and at least 10 mg / liter in mask mode. The measuring cable to be used with the device must be able to supply the heat from both points (via the ports on the inspiration line) heat from the single point (from the port near the chamber on the inspiration line). If the heated humidification unit to be supplied doesn't have a fully automatic operation principle, the temperature control should be made on the control panel of the device. Heat changes should be made with the help of different keys. The device must provide natural moisture to the patient at each flow rate.	The humidifier unit of the device should be designed to be used for neonatal patients. If the heated humidification unit to be supplied has an automatic (servo) operating principle; the control panel should operate without the need for anyadditional adjustment, except the for the selection that patient is ventilated via intubationor mask. The moisture performance of the device should be at least 33 mg / liter in intubation mode and at least 10 mg / liter in mask mode. The measuring cable to be used with the device must be able to supply the heat from both points (via the ports on the inspiration line) and from the single point (from the port near the chamber on the inspiration line). If the heated humidification unit to be supplied doesn't have a fully automatic operation principle, the temperature control should be made on the control panel of the device. Heat changes should be made with the help of different keys.

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			Measure should be made with a heat probe that performs temperature measurement at two points in the humidifier.	The device must provide natural moisture to the patient at each flow rate. Measurement should be made with a heat probe that performs temperature measurement at two points in the humidifier.
14	TS	1.17.2	There must be a digital display on the device that continuously displays the airway gas temperature. The temperature of the water tank at the same display with a button and the sensor temperature at the end of the patient circuit must be displayed separately and the sets to be used in the device must have the heater assembly. In order to prevent misuse and possible problems (infection, condensation, etc.), a producer approved set must be used which is fully compatible with the humidification system.	There must be a digital display on the device that continuously displays the airway gas temperature. The temperature of the water chamber and the sensor at the end of patient circuit must be displayed separately in the same indicator with a button and the sets to be used in the device must have the heater assembly. In order to prevent misuse and possible problems (infection, condensation, etc.), a producer approved set must be used which is fully compatible with the humidification system.
15	TS	1.17.3	If the heated humidification unit to be supplied has a fully automatic (servo) operating principle, the temperature of the device in intubation mode should be at least 33.5 C-37 C. The temperature of the device in mask mode must be at least 31 ° C to 34 ° C. Alarm status of the device should be monitored visually and audibly from the control panel. If the heated humidification unit to be supplied does not have these properties, it must have the following characteristics: When the device is in IPPV (Invasive) mode, the patient end outlet temperature of the circuit should be 40 C and the chamber outlet temperature should be 37 C. In hypothermic and hyperthermic patients, the user should be able to increase in 1 degree according to his / her needs in manual mode, and adjust the chamber outlet temperature between 26 and 43 ° C and the patient end outlet temperature between 30 and 40 ° C. The device must alarm if the temperature set at the patient end probe of the circuit is below 2 C or above 43 C or if the set	If the heated humidification unit to be supplied has a fully automatic (servo) operating principle; the temperature of the device should automatically work at least between 35.5 °C-37 °C. The temperature of the device in mask mode should automatically work between 31 °C and 34 °C. Alarm statuses of the device should be tracked from the control panel visually and audibly or if the heated humidification unit to be supplied does not have this feature, it should have the features below. In IPPV (invasive) mode, the device should work automatically in the way that the patient end outlet temperature of the circuit is 40 °C and the chamber outlet temperature is 37 °C. For hypothermic and hyperthermic patients, the user shall be able to a adjust the chamber outlet temperature between 26 °C and 43 °C and the patient end outlet temperature between 30 °C and 40 °C by increments of 1 °C according to the need. In case the temperature set at

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			temperature is below for 4 C. The device must alarm if the measured temperature of the probe at the reservoir outlet is 4 ° above or below the set temperature for 20 minutes.	the patient end probe of the circuit is 2 °C above the set temperature, above 43 °C or 4 °C below the set temperature, the device must alarm. The device must alarm if the temperature measured at the probe in the chamber outlet is 4 °C above or below the set temperature for 20 minutes.
16	TS	1.17.4	The device must have the following accessories. The accessories must be the same brand as the heating humidifier and must be approved by the manufacturer so that they do not affect device performance or patient health negatively. - Sensor cable measuring the flow or passing gas flow - Heater connecting cable compatible with single and double heater circuits which connects the patient circuit heater wire to the humidifier.	The device must have the following accessories. The accessories must be the same brand as the heating humidifier and must be approved by the manufacturer so that they do not affect device performance or patient health negatively. - Sensor cable measuring the **heat** or passing gas flow - Heater connecting cable compatible with single and double heater circuits which connects the patient circuit heater wire to the humidifier.
17	TS	1.18	The following measured values must be monitored digitally on the internal monitor of the device: Pressure measurements: Numerical values: - Peak Pressure (Ppeak) - PEEP Pressure - Airway Average Pressure (Pmean) Graphical indicators: Pressure Bar Graph or Airway Pressure	The following **measurement** values must be monitored digitally on the internal monitor of the device: Pressure measurements: Numerical values: - Peak Pressure (Ppeak) - PEEP Pressure - Airway Average Pressure (Pmean) Graphical indicators: Pressure Bar Graph or Airway

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			Curve Flow and Volume Measurements Numerical values: - Tidal volume (Vt) - Leakage amount (Leaking % or ml) - Spontaneous volume of the patient (Mvspon) or Minute volume (MV) / Vmin - Respiratory frequency -RVR (Rate Volume Ratio) or ET tube leakage or leakage Graphical indicators: Airway flow curve Patient Liver Measurements: - Respiratory system compliance measurement -C - Resistance measurement – R	Pressure Curve Flow and Volume Measurements Numerical values: - Tidal volume (Vt) - Leakage amount (Leaking % or ml) - Spontaneous volume of the patient (Mvspon) or Minute volume (MV) / Vmin - Respiratory frequency -RVR (Rate Volume Ratio) or ET tube leakage or leakage Graphical indicators: Airway flow curve Patient Liver Measurements: - Respiratory system compliance measurement -C - Resistance measurement – R
18	TS	1.19	The device must contain the following alarms: - Air and oxygen shutdown alarm or gas pressures low alarm -System failure alarm	The device must contain the following alarms: - Air and oxygen shutdown alarm or gas pressures low alarm -System failure alarm

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			-High airway pressure alarm - Low airway pressure alarm or PEEP alarm - High and low oxygen concentration alarm or oxygen value deviation alarm - Flow sensor failure alarm - Flow sensor blocked (dirty) alarm or flow sensor failure -Disconnection or cycle fail alarm (leakage or connection error in the patient circuit) - High minute volume alarm - Low minute volume alarm - Low tidal volume alarm or low minute volume alarm - Apnea alarm - Endotracheal tube clogged alarm or high pressure alarm in the inspiratory tube or airway pressure or P Op high alarm - Blockage in the patient circuit or high airway pressure or resistance height alarm or inspiration-expiratory tube alarm (Against the increase in resistance due to clogging or curling in the patient circuit)	-High airway pressure alarm - Low airway pressure alarm or PEEP alarm - High and low oxygen concentration alarm or oxygen value deviation alarm - Flow sensor failure alarm **- Oxygen sensor failure alarm** - Flow sensor **clogged** (dirty) alarm or flow sensor failure -Disconnection or cycle fail alarm (leakage or connection error in the patient circuit) - High minute volume alarm - Low minute volume alarm - Low tidal volume alarm or low minute volume alarm - Apnea alarm - Endotracheal tube clogged alarm or high pressure in the inspiratory tube alarm or high airway pressure alarm or P Op high alarm - **Clogging** in the patient circuit or high airway pressure or resistance height alarm or inspiration-expiratory tube alarm (Against the increase in resistance due to clogging or curling in the patient circuit)

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19	TS	1.20	Of the alarms defined above, upper and lower limits of all alarms except from “High and low minute volume alarm” and “Apnea alarm” should be determined by the device automatically or all alarms should be saved using autoset. This means that the alarm limits need not be changed by the user after parameter adjustments.	Of the alarms defined above, the device should automatically determine upper and lower limits of all alarms except from “High and low minute volume alarm and Apnea alarm” or all alarms should be set automatically with auto-set function;so there will be no need change the alarm limits by the user following the parameter adjustments.
20	TS	1.24	The device must have separate oxygen and medical air gas inlets on.	The device must have separate oxygen and medical air gas **inputs.**
21	TS	1.25	The expiratory valve or exhalation blog of the expiratory line in which the patient circuit in contact with the patient breath in the device is inserted must be removed without any tools and autoclaved with steam.	The expiratory valve or exhalation block belonging to the expiratory line in which the patient circuit contacting with the patient breath in the device is inserted must be removed without the need of any tools and it should be able to be autoclaved with steam.
22	TS	1.26	There should be a led indicator on the device or on the uninterruptible power supply indicating the electrical connection. In the absence of the mains supply, the user must be warned by the battery indicator of the device or uninterruptible power supply.	There should be a led indicator on the device or on the uninterruptible power supply indicating the electrical connection. In the absence of the mains supply, the battery indicator of the device or uninterruptible power supply indicator must warn the user.
23	TS	1.27	In the event of a power failure, an internal battery or uninterruptible power supply must be provided to supply the ventilator device for at least 30 minutes, including the display.	An internal battery or uninterruptible power supply must be provided, which will supply the ventilator device, including the screen, for at least 30 minutes in the event of a power failure.
24	TS	1.28	Pressure-Volume, Pressure-Flow, Flow-Volume breathing cycles must be monitored via the instrument display.	Pressure-Volume, Pressure-Flow, Flow-Volume respirator cycles should be monitored via the device display.

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25	TS	1.30	**Materials To Be Supplied With The Ventilator** The following accessories will be provided for the operation of the device together with the ventilator and their suitability for the current system will be indicated. 1- Oxygen central system connection hose: 1 pc 2- Central system air connection hose: 1 pc 3- Dual line heated disposable air circuit (Inspiration and expirium line heater assembly) should be present. The disposable Chamber with automatic filling must be double float. In addition, there must be a pressure flow limiter for the pressure-controlled mechanical ventilators in the set package. Devices of the companies that offer mechanical ventilator with this feature should be fully compatible. All parts (chamber, patient set, flow limiter and other accessories) must be the same brand with moisturizing device and original. Disposable sets of materials from different manufacturers shall not be accepted. :20 pcs 4- Disposable nasal CPAP set: 10 sets (Each nasal set will contain prong, mask, bone, and interconnection devices, if any. Prong, mask and bone should have different size options.) 5- Suspension arm for patient circuit: 1 piece 6-Reusable flow sensor. For systems with hot wire principle: 5	**Materials To Be Supplied With The Ventilator** The following accessories will be provided for the operation of the device and their suitability for the current system will be indicated. 1- Oxygen central system connection hose: 1 pc 2- Central system air connection hose: 1 pc 3- Dual line heated disposable air circuit (Inspiration and expirium line heater assembly)should be provided. The disposable Chamber with automatic filling must be double floated. In addition, there must be a pressure flow limiter for the mechanical ventilators with pressure control in the set package. Devices of the companies that offer mechanical ventilator with this feature should be fully compatible. All parts (chamber, patient set, flow limiter and other accessories) must be original and the same brand with moisturizing device.. Disposable sets of materials from different manufacturers shall not be accepted. :20 pcs 4- Disposable nasal CPAP set: 10 sets (Each nasal set will contain prong, mask, bone, and if any, interconnection devices. Prong, mask and bone should have different size options.) 5- Sling arm for patient circuit: 1 pc 6- For systems working with hot wire principle, reusable

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			pcs 7- Test lung: 1 piece 8- Humidifier unit and accessories: 1 pc 9- Expiration or exhalation set (full set): 1 pc	flow sensor: 5 pcs 7- Test lung: 1 piece 8- Humidifier unit and accessories: 1 pc 9- Expiration or exhalation set (full set): 1 pc
26	TS	1.31	In the future, when the device is requested to add HFO, the software and hardware HFO cost must not exceed 15% of the unit price offered.	In the future, when it is requested to add HFO to the device the HFO software and hardware cost must not exceed 15% of the offered unit price.
27	TS	1.32	The document/certificate provided by the contractor, which is valid during the examination, given by the accredited company/firm or institution which performed calibration indicating the calibration of all devices and measurement tools to be used during examinations is performed shall be presented to examination and acceptance commission during examinations.	The document/certificate provided by the contractor, which indicates that the calibration of all devices and measurement tools to be used during examinations is performed and which is valid during the examination, given by the accredited company/firm or institution which performed calibration, shall be presented to examination and acceptance commission during examinations.
28	TS	1.33	The devices to be delivered by the contractor shall have at least 5 (five) years of warrantee period after they are accepted. The contractor is responsible for arranging the warranty documents belonging to these devices in the name of the administration and presenting their original copies to the administration. In case it is not possible to arrange warranty documents of the received devices in the name of the administration, the Contractor is obliged to present a document containing warranty undertakings to the administration. The contractor shall undertake the removal of the faults, defects and deficiencies determined in the device under the scope of warranty within the duration of the contract by the warranty	The devices to be delivered by the contractor shall have at least 5 (five) years of warranty following the provisional acceptance. The contractor is obliged to arrange the warranty documents of the devices in the name of the administration and present as original to the administration. In case it is not possible to arrange warranty documents in the name of the administration, the Contractor is obliged to present a document containing warranty undertakings to the administration. The contractor shall undertake to enable removal of the faults, defects and deficiencies determined in the device by the warranty providing person or institution under the scope of warranty within the duration

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			provider person or institution. In case this obligation is not fulfilled by the contractor, the administration shall deduct all cost for the provision of the warranty from the receivables of the contractor or collect the costs by forfeiting.	of the contract. In case this obligation is not fulfilled by the contractor, the administration shall deduct all cost for the provision of the warranty from the receivables of the contractor or collect the costs by forfeiturıng.
29	TS	1.34	During the warranty period, the contractor shall realize the periodical maintenances of the device (not being less than 4 times a year) in place, all expendables being its own.	During the warranty period, the contractor shall realize the periodical maintenances of the device (not being less than 4 times a year) in place, at its own expense including all expendables.
30	TS	1.35	Before the contract is signed, the contractor is obliged to present the price list of all spare parts, accessories and expendables including lifed parts with no exceptions in the tender offer file, which will not exceed %150 of the unit device price. All parts, the types or amounts of which are not included in the price list of all spare parts, accessories and expendables including lifed parts with no exceptions by the contractor shall be provided during the warranty period and for 5 years after the warranty if the administration demands free of any charges under the name of workmanship, assembly etc.	Before the contract is signed, the contractor is obliged to present the price list of all spare parts, accessories and expendables including life-limited parts with no exceptions in the tender offer file, which will not exceed %150 of the unit device price. All parts, the types or amounts of which are not included in the price list of all spare parts, accessories and expendables including life-limited parts with no exceptions by the contractor shall be provided during the warranty period and for 5 years after the warranty if the administration demands free of any charges under the name of workmanship, assembly etc.
31	TS	1.36	Software received along with the device shall continuously be controlled and upgraded. Existing software delivered along with the device should be the latest version. During the warranty period and during an additional duration in case a contract is made after warranty by the administrations, the latest versions of the software given with the device shall be uploaded free of charge.	Software received along with the device shall continuously be controlled and upgraded. Existing software delivered along with the device should be the latest version. During the warranty period and during an additional duration in case a contract is made after warranty by the administrations, the latest versions of the software given with the device shall be uploaded free of charge.

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32	TS	1.37	The contractor shall deliver a copy of spare part price list to the health facilities in the examination and acceptance stage. Within the 5 years after the warranty, if the health facilities demand spare parts, accessories and expendables including lifed parts with no exceptions, the demands of the health facilities shall be met on condition that the financial amount defined in this list being the upper limit. Sales cannot be offered by the contractor by demanding any price or additional price under the name of exception or out of coverage.	The contractor shall deliver a copy of spare part price list to the health facilities in the examination and acceptance stage. Within the 5 years after the warranty, if the health facilities demand spare parts, accessories and expendables including life-limited parts with no exceptions, the demands of the health facilities shall be met on condition that the financial amount defined in this list being the upper limit. Sales cannot be offered by the contractor by demanding any price or additional price under the name of "exception" or "out of scope".
33	TS	1.44	If the property breaks down within the warranty period due to faults of material and workmanship, the contractor is obliged to make or provide repair service free of any charges under the names of changed part, workmanship cost etc.	If the property breaks down within the warranty period due to faults of material, assembly and workmanship, the contractor is obliged to make or provide repair service free of any charges under the names of changed part, workmanship cost etc.
34	TS	1.46	Starting from the date the property is delivered to the administration, on condition of being within the warranty durations defined above, if the same fault occurs more than 2 times or different faults occur more than 4 times in one year, or the total number of different faults is more than 10 within the defined duration of warranty and this faults result in not being able to benefit from the property, the contractor is obliged to replace the property. However, if the property consists of more than one unit, contractor is obliged to replace the faulty unit or units only.	Starting from the date when the property is delivered to the administration, on condition of being within the warranty durations defined above, if the same fault occurs more than 2 times or different faults occur more than 4 times in one year, or the total number of different faults is more than 10 within the defined duration of warranty and this faults result in not being able to benefit from the property, the contractor is obliged to replace the property. However, if the property consists of more than one unit, the contractor is obliged to replace the faulty unit or units only.
35	TS	2.3	The device should operate via internal turbine system or micro piston system or injector principle and it shouldn't require an external compressor or pressure air source.	The device should operate via internal turbine system or micro piston system or injector principle and it shouldn't require an external compressor or pressure air source for

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				the operation.
36	TS	2.4	The device should work for the respiration types indicated below. a) Volume-controlled b) Pressure-controlled c) Pressure-supported d) Spontaneous	The device should work **at least** with the respiration types indicated below. a) Volume-controlled b) Pressure-controlled c) Pressure-supported d) Spontaneous
37	TS	2.5	In the ventilator, the parameters defined below should be adjusted at least in defined intervals. a) Tidal volume: 50-200 ml b) Respiration frequency: 5-60 breathes/minute c) Inspiration time: 0.3-3.0 seconds or I:E ratio is at least 1:4- 3:1 d) PEEP/CPAP: 0/off-20 cmH_2O e) Pressure Control Ventilation Mode Pressure (PCV pressure/Pinsp): 5-55 cm H_2O f) Spontaneous Respiration Pressure Support (PSV Pressure): 2-35 cmH_2O g) FiO_2: Should be adjusted at least between %40-%100 h) Flow value should go up to 100 liters/minute at least. i) Pressure Triggering: Between (-9) and (0,1) cmH_2O or flow trigger should be between 1 and 9 liter/minute at least.	In the ventilator, the parameters defined below should be adjusted at least in defined intervals. a) Tidal volume: 50-**2000** ml b) Respiration frequency: 5-60 breathes/minute c) Inspiration time: 0.3-3.0 seconds or I:E ratio is at least 1:4-3:1 d) PEEP/CPAP: 0/off-20 cmH_2O e) Pressure Control Ventilation Mode Pressure (PCV pressure/Pinsp): 5-55 cmH_2O f) Spontaneous Respiration Pressure Support (PSV Pressure): 2-35 cmH_2O g) FiO_2: Should be adjusted at least between %40-%100 h) Flow value should go up to 100 liters/minute at least. i) Pressure Triggering: Between (-9) and **(-0.1**) cmH_2O or flow trigger should be between 1 and 9 liter/minute at least.
38	TS	2.6	The device should have respiration modes with the parameters written below. a) Assisted/ Volume-controlled Forced Respiration (A/CMV-V.AC)	The device should have respiration modes with the parameters written below. a) Assisted/ Volume-controlled **Mandatory** Respiration (A/CMV-V.AC)

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			b) Pressure Controlled Synchronized Interval Forced Respiration (P-SIMV-PC-BIPAP/PS) c) Volume Controlled Synchronized Interval Forced Respiration (/V-SIMV-VC-SIMV) d) Pressure Supported Ventilation (PSV) or Spontaneous Respiration (SPONT-SpnCPAP/PS) e) Continuous Positive Airway Pressure (CPAP-SpnCPAP) f) Back-up ventilation or apnea back-up ventilation	b) Pressure Controlled Synchronized Interval **Mandatory** Respiration (P-SIMV-PC-BIPAP/PS) c) Volume Controlled Synchronized Interval **Mandatory** Respiration (/V-SIMV-VC-SIMV) d) Pressure Supported Ventilation (PSV) or Spontaneous Respiration (SPONT-SpnCPAP/PS) e) Continuous Positive Airway Pressure (CPAP-SpnCPAP) f) Back-up ventilation or apnea back-up ventilation
39	TS	2.11	Alarm limits of the device should be adjustable by the user.	Alarm limits of the **ventilator** should be adjustable by the user.
40	TS	2.15	The structure of the ventilator should have an at least 4,5 inch internal TFT or LCD and Electro-Luminescence (EL) screen from which the monitorized parameters and alarm status can be monitored in writing.	There should be an internal TFT or LCD or Electro-Luminescence (EL) screen at least 4,5 inch in dimension, through which monitorized parameters and alarm statuses can be monitored in writing, in the structure of the ventilator.
41	TS	2.20	Those shall be provided with each device: a) 3 adult type, 3 pediatric type reusable respiration circuit and current sensors and/or 3 expiratory valve systems or cassettes. b) One original carrier bag and stand, oxygen tube of 3,5 lt and regulator clock, assembly apparatus for patient's bed or carrier. c) At least 2 meters long oxygen hose and required lock clip, sleeves, connectors etc.	The followings shall be provided with each device: d) 3 adult type, 3 pediatric type reusable respiration circuits and current sensors and/or 3 expiratory valve systems or cassettes. e) One original carrier bag and stand, 3.5 lt oxygen tube and regulator clock, assembly apparatus for patient's bed or stretcher. f) At least 2 meters long oxygen hose and required lock clip, sleeves, connectors etc.
42	TS	2.33	If the property breaks down within the warranty period due to faults of material and workmanship, the contractor is obliged to make or provide repair service free of any charges under the names of changed part, workmanship cost etc.	If the property breaks down within the warranty period due to faults of material, assembly and workmanship, the contractor is obliged to make or provide repair service free of any charges under the names of changed part,

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				workmanship cost etc.
43	TS	3.7	The system must be able to connect to PACS, RIS and HIS. For this reason, DICOM 3.0 must include all components of communication protocols (send / receive, store, storage commitment, worklist HIS / RIS) and comply with MPPS standards. They should be included in the system. There must be a worklist function to remove manuel input of patient data from the PACS system to take patient data from the PACS and to send images to the PACS.	The system must be able to connect to PACS, RIS and HIS, for this reason, all components of DICOM 3.0 communication protocols should be included and (send / receive, store, storage commitment, worklist HIS / RIS) and comply with MPPS standards and they should be included in the system. There must be a worklist function to remove manuel input of patient data from the PACS system to take patient data from the PACS and to send images to the PACS.
44	TS	3.10.10	There will be a tube heating indicator on the display or control panel and the tube status will be checked here.	There will be a tube heating indicator on the display or control panel and the tube status will be **tracked** here.
45	TS	3.12.2	The X-ray tube should be double-focused. Small focus size should not be more than 0.3 mm, the largest focus size should be no more than 0.6 mm.	X-ray tube should be double focused. The small focus dimensions shall be 0.3 mm at most and the large focus dimension shall be at least 0.6 mm.
46	TS	3.12.4	Anode cooling heat capacity shall be at least 73.000 HU / min.	Anode cooling capacity shall be at least 73.000 HU / min.
47	TS	3.12.6	There will be 0.1 mm copper (Cu) and 3 mm aluminum (Al) filter to filter out the harmful emission rays at the tube outlet.	There will be 0.1 mm copper (Cu) and 3 mm aluminum (Al) filter at the tube outlet to filter the harmful emission rays.

#	DOC	ART / ITEM	FORMER TEXT	SHALL READ AS NEW TEXT
48	TS	3.12.7	The system must have at least one of the following special software that improves the image quality. Companies will show this feature in their original catalogs. EASY (Enhanced Acquisition System) with automatic dose adjustment.	The system must have at least one of the following special software that improves the image quality. Companies will show this feature in their original catalogues: - EASY (Enhanced Acquisition System) with automatic dose adjustment - ODDC (Object Detected Dose Control) that can make automatic dose adjustment by detecting object and motion - Anatomically Programmed Fluoroscopy (APF) control system - A feature that automatically adjusts contrast and brightness and ensure the production of sharp, low-dose images (IDEAL: Intelligent Dose Efficiency Algorithm)
49	TS	3.12.7.1	EASY (Enhanced Acquisition System) with automatic dose adjustment.	**DELETED**
50	TS	3.12.7.2	ODDC (Object Detected Dose Control) that can make automatic dose adjustment by detecting object and motion.	**DELETED**
51	TS	3.12.7.3	ODDC (Object Detected Dose Control) that can make automatic dose adjustment by detecting object and motion.	**DELETED**
52	TS	3.12.7.4	A feature that automatically adjusts contrast and brightness to produce sharp, low-dose images (IDEAL: Intelligent Dose Efficacy Algorithm).	**DELETED**

#	DOC	ART / ITEM	FORMER TEXT	SHALL READ AS NEW TEXT
53	TS	3.13.2	There will be a laser or illuminated centering mechanism at the image amplifier section.	The image amplifier section will have a laser or lighted centering device.
54	TS	3.14.1	The image amplifier must be at least 12 inches in diameter.	The diameter of image amplifier must be at least 12 inches
55	TS	3.15.3	The image processing features of the system should be able to keep the final image on the monitor.	The image processing features of the system should include feature that is able to keep the final image on the monitor.
56	TS	3.15.4	There must be special software in the system that improves the image quality. There should be ODDC (Object Detected Dose Control) which can adjust dose automatically by perceiving object and motion, EASY (Enhanced Acquisition System) or the property which generates sharp and low dose images by automatically adjusting the contrast and brightness or the filter which reduces the motion blur by perceiving the dynamic motion due to motion adaptation and asymmetrical double-leaf collimator (IDEAL: Intelligent Dose Efficiency Algorithm). Companies will show these features in their original catalogs.	There should be special software in the device which improves the image quality. There should be ODDC (Object Detected Dose Control) or EASY (Enhanced Acquisition System) which can make automatic dose adjustment by detecting object and motion or the filter which reduces motion blur by detecting dynamic motion by means of motion adaptation and double leaf collimator which can function asymmetrically or the property (IDEAL= Intelligent Dose Efficiency Algorithm) which enables the formation sharp images with low dose by automatically setting the contrast and brightness in the device. The companies shall indicate this property in original catalogues.
57	TS	3.15.8	The image should be converted to negative and can be enlarged.	The image should be converted to negative and can be enlarged.
58	TS	3.16.1	Monitors must be mounted on a stand-alone stand or on a stand-up bracket separate from the C-arm system.	Monitors must be mounted on a mobile stand separated from the C-arm or stative.

#	DOC	ART / ITEM	FORMER TEXT	SHALL READ AS NEW TEXT
59	TS	3.16.3	Monitors should be on a separate transport stand, only the monitors should be rotated 180 degrees without moving the tripod or the live image should be rotated up to 180 degrees in total with the touch control panel displayed and should be able to tilt.	Monitors should be on a separate transport stand, if needed only the monitors should be rotated at 180° without moving the tripod or the live image should be rotated up to 180° in total with the touch control panel displayed and they should be able to tilt.
60	TS	3.17.2	The following features and amounts of radiation shielding will be delivered.	Radiation shielding with the following features and amounts shall be delivered. - 4 skirt-vest lead aprons which are easy to wear (with touch fasteners on the shoulder) in sizes of 1 large, 1 small and 2 medium sizes, which don't contain lead, the weight of which will be at most 10 kg in 0.5 mm Pb equivalent or at most 4 kg in 0,5 mm Pb equivalent. - 1 adult male, 1 adult female and 1 pediatric gonad protectors which do not contain lead in 0,5 Pb equivalent or equal to 0,5 mm Pb - 2 adult, 1 pediatric thyroid protectors which do not contain lead in in 0,5 Pb equivalent or equal to 0,5 mm Pb
61	TS	3.17.2.1	4 skirt-vest lead aprons which are easy to wear (side adhesive instead of shoulder), 1 large, 1 small and 2 medium sizes, which don't contain lead, the weight of which will be at most 10 kg in 0.5 mm Pb equivalent or at most 4 kg in 0,5 mm Pb equivalent.	**DELETED**
62	TS	3.17.2.2	1 adult male, 1 adult female and 1 pediatric gonad protectors not containing lead in 0,5 Pb equivalent or 0,5 mm Pb equivalent.	**DELETED**
63	TS	3.17.2.3	2 adult, 1 pediatric thyroid protectors not containing lead in in 0,5 Pb equivalent or 0,5 mm Pb equivalent.	**DELETED**

#	DOC	ART / ITEM	FORMER TEXT	SHALL READ AS NEW TEXT
64	TS	4.4	The device will operate at 220-230 Volts and 50-60 Hz. The device will not be affected by 10-12% voltage changes. The amount of electricity and water spent during dialysis and disinfection will be indicated.	The device will operate at 220-230 Volts and 50-60 Hz. The device will not be affected by ±10-12% voltage fluctuations. The amount of electricity and water spent during dialysis and disinfection will be indicated.
65	TS	4.6	The data on the display of the device should be in Turkish or the buttons should be expressed as symbols.	The data on the display of the device should be in Turkish or the buttons should be expressed with symbols.
66	TS	4.7	All treatment options on the device screen should be easily adjusted by the user.	All treatment options should be easily adjusted by the user on the device screen.
67	TS	4.9	All parameters related to dialysis treatment, fluid to be withdrawn, amount of fluid to be withdrawn per hour and remaining time should be monitored and changed. The user should be warned with sound and light when the desired fluid extraction is completed.	All parameters related to dialysis treatment, fluid to be extracted, amount of fluid to be extracted per hour and remaining time should be monitored and modified on the display. The user should be warned with audible alarm and illuminated alarm when the desired fluid extraction is completed.
68	TS	4.10	The device must be screened and microprocessor-controlled or equipped with digital indicators.	The device should have screen, microprocessor control and it should be equipped with digital indicators.
69	TS	4.11	The device must deliver the amount of ultrafiltration between 0 and 4000 ml / h. It should operate on the basis of volume ultrafiltration and the amount of UF drawn must be equal to the liquid.	The device must deliver the amount of ultrafiltration between 0 and 4000 ml / h with precision. It should operate on the basis of volume ultrafiltration and the amount of UF drawn must be equal to the liquid.
70	TS	4.12	The air and blood leakage alarm system in the device should be audible, lighted and sensitive. In the event of an alarm, the hemodialysis procedure should stop automatically.	The air and blood leakage alarm system in the device should be audible, illuminated and sensitive. In the event of an alarm, the hemodialysis procedure should stop automatically.

#	DOC	ART / ITEM	FORMER TEXT	SHALL READ AS NEW TEXT
71	TS	4.22	The single needle click-on system should be standard in the device. In case of fistula occlusion during normal dialysis, single needle click-on dialysis should be started.	The single needle click-clack system should be standard in the device. In case of fistula occlusion during normal dialysis, single needle click-clack dialysis should be started.
72	TS	4.25	Aeteriovenous sets to be used in the device should not be manufactured according to a single company, all universal arteriovenous sets should be used and adjustments should be made easily. Written declaration must be given in this regard.	Arteriovenous sets to be used in the device should not be manufactured according to a single company, all universal arteriovenous sets should be used with the device and adjustments should be made easily. Written commitment shall be included in the tender dossier in this regard.
73	TS	4.27	The device should perform high-flux dialysis treatment using high permeable membranes.	The device should perform high-flux dialysis treatment by using high permeable membranes.
74	TS	4.29	When the dialysis features are out of the limit, the device will alarm and the device will automatically stop the flow and switch to the by-pass position.	When the dialysis features are out of the limit, the device should alarm and the device should automatically stop the dialysate flow and switch to the by-pass position.
75	TS	4.33	The dialysate temperature of the device should be in the range of 35 ° C to 39 ° C and should be adjusted to a maximum of 10 (ten) ml / min.	The dialysate temperature of the device should be between 35 ° C to 39 ° C interval and it should be adjusted with 10 (ten) ml / min. increments max.
76	TS	4.35	The device must conform to the endotoxin filter to keep the endotoxins in the dialysis.	The device must be suitable for the endotoxin filter affixation to keep the endotoxins in the dialysis.
77	TS	4.38	The device must be capable of self-test. The test program should detect the current fault and calibration errors in the system, alert the users, and cover all electronic, electromechanical and hydromechanical sections.	The device must be capable of self-test. The test program should detect the current fault and calibration errors in the system, alert the users, cover all electronic, electromechanical and hydro-mechanical sections.

#	DOC	ART / ITEM	FORMER TEXT	SHALL READ AS NEW TEXT
78	TS	4.43	The document/certificate provided by the contractor, which is valid during the examination, given by the accredited company/firm or institution which performed calibration indicating the calibration of all devices and measurement tools to be used during examinations is performed shall be presented to examination and acceptance commission during examinations.	The document/certificate provided by the contractor, which indicates that the calibration of all devices and measurement tools to be used during examinations is performed and which is valid during the examination, given by the accredited company/firm or institution which performed calibration shall be presented to examination and acceptance commission during examinations.
79	TS	4.45	During the warranty period, the contractor shall realize the periodical maintenances of the device (not being less than 4 times a year) in place, all expendables being its own.	During the warranty period, the contractor shall realize the periodical maintenances of the device (not being less than 4 times a year) in place, all expendables being its own. Endotoxine filters shall be changed once in at least 3 (three) months in a year free of charge during the warranty period within this scope.
80	TS	4.46	Before the contract is signed, the contractor is obliged to present the price list of all spare parts, accessories and expendables including lifed parts with no exceptions in the tender offer file, which will not exceed %150 of the unit device price. All parts, the types or amounts of which are not included in the price list of all spare parts, accessories and expendables including lifed parts with no exceptions by the contractor shall be provided during the warranty period and for 5 years after the warranty if the administration demands free of any charges under the name of workmanship, assembly etc.	Before the contract is signed, the contractor is obliged to present the price list of all spare parts, accessories and expendables including lifed parts with no exceptions in the tender offer file, which will not exceed %150 of the unit device price. Endotoxine filter shall also be indicated within the scope of this list. All parts, the types or amounts of which are not included in the price list of all spare parts, accessories and expendables including lifed parts with no exceptions by the contractor shall be provided during the warranty period and for 5 years after the warranty if the administration demands free of any charges under the name of workmanship, assembly etc.
81	Ann V	-	Reference: EuropeAid/139959/ID/SUP/TR	SIHHAT/2018/SUP/INT/10-BIS

#	DOC	ART / ITEM	FORMER TEXT	SHALL READ AS NEW TEXT
82	Ann V	6	All equipment must have at least 5 years for Lot-1, Lot-2 and Lot-3 and 2 years for Lot-4 (Please select the relevant option corresponding the Lot you are tendering for) of commercial warranty.	All equipment must have at least 5 years of commercial warranty.
83	SC	32.6	The Contractor shall warrant that the supplies are new, unused, of the most recent models and incorporate all recent improvements in design and materials. The Contractor shall further warrant that none of the supplies have any defect arising from design, materials or workmanship. During the contractual warranty mentioned under article 32.7, in any case resulting from deficiency or any other problem of the goods: - All design, workmanship, manufacturing, material and montage related problems and possible damages come out of these problems should be fixed during the guarantee period by the supplier. - The warranty must remain valid for 5 (five) years for Lot-1, Lot-2 and Lot-3 and 2 (two) years for Lot-4 after provisional acceptance and in any case shall be in compliance with the requirements in the Technical Specifications, Annex II + III. and Commercial warranty as granted by the manufacturer. - Response time: Contractor shall troubleshoot within 24 hours (online or via phone). If the problem cannot be solved online or via phone support, Contractor shall be available or act on site within 3 days. - Repair time: Within 30 calendar days from the receipt of the malfunctioning goods. If during 30 calendar days, it is foreseen that the goods cannot be repaired	The relevant requirements and conditions of the Annex II-III Technical Specifications Technical Offer for warranty obligations will apply to the contract. All equipment must have at least 5 years of commercial warranty. Contractor should be authorised by the manufacturer(s) maintenance service centre(s) or should have a contract with such service centre(s) for the time of the implementation and contractual warranty period of all goods. Please refer to the current Turkish Law on Consumer Rights and regulations.

#	DOC	ART / ITEM	FORMER TEXT	SHALL READ AS NEW TEXT
			and the malfunction is not fault of the operator, corresponding functional item should be provided until malfunctioning goods is repaired. - All duration that may be passed in the repairing in the warranty duration, should be added to original guarantee period. - Only original or approved by the manufacturer(s) spare parts should be used in any repair service - Contractor should be authorised by the manufacturer(s) maintenance service centre(s) or should have a contract with such service centre(s) for the time of the implementation and contractual warranty period of all goods. All goods supplied under this contract shall also be accompanied by a commercial (manufacturer) warranty pursuant to the provisions of the 07/11/2013 dated and 6502 numbered Turkish Law on Consumer Rights and relevant regulations (if applicable). Please refer to the following links for the current Turkish Law on Consumer Rights and regulations: http://www.resmigazete.gov.tr/main.aspx?home http://www.resmigazete.gov.tr/eskiler/2013/11/20131128.htm& resmigazete.gov.tr/eskiler/2013/11/20131128.htm	

#	DOC	ART / ITEM	FORMER TEXT	SHALL READ AS NEW TEXT
84	SC	32.7	The warranty must remain valid for 5 (five) years for Lot-1, Lot-2 and Lot-3 and 2 (two) years for Lot-4 after provisional acceptance and in any case shall be in compliance with the requirements in the Technical Specifications, Annex II + III. and Commercial warranty as granted by the manufacturer. The requirements in the technical specifications have precedence in terms of warranty obligations.	The warranty must remain valid for one year after provisional acceptance.
85	App B	3	The contractor shall perform training of 2 (two) users per each system on-site in operation of all supplied equipment for 1 day. Trainings might be delivered in a single location subject to the approval of the Contracting Authority.	The contractor shall perform trainings in line with the requirements in Annex II-III Technical Specifications Technical Offer. Trainings might be delivered in a single location subject to the approval of the Contracting Authority.
86	Ann IV	Lot-1	High Level Intensive Care Incubator	High Level Ventilator – Neonatal
87	Ann IV	4.1.2	LOT 6 - Hemodialysis Device	LOT 4 - Hemodialysis Device

All other terms and conditions of the tender dossier remain unchanged. The above alterations and /or corrections to the tender dossier are integral part of the tender dossier.

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