

**MINUTES OF GRIEVANCE COMMITTEE MEETING
FAISALABAD INSTITUTE OF CARDIOLOGY, FAISALABAD**

A meeting of Grievance Committee for purchase of Electro-medical Equipment (ADP FY2019-2020) was held on 10-02-2020 at 09:00AM in the office of the Chairman Grievance Committee, Faisalabad Institute of Cardiology, Faisalabad.

HEART LUNG MACHINE

Sr.	Company Name	TAC Observations	Firm's Grievances/Clarification	GC Observation
1	Universal Enterprises	<ul style="list-style-type: none"> No Embassy Attested Authorization 5 years warranty from the manufacturer not provided Hand crank offered 02 instead of 10 Nos. Level sensor pads offered 60 instead of 200 Nos. Two pressure offered instead of four Cardioplegia monitoring Unit not offered Halogen lamp offered instead of LED 	<ul style="list-style-type: none"> We have quoted latest and advanced Heart & Lung Machine We will supply equipment and accessories as per our submitted bid. Our bid and submitted documents are complete and nothing is deficient Quoted unit is highly advanced modular equipment with built-in extra features. Our Heart and Lung Machines are installed and serving the end-users up to their satisfaction in Pakistan, Globally and above all in your prestigious institute FIC 	<ul style="list-style-type: none"> Hand crank offered 02 instead of 10 Nos. Level sensor pads offered 60 instead of 200 Nos. Two pressure offered instead of four Cardioplegia monitoring Unit not offered <p>The committee unanimously decided that deficient technical proposal is not acceptable as per PPRRA rule 33 Clause 1 hence grievance / clarification of M/s Universal is rejected and TAC decision upheld.</p>
2	Medica	<ul style="list-style-type: none"> After calculation battery backup on full load (1000 Watts) will be only 8 minutes as per attached catalog 1, page # 38&39 whereas required backup is 90mins on full load Optional monitor not offered 	<ul style="list-style-type: none"> Manufacturer declaration attached which showed that S5 can continue operation on battery backup for up to 130 minutes and more than 180 minutes for only arterial pump Technical offer of Optional monitor was not offered, revised technical offer submitted, Price is already offered in financial offer. 	<p>There is huge battery backup difference in between already provided catalogue with bid and newly submitted undertaking, which is questionable, Furthermore M/s Medica submitted revised technical offer which is not acceptable as per PPRRA rule 33 Clause 1 hence grievance of M/s Medica is rejected and TAC decision upheld.</p>

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Item Name	Firm's Grievances	Firm's Grievances/Clarification	GC Observation
Heart Lung Machine	<p>M/s Universal Enterprises against M/s Mediland</p> <ul style="list-style-type: none"> Quoted model (HL20) is not completely modular Quoted model (HL20) doesn't provide battery backup to whole system Quoted model (HL20) is less than 180mins for arterial pump M/s Mediland offered HL20 instead of HL30 (which is more advanced Model) 	<p>HL20 is completely modular and whole system may operate on battery backup furthermore arterial pump can operate for more than 180mins.</p> <p>Quoted model is in current production line and fully complied with advertised specifications.</p>	<p>The Committee evaluated provided documents / evidences of both firms and decided that grievance of M/s Universal Enterprises is baseless; hence grievance of M/s Universal enterprises is rejected.</p>
	<p>M/s Medica against M/s Mediland</p> <ul style="list-style-type: none"> Quoted model (HL20) is not completely modular as only pumps are modular 7 segments display with buttons or keys offered if any single key become faulty, whole panel will be replace, so system display is not modular. Lamp doesn't work on battery backup HL20 can't run all pumps at full load HL20 arterial pump operation on battery backup is required 180mins but not mentioned on brochure. Roller pump of HL20 is not self-diagnostic. HL20 have fixed sensor modules FDA recalls "liquid is leaking into the electric board". FDA recalls "pump if placed in different slot position available on console may cause malfunctioning". 	<p>HL20 is completely Modular and whole system may operate on battery backup furthermore arterial pump can operate for more than 180mins.</p> <p>Quoted model is in current production line and fully complied with advertised specifications. Only display of parameters demanded regardless to the type of screen/LCD</p> <p>HL20 provide battery backup to whole system for 90 minutes, Although battery backup of LED lamp is not demanded in advertised specifications, however battery backup option for lamp is available in machine and will be supplied with battery backup. There is no FDA recall open for quoted model, authorities may verify from FDA website.</p>	<p>The Committee viewed provided documents / evidences of both firms and decided that grievance of M/s Medica is groundless; hence grievance of M/s Medica is rejected.</p>
<p>M/s Mediland against M/s Medica</p> <ul style="list-style-type: none"> Pressure trend indicator not available Pressure read out and Overwrite facility not available Not fully modular, single cable machine, if software crashed not a single pump will operate. Can't sense micro bubbles up to microns 	<p>All objections are invalid / baseless, furthermore and available on attached brochure.</p>	<p>The Committee evaluated provided documents / evidences of both firms and decided that grievances of M/s Mediland are baseless, hence grievance of M/s Mediland for these points is rejected.</p>	

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STERNUM SAW

Sr.	Company Name	TAC Observations	Firm's Grievances/Clarification	GC Observation
1	Claris Medical	<ul style="list-style-type: none"> No Embassy Attested Authorization Blade quoted 200 instead of 600 	<p>Embassy Attested Authorization attached. It was not clear in advertised specifications that either 200 blades are required for each machine or for three machines so we quoted unit price of sterna saw blade, Authorities may calculate prices of 600 blades by multiplying unit price for comparative purpose.</p>	<p>Provided Embassy attested authorization was accepted by the committee.</p> <p>As per clause no. 26.1 & 27.2 of Standard Bidding Document the Price of deficient blades will be count as per unit price of blade and will be added in total amount of Financial Proposal at the time of Financial Proposal opening. Clarifications ACCEPTED and reverted the decision of TAC and declared as Responsive.</p>
2	KASBN International	<ul style="list-style-type: none"> No Sale reference/ satisfactory report attached No CE for sternum saw as per listed scope on attached certificate 	<ul style="list-style-type: none"> Sale reference attached CE certificate attached 	<p>Provided sale reference and satisfactory report was irrelevant, CE declaration provided from the manufacturer was also not accepted by the committee as scope mentioned in already provided CE in bid was different, hence grievance of M/s KASBN International is rejected and TAC decision upheld.</p>

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TEMPORARY PACEMAKER


Sr.	Company Name	TAC Observations	Firm's Grievances/Clarification	GC Observation
1	Claris Medical	No DRAP Registration No backup operation during battery change	DRAP Registration provided Quoted product have battery backup life of 38 days	Backup operation during battery change is major deviation as this is potential life threatening hence grievance of M/s Claris Medical is rejected and TAC decision upheld
2	Alliance Medical	No backup operation during battery change	Undertaking given from Osypka AG that quoted model have 30 second buffer during battery change and same model is already installed in FIC	The committee physically checked and found that there is no backup operation during battery change in already provided model. Backup operation during battery change is major deviation hence grievance of M/s Alliance Medical is rejected and TAC decision upheld.


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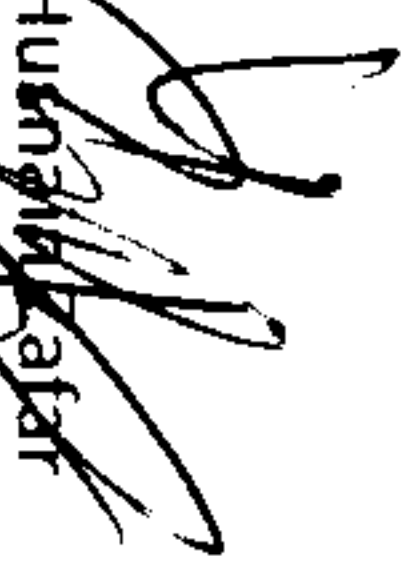

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CSSD


Sr.	Company Name	TAC Observations	Firm's Grievances/Clarification	GC Observation
1	Vertex Medical (Pvt) Ltd	Heavy, medium & electronic steam sterilizer have touchpad screen instead of color touch screen	In Heavy, medium & electronic steam sterilizer touchpad screen does not affect major function/application so consider it as a Minor Deviation. Precedent of PIC attached.	Committee unanimously considered it a minor deviation as already considered minor deviation PIC Lahore, hence clarification of M/s Vertex ACCEPTED and declared as Substantially Responsive.
2	Clinical Life Inc.	<ul style="list-style-type: none"> No Satisfactory Report of washer disinfecter Medium sterilizer model not available on manufacturer website 	<ul style="list-style-type: none"> Past performance of quoted model is attached. Quoted model of medium steam sterilizer is updated on its official website. 	Provided past performance/service report was accepted by the committee. Quoted Medium Steam sterilizer model is available on manufacturer's website however during verification it was noticed that heavy duty steam sterilizer model is not available on manufacturer's website. Hence technical offer of M/s Clinical life will remain non responsive.


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Item Name	Firm's Grievances	Firm's Grievances/Clarification	GC Observation
SSSD	<p>M/s Clinical Life against M/s Mediland (for Electronic Autoclave)</p> <ul style="list-style-type: none"> • Door is not made of stainless steel 316L • Jacket is not made of stainless steel 316L <p>(for Medium Steam Sterilizer)</p> <ul style="list-style-type: none"> • Door is not made of stainless steel 316L • Original manufacturer of quoted model TS330EC2NX is Trans Medikal which is located in Turkey • Quoted model is not available on official website of Getinge infection control, Sweden. <p>(for Heavy Duty Steam Sterilizer)</p> <ul style="list-style-type: none"> • Door is not made of stainless steel 316L • Original manufacturer of quoted model is Trans Medikal which is located in Turkey • Quoted model is not available on official website of Getinge infection control. • CE and ISO of quoted model are on the name of "Trans Medikal Turkey" which shows that Getinge Infection Control is not the original manufacturer of quoted product. 	<p>Door of electronic, medium and heavy duty steam sterilizers are made of SS. Declaration from the manufacturer is attached. Trans Medikal is owned by Getinge group with same quality standards. Declaration from the manufacturer Getinge Group AB is annexed.</p>	<p>The Committee evaluated provided documents / evidences of both bidders and decided that grievances of M/s Clinical Life are baseless hence grievance of M/s Clinical Life is rejected.</p>


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Item Name	Firm's Grievances	Firm's Grievances/Clarification	GC Observation
<p align="center">CSSD</p>	<p>M/s Mediland against M/s Clinical Life (for Washer Disinfector)</p> <ul style="list-style-type: none"> Quoted washer disinfector doesn't have provision of fast/short cycle disinfection program of around 30mins Quoted model doesn't have stainless steel construction Quoted model doesn't have complete exhaust air condenser for outgoing air with condensate drain and heat exchanger AJ Coasta is not the OEM for the quoted washer disinfector Bidder doesn't have satisfactory past experience for quoted product. <p>(for Heavy Duty Steam Sterilizer)</p> <ul style="list-style-type: none"> Bidder doesn't have satisfactory past experience for quoted product Quoted model doesn't have good quality of stainless steel <p>(for Medium Steam Sterilizer)</p> <ul style="list-style-type: none"> Bidder doesn't have satisfactory past experience for quoted product. Quoted model doesn't have good quality of stainless steel <p>(for Electronic Autoclave)</p> <ul style="list-style-type: none"> Bidder doesn't have satisfactory past experience for quoted product. Quoted model doesn't have good quality of stainless steel 	<p>All objections are invalid / baseless Committee can verify from official website, technical literature and manuals of the manufacturer.</p>	<p>The Committee viewed provided documents / evidences of both firms and decided that grievances of M/s Mediland are baseless hence grievance of M/s Mediland is rejected.</p>


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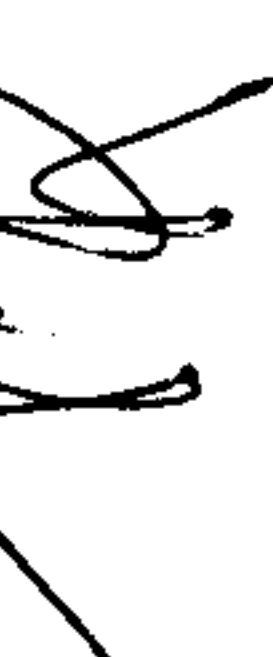

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Item Name	Firm's Grievances	Firm's Grievances/Clarification	GC Observation
<p align="center">CSSD</p>	<p>M/s Mediland against M/s Total Technology (for Washer Disinfector)</p> <ul style="list-style-type: none"> The washing arm, pre heating tanks and water filters of quoted model are not made of AISI 316L Quoted model doesn't have proper drying system and disinfecting. Quoted model doesn't have optimal cleaning of internal surface of the instrument and indicates incomplete disinfection Quoted model doesn't have flow meters and sensors incorporated in the dosing pump, so no information regarding utilized and available detergent can be obtained Quoted model doesn't have 8-10 pre-set cycle Quoted washer disinfector doesn't have provision of fast/short cycle disinfection program of around 30mins Quoted model doesn't have complete exhaust air condenser for outgoing air with condensate drain and heat exchanger (for Electronic Autoclave) <ul style="list-style-type: none"> The quoted model doesn't have removable shelf, and is not capable of taking packets and containers of all standard sizes Quoted model have 02STU Chamber Capacity instead of 01STU (for Heavy Duty Steam Sterilizer & Medium Steam Sterilizer) In the quoted models, there is no any gauge in front of panel for indication of chamber pressure The quoted model doesn't have proper drying system and shows incomplete and un-verified assurance for disinfection The quoted model doesn't have dedicated service areas and this leads to breakdown of hygienic barrier between clean and sterile area. The warranty of RO system is usually not covered properly by M/s Total Technologies. We hereby request to procuring agency to re-verify this 	<p>All objections are invalid / baseless Committee can verify from official website, technical literature and manuals of the manufacturer.</p>	<p>The Committee evaluated provided documents / evidences of both firms and decided that grievances of M/s Mediland are baseless hence grievance of M/s Mediland is rejected and TAC observations are upheld.</p>


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ANESTHESIA MACHINE (1A)


Sr.	Company Name	TAC Observations	Firm's Grievances/Clarification	GC Observation
1	Eastern Medical	<p>No legal attested sole authorization No sale reference/ satisfactory report from end-user Warranty of batteries, O₂ sensor and flow sensor not offered Absorber support bag not offered</p>	<p>Legal attested sole authorization was not demanded. Thus it is not a valid objection Sale reference attached Mentioned on covering letter of our quotation that warranty as per tender enquiry and all terms and conditions confirmed as per tender advertisement We offered breathing system/Absorber and breathing bag(see brochure)</p>	<p>Firm failed to provide legal attested sole authorization and satisfactory report of the quoted product which were mandatory requirements as per bidding documents ITB clause 3.2 and 29.2 sub clause 8 hence both objections of TAC will be sustained and M/s Eastern Medical will remain non-responsive.</p>


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ANESTHESIA MACHINE (1B)

Sr.	Company Name	TAC Observations	Firm's Grievances/Clarification	GC Observation
1	Eastern Medical	<ul style="list-style-type: none"> No legal attested sole authorization No sale reference/ satisfactory report from end-user Cardiac Bypass Mode not offered Quoted monitor is not compatible with the machine Quoted monitor is not from the same manufacturer no electronic mixing cylinder gauge is not available power outlets with sockets only 1 instead of 3-4 Scavenging system is not available 	<p>Not demanded legal attested sole authorization certificate. Thus it is not a valid objection</p> <p>Sale reference attached</p> <p>According to your tender specification, it was Optionally demanded Cardiac bypass mode/HLM/Spontaneous mode in machine thus accordingly we have offered spontaneous mode (PSV) and also offered Manual mode equivalent to Cardiac Bypass mode</p>	<p>Bidder failed to provide legal attested sole authorization and sale satisfactory report of the quoted product which were mandatory requirements as per bidding documents ITB clause 3.2 and 29.2 sub clause 8 hence both objections of TAC will be sustained furthermore quoted model is also not from the same manufacturer hence M/s Eastern Medical will remain non-responsive.</p>
2	Radiant Medical (Pvt) Ltd	<p>Tidal volume started from 20ml instead of 5ml</p> <p>No SIMV with PS mode</p> <p>No integrated heating system</p> <p>PEEP min value is 4 instead of 3</p>	<p>Datasheet attached, Tidal volume of our quoted model AX-700 is from 5ml-1500ml</p> <p>PRVT which is most advanced, equivalent and better than SIMV-PS quoted</p> <p>Peep 0-20 mentioned on brochure</p> <p>Quoted Moisture tolerant—Vertical Integrated breathing System in which heating system not required</p>	<p>After detailed scrutiny the committee found that SIMV with PS mode, integrated heating system and Peep min value is 4 instead of 3 not available in quoted machine hence these three objections of TAC will be sustained and offer of M/s Radiant Medical will remain non-responsive.</p>
3	Digionics (Pvt) Ltd.	<p>Demo unit not provided</p>	<p>Quoted models of Anesthesia machine and workstation have installation in various government hospitals</p> <p>Earlier model SP-102 are already running in FIC for past 10 years and are still working fine</p>	<p>Demo units were called by TAC from all eligible bidders to verify demanded specifications and to verify their performance on cardiac surgery procedures. As M/s Digionics not provided demo unit hence grievance of M/s Digionics is hereby rejected and TAC decision upheld.</p>

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Item Name	Firm's Grievances	Firm's Grievances/Clarification	GC Observation
<p align="center">Anesthesia Machine (1A& 1B)</p>	<p>M/s Vertex Medical against M/s Clinical Life (for 1B)</p> <ul style="list-style-type: none"> Tidal volume can be controlled in volume control mode of ventilation while in pressure control mode, only pressure is controlled but tidal volume is just monitored, which keeps on varying depending upon the lungs compliance and resistance The quoted model deviates the required tender specification 	<p>All objections are invalid / baseless and our quoted models fully complied with advertised specifications furthermore all specifications/ points were verified by the end user and TAC.</p>	<p>The committee upheld the decision of TAC after detailed scrutiny hence grievance of M/s Vertex Medical is hereby rejected.</p>
	<p>M/s Shirazi Trading against M/s Clinical Life (for 1B)</p> <ul style="list-style-type: none"> SPO₂ is required with motion tolerance technology but not available in quoted model (XL189) CO₂ observer not changeable during surgery No past performance & sole distribution No CE authorized for monitor 	<p>All objections are invalid / baseless and our quoted monitor model fully complied with advertised specifications furthermore all specifications/ points were verified by the end user and TAC during demonstration. CE and performance reports are already attached with bid and once again submitted for reference.</p>	<p>The committee verified the submitted past performance reports through telecom from the concerned institute's authorities and found satisfactory, furthermore committee evaluated provided evidences from both bidders and decided that grievance of M/s Shirazi Trading is rejected.</p>
	<p>M/s Shirazi Trading against M/s Radiant Medical (for 1B)</p> <ul style="list-style-type: none"> No sole distribution (Dameca is now part of Lowenstien Medical instead of Philips) No after sale services & Past Performance No engineering staff available 	<p>All documents are already attached with bid.</p>	<p>The committee upheld the decision of TAC after detailed scrutiny hence grievance of M/s Shirazi Trading is hereby rejected.</p>
<p>M/s Radiant Medical against M/s Digionics (for 1A)</p> <ul style="list-style-type: none"> Not comply with the requirement of tidal volume as per tender specification 	<p>Objection is invalid / baseless as tidal volume start from 0 in PS mode which is better than required.</p>	<p>The Committee evaluated provided documents of both bidders and decided that grievance of M/s Radiant Medical is baseless hence grievance of M/s Radiant Medical is rejected.</p>	

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Item Name	Firm's Grievances	Firm's Grievances/Clarification	GC Observation
Anesthesia Machine (1A& 1B)	<p>M/s Radiant Medical against M/s vertex Medical (for 1A)</p> <ul style="list-style-type: none"> Not comply with the requirement of tidal volume as per tender specification 	<p>Objection is invalid / baseless as tidal volume start from 0 in PS mode which is better than required.</p>	<p>The Committee evaluated provided documents of both firms and decided that grievance of M/s Radiant Medical is baseless hence grievance of M/s Radiant Medical is rejected.</p>
	<p>M/s Clinical Life against M/s Vertex Medical</p> <ul style="list-style-type: none"> No PS with apnea backup Pipeline and cylinder gauges for O₂ N₂O and air are not available in quoted model 30mins battery backup at full load instead of 60mins In pressure mode tidal volume range start from 10ml instead of 5ml 	<p>All objections are invalid / baseless and all options are available in machine, which were verified by the TAC during technical evaluation.</p>	<p>The Committee listened stance and seen provided documents of both firms and decided that grievances of M/s Clinical Life are baseless hence grievance of M/s Clinical Life is rejected and TAC decision upheld.</p>
	<p>M/s Clinical Life against M/s Shirazi Trading</p> <ul style="list-style-type: none"> SIMV with PS not available Pipeline and cylinder gauges for O₂ N₂O and air are not available in quoted model 30mins battery backup at full load instead of 60mins as per brochure 	<p>All objections are invalid / baseless and all options are available in machine, which were verified by the TAC during technical evaluation.</p>	<p>The Committee listened stance and seen provided documents of both firms and decided that grievances of M/s Clinical Life are baseless hence grievance of M/s Clinical Life is rejected and TAC observations are upheld.</p>

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CARDIAC MONITOR (3A)

Sr.	Company Name	TAC Observations	Firm's Grievances/Clarification	GC Observation
1	Radiant Medical (Pvt) Ltd	<p>No legal attested sole authorization Monitor is not intended for pediatric patients arrhythmia and ST Analysis as clearly mentioned on FDA 510K summary</p>	<p>Sole distributor letter attached We hereby confirm that our quoted model A8 intended for pediatric patient for arrhythmia and ST Analysis We have arranged demonstration of our quoted model</p>	<p>Bidder failed to provide legal attested sole authorization which was mandatory requirement as per bidding documents ITB clause 3.2 As per FDA510k summary arrhythmia and ST analysis of monitor are not intended to use with pediatric patient which raises serious safety concerns in pediatric patients hence the committee upheld the decision of TAC and grievance of M/s Radiant Medical is rejected.</p>
2	Total Technologies	<p>Monitor is not intended for pediatric patients arrhythmia and ST Analysis as clearly mentioned on FDA 510K summary There are different Module models of same parameters with different specification mentioned in catalog whereas firm didn't mentioned specific model in technical offer</p>	<p>Elite V8 can do arrhythmia and ST Analysis for neonatal, pediatric and adult just not specially designed for neonates and pediatric</p>	<p>As per FDA510k summary arrhythmia and ST analysis of monitor are not intended to use with pediatric patient which raises serious safety concerns in pediatric patients hence the committee upheld the decision of TAC and grievance of M/s Total Technology is hereby rejected.</p>

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3	Medequips	Local made wall stand is offered External battery backup offered	Imported wall stand not demanded and Transport module / basic monitor have battery backup of 5 hours and external battery backup is offered for display so consider it minor deviation.	Committee unanimously considered it as minor deviation hence clarification of M/s Medequips ACCEPTED and declared as Substantially Responsive.
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CARDIAC MONITOR (3B)

Sr.	Company Name	TAC Observations	Firm's Grievances/Clarification	GC Observation
1	Radiant Medical (Pvt) Ltd	No legal attested sole authorization Monitor is not intended for pediatric patients arrhythmia and ST Analysis as clearly mentioned on FDA 510K summary	Exclusive distributor letter attached We hereby confirm that our quoted model Q7 intended for pediatric patient for arrhythmia and ST Analysis. We have arranged demonstration of our quoted model.	Bidder failed to provide legal attested sole authorization which was mandatory requirement as per bidding documents ITB clause 3.2 As per FDA510k summary arrhythmia of monitor is not intended to use with pediatric patient which raises serious safety concerns in pediatric patients hence the committee upheld the decision of TAC and grievance of M/s Radiant Medical is rejected.
2	Total Technologies	Monitor launch date is Nov 2011 as mentioned on FDA 510K summary which is 8 years old instead of maximum 5 years`	Quoted model is in our current production line and its upgradation with the present need is a continuous process recently upgraded in 2019. Declaration for availability of spare parts for next ten years is attached.	The committee accepted clarifications of M/s Total Technology and reverted TAC decision and offer of M/s Total Technology declared Responsive

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Item Name	Firm's Grievances	Firm's Grievances/Clarification	GC Observation
	Firm's Grievances M/s Medequips against M/s Friends Trader <ul style="list-style-type: none"> No satisfactory past performance of the bidder No installation for quoted model 	Firm's Grievances/Clarification Multiple satisfactory reports of same product as well as same models are already attached with bid	GC Observation The Committee re-verified satisfactory reports submitted by M/s Friend Traders and rejected objections of M/s Medequips.
	M/s Medequips against M/s Mediland <ul style="list-style-type: none"> No satisfactory past performance of the bidder No installation for quoted model 	Multiple satisfactory reports of same product are already attached with bid	The Committee re-verified satisfactory reports submitted by M/s Friend Traders and rejected objections of M/s Medequips.
	M/s Radiant Medical against M/s Friends Trader (for 3A) <ul style="list-style-type: none"> FDA 510K 182075 issued to Shenzhen Mindray Bio medical Bene Vision N17 clarifying that all parameters can be monitored on single adult, Paeds and neonatal patients except for arrhythmia detection, RM monitoring, CCO monitoring and SvO₂ monitoring 	The monitor is intended to use with paed and adult patient of required parameters demanded in tender specification. FDA 510k summary endorses the same, committee can verify online.	The Committee seen provided evidences / documents of both firms and decided that grievances of M/s Radiant Medical are baseless hence grievance of M/s Radiant Medical is rejected and TAC observations are upheld.
	M/s Radiant Medical against M/s Mediland (for 3A) <ul style="list-style-type: none"> As per FDA 510K # 182979, quoted model MX-800 ST-segment monitoring is intended only for adult patients and not validated for Paeds and neonatal patients 	The monitor have capability to monitor ST segment for paed patient.	The Committee reviewed FDA510K summary and decided that grievances of M/s Radiant is valid and reverted the decision of TAC, hence M/s Mediland declared as Non Responsive .
	M/s Radiant Medical against M/s Friends Trader (for 3B) <ul style="list-style-type: none"> As per FDA 510K quoted model is only use for adult patients 	The monitor is intended to use with paed and adult patient of required parameters demanded in tender specification. FDA 510k summary endorses the same, committee can verify online.	The Committee seen provided evidences / documents of both firms and decided that grievances of M/s Radiant Medical are baseless hence grievance of M/s Radiant Medical is rejected and TAC observations are upheld.
Cardiac Monitor (3A&3B)	M/s Radiant Medical against M/s Mediland (for 3B) As per FDA 510K # 151812, quoted model is only for adult patients	The monitor is intended to use with paed and adult patient of required parameters demanded in tender specification. FDA	The Committee seen provided evidences / documents of both firms and decided that grievances of M/s Radiant Medical are baseless hence grievance of M/s Radiant

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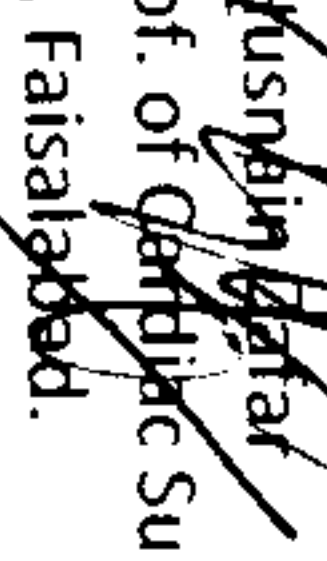
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	<ul style="list-style-type: none"> No sale reference/ satisfactory past performance 	510k summery endorses the same, committee can verify online.	Medical is rejected and TAC observations are upheld.
	<p>M/s Radiant Medical against M/s Medequips (for 3B)</p> <ul style="list-style-type: none"> 12 years old model quoted instead of 5 years 	Monitor is upgraded in 2019, upgradation undertaken from the manufacturer and ten years spare parts availability certificates are attached	The Committee seen provided evidences / documents of both firms and decided that grievances of M/s Radiant are baseless hence grievance of M/s Radiant is rejected and TAC observations are upheld.


INTRA AORTIC BALLOON PUMP


Item #	Company Name	TAC Observations	Firm's Grievances/Clarification	GC Observation
	UDL Distribution (Pvt) Ltd	<ul style="list-style-type: none"> No Embassy attested authorization Poor Backup Services 5 years comprehensive warranty from manufacturer not offered No control of deflation point in automatic mode 	Embassy attested authorization is attached and list of sale reference was already attached in bid. We offered warranty as required by the tender. Control of deflation point is available in manual mode furthermore undertaking from Teleflex submitted that they have equivalent feature for control of Deflation point as deflation timing management.	Provided Embassy attested authorization, and five Years comprehensive warranty from manufacture are accepted by the committee. Control of deflation point was demanded in automatic mode instead of manual hence clarification of M/s UDL Distribution and undertaking of the manufacturer is ambiguous and TAC observation for this point will sustained and firm will remain non-responsive.


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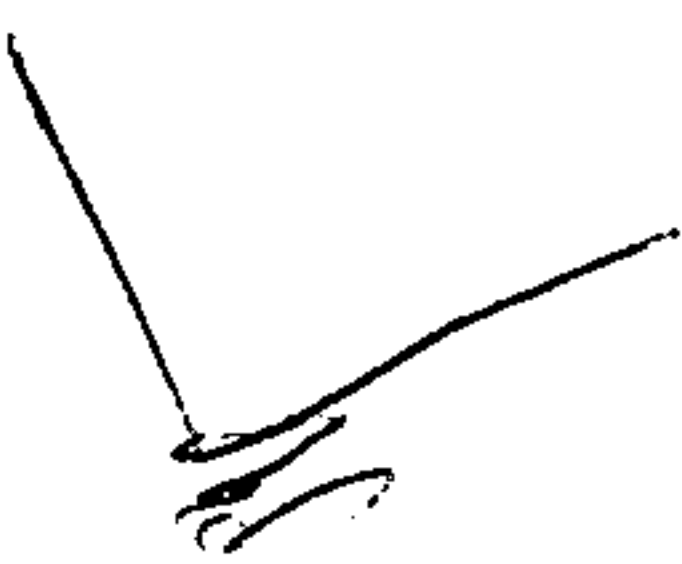
Item Name	Firm's Grievances	Firm's Grievances/Clarification	GC Observation
<p>Intra Aortic Balloon Pump</p>	<p>M/s UDL Distribution against M/s Mediland</p> <ul style="list-style-type: none"> • 6 FDA recalls in past 2 years regarding battery backup and locomotion of patient with IABP <p>M/s Mediland against M/s UDL Distribution</p> <ul style="list-style-type: none"> • UDL not competing advertised specification • UDL have no sale reference/installation nationwide for quoted model • No engineering department/technical facility and firm is rejected due to poor past performance in PIC presently. • Quoted model have no internal helium cylinder, Internal battery for continuous operation and mobile console • Quoted model have no automatic condensation removal system and internal simulator • No automatic in vivo calibration • No manual helium refilling of control 	<p>5 recalls are terminated by FDA and remaining 1 recall is due to "use error" as determined by FDA, committee can verify online. Furthermore we were qualified by PIC in recent tender, copy enclosed.</p> <p>All objections are invalid / baseless and our quoted models fully complied with advertised specifications. We have technical trained engineers and relevant testing tools</p>	<p>The Committee listened stance and seen provided documents of both firms and decided that grievance of M/s UDL Distribution is baseless hence grievance of M/s UDL Distribution is rejected and TAC observations are upheld.</p> <p>The Committee listened stance and seen provided documents of both firms and decided that M/s UDL Distribution have no proper after sale technical support setup as they already rejected by Punjab Institute of Cardiology on same grounds hence M/s UDL Distribution is rejected and TAC observations for poor backup services upheld.</p>



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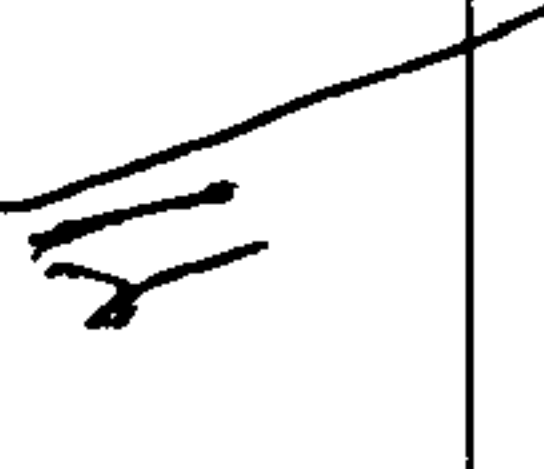
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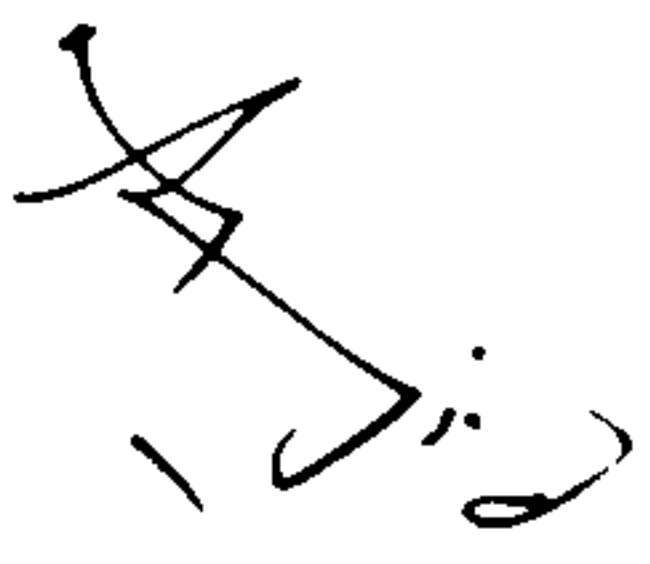
HYPOTHERMIA MACHINE


Item Name	Firm's Grievances	Firm's Grievances/Clarification	GC Observation
<p>Hypo hyperthermia Machine</p>	<p>M/s Mediland against M/s Medica</p> <ul style="list-style-type: none"> • Non tuberculous mycobacterium infection risk in open heart surgery reported for quoted model. • FDA recalls "cause of bacterial infection during cardiac surgery" • Serious infection leading to 6 deaths • No backup service. <p>M/s Mediland against M/s Universal Enterprises</p> <ul style="list-style-type: none"> • No +2 degree Celsius cooling capability in quoted model • Spared flow control system not available in quoted model • Pump flow reduce to 7-8L/min on load instead of 10-16L/min • No sale references/installation by bidder • Non responsive in PLC due to incomplete technical offer and deficient accessories • Non exclusivity and director supplier provide poor after sale service 	<p>All objections are invalid / baseless. Manufacture has development a vacuum canister and internal sealing design change that is intended to further mitigate the risk of airborne transmission of non-tuberculosis mycobacterium (NTM) from the 3T device.</p>	<p>The committee found that there are serious FDA recalls on quoted model in which FDA declared it "design error" so grievance of M/s Mediland hereby Accepted.</p> <p>The committee upheld TAC decision after scrutiny.</p>


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