FILE No.															
Creator :Ritika Gupta				Moderator : Shri A.V.Muralidharan (Dy. CEO GeM)								Approver : A.K Kamra			
	Sub Category :														
	Pneumatic Compression Machine														
S.No.	Parameters			Value 1	Value2	Value 3	Value 4	Value 5	Value 6	Validation	Golden parameter	Remarks	priority	Unit	Demand Aggregation
Standards															
1	Confirmity to standards	S	E	**European CE (Notified Body)With 4 Digit Notified Body No**	**USFDA**	BIS					G				
2	Confirmity to Quality Management Sytems for Medical Devices	S	E	ISO 13485	Yes	No					G				
3	Confirmity to medical electrical safety standards	S	E	IEC 60601-1 -2, **IEC 61000-3 -3**	Yes	No					G				
Performance Parameters															
4	Purpose	P	E	DVT Pump is used for intermittent pneumatic compression which is is a therapeutic technique and include an air *pump* and inflatable auxiliary sleeves, gloves or boots in a system designed to improve venous circulation in the limbs of patients who suffer edema or the risk of *deep vein thrombosis* (*DVT*)											
5	DVT Pump shall be light weight portable and sturdy	P	E	**Less Then 3 kgs**	**Less Then 4 kgs**	**Less Then 5 kgs**									
6	DVT Pump to be provided with a strong hanging hook	P	E	Yes	**No**										
7	DVT pump should be hangable on bed side /OT Table railing	P	E	Yes	**No**										
8	DVT Pump Should be quite and vibration free ,sequential gradient	P	E	Yes	**No**										
9	**Set pressure should be displayed**			**Yes**	**No**										
10	DISPLAY	P	E	Large easy to read with feather touch switches											
11	**Battery Backup**			**2 Hrs.**	**4 Hrs.**	**6 Hrs.**	**8 Hrs.**	**10 Hrs.**							

12	Size of screen in inches			**2.5 Inch**	**3. Inch**	**3.5 Inch**	**4 Inch**	**More**							
13	Display should show which part of of leg air is pressed in to			Yes	**No**										
14	Parameters displayed			Total time,pressure time,interval,pressure, mode,battery status and graphical representation of limb											
15	Number of air pockets in each cuff to ensure proper flow accelaration	P	E	**2**	**3**	**4**								m l	
16	Type of pressure regulator	P	E	Electronic											
17	Pressure range adjustavbility	P	E	30-140 mm Hg											
18	default pressure setting for for calf and thigh	P	E	40 mm HG											
19	Default pressure setting for foot	P	E	**120-140 mm Hg**											
20	Availability of appropriate connectors/tubings			Yes	No										
21	Mode of working			**Manual**	**Automatic**	**Both**									
22	Single leg mode option to be available			Yes	No										
23	Timer setting ranges			**28-60 seconds**											
24	Swiches should be finger sensitive			Yes	No										
25	**Availability of appropriately designed garments for calf, thigh, foot and boot**			Yes											
26	**Should have an option for Lymph mode.**			**Yes**	**No**										
27	**Automatic Safety Alarm System for Cuff checking and attaching, perssure checking, battery checking**			**Yes**	**No**										

28	**Automatic Switching System from mains to battery in case of power failure**			**Yes**	**No**										
29	Material of garment			Poly foam											
30	Garment Construction			in side cotton lining with velcro closure for patient complince											
31	All three Tubings of each leg to be moulded in to one			Yes	No										
32	Sizes of calf garment provided with DVT Pump			**Small**	**Medium**	**Large**	**Extra large**								
33	size of thigh garment provided with DVT Pump			**Small**	**Medium**	**Large**	**Extra large**								
34	size of foot garment provided with DVT Pump			**Small**	**Medium**	**Large**	**Extra large**								
34	**size of boot garment provided with DVT Pump**			**Small**	**Medium**	**Large**	**Extra large**								
39	Power supply	P	E	Single phase, 230 V 50 HZ AC Source											
40	Power concumption in watts	P	N												
42	Dimensions of DVT Pump	D	T												
43	Length of Power cord in meters	D	N	**2**	**3**	**5**									
41	Warrantly period for equipment in years	P	E	1	2	3	4	5							
44	The Equipment shall be installed and demonstrated before Acceptance installation and demonstration			Yes	No										
Additional Parameters															
35	Number of pairs of Thigh garment supplied additional			**5**	**10**	**15**	**20**	**25**	**30**						
				35	**40**	**45**	**50**	**Not supplied**							
36	Number of pairs of calf garment supplied additional			**5**	**10**	**15**	**20**	**25**	**30**						
				35	**40**	**45**	**50**	**Not supplied**							
37	Number of pairs of foot garment supplied additional			**5**	**10**	**15**	**20**	**25**	**30**						
				35	**40**	**45**	**50**	**Not supplied**							

38	**Number of pairs of boot garment supplied additional**			**5**	**10**	**15**	**20**	**25**	**30**						
				35	**40**	**45**	**50**	**Not supplied**							