

Corrigendum

In Tender Document **Tender Enquiry 24/PMR/272(II)/2017-Rish(ADMN)**

Dated: 11/11/2017

Technical Specification which is mentioned at page no. 18-23 in tender document may be read as following:

Specifications for Advance Robotic Rehabilitation System

Advance Robotic Rehabilitation System for Rehabilitation of Lower and Upper Limb of Patients in Trauma & Neurological Conditions

System should comprise of:

A. ROBOTIC GAIT TRAINING SYSTEM WITH FOLLOWING SPECIFICATION

1. The unit should be equipped with an electrically driven gait orthosis operated in combination with a treadmill and body weight support system, controlled via PC.
2. The unit should allow intensive gait training for patients with walking disabilities.
3. The unit enables training with a physiologic gait pattern and with active patient participation.
4. The unit should be equipped with Augmented Performance Feedback in which specific gait exercises can be performed in a playful way.
5. The unit should allow for training progression and ability matched challenge by reducing the support given to the patient gradually during the rehabilitation process.
6. Equipped with assessment tools to analyze and document the patient's progress.
7. Capable of operation by a single therapist, easy to use and should relieve therapist from the strain of guiding legs; enabling him to focus on the optimum therapy of the patient.
8. The unit should be upgradable to train children on same unit with an interchangeable pair of paediatric orthosis. The paediatric unit should also have Augmented Performance Feedback software specially designed for use in paediatric patients as a later edition.
9. Application and efficacy of the unit should have been studied by independent researchers in stroke, spinal cord injury, traumatic brain injury, Multiple sclerosis, Parkinsonism and cerebral palsy.
10. There should be evidence available from trials with the unit showing gait quality improvement, sustained long term benefits, increase in aerobic capacity as a result of training with the unit.

Robotic gait orthosis

11. The gait robot should have electrical drives in knee and hip joints
12. Ankle joint dorsiflexion should be supported passively by foot lifters.
13. The gait orthosis should be adjustable to individuals leg length.
14. The centers of rotation of the joints of the gait orthosis should be adjustable to be congruent with the centers of rotation of the patient's joints for allowing optimum gait trajectories.
15. The upper leg length of the adult gait orthosis should be adjustable between 350 and 470 mm.
16. Should also have adjustable pelvis width.

Robotic orthosis Module for pelvic movements

17. The unit should contain a Pelvic module with an electrical drive for combined lateral translation and transverse rotation to enable lateral weight shift over stance leg.
18. The Pelvis module should contain an integrated force sensor.
19. The unit should provide Driven lateral translation of body weight support, synchronized to the pelvic movement.
20. The unit should contain slidable cuffs to allow for hip abduction and adduction movements associated with the lateral translation and transverse rotation movements of the pelvis.

Treadmill

21. The treadmill should be operated together with the robotic gait orthosis for performing robotic gait training.
22. Should also be operable as a stand-alone for performing manual treadmill training..
23. The speed of the treadmill should be adjustable from 0.5-3 km/h. during robotic gait training and up to 0.5-8 km/h during manual gait training
24. Belt Surface Dimensions of the treadmill should be minimum (L x W) 140 x 65 cm.

Body Weight Support System

25. The unit should be equipped with a patient lift to allow the lifting of a patient from wheel chair.
26. The unit should have facility of static and dynamic unloading.
27. The unit should allow static unloading of minimum 125 kg.
28. Have the facility of continuous adjustable unloading of the patient's weight between 0 and 80 kg in the dynamic condition.
29. During the dynamic condition, the unit should promote a physiological vertical movement of the body.
30. Should have electronically operated unloading of the unit using remote control
31. Equipped with inbuilt electronic weighing scale for real time display of approximate static patient weight and the dynamic weight support.

Unit design

32. The unit should be accessible in the wheel chair.
33. The Unit should allow easy lifting and setting up the patient in the device without turning the patient around.
34. Equipped with easy to reach handrails for the patient. Handrails should be adjustable in width and height according to patient's body dimensions.
35. The unit should allow the therapist to access the unit from front and side.
36. The unit should have adjustable seats for the therapist and should allow observation of the patients gait by therapist without any visual obstacles.

User Interface and software

37. The unit should be equipped with user-friendly touch screen.
38. The software of the unit should allow adjustment of range of motion of the right & left hip and knee joints individually in order to adjust to asymmetries of neurologic patients.
39. The unit software should allow adjustment of the orthosis speed between robotic gait orthosis and treadmill.
40. The software should allow adjustment of gait velocity specific changes in stride length and cadance.
41. The unit should have facility to store all measured parameters and patient notes during the individual training sessions for review and records.
42. The software should allow the therapist to continuously access patient history and patient personal notes during the entire training.

Feedback

43. The unit should be equipped with a patient feedback screen’
44. The system should have facility to measure gait performance via force sensors.
45. The system should continuously record knee and hip joint activity and should display values for the swing and the stance phase of walking, as well as for the right and left leg.
46. The unit should provide visualization of the gait performance in graphs.
47. The unit should provide a motivating and instructive functional feedback for the subject in virtual environments.
48. The unit should provide Augmented Performance Feedback exercises with adjustable settings, for subjects specifically focused on
 - i) Attention and motivation ii) Endurance iii) Activity timing.
 - iv) Movement pattern v) Gait symmetry vi) Step length.
49. The unit should provide enhanced assist as needed support to the subject to enable free timing of movements while ensuring a physiologic gait pattern.
50. The unit should have facility to automatically reward patient activity with higher walking speeds.
51. The unit should have Gait Variation facility to introduce small variations in gait pattern even for patient who require maximal Guidance Force.
52. The unit provides Augmented Performance Feedback allows the therapist choose between different Avatars for the exercises (Man/Woman/Boy/Girl/Elvis/Robot)

Active training

53. For active training the system should have facility of guidance force control to allow continuous adjustable level of gait assistance for each leg between full and zero guidance to encourage patient to work harder.
54. Should have facility to select the level of guidance individually for left and right leg of the neurologic patient
55. The system should contain pre-programmable training parameters to automatically vary training parameters as per need.
56. The unit should have speed and unloading training programs and should also allow interval or pyramid training.

Assessment Tools

57. The unit should have assessment tools for following assessment of neurological patients
 - i) Stiffness in the patient’s hip and knee joints.
 - ii) Isometric force generated by the patient.
 - iii) Patient’s hip and knee- passive range of motion.

Research & reporting Tools

58. The unit should have a research function which allow to collect a wide range of training data, to record data with atleast 10 signals, to allow the therapist to choose and create his own data sets for recording for later export and analysis.
59. The unit should have facility to display data of single session, summarize all training data as therapy progression format and generate individual patient therapy reports
60. It should be possible to export data of the device usage (hours, session, patients) for records and analysis

Connectivity and remote support

61. It should be possible to print reports from the unit into the clinic network.
62. It should be possible to access the unit from remote location for clinical and technical support and software updates.

Safety Mechanisms

63. The unit should be equipped with wireless remote control that must be pressed by the user to confirm that the system is running safely and correctly.
64. The unit should have clearly red marked emergency stop button.
65. The system should detect undesired movements and stop automatically if the range of movement is beyond a certain threshold or if a patient is stumbling
66. The system should contain a torque monitoring system to automatically stops the machine if the torque is beyond the normal range or if a patient generates too high forces, which could be generated through the patient's spasticity.
67. The body weight support system of the unit should be equipped with an emergency release feature.

System should be supplied complete with following materials

68. Patients' harnesses (adult) in different sizes for different sized patients- 1 no each
69. Cuffs for the upper, middle and lower legs in different sizes – I set
70. Foot lifter – 1 set.
71. The harnesses/cuffs should be washable at 60°C in the washing machine.
72. cushioning material for harnesses/cuffs
73. Wall mount storage device.

Size and dimensions

74. The unit should be compact to be easily installed in a room of size 6m L x 4m W
75. The unit should be extendable in height to accommodate patients with more height
76. The unit should be suitable for training of patients with height of up to 200 cm

Certification and compliances

77. It should be USFDA registered device with verifiable documents
78. Should be electromagnetic compatibility Class A device (CISPR 11).
79. The unit should meet the requirements of EN 60601-1-2., meet the protective class SK 1.
80. The unit should be a class IIa device according to the European medical device directive 93/42/EC.

B) SUBJECT DRIVEN UPPER EXTREMITY FUNCTIONAL THERAPY SYSTEM WITH FOLLOWING SPECIFICATIONS

1. Instrumented arm orthosis with integrated weight compensation mechanism with Augmented feedback
2. The Arm Weight Support should be based on an exoskeleton with integrated spring mechanism for Arm Weight Support.
3. The Arm Weight support should be designed to counterbalance (middle length setting / horizontal position)
4. forearm weight: 0.7 kg - 2.5 kg
5. upper arm weight: 0.5 kg - 4 kg
6. The size exoskeleton of the exoskeleton should be adjustable to different arm sizes of adult persons; minimum settings are
 - i. forearm lengths (elbow to handgrip): 300 - 400 mm
 - ii. upper arm lengths (shoulder to elbow): 200 - 300 mm
7. The exoskeleton should contain the (lockable) distal degrees of freedom for pro Supination and wrist flexion / extension
8. The exoskeleton should be equipped with at least 7 joint angle sensors to detect movements in all relevant degrees of freedom

9. The exoskeleton should contain a pressure sensitive handle to detect trace amounts of grasping activity of a patient
10. The exoskeleton should be usable for the left and the right arm
11. The exoskeleton should contain braces to position the patients' arms
12. The braces should be eudermic and washable
13. The exoskeleton should be mounted on an electric lifting column (Adjustable Range: 400 mm)
14. The exoskeleton should be mounted on a trolley and be movable by one person
15. The Augmented Feedback should contain different functional exercises or games
16. The Augmented Feedback should contain functional exercises in a 1D, 2D and 3 Dimensional workspace.
17. The library of Augmented Feedback functional exercises should be filterable according to therapy goals and the joints involved
18. The Augmented Feedback workspace for 2D and 3D exercises should be automatically personalized according to the physiological volume reachable by the patient in 3D.
19. The Augmented Feedback should contain reach to grasp type exercises (involving Arm and Hand treatment at the same time)
20. The Augmented Feedback should contain a user database to manage individual patients' therapy plans
21. The Augmented Feedback should automatically progress through all exercises in patient's individual therapy plan, without staff intervention.
22. The Augmented Feedback should store all therapy activities and contain export routines to access raw data
23. The user database should support at least 500 Patients data
24. The system should have facility of automatic backup of user data
25. The Augmented Feedback should contain assessment capabilities to quantify
 - i. Patients' coordination ability
 - ii. Patients' range of motion in each degree of freedom.
 - iii. Physiological volume reachable by the patient in 3D.
26. The level of difficulty of therapy exercises in the Augmented Feedback should be adjustable
27. Within each level of difficulty in the Augmented Feedback, there should be multiple exercise levels to allow for gradual progression in exercise challenge.
28. The level of visual detail of therapy exercises in the Augmented Feedback should be adjustable to patient's visual or cognitive impairment.
29. The Therapy system should be adaptable to the individual patients' active range of motion in the impaired arm
30. The Augmented Feedback should contain reporting capabilities to automatically generate reports in PDF format with patients' exercise scores and assessment results over time and with information about device usage for the hospital managers.
31. The system should contain PC and a 24'' screen for visualization of the exercises
32. The therapy system should also be supplied complete with a hand module for training in grasping function for patients with impaired hand functions
33. The hand module should support a hand opening movement with a non-powered spring mechanism
 The hand module should work in plug-and-play manner during therapy sessions. Hand Module should also have Augmented Feedback containing exercises specifically designed for combined hand and arm control.
34. Application and efficacy of use of the unit should be established by independent researches in stroke, spinal cord injury, traumatic brain injury, multiple sclerosis, Parkinson and in patients with cerebral palsy.
35. There should be sufficient Evidence available from trials with the unit showing functional improvement, sustained long term benefits, increase upper extremity capacity as a result of training with the unit.
36. Certification and compliances
 - i. **It should be USFDA registered device with verifiable documents**
 - ii. **The unit should have CE market clearance and should meet the requirements of EN 60601-1 standards**

37. Common specifications to be fulfilled by both the systems
- i. The system should be in wide use all over the world
 - ii. There should be minimum 4 satisfactory working installation of the system in reputed Govt or private hospitals in India.
 - iii. The vendor should provide satisfactory performance certificates from minimum 3 users from India
 - iv. The vendor must demonstrate the quoted system anywhere in India at own expenses to the hospital doctors.
38. The system should be operated on Normal Indian Power supply 230 V 50/60 Hz.
39. A user training by a clinical application specialist should be contained in the scope of delivery
40. Wear parts should be contained in the scope of delivery.

Installation & Training

The vendor should undertake to provide free installation and training for technical and clinical staff at site of installation by their engineer including operation and upkeep of the equipment.
The vendor must demonstrate the quoted system anywhere in India at own expenses to the hospital doctors.

Warranty

The unit should be covered under warranty for a period of 5 years

Compatible software updates should be provided free of charge during the warranty period.

The unit's manufacturer should provide remote technical support and clinical support for questions via email and phone

The manufacturer should provide a clinical knowledge platform with latest information about products, state of the art clinical research and the possibility to exchange with other professionals in the community.