Owner's Manual - v K

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Read this manual before using this product. This manual contains important safety, operation and maintenance information. Make this manual available to all persons responsible for the operation and maintenance of these products.

Document No: HDT-R001032-RevK

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KineAssist® Technology History

The KineAssist began as a joint project of robotics researchers and physical therapy researchers and clinicians from Northwestern University and the Rehabilitation Institute of Chicago, together with professional engineers at Kinea Design LLC. In 2003 when the project began, members of the same team had been deeply involved in the invention and introduction of cobots, collaborative robots for direct physical interaction with people. This now-popular model was a marked departure from the prevailing fenced isolation of robots in industry. Opening the gates required advances in the sensing of human intent, shared control of force and motion, and safety.

Physical therapy promised a challenging and valuable new opportunity for robot/human interaction. With funding from the *Department of Commerce NIST-ATP* program and the *Rehabilitation Institute of Chicago*, the team began a disciplined exercise in user-oriented design, guided and assisted by the product design firm IDEO.

From the beginning the team's objective was to create a robotic tool for the clinician, as opposed to a robot that would itself provide physical therapy. Preserving the subtle physical give and take between a clinician and her patient was a key issue. The sensory environment presented to the patient was also crucial, as was making it possible for the clinician to work creatively and flexibly with the patient without hindrance by the machine or undue attention to its operation.

The team's intensive investigations, observations, prototyping, and ongoing integration of clinician feedback was recognized by an IDEA award as an exemplary design process. The up-front investment was also rewarded by a successful and rapid engineering design and development effort, with an FDA-approved product in clinical operation within 12 months.

In 2005, with early models of the KineAssist in use in several hospitals and clinics, the project was transferred to the ownership and control of the Rehabilitation Institute of Chicago. Today RIC continues to use, study, and share a new kind of robotic rehabilitation tool, one which coordinates motion with and responds to and respects the intentions of two people, both a patient and a clinician. Kinea Design's engineers, now members of HDT Expeditionary Systems, continue their commitment to support and advance the KineAssist.

Chapter 1: Getting Started

1.1 Product Description

The KineAssist-MX™ device is intended for use by physical and or occupational therapists in a rehabilitation setting for assisting/enabling therapeutic exercises prescribed to patients for gait and balance training.

The *KineAssist-MX*™ is a microprocessor controlled, motor actuated robotic device that will assist clinicians in maintaining patient safety while performing challenging therapeutic activities. The device has a relatively small foot print and does not require any changes to a clinic's infrastructure.

The device has programmable modes to address the needs of both low level in-patients with impaired mobility on a basic functional level as well as more advanced outpatients with fall risk.

1.2 Important Safety Instructions

All KineAssist-MX are built to specifications and intended for commercial use.

The main power switch is located near the location of the power cord. The switch has "I" and "O".

"I" Position: When the switch is in the "I" position the KineAssist-MX is turned on and the belt is held tight, and the device is functional.

"O" Position: When the switch is in the "O" position the treadmill is turned off and the belt is free moving.

This equipment must be operated by trained staff and serviced only by duly qualified service personnel. All information in this manual is directed towards such persons only. They ensure the safety of the patient, user and the equipment.

DANGER – To Reduce the Risk of Electrical Shock

- Read all instructions before using.
- Do not modify the plug provided with the treadmill. It is equipped with a power cord with a grounding plug. If it will not fit in the outlet, have a proper outlet installed by a qualified electrician.
- Do not use any adapters, especially ones without grounding provisions. To do so could result in electrical shock.
- Do not operate electrically powered treadmills in damp or wet locations.
- Before opening the electronic enclosure cover the power cord must be unplugged.
- Do not soak the treadmill surfaces with any liquid; use a sprayer or damp cloth. Keep all electric components, such as the motor, power cord, and power switch away from water.
- Do not place any open liquid containers on any part of the treadmill. The use of sport bottles with closeable tops is acceptable to be used.
- Do not attempt to service your treadmill yourself if you feel at risk.
- Always keep the running surface clean.

CAUTION:

- Proper heart rate, blood pressure, and symptoms of discomfort, anxiety or fear must be monitored by the clinician who works with patients under high intensity exercise conditions.
- A qualified mechanic should perform service or repair work. It is preferable that mechanics have successfully completed our factory-authorized service school or equivalent.

WARNING – To reduce the risk of injury

- Set up and operate treadmills on a solid, level surface.
- Keep all loose clothing and towels away from the treadmill running surface. It is also important that shoe laces do not extend past the bottom of the sole of the shoe.
- Keep hands away from all moving parts.
- Never leave children unsupervised around a treadmill.
- Inspect the treadmill for worn or loose components prior to use. Tighten/replace any worn or loose components prior to use.
- Read, understand and test the emergency stop procedures.
- Care should be taken when mounting and dismounting the treadmill. Never mount or dismount the treadmill while the running belt is moving.
- Wear proper athletic shoes, such as those with rubber or high-traction soles. Do not use shoes with heels or leather soles. Make sure no stones are embedded in the soles.
- The safety and integrity designed into the machine can only be maintained when the treadmill is regularly examined for damage and repaired. It is the sole responsibility of the user/owner or facility operator to ensure that regular maintenance is performed. Worn or damaged components should be replaced immediately or the treadmill removed from service until the repair is made. Only manufacturer supplied or approved components should be used to maintain and repair the treadmill.
- Only trained individuals should operate the KineAssist-MX.
- These qualified individuals must have the accompanying documentation available at all times when operating the device.
- Do not carry out any exercises with the KineAssist-MX if it cannot be correctly adjusted to the patient.
- When the patient is harnessed in the KineAssist-MX following preparation for training check that the device has been attached correctly and that the buckles are secure.
- Check all locking pins to make sure they are in the desired position.
- Check that the un-weighting setting has been set correctly before each session.
- The KineAssist should not be operated if any of the protective covers has not been mounted correctly.
- In the event of faults or irregularities, or any indication of damage (e.g. abnormal noise), the session must be stopped immediately. Perform a maintenance check and do not carry out further therapy until the problem has been remedied.
- The clinician should always be in close proximity to the emergency stop.

- Make sure that the Body Weight Support is set to zero when there is no one in the KineAssist. Unintended upward motion of the support arms will result if BWS is active with no one in the KineAssist
- Improperly resetting the force sensors could result in unpredictable behavior of the KineAssist and possible injury. For example, if somebody is leaning on the pelvic arms or something other than the pelvic harness is hanging from it - while re-zeroing - the force sensors will not be properly reset.
- The patient should not be left unattended/unassisted in Sit/Stand mode. The therapist should use the PT assist rings to help lower and raise the patient (to and from the bench) until the patient has gained confidence in this activity.
- The instructions provided for replacing any components internal to the electronic enclosure must be followed exactly.
- When replacing the slat; it is vital that new parts are used. If the old screws are used again the new slats could come loose from the mat surface and cause severe injuries.
- When using the steps, make sure there is plenty of room for the patient to step up, and ensure that the patient's head does not hit the ceiling
- When the PT is on the device they should always be standing on the non-moving surfaces of the treadmill when the device is in an active mode.
- Incorrect installation of the Pelvic Harness connector could lead to a hazard.
- When reconnecting harness confirm that the Lock Tabs fall back into place in the PM Harness Anchor
- Do not pull on the PM sliders themselves as this may create a pinching hazard use the push-pull knobs provided.
- Always use a transfer board when transferring a patient from a seated position to another seated position
- Always buckle in torso harness strap, and adjust its length accordingly in order to prevent hitting his head on the floor if they lose their balance.
- Patient should not be left unattended without the Pelvic and Torso harnessed donned.
- Do not step on the electrical enclosure of the KineAssist.

1.2.1 Earthing the system

The KineAssist-MX must be correctly earthed. In the event of a malfunction or failure of components, the earthing device provides the route of least resistance for the electrical current, thus reducing the risk of electric shocks. The unit is equipped with a mains cable with earthed plug. The plug must be connected to a suitable, correctly fitted and earthed main socket.

DANGER: The plug supplied with the treadmill should not be manipulated in any way. If necessary, a suitable mains socket must be fitted by a qualified electrician. Adapters may not be used because of the risk of electric shocks.

1.3 Technical Data

1.3.1 User Data

Maximum Patient weight:	350 lbs	159 kgs
Maximum Patient unweighing during training:	175 lbs	79 kgs
Rated Patient Width Range:	11.5 – 22 in	29 – 56 cm
Rated Patient Height Range:	4'10" – 6'3"	147 – 190 cm

1.3.2 Mechanical Data

Overall dimensions (L x W x H):	92" x 48" x 86"	234 x 122 x 218 cm
Weight:	Approx. 1289 lbs	586 kgs
Stand:	Base frame (and 4ea "shimming" feet)	
MAX Treadmill speed:	6.7 mph	10.8 km/h (3 m/s)
Running Belt Hardness:	43-47 Shore A	
MAX Pelvic Rotation (about vertical axis)	± 45°	
MAX Lateral Pelvic Movement	± 4 in	± 10 cm
Vertical Range of Motion (measured from Surface of the treadmill)	16.5 – 60 in	42 – 152 cm

1.3.3 Electrical Data

Mains connection:	120 VAC, 15 A, 50/60 Hz; 220 VAC option
Rated Power:	1,800 VA
Treadmill motor:	DC with tachometer, 1 kW
Lifting motor:	DC with absolute encoder, 1.27 kW
Mains cable:	5 m, 2 pole CEE 7/7 (earthed safety plug)
Mains circuit breaker:	240 VAC, 20 A, 2 poles
Logic power breaker:	32 VDC, 5 A, 1 pole, pushbutton

1.3.4 Treadmill Data

General:	Slats, overlapping, replaceable
Slat Type:	Rubber over aluminum support
Running Belt Hardness:	Approximately 40 Shore A
Standard Color:	Black
Support:	114 roller bearings, 12 roller guides

1.3.5 Electrical Specifications

Electrical Requirements – Below are the standard electrical requirements, if you have a different electrical configuration please contact your sales representative. There are two different options depending on which model you own.

Power Requirements:

- 120 VAC: 15 Amp, 60 Hertz
- Optional 220 VAC, 50/60 hertz

Outlet Compatibility:

- The 120 VAC input version comes standard with a 3-prong plug (NEMA 5-15 P).
- The US optional 220 VAC input version has a 3-prong plug (NEMA 6-15 P). DO NOT BEND OR REMOVE PRONGS. If other power cord plugs are required, please consult the factory. International installations will come with a country specific plug.

Note: For grounding reliability, only connect to the proper receptacle marked "Hospital Grade".

1.3.6 Electromagnetic Compatibility (EMC)

Electrical Medical Equipment is subject to special precautions regarding electromagnetic compatibility (EMC). They must be installed and operated accordingly.

The KineAssist-MX meets the requirements of EN 60601-1-2, EN 61000-3-2 and EN 61000-3-3.

It should be noted that portable and mobile RF communications equipment and other devices with interference beyond the permissible values can affect the electronics of the treadmill.

Detailed information and proof relating to electromagnetic compatibility can be viewed at the manufacturer upon request.

1.3.7 Environmental Specifications

Ambient conditions for operation:	
Temperature	+10°C to +40°C (0°F to +104°F)
Relative Humidity	20 - 95%, RH (noncondensing)
Atmospheric Pressure Range	700hPA to 1060hPA (20.67 to 31.3 inches of Mercury)
Ambient conditions for storage and transport:	
Temperature:	-10°C to +70°C
Relative humidity:	15 – 85% (noncondensing)
Air Pressure:	400hPA to 1060hPA

1.3.8 Classification and Mode of Operation

Classification: Safety Class I, Type B application

Degree of protection against ingress of water: IP2X

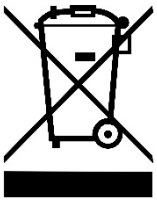
Mode of Operation: This device is designed for continuous operation.

1.4 Safety Symbols

Throughout this manual are NOTES, CAUTIONS, and WARNINGS. They are defined as follows:

	NOTES are general in nature and are intended to emphasize information
	CAUTIONS are to alert personnel to actions that could cause equipment damage, resulting in the equipment becoming unsafe.
	WARNINGS serve to make personnel aware of potentially hazardous actions that may result in personal injury.

1.5 Disposal



Disposal of the equipment must be in accordance with respective national regulations.

Electrical and electronic devices must be disposed of separately from normal household waste.

An appropriate waste disposal company should be contacted. Properly dispose of the device at the end of its service life.

- Device packaging is disposed of through resource recycling.
- Metal parts of the machine go to scrap metal disposal.
- Plastic parts are given to plastics recycling.
- Electric components and printed circuit boards are disposed of as electronic scrap unless an authorized recycler is available.
- Rubber parts are disposed of as hazardous waste unless an authorized rubber recycler is available.

Disposal of the equipment must be in accordance with the respective national regulations.

Wear parts are considered hazardous waste unless an authorized recycler for those parts is available. After being replaced, wear parts must be disposed of according to country-specific waste laws.

1.6 Document Revision Changes

Revision changes in this document are identified by a single line in the right margin; as shown in this line.

Chapter 2: KineAssist-MX Installation

2.1 Installation

It is recommended that transport, installation and assembly of the treadmill to be carried out by HDT or an authorized dealer or service provider. Otherwise damage or improper installation and assembly of the treadmill could cause a hazard when using the device.

	Before the device is installed the "ground" surface must be prepared. The total weight of the device with all the accessories and options is to be considered.

The following guidance for installation is to be observed:

- When installed on upper floors, the device must be placed as close as possible to a corner of the room so that sufficient stability is guaranteed, even at maximum speed. The structure of the building must be checked in advance.
- The KineAssist-MX should not be installed close to a radiator or other heat source. This could cause technical defects.
- Particular attention must be paid to the ceiling/floor load capacity at the installation site. This must be higher than 665 kg/m^2 and approved by an authorized authority with the treadmill representative. (*Calculation: Frame area: 80 x 201 cm = 1.6 m^2; KineAssist-MX weight: 586 kg; Weight of patient running (dynamic): 477 kg (=159kg x 3); Total weight on floor space; 1,063 kg; Therefore, the required capacity of the floor space in this case is 665 kg/m^2.*

2.1.1 Adjusting Shimming feet

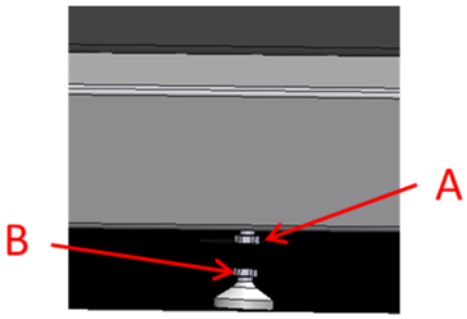


Figure 1 - Illustration of one of the shimming feet. There are 2ea shimming feet on the left and right sides of the KineAssist below the multi-purpose rails.

The KineAssist-MX's frame is designed to be in direct contact with the floor without having to deploy any of the shimming feet. To the extent the device is wobbling after installation due to an uneven (not flat) floor deploy the "shimming" feet by backing off jam nut 'A' and then turn nut 'B' (see Figure 1) until the device stops wobbling, and then re-securing nut 'A'. In most instances deploying only one shimming feet will be sufficient.

2.2 Transporting Your KineAssist-MX

DELIVERY:

- The KineAssist will be delivered and installed by HDT personnel or its designated agents.
- In case it is necessary to move the KineAssist, please contact HDT for support. It is possible to move it without on-site support, but the KineAssist is heavy and can cause injury if lifted incorrectly. HDT will provide written and phone support to help you properly accomplish the move, or you can hire HDT to perform the move for you.

2.3 Electrical Connection

	The formation of condensation on the cooled electronic parts may cause the KineAssist-MX to malfunction and damage the electronics. Before turning the system on, after storage or transport, the device must stand at room temperature for approximately 3 hours to become acclimatized.
	Improper handling of electrical equipment by unqualified persons can cause fatal electrical shock. • If necessary, allow only qualified personnel to perform electrical installation. • The power cord must not come into contact with hot surfaces or sharp edges. • Electrical parts such as motor, power cord and power switch must not come in contact with water.

In the US the KineAssist-MX is supplied with a 2-pole, 3-prong plug as standard feature and can therefore only be connected to a NEMA 5-15 R (120V) or NEMA 6-15 R (220V) socket. For installations in other countries the KineAssist-MX will be supplied with a country specific plug.

	The power cord is to be used for mains disconnection.

The maximum electrical power requirements of your KineAssist-MX at top operating speed is 15 A at 120 VAC. The unit must therefore be connected to a correctly earthed and adequately fused mains socket, preferably a dedicated socket that is not fused by any other electrical appliances. If an extension lead has to be used, it must have the following properties: at least 12 AWG, earthed, maximum length of 10 feet.

Chapter 3: KineAssist-MX Description

The following describes the KineAssist-MX's theory of operation, subcomponents and labeling of the KineAssist-MX device.

3.1 Intended Use

The KineAssist™ -MX device is intended for use by licensed clinicians such as physical and/or occupational therapists, in a rehabilitation setting or in fitness centers (with adequate supervision over training regimens) for assisting/enabling therapeutic exercises prescribed for individuals with mobility disabilities to improve functional balance and walking ability so as to participate more fully in important life roles, and facilitate activities of daily living.

Use this appliance only for its intended purpose as described in the manual. Do not use attachments not specified by the manufacturer.

3.1.1 Indications

- Incomplete Spinal Cord Injury (patients must still be able to bear some weight on their legs)
- Cerebral Vascular Accident (Stroke)
- Traumatic Brain Injury
- Parkinson's Disease
- Multiple Sclerosis
- Cerebral Palsy
- Post-lower limb amputation
- Balance disorders/high fall risk
- Cardiac and pulmonary deconditioning
- Musculoskeletal disorders that impact walking ability

3.1.2 Contraindications

- Complete restrictions on weight-bearing
- Fractured Ribs
- Unresolved large vertebral disc herniation/rupture
- Infections/open wounds in the pelvic region
- Unhealed skin grafts in the pelvic region

3.1.3 Precautions

- Gastrointestinal tubes
- Colostomy

- Non-stabilized total hip replacements
- Non-stabilized hip fractures
- Unstable spine
- Compromised skin integrity
- Post cardiac events
- Low oxygen saturation levels at rest or with activity (less than 92%)

3.1.4 Adverse Effects

The KineAssist Walking and Balance System is uniquely designed to catch any participant who experiences a balance loss. The device can catch and hold anyone up to 350 lbs/159 kg of weight. The catching mechanism is triggered by a drop of the height of the pelvis by 3-4 inches/7-10 cm – the treadmill automatically stops and the person is held in the harness where they can be restored to a standing resting position by the experimenter who can lift a person using "lift rings" that exist on the pelvic mechanism. After 10 years of use in various experiments, no participant has experienced harm in this device. However, possible adverse effects are:

- Slight skin irritation around the harness and/or thigh straps

3.2 Theory of operation

The KineAssist provides greater ease and improved safety in treating patients with mobility impairments. The system is built to seamlessly integrate into the existing therapy framework. When used under the supervision of an occupational or physical therapist, the KineAssist can be used to help patients progress from basic motor training to more complex multi-plane movement patterns.

With the KineAssist, intelligent electronics sense when a patient wants to move and the device safely follows. The robotics, in combination with controls software for Neuro-Rehabilitation interventions, allow for safe and effective treatment to occur in the rehabilitation setting.

3.2.1 Intent Driven Motion

The KineAssist uses information it gathers continuously from several sources to determine what motion is being requested by the patient or patient/therapist combination. Components include a user interface screen, a joystick and a treadmill based frame. The system platform embeds system software in a robotic device that is worn and controlled by the end user. The KineAssist's control software continuously monitors the patient's movement forces at the pelvis. The system then filters and processes the data and sends commands to a motors to enable the desired motion. By transparently sensing the patient's intended movement, the KineAssist enables patients to self-initiate and complete complex gait and balance tasks without the fear of falling. This security is provided by a torso and pelvic harness system. Using the device, patients can alternate between balance and gait exercises.

3.3 KineAssist-MX Components

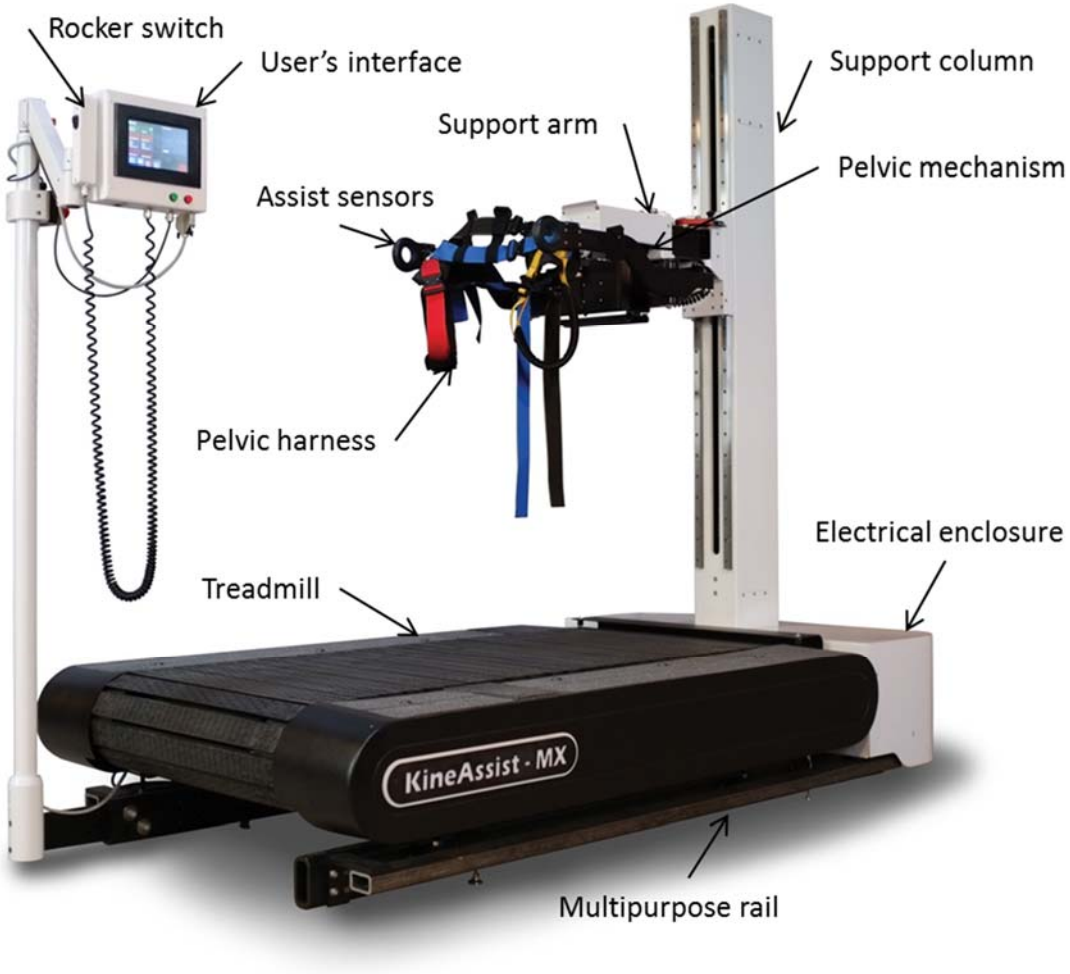


Figure 2 - Picture of a KineAssist-MX

⚠	Do not step on the electrical enclosure of the KineAssist.

3.3.1 Support Arm

The *Support Arm* carries the patient's weight and travels up and down along the *Support Column* under motorized control. Its main feature is a parallelogram linkage that can be locked to provide a rigid beam-like support for the patient or unlocked to allow for the natural lateral and rotational excursions of the pelvis that occur during walking. Together, the *Pelvic Mechanism*, and the Support Arm stabilize, limit and control the ranges of motion of the pelvis while still allowing the patient to walk and balance without fear of falling.

When the locking pin is released and both limiting brackets are in their widest positions the Support Arm is free to move 4" to the left or the right. The brackets can be used singly or symmetrically. That is, they can be used to allow equal travel to both the right and left or different limits can be applied to the two directions.

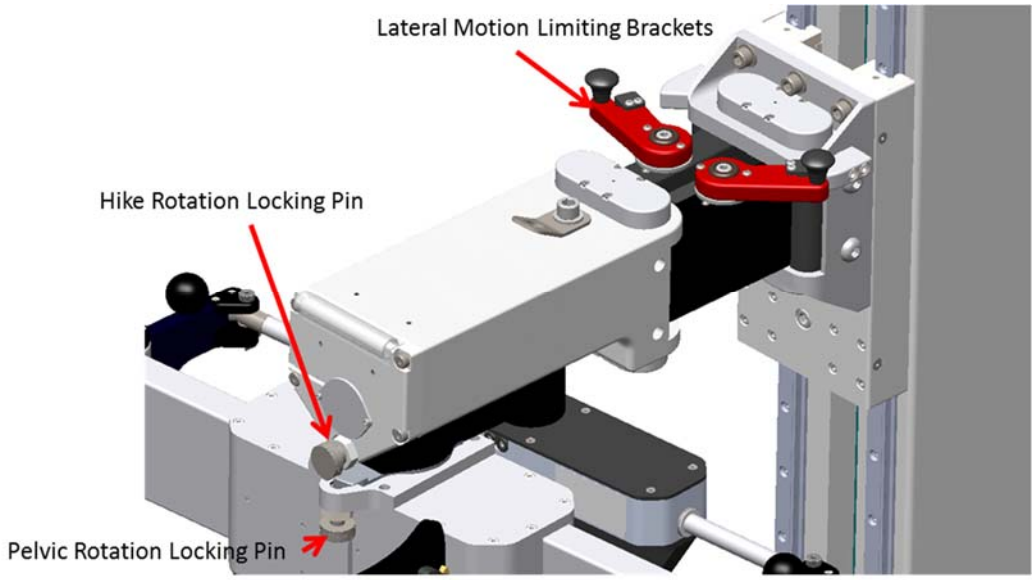


Figure 3 – Passive motion locking mechanisms.

3.3.2 Pelvic Mechanism

The Pelvic Mechanism and the torso harness are the mechanisms that support the person's trunk and pelvis while allowing the natural cyclical movements that occur in walking and balance exercises. The Pelvic Mechanism is designed to allow gait and balance activities to occur unimpeded while providing safety. It is used as a stabilizer, body weight support system and as a vertical fall prevention safety mechanism. It can also be used to limit the range of motion of hip roll (also known as hike), and hip yaw (rotation in the axial plane about axis of the spine). Either of these limits can be applied in combination or independently. The limitations on hip yaw can be applied either symmetrically to both the left and right side, or one side can be limited while the other is free. Hip roll is either locked or unlocked. It cannot be asymmetrically limited. Accommodation for flexion/extension is provided by the ball and socket joints where the pelvic harness attaches to the Pelvic Mechanism's arms. These joints do not limit flexion/extension. Overall support over flexion/extension is supplied by the torso harness.

The Torso Harness provides support to the trunk in the event the patient loses his balance and lunges forward. The strap connecting the torso harness to the support arm can be used to limit the range of motion of the trunk both in flexion/extension.

There are two harnesses, a vest-like torso harness and a pelvic harness which is similar to a rock climbing harness. The harnesses serve as the connection points between the patient and the machine and provide the means of comfortably applying desired forces to the body as well as acting as fall arrest devices. The pelvic harness is the main attachment point for the patient. The torso harness is attached directly to an anchoring point on the Support Arm. The two piece design further simplifies harness management issues that arise while the patient is being secured.

⚠	Always buckle in torso harness strap, and adjust its length accordingly in order to prevent the possibility of the patient hitting their head on the floor if they lose their balance and swing forward (see Figure 4).
⚠	Patient should not be left unattended without the Pelvic and Torso harnessed donned.

Figure 4 - Pelvic Mechanism with Torso Harness, showing torso harness and pelvic harness.

Pelvic Mechanism Arm Width Adjustment:

The spacing between the arms of the Pelvic Mechanism can be adjusted to accommodate the patient's hip. Once set to a particular width the spacing is held by an electrically powered brake. There are two brake release buttons, one on each arm. To release the brake, press and hold either one of the buttons. While holding the button in with one hand pull on the black, ball-shaped knob with the other to widen the spacing or push in to make the spacing narrower. If the pelvic harness has been fitted to accommodate a very narrow-hipped patient it may hinder pulling the arms apart so be sure to undo any straps that may have been drawn up tight across the back of the harness.

⚠	Do not pull on the PM sliders themselves as this may create a pinching hazard use the push-pull knobs provided (see Figure 5).

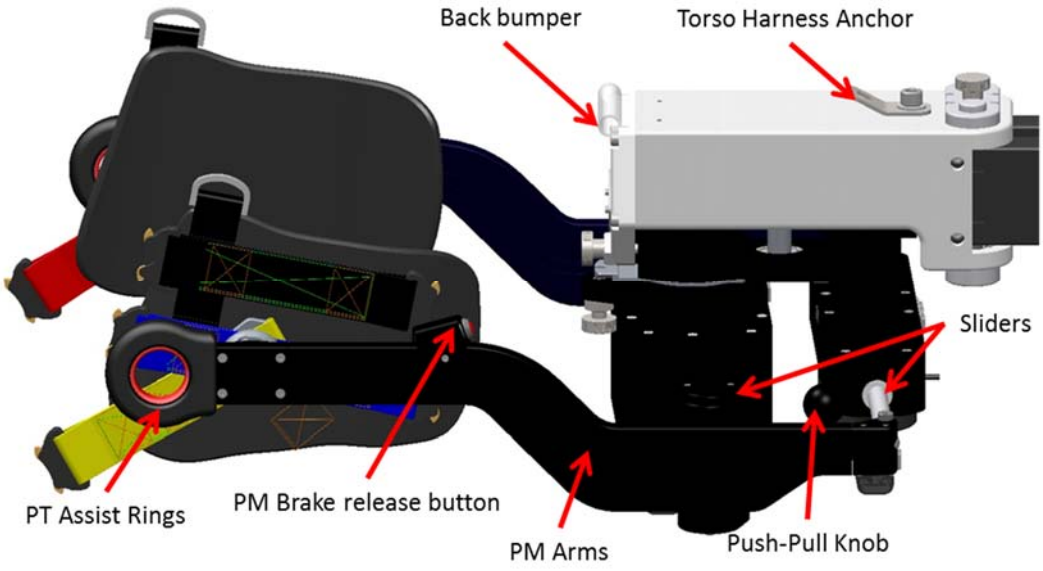


Figure 5 - Pelvic Mechanism components

Intent Sensors:

The KineAssist uses two pairs of force measuring sensors to determine the intended motion from the patient and the therapist. Because of this they are called Intent Sensors. Where the patient's pelvic harness attaches to each of the two support arms there is a ball-and-socket type connection that allows the harness attachment to rotate freely about three axes. Behind this socket is a load cell that measures the forces the patient applies to the support arms in the forward-backwards and up-down directions. When a patient walks, their hips apply forces to the arms. The KineAssist senses these forces and sends commands to the motors to make the KineAssist go in the same direction as the patient is moving (unless constrained by the parameters of the mode within which the KineAssist is operating; for example the treadmill belt will not move while in Setup mode even if the patient is pushing against the arms as if wanting to walk). These forces are not only used to command the KineAssist to move, they're also used to control the vertical height of the support arms. For example, when in Stand-Sit mode the patient's input to the patient intent sensors will cause the KineAssist to lower the support arms while at the same time still guarding against a fall.

Similarly, the PT assist rings measure forces applied against them by the therapist's fingers (also in the forward-backwards and up-down directions) and send this intended motion information to the KineAssist's computers to be resolved into the appropriate motor commands. The control algorithm applied to the commands make the PT assist rings "feel" more sensitive in the up direction than in going down. In other words they result in faster motion up for a given input force than when going down. This is because it has been determined to be better to limit the ability to "drive" the patient down quickly while still allowing crisp response in raising the patient. The PT assist rings also take precedence over the patient intent sensor, so the therapist can always override the patient's inputs to the KineAssist.

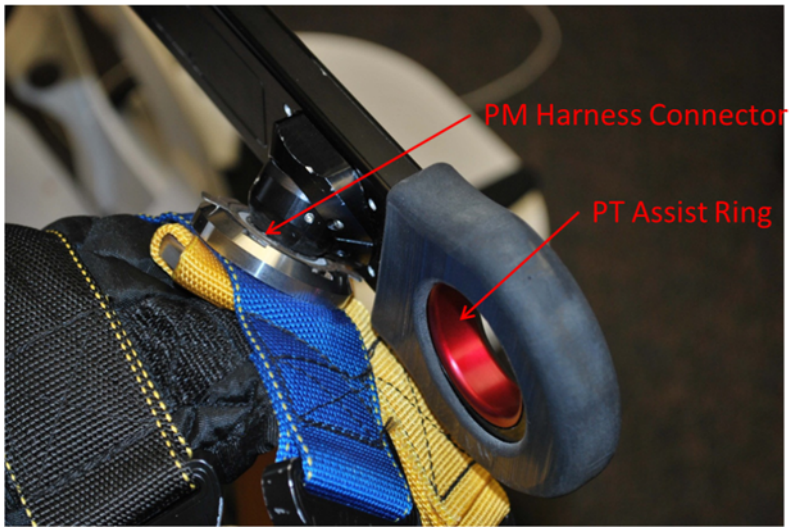


Figure 6 - PT Assist Ring sensors and PM Harness connector

3.3.3 User Interface Console

The user interface console is the primary control interface for the therapist to adjust and configure the system. It receives commands from two pushbuttons, a joystick, touch screen and a hand-held remote control unit. The touch screen displays system messages and the menu-driven command interface. Its features and operation are described in detail in 5.

Electronics Enclosure:

The electronics enclosure houses the computerized motor controller and its ancillary electronics.

Bump switches:

There are bump switches mounted along the bottom face of the pelvic mechanism. The switches respond to a bump anywhere along their length by prohibiting downward motion of the pelvic mechanism while the bump switches are engaged. Thus, they act as a safety in case the user runs into any object. A warning will be displayed on the LCD screen indicating when the bump switch is initially engaged. When the warning is displayed, move the pelvic mechanism upward until the obstruction no longer contacts the bump switches.

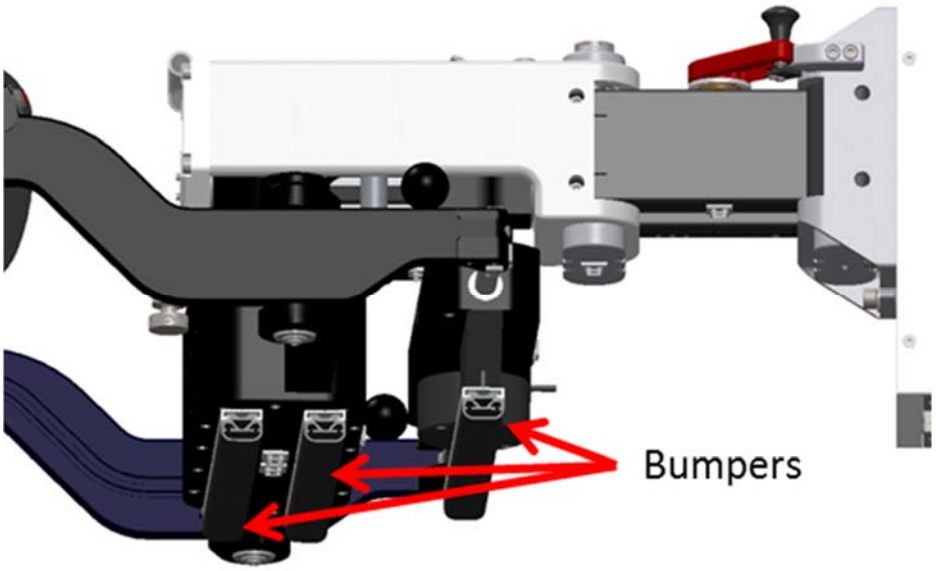


Figure 7 - Illustration of bumper switches.

Power Switch Block:

The power entry block is mounted on the back-right side of the electronic enclosure. It comprises the main power on/off switch, an Ethernet port and a resettable circuit breaker. The on/off switch follows the standard convention whereby "O" is OFF and "|" is ON. When it is off all power to the KineAssist is disconnected.

The Ethernet port can be used to communicate with the on-board computer by maintenance personnel.

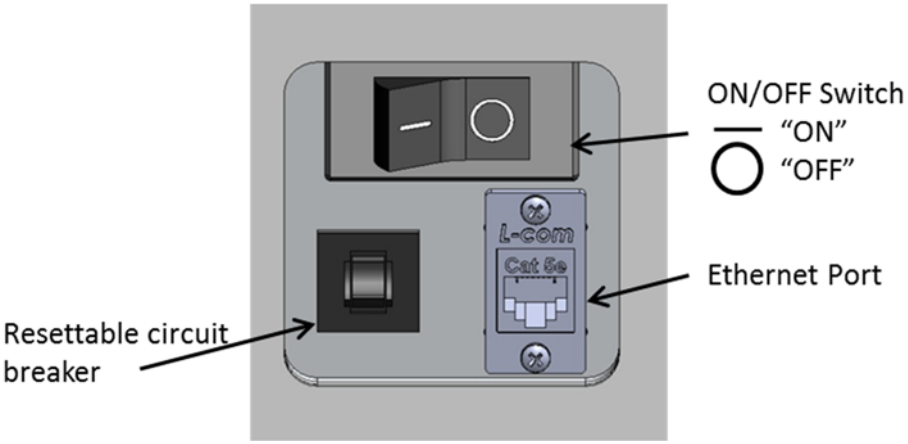


Figure 8 – KineAssist-MX power switch, resettable fuse, and Ethernet port.

i	Ethernet port is for use by maintenance personnel only.

3.3.4 Emergency Stop

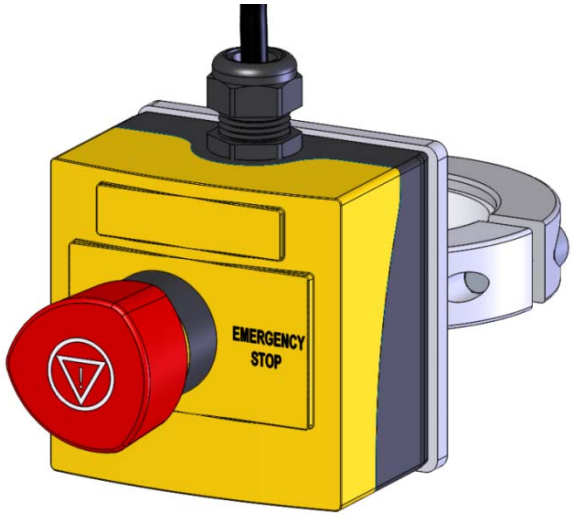


Figure 9 - E-stop Button

The emergency stop switch (red mushroom-shaped) is mounted on the display post and is to be used in an emergency. Pressing the emergency stop switch will interrupt the power to the motor amplifiers and prevent any motion. You can release the E-stop switch by turning the red mushroom head clockwise; its internal spring will make it pop out.

3.4 Product Labels

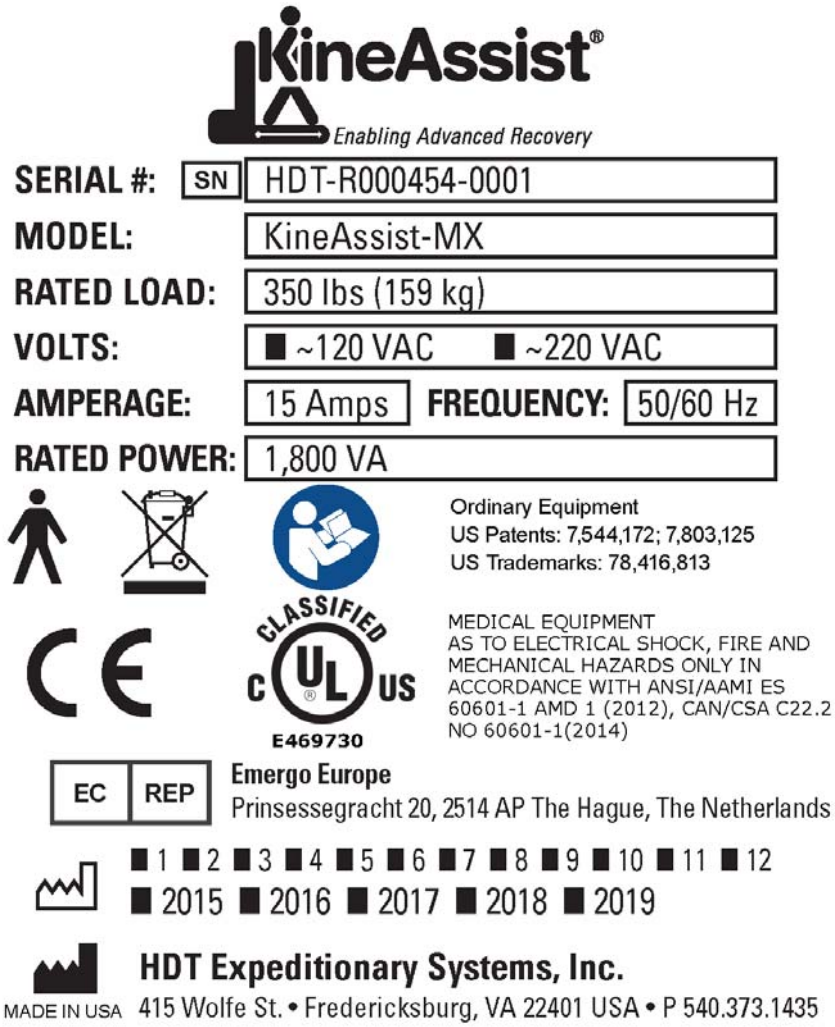


Figure 10 - KineAssist-MX Product Label

Consult instructions for use.

Alternating Current

“OFF” (power) / “ON” (power)

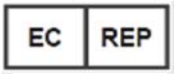
Symbol for type B, not conductive applied part and earthed.

Emergency Stop

Date of manufacture

Manufacturer

Serial Number



European Representative

Disposal Information

Do NOT step or stand on this surface

Disconnect Mains Plug

Connect an Earth Terminal to the Ground

Electrical Shock

Pinch Point

Grounding reliability

Chapter 4: Turning on & Setting Up the Device

4.1 Turning it on

1. Turn the power switch to ON (see Figure 8).
2. After the device boots up (in about 15 seconds), look at the user interface menu. It should display the main Basic Modes screen (Figure 11).
3. Press the Start button on the remote control. Pushing the green button on the user interface at this point will not enable the KineAssist to start. Instead a warning will appear on the screen indicating that the E-stop may still be engaged. Clear this warning by touching the OK button and then push the Start button on the remote. Pushing the Start button will start the KineAssist's short initialization procedure during which it tests for proper orientation of the wheels, checks that the pelvic mechanism is free to travel up and down, and that there are not undue forces already acting on any of the input sensors. After initializing is done, the screen will change from start to run mode.

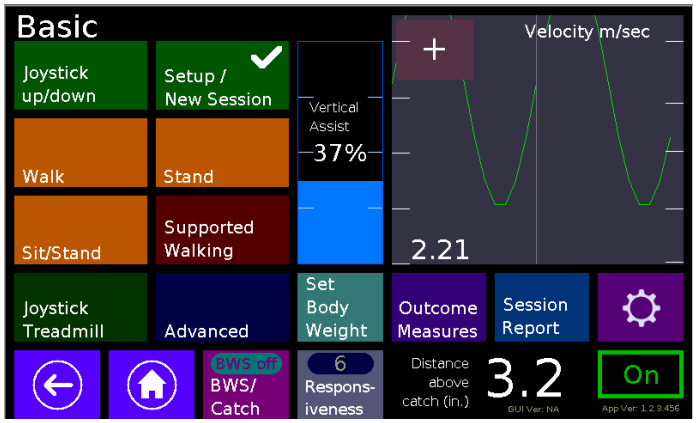


Figure 11 - Basic Screen

4.2 Donning the Harnesses

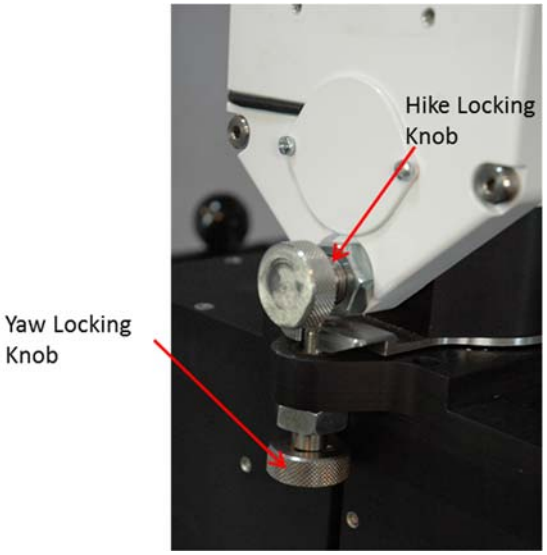


Figure 12 – Locking Knobs

1. The patient should now put on the torso harness. The torso harness is a vest with two torso straps and two shoulder straps. The shoulder straps may be opened to accommodate for someone with shoulder pain or high tone. The straps should all be tightened so that the harness has a snug but not uncomfortable fit. If the patient is in a wheel chair it is recommended that the torso harness be donned while he/she is still in the wheel chair.

2. Make sure all the joints of the Pelvic Mechanism and the Support Arm are locked. Doing this involves turning and releasing the hike locking knob; the yaw locking knob (Figure 12). The Support Arm limiting brackets should also be engaged (Figure 3).

3. Push the **Setup** mode button on the user interface.

4. The arms of the pelvic mechanism can be spaced farther apart or closer together to comfortably accommodate wider or thinner patients. (Once set, the arms' spacing is held by a brake mechanism.) Widen the arms on the pelvic mechanism by depressing either of the red brake release buttons on the top of the pelvic arms and manually pulling the arms apart by grasping the large black ball on the top of the arm.

Figure 13 – Basic Screen

Do not pull on the PM sliders themselves as this may create a pinching hazard, use the Push-Pull knob provided (see Figure 5).

5. Gently guide the patient into the device by having him/her step backwards or in the seated position.

6. The next step is to attach the torso harness to the device. This is done by clipping the buckle on the strap attached to the top of the Pelvic Mechanism to the buckle on the back of the torso harness (see Figure 4). You will adjust this strap to its final length in a later step.

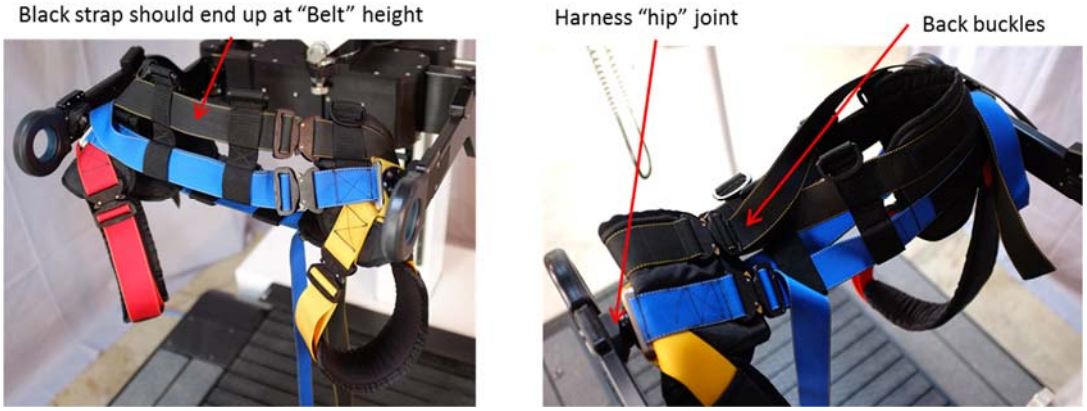


Figure 14 – Pelvic Harness

7. Lower or raise the pelvic mechanism so that top most horizontal strap is over the patients "belt" area.

8. Depress either of the red brake release buttons, and with the other hand provide medial pressure until the sides of the pelvic harness are snug on the patient, then release the red button.
9. To attach the pelvic harness first connect (but do not tighten) the front straps, and the back straps (NOTE: the straps are color coded). Tighten the front straps, and back straps while maintaining the harness' hip joint approximately in the center (forward/back) of the patient (Figure 15). Then buckle the leg straps making sure that the pads are flush with the legs. Now tighten all the straps by tugging gently.
10. Release the degrees of freedom. Release all the latches and locking pins you had engaged or locked previously. Have the patient rotate his/her hips. If the patient is unable to move freely a pin or latch is not disengaged. You can now proceed with the therapy session.
11. When the session is over hit the Red button and unstrap the patient from the harness. At this point the patient can walk away from the device.

Figure 15 – Patient Alignment

4.3 Removing the harness for cleaning

1. Locate the lock tabs on the PM Harness Anchor
2. Pull the tabs back and slightly twist the harness
3. To replace, simply match the slots, push, and twist slightly until the lock tabs fall back into the grooves on the PM Harness Anchor.
4. The harness can be sprayed with a disinfecting (cleaning) solution.
5. Do not place in a washer, as the components will cause damage to it.

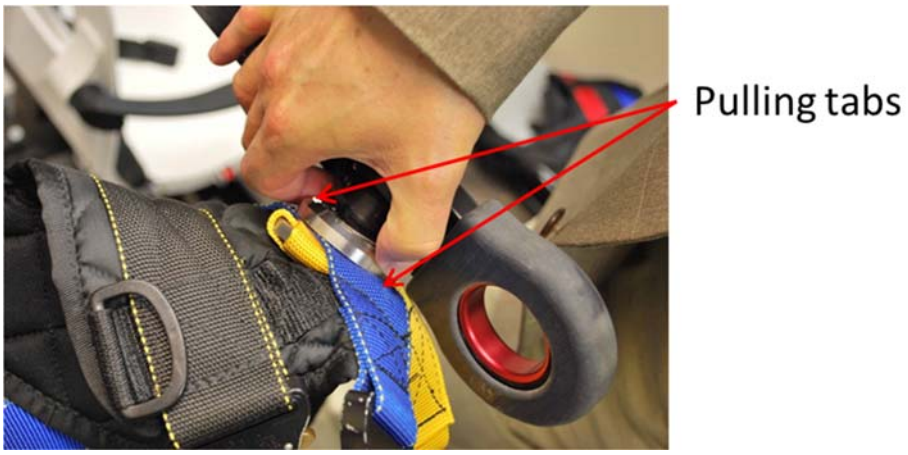


Figure 16 – Pelvic Harness Connector

	Incorrect installation of the Pelvic Harness connector could lead to an injury. When reconnecting harness confirm that the Lock Tabs fall back into place in the PM Harness anchor grooves.

Chapter 5: Description of KineAssist-MX Controls

5.1 Introduction

The user interface console is the primary user interfaces and the only point for adjusting and configuring the system. The user interface console consists of an LCD touch screen and joystick. The LCD touch screen interface is responsible for providing feedback to the user on the current status of the KineAssist as well as allowing the user to configure the KineAssist. The joystick can be used to move the KineAssist (when a patient is not strapped in).

5.2 The User Interface Console

This section details the operation of the user interface console on the KineAssist, which includes the joystick, LCD touch screen, and the start and stop buttons. These are the main input/output device for the operator, so the following sections are important both for system understanding and operating the system effectively.

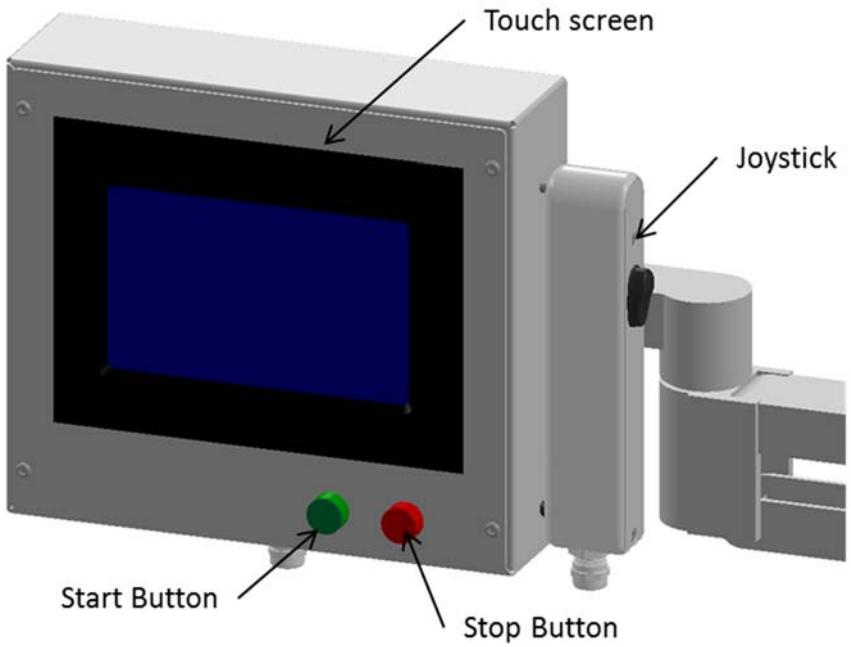


Figure 17 - Illustration of the operator interface.

5.2.1 Start and Stop Buttons

The Start and Stop buttons are the **green** and **red** buttons respectively, located at the lower right corner of the console, immediately beneath the touch screen. These buttons allow the user to switch the KineAssist from the STOP-to-RUN state (**green** button) and from the RUN-to-STOP state (**red** button). While in the STOP state, all the KineAssist's motors are disengaged, and the KineAssist will not actively move. When in RUN, the motors are engaged and allowed to move the

KineAssist. Stopping the KineAssist with the red STOP button will cause “stop” to be displayed as the status of the KineAssist on the bottom right corner of the screen.

⚠	When the PT is on the device they should always be standing on the non-moving surfaces of the treadmill when the device is in an active mode.

5.2.2 Joystick

The user can directly control the vertical position (height) of the pelvic mechanism via the joystick. When not in use, the joystick hangs from the console enclosure (see Figure 17). When using the joystick it is recommended that the corded side of the joystick (the side facing down in Figure 17) is towards the user. This orientation promotes intuitive manipulation of the KineAssist.

i	The joystick is only responsive when the KineAssist is in a Joystick mode or in specific modes described in section Sections 5.3 and 5.4.

5.2.3 Touch Screen

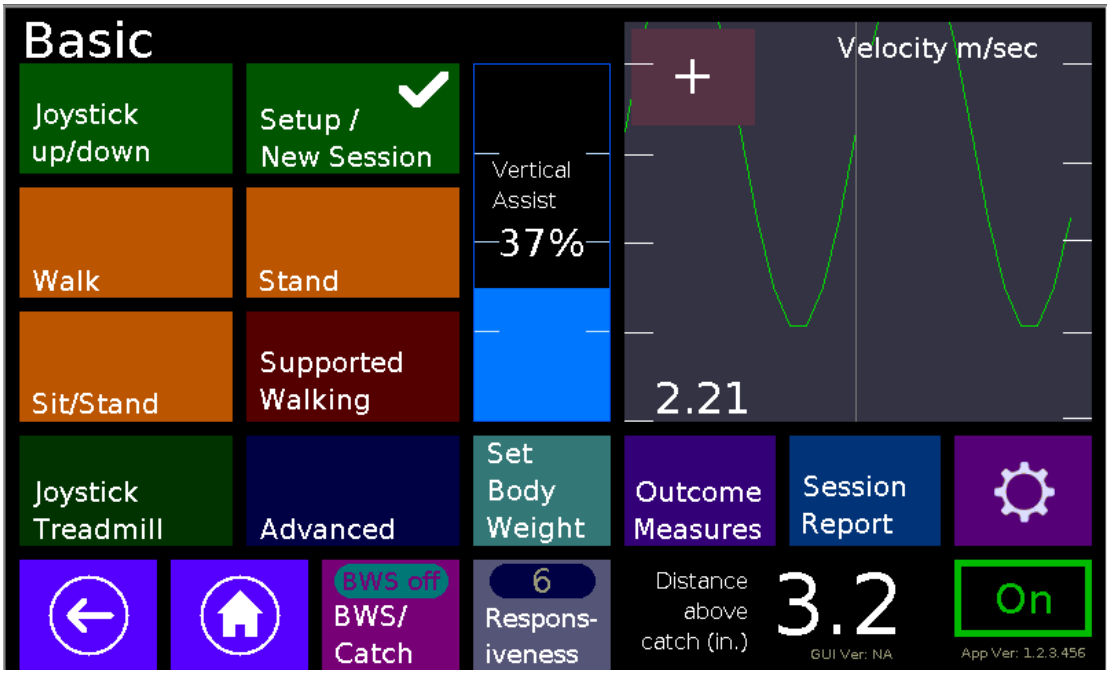


Figure 18 - Main menu screen of the User interface.

The Main Menu Screen is the initial screen displayed on the touch screen after startup and is the primary user interface of the KineAssist. The Touch Screen is the only means of selecting modes and specifying session parameters.

Choosing Different Modes

The columns of virtual buttons along the left edge of the Main Menu Screen allow the user to set the mode of the KineAssist. Details of each of the KineAssist’s modes are described in Section 5.3 and 5.4. For example, touching the “Walk” button enables the walking exercise mode on the device.

Some buttons are single action buttons and other buttons will deploy a secondary screen with more parameters and options as required by that particular mode.

Set System Parameters

In the bottom region of the Main Menu Screen, the user can manipulate three parameters of the KineAssist.

CATCHING DISTANCE:

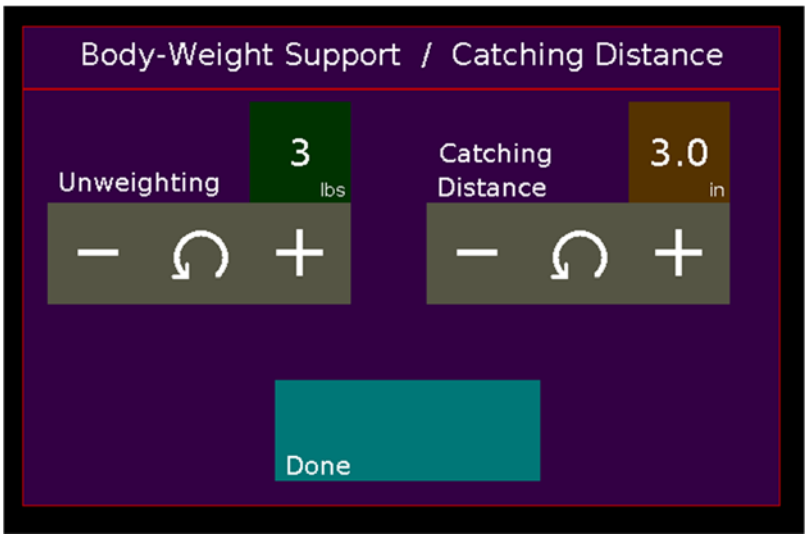


Figure 19 – Body Weight Support / Catching Distance parameters screen.

The Catching Distance parameter specifies how far the pelvic mechanism can nominally descend – from the height when entering a Walk mode – before a Safety Catch is invoked.

- Default Settings – 3 inches

i	The KineAssist can detect a patient's fall based by sensing a change in height of the arms that hold the pelvic harness that is beyond a threshold change set by the therapist (i.e. the catching distance). There is a normal change in the height of the support arms when the patient is walking or performing other tasks in the KineAssist so the therapist must set the Catching Distance to be larger than normal walking vertical motion. If the KineAssist detects the patient falling, it will invoke a safety catch. When in Safety Catch mode the treadmill is immobilized and the KineAssist will not allow downward motion of the pelvic mechanism below the preset catch height, but will still allow slow upward motion in response to either the PT assist rings or the pelvic harness or the joystick. Thus, either the PT or the patient himself can recover from the safety catch. After the patient has recovered his balance the KineAssist will still be in Safety Catch mode. The clinician must clear the Safety Catch Mode by pushing the "Resume" button on the screen.

Figure 20 – Warning screen. A message will be displayed depending on the reason for the warning.

UNWEIGHTING

The Unweighting parameter specifies the body weight support provided by the KineAssist.

The KineAssist implements unweighting by pulling up with a constant force (the specified force) so that the patient's weight on the floor will be lessened. The therapist can set this force in 1 lb increments up to 175 lbs. The therapist should be aware that for the patient this mode will result in the pelvic harness carrying more of the patient's weight and therefore care should be taken that the harness is positioned in a comfortable and secure manner. The therapist should also take care that the BWS is set back to zero at the end of the session. If it is not set to zero and the patient is removed from the harness and then Walk mode is activated the empty support arms will start to rise up seemingly on their own. The speed at which they will go up is determined by how high the BWS force (in pounds) is set. So, for example, if BWS is set at 35 lbs and nobody is in the harness and Walk mode is activated the arms will rise up at a fast speed.

- Default Settings – 0 lbs (0 kg)

⚠	Make sure that the Body Weight Support is set to zero when there is no one in the KineAssist. Unintended upward motion of the support arms will result if BWS is active with no one in the KineAssist.

RESPONSIVENESS

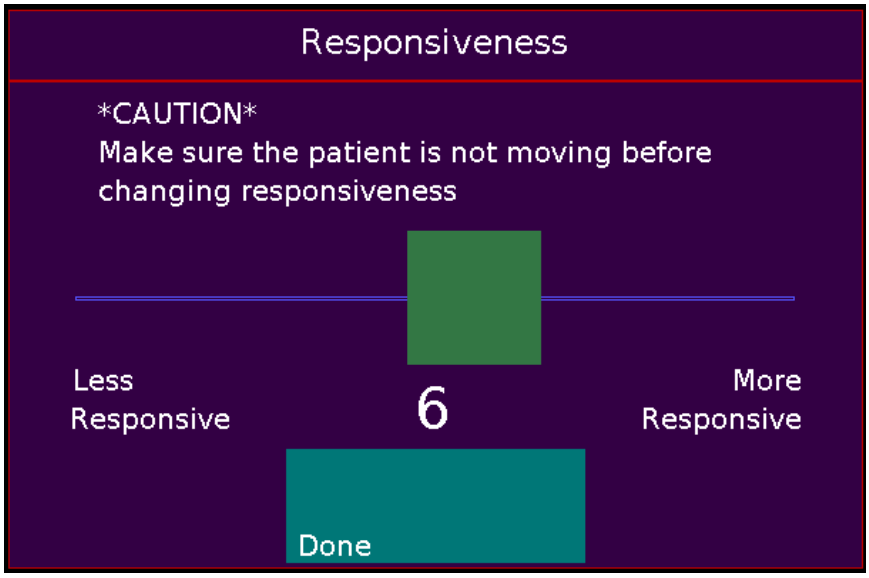


Figure 21 – Responsiveness parameter screen.

The Responsiveness parameter specifies how responsive the treadmill belt motion should be in relation to the patient's intent. The responsiveness is selected by sliding the green square along the blue line. The responsive scale ranges from 1 to 10, where 10 is the most responsive. If it is set towards the "More Responsiveness" setting (e.g., 8, 9, or 10) the treadmill requires less patient intent force than if it is closer to the "Less Responsiveness" side (e.g., 1, 2, or 3).

- Default setting – 6 out of 10.

i	When working with a weaker patient it is recommended that a less responsive setting is selected, such as 1, 2, or 3.

Observe System Measurements

In the Main Menu Screen the following system measurements can be observed:

1. Velocity in m/s: Displays the current velocity of the KineAssist in meters per second.
2. Velocity plot: A rolling plot of the velocity of the KineAssist

Observe System Information

The bottom portion of the Main Menu Screen displays pertinent information about the KineAssist:

1. Mode: Displays the current mode of the KineAssist (e.g., Joystick, or Stand to Sit)
2. State: The possible KineAssist states are RUN or STOP, which is indicated as "On" or "Off", respectively, in the lower-right corner. To operate the KineAssist it must be in RUN. Upon a fault, the KineAssist automatically enters STOP state.
3. Fault: When a fault occurs, its description is displayed here.

5.3 Modes of Operation

This section details the modes of operation available on the KineAssist.

⚠	When the PT is on the device they should always be standing on the non-moving surfaces of the treadmill when the device is in an active mode.

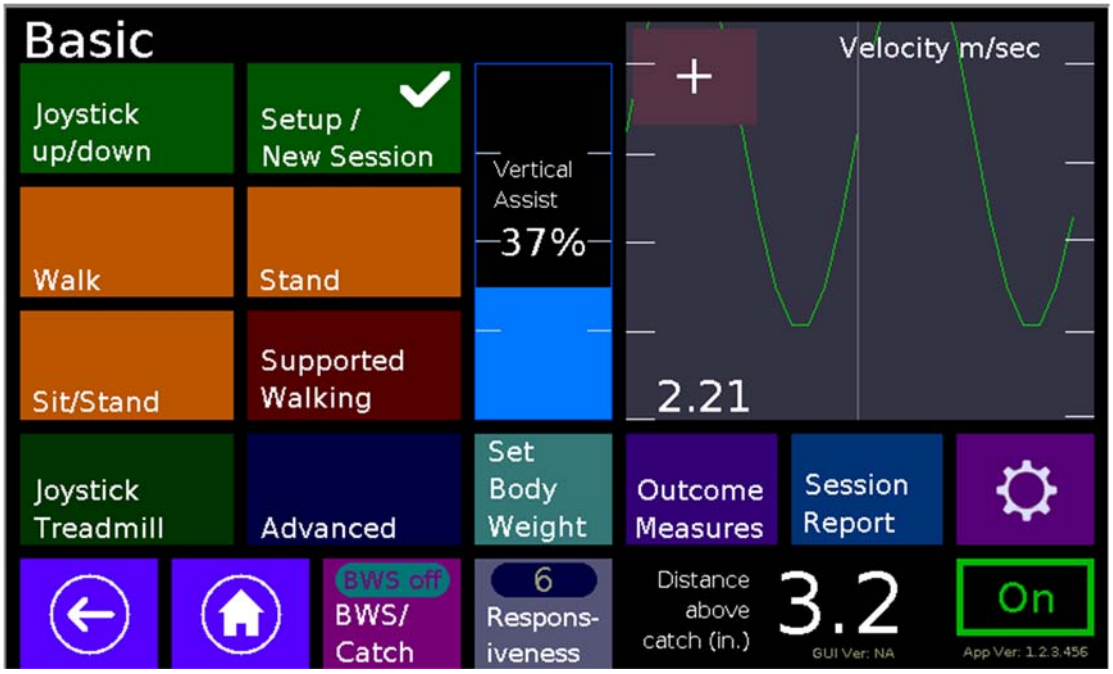


Figure 22 – Basic Modes selection screen.

5.3.1 Setup/New Session mode

Setup/New Session mode is used for getting patients in and out of the KineAssist and/or to start a new exercise session. When the *Setup/New Session* mode button is selected a dialog screen pops-up prompting for the operator's intention, see Figure 23.

1. If the intent is to start a new exercise session with a patient, then select the ***Yes. Change Patient*** button. Once the button is selected use the keyboard dialog (Figure 24) that pops-up to enter the patient de-identifier. The patient de-identifier can be alpha-numeric, and it must not – in any way – reveal Protected Health Information (PHI), such as the patients name, phone, email, or other common identifier. Once a patient de-identifier is written, hit the **[enter]** key to proceed.

i	Do not enter real patient names or other common identifier to avoid disclosing Protected Health Information (PHI).
i	With respect to *session data*, when the ***Yes. Change patient.*** button is selected the patient data will be saved for the current session and a new session will be started. This

	will happen regardless of whether the operator *cancels* out of the Keyboard dialog or re-enters the same patient de-identifier; selecting the *cancel* button is the same as re-entering the same patient de-identifier.
i	The **[clr]** button on the Keyboard dialog is provided in order to quickly clear the entry value.

2. Otherwise if the *Setup/New Session* button was selected by mistake or to simply accommodate/re-setup the patient select the ***No. Keep current patient*** button.

i	With respect to *session data*, when the operator selects the ***No. Keep current patient***. button the current session values will continue to increment, and the current patient de-identifier will be maintained.
i	The default user is **guest**. The **guest** user does not maintain a historical record.

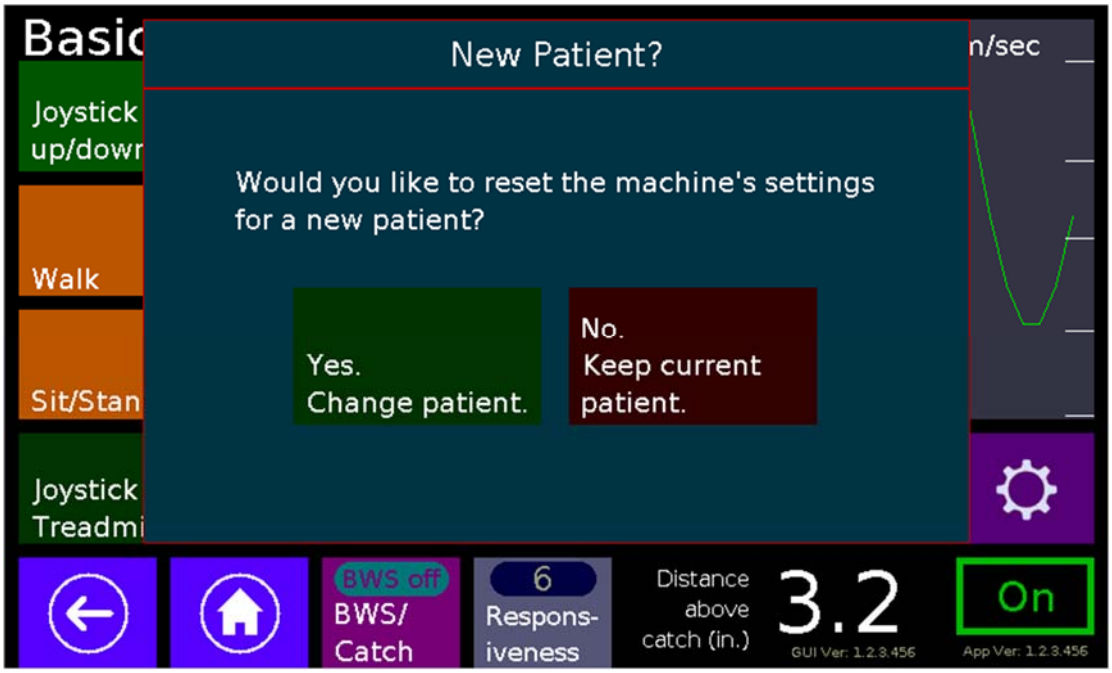


Figure 23 – Dialog that pops-up after touching the Setup/New Session button.

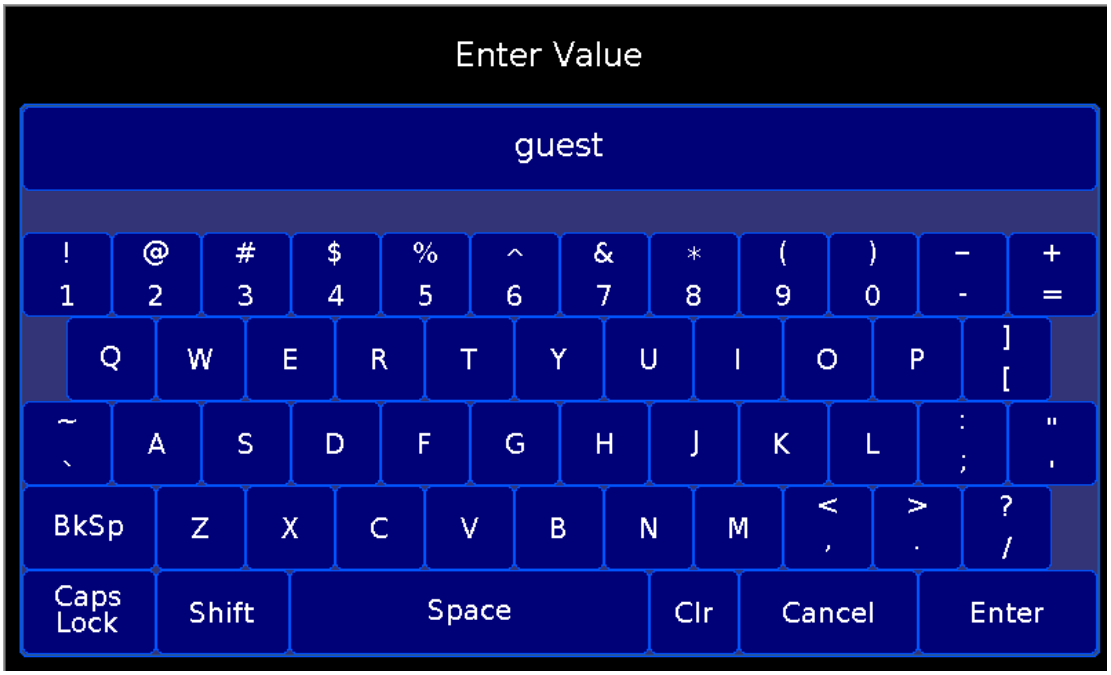


Figure 24 – Keyboard dialog for entering the patient de-identifier. **Guest** is the default user identifier.

Device behavior while in setup mode

While in this mode the treadmill belt is immobilized but the pelvic mechanism will move slowly up or down in response to inputs to either the PT assist rings or the pelvic harness sensors. However, the commands from the PT assist rings always take precedence. In this way the clinician always has full authority to control the vertical motion of the pelvic mechanism (and the patient) even if the patient were to stumble or slump.

i	While in setup mode the pelvic mechanism can move – albeit slowly – all the way down to the lower vertical virtual stop. In other words it will not catch the person at the specified "catch distance". This is the only operational mode where this is the case, and is required in order to be able to setup people of different heights, and/or from the seated position.

5.3.2 Joystick up/down Mode

When in a joystick up/down mode the height of the pelvic mechanism is directly controlled via the corded joystick plugged into the side of the LCD touch screen. In Joystick up/down mode only the height of the pelvic mechanism can be controlled by the joystick. This mode is used when the clinician wishes to lift the patient from a lower height to a higher height.

5.3.3 Stand Mode

Stand mode is similar to walk mode, except the treadmill is locked. The KineAssist will respond to vertical input forces, but horizontal inputs will be ignored. As with Walk mode the KineAssist will catch the patient if a fall is detected. Body-weight support also works in Stand mode.

While in either Walk or Stand modes, the "Distance above catch" in inches is displayed. This is how far the pelvic mechanism needs to drop before a safety catch is initiated. If there is currently a fault it will be displayed over the Distance above catch display.

5.3.4 Walk Mode

The Walk modes allow the patient to freely walk while safely harnessed into the KineAssist. The KineAssist will catch the patient if an impending fall is detected. The patient's motion dictates the motion of the KineAssist through the help of various sensors in the pelvic mechanism. These sensors include force sensors in the pelvic mechanism arms. In addition, forward and backward motion of the treadmill belt as well as up and down motion of the pelvic mechanism can be controlled via the PT assist rings on the arms of the pelvic mechanism. In Walk mode, the KineAssist should remain mostly transparent (feel as if it weren't there) to the patient unless the KineAssist detects the patient is falling. In other words, the KineAssist will follow the patient and only impede his or her motion when a fall is detected. However, the KineAssist will also constrain the allowable motions of the treadmill belt.

While in Walk mode the patient can control the treadmill belt to move forwards and backwards. Force sensors connecting the pelvic harness to the pelvic mechanism as well as force sensors in the clinician rings dictate the forward/backward velocity of the treadmill belt. When the patient generates higher force against the pelvic mechanism, the KineAssist surface will move faster, up to its maximum velocity limit. Patients can practice walking with a variety of assistive devices, similar to activities that can be accomplished overground.

5.3.5 Supported Walking

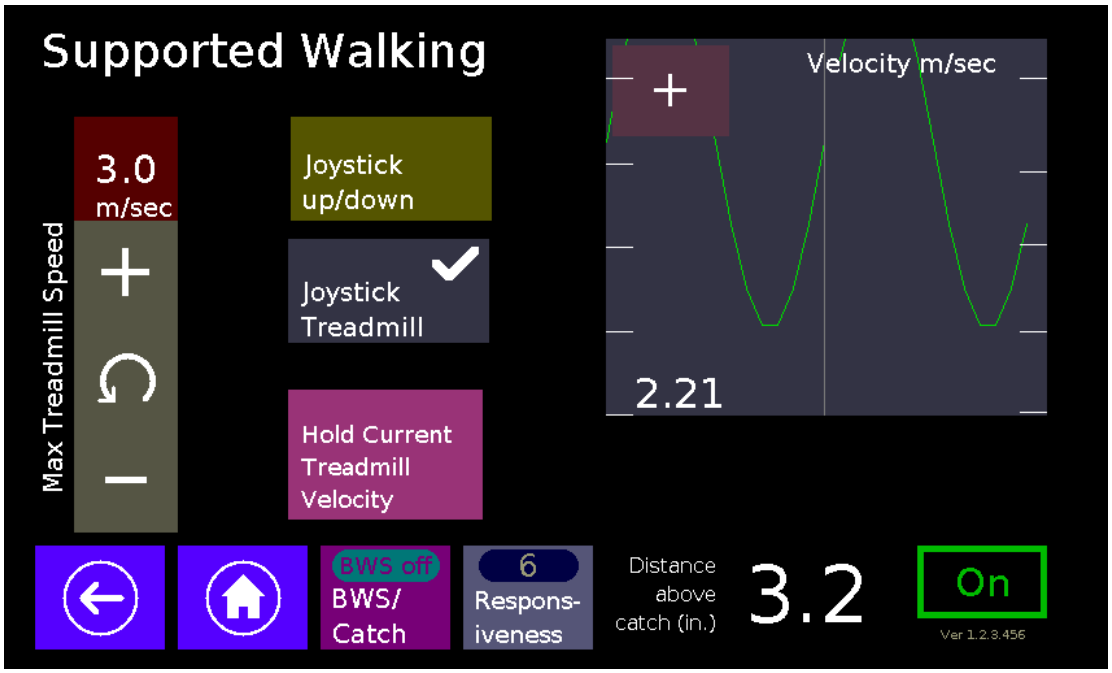


Figure 25 - Supported Walking screen

This mode is designed for the more dependent patients who are practicing in the earliest phases of walking. It is a combination of BWS and Pre-gait activities. It allows the operator to adjust the height of the pelvic mechanism using the joystick. They, while the pelvic mechanism supports the weight of the patient, the joystick is used to slowly walk a person's legs.

Supported walking allows patients that do not have the ability to support their own weigh to experience walking by locking the pelvic mechanism in place and having the therapist move the treadmill in joystick mode. After transferring the patient and standing them using Sit/Stand, switch to Supported Walking. This locks the treadmill and the patient can rest in the harness. The

therapist can adjust the patient's height by using Joystick up/down, and then push Joystick Treadmill to begin walking. The Hold Current Treadmill Velocity button allows the therapist to lock the speed so that the joystick button does not need constant pressure. When finished, ensure the patient is supported with the lift rings before you press the back or home buttons.

5.3.6 Sit/Stand

In this mode the patient can safely practice standing up from a sitting position or sitting down from a standing position. The KineAssist will catch the patient when an impending fall is detected (i.e. sitting straight down). In addition the clinician can assist the patient via the clinician rings. Horizontal assistance is provided when the clinician adds force in the horizontal direction, whereas vertical assistance is provided when an upward force is added. Combinations of these two forces can be provided, proportionally, by adding force at intermediate positions between the vertical and horizontal directions. The treadmill belt motion is controlled via the force sensors in the clinician rings and in the pelvic harness (as in Walk mode). Additional constraints are imposed on the range of motion of the buggy and pelvic mechanism. The nature of these constraints depends on the particular action being performed (i.e. Standing, or Sitting) and is described below.

The patient should not be left unattended/unassisted in Sit/Stand mode. The therapist should use the PT assist rings to help lower and raise the patient (to and from the bench) until the patient has gained confidence in this activity.

Standing to Sitting Transition

In this mode the patient starts from a standing position and then proceeds to sit down. The treadmill is largely limited to moving backward only (with only a small amount of forward motion permitted). This allows for a posterior weight shift. If the pelvic mechanism moves down without also moving backward the KineAssist will enter Safety Slowdown mode, where the belt is immobilized and the downward velocity of the pelvic mechanism is limited.

While in the sitting position, the clinician can work with the patient on a variety of exercises.

Sitting to Standing Transition

In this mode the patient starts from a sitting position and then proceeds to stand up. The treadmill is mostly limited to moving forward with only a small amount of backward motion allowed. This allows for anterior weight shift. If the pelvic mechanism drops by more than 8 cm (about 3 inches) the KineAssist will enter Safety Slowdown mode.

While in the standing position, the clinician can work with the patient on a variety of exercises.

5.3.7 Joystick Treadmill Mode

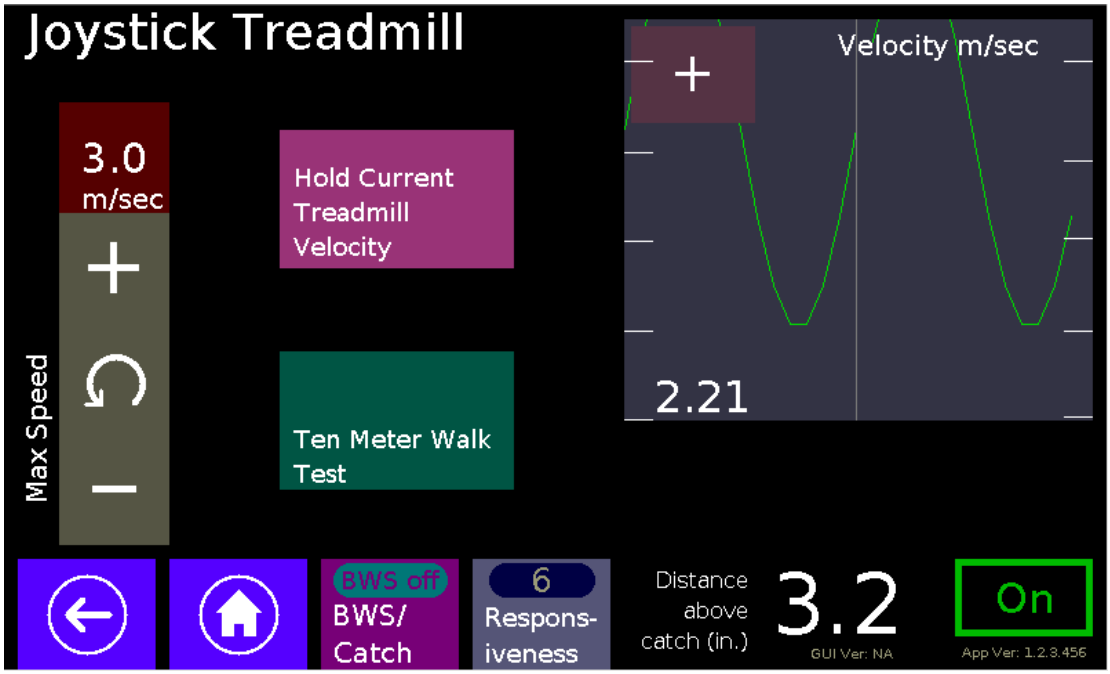


Figure 26 - Joystick Treadmill screen

This mode was designed to provide the clinician a way of prescribing a specific walking speed to the patient.

The clinician can specify maximum treadmill speeds between 0.1 - 3 m/s in 0.1m/s increments. Within that range the clinician can either proportionally control the treadmill speed or Hold a specific treadmill belt speed. This mode works similar to a conventional treadmill system where a speed is initially specified and the patient then needs to follow at that speed.

5.3.8 Set Body Weight

The set body weight button can be used to enter the patient's weight in order to view the dynamic vertical assistance provided by the KineAssist, as a percent (%) of their body weight.

i	The patient's weight must be specified for the behavioral effects of interacting with the VR game work properly.

5.3.9 Outcomes Measures

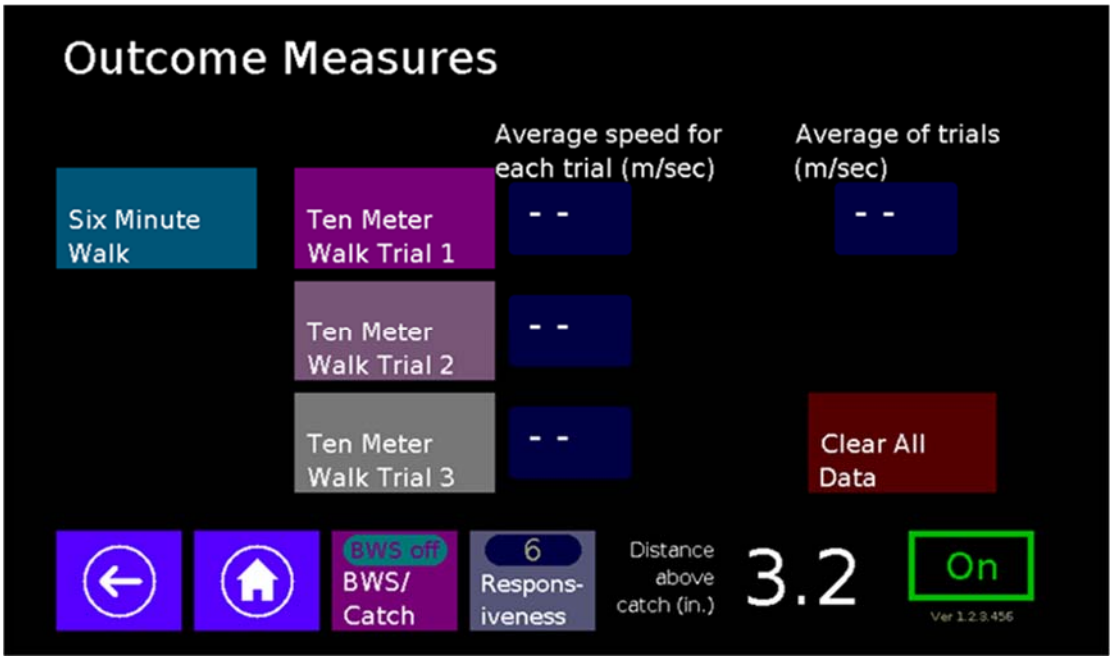


Figure 27 – Outcome Measures screen

Outcome measures allow clinicians to test and document 10m walk test and 6 min walk test outcomes. Testing both before and after a course of walking and balance training, will allow the clinician to document progress in a standardized and quantifiable manner.

- **Six minute walk test**; See Six Minute Walk Test description in earlier section.
- **Ten Meter Walk**: Opportunities for three separate trials allow the clinician to collect up to three samples and calculate an average speed.

Six Minute Walk Assessment

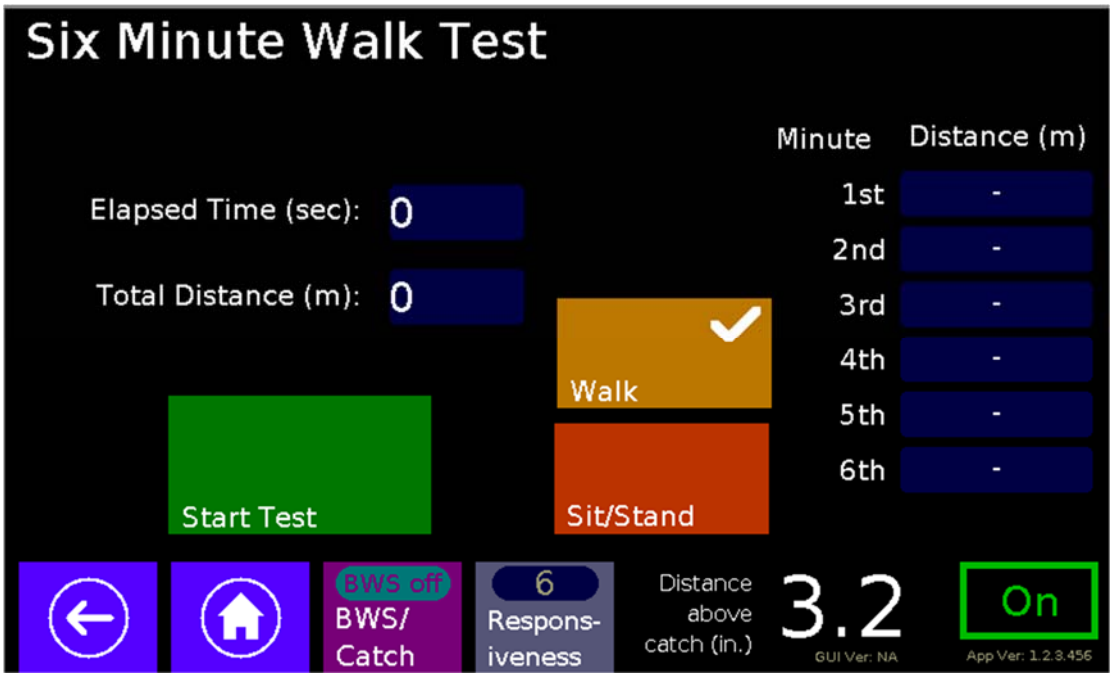


Figure 28 - Six Minute Walk Test screen.

This is a standardized clinical assessment tool to assess walking endurance. The test is meant to capture the amount of distance that a person can cover within a fixed amount of time (6 minutes). The test can be modified to shorter periods if desired by the clinician. Each one minute interval of testing generates a minute-by-minute distance measurement. Patients are advised to stop and rest during the test if they get tired, short of breath, etc. In this case, the timer will continue to run, and the distance values will remain until the patient is ready to continue with test. The Sit/Stand button is also provided should the person need to sit during the test. Results are reported as distance in meters.

10 m Walk Assessment

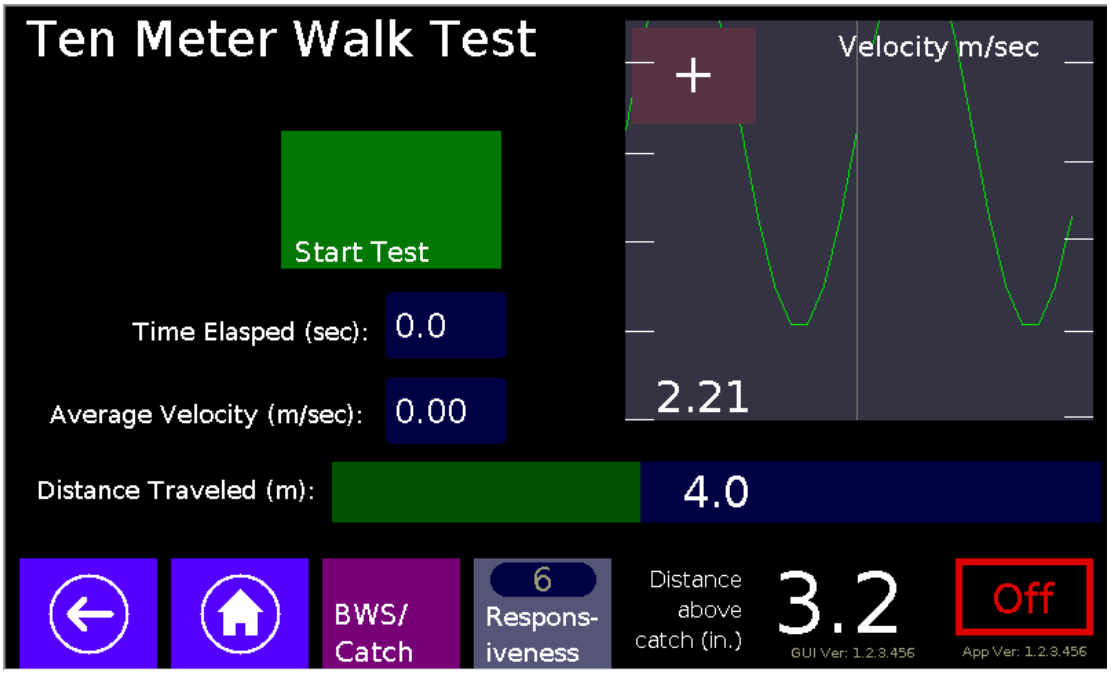


Figure 29 – 10m Walk Test screen.

This is a standardized clinical assessment tool to assess walking velocity. The test is meant to capture the amount of time that a person takes to walk over a 10m distance. The clinician asks the patient to begin walking until they reach a steady state of speed (as observed by viewing the velocity graph). Once steady state is achieved, the clinician hits the "start" button and the test begins until 10m of distance is covered by the patient. This test can be performed with the patient walking at a steady state comfortable velocity or at a steady state maximum velocity. Results are reported as velocity in meters per second.

5.3.10 Session Report

Figure 30 - Session Report screen.

To view information regarding the current exercise session, select *Session Report* from the *Basic* screen. The screen will display Figure 30 which includes the following metrics:

- **Total forward distance:** The cumulative forward travel (distance) of the treadmill. Backward walking and treadmill motion during sit-to-stand activities are ignored.
- **Total backwards distance:** The cumulative backward travel of the treadmill. Forward walking and treadmill motion during sit-to-stand activities are ignored.
- **Number of safety catches:** The total number of times the KineAssist caught the patient with a safety catch.
- **Number of sit to stands:** The total number of sit-to-stand transitions (stand-to-sit transitions are ignored).
- **Number of perturbations:** The total number of successful (patient did not "fall") perturbations executed.
- **Exercise time:** The total time since a new session was started and until the Red stop button is pressed or the New Session button is pressed.
- **Walking time:** The total time spent in walking modes, which include Walk, Supported Walking, Joystick Treadmill modes, as well as the other advanced activities.
- **BWS time:** The total time spent with non-zero body-weight support, includes the time in Walking modes as well as Stand mode.
- **Average BWS:** The time-weighted average body-weight support for the entire session (includes walking and standing activities with active BWS).
    - For example, if a patient walked for 10s at 20 lbs BWS and 20s at 10 lbs BWS the Average BWS is calculated as such: (10s * 20 lbs + 20s * 10 lbs)/(30s) = 13 lbs.

- **Average Walk responsiveness:** The time-weighted average responsiveness while in Walking modes.
    - For example, if a patient walked for 20s at 2 (responsiveness) and 10s at 5 and 5s at 10 the Average Walk Responsiveness is calculated as such: (20s * 2 + 10s * 5 + 5s *10)/35s = 3.5.
- **Average Sit/Stand responsiveness:** The sit-to-stand-weighted average responsiveness while in Sit-to-Stand mode.
    - For example, if a patient sit/stand 3 times at 2 (responsiveness) and 4 times at 5 and 5 times at 7 the Average Sit-to-Stand Responsiveness is calculated as such: (3sts * 2 + 4sts * 5 + 5sts *7)/(12sts) = 5.
- **Perturbation with MAX Peak Velocity Change:** Captures both Perturbation parameters (i.e. Peak Velocity Change and Extra Travel Distance) for the successful Perturbation with the largest Peak Velocity Change during the session. Note these parameters are only recorded for successfully completed perturbations, i.e. the patient did not "fall" during the activity.
- **Perturbation with MAX Extra Travel Distance:** Captures both Perturbation parameters (i.e. Peak Velocity Change and Extra Travel Distance) for the successful Perturbation with the largest Extra Travel Distance during the session. Note these parameters are only recorded for successfully completed perturbations, i.e. the patient did not "fall" during the activity.
- **Date:** Timestamp - date and time - of the session data being displayed (the time is displayed in 24 hr format).
- **Patient:** Patient de-identifier of the session data being displayed. Must not be the patient's real name.
- **Patient History** (button)**:** displays the chronological list of *timestamps* of all the sessions to date, see Figure 31. Each row in the Patient History dialog can be selected in order to display that specific session data.

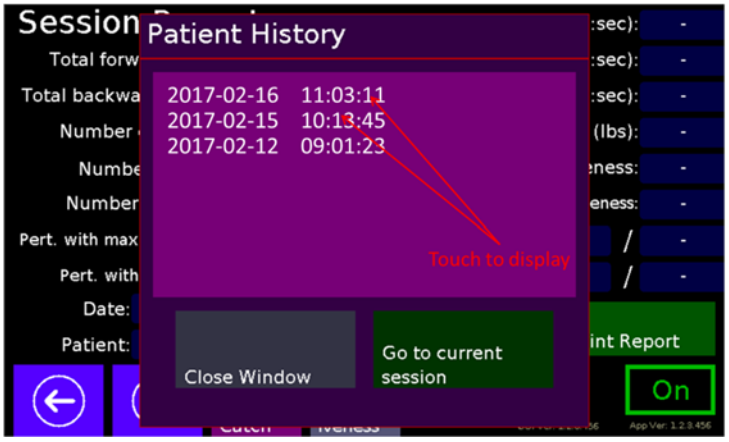


Figure 31 - Patient History dialog box.

- **Print Report** (button)**:** This button prints a paper report with the history of the patient's session data; requires the KineAssist's printer accessory kit.

Sparklines:

A *sparkline* is a small graphic line chart that represents the general shape of the variation (overtime) in some measurement (see Figure 32). The *Session Report* screen incorporates sparklines in order to quickly and succinctly visualize the general trend of any of the measurements that are being tracked by the device.

Figure 32 – Example of a *sparkline.*

Figure 33 - The blue data fields can be touched to display a *sparkline* of that particular data field.

For every measurement displayed in the *Session Report* screen a sparkline can be displayed by selecting the – blue rectangular – data field itself, see Figure 33. The sparkline – capturing the last 30 data points – for that measurement will pop-up as shown in Figure 34.

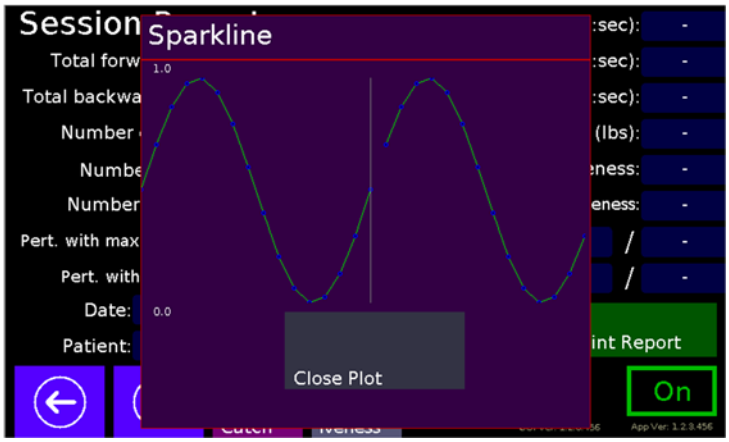


Figure 34 – Sparkline dialog box.

5.4 Advanced Modes of Operation

Figure 35 – Advanced Modes selection screen.

The "**Advanced Modes**" screen allows clinicians to choose advanced testing and training modalities for specific clinical patient problems.

Progressive-resistive strength training can be used to test and improve muscle strength and power in leg muscles used during walking.

Speed interval training can be used to test and improve speed of movement and balance at high speeds of walking.

Walking challenge training can be used to test and train individuals to walk while dealing with complex challenges, similar to those that are encountered in daily life.

BWS endurance training can be used to train patients to improve cardiovascular health and walking endurance.

Dynamic balance training can be used to test and train patients to improve balance under a wide variety of task conditions that are similar to those that are encountered in daily life.

Timed Walk can be used to have the patient walk at their own pace for a specific (prescribed by the therapist) amount of time. *If the patient does not walk at a speed equal to or greater than 0.1m/s the Walking Timer does not incremented.*

Perturbation can be used for testing and training patients to respond to sudden/unexpected "disturbances".

Game control can be used for connecting to, and setting the parameters of the NatureWalk Virtual reality game[1]. For more information about the NatureWalk game refer to *H016341 – KineAssist-MX Owner's Manual Addendum – NatureWalk App.doc.*

[1] NatureWalk virtual reality game is available to be purchased separately.

5.4.1 Progressive-Resistance Strength Training

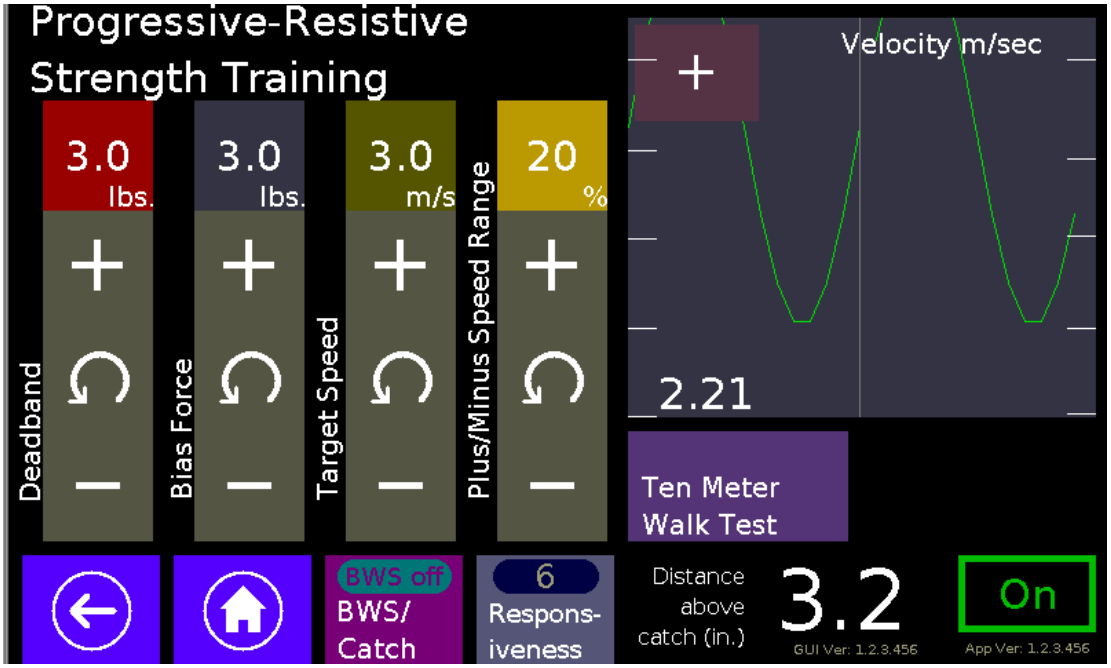


Figure 36 - Progressive-Resistance Strength Training screen.

Progressive-resistive strength training can be used to test and improve muscle strength and power in leg muscles used during walking. This mode allows a clinician to provide horizontally-directed forces as a resistance during walking. This is accomplished by asking the patient to walk at a comfortable speed while a ten meter walk test is conducted. Once the comfortable speed is determined, the clinician sets the target speed to the comfortable walking speed, and sets the % Speed Range function to an amount that is desired. The patient begins walking while trying to maintain walking speed in within the target speed range while the clinician gradually increases the "Deadband" value, which provides added resistance. The patient is asked to maintain walking speed against these higher resistive forces for a given number of steps. Due to the high intensity nature of this strength training regimen, it is highly recommended that clinicians count the number of steps that the patient attempts. Additionally, the "Bias Force" imposes a virtual horizontal force. When the bias force is positive, it will feel like the device is pulling forward, and the treadmill will go faster in the forward direction for the same intent input. As the bias force is increased, the treadmill will move forward without any intent input. When the bias force is negative, it will feel like the device is pulling in the backward direction, and treadmill will go slower in the forward direction for the same forward intent input.

⚠	The Bias Force adds a virtual intent force to the controller of the KineAssist. Increasing the Bias Force (in either positive or negative direction) could cause the treadmill to move at high velocities, without any other input from the operator or patient. Unlike the Deadband, which can only provide resistive force (i.e., force against the direction of motion), the Bias Force will continue to push/pull (via the treadmill) at a constant rate until the Bias Force is set to 0 or the KineAssist is set to STOP.

5.4.2 Speed Interval Training

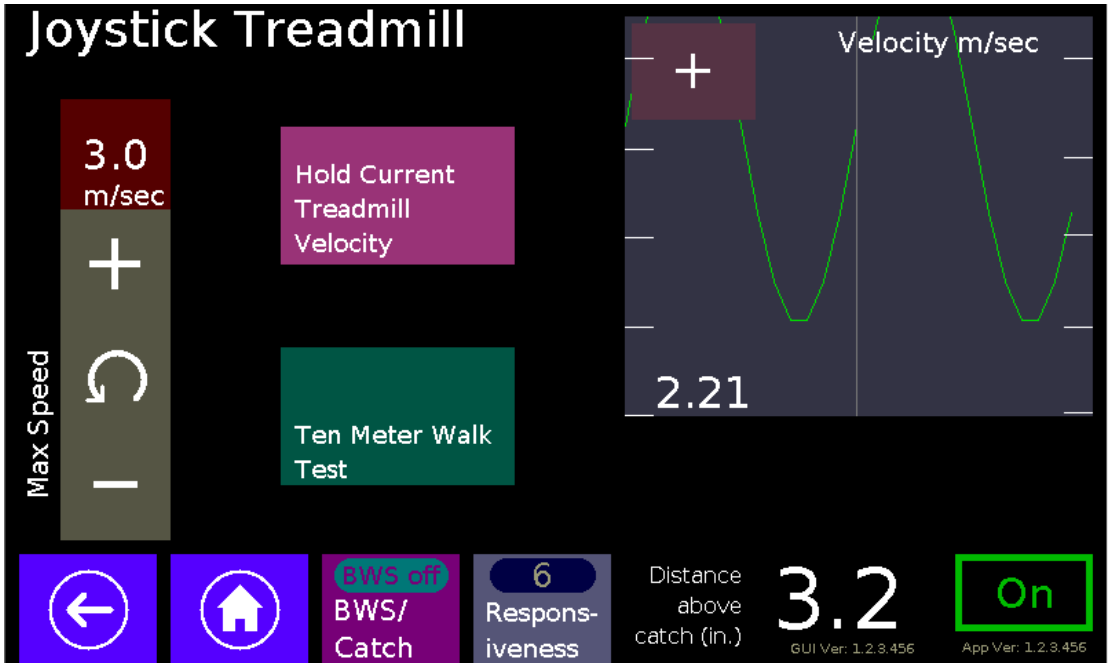


Figure 37 – Joystick Treadmill screen.

Speed interval training (i.e., Joystick Treadmill mode) can be used to test and improve speed of movement and balance at high speeds of walking. This mode allows a clinician to set treadmill-belt-driven speeds to high levels to challenge the patient to remain walking at fast speeds. First, the clinician performs a ten meter walk test to determine the patient's fastest self-driven walking speed. Once this is determined, the clinician can set the max speed for the treadmill at some faster speed to challenge the patient. When ready to begin, the clinician uses the "joystick" to control the treadmill-belt walking speed and gradually increases the belt speed until the max speed target has been reached. The clinician determines a suitable interval of time for the patient to remain at this max speed, and then the clinician uses the joystick to reduce the speed back down to a very slow and comfortable "recovery" speed. This sequence is repeated multiple times, as determined by the clinician. The Hold Current Velocity button will lock the treadmill speed so that the therapist does not to keep pressure on the joystick button.

5.4.3 Walking Challenge Training

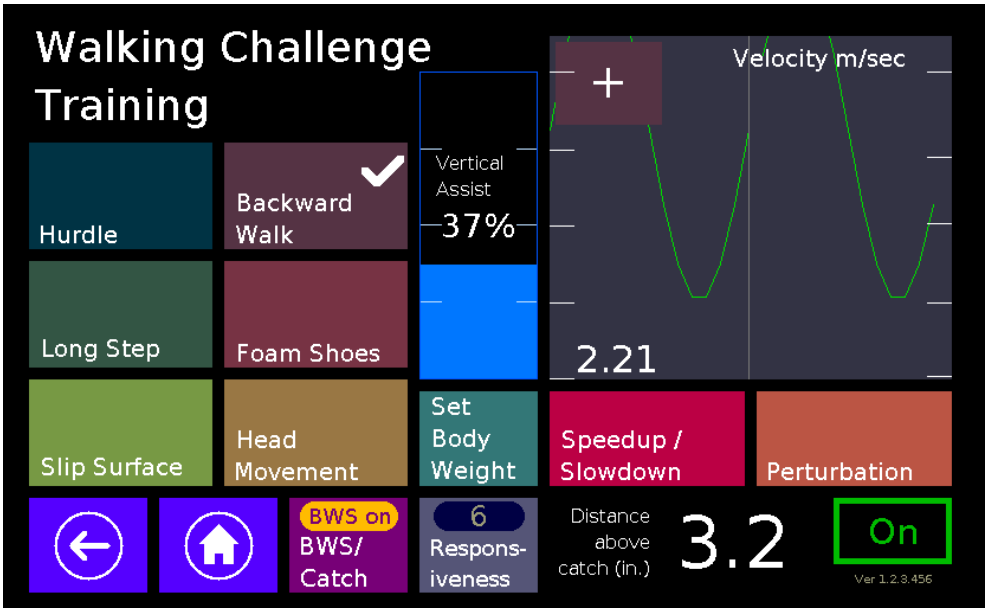


Figure 38 – Walking Challenge Training screen.

Walking challenge training can be used to test and train individuals to walk while dealing with complex challenges, similar to those that are encountered in daily life. The clinician can choose from eight walking challenge tasks. Each task is designed to address a key component to walking skill recovery.

- **Hurdle**: By placing the hurdle interface on the treadmill, patients are asked to walk and step over with either or both legs. The hurdle height can be adjusted to further challenge the step height that the patient must achieve to be successful.
- **Long Step**: By using the laser light interface on the treadmill, patients are asked to continually and repeatedly step forward as far as possible while stepping over the target laserlight. Patients can be challenged by gradually moving the laserlight target further away.
- **Backward walking**: Patients are asked to walk backwards while maintaining balance.
- **Foam Surface**: A foam surface is provided that can alter a compliant step challenge as patients are asked to continually and repeatedly step forward and back.
- **Head movement**: Patients are occasionally and repeatedly asked to “Look UP”, “Look Down” “Look left” or “Look right” while continually and repeatedly asked to walk forward.
- **Speed up slow down mode:** Patients are occasionally and repeatedly asked to speed up or slow down to reach randomly changing target speeds. See below for further information about this mode.
- **Perturbation**: Disturbances can be provided in both the forward and backward directions. Both velocity and length of perturbation can be manipulated. See “Perturbation” section for further information about this mode of operation. Forward disturbances are provided during backward walking, and backward disturbances are provided during forward walking.

Speedup/Slowdown Mode

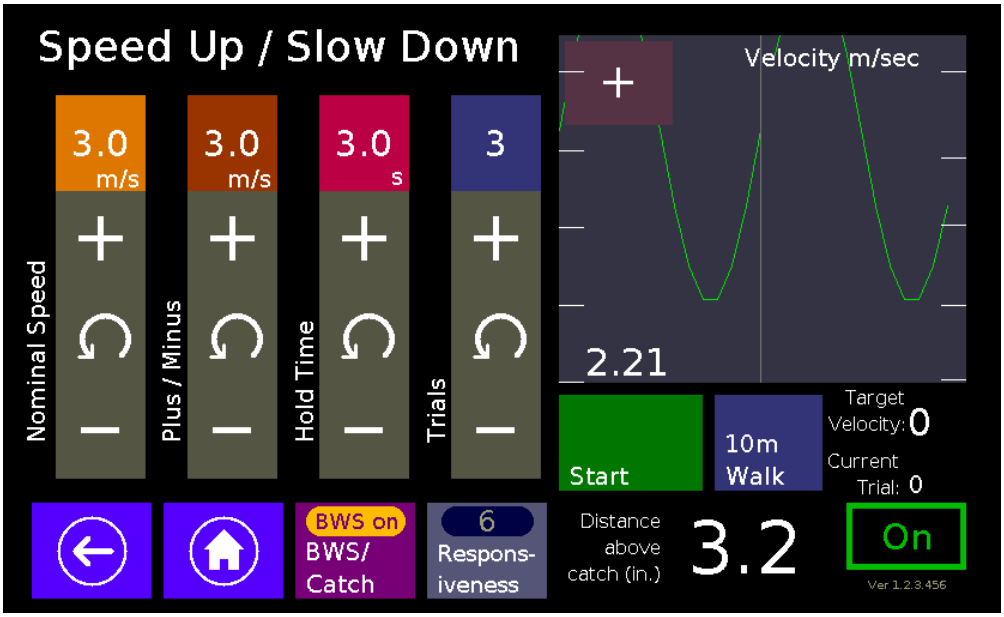


Figure 39 - Speed Up/Slow down Mode screen.

Patients are occasionally and repeatedly asked to speed up or slow down to reach randomly changing target speeds. See below for further information about this mode. The clinician first sets a nominal walking speed close to the patient's comfortable walking speed. The clinician then sets a plus/minus range of targets, a hold time for the amount of time that each target will be maintained, and a number of trial repetitions. When the patient is ready to begin, the clinician presses the start button and reminds the patient to try to achieve a walking sped that matches the target on the screen.

5.4.4 Body-Weight Supported Endurance Training

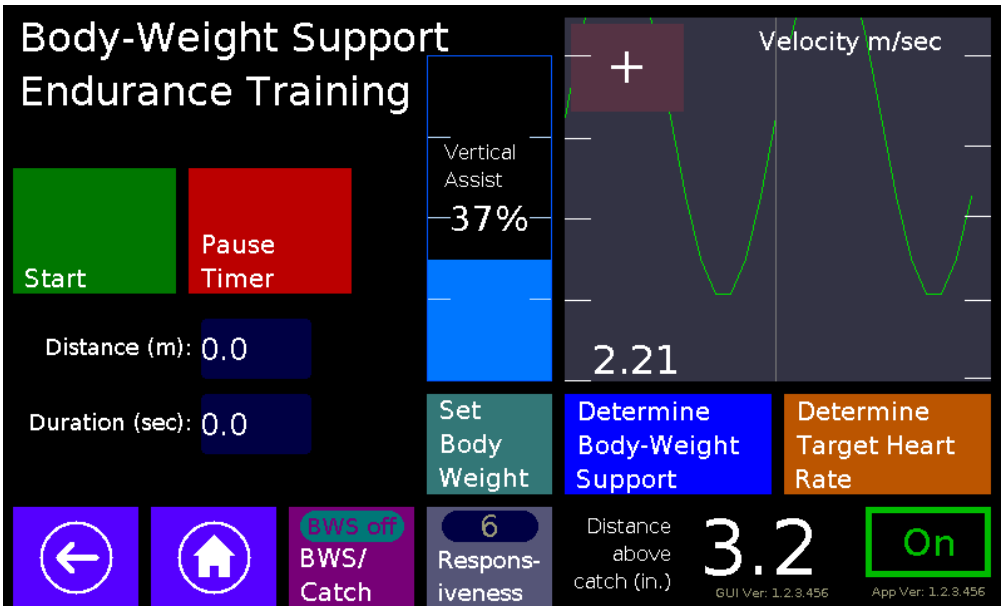


Figure 40 – Body-Weight Support Endurance Training screen.

BWS endurance training can be used to train patients to improve cardiovascular health and walking endurance. This mode allows clinicians to calculate a specific range of target heart rates (Using the Karvonen method for heart rate reserve). It also allows clinicians to determine an appropriate body-weight support level based upon actual walking velocity results at different BWS levels. When the patient is ready to begin, the "Start Timer" button is pressed and distance and duration are determined as a running total. Also, walking velocity is displayed so that the clinician can ask a person to speed up or slow down if they want the heart rate to be higher or lower.

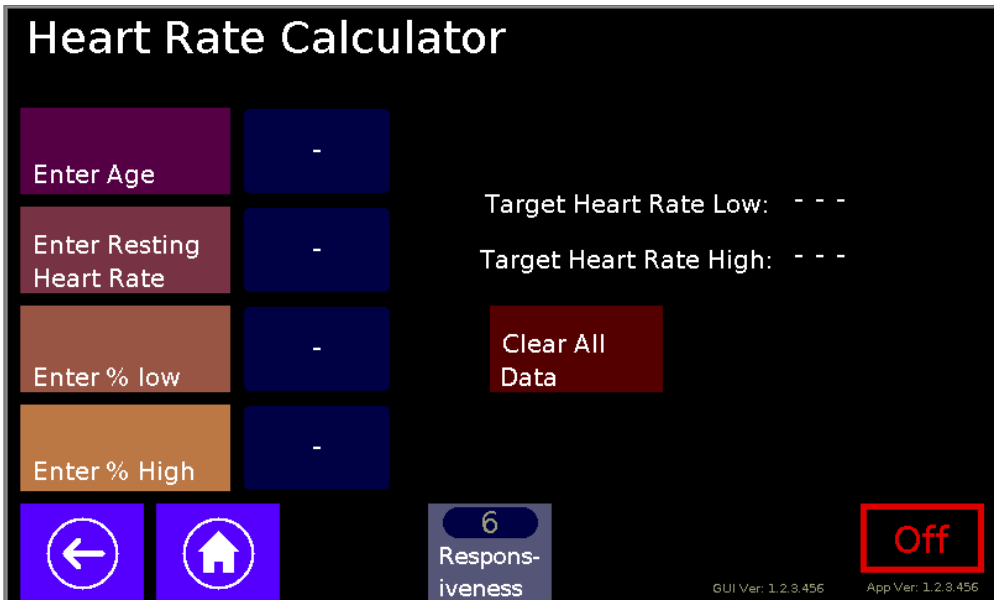


Figure 41 – Heart Rate Calculator screen

5.4.5 Dynamic Balance Training

Figure 42 - Dynamic Balance Training screen.

Dynamic balance training can be used to test and train patients to improve balance under a wide variety of task conditions that are similar to those that are encountered in daily life. The clinician can choose from eight balance tasks. Each task is designed to address a key component to balance skill recovery.

- **Hurdle**: By placing the hurdle interface on the treadmill, patients are asked to stand in front of the hurdle and step over with either or both legs. The hurdle height can be adjusted to further challenge the step height that the patient must achieve to be successful.
- **Long Step**: By using the laser light interface on the treadmill, patients are asked to step forward as far as possible while stepping over the target laserlight. Patients can be challenged by gradually moving the laserlight target further away.
- **Solid Steps**: Solid steps are provided that can alter a step height challenge anywhere from 1 in to 16 ins. Patients are asked to step up onto the surface, with either leg leading, then stand on the surface and step backwards off of the surface. Patients can be challenged by adding one in. increments to the step height, as appropriate.

When using the steps, make sure there is plenty of room for the patient to step up, and ensure that the patient's head does not hit the ceiling.

- **Foam Surface**: A foam surface is provided that can alter a compliant step height challenge anywhere from 2 in to 16 ins. Patients are asked to step up onto the surface, with either leg leading, then stand on the surface and step backwards off of the surface. Patients can be challenged by adding two in. increments to the step height, as appropriate.
- **Forward reach**: By placing the forward reach target device on the treadmill, clinicians can provide a graded and measureable target for patients to reach forward towards. Patients can be challenged by gradually moving the target further away from the patient.
- **Sit to Stand**: By placing the solid steps on the treadmill surface, the clinician can provide graded-height surfaces for the patient to attempt sit to stand. Patients can be challenged by decreasing the height of the solid step surfaces in one in. increments.
- **Perturbation**: Disturbances can be provided in both the forward and backward directions. Both velocity and length of perturbation can be manipulated. See "Perturbation" section for further information about this mode of operation. Patients can be challenged by increasing the velocity or length parameters as appropriate.

5.4.1 Timed Walk Mode

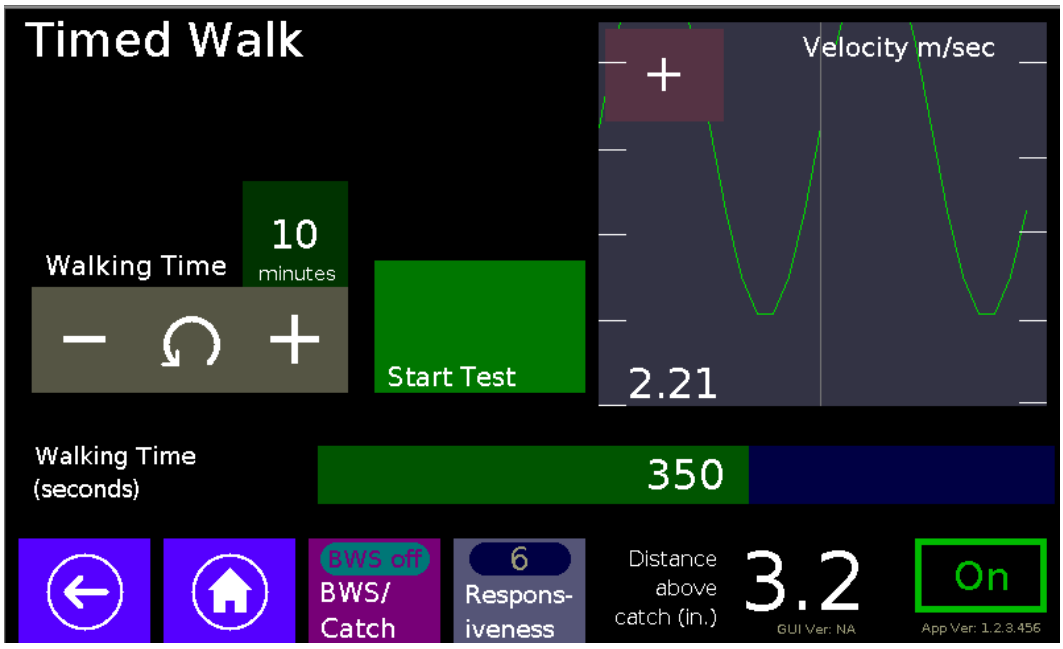


Figure 43 – Timed walk screen

Timed Walk mode is used in order to allow the clinician to specify a specific amount of walking time in 1min increments. In this mode the patient walks at their own pace, however if the patient stops walking below a speed of 0.1m/s the timer stops incrementing, in other words the patient must walk the specified amount of time in order for the timer to complete.

5.4.2 Perturbation Mode

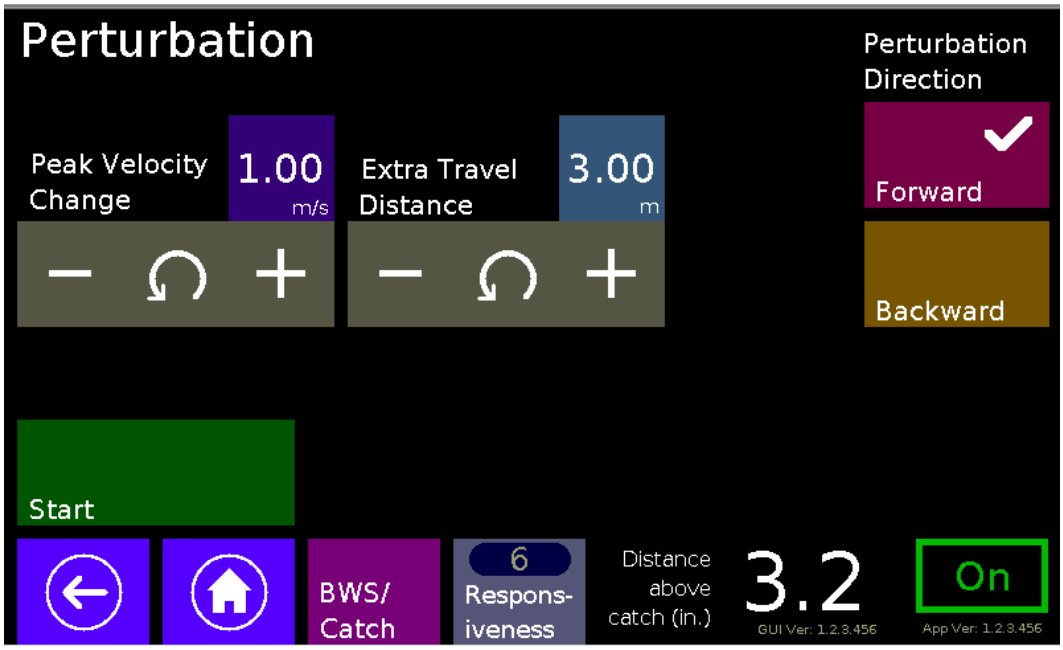


Figure 44 – Perturbation Mode screen.

Perturbations or “disturbances” are used for both testing and training. As a test, perturbation distance and/or velocity can be methodically introduced while a patient is quietly standing or walking. The clinician can observe the patient’s response to the differing amounts of perturbation. When training, these perturbations can be used to teach a patient how to respond appropriately and remain upright and stable after the disturbance. Patients can be progressed by the clinician by increasing either peak velocity or travel distance or combinations of both parameters.

5.4.3 Game Control

i	The **Game Control** mode requires the *NatureWalk virtual reality game* which is available to be purchased separately. For more information about the NatureWalk game refer to *H016341 – KineAssist-MX Owner’s Manual Addendum – NatureWalk App.doc.*
i	The NatureWalk virtual reality application is designed to provide an engaging visual and physical experience during a patient’s KineAssist-MX therapy session.

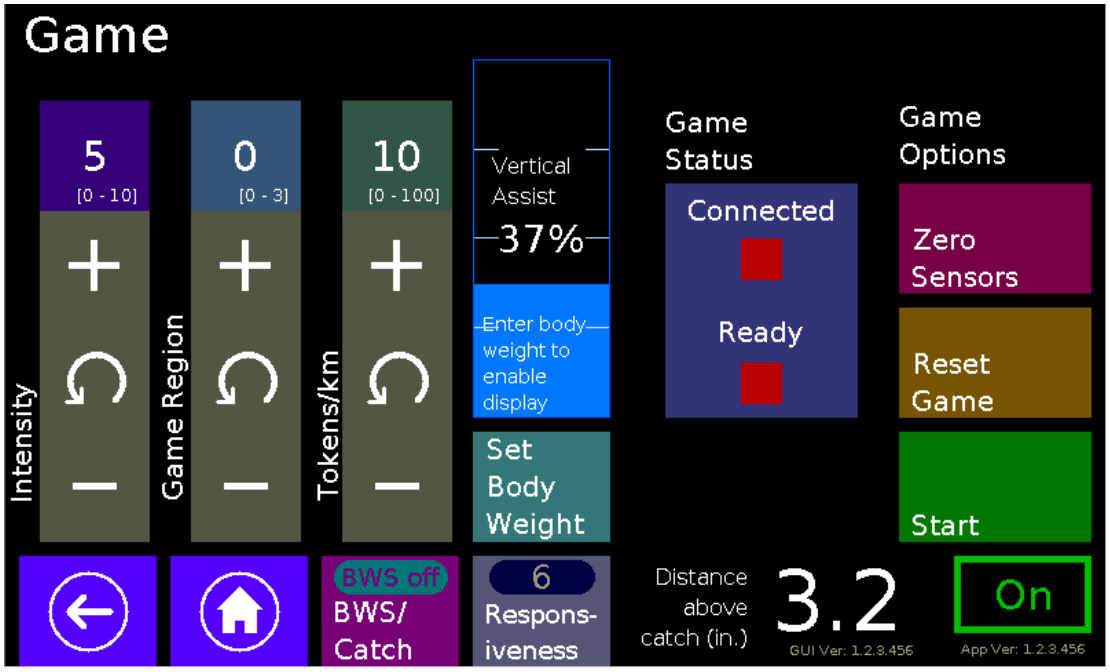


Figure 45 - NatureWalk game control panel

Reference *H016341 - KineAssist-MX Owner's Manual Addendum - NatureWalk App*, provided with the NatureWalk VR application for a description of the game control screen.

5.4.4 System Configuration

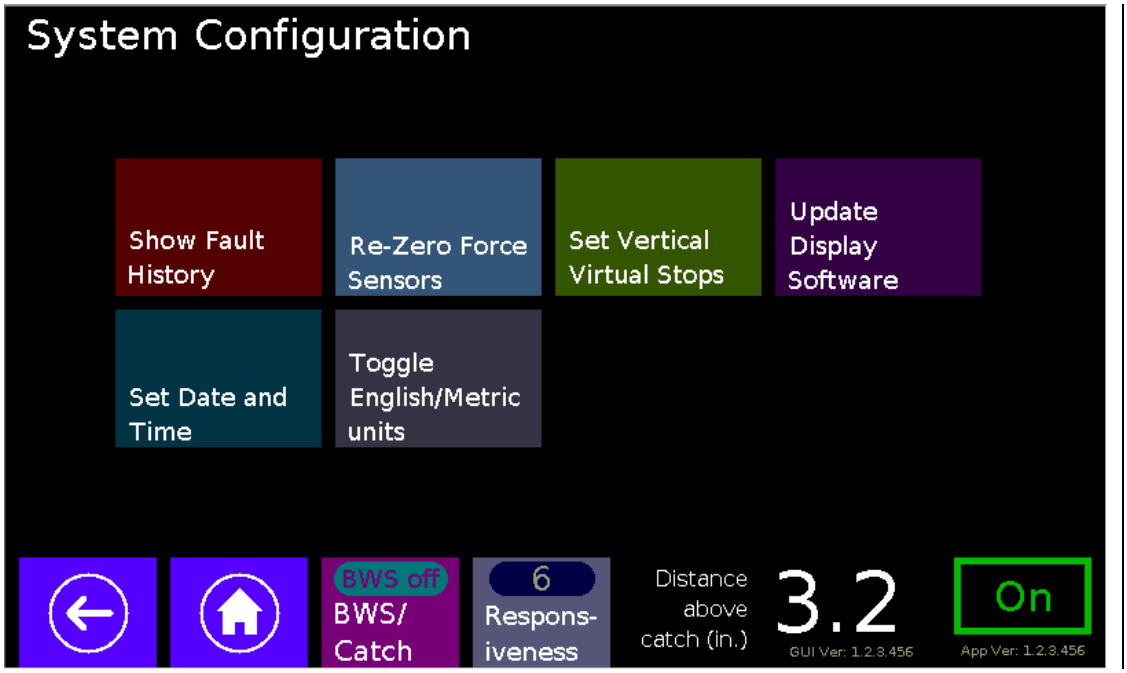


Figure 46 - System configuration screen.

The gear button  near the bottom right portion of the Main Menu Screen will bring you to the System Configuration screen, where you can:

1. **Show Fault History:** The user can review the most recent faults logged by the KineAssist.

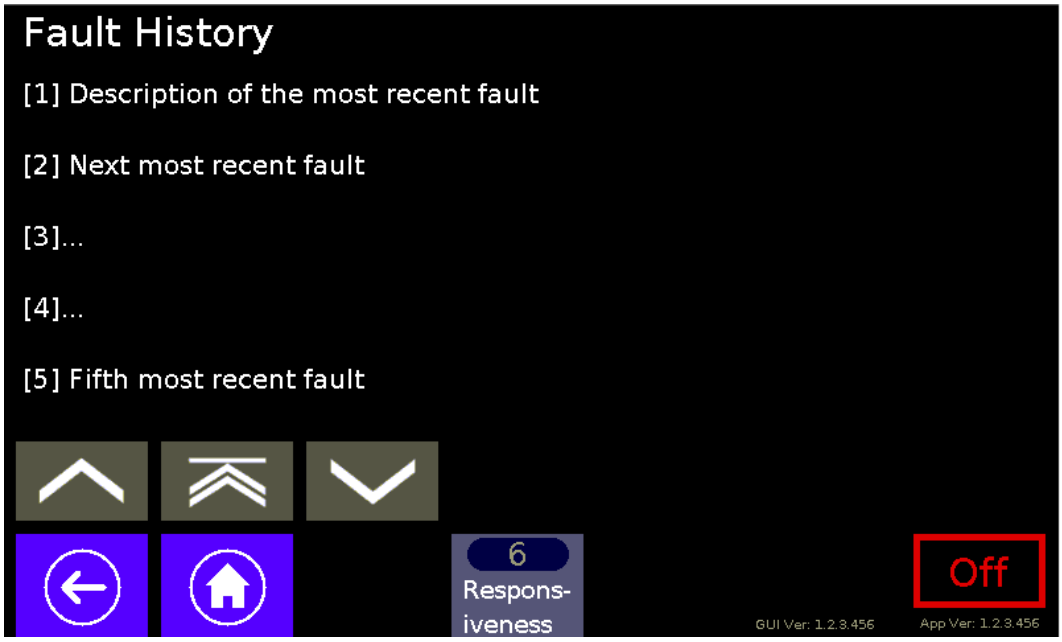


Figure 47 - Fault History Log

2. **Re-Zero force sensors:** This will allow the user to reset the KineAssist's force sensors. This functionality should only be used by trained personnel when there is a problem with a force sensor.

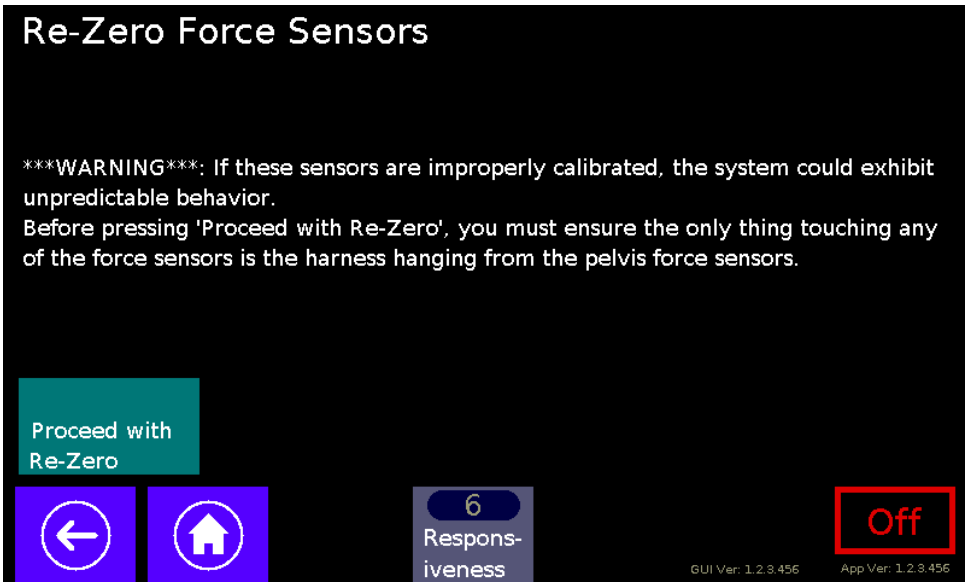


Figure 48 – Re-Zero force sensors screen.

For re-zeroing the force sensors please follow the instructions displayed on the screen. Note that nothing other than the pelvic harness should be touching the pelvic mechanism arms, it should look like Figure 5.

⚠	Improperly resetting the force sensors could result in unpredictable behavior of the KineAssist and possible injury. For example, if somebody is leaning on the pelvic arms or something other than the pelvic harness is hanging from it - while re-zeroing - the force sensors will not be properly reset.

3. **Set Vertical stops button:** The user can set the upper and lower limits of the vertical stops. This is helpful if the KineAssist is in a room with a lower ceiling, or you want to accommodate for a very short patient, etc.

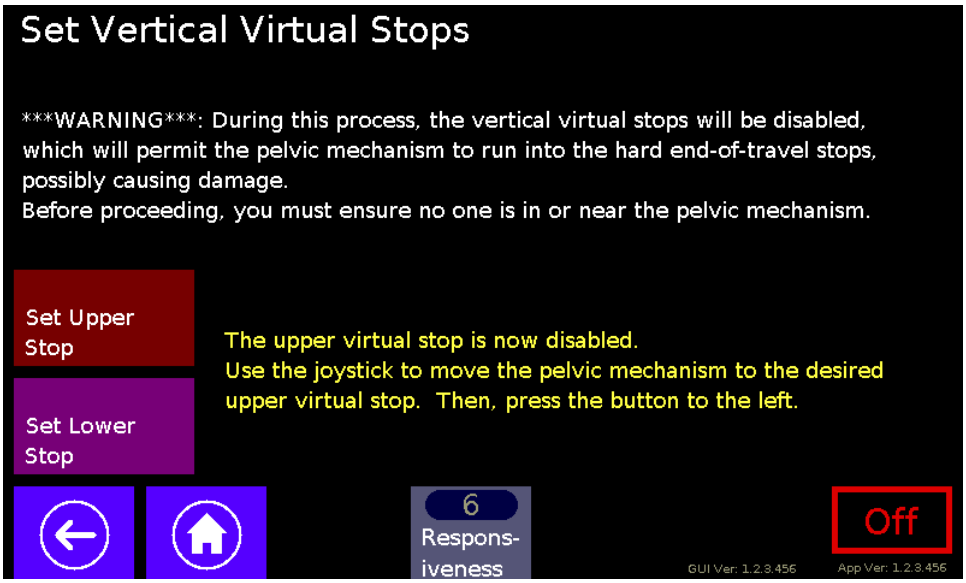


Figure 49 - Set Vertical Virtual Stops

	While the virtual stops are being set, the software will not limit the travel of the pelvic mechanism. Thus, the operator is able to move the pelvic mechanism past the end of travel and run into the bumpers. It is strongly advised not to allow the pelvic mechanism to engage the end-of-travel bumpers. The virtual stops should be set without contacting the end-of-travel bumpers.

4. **Update Display Software:** This button enters the Display into software upgrade mode. It is used to update the software of the Touch screen.

	Only trained personnel should use this option.

5. **Set Date and Time:** The operator can and should set the systems local Date and Time.

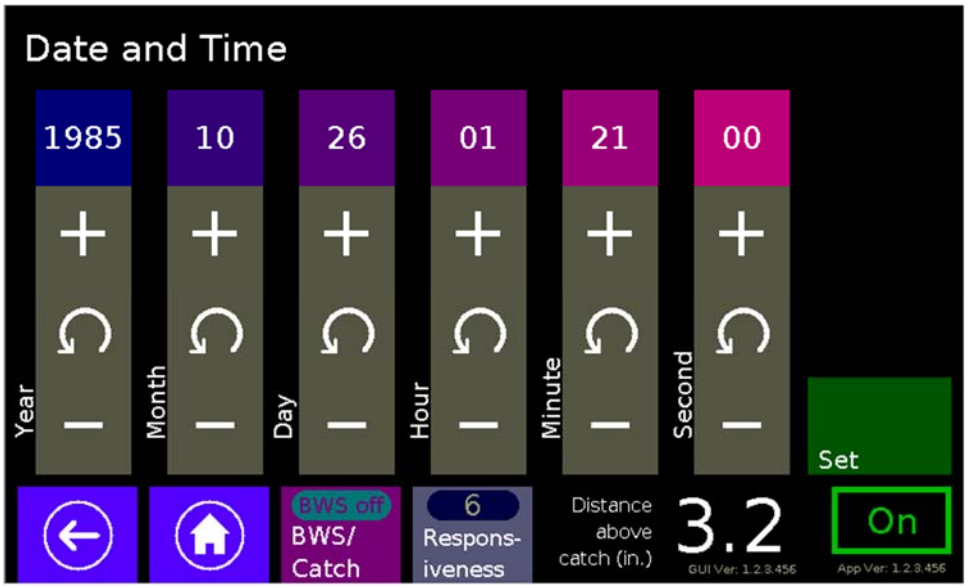


Figure 50 – Set Date and Time screenshot.

i	If the date and time are not entered correctly the timestamps on the Session Reports will be incorrect.

6. **<u>Toggle English/Metric units</u>:** Use this button to change between Metric (Newtons – N) and English (pounds – lbs) units.

Chapter 6: Maintenance and Cleaning

6.1 Maintenance and Service Statement

	If maintenance or repairs are not carried out by professionally qualified personnel, this may cause material damage and serious injury. ➢ Maintenance and repair work may only be performed by qualified personnel! ➢ It is the sole responsibility of the representative to assign qualified personnel for maintenance and repair work. ➢ In case of doubt or questions always contact the HDT customer service or dealer! ➢ The manufacturer is not liable for personal injury and material damage caused by a lack of qualifications!

Service work that goes beyond the routine maintenance described in this operation manual must be performed only by the manufacturer or their duly authorized service agents, never by the operator. We are not liable for damages resulting from unauthorized service or from improper maintenance performed by unauthorized persons.

Perform maintenance on the treadmill only as described in this chapter. Opening the housing can lead to electrical shock and other damage or injury. It is absolutely essential to pull the power cable plug out of the electrical socket before opening the housing. Modifications to the treadmill other than those described in the operation manual can cause damage and thereby necessitate repairs not covered under warranty.

After maintenance or repair of medical devices structural and functional features that are essential for the safety and functionality must be checked, insofar as they may have been affected by the maintenance measures.

6.2 Cleaning and Inspection

Periodic cleaning and inspection of your KineAssist-MX will help to lengthen its life while helping keep it looking like new. By performing preventive maintenance any issues can be identified and resolved before it becomes an issue.

Below is the recommended cleaning and maintenance intervals. If your KineAssist-MX is located in a dirty environment or under heavy-duty use, cleaning and inspection should be implemented more often. Clean using a damp cloth and do not use abrasive brushes or cleaners, as they may damage paint and anodized surfaces. Do not soak any surface; the sensitive electronics may be harmed.

Cleaning agent: For cleaning and disinfection of parts that are touched (pelvic mechanism arms, harness, display, etc…) a formaldehyde-free rapid disinfectant such as “Bacillol plus” or “Descosept” is recommended.

The slat-belt treadmill should be thoroughly cleaned at regular intervals, depending on the intensity of use.

	The use of water and liquid detergents as part of cleaning work can cause serious or fatal electrical shock. ➢ No liquids may come in contact with electrical parts such as motor, power cord and power switch, control monitors. ➢ Do not spray the device with a water jet. ➢ Pull power plug before cleaning, equipment must not be connected to power! Ensure the device cannot be switched back on.

6.3 Maintenance Intervals

In the addendum at the end of this manual is a convenient PM log for your record-keeping. It is also available in electronic form.

6.3.1 Monthly

- Clean pelvic mechanism, display, and cosmetic covers with a damp cloth.
- Clean the treadmill walking surface with a damp, lint-free cloth
- Visually inspect the main power cable to make sure it is not damaged.
- Check the wires/connectors to the display enclosure.
- Check calibration and re-zero sensors if needed (see section ***System Configuration***-Step 1).
- Check that the pelvic harness connectors and their locking tabs are well seated in the mating part (see Figure 16).
- Check the straps around the harness connectors for excessive wear.
- Check that the swing-arm and the monitor itself are free to rotate smoothly through their entire range of motion and is not tugging on the cables.
- Check overall condition of the treadmill, pelvic mechanism, and vertical tower.
- Verify that the pelvic mechanism moves freely in all its intended directions without sticking and with no grinding noises.

	Worn or damaged components must be replaced immediately. If the observed deficiency can cause danger to the user or operator of the treadmill, it needs to be taken out of service until repaired.

6.3.2 Quarterly Functional Check

A functional test of the KineAssist-MX must be carried out every quarter. The functional test includes:

1. Using the “Joystick Treadmill” mode at speeds of 2-3 m/s. Do unusual noises occur?
2. Using the “Joystick Up/Down” mode and moving the Support Arm through its entire range of motion, do unusual noises occur?

3. Using the “10 m Walk Test” mode confirm the “Distance Traveled” is correctly displayed (to within 10%).
4. Check the functionality of the emergency stop (E-Stop) mushroom switch. Is the emergency stop initiated?
5. Check calibration and re-zero sensors if needed (see section ***System Configuration***- Step 1).
6. Check the functionality of the red and green buttons on the User Interface enclosure. Do they toggle the system between On/Off states?
7. Set the device to “Setup” mode. Confirm that the running surface is very difficult to move.

	If there are deficiencies or deviations in the control function, notify the HDT customer service immediately. The device must be taken out of service and disabled until repaired. Repairs may only be carried out by trained and authorized personnel.

6.3.3 Every 6 to 10 Months

The check should also be performed if the KineAssist appears to be faulty (e.g. unusual noises, binding passive motions, etc…)

The check should follow the checklist below:

1) Treadmill

Before starting any maintenance on the treadmill the side panels are to be removed (NOT the electronic covers).

Preventive maintenance consists of the following measures:

-
- Clean the inside of the treadmill with a vacuum cleaner. Do not touch the electrical components (cable, connectors, etc…).
- Check the drive unit toothed belt (drive belt) for cracks and other wear and missing or broken teeth (visual inspection).
- Check the aluminum profiles of the slats with a flashlight for damage (visual inspection).
- Check all mechanical components for damage (welded frame, side panels, treadmill feet, railings) (visual inspection).
- In rare cases there may be bearing damage. Under certain circumstances this can be detected through excessive grease leakage from the bearing housing.

2) Support Arm and Column

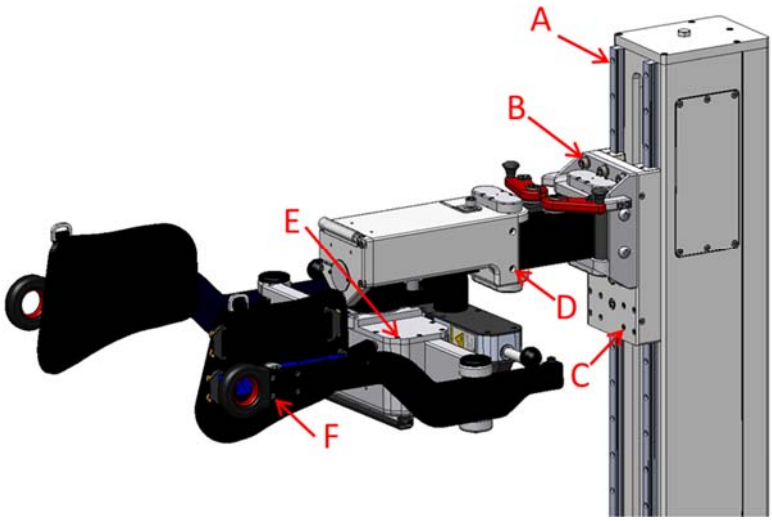


Figure 51 - Illustration marking referenced screws.

- Check that all screws are tight on the vertical rails (see Figure 51 – A).
- Check that the screws securing the carriage plate to the traveling bearing blocks are secure (see Figure 51 – B, C).
- Check that all the screws on the pelvic rotation locks and lateral motion limiting brackets are tight (see Figure 3).
- With the pelvic rotation locks disengaged, check that the arms of the pelvic mechanism swivel freely (see Figure 12).
- Check for proper operation of the bumper switches attached to the underside of the pelvic mechanism (see Figure 7).
- Check that the flat head screws along the top of the slide lateral tube are tight (see Figure 51 – E).
- Check that the flat head screws securing the lateral arm cover on the right (and left) side are secure (see Figure 51 – F).
    - NOTE: Tightening these screws will require a re-zeroing of the sensors.
- Check that the flat head screws securing the right (and left) side harness socket to the harness are tight (Figure 52 - G).
- Check that the flat head screws securing the right (and left) side harness plug to the pelvic arm are tight (Figure 52 - H).

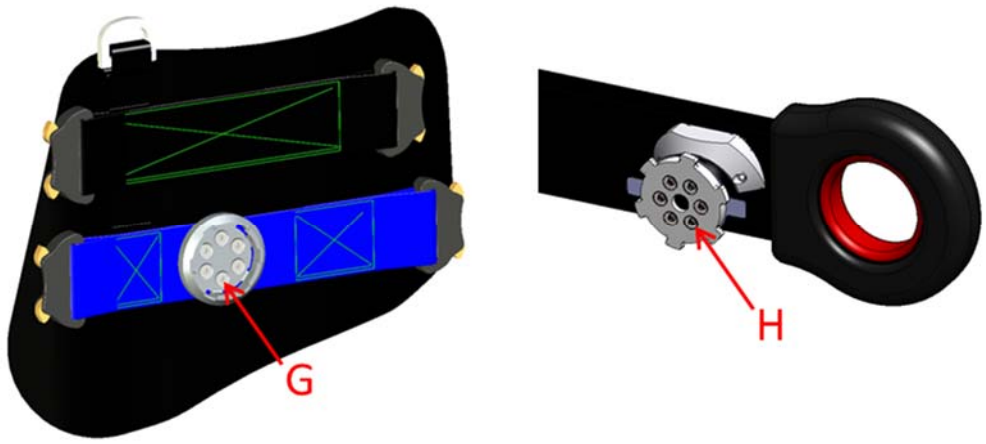


Figure 52 - Illustration showing Pelvic Harness screws

3) Functional Tests:

- See section *6.3.2-Quarterly* Functional Check

4) A repair must take place:

- If liquid has gotten into the device,
- with damaged power cord (cable, plug)
- if the treadmill or vertical tower drive systems show deficiencies
- in case of suspected bearing damage,
- if a defect on the device is suspected or has already been established
- in case bucking, sudden stopping or accelerating of the running surface,
- if buttons fail to function
- in case of burning smell, smoke, or unusual noises,
- in case of malfunction (failure) of the emergency stop button,
- in case of damage to the running surface belt and
- for all other defects which may affect the safety of the device

6.3.4 Yearly

The proper maintenance of the KineAssist must take place annually in conjunction with the technical safety checks (TSC).

Annual Maintenance:

- Check the tension on the Support Column belt. *This can be done by HDT personnel or customer maintenance personnel with HDT support and instruction. Please contact HDT for assistance in completing this task.*
- Check that the vertical belt is running between the pulley flanges on both top and bottom pulleys as the carriage is moved up and down. *This can be done by HDT personnel or*

customer maintenance personnel with HDT support and instruction. Please contact HDT for assistance in completing this task.

6.3.5 Technical Safety Checks

The KineAssist-MX is a device in protection Class I and has an application part Type B, and has a non-removable power cord.

Permanent connection

The KineAssist-MX is not intended for permanent connection. The installation of a permanent connection, if required, must be performed by suitably trained personnel. For the safety checks on permanently connected equipment, the applicable regulations in the country of use are to be observed.

Checks and measurements

Tests and measurements shall be carried out in a properly functioning device. Any repairs must be performed by qualified personnel before the technical safety inspection.

Country-specific requirements

When carrying out the prescribed measurements and checks, country-specific regulations, instructions and test steps are to be observed.

Manufacturer's Recommendations

Prior to the tests, manufacturer's recommendations for the maintenance of the KineAssist-MX are to be considered in accordance with EN 62353. For this reason these instructions are to be read completely and carefully. If accessories are used, the manufacturer recommendation for the accessory is to be observed accordingly.

Multiple devices

If the KineAssist-MX is used along with other medical electrical equipment, the requirements set out for Medical Electrical system ("ME- System") in accordance with definition 3.24 of standard EN 62353:2014 apply.

Data lines and functional grounds are to be separated for the duration of the measurements, along with other connections to other devices.

	For safety reasons, the use of power strips and the simultaneous operation of other equipment on the same supply line are prohibited.

Inspection intervals

The Technical Safety Check must be performed annually by qualified personnel (electricians). These are "recurrent test(s)" in accordance with section 4.3 of EN 62353:2014.

Visual inspection

According to section 5.2 of EN 62353:2014, a visual inspection is carried out prior to the measurements. The following points must be checked on the KineAssist-MX device:

1. KineAssist-MX owner's manual. Is the owner's manual for the device immediately available for the user?
2. Accessory manual: Is the operating manual for accessories and options available?

3. Labels: Are all labels on the device legible and complete (product label, safety labels)?
4. Visual condition of the KineAssist-MX: is the device undamaged and properly cleaned? Are slats possibly broken/cracked? Are screws loose?
5. Harnesses: Condition of pelvic and torso harnesses?
6. Power strips: Are power strips used? For safety reasons the use of power strips is forbidden.

Measurements (per EN 62353:2014)

The values determined in these tests are to be documented together with the measurement method and evaluated. Measurements are to be carried out in accordance with section 5.3 of the standard. The (i) protective earth conductor resistance (section 5.3.2 of the standard), and (ii) the device leakage current (section 5.3.4) are to be measured. A measurement of the leakage current from the applied part according to section 5.3.4.3 of the standard is not required. For the measurement of the device leakage current, the direct measurement method or differential method may be used.

For the measurement of protective earth conductor resistance, the electrical enclosure cover must be removed. During the measurement the power cable must be moved over the entire length. If changes in resistance are observed during movement, it must be assumed that the ground wire is damaged or has a bad connection.

If the measured values are between 90% and 100% of the allowable limit, the previously measured values (reference values) for evaluation of the electrical safety of the device shall be considered. Note that the measured values of the factory test may differ slightly from the measured values at each KineAssist location due to different test conditions.

The measured values must not exceed the permissible limits specified in the following table:

Measurement	**Limit Value**
Protective earth conductor resistance – non-removable power cord Resistance between the protective earth conductor of the power cord and the protective conductor connected, exposed conductive parts of the unit (electrical enclosure base plate)	300 mΩ
Device leakage current – direct measurement or differential current measurement Measuring procedure defined in section 5.3.4 of EN 62353	0.5 mA

Functional test

After examination (inspection and measurement) a functional test must be performed in accordance with section 6.3.2 of this manual; this is to ensure that the treadmill has been restored to its necessary Condition for “Intended use”, i.e. that it is operational and safe.

Test report

The test report must meet the requirements in EN 62353:2014 (see section 6.1 and Annex G).

A final evaluation of the device must be carried out and the deadline for the next Technical Safety Check established. In accordance with section 6.2 of the standard this review can only be carried out by qualified electricians (as defined in IEC 61140), who have adequate training on the inspected device.

The tested KineAssist-MX must be marked with the test date (inspection sticker).

The examiner and the person responsible for maintenance of the KineAssist-MX sign the test report. This document is prepared with three copies, wherein a copy remains with the representative of the KineAssist-MX and one for the tester's records. The third copy should be sent to HDT customer service. In this way, they can provide efficient and reliable support.

If technical safety inspections are required by the manufacturer, the operator must carry these out or have these carried out according to the generally recognized rules of technology and within the time specified by the manufacturer.

The reason for the safety checks is to determine if a medical device is operational at the time of the audit, if it is in good condition and it is also expected to correspond to safety inspection requirements until the next safety inspection.

Technical safety checks (after repeat tests or testing after maintenance and repair) may only be performed by, one who has the responsibility for proper implementation of safety controls due to their training, knowledge and experience and has the appropriate measuring and testing equipment.

Personnel requirements

The operator may only appoint persons that meet the above conditions for the implementation of safety-related controls. The fulfillment of the prerequisites must be presented at the request of the competent authority.

A report must be filled about the entire safety inspection, which is kept at least until the next Technical Safety Check. The following information should be included:

- Date that the technical safety checks were carried out
- Results of the technical safety checks
- Indication of the measured values
- Measuring procedure
- Other test results

The representative shall keep the report at least until the next safety inspection.

6.4 Lubrication

6.4.1 Treadmill Bearings

Almost all of the bearings used in the treadmill are pre-lubricated and do not need to be greased. On a yearly basis, the four (4) bearings located at the front and rear shaft will need to be lubricated, using a standard grease gun.

6.4.2 Tower Linear Bearings

If the tower rails become dry they should be lubricated by applying a thin film of oil (i.e. DTE Oil by Exxon Mobil or equivalent).

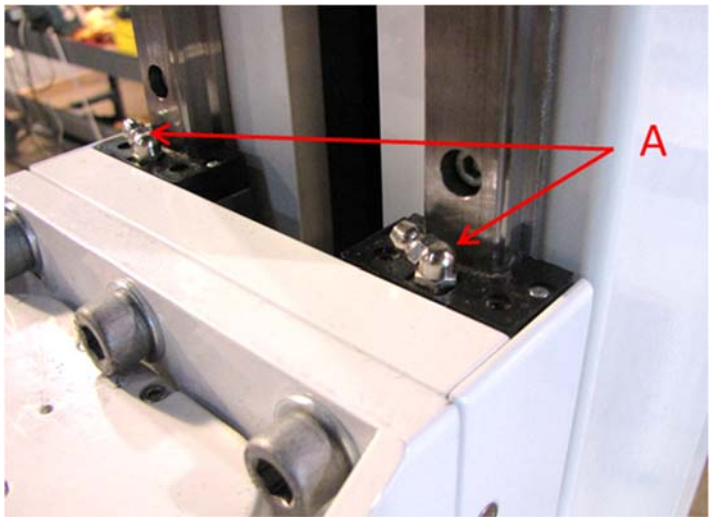
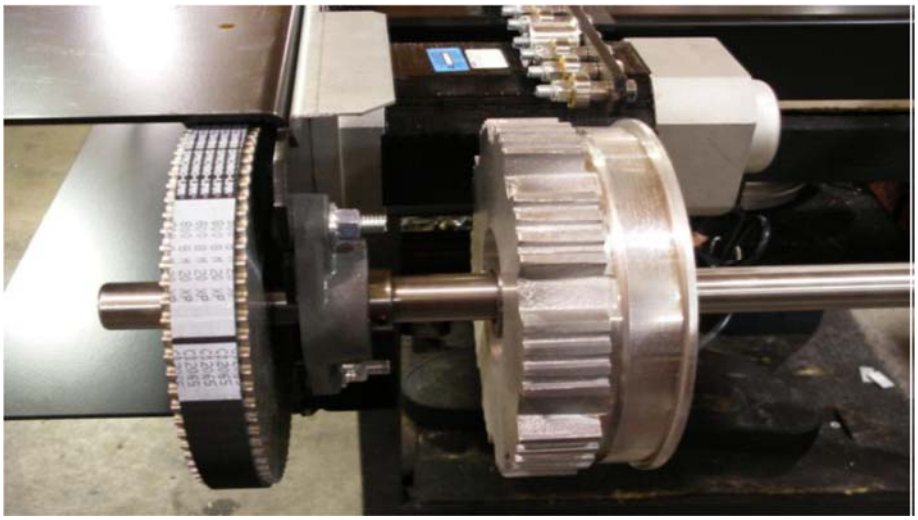


Figure 53 - Picture of the carriage linear bearing grease fittings. NOTE: There are two other bearings located on the bottom side of the carriage (not shown in this picture).

The four (4) linear bearings located behind the carriage plate (Figure 53 - A) on the tower are pre-lubricated, however they should inspected on a yearly basis and if need be lubricated using a standard grease gun.

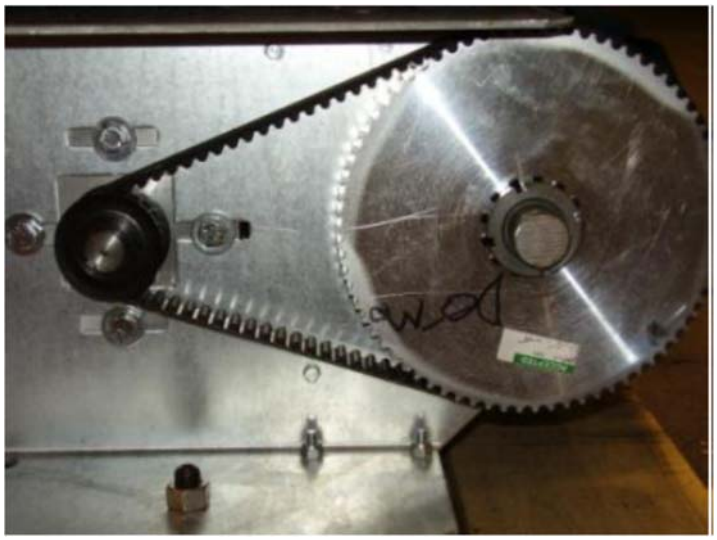
6.4.3 Running Belt/Drive Shaft

The teeth on the bottom of the running belt are pre-lubricated to aid in reducing noise. There is no need to lubricate the teeth. If running belt is rubbing against the side of the drive pulleys, then a small amount of grease (i.e. Molykote or equal) on the edges of the belt slats will help reduce noise. Apply grease to the teeth on the back drive shaft to help the belt stay aligned properly.



6.4.4 Drive Belt

As in the case of the running belt, the application of grease on the edge of the drive belt is only needed to reduce belt squeak and should be used sparingly.



***NOTE**: Use minimal amount of lubrication to prevent excess dirt and debris from sticking to the machine after cleaning.*

Chapter 7: Replacing Parts

7.1 Replacing Components in the Electronic Enclosure

It is highly unlikely that the parts listed below will require replacement. Should it be required, HDT personnel can provide the service or provide guidance and support to customer personnel.

Any component that requires replacement in the electronic enclosure will be delivered with specific instructions for replacement. In all instances however before the electronic enclosure cover is removed the power cable must be unplugged.

	The instructions provided for replacing any components internal to the electronic enclosure must be followed exactly.
	Before opening the electronic enclosure cover the power cord must be unplugged.

7.2 Treadmill Outer Coverings

Required Tools: Cross-recess screwdriver

Removal:

Disconnect the treadmill from the mains and remove the seven (7) large screws in the outer covering using a cross-recess screwdriver. The covers can then be pulled laterally from the frame of the treadmill.

Replacement:

Slide in the two outer coverings on both sides of the frame assuring that it fits/engages properly around the outside of the frame (and below). Then tighten the large screws. It is important to check whether the treadmill scrapes on the covering panels by moving the mat backwards and forwards. If this is in fact the case, the screws must be loosened again and the covers moved away from the mat.

7.3 Treadmill Drive Motor & Pulley

The instructions are supplied with the new or replacement motor, pulley is included.

7.4 Treadmill Drive Belt

Required tools: 2 ring fork wrenches 17, 17 / 10 socket nut, ratchet

Removal:

1) Mark the position of the right-hand bearing support. This bearing holds the front shaft on the frame. Then measure the distance between the upper and lower part of the treadmill belt (in the middle). This measurement is made exactly between the inner edges of the belt teeth and the value is kept for future reference.

2) Unscrew the two screws of the bearing support, but DO NOT REMOVE.
3) Take the drive belt off the drive motor.
4) Remove the outer bearing screw and pull the drive belt out from under the bearing support.
5) Replace the outer bearing screw and nut. The nut must sit firmly on the screw.
6) Remove the inner bearing screw and pull the drive belt out from under the bearing support (alternatively, cut the old belt). Place the new drive belt under the bearing support (with the teeth UPWARDS).

Replacement:

1. Install the inner bearing block. Remove the outer bearing block and pull the drive belt out from the under the block. Then position the drive belt in the pulley on the front shaft, checking that the teeth engage correctly. Then replace the screw and all other parts.
2. Pull the front shaft using a rod or C clamp to pull the running belt tight. Measure the clearance between the running surfaces and adjust the value noted above. This should be approx. 20.5 cm (optimum running).
3. Screw the bearing block screws to 45-50 foot pounds.
4. Check that the drive belt runs correctly in both pulleys and can be moved easily in the middle by a width of 1 - 2 fingers.
5. Then push the mat on by hand and ensure that it runs smoothly and is not blocked anywhere.
6. Switch the treadmill on and let it run at the various speeds. If any unusual vibrations or noises occur, switch the treadmill off and check the dimensions. If the noises and vibrations persist, please contact your representative or the factory.
7. Replace the outer covers.

7.5 Individual Slats

Required tools: T20 TORX element: 10” extension and/or electric screwdriver

Removal:

1. Disconnect from the mains and remove the side covering. Turn the mat until the defect slat is at the front underneath the appliance. (The screws are most easily accessible in this position).
2. Remove the two screws and plates on either side. Then take the defect slat crosswise off the belt.

When replacing the slat; it is vital that new parts are used. If the old screws are used again the new slats could come loose from the mat surface and cause severe injuries.

Replacement:

1. Place the new slat crosswise on the mat. Screw in two new screws on either side. NOTE: All four (4) screws must be positioned in the slat before tightening the individual screws.
2. Then mount the covers back in position.

Chapter 8: Warranty Information

	Parts & Labor
Medical Use	2 years

Warranty: Subject to the following conditions, HDT Expeditionary Systems, Inc. (the "Seller") warrants that the KineAssist-MX sold by Seller shall be free from defects in material and workmanship from the date of shipment for the period of 24 Months. This Warranty inures to the benefit of Seller's customer (the "Buyer") only and is not transferable without Seller's express written consent. Seller's obligation under the Warranty is specifically limited to repair or replacement of the Products, at Seller's option.

Restrictions may apply for international sales. Warranties contained in a contract, signed by both the Seller and the Buyer, shall supersede the Warranty period stated above.

The repair or replacement of any Products shall be performed at the location specified by Seller.

Seller's obligations hereunder are expressly conditioned upon Seller's receipt of written notice of Buyer's claim within thirty (30) days of the occurrence of the claim. Products that are repaired or replaced by Seller, for any reason, shall only be warranted for the unexpired portion of their original warranty period.

Seller shall have no obligation hereunder if the Products provided by Seller: (a) have been subjected to improper maintenance or storage not in accordance with Seller's specifications, (b) have been subjected to abuse in handling or installation, (c) are damaged or misused after delivery to the Buyer; (d) if the Products have been altered or modified in a manner not approved in writing by Seller; or (e) Product is used beyond specified service life (if applicable).

NO WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, OR OTHER WARRANTY, EXPRESS, IMPLIED OR STATUTORY, NOR ANY AFFIRMATION OF FACT OR PROMISE IS MADE BY SELLER WITH RESPECT TO THE PRODUCTS WHICH ARE THE SUBJECT OF THE WARRANTY.

Warranty Service: HDT strives to provide the best possible Warranty service to the Customer. As soon as HDT receives a Warranty service request during normal business hours – 8:00 AM – 5:00 PM CST – HDT will respond via phone within 3 business hours. Many issues can be resolved over the phone or by remote connection, but should on-site service be required, HDT's goal is to resolve the issue within **72** hours, pending availability of parts and appropriate transportation to the Customer location.

When appropriate, HDT may work with the Customer to perform minimal repairs or install shipped replacement parts to minimize the down time of the KineAssist-MX during warranty repair. In the event that HDT chooses this course of action, HDT will provide the written and phone support to the Customer. HDT shall hold harmless and indemnify the Customer for any damages that occur to the KineAssist-MX when acting at the direction of HDT in providing warranty repair services.

Requesting Service: To request service, simply call HDT's Evanston, IL office at **540-479-8045** and provide the following:

- Name
- Facility
- Contact phone number
- Machine Serial Number
- Date/time of issue
- Type of issue

Chapter 9: Troubleshooting

The following matrix shows possible symptoms, causes, and fixes for various conditions that may be encountered. If a symptom is not listed or suggested fixes fail to solve the problem do not hesitate to call HDT technical support department for further assistance.

9.1 Possible Symptoms

The following are symptoms that may occur.

Table 1 – Troubleshooting table.

Symptom	Possible Cause	Potential Solution
KineAssist doesn't respond to Start command from green button; screen displays warning that the e-stop may be engaged.	E-stop button is pushed in.	Untwist and pull out the E-stop button and push start button.
KineAssist doesn't respond to Start button.	E-stop button is pushed in.	
KineAssist stops and displays "E-stop fault" on UI screen.	E-stop button may have been inadvertently pushed.	
KineAssist doesn't respond to joystick rocker switch.	Wrong mode selected.	KineAssist must be in the joystick modes.
Received "Unexpected Force" fault	Loading of the patient or PT load cells while changing modes	Unload the force sensors and try again.
Pelvic Mechanism drifts up/down or treadmill moves when unoccupied and in either Walk or Stand mode	Load cells are losing calibration	Re-zero load cells
Received "Unexpected Joystick Command" fault	Joystick is being pressed while entering active joystick mode	Do not activate joystick until after the KineAssist is in an active joystick mode
Time stamps on session data are incorrect	Date & Time has not been configured	Specify system date & time see section

Preventive Maintenance Log

Note: Refer to electronic document HDT-R003375 – KineAssist-MX Preventive Maintenance Log for a comprehensive checklist and log of all PM activities.

Date	Maintenance Performed?	By	Result

DECLARATION OF CONFORMITY

KineAssist-MX

Class I device per directive 93/42/EEC with amendments by 2007/47/EC

In conformity with the following standards:

ISO 13785:2003

ISO 9001:2008

Directive 2007/47/EC

EN60601-1-2, EN61000-3-2, EN61000-3-3

AAMI ES60601-1, CAN/CSA-C22.2 No. 60601-1:14

IEC60601-1:2005+CORR. 1:2006 + CORR. 2:2007 + AM1:2012 (or IEC 60601-1:2012 reprint)

Ordinary Equipment
US Patents: 7,544,172; 7,803,125
US Trademarks: 78,416,813

CLASSIFIED
C UL US
E469730

MEDICAL EQUIPMENT
AS TO ELECTRICAL SHOCK, FIRE AND MECHANICAL HAZARDS ONLY IN ACCORDANCE WITH ANSI/AAMI ES 60601-1 AMD 1 (2012), CAN/CSA C22.2 NO 60601-1(2014)

EC REP **Emergo Europe**
Prinsessegracht 20, 2514 AP The Hague, The Netherlands

■ 1 ■ 2 ■ 3 ■ 4 ■ 5 ■ 6 ■ 7 ■ 8 ■ 9 ■ 10 ■ 11 ■ 12
■ 2015 ■ 2016 ■ 2017 ■ 2018 ■ 2019

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