ERGO-FLEX TECHNOLOGIES	**Back on Trac** **User Manual**	Doc No.	UM-BOT-7001-14
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Introduction

The Back On Trac User Manual provides procedures and information applicable to the Back On Trac. Each of the major sections provides product specific procedures and information, safety warnings, and precautions. Do not operate this equipment without first reading and understanding the warnings, precautions, and the operating procedures contained in this manual as well as the accompanying documents.

The accompanying documents shall specify special skills, training, and knowledge required of the intended operator or the responsible organization. Accompanying documents are the BOTGEN1 Tablet Training Quick Guide, and Ergo-Flex Online Resource Center. To become an expert operator, it is our best recommendation to read, review, and study all three.

The operator will then be trained in the following: intended use, user interface, initial set-up, patient set-up, additional treatment options, calibrating, operating instructions, operating features, controls and indicators, warning and cautions, alarms errors and messages, equipment care and maintenance, electronic specifications, protocols, troubleshooting tips, applied parts and accessories and warranty guidelines.

The **Online Resource Center** will provide training videos, protocols and clinical documents, educational videos, troubleshooting videos, marketing material, webinar's and replacing parts.

Accompanying Documentation	
Tablet BOTGEN1 Training Guide	Operator must read all instructions before use.
Online Resource Center	Operator must read all instructions before use.
Cervi-Trac System **Purchased as an accessory to the Back On Trac* *UM-CT-7001-Cervi-Trac User Manual*	Operator must read all instructions before use.

CAUTION

Rx Only

Prescription use only in professional healthcare facilities, to relieve pressures on structures that may be causing pain of skeletal or muscular origin (cervical, thoracic, lumbar, hip, shoulder).

Features of Back On Trac

Intended Use

The Back on Trac is intended for use in professional healthcare facilities, to relieve pressures on structures that may be causing pain of skeletal or muscular origin (cervical, thoracic, lumbar, hip, shoulder). The device may be used to manage, and reduce pain associated with the following conditions: facet syndrome, herniated disc, protruding disc, extruded disc, sciatica, spondylosis (degenerative disc disease & facet syndrome), and joint pain.

Vibration and heat are available options that can be utilized with the Back on Trac at the discretion of the healthcare professional. When activated, the vibration mode can provide muscle relaxation and temporary relief of minor aches and pains. The heat mode, when activated, can provide temporary relief of minor aches and pains. The local warmth temporarily stimulates local blood circulation in your lower back.

All data entry and validation of protocol parameters is performed by the trained healthcare professional according to a physician's order. Trained healthcare professionals included physicians, massage therapists, nurses, occupational therapists, physical therapists, physician assistants and service technicians. A user can also be for all humans that might handle, operate, or interact with the medical device. This includes installers, engineers, technicians, clinicians, care givers, cleaners, sales, marketing, production technicians and any members of Ergo-Flex Technologies, LLC.

The patient population ranges from young adults to senior adults.

The Back On Trac is a system capable of communicating and capturing data accurately, effectively, securely, and consistently with different information technology systems, software applications, and networks, in various settings; and exchanging data such that the clinical or operational purpose and meaning of the data are preserved and unaltered.

WARNINGS AND CAUTIONS:

Product-specific warnings and cautions, covered in the applicable sections of this user manual, provide information needed to safely and effectively use the Back On Trac.

WARNING 

A statement that alerts the user to the possibility of injury, death, or other serious adverse reactions associated with the use or misuse of the device.

CAUTION 

A statement that alerts the user to the possibility of a problem with the device associated with the use or misuse of the device.

Symbols	
Symbol	**Meaning**
	Warning
	Operating Instructions
	Do not stack
	Non-ionizing electromagnetic radiation
	Type B applied part
	Manufacture
	ON
	OFF
	Instruction manual must be read

Application Symbols	
	Select Patient
	Configure Device
	Left
	Override the Mid-Point
	Right
	Upper Vibration
	Lower Vibration
	Heating Element
	Pause
	Add Protocol
	Settings
X	Exit
>	Add a Patient
	In Progress

Technical Data

Equipment Length	Total	56 inches Max. 60 inches (153 cm.)
Equipment Width	Total	24 inches (61 cm) Max. 36 inches (92 cm.)
Equipment Height	Total	43 inches (109.2 cm.) Max. 50 inches (127cm.)
Operational Footprint	Total	60 inches X 36 inches (153 cm. X 92 cm.)
Equipment Weight	Total	261 lbs. (118.4 kg)
Angle Adjustment	Leg Section	Flexion Degrees: Min 0° to Max. 20°, Bilateral
		Traction Length: Min 1in to Max 5 ½ in
Patient Capacity	Not More Than	300lbs
Power and security requirements	Voltage frequency, current consumption	240 VAC+-10% ;50-60 Hz; .400Amps
	Maximum Power Consumption	44 Watts
	Applied part	Type B 
	Medical Device	Class II
	Protection class	Class I
	Service Life	The shelf life of the Back on Trac (BOT) devices has been evaluated and determined that these devices are not susceptible to product degradation that would lead to product failure.
	Power Supply	Input: 100-240V~1.4A 50/60Hz
		Output: 12V ⎓ 10.0A
		AC Power Cords AC Power Cord North America, C7 for C8 inlet, 18 AWG, 6', Black
		Medical Grade, UL/CE Certified.
Environment Conditions (temperature, relative humidity, air pressure)	work	+10°C to +40°C from 30% to 75% non-condensing, 700-1060hPa
	storage	+5°C to +45°C. not exceeding 75% non-condensing, 700-1060hPa
	transport	-10°C to +45°C, from 20% to 95% non-condensing, 700-1060hPa
	Altitude Range	0ft - 9842.52ft = 3,000m
ASTM A-36 Structural Carbon Steel	Tensile Strength	58,000-80,000 psi
	Min Yield Strength	36,000 psi (Over 8” 32,000 psi)
Vinyl Specification	Flame Retardancy Specifications	CAL-TB 117-2013-Passes NFPA 260-Passes FMVSS 302-Passes UFAC Class 1-Passes BIFMA Class A-Passes IMO Part 8)3.1 & 3.2)-Passes
	Performance Specifications	Abrasion 1,800,000 + DR Cold Crack -20° UV Resistance 650 Hours Mildew Resistance-Yes Sulfide Stain Resistant-Yes
	Recommended Applications	Workspace, Fitness, Healthcare, Hospitality, Outdoor, Restaurant, Senior Living
Foam	Product Name	Polyether Polyurethane Foam

	Auto-ignition Point	Between 370°C to 427°C
Wood	Product Name	Hardwood plywood (Urea-Formaldehyde Bonded) *
	Description	This panel product contains a hardwood veneer face bonded to wood components such as other wood veneer lumber or veneer strips using urea-formaldehyde resin.
Vibrators & Heat	Upper Vibrators Lumbar Vibrators	Specification Requirements: 12 Volt Motor Max Current 03A Voltage Current 12V>=0.3A
	Lower Vibrator	Specification Requirements: 12 Volt Motor Load Current .07A(max) Voltage Current 12V ≥.038A
	Heat	Heating Wire: Ll.65m, 16Ω/m Heating Pad: 14*23cm Power: 5.4W (12V/450mA) Non-woven fabric surface temperature: 45.9℃ at highest Towel surface temperature:39.2℃ at highest

Approved Parts Recommendation

Ergo-Flex Technologies, LLC recommends the use of Ergo-Flex manufactured parts in the operation and maintenance of your Back On Trac equipment. Customer's use of repair or service parts applied parts, or accessories that are not approved by Ergo-Flex Technologies, LLC is at Customer's own risk and may void the product warranty provided by Ergo-Flex Technologies, LLC.

Inspection

The Back On Trac is inspected, tested, and calibrated before packaged for shipment. To ensure proper operation after shipment, it is recommended that an incoming inspection be performed before placing the equipment in use. It is recommended to carefully remove the back top cushion with a tool, in order to inspect all wires and connectors, to ensure all are secure and were not loosened from travel. The Back On Trac is delivered fully assembled with all accessories and applied parts in their proper place.

WARNING

Carefully examine before using. Check for any damaged parts. Check the alignment of all parts for binding, broken, bent or any other condition that may affect proper operation.

CAUTION

Vibrator wires are connected to the back upper cushion and should be removed gently not to pull the wires from the PCB board.

General Setup and Operation

The Back On Trac is designed and operated with customizable controls not to exceed limits for protocols, time, traction amount and flexion amount outlined by Ergo-Flex Technologies.

CAUTION

Back On Trac has an operational footprint that is larger than the static footprint due to recline and flexion functions.

CAUTION

Proper set up of the arm bolsters and ankle strap are required for optimal treatment.

CAUTION

Should the chair deviate from standard use or exhibit some unusual movements or alignment issues that results in a patient unable to safely dismount the equipment, help the patient off slowly. Once the patient is safely off the equipment, restart the Back On Trac and run a few protocols for troubleshooting purposes. If problem continues, contact Ergo-Flex Technologies, LLC Technical Support.

CAUTION

Should the patient become anxious, fearful, or uncomfortable, simply have the patient lift their arms from the bolsters and have the operator remove the ankle strap and the patient is no longer restrained.

CAUTION

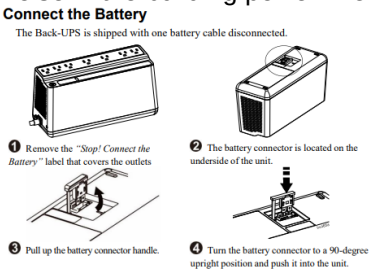
The actuator position is continually monitored in the firmware by reading the actuator potentiometer voltage. If the actuator is not performing optimally, contact Ergo-Flex Technologies, LLC for service.

CAUTION

The Back On Trac comes equipped with a mild heat function. Should the patient have a possible sensitivity to a mild heat, it is recommended to eliminate the heat function from treatment.

Battery Backup Setup

The Back On Trac is delivered with a standard battery back-up. A source used to protect the electronics from harmful surges and noise in the building power. Remove the battery back-up from the box and follow these steps below.



WARNING

Battery back-up is required for use of the equipment to prevent most electromagnetic disturbances. Should a disturbance effect the operation of the equipment, the operator will have to cycle the power and reset the machine. Minimal risk if a disturbance occurs. **Do not use an extension cord of any sort to supply power.**

Plug the power cable into an outlet near the location where the Back On Trac is to be installed. Press the power button on the battery back-up until it starts flashing green. After a moment it will stop flashing and will be solid green.

Power supply mains, plug & positioning

The Back On Trac is powered by an external A/C to D/C converter. The external power supply will be plugged into the battery + surge side of the battery back-up which is connected to the mains. The external supply delivers 12 V D/C to the Back On Trac via a four-wire cable to an inlet connector. This removes the potentially harmful A/C mains power as well as any leakage currents developed by the power supply from the chassis of the Back On Trac (Fig.7)

Position the Back On Trac in the desired location of the clinic and check for leveling. To level the Back On Trac, adjust the leveling feet on each corner of the lower frame using a 5/16 wrench to turn the levelers either clockwise to raise the corner, or counterclockwise to lower the corner, until the chair is stable and does not rock. It is recommended not to position the equipment so that it is

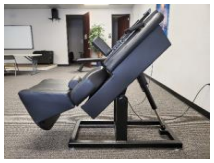


Fig 7

difficult to operate or disconnect the device. Always adhere to the operational footprint of the equipment.

WARNING

Moving Parts. Failure to allow the proper distance could result in injury to staff and patients as well as property damage. Back on Trac has a unique footprint of 57 inches when reclined.

WARNING

Possible Pinch Point. Although covered with a protective shell, stay clear of reclining actuator while in motion. If serviced, this should only be performed by a trained authorized service technician out of way of trapping zone.

WARNING

Metal Arm Bolsters must be removed from upper back cushion when servicing.

WARNING

This equipment is extremely heavy. To limit the possibility of injury when installing or moving this equipment, use the appropriate tools and equipment as well as help from others. Do not attempt to slide the equipment on rubberized flooring as there is a possibility of tipping over.

Start-Up

Accompanying Document. Reference BOTGEN1 Tablet Training Quick Guide for further instructions.

Patient Setup

Accompanying Document. Reference BOTGEN1 Tablet Training Quick Guide for further instructions.
For more details on patient setup, please visit Ergo-Flex Online Resource Center on our website at https://ergoflextechnologies.com for videos, additional literature, and training.

WARNING

Proper set up and positioning of the arm bolsters and leg strap is required for optimal treatment, as this holds the upper body and lower body in place during the session. The arm bolster must be placed directly under the deltoid of each patient.

WARNING

If the patient is placed in the wrong position relative to the moving parts of the bed, there is a risk of injury to the body or table structure. Help the patient to maintain proper position before treatment. The manufacturer is not liable for the consequences of improper use of the Back On Trac.

Power Off Equipment

Ergo-Flex Technologies, LLC recommends turning off the Back On Trac at the end of every day. Turn off the power switch to OFF, located on the underside of the Back On Trac. 

General

WARNING

Do not modify this equipment without authorization of the manufacturer.

WARNING

- When using electric and /or electronic equipment or machines, basic safety precautions should always be followed to reduce the risk of fire, electrical shock, and personal injury to both patients and staff. Read this manual as well as the operating

instructions before using this equipment.

WARNING

- Due to the intermittent nature of a wireless environment, some data can be lost if a connection cannot be established or is lost. The Ergo-Flex portal system and wireless network is designed to minimize these incidents but cannot eliminate them.

WARNING

- The Back On Trac is not intended to replace supervision by medical personnel. The user must become thoroughly familiar with the Back On Trac features, operation, and accessories prior to use. Always examine the chosen protocol before prescribing to the patient.

WARNING

- Should the tablet or an accessory be dropped or jarred, it should be immediately taken out of use and inspected by qualified service personnel to ensure its proper function prior to reuse.

WARNING

- If the equipment appears damaged, contact Ergo-Flex Technologies, LLC for authorization to repair.

WARNING

- Do not leave power cord laying across areas with foot traffic. It can be a tripping hazard. Do not handle the power cord with wet hands. Do not yank to disconnect.

WARNING

- The Back On Trac shall not be serviced while in use with a patient.

WARNING

- Do not calibrate the Back On Trac during a patient session.

WARNING

- When servicing, keep hair, loose clothing, and hands away from any moving parts. Should a problem become apparent, quickly turn equipment off.

WARNING

- The items shall not be vertically stacked by transport or by the nature of the item itself. 

WARNING

- Use only accessories provided by the manufacturer.

WARNING

- The Back On Trac should not be used adjacent to or stacked with other equipment. If adjacent use is necessary, monitor the Back On Trac to verify that it is operating normally.

CAUTION

- The Back On Trac has a limited load capacity. The safe working load should not exceed 300 lbs. limit, 136.078 kg.

CAUTION

- When setting or changing the place of use of the Back On Trac, ensure that there are no objects in the space below the bottom frame of the table. Do not allow access to children or animals. Except the Battery back-up.

CAUTION

Heat and Vibration is considered an addition. No excessive heat can occur. Mild heat and is either On or Off. Vibration cannot occur in excess. Vibration is either On or Off.

Electromagnetic Compatibility

WARNING

Do not use the Back On Trac near Therapeutic Radiation equipment. In addition, the Back on Trac is not compatible with HF

surgical equipment.

- **WARNING**
- The Emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 Class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

WARNING

- Disconnect from main (AC) and battery power when performing maintenance.

WARNING

- The equipment is fitted with a power cord that includes a grounding conductor and plug. The plug must be inserted into an outlet that is properly grounded according to local codes and ordinances. Grounding provides a path to reduce the possibility of electrical shock if a malfunction occurs. The third conductor in the power supply cord is only a functional earth. Do not use power cord other than provided by the manufacturer.

WARNING

- Do not place PEMF (Pulsed Electromagnetic Field) and similar devices on the same circuit with Back On Trac. Use of these electromagnetic field devices on or near our equipment will VOID the manufacturer warranty of the Back On Trac.

WARNING

If the Back On Trac should malfunction due to an electromagnetic disturbance the operator could expect the equipment not to perform optimally. The operator should turn off the equipment and call Ergo-Flex Technologies for assistance.

WARNING

- RF communications equipment should be used no closer than 23m to any part the Back on Trac, including cables specified by the manufacturer.

WARNING

- Other cables and accessories may negatively affect EMC performance.

WARNING

- Do not use the Back On Trac in a room with high relative humidity.

CAUTION

- The third pin on the power supply cord is for functional earth on the power supply only.

CAUTION

- Do not allow liquids (coffee, tea, water, detergents, and disinfectants) to contact the actuator electrical wiring and other components of the equipment. In the case of water damage to electrical wiring or actuator conduit the equipment should be immediately disconnected from the power supply by removing the plug from the outlet. It is recommended to have the equipment examined by a qualified technician.

-

Alarms, Errors, Messages

Alarms

Back On Trac Status	Power Button Illumination	Audible	Audible Indicator Terminates
Back On Trac has finished the session	None	Chime	N/A
Battery Back-up Status	**Power Button Illumination**	**Audible Indicator On**	**Audible Indicator Terminates**
Power On Supplying AC power to connected equipment	Solid green	None	N/A
On Battery Supplying battery power to battery back-up outlets	Solid green and flashes twice every 2 seconds.	The audible alarm depends on the ON Battery Indicator mode setting. See the *ON Battery Indicator Modes* section for full details	-Using Quick Mute. -Beeping stops when AC power is restored, or the Back-up is turned off. Applies only to modes where the on-battery alarm is audible.
Low Battery notification Supplying battery power to the battery back-up outlets and the battery is near a total discharge state	Flashes green in rapid succession.		
Low Battery shutdown Battery has been completely discharged while the Back-up is on battery, the UPS will shut down	None		-AC power is restored. -AC is not restored with 32 seconds. -The Back-up is turned off.
Sleep Mode The UPS has shut down and will "awaken' once AC power is restored	None	None	N/A
Replace Battery The battery is disconnected. The Battery needs to be charged or replaced.	Alternates green, red	Constant tone	-Back-up is turned off. -If battery is disconnected, unplug the Back-up from AC source and then turn it off. Refer to the section *"Connect the Battery" on page 2*. -If battery needs replacement, refer to the section *"Battery Replacement" on page 8* for details.
Detected Overload An overload condition has occurred in one or more of the battery backup outlets while operating on battery power**.**	Green red alternately flashing	Beeping (every 0.5 second)	N/A
Overload Shutdown An overload condition has occurred in one or more of the battery back-up outlets while the Back-up is operating on battery power.	None	Constant tone	If overload occurs in line mode, Back-up will enter fault mode. If overload occurs in battery mode, Back-up can be turned off

Errors

Catastrophic Failure	Back On Trac has stopped during a session and will not respond	Red banner will appear, informing failure has occurred. Contact Ergo-Flex Technologies Technical support.

Messages

Message	Meaning	Response
Calibration Command	The chair is about to start a calibration. Please make sure the patient is NOT on the chair. Do you want to proceed with the calibration?	User will choose YES or NO to proceed.

Device not registered	User will see a message saying the user has to register this device to use it. The device registration process will be handled using web portal.	If the device is not registered, contact Ergo-Flex Technologies Technical Support.
Higher firmware version	User will prompt dialog, “Do you really want to update the firmware on device01”.	If confirmed - start upgrading firmware. If not, cancel.
Lower firmware version	User will prompt dialog, “Do you really want to update the app. After updating you will not be able to connect with connected devices”.	If confirmed - disconnect devices Go to play store Cancel Same firmware version User can continue as usual.

Display Color

Communication	**Color**	**Description**
Ready	**Green**	Device is ready to start.
Running	**Blue**	Device is working on a therapy
Paused	**Orange**	Device has paused a therapy
Error	**Red**	An error occurred in the device
Calibrating	**Blue Green**	Device is executing the calibration commands
Initiating	**Orange**	Device is executing the home position command.

Log Data

User can see list of all data records that are received from the BOT device and some other actions related to the BOT device in the log screen. All the entries which are logged in will be displayed on the screen. In each item user can see description of received data. This data is strictly for troubleshooting and diagnostics for Ergo-Flex technical support.

The Ergo-Flex Portal is accessible to designated users; Super Users, Administrative Users and Users.

The responsibility of a super user is to install proprietary software to Ergo-Flex equipment to Ergo-Flex customers. The super user will assign administrative users and users, that are clinic specific to the purchased Ergo-Flex Equipment during the software setup.
A super user must always protect the username and password that has been assigned. A super user cannot create, modify, or access patient file data.

The responsibility of administrative user can create other administrative users and users. They have the ability to access patient files and securities are in place to only allow access to data from that clinic and no other. This is accomplished by assigning a unique encrypted clinic ID that is embedded in a muti-level application programming interface. This identifies and verifies the clinic and the machine MAC address as valid, in that clinic location, before the application can come online. As an added level of security, a unique username and password is required to access that clinic’s files in the portal, as well as requiring subsequent usernames and passwords for all additional users in that clinic.

CAUTION 

If the trained professional was selected to wrong user interface parameters, simply re-define the status of the user.

Log	**Color**	**Severity**
Connecting to device	Green	Low
Disconnecting to device	Red	High
Completing protocol	Orange	Medium
Completing a treatment command	Red	High
When error occurs	X	Error

After sending a treatment command	Green	Low
After pausing a protocol	Green	Low
After resuming a protocol	Green	Low
After stopping a protocol	Red	High
When changing options in protocol	Green	Low
When changing configuration in protocol	Green	Low
When start updating firmware	Red	High
After updating firmware	Red	High
If the device name is changed	Green	Low

Features and Definitions

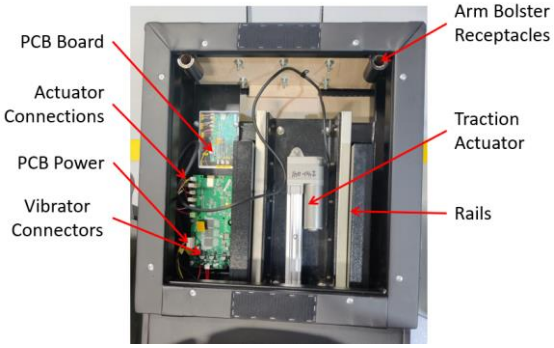
Features and displays

Ergo-Flex Portal	Ergo Flex's backend web portal utilizing the webservices API to communicate and manage patients, practices, doctors, operators, and therapy records. The main users will be the doctors and therapy administrators at the clinics.
Client ID	Client will be provided with a username and password. A doctor is assigned to a clinic by the web admin panel. There are locations to a clinic. Those locations are also added by the Ergo Flex admin panel.
Patient ID	An optional alphanumeric patient identifier can be entered and displayed with first and last name, birthdate, email, phone number and notes section.
Devices	These BOT devices are the BOT devices that are available for the device Bluetooth range.
Dashboard	Each item in the dashboard will represent a currently connected BOT device. Maximum number devices supported at a given time is 6.
Select Therapy/Configure Device	Users can use the Configure Device icon to start creating a treatment command.
Device Name	The machine name Ergo-Flex provided during registering the device through the web portal.
Protocol	A protocol configuration can be created with protocol, time, and length. Then the user can send a treatment command as a single protocol configuration or sequence of protocol configurations.
Stacked Protocols	User can add multiple protocols to a treatment, up to 8 at a time.
Sending Command/In Progress	Displayed by three dots, confirming that a function is working and not yet complete.
Time	The minimum required time for a treatment is 1 minute. If the selected treatment to rerun from the history is less than 1 minute, the time is automatically selected to 1 minute for BOT therapies.
Treatment History	Patient treatment history is available and can run a treatment again from the treatment history using the red Re-run icon.
Clinical Data Input	User can see a list of all data records that are received from the BOT device and some other actions related to the BOT device (device name change) in the log screen.

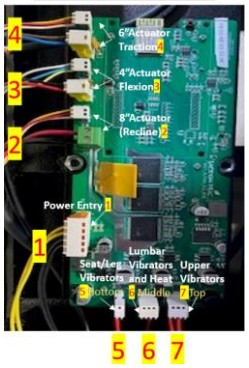
	All the entries which are logged, will be displayed on the screen.
Calibrate Device	Calibration is the process of configuring the Back On Trac to provide a reset to an acceptable range.
Home Position	Starting position for the Back On Trac.
Override the Mid-Point	User can send the Swing Mid-Point Override command to calculate the mid position of the swing motor of the device.
Supporting Platform	Android, higher than Android 5.0 (API level 21).
Permissions	Bluetooth-app uses Bluetooth to connect with device. Internet-should enable internet to use the application to connect to portal.

Operating Features, Controls, Indicators

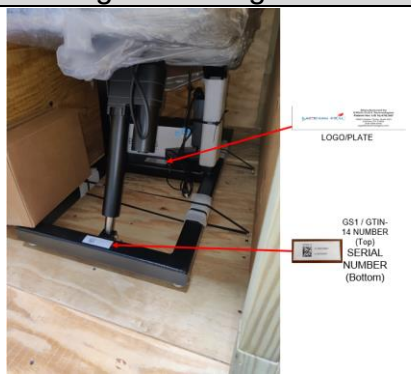
Connection Diagram



PCB Board Diagram



Labeling & Markings



GS1 Company Prefix:
A globally unique number licensed to a company.
GTIN Number (01):
A Global Trade Item Number (GTIN) is the globally unique GS1 Identification Key used to identify trade items and one of the main building blocks of the GS1 system. GTINs are assigned by the brand owner of the product and are used to identify products as they move through the global supply chain.
Serial Number (21)
The GS1 Application Identifier (21) indicates that the data field contains a serial number. A serial number is assigned to an entity for its lifetime. The number is made up of:
K: Back On Trac, Date of Manufacturing, and a unique identifying number.
Logo/Patent Plate:
Contains the information of the manufacturer and the patent number specific to the equipment.
Note: Logo Plate is made with Dynasub 020 aluminum silver plate and uses a Tesa double-sided universal tape.

Transport & Storage

Ergo-Flex Technologies, LLC equipment is delivered on a customized pallet and is protected by a hand-crafted custom crate.

Fig. 2

Located on the exterior of the Back On Trac packaging, you will see markings indicating special handling, and delivery requirements.

To begin the process of unpackaging, you must first remove the crate. You will need a #2 phillips screwdriver or cordless screwdriver to remove the screws holding the crate together. It is recommended to position the crate in the area in which the equipment will remain.

The crate is constructed so the customer can remove either end cap (blue arrow Fig.2) of the crate by backing out the screws that hold the end cap in place. Once the end cap is removed, proceed.

The next step is to remove the screws on the sides near the bottom, where the sides of the crate are attached to the pallet rails. There will be four to five screws. Once this is complete, proceed.

With at least two people, the crate can now be carefully lifted about 8 to 12 inches. While observing clearances with the ceiling and other equipment, lift and slide the crate. If there is a problem with having a clear space to perform this step safely, the crate can certainly be dismantled, one piece at a time, with a cordless screwdriver, then discarded.
When the crate has been removed, the wrapping material (green arrow, Fig. 3) can be carefully removed.

Fig 2

Fig 3

WARNING

If a blade is to be used to cut the chair free, it must be done with extreme caution to prevent injuries and damage to the upholstery and other parts of the Back On Trac.

With the wrapping material removed, remove the Back On Trac from the pallet. Remove the accessory box and the battery back-up from the pallet, and carefully cut the strapping (blue arrow Fig. 2) holding the Back On Trac to the pallet front and back. Remove the strapping and discard.

With help from several hands, grasp the chair from under the box (not the cushion) at the head of the chair, and under the upholstered foot section (yellow arrows fig.4), and carefully lift the chair up and off the pallet. Discard the pallet.
Position the Back On Trac in the desired location of the clinic and check for leveling. To level the Back On Trac, adjust the leveling feet (orange arrow fig.4) on each corner of the lower frame using a 5/16” wrench to turn the levelers, either clockwise to raise the corner, or counterclockwise to lower the corner, until the chair is stable, and does not rock.

Fig 4

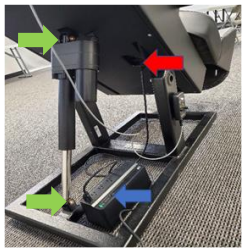


Fig 5

Safe Operation

Requirements for safe operation, you will find the power cord zip tied underneath with the power supply to the chair frame,

safely cut the zip ties and plug the power cord into one of the outlets on the backup and surge side of the battery back-up (blue arrow Fig.5).
Next, install the arm bolster cushions onto the metal arm bolsters, and refer to the operating instructions before powering the Back On Trac and before operating.

WARNING Stacking is prohibited.

Equipment Care and Maintenance

The life expectancy of the Back On Trac is dependent on the amount of use and the depth of wear and tear on the equipment. Generally, the equipment has the longest life, if the Back On Trac is cleaned after each use to remove any residue. 3 in 1 oil is used on the reclining actuators two brass mounting pins(green arrows Fig.5), to keep parts functioning. A calibration must be performed every time the power is cycled to reset any abnormalities and ensure optimal functionality. If accessories are torn, worn, or could cause discomfort to the patient, they have reached the life expectancy and will need to be replaced with new Ergo-Flex Technologies, LLC accessories.

If any applied parts: upper back cushion, lumbar cushion, seat cushion, begin to wear, crack, tear, or rip, or could cause discomfort to the patient, they have reached the life expectancy, and will need to be replaced with new Ergo-Flex Technologies, LLC applied parts.

If the metal arm bolsters break or crack in any fashion, contact Ergo-Flex Technologies, LLC to have them replaced.

Ergo-Flex Technologies, LLC will make available on request, component part lists, descriptions, calibration instructions, or other information, that will assist service personnel, to repair those parts of the Back On Trac that are designated by Ergo-Flex Technologies, LLC as repairable by service personnel.

What to do if a part of your Back On Trac equipment needs service?
Contact Ergo-Flex Technologies, LLC technical support to determine where servicing will occur. Please call our direct service department at 936-339-0046 or email service@ergoflextechnologies.com from there Ergo-Flex Technologies, LLC will assist you in isolating the problem to a specific component. Have the equipment available when you call so that you can supply the appropriate serial numbers and a detailed description of the problem. If it becomes necessary to replace a part, a replacement part will be provided and you will return the damaged part directly back to Ergo-Flex Technologies, LLC, and the company will dispose of the part properly, according to the standard guidelines for disposal. If the Back On Trac as a whole, needs to be disposed of, please contact Ergo-Flex Technologies, LLC and we as a company will make the necessary arrangements for disposal.
If the repair or replacement is covered by the warranty, Ergo-Flex Technologies, LLC will bear the costs of shipping the repaired or replacement part back to the user. All other shipping costs shall be paid by the user. Service replacement videos are available on Ergo-Flex Technologies, LLC Online Resource Center.

Operational Maintenance

CAUTION
There are no user serviceable parts inside the equipment. Repairs should be guided by an Ergo-Flex Technologies technical support representative and performed by a qualified technician. Should it be needed, Ergo-Flex Technologies will provide upon request circuit diagrams, component part lists, descriptions, calibration instructions, or other information. Our service division will provide all documentation needed to perform necessary repairs.

CAUTION

All service and maintenance must be performed by the trained service professional. A trained service professional is defined by personnel that might handle, operate, or interact with the medical device that has reviewed the operations manual and is instructed by an Ergo-Flex service technician. A trained service professional may temporarily be physicians, massage therapists, nurses, occupational therapists, physical therapists, physician assistants and service technicians, installers, engineers, technicians, clinicians, care givers, cleaners, sales, marketing, production technicians and any members of Ergo-Flex Technologies, LLC.

CAUTION

Any action in which the back cushion is removed for troubleshooting or repair, use caution to prevent damage to the back cushion vibrator wires, the connector, or the PCB board.

CAUTION

Should your Back On Trac shudder and make a low-pitched squeaking noise while reclining, there are four areas that may need a drop of lubricant, such as 3-in-1® Oil. The first two areas are located on the reclining actuator. There is a brass pin connecting it to the frame, and a brass pin connecting it to the back of the chair bed. Put a couple of drops on the brass pin at both ends. The second focus areas will be located on the bearings. They are located at the pivot points on either side of the chair, where the frame uprights support the chair bed. A couple of drops on the inside contact points should eliminate the squeaking noise.

CAUTION

Should the chair deviate from standard use or exhibit some unusual movements or alignment issues, it may be necessary to calibrate the Back On Trac. Visit the resource center at www.ergoflextechnologies.com to educate you on how to perform the calibration procedure successfully. Our technical support team is available to assist your staff with the calibration if needed. Also, reference the Tablet BOTGEN1 Training Guide for full instruction on the tablet and where you can find the calibration icon on the tablet.

For any other maintenance issue, please call Ergo-Flex Technologies Technical Support. Visit our website for contact information at www.ergoflextechnologies.com or email our service department directly at service@ergoflextechnologies.com

CAUTION

Occasional dusting of the lower frame will keep your Back On Trac looking clean and inviting.

CAUTION

Do not attempt to remove any part of the chair to clean on the inside unless directed to do so by a technical support representative from Ergo-Flex Technologies, LLC.

CAUTION

A screen or glass wipe is suggested to clean the Samsung ® tablet to remove any fingerprints.

CAUTION

Electrical connectors are not accessible without a proper tool.

Upholstery Maintenance

Ergo-Flex Technologies, LLC recommends cleaning the Back On Trac upholstery after each use. It is recommended to wipe down the cushions with a solution of mild detergent or soap. Multiple cleaning, or even excessive cleaning, will not harm the upholstery, as long as the correct solution is used.

CAUTION

Clean the upholstery with a solution of mild detergent (e.g., soap) solution; use a soft cloth or sponge and water. Spray on upholstery or on a soft cloth and wipe. Be sure to cover all areas. Avoid liquids of any kind. Never use cleaning paste, wax, sprays, strong detergents, solvents, and cleaning agents containing solvents, cleaning preparations for natural leather.

CAUTION

Do not use an alcohol based or chlorine bleach-based cleaner on any part of the chair. Chemical agents including but not limited to Ethylene Chloride and oil-based products such as Pine-Sol®, Lysol®, and Lestol® are not to be used on any part of the chair.

CAUTION

Do not use any type of leather conditioner such as Armor-All® or upholstery cleaner on any part of the chair.

CAUTION

Disinfecting wipes must be alcohol or chlorine bleach free. Disinfection with the use of the UV rays does not affect the surface of the upholstery.

CAUTION

Upholstery is not covered under your warranty. Some pieces will wear over time, such as the arm bolster cushions and the neck pillow. Frequent cleaning of these parts will keep them looking and functioning well. Should it be necessary to replace any part of your Back On Trac upholstery, they are readily available for purchase from Ergo-Flex Technologies, LLC.

CAUTION

The Velcro bindings on the straps, may become filled with debris. Cleaning with a brass wire brush may help the performance. Replacement straps are not covered under warranty and are available for purchase from Ergo-Flex Technologies, LLC.

Wireless Connection

Wireless Connection Scenarios

At various locations, the PC unit may or may not be able to complete a wireless connection. When connected, the connection icon turns green. If the PC unit cannot connect, the connection icon does not turn green, and device data is stored until a connection can be completed.

NOTE: If a user encounters a network connectivity issue while loading the patients list, it will prompt a message to the user saying “Please enable the network connection” - Ok

When the user comes online again, he can swipe down and refresh the screen to get the patient list from the server.

Reconnecting to device: App can reconnect to device when connection loses (battery drains / signal loses) without user intervention.

EMC Testing

Guidance and Manufacturers Declarations Electrical Emissions

Emissions Test	Compliance	Electromagnetic Environment
RF Radiated emissions CISPR 11	Class A	The Back on Trac communicates with the control tablet with BLE at 2.4 GHz. There are no other transmitters or receivers utilized in this equipment. Therefore, RF emissions are very low and unlikely to cause any interference in nearby electronic equipment.
RF Conducted emissions CISPR 11	Class A	The Back on Trac is suitable for use in a clinical or hospital environment only and operated by trained qualified personnel. It is not intended to be used in a domestic setting. The equipment is to be connected to the public low voltage power supply network that supplies buildings and for domestic purposes.
Harmonic emissions IEC 61000-4-2	Class A	complies
Voltage fluctuations/ flicker emissions IEC61000-3-3	Class A	complies

Guidance and Manufacturers Declarations Electromagnetic Immunity

Phenomenon	Basic EMC standard or test method	Immunity Test Levels Professional Healthcare Facility environment
Electromagnetic Discharge	IEC 61000-4-2	±8KV contact ±2KV, ± 4KV, ±8KV, ±15KV air
Radiated RF EM fields [a)]	IEC 61000-4-3	3V/m[f)] 80 MHz-2,7 GHz [b)] 80% AM at 1 kHz [c)]

Proximity fields from RF wireless communications equipment	IEC 61000-4-3	See Table Below
Electrical fast transient/burst	IEC 61000-4-4	±2 KV for power supply lines ±2 KV ±1 KV input/output lines
Surge	IEC 61000-4-5	±1KV line to line ±2KV line to earth
Conducted RF	IEC 61000-4-6	3 Vrms
ISM bands	IEC 61000-4-6	0,15 MHz-80 MHz 6 V in ISM bands between 0,15 MHz and 80 MHz 80% AM at 1kHz
Power frequency (50/60 Hz) magnetic field	IEC 61000-4-8	30 A/m
Voltage dips, short interruptions, and voltage variations on power supply input lines	IEC 61000-4-11	IEC 61000-4-11 at 0% for 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°. 0% for 1 cycle. 70% for 25/30 cycles. 0% for 250/300 cycles.
Note U_1 is the A. C. main voltage prior to application of the test level.		

Recommended separation distances between portable and mobile RF communications equipment and the Back on Trac units

The Back On Trac is intended for use in an electromagnetic environment in which RF disturbances are controlled. The user of the Back On Trac can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communication equipment (transmitters) and the Back On Trac as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter M		
	150 kHz to 80 MHz $d=1.2\sqrt{P}$	80 MHz to 800 MHz $d=1.2\sqrt{P}$	800 MHz to 2.4 GHz $d=1.2\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Table-Test specifications for Enclosure Port Immunity to RFD wireless communications equipment

Test frequency (MHz)	Band [a] (MHz)	Service [a]	Modulation [b]	Maximum power (W)	Distance (m)	IMMUNITY TEST LEVEL (V/m)
385	380 –390	TETRA 400	Pulse modulation [b] 18 Hz	1,8	0,3	27
450	430 – 470	GMRS 460, FRS 460	FM [c] ± 5 kHz deviation 1 kHz sine	2	0,3	28
710	704 – 787	LTE Band 13, 17	Pulse modulation [b] 217 Hz	0,2	0,3	9
745						
780						
810	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation [b] 18 Hz	2	0,3	28
870						
930						
1 720	1 700 – 1 990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation [b] 217 Hz	2	0,3	28
1 845						
1 970						
2 450	2 400 – 2 570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation [b] 217 Hz	2	0,3	28
5 240	5 100 – 5 800	WLAN 802.11 a/n	Pulse modulation [b] 217 Hz	0,2	0,3	9
5 500						
5 785						

NOTE If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.

[a] For some services, only the uplink frequencies are included.

[b] The carrier shall be modulated using a 50 % duty cycle square wave signal.

[c] As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

Conventions	
Gradient Traction	It is understood that when a “gradient traction” is referred to, that the chair will follow these steps: • Initially extend the traction actuator out to ½ of the set scale • It will add 1/3 of the difference between half scale and the final set-point for the next three repetitions to get to set point. • The first extension is 50% of the set point • The second extension is 66% of the set point • The third extension is 83% of the set point • The last extension is the complete set point
Repeated Traction	“Repeated traction” type of protocol will behave in the following way: The chair will start by extending out to the full traction set point • It will then release traction by ½”. • After the traction is released, a flexion event can occur if the protocol calls for it • It will then repeat the first step and the traction will be extend back out to the traction set point

Protocol List

A

Static Traction
Tractions full prescribed length.

B

Gradient Traction
Tractions out to 1/3" prescribed length; holds for 30 seconds
Retracts ½"; holds for 15 seconds
Tractions to 2/3" prescribed length; holds for 30 seconds
Retracts ½"; holds for 15 seconds
Tractions to full prescribed length; holds for 30 seconds
Retracts ½" and holds for 15 seconds
Repeats until end of session time

C

Intermittent Traction
Tractions full prescribed length; holds for 30 seconds
Retracts ½"; holds for 15 seconds
Repeats until end of session time

D

Static with 10 degree Right Lateral Flexion
Tractions full prescribed length; holds for 30 seconds
Flexes 10 degrees right; holds for 30 seconds
Repeats until end of session time

E

Static with 20 degree Right Lateral Flexion
Tractions to full prescribed length; holds for 30 seconds
Flexes 20 degrees right; holds for 30 seconds
Repeats until end of session time

F

Static with 10 degree Left Lateral Flexion
Tractions to full prescribed length; holds for 30 seconds
Flexes 20 degrees right; holds for 30 seconds
Repeats until end of session time

G

Static with 20 degree Left Lateral Flexion
Tractions to full prescribed length; holds for 30 seconds
Flexes 20 degrees left; holds for 30 seconds
Repeats until end of session time

H

Gradient with 10 degree Right Lateral Flexion

Tractions to full prescribed length
Tractions 1/3" of prescribed length; holds for 30 seconds
Retracts ½"; holds for 15 seconds
Tractions to 2/3"; holds for 30 seconds
Retracts ½"; holds for 15 seconds
Tractions to full prescribed length; holds for 30 seconds
Retracts ½"; holds for 15 seconds
Repeats last two steps until end of session

I

Gradient with 20 degree Right Lateral Flexion

Tractions full prescribed length
Tractions 1/3 prescribed length; holds for 30 seconds
Retracts ½"; holds for 15 seconds
Tractions to 2/3"; holds for 30 seconds
Retracts ½"; holds for 15 seconds
Tractions to full prescribed length; holds for 30seconds
Retracts ½"; holds for 15 seconds
Repeats until end of session

J

Gradient with 10 degree Left Lateral Flexion

Tractions to full prescribed length
Retracts ½"; holds for 15 seconds
Tractions to full length; holds for 30 seconds
Retracts ½"; holds for 15 seconds
Tractions 2/3"; holds for 30 seconds
Retracts ½"; holds for 15 seconds
Tractions to 1/3"; holds for 30 seconds

K

Gradient with 20 degree Left Lateral Flexion

Tractions full prescribed length
Retracts ½"; holds for 15 seconds
Tractions to full prescribed length; holds for 30 seconds
Retracts ½"; holds for 15 seconds
Tractions to 2/3"; holds for 30 seconds
Retracts ½"; holds for 15 seconds
Tractions to 1/3"; holds for 30 seconds

L

Static with 10 degree Bilateral Lateral Flexion

Tractions full prescribed length
Flexes left 10 degrees; holds for 5 seconds
Returns to neutral position; holds for 5 seconds
Flexes right 10 degrees; holds for 5 seconds
Repeats until end of session time

M

Static with 20 degree Bilateral Lateral Flexion

Tractions to full prescribed length
Tractions 20 degrees left; holds for 2 seconds
Tractions to neutral position; holds for 2 seconds
Tractions 20 degrees right; holds for 2 seconds
Repeats until end of the session time

N

Static with sweeping 10 degree Bilateral Flexion

Tractions full prescribed length
Flexes left 10 degrees; holds for 2 seconds
Returns to neutral position; holds for 2 seconds
Flexes right 10 degrees; holds for 2 seconds
Repeats until end of session time

O

Static with sweeping 20 degree Bilateral Lateral Flexion

Tractions full prescribed length
Flexes left 20 degrees; holds for 2 seconds
Returns to neutral position; holds for 2 seconds
Flexes right 20 degrees; holds for 2 seconds
Repeats until end of session time

P

Intermittent with 10 degree Right Lateral Flexion

Tractions out to full prescribed length; holds for 30 seconds
Retracts ½"; holds 5 seconds
Flexes 10 degrees to the right
Tractions out to fully prescribed length; holds for 30 seconds
Retracts ½", returns to center; holds for 5 seconds
Repeats until end of session time.

Q

Intermittent with 20 degree Right Lateral Flexion

Tractions out to full prescribed length; holds for 30 seconds
Retracts ½"; holds 5 seconds
Flexes 20 degrees to the right
Tractions out to fully prescribed length; holds for 30 seconds
Retracts ½"; holds for 5 seconds
Repeats until end of session time.

R

Intermittent with 10 degree Left Lateral Flexion

Tractions out to full prescribed length; holds for 30 seconds
Retracts ½"; holds 5 seconds
Flexes 10 degrees to the left
Tractions out to fully prescribed length; holds for 30 seconds
Retracts ½", returns to center; holds for 5 seconds
Repeats until end of session time.

S

Intermittent with 20 degree Left Lateral Flexion

Tractions out to full prescribed length; holds for 30 seconds
Retracts ½"; holds 5 seconds
Flexes 20 degrees to the left
Tractions out to fully prescribed length; holds for 30 seconds
Retracts ½"; holds for 5 seconds
Repeats until end of session time.

T

Intermittent with 10 degree Bilateral Lateral Flexion

Tractions out to fully prescribed length
Retracts ½"
Flexes 10 degrees to the left; holds for 30 seconds
Tractions out to traction setting, releases ½", returns to center.
Tractions out to traction setting, releases ½", flexes 10 degrees to the right.
Tractions out to traction setting, releases ½", returns to center.
Repeats until end of session time.

U

Intermittent with 20 degree Bilateral Lateral Flexion

Tractions out to traction setting, releases ½", flexes 20 degrees to the left.
Tractions out to traction setting, releases ½", returns to center.
Tractions out to traction setting, releases ½", flexes 20 degrees to the right.
Tractions out to traction setting, releases ½", returns to center.
Repeats until end of session time.

Troubleshooting Tips

Problem	Probable Cause	Possible Solution
Unit does not operate	Battery back-up not plugged in.	Please refer to page 8 “Battery Back Up Setup”.
	Battery back-up not turned on.	Press the On button on the battery back-up until the green light is blinking. Within a few seconds it should stay on.
	Power cord not plugged into the battery back-up.	Check power cord at both ends. Ensure a secure connection to equipment.
	No power at electrical outlet.	Check power source, wall switch, or circuit breaker in clinic.
	Power switch is off. Turn On OFF  ON	Press the switch to the On position located on underneath the machine next to the power cord.
	If above steps did not resolve issue.	Contact Ergo-Flex Technologies, LLC Technical Support for assistance.
Back On Trac is unstable, the chair rocks diagonally.	The levelers on the four corners of the frame need adjustment.	To adjust the levelers, a 5/16-inch open end wrench is required. To adjust the levelers, turn the wrench clockwise to lower that corner and counterclockwise to raise the corner. Adjust until chair no longer rocks.
Back On Trac does not recline.		Remove the metal arm bolsters and the back cushion. Check the connection to the large green connector on the relay board (Operating Features, Controls, Indicators) by tugging lightly on the red and black wires. Tighten if loose with a small flathead screwdriver. Check the three-pin connector, next to the green connector by pushing down.
Chair Reclines but will not traction or flex.	Chair must recline to supine position before traction can start. Traction must complete before flexing.	Remove the arm bolsters, and the cushion. Check the connectors on the left side of the PCB by gently pushing the connectors to secure it to the PCB.

Troubleshooting Tips Cont.

Problem	Probable Cause	Possible Solution
Chair reclines and tractions out but does not flex	Chair must recline to supine position and traction out to set point before it will start flexion.	Refer to the previous section. Check the connectors on the left side of the PCB board for good connection.
Vibrators and or heat does not function.	Press the icon for heat and or vibration.	Refer to the previous section. Check the connectors on the lower side of the PCB board (toward the front) for good connection.
The chair made an unusual movement and is stuck.	A problem error has occurred causing the equipment to stop responding.	If the equipment does not return home, try switching it off. Wait for fifteen seconds and switching it on. If it does not respond, call Ergo-Flex Technologies Technical Support for assistance. Or email service@ergoflextechnologies.com
The chair is making a grinding sound, or movements seem to be binding	A mechanical failure in the equipment has happened.	Discontinue use of the equipment and call Ergo-Flex Technologies, LLC Technical Support for assistance.
Messages	Error Message	Action by the Operator. If this persists, call Ergo-Flex Technologies, LLC Technical Support for assistance.

Parts, Applied Parts, and Accessories

The Back On Trac does not include applied parts that consist of electrodes and those parts of patient leads, or patient cable that need to physically contact the patient in normal use. An applied part is defined as; a part of medical electrical equipment that comes into physical contact with the patient to perform its function. See table below for further details.

Accessories	Operator Contact	Patient Contact	Explanation
Neck Pillow	YES	YES	Physical contact during patient set up by Operator and is added for desired comfort level for the patient.
Samsung® Tablet (Gen-1 Tablet model)	YES	NO	Physical contact during patient set up, maintenance, and service by Operator and is not to be operated by the patient.
Battery Back-up	YES	NO	Physical contact to Operator only.
Cervi-Trac System *An accessory of the parent device. *Purchased separately or at the time of purchase of the Back On Trac. See Cervi-Trac User Manual UM-CT-7001 for more details.*	YES	YES	Physical contact during patient set up by Operator. Patient treatment optional and can be removed from Back On Trac. Device is not a permanent fixture.
Parts	**Operator Contact**	**Patient Contact**	**Explanation**
Levelers	YES	NO	Physical contact to Operator only.
Controller PCB (Gen-1 Tablet model)	YES	NO	Physical contact to Operator only for maintenance and service. Internal components.
8-inch Recline Actuator	YES	NO	Physical contact to Operator only for maintenance and service. Internal components.
6-inch Traction Actuator	YES	NO	Physical contact to Operator only for maintenance and service. Internal components.
4-inch Flexion Actuator	YES	NO	Physical contact to Operator only for maintenance and service. Internal components.
Power Cord	YES	NO	Physical contact to Operator only.
Vibrator Connections	YES	NO	Physical contact to Operator only for maintenance and service. Internal components.
Power Supply	YES	NO	Physical contact to Operator only for maintenance and service. External components.
Internal Connections	YES	NO	Physical contact to Operator only for maintenance and service. Internal components.
Rails	YES	NO	Physical contact to Operator only for maintenance and service. Internal components.
Power Entry	YES	NO	Physical contact to Operator only for maintenance and service. Internal components.
Upper, Lumbar, Seat Vibrators	NO	NO	No physical contact with the Operator or the patient. Vibration is located inside the cushion.
Heating Pad	NO	NO	No physical contact with the Operator, however the patient will

			feel a mild heat applied to the lumbar region.
Applied Part	Operator Contact	Patient Contact	Explanation
Upper Back Cushion	YES	YES, Type B Applied Parts, duration max of 30 minutes	Physical contact during patient set up, maintenance, and service by Operator and is a required piece of the equipment for the patient.
Lumbar Cushion	YES	YES, Type B Applied Parts, duration max of 30 minutes	Physical contact during patient set up, maintenance, and service by Operator and is a required piece of the equipment for the patient.
Seat Cushion	YES	YES, Type B Applied Parts, duration max of 30 minutes	Physical contact during patient set up, maintenance, and service by Operator and is a required piece of the equipment for the patient.
Metal Arm Bolsters	YES	NO	Physical contact during patient set up, maintenance, and service by Operator and is a required piece of the equipment for the patient.
Arm Bolster Cushions	YES	YES, Type B Applied Parts, duration max of 30 minutes	Physical contact during patient set up by Operator and is required for proper positioning and treatment to patient.
Leg Strap	YES	YES, Type B Applied Parts, duration max of 30 minutes	Physical contact during patient set up by Operator and is required for proper positioning and treatment to patient.

Warranty

ERGO-FLEX TECHNOLOGIES, LLC

LIMITED WARRANTY FOR THE BACK ON TRAC

THIS LIMITED WARRANTY GIVES YOU SPECIFIC LEGAL RIGHTS REGARDING THE BACK ON TRAC PURCHASED DIRECTLY FROM ERGO-FLEX TECHNOLOGIES, LLC ("*ERGO-FLEX*") OR ONE OF ITS AUTHORIZED DISTRIBUTORS.

ERGO-FLEX WARRANTS THAT FOR A PERIOD OF ONE YEAR FROM THE FIRST DATE OF PURCHASE BY THE ORIGINAL BUYER, THE PRODUCT WILL BE FREE FROM MATERIAL DEFECTS IN MATERIALS AND WORKMANSHIP.

***ERGO-FLEX HEREBY DISCLAIMS ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION THE IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE*. IN THE EVENT APPLICABLE LAW DOES NOT PERMIT A WAIVER OF ANY IMPLIED WARRANTIES THEN THE DURATION AND REMEDIES OF ALL SUCH IMPLIED WARRANTIES ARE HEREBY LIMITED TO THE DURATION OF THIS EXPRESS LIMITED WARRANTY. SOME STATES DO NOT ALLOW LIMITATIONS ON HOW LONG AN IMPLIED WARRANTY LASTS, SO THE ABOVE LIMITATION MAY NOT APPLY TO YOU.**

ERGO-FLEX'S RESPONSIBILITY FOR A DEFECTIVE PRODUCT IS LIMITED TO REPAIR OR REPLACEMENT OR REFUND AS DESCRIBED BELOW IN THIS LIMITED WARRANTY.

WHAT DOES THIS WARRANTY COVER?

This limited warranty covers material defects in materials and workmanship of the Back On Trac (the "**product**") for the Warranty Period as defined below. This limited warranty does not apply to upholstery cushions, arm bolster cushions, neck pillows or straps.

WHO MAY USE THIS WARRANTY?

ERGO-FLEX extends this limited warranty only to the consumer who originally purchased the product ("**you**"). It does not extend to any subsequent owner or other transferee of the product.

WHAT DOES THIS WARRANTY NOT COVER?

This limited warranty does not cover any damage due to: (a) transportation; (b) storage; (c) improper use; (d) failure to follow the product instructions or to perform any preventive maintenance; (e) modifications; (f) unauthorized repair; (g) normal wear and tear; or (h) external causes such as accidents, negligence, abuse, or other actions or events beyond Ergo-Flex's reasonable control. In addition, this limited warranty does not cover the cost of labor to repair or replace a product, which may or may not include travel costs.

WHAT IS THE PERIOD OF COVERAGE?

This limited warranty starts on the date of your purchase and lasts for one year (the "**Warranty Period**"). The Warranty Period is not extended if Ergo-Flex repairs or replaces the product. Ergo-Flex may change the availability of this limited warranty at Ergo-Flex's discretion, but any changes will not be retroactive.

WHAT ARE YOUR REMEDIES UNDER THIS WARRANTY?

With respect to any defective product during the Warranty Period, Ergo-Flex will, in Ergo-Flex's sole discretion, either: (a) repair or replace such product (or the defective part) free of charge or (b) refund the purchase price of such product. Ergo-Flex will also pay for shipping and handling fees to return the repaired or replacement product to you if Ergo-Flex elects to repair or replace the defective product.

HOW DO YOU OBTAIN WARRANTY SERVICE?

To obtain warranty service, you must email proof of purchase and an explanation of the alleged defect to Ergo-Flex's Customer Service Department at service@ergoflextechnologies.com during the Warranty Period.

LIMITATION OF LIABILITY

THE REMEDIES DESCRIBED ABOVE ARE YOUR SOLE AND EXCLUSIVE REMEDIES AND ERGO-FLEX'S ENTIRE LIABILITY FOR ANY BREACH OF THIS LIMITED WARRANTY. ERGO-FLEX'S LIABILITY SHALL UNDER NO CIRCUMSTANCES EXCEED THE ACTUAL AMOUNT PAID BY YOU FOR THE DEFECTIVE PRODUCT, NOR SHALL ERGO-FLEX UNDER ANY CIRCUMSTANCES BE LIABLE FOR ANY CONSEQUENTIAL, INCIDENTAL, SPECIAL OR PUNITIVE DAMAGES OR LOSSES, WHETHER DIRECT OR INDIRECT.

SOME STATES DO NOT ALLOW THE EXCLUSION OR LIMITATION OF INCIDENTAL OR CONSEQUENTIAL DAMAGES, SO THE ABOVE LIMITATION OR EXCLUSION MAY NOT APPLY TO YOU.

COST OF REPAIR OR REPLACEMENT.

If Ergo-Flex determines there is no defect to the product, or that the defect resulted from causes not within the scope of this limited warranty, then you will bear all costs to repair the product.

Glossary

Actuator- Motor driven mechanism used by the Back On Trac to recline, apply traction, and apply flexion.

Arm Bolsters- A set of attachment cushions to fit under the arms and keep the patient in the proper position during a session.

Back On Trac- The name given to the equipment by Ergo-Flex Technologies, LLC Technologies LLC.

BOL- Bill of Lading attached to the packing crate to identify the shipper and receiver.

BOT- Acronym for the Back On Trac.

EEPROM- Electronically erasable programmable read only memory used to store the firmware that operates the

Back on Trac.

Firmware- Semi-permanent memory used to program the controller in the controller PCB.

Flexion- Anatomical name for forward bending. In the lower back, approximately 50% of flexion occurs at the hips, and 50% occurs at the lower spine. Motion is divided between the five motion segments in the lower back, although, a disproportionate amount of the motion is at L4-L5 (lumbar segment 4 & %) and L3-L4 (lumbar segment 3 & 4).

Handgrips- An accessory supplied with the Back On Trac to assist the patients' arms to remain stationary.

PCB- The Printed Circuit Board is the hardware that controls the components of the Back On Trac.

Software- The program that runs the protocols associated with the Back on Trac.

Supine- Lying horizontally with the face and torso facing up, as opposed to the prone position. It grants access to the peritoneal, thoracic and pericardial regions, as well as the head, neck and extremities.

Traction- a directional pull on the trunk or on an extremity. Placing a stretch on the spine separates the vertebrae, and helps to relieve direct nerve pressure and stress on the vertebral discs.