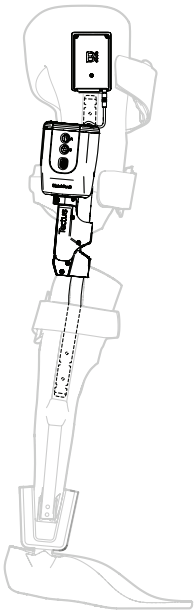


Tectus

User Guide

TEC-L, TEC-R

Blatchford

Contents

EN

Please read all safety warnings in Section 2 and 7 before setting up or using the device.

1 Description and Intended Purpose

These instructions are for the user (wearer) only.

The term device is used throughout these instructions for use to refer to Tectus, a knee system comprising Tectus knee module, follower joint, battery pack, side-bars and associated key fob controllers. The terms Tectus KAFO (Knee-Ankle-Foot Orthosis) or brace are used throughout these instructions for use to refer to a custom-made full leg orthosis incorporating the device and manufactured to a practitioner's prescription.

Note… The ankle joint is not manufactured by Blatchford and not covered by these instructions for use. Refer to manufacturer's documentation.

The term *programming device* is used throughout these instructions for use to refer to a tablet or mobile phone running an Android or iOS operating system.

The term *app* is used throughout these instructions for use to refer to the Tectus programming application which resides on the programming device.

Make sure that you understand all instructions for use, drawing particular attention to all maintenance and safety information sections.

Application

This device is to be used exclusively as part of a lower limb orthosis.

Intended for a single user.

This device is a Class I CE marked medical device according to the Medical Device Regulation 2017/745 that is for use as a component of a lower limb orthosis. The brace is a custom-made medical device. The device, when assembled as part of a KAFO, is a microprocessor-controlled swing and stance device allowing automatic adjustment of flexion resistance and manual adjustment of extension resistance.

The device allows you to undertake activities such as walking, standing, sitting and descending stairs. You can control the device by switching it between different operating modes for different activities, using control buttons on the device and/or control buttons on a key fob. The practitioner can also use these controls in conjunction with the app to customise device operation to suit your requirements.

2 Safety Information

This warning symbol highlights important safety information which must be followed carefully.

Contact your practitioner if your condition changes.

Regularly check the limb on which the Tectus KAFO is worn for signs of skin irritation, tissue damage, pressure sores or discomfort and report any such signs to your practitioner.

Assembly, programming, maintenance and repair of the device (including handling and replacement of the battery unit) must only be carried out by a suitably qualified practitioner or technician that has attended an approved training course.

Be aware of finger trap hazards at all times.

Do not place near any heat source. Do not leave in direct sunshine or inside a car in hot weather.

Avoid strong magnetic fields, radioactive environments, sources of electrical interference, atmospheres containing liquids and/or powders.

Do not wear the device during any scanning procedures (e.g. X-ray, CT or MRI scan).

The device is not intended for use when immersed in water or as a shower orthosis. If the orthosis comes into contact with water remove and dry immediately.

Any excessive changes in heel height after programming will adversely affect the function of the orthosis. Only footwear approved by the practitioner should be used with the orthosis.

Advise your practitioner if you use a pacemaker or any other electronic medical equipment before using the device.

Ensure no water enters the charger plug socket and the cover is only removed during charging.

See also additional safety information in Section 7.1 *Battery Charging Safety Information*.

Observe the following warnings when using the device:

Any changes in the performance or function of the device e.g. restricted movement, non-smooth motion or unusual noises should be immediately reported to your practitioner or service provider.

Ensure only suitably retrofitted vehicles are used when driving. All persons are required to observe their respective driving laws when operating motor vehicles. While wearing the orthosis, the leg on which the orthosis is worn must not be used to control the vehicle or its components (e.g. clutch pedal, brake pedal, accelerator).

You must not operate heavy machinery while wearing the device.

Always use a handrail when ascending and descending stairs and at any other time if available.

Leg-over-leg stairs descent should only be undertaken if you have received suitable training and have been approved to do so by your practitioner. Otherwise a step-to-step gait should be used descending stairs.

When starting to walk, you should always lead with the unaffected leg. If walking is initiated with the braced limb, the device may not recognize the movement and as a safety measure will switch to *Lock* mode.

Confirm that *Stairs* mode is engaged before attempting to descend stairs.

Confirm that *Sit* mode is engaged before attempting to sit.

The device must not be used for unusual activities, including, for example, extreme sports (free climbing, parachuting, paragliding, etc.), sport activities that involve jumping, sudden movements or fast sequences of steps (e.g., running, cycle racing, basketball, badminton, ice and snow sports) or extreme slopes and steps.

Avoid, where possible, using the device on slippery or unfirm surfaces (sand, snow, mud, etc.). If unavoidable, proceed with extreme caution.

If the critical service indicator is activated and cannot be reset (see Section 5.1 ***Critical Service Indicator*****), stop using the device as soon as is practicable and contact your practitioner to arrange a service.**

You must not adjust or tamper with the setup of the device.

Do not modify or replace the KAFO straps or padding prescribed by the practitioner.

After continuous use the knee module may become hot to the touch.

To minimize the risk of slipping and tripping, appropriate footwear that fits securely around the foot components must be used at all times.

Carrying loads might affect your posture and ability to meet the required parameters for the knee to release from stance.

Keep the key fob on a lanyard separate from any other keys to prevent accidental mode switching.

To prevent damage to clothing take care not to trap clothing in the moving parts of the device.

Avoid any strangulation hazard that the key fob lanyard may present to the user when worn, such as catching the cord in rotating machinery.

When the key fob lanyard is not in use always store it away safely to avoid any strangulation hazard that it may present to children.

The device is not designed for walking backwards. Do not attempt to walk backwards as the device may not support you.

In *Walk* mode, when backwards motion is detected, the device will lock in extension to provide standing support only. See Section 10.3 *Activities and Associated User Modes* for details.

Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

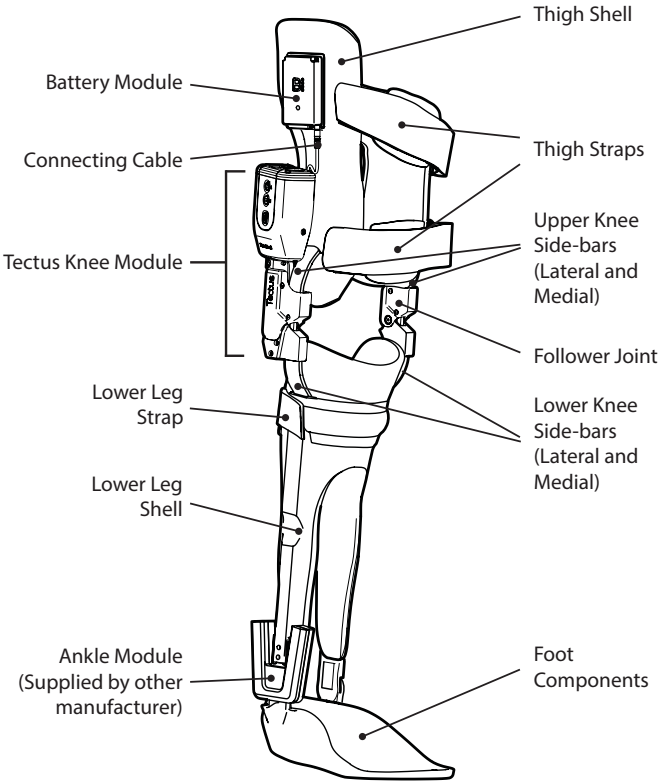
WARNING: Portable RF (radio frequency) communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the device, including cables specified by the manufacturer; this may otherwise result in the degradation of performance of the device.

3 Construction

Principal Parts

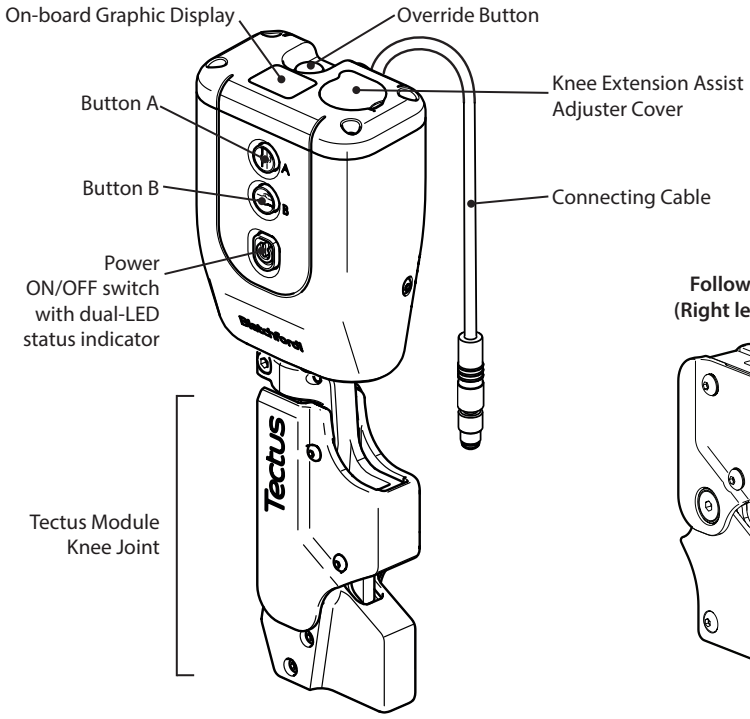
• Tectus Knee Module	Titanium, stainless steel, aluminum, elastomer, thermoplastic, electronic components, hydraulic fluid
• Battery Module	NiMH battery, thermoplastic
• Follower Joint	Stainless steel, aluminum, elastomer, thermoplastic
• Knee Side-bars	Titanium
• Battery Charger	Thermoplastic, electronic components
• Key Fobs	Thermoplastic, electronic components, Lithium battery
• Thigh, Lower Leg Shell, Straps, Ankle Module and Foot Components	Refer to manufacturer's documentation

Component Identification

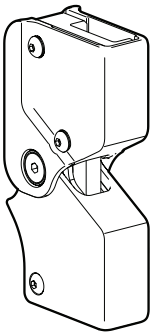


Note… For illustrative purposes, only the right leg Tectus KAFO is shown.

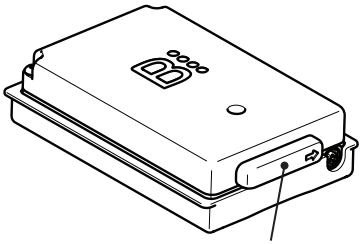
Tectus Knee Module
(Right leg shown)



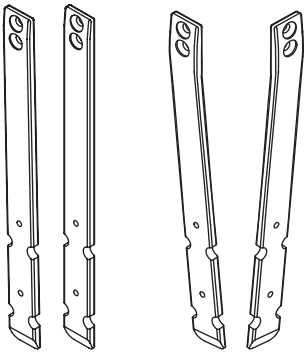
Follower Joint
(Right leg shown)



Battery Module



Knee Side-bars



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4 Key Points

The microprocessor-controlled device is configured by your practitioner for your individual gait needs, and adapts in real time to your current motion situation.

A power ON/OFF button and two push buttons (A and B) on the device provide the local control through various switch pressing combinations. See Section 10.8 *Mode Switching on the Device Using Tectus Module Buttons A and/or B*.

You cannot make any adjustments to the programmed performance of the device, these must be carried out by your practitioner. However, the device allows you to switch operating modes manually using the 4-button key fob and/or A and B buttons so you can adapt device operation for specific circumstances. For example, to walk down stairs you would select ***Stairs*** mode just prior to starting to walk down the stairs. In ***Stairs*** mode the device will provide necessary additional support by increasing flexion resistance. Operation of the device and the operating modes available to the user are described in Section 10 *Tectus Knee Module Operation*.

A four-button key fob on a lanyard provides you with a remote control capability to switch the device between operating modes. See Section 10.6 *Mode Switching on the Device Using The Key Fob*.

In the event of any malfunction of the electronic or the hydraulic control system, or when the battery is fully discharged, the device automatically switches to a ***Safety*** mode. In this ***Safety*** mode the device reverts to pre-programmed resistance parameters and allows only limited functionality. Normal operation resumes when the device is first time powered on after the malfunction has been resolved, or the battery has been recharged. See Section 5.1 *Critical Service Indicator* and Section 7.3.2 *Low Battery Behavior*.

The device has a mechanical override button which allows knee flexion while pressed. See Section 10.8 *Mechanical Override Operation*.

5 Maintenance

The Tectus KAFO requires a routine inspection at the following times after fitting:

2 weeks	3 months	6 months	12 months	24 months

These inspections must be carried out by competent personnel according to the routine inspections schedule available from Blatchford ACS.

⚠ **Completion of routine inspections according to the prescribed maintenance schedule and notification of Blatchford of the results is necessary to maintain the validity of the warranty.**

Do not carry out maintenance on this device yourself. Instead, return it to your practitioner/ service provider for maintenance. If the device is still under warranty, we will loan you another knee unit while we carry out maintenance. The loan device and the device returned after maintenance must be set up by the practitioner before use.

Any changes in performance of this device must be reported to the practitioner.

Changes in performance may include:

- Increase or decrease in knee stiffness
- Instability

- Reduced knee support (free movement)
- Any unrecognized beeps, warning lights, on-screen indications or device vibrations*
- Any unusual noise

*The device emits vibrations when operating modes change. This is normal behavior.

Do not lubricate the device yourself, this will be carried out during servicing with the appropriate lubricants.

Never use WD40 or any other water dispersant on any of the device moving parts in an attempt to fix unusual noises, squeaking or stiff joints.

Check the device every time before use for physical damage to the KAFO and:

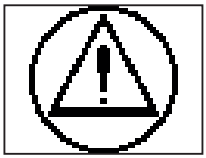
- Signs of wear or tear
- Hydraulic leakage
- Security of the joint covers
- Security and condition of the straps

Replace the key fob battery either every six months or:

- when switching between knee modes becomes inconsistent or
- if the key fob LED does not illuminate every time a button is pressed

See Section 5.4 ***Replacing the Key Fob Battery***. If for any reason you are unable to carry out this procedure contact your practitioner or service provider to arrange replacing your battery for you.

5.1 Critical Service Indicator



In the event of the device detecting a malfunction, the critical service indicator graphic will be activated and flash on the device screen (see image) and the device will attempt go into ***Safety*** mode with higher than normal knee flexion and extension resistance. Simultaneously button B will start and continue flashing Red until the malfunction is resolved.

In this ***Safety*** mode you can slowly extend or flex the knee to allow you to move to a safe position to remove the device.

If for any reason *Safety* mode does not engage, stop using the device immediately.

If adjustment of the knee angle is required, the device can be allowed to flex or extend freely by operating the override button, please refer to Section 10.8.

WARNING! Only use the override button if it is safe to do so.

If the device malfunctions, and performing a hard reset (see Section 5.2) does not fix the fault, or if the Critical Service Indicator is displayed, contact your practitioner as soon as is possible, and you must not use the device until the malfunction has been fixed and/or service has been carried out as necessary.

The critical service indicator will continuously flash and the knee will remain in this mode until the malfunction is resolved. If you power down with the critical service indicator on, it will extinguish however when you next power on the device the critical service indicator will begin to flash again and continue until the malfunction is resolved.

5.2 Hard Reset

In the case of a minor and non-recurring malfunction a hard reset may be attempted to allow device self-recovery. To conduct a hard reset, power the device OFF and ON via the power ON\ OFF button located on the knee module.

⚠ **If the malfunction is persistent contact your practitioner.**

5.3 Cleaning

Blatchford recommends cleaning the device daily. Use a damp cloth and mild soap to clean outside surfaces, DO NOT use aggressive cleansers or bleach. Do not machine wash/tumble dry or use any hose, pressure washer/drier system.

Ensure water/liquids do not enter the charging socket. Thoroughly dry before use.

5.4 Replacing the Key Fob Battery

The key fob operates using a CR 2032 button battery. Replacement is necessary every six months or when switching between knee modes becomes inconsistent or if the key fob LED does not illuminate every time a button is pressed.

1

Place the key fob on a flat surface with the battery compartment lid facing upwards.

2

Using an appropriate cross head screwdriver, remove both screws and put aside for later.

3

Using an appropriate flat head screwdriver pry open the cover only from the key ring end as shown to prevent damage to the gasket.

4

Remove the discharged battery and dispose it according to the local recycling regulations.

⚠ **Batteries should be kept out of reach of children and pets. In case of ingestion, seek medical attention.**

5

With the side marked **+** facing outwards, place the new battery into the battery compartment by pressing it first against the side contact springs then into the compartment.

6

Ensure that the mating surfaces of the battery compartment and lid are clean. If required, use a dry cotton bud to clean these surfaces.

7

To ensure continued protection against ingress of moisture, make sure that the lid gasket is fitted without creases and free of damage.

8

Replace cover and screws as shown and tighten screws until hand tight. Do not overtighten!

After battery replacement, confirm all key fob functionality by testing that all buttons achieve the required knee mode change when pressed and that the LED on the fob illuminates once after each time a button has been pressed.

6 Limitations on Use

Lifting Loads

User weight and activity is governed by the stated limits.

Load carrying by the user should be based on a local risk assessment. The assessment should take into account that carrying loads might affect posture and ability to meet the required parameters for the knee to release from stance.

The combined user weight and lifting load must not exceed 100 kg in all cases.

Environment

Avoid exposing the Tectus KAFO to corrosive elements such as water, acids and other liquids. Also avoid abrasive environments such as those containing sand for example as these may promote premature wear.

Note… Only the knee module and battery pack are waterproof to IP54 standard.

Exclusively for use between -10 °C and 50 °C (14 °F to 122 °F).

Suitable for outdoor use

7 Battery Charging

7.1 Battery Charging Safety Information

Never connect the charger to the device whilst still wearing it.

The battery should only be charged in temperatures between 0 °C to 35 °C (32 °F to 95 °F).

The battery charger can be used with electrical outlets rated between 100 V and 240 V AC, 50/60 Hz.

Only charge the battery of the device using the charger and charging cable supplied with the product. Do not use this charger to charge any other device.

Ensure the appropriate, country-specific mains adapter plug is fitted to the charger. Never force the plug into an incompatible mains socket.

Before charging ensure charging surfaces are dry, free from contamination and debris build-up, because this can prevent charging.

If any unusual noise or smell is noticed whilst charging, disconnect the charger and power off both charger and knee module. Report the problem to your practitioner.

The battery module and battery charger connectors contain strong magnets. Always keep a safe distance (at least 10 cm) between these magnets and all objects that can be affected by magnetism, such as watches, pacemakers, bank cards or any magnetically stored media.

Do not allow any ferrous material to attach itself to the charging surfaces.

Do not dismantle the adapter plug or battery charger.

Immediately replace damaged adapter plugs or battery chargers with parts supplied by Blatchford.

During a charging the device will power down. Once charged, the device will require powering on via the ON\OFF button located on the outer surface of the Tectus knee module.

Do not remove the batteries, they are not field replaceable and will be replaced as necessary, during routine inspection.

If the device has been subjected to temperatures lower than -10 °C (14 °F) it must be returned to Blatchford for inspection for possible damage to the battery pack.

7.2 Before Charging

The device should not be charged while being worn; remove the Tectus KAFO before charging. Do not don the device while it is connected to the charger.

Always check the battery charge level before use, ensuring a sufficient amount of charge for daily activities. It is recommended to charge the device every day when using it on a daily basis.

It is recommended that you switch the device to ***Lock*** mode and, before charging, lay the Tectus KAFO down in a horizontal position (on a flat surface or floor), with the knee module facing upwards and with 5 degrees of knee flexion so that it is secure and does not roll over.

Note… As soon as the charger is connected, the knee module automatically switches off.

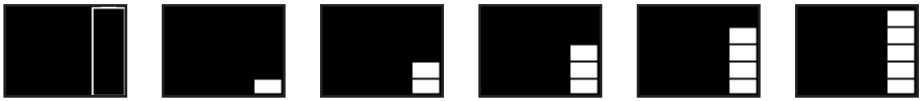
7.3 On-Screen Battery Level Indicator

7.3.1 Normal Indications

The battery level indicator will appear for 5 seconds on the side of the on-board graphic display:

- During mode switching.
- Long pressing button A and B together.

The following battery level indications are available:

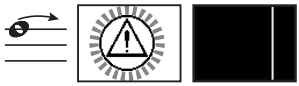


7.3.2 Low Battery Behavior

Low Battery Warning

The device will warn you when the battery charge level shown drops to 20% by emitting two short high-tone beeps and also displaying the warning symbol followed by one bar on the graphic display. This warning will be repeated every 10 minutes and/or when any button is pressed on the device until the charge in the battery reaches the critically low level.

Critically Low Battery Warning



A critically low battery level will be indicated by the warning symbol flashing and one long high-tone beep. The device will revert to a ***Safe*** mode identical to the one described in Section 5.1 *Critical Service Indicator.*

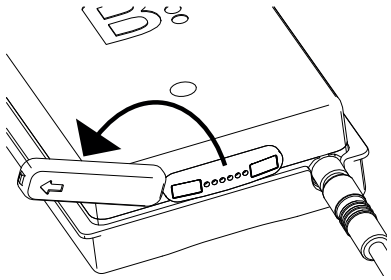
When the Critically Low Battery warning is indicated, you must stop using the device and not to reuse until the device has been recharged.

7.3.3 No Display after Connecting the Battery Charger

If after connecting and switching on the battery charger the device graphic display remains blank, the battery may be completely discharged. Leave the battery charger connected for at least 15 minutes and check the charge level by disconnecting and re-connecting the battery charger.

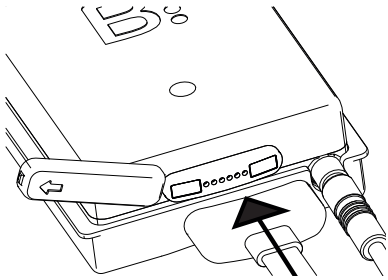
7.4 Connecting and Disconnecting the Charger

1



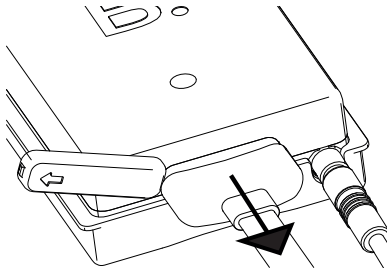
Open the charging connector cover.

2



Present the magnetic charger connector to the battery charger connector.

3



Allow the magnets to naturally attract to each other. Do not use force when connecting the cable plug to the battery charger.

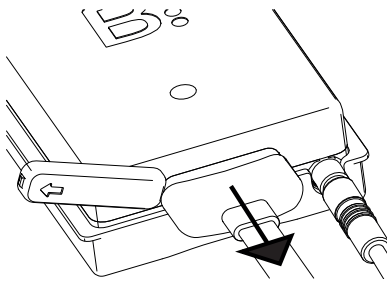
4

Plug the battery charger into the wall socket and power on. When the indicator on the battery charger is green then the battery is fully charged.

(For further information on the battery charger indicator LED see Section 7.5 *Battery Charger LED Indications*.)

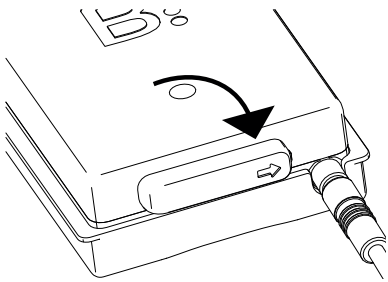
During charging Tectus will remain powered off.

5



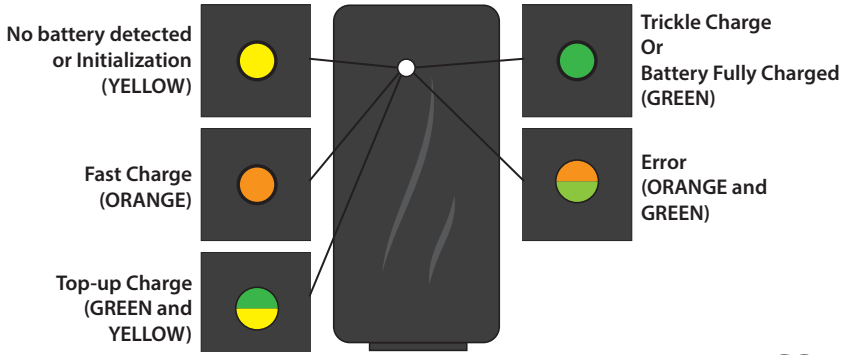
Disconnect the magnetic charging connector once charging is complete.

6



Close the charging connector cover.

7.5 Battery Charger LED Indications



Note… Refer to the reverse side of the battery charger module and the instructions supplied with the charger for further information.

Start-Up Sequence

With the charger plugged into the mains socket, and connected to the device, switch on at the socket. The charger LED will illuminate in the following color sequence in approximately 10 seconds to indicate the device is charging.

7.6 Charging and Operating Reference Times

Process	Time
Time to fully charge battery. (From fully discharged state.)	Approximately 2 hours
Minimum charging time before use. (From fully discharged state.)	At least 1 hour
Maximum battery duration, from fully charged, under continuous device operation i.e. uninterrupted walking. (Subject to operating temperatures)	18 hours (see notes i and ii)

Notes: i) For the maximum operating time with one battery charge, turning the device off when it is not being used is recommended.

ii) The operating time of the device may be reduced at low ambient temperatures or due to aging of the battery.

8 How to Don and Doff the Tectus KAFO

8.1 Donning the Tectus KAFO

Notes: i) Charge the device before donning. (See Section 7 ***Battery Charging***.)

ii) Inspect daily for signs of deterioration or damage that might affect the safety or function of the device. If anything unusual is noticed, contact your practitioner for advice.

1. Completely undo and fully open all closure straps so they are clear of the shell openings.
2. Remove the shoe.
3. Sit on the front edge of a chair.
4. Power ON the device. (See Section 9.)
5. If powered ON with the device lying horizontal, the device should be in ***Free*** mode after power ON; if not, then set the device to ***Free*** mode via key fob or module buttons.
6. Flex the Tectus KAFO at the knee.
7. Slightly extend the leg and insert the thigh into the thigh shell.
8. Insert the foot into the foot component, positioning the heel first and insert the lower leg into the lower leg shell.
9. Fasten all straps. Do not overtighten.
10. Check the fit of the orthosis for comfort. (Alter as required e.g. appropriate trim lines.)
11. Put the shoe on over the foot component. (Some users may prefer donning the Tectus KAFO with the shoe already in place.)
12. Set the device to ***Walk*** mode and stand up (holding on to chair for support as necessary) and adjust all closures/securing straps as required.
13. If worn over clothing, ensure clothing is folded neatly to avoid discomfort.
    If worn under clothing (i.e. dress, skirt, loosely fitting trousers), a sock or a thin under garment covering the full length of the leg should be worn.

⚠ **To prevent damage to clothing take care not to trap clothing between the moving parts of the device.**

14. Set the device to ***Sit*** mode and sit down again carefully.
15. Set the device to ***Free*** mode and gently flex and extend the knee to confirm that Tectus KAFO fits comfortably throughout the range of movement.
16. Set the device back to ***Walk*** mode before standing up.

8.2 Doffing the Tectus KAFO

1. Set the device to ***Sit*** mode.
2. Sit down on the front half of a chair (holding on to chair for support as necessary).
3. Set the device to ***Free*** mode.
4. Remove the shoe.
5. Open all fastening straps.
6. Remove Tectus KAFO.
7. Extend the Tectus KAFO to 5 degrees knee flexion and activate ***Lock*** mode on the device.
8. Power OFF the device.
9. Lay the Tectus KAFO down in a horizontal position (on a flat surface or floor), with the knee module facing upwards and with 5 degrees of knee flexion so that it is secure and does not roll over.

Note… It is recommended to put the device on charge every time after use.

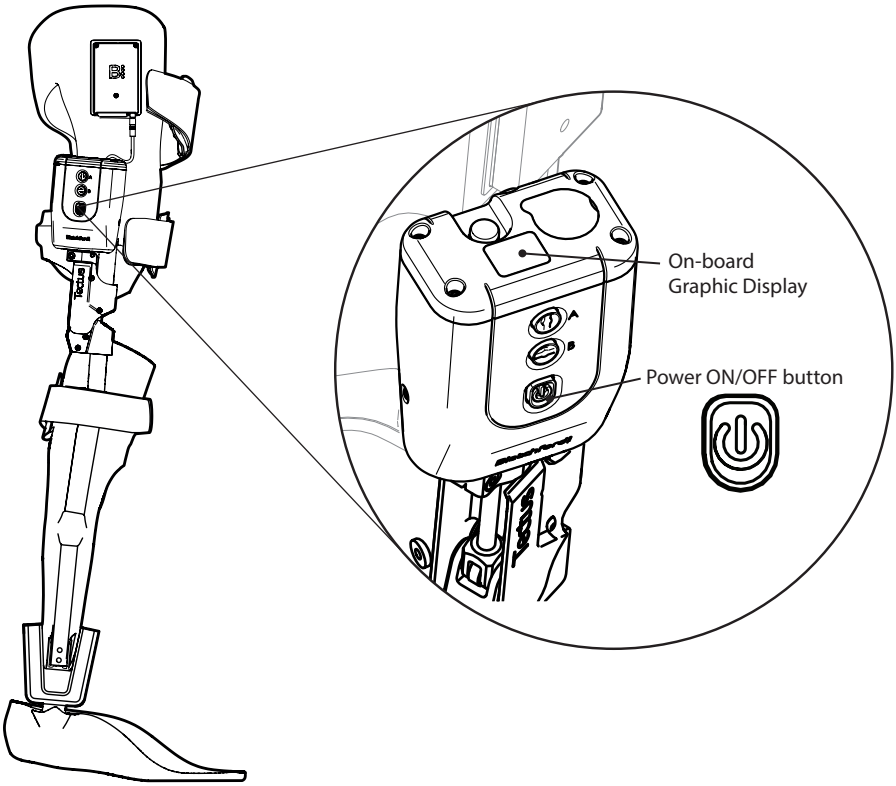
⚠ **Regularly check the limb on which the Tectus KAFO is worn for signs of skin irritation, tissue damage, pressure sores or discomfort and report any such signs to your practitioner.**

9 Turning the Device ON/OFF

The device is powered on or off via the Power ON/OFF switch on the device, there is no Power ON/OFF switch on the key fob.

Powering ON

To power on the device, press and hold the ON/OFF switch until LED illuminates green. Short beeps and vibrations will then occur during the start-up sequence; when they finish, then release.

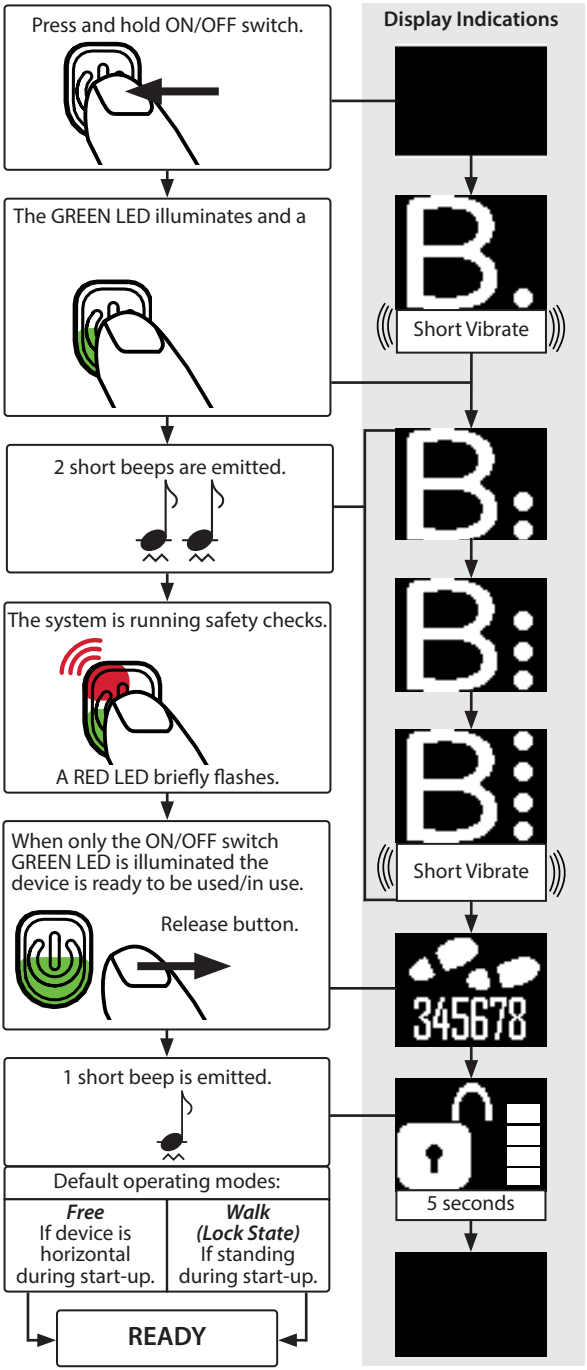


Powering OFF

To initiate the shut-down sequence, press and hold the ON/OFF switch until two short beeps with two short vibrations are emitted, then release.

Start-up Sequence

Powering ON initiates the automatic start-up sequence during which the LED and graphic display indications change, audible beeps sound and the device vibrates as shown. The sequence lasts for approximately 4 seconds.



⚠ **Do not use the device if the BLUE LED continues flashing during, and on completion of, the start-up sequence. This indicates the programming of the device has not been previously completed. Contact your practitioner before using the device.**

The device is powered ON and ready for use when the default ***Free/Walk*** mode (depending on device orientation during start-up) is displayed on the on-board graphic display, (see sequence shown on right).

Note… The display goes into sleep mode (display goes blank) after 5 seconds of inactivity but is reactivated after every user mode change initiated by either buttons A/B on the device, or buttons on the key fob.

10 Tectus Knee Module Operation

10.1 User Modes

The device has the following user-selectable operating modes:

- ***Walk***
- ***Sit***
- ***Stairs***
- ***Lock***
- ***Free***
- ***Silent***

The device may enter automatically the following modes:

- ***Critical Service***
- ***Safe***

The device has the following practitioner-only selectable operating mode:

- ***Training***

10.2 Safety While Switching Between User Modes

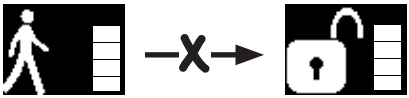
10.2.1 Default User Mode

The device after start-up, by default, switches to ***Free*** mode if the user is seated or ***Lock*** state of ***Walk*** mode if the user is standing. During start-up ***Free*** mode is only intended to be used for donning the device. Another mode (typically ***Walk*** mode) should be selected before standing after donning the device.

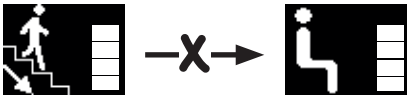
10.2.2 Safety Restrictions to User Mode Switching

The device will not allow switching to ***Free*** mode when the user is walking, descending stairs or standing with the knee locked. This is for safety reasons as the consequent sudden loss of support poses a considerable risk of falling. Therefore the following mode switching combinations will not be executed by the device:

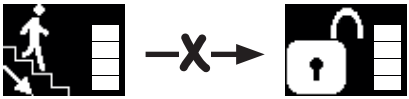
Walk mode to ***Free*** mode



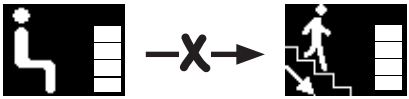
Stairs mode to ***Sit*** mode



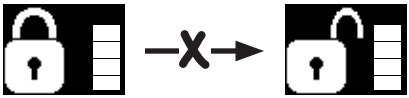
Stairs mode to ***Free*** mode



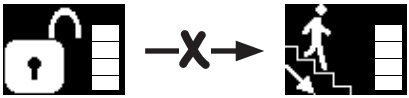
Sit mode to ***Stairs*** mode



Lock mode to ***Free*** mode



Free mode to ***Stairs*** mode

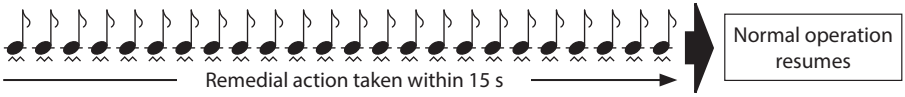


10.2.3 Device Over-Stress Warning

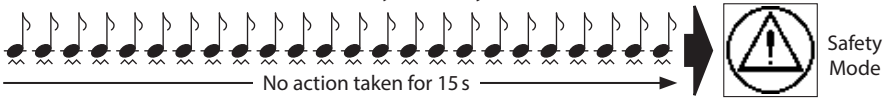
Very rarely, and under special circumstances, the device may emit a rapid beeping audio and vibration alarm, for up to 15 seconds. This indicates the device is over-stressed, through not being used as intended, or due to an internal fault.

When Stress Warning Occurs

If you take (or the device itself takes) successful remedial action to remove the over-stress condition before the end of the 15 seconds alarm period, then the alarms stop and the device resumes normal operation.



If you do not (or the device itself does not) take successful remedial action to remove the over-stress condition before the end of the 15 seconds alarm period, then the device interprets this as a fault situation and switches automatically to ***Safety*** mode.



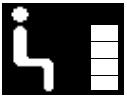
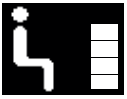
Occurrence and Avoidance of Over-stressing the Device

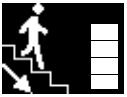
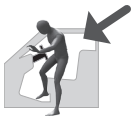
The following table summarizes the scenarios in which the device might be over-stressed and the possible remedial actions.

Alarm Occurrence	Reason	Remedial Action
During Mode Switching	You may have attempted to change between user modes when the previous activity had not been fully completed and the hydraulic system was not ready to adjust to the new settings.	Try to reduce the load on the device until it can execute the mode switching command. The rapid beeping should stop immediately to indicate that normal operation has been resumed. Always allow sufficient time for the device to respond to mode switching commands.
During Sitting Down	During the process of sitting down the device automatically switches to a lower resistance after about a 45° of movement. If you attempt to sit down too quickly and forcefully, it over-stresses the hydraulic system during mode switching.	Try to reduce the load on the device until it is able to switch to ***Free*** mode. Follow your practitioner's advice on the correct way and speed of sitting down while wearing the device.
In Case of a Malfunction	If the remedial action does not fix the problem within the 15 seconds alarm period at the end of this period, the device will assume there is a malfunction and revert to ***Safety*** mode and the critical service indicator will appear on the device screen.	Please refer to Section 5.1 ***Critical Service Indicator*** on how to deal with a malfunction and for the description of ***Safety*** mode

10.3 Activities and Associated User Modes

Activity	Mode Activated and Displayed	Function and Procedure Guidance
Walking 	***Walk*** 	Automatically provides support during stance and release during swing. Although not microprocessor controlled, knee extension assist is always active.
Standing 	***Walk***  ***Lock*** 	If you stand still while in ***Walk*** mode, you will be supported. From standing, the device will be alert to any movement, such as a forward or backward step and provide support accordingly. To provide appropriate support, using ***Lock*** mode is recommended when standing for an extended period of time (e.g., queueing) or in an environment where your balance can be compromised (e.g., standing in a crowd). Note… ***Lock*** mode is a fixed mode, and the device does not monitor for movement. ***Lock*** mode needs to be set and released manually.
Backstep 	***Walk*** 	If you step backwards or lean backwards while in Walk mode, the device goes into a locked state called Backstep. This gives you support while you rebalance. Note… ***Backstep*** is a state within ***Walk*** mode and is not the same as the user-selectable Lock mode. If ***Training*** mode is enabled, the device indicates it has gone into this ***Backstep*** state by emitting 1 long high-tone beep and 1 vibration. The device reverts to standing ***Lock*** state only after you have returned to and remained in the standing position for at least 2 seconds. If ***Training*** mode is enabled, this is indicated by the device emitting two beeps and vibrations.
Lock	***Lock*** 	Knee locked against flexion but free to extend until maximum extension is achieved. ***Lock*** mode will remain active until another mode is selected or until the mechanical override button is pressed.
Free	***Free*** 	The device provides minimal resistance in flexion and minimum amount extension assist resistance in extension. ***Free*** mode will remain active until another mode is selected. ⚠ **This mode does not provide sufficient support for standing.**

Activity	Mode Activated and Displayed	Function and Procedure Guidance
Stand-to-Sit 	***Sit*** 	Fixed resistance at knee to provide support while moving to seated position, the geometry of the module provides deep yield functionality. To sit, you must manually activate ***Sit*** mode via mode switching buttons on the device or on the key fob. Be aware of the surroundings before sitting down. Load both legs equally when sitting down. Bend forward at the waist, push buttocks rearward, place hands on armrests (if available) and bend the legs, sitting down in a smooth motion.
Sitting 	***Sit***  ***Free*** 	In ***Sit*** mode after 2 seconds of achieving a resting position the device automatically switches to ***Free*** mode to allow, if necessary, adjustment of limb position while sitting. Note… The device will start up in this ***Free*** mode when start-up is initiated while you are in a seated position. While in ***Sit*** mode the device will detect when you attempt to stand and locks against flexion as you rise, so you cannot sit back down again until either the leg is fully extended or the override button is pressed.
Sit-to-Walk 	***Sit*** 	When in ***Sit*** mode the device detects when you attempt to stand up and start walking and enters into ***Walk*** mode automatically. To stand up, the feet should be placed evenly, move the trunk forward and stand up with the support of your arms. Try to load weight through the orthosis and begin walking. ⚠ **If you do not complete the motion and attempt to sit back down again the device will lock against flexion.**
Stairs Ascent 	***Lock*** 	⚠ **For safety, switch manually to *Lock* mode before starting to ascend stairs.** ⚠ **Where possible, handrails must always be used.** When ***Lock*** mode is used the knee will not yield (although it can extend), so a "step-to" gait should be used leading with the sound limb going up stairs.

Activity	Mode Activated and Displayed	Function and Procedure Guidance
Stairs Descent 	***Stairs***  ***Lock*** 	⚠ **In *Stairs* mode, do not attempt to descend stairs using leg-over-leg gait until you have had adequate physiotherapy and completed supervised training signed off by your practitioner!** ⚠ **Always approach stairs with caution and be aware of your surroundings.** ⚠ **Where possible, handrails must always be used.** ⚠ **For stairs decent, either *Stairs* mode or *Lock* mode must be enabled before starting descent and once selected, you must not change it to another mode until the stairs decent is complete.** ***Stairs*** mode provides appropriate support for leg-over-leg descent with programmed flexion resistance combined with appropriate extension bias. Note… Place only the posterior half of the foot on the step then load orthosis and push it in to knee flexion, step down with the sound limb and allow knee flexion on the orthotic limb. When ***Lock*** mode is used the knee will not yield, it is locked in full extension, so a "step-to" gait should be used, leading with the locked fitted limb going down the stairs.
Entering Vehicle 	***Sit*** 	⚠ **Always approach vehicles with caution and be aware of your surroundings.** To sit into the vehicle, you should activate ***Sit*** mode. The device will enter ***Free State*** of ***Sit*** mode when the thigh is horizontal. (Not identical to ***Free*** mode.) This allows you to manoeuvre the limb into a comfortable and safe position. Note… If the thigh angle is not horizontal e.g., due to the angle of the vehicle seating surface, then the device will enter ***Sit-to-Stand State*** of ***Sit*** mode and can only be positioned by using the mechanical override button.
Exiting Vehicle 	***Sit*** 	Before exiting the vehicle make sure the device is in ***Sit*** mode so that when you exit the vehicle you are supported as you move from sitting to standing and is ready to switch automatically to ***Walk*** mode.

Activity	Mode Activated and Displayed	Function and Procedure Guidance
Driving 	***Free*** 	⚠ **You must not operate the device controls or key fob while driving.** ⚠ **Warnings in this document and any national guidance must be followed when considering driving while wearing a Tectus KAFO.** ⚠ **Only the unaffected leg may be used to operate controls of a car.** For driving, the device should be manually switched to ***Free*** mode via the key fob or the device buttons.
Safe Mode Critical Service		The device will revert into ***Safe*** mode every time a malfunction or critically low battery level is detected, or when the service mode warning period has expired. In ***Safe*** mode the device will switch to high yielding knee flexion resistance. See Section 5.1 *Critical Service Indicator* and Section 7.3.2 *Low Battery Behavior* for more details.
Training	***Training***	Note… Training mode can only be enabled through practitioner (clinician) level access to the app. In ***Training*** mode, aural and vibrational cues are provided to indicate when an operating state change within ***Walk*** mode has been made to help you learn how to use the device. For example, when you make the appropriate first step movement from stationary to activate ***Backwards Walk*** state, the device emits one long beep and vibrates to confirm ***Backwards Walk*** state has been selected. Similarly, if you stop walking to stand still, the device emits two short beeps and vibrates to confirm ***Lock*** state has been selected.

10.4 Operating Actions and Device Indications

Device and Key Fob Button Operation

The device is manually operated by pressing either buttons A and/or B on the device, or by pressing buttons on one of the key fobs. The button or button combination pressed, together with the hold duration (Short, Long or Very Long) of the press determines which operation is selected.

Note… Key fob buttons have only two options; Short or Long press.

To help the user distinguish between the three different press durations, for each press duration the device emits a corresponding unique pattern of beeps and vibrations, and displays a corresponding icon on the screen, as shown in the following table:

Name	Duration	Timing Beeps with Vibrations	On-screen Icon	Symbol Used in Document
Short Press	Max. 2 seconds			
Long Press	2-4 seconds			
Very Long Press	Longer than 4 seconds			

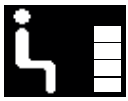
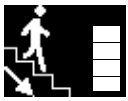
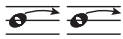
Device Indications

The device will acknowledge that the requested operation, e.g. change of mode, has been registered by the device by emitting audible and/or vibrational cues as shown in the following table:

Type of Indication		Symbol Used in Document	
		Short	**Long**
Audible (Beep)	**High Tone**		
	Medium Tone		
	Low Tone		
Vibration			
On Screen		See detailed description in Section 10.3, 10.5 and 10.6.	
ON/OFF Switch LED Light		See detailed description in Section 9.	

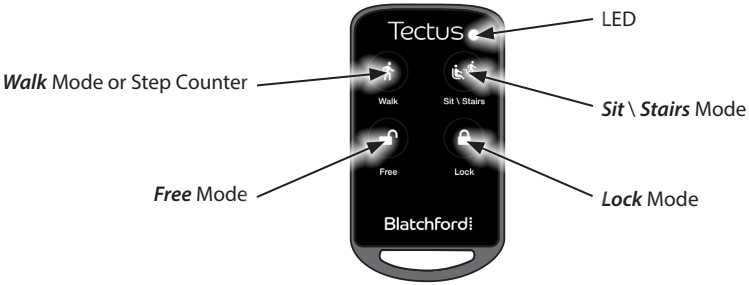
10.5 Mode Switching on the Device Using Tectus Module Buttons A and/or B

Once start-up routine has successfully completed, the device can be controlled with button combinations on the Tectus Knee Module or Key Fob.

Modes	Initiation (On Device)	Timing Aid		Device Response		
		On Screen	Beep & Vibrate	Beep Signal	Vibrate Signal	Displayed Symbol
Walk	Short Press button A 		1 	2×Low tone short 	2×Short	
Sit	Long Press button B 		1+2 	1×Medium tone short 	1×Short 	
Stairs	Short Press button B 		1 	2×Medium tone short 	2×Short 	
Free	Short Press button A&B 		1 	1×Medium tone long 	1×Long 	
Lock	Long Press button A 		1+2 	2×Medium tone long 	2×Long 	
Silent	Very Long Press button A 		1+2+3 	2×Medium tone short 	2×Short 	

Note… Do not press button B for more than 4 seconds or you may accidentally switch on ***Bluetooth®*** as indicated by the power button illuminating flashing blue and steady green and emitting three low tones and vibrations. This is not a user function and must be switched off. To do this, power off the device and power on again using the ON/OFF switch (see Section 9), or press button B for longer than 4 seconds.

10.6 Mode Switching on the Device Using The Key Fob



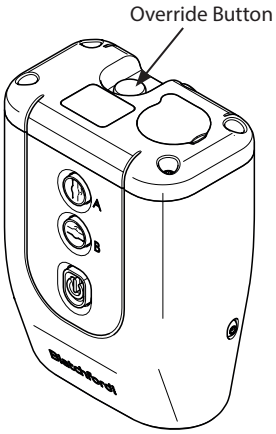
Modes	Initiation (On Fob)	Timing Aid		Device Response		
		On Screen	Beep & Vibrate	Beep Signal	Vibrate Signal	Displayed Symbol
Walk	Short Press Walk button	●	1	2×Low tone short	2×Short	
Sit	Short Press Sit \ Stairs Button	●	1	1×Med. tone short	1×Short	
Stairs	Long Press Sit \ Stairs Button	◎	1+2	2×Med. tone short	2×Short	
Free	Short Press Free button	●	1	1×Med. tone long	1×Long	
Lock	Short Press Lock button	●	1	2×Med. tone short	2×Short	

10.7 Additional Key Fob Functions

Modes	Initiation (On Fob)	Timing Aid		Device Response		
		On Screen	Beep & Vibrate	Beep Signal	Vibrate Signal	Displayed Symbol
Step Counter	Long Press Walk button	◎	1+2	-	-	345678
Connection Code	Long Press Lock Button	◎	1+2	-	-	3456

10.8 Mechanical Override Operation

The knee can be flexed in any mode by pressing the manual override button located on the top surface of the control module. The button must be pressed and held down fully until the desired knee flexion angle has been achieved.



⚠ **Do not use any object (e.g. screwdriver, pen) to press the override button.**

⚠ **This operation should only be used in exceptional circumstances (e.g. device malfunction, battery depletion).**

Once the manual override button is released the knee flexion reverts to the same resistance it had before the manual override button was pressed.

Note… The hydraulic module has been designed to always permit free leg extension.

⚠ **Be aware of finger trap hazard at all times when flexing the device.**

11 Transport and Storage

1. It is recommended to store the device upright with the device put into ***Lock*** mode before switching off.
2. If the Tectus KAFO is to be stored upright then secure the device to prevent it falling over.
3. If the device is shipped either on its own or built into a Tectus KAFO it should be put into ***Lock*** mode in an extended position and packaged in a suitable box to allow this.
4. If a device is to be returned, contact Blatchford prior to sending if any obvious physical damage has occurred to the battery pack.
5. For transport purposes the unit must be switched off, and packed securely so that
    a) it cannot be inadvertently switched on and become operative while in transit,
    b) the Tectus KAFO/device is thoroughly protected from damage in transit.

FCC Compliance Statement

This device complies with part 15 of the FCC Rules.

Operation is subject to the following two conditions:

1. This device may not cause harmful interference.
2. This device must accept any interference received, Including interference that may cause undesired operation.

Note… Contains pre-approved ***Bluetooth®*** module: FCC ID: QOQ-GM220P IC: BGM220PC22HNA2.

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

—Reorient or relocate the receiving antenna.

—Increase the separation between the equipment and receiver.

—Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.

—Consult the dealer or an experienced radio/ TV technician for help.

Any changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

Caution: Exposure to Radio Frequency Radiation. This device must not be co-located or operating in conjunction with any other antenna or transmitter.

Responsible party: Blatchford Inc.

1031 Byers Road, Miamisburg, OH 45342
800-548-3534 (toll free) | 937-291-3636
customerservice@blatchfordus.com

RSS Compliance Statement

This device complies with RSS 210 of Industry Canada.

Operation is subject to the following two conditions:

1. this device may not cause interference, and
2. this device must accept any interference, including interference that may cause undesired operation of this device.

L' utilisation de ce dispositif est autorisée seulement aux conditions suivantes:

1. il ne doit pas produire d'interference et
2. l' utilisateur du dispositif doit étre prêt à accepter toute interference radioélectrique reçu, même si celle-ci est susceptible de compromettre le fonctionnement du dispositif.

Caution: Exposure to Radio Frequency Radiation.

The installer of this radio equipment must ensure that the antenna is located or pointed such that it does not emit RF field in excess of Health Canada limits for the general population; consult Safety Code 6, obtainable from Health Canada's website Blatchford Inc. 1031 Byers Road, Miamisburg, OH 45342.

800-548-3534 (toll free) | 937-291-3636 customerservice@blatchfordus.com

Liability

The manufacturer recommends using the device only under the specified conditions and for the intended purposes. The device must be maintained according to the instructions for use supplied with the device. The manufacturer is not liable for any adverse outcome caused by any component combinations that were not authorized by them.

CE Conformity

This product meets the requirements of the European Regulation EU 2017/745 for medical devices. This product has been classified as a class I device according to the classification rules outlined in Annex VIII of the regulation. The EU declaration of conformity certificate is available at the following internet address: **www.blatchford.co.uk**

Medical Device

Single Patient – multiple use

Warranty

This device is warranted for 36 months.

A routine inspection of the device is required after 2 weeks, 3 months, 6 months, 12 months and 24 months.

The user should be aware that changes or modifications not expressly approved could void the warranty, operating licenses and exemptions.

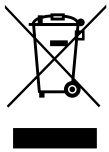
The above may vary by market; consult your local representative for details.

See the Blatchford website for the current full warranty statement.

Reporting of Serious Incidents

In the unlikely event of a serious incident occurring in relation to this device it should be reported to the manufacturer and your national competent authority.

Environmental Aspects



This symbol indicates that the product contains electrical/electronic components and/or batteries that should not be disposed of in general waste or be incinerated at the end of the product's life.

At the end of the product's life, all electrical/electronic components and/or batteries should be recycled or disposed of in accordance with the current regulations for the handling of WEEE (Waste Electrical and Electronic Equipment), or equivalent local regulations. The remainder of the product should also be recycled where possible in accordance with local waste recycling regulations.

To help prevent potential harm to the environment or to human health from uncontrolled waste disposal, Blatchford offers a take-back service. Please contact Customer Services for details.

Trademark Acknowledgements

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