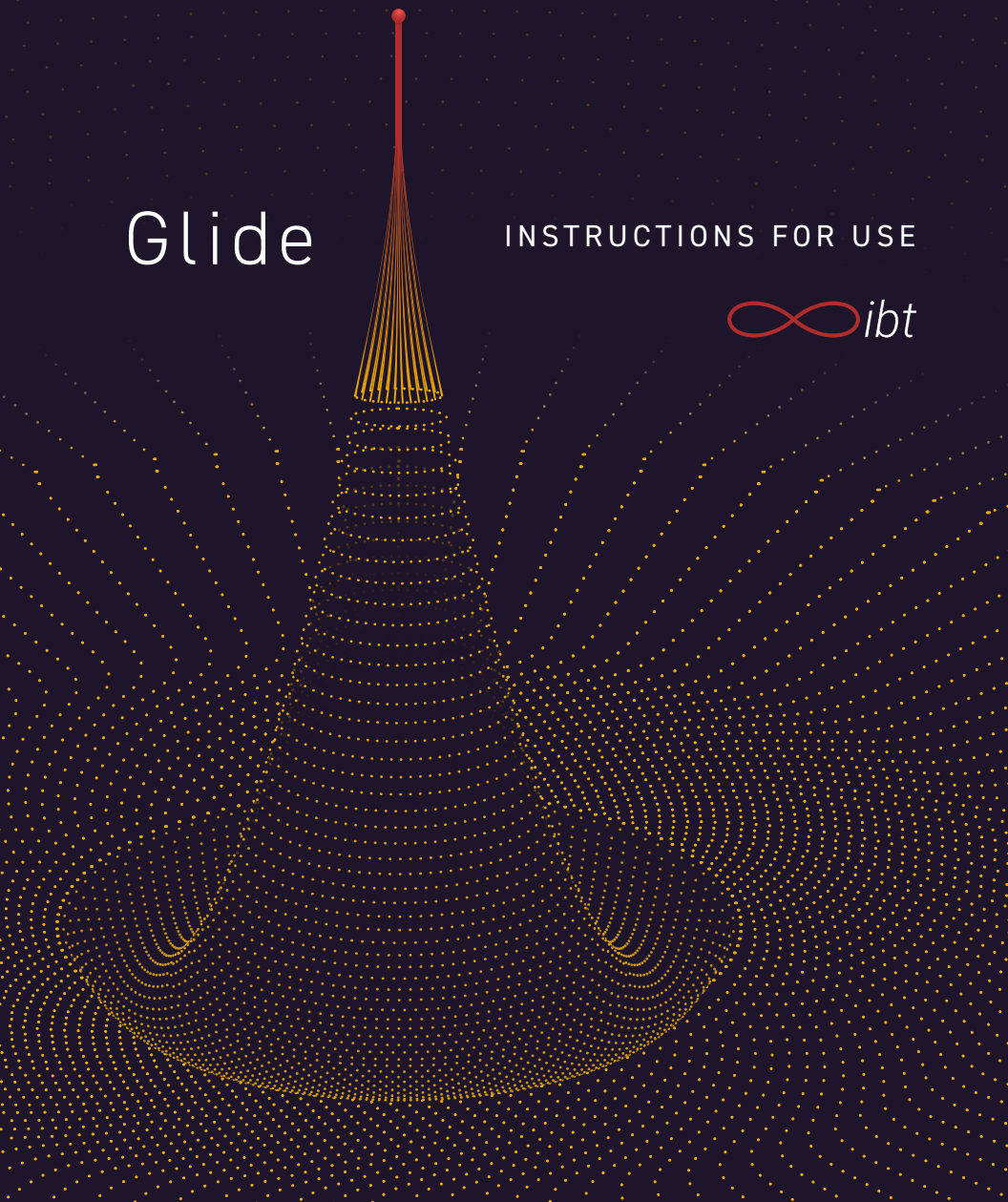
Glide

INSTRUCTIONS FOR USE

ibt



Z0000118rev3
Last Updated: 28th May, 2024

This document provides information for the prosthetist who will be installing Glide.

The Instructions for Use shall be in English and French for the intended operator.

Contains FCC ID: XDULE40-D2 Contains IC: 8456A-LE4D2

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www.i-biomed.com/support.html

FORMAT OF SAFETY INSTRUCTIONS

This heading describes the source and/or the type of hazard.

Subsequent text describes possible consequences in case of failure to observe the safety instructions.

Text in this section identifies actions or measures to be taken to avert the hazard.

SYMBOLS USED

Graphics	Title	Description	Standard Reference
MD	Medical	Indicates that the device is a medical device.	ISO 15223-1, Clause 5.7.7
	Consult instructions for use or consult electronic instructions for use	Indicates the need for the user to consult the instructions for use.	ISO 15223-1, Clause 5.4.3 ISO 7000-1641
	Keep dry	Indicates a medical device that needs to be protected from moisture.	ISO 15223-1, Cause 5.3.4 ISO 7000-0626
	Distributor	Indicates the entity distributing the medical device into the locale.	ISO 15223-1, Clause 5.1.9 ISO 7000-3724

Graphics	Title	Description	Standard Reference
	Importer	Indicates the entity importing the medical device into the locale.	ISO 15223-1, Clause 5.1.8 ISO 7000-3725
SN	Serial number	Indicates the manufacturer's serial number so that the medical device can be identified.	ISO 15223-1, Clause 5.1.7 ISO 7000-2498
	Translation	Indicates that the original medical device information has undergone a translation which supplements or replaces the original information.	ISO 15223 Clause 5.7.8 ISO 7000-3728
	Manufacturer	Indicates the medical device manufacturer.	ISO 15223-, Cuase 5.1.1 ISO 7000-3082
REF	Catalogue number	Indicates the manufacturer's Catalog number for the medical device information.	ISO 15223-1, Clause 5.1.6 ISO 7000-2493
#	Model number	Indicates the model number or type number of a product.	ISO 15223-1, Clause 5.1.10 ISO 7000-6050
Rx Only	Prescription Only	Labeling - Medical devices; prominence of required label statements.	21 CFR 801.15(c)(1)(i)f
		Labeling - Prescription devices.	21 CFR 801.109
	Caution	Indicates that caution is necessary when operating the device or control close to where the symbol is placed, or that the current situation needs operator awareness or operator action in order to avoid undesirable consequences.	ISO 15223-1, Clause 5.4.4 ISO 7000-0434A
	Non-ionizing electromagnetic radiation	Indicates generally elevated, potentially hazardous, levels of non-ionizing radiation, or to indicate equipment or systems.	ISO 60417 - 5140 IEC 60601-1; IEC 60601-1-2
	Type BF applied part	Indicates a type BF applied part complying with IEC 60601-1.	ISO 7000-5333 IEC 60601-1
WARNING Projectile Hazard	MR unsafe	Indicate that the medical device is MR Unsafe and should remain outside the MRI scanner room.	ASTM F2503
	Single patient Multiple use	Indicates this device may be used multiple times on a single patient.	ISO 15223-1, Clause 5.4.12 ISO 7000-3706
FC	Federal Communications Commission	Indicates this device is certified with the United States Federal Communications Comission.	21 CFR Part 15

Glide™ uses signals from surface electromyography electrodes and outputs movement commands for myoelectric control an upper limb prosthesis. Glide is compatible with most commercially available elbows, wrists, and terminal devices (see Page 8). Glide does not replace the normal functionality and control available within the other components in the prosthesis.

Glide is to be used in a home healthcare environment.

INTENDED USE

Glide is intended to detect, process, and transmit physiological signals for use with a prosthesis.

INDICATIONS FOR USE

Glide is to be used exclusively for exoprosthetic fittings of the upper limb.

CONDITIONS FOR USE / PATIENT TARGET GROUP

Glide is suitable for control of upper limb myoelectric prostheses. It is intended for use on one patient only, for users with unliteral or bilateral upper limb amputation or dysmelia.

Reuse of the product on another patient once fabricated into a prosthesis is not approved by the manufacturer. Installation of the system should be performed exclusively by a certified prosthetist or trained technician. Any unauthorized handling or installation of Glide could void its warranty.

Have any questions? We're happy to help. Call us or send us an email:

+1 (443) 451-7175
support@i-biomed.com

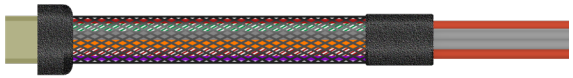
Table of Contents

1 Meet Glide

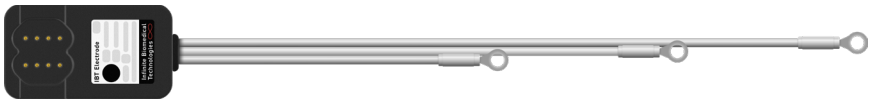
COMPONENTS

Core2 Controller (90010)

Output Cable (90020-XX)

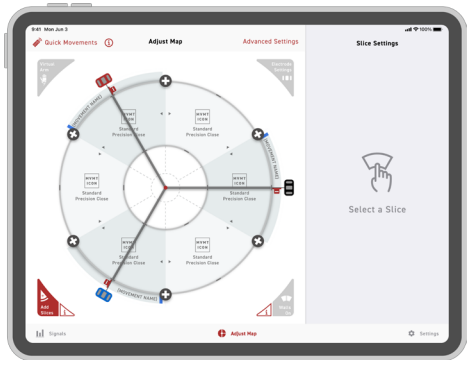


Up to 8 IBT Remote Dome Electrodes (90041-XX), where XX indicates the color code.
The IBT Remote Dome Electrodes are compatible with industry-standard domes.



Electrode Cables (90030-XXX), where XXX indicates the cable length.

Core2 Fabrication Kit (94001)



IBT Control Application

2 Specifications

DIMENSIONS AND WEIGHT

Core2 Controller, Box Only, LxWxH	59mm x 27.8mm x 9.8mm 10g
Remote Dome Electrode, Box Only, LxWxH	26.8mm x 14.8mm x 7.5mm 3.7g

TEMPERATURE & ENVIRONMENT

Temperature Range (Use, Transport, Storage)	-10°C - 60°C (14°F - 140°F)
Humidity Range (Use, Transport, Storage)	15% - 90%
Atmospheric Pressure Range	860 hPa - 1060 hPa

BLUETOOTH

Quality of Service	1 Mbps, GFSK
Frequency	2.4 GHz
Power	3 dBM
Operating Distance	500m LOS
Bluetooth	FCC, IC, CE, RoHS, and Bluetooth® 4.0 Certified ISM 2.4GHz module

MISCELLANEOUS

Input Voltage	7.4 - 16 VDC
Maximum Output Current	6A
Power Source	Glide receives power from the prosthesis
Expected Service Life	3 Years
Compatible Electrode	IBT Remote Dome Electrode (90041-XX)

DEVICES THAT HAVE BEEN TESTED FOR COMPATIBILITY WITH GLIDE

Glide shall be pre-configured for the selected devices at the time of order.

Terminal Devices (Direct Grip Control)

TASKA HandGen1, 2	i-Limb Quantum	COVVI Hand
TASKA CX	Zeus Hand	Ability Hand

Terminal Devices (Analog Inputs Only)

Basic Hand*	SensorHand Speed	i-Limb Access
Myo Kinisi	MyoHand VariPlus Speed	i-Limb Ultra
ProPlus ETD	System Electric Greifer	bebionic
ProPlus ETD2	Michelangelo Hand	
ProPlus Hand	AxonHook	

* Any terminal device with 5V analog inputs

Wrists

MC ProWrist (with a 4 or 6 band Coaxial Plug)	MC Standard Wrist (with a 4 or 6 band Coaxial Plug)
10S17 Electric Wrist	10S17 with MyoRotronic
AxonRotation	

Elbows

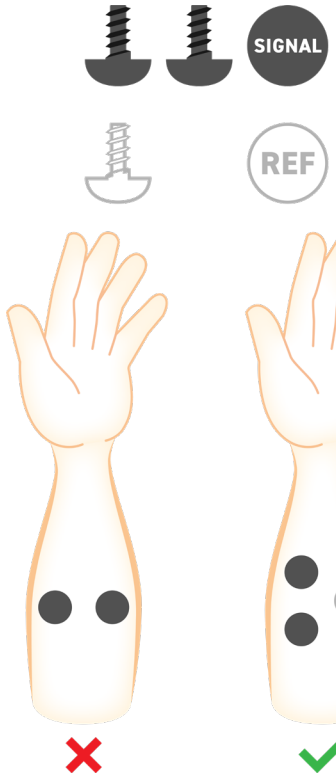
Motion E2	U3+	
Espire Classic Plus	Espire Hybrid	Espire Pro
DynamicArm	DynamicArm Plus	ErgoArm Hybrid Plus
ErgoArm Electronic Plus	AxonArm Ergo	
Motion Arm Hybrid Manual Lock	Motion Arm Hybrid Electric Lock	

3 Installation

BEFORE YOU BEGIN

What's Inside

1. Core2 Controller
2. Cables
3. Up to 8 IBT Remote Dome Electrodes
4. Core2 Fabrication Kit
5. Documentation
6. Optional Add-Ons:
   - Dome Fabrication Kit



INCORPORATING IBT ELECTRODES INTO THE SOCKET

Selecting Ideal Electrode Dome Sites

Select electrode dome sites in a similar manner to direct control, aiming to find independently activated muscle groups. Use the Signals page on the IBT Control Application to view contraction strengths of the signal at each site.

Figure: Ideal electrode dome orientation when placed on the limb, along the longitudinal axis of the muscle fibers.

Incorrect electrode dome placement

Incorrect placement of electrode domes can cause degraded signals and prosthesis malfunction leading to user frustration.

Please ensure that electrode domes are placed and connected as recommended in Section 3 above.

Ideal muscle locations:

- Do not have to be completely independent of one another.
- Should be active with medium strength contractions as indicated by the patient.
- Should not be placed on boney prominences, on sensitive tissue, outside the socket trimlines, or in areas that will not stay in contact with the socket.

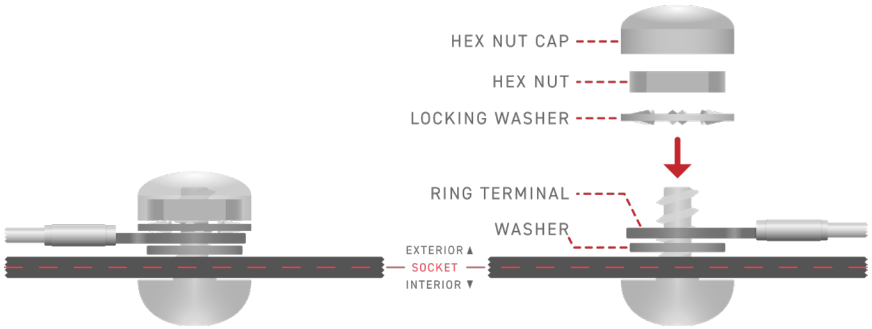
Skin irritation from prosthesis use

Placing the electrode domes on irritated skin can led to user injury.

» Check for skin irritation and pressure sores after removing prosthesis.
» Discontinue use if skin irritation is present.

Assembly of domes in inner socket

Electrode dome assembly will depend on the chosen industry standard dome. By default, follow the instructions in the figure below to assemble the dome components. If using the Steeper domes, apply the locking washers and hex nut caps from the provided kit to complete the assembly. If using the Coapt ControlSeal™ domes, follow the instructions provided with the packaging.

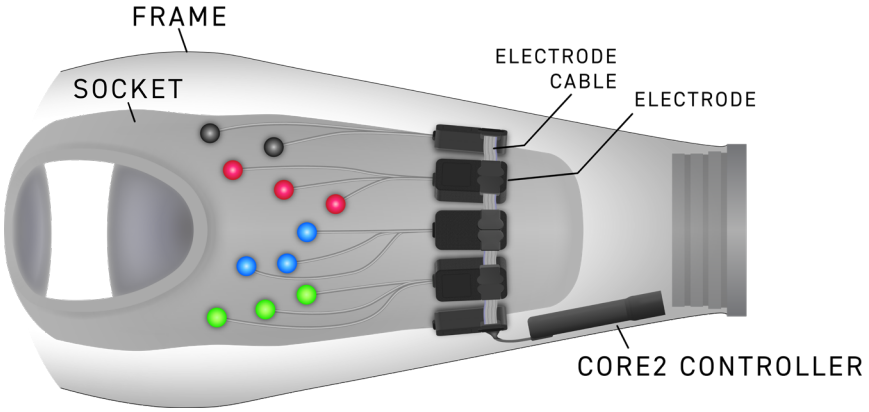


Insufficient trimming of electrode studs

Sharp edges and protrusions can damage other components inside the prosthesis as well as the socket materials.

Ensure that all dome posts are sufficiently shortened, smoothed, and have caps installed.

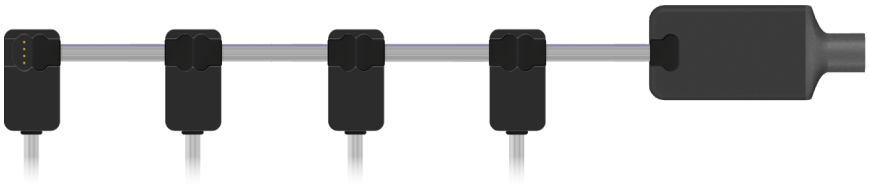
Final prosthesis assembly



For more information on fabrication and assembly of Glide, see the Core2 Fabrication Guide.

INSTALLING GLIDE INTO THE PROSTHESIS

Connect the Core2 Controller to the first electrode as shown below. Continue connecting the remaining Electrode Cables to electrodes in this manner, forming a chain.



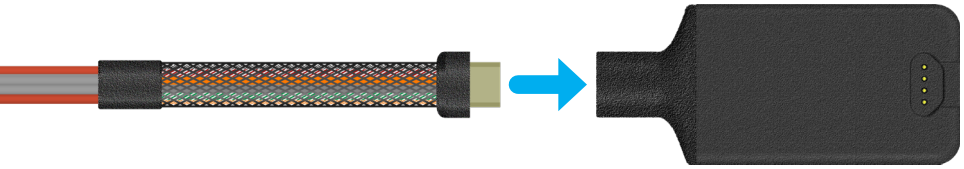
Disconnection of electrode cable

Any connection interruption between an electrode or the Core2 Controller can cause prosthesis malfunction.

All Electrode Cables in the system should be securely connected.

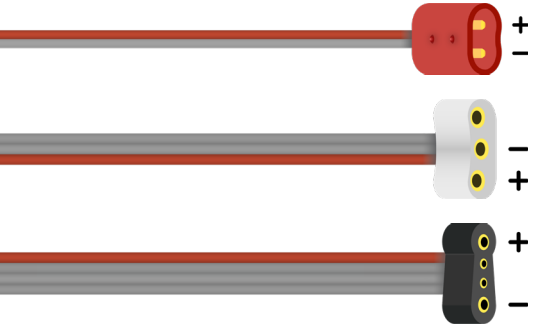
Connecting to the terminal device, wrist, and elbow

Plug the Output Cable into the Core2 Controller



Refer to the Core2 Connections Guide for connecting to prosthetic devices. For assistance, contact IBT.

Powering the Core2 Controller



Please refer to the prosthesis powering battery's instructions for use for battery related information.

Changing the terminal device while powered on

Failure to power off the prosthesis may cause damage to the device and cause malfunctions or unintended prosthesis movement, resulting in minor user injury.

Turn off power to the prosthesis before removing or attaching terminal devices.

Connecting an active power source to device incorrectly

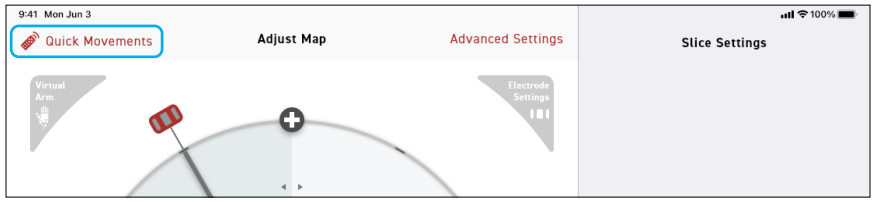
Incorrect connection could cause permanent damage to the prosthesis and Glide.

» Connect the Output Cable only as specified.
» Ensure the prosthesis is OFF before plugging in any cables.

4 Testing Glide

Please test Glide before fitting the patient with the prosthesis. Connect all the prosthesis components and Glide. Connect to the IBT Control Application and navigate to the Signals page.

- Signals should be flat at rest.
- Tapping the electrode domes should create a peak on each signal.
- Use the "Quick Movements" menu to confirm the prosthesis components are connected correctly.



Core2 Controller LED Statuses

Color	Condition	Resolution
Blue, Blinking	Normal Operation	All is well.
Magenta	Electrode Communication Error	Check cable connections between electrodes and controller.
Yellow	Digital terminal device unresponsive	Check cable connections between controller and terminal device.
Red	Core2 Controller Overheated	Power off the prosthesis and let device cool. Remove the prosthesis from sunlight or heat source if applicable.
Green, Blinking	Core2 Controller Recovery Mode	Power off then on the prosthesis. If this occurs repeatedly, contact IBT.
Green, Solid	Core2 Controller Boot Mode	Controller is beginning operations.

5 Glide Software

MINIMUM SYSTEM REQUIREMENTS

Apple iPads that support iPadOS 15 or newer.

SOFTWARE SETUP

Download the IBT Control Application from the App Store. If you are unable to install the IBT Control Application, contact IBT for assistance.

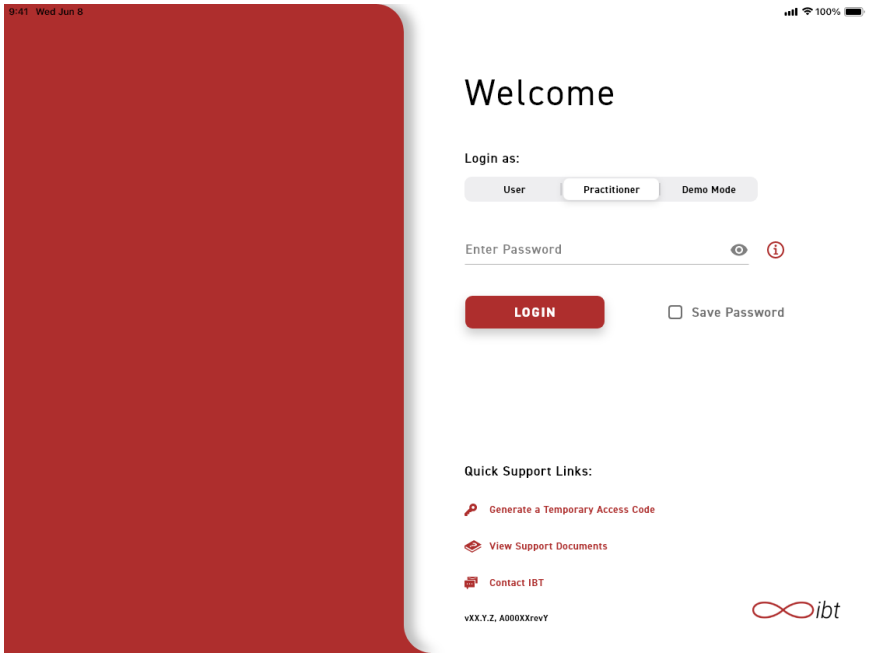
Launch the IBT Control Application by tapping on the icon named "IBT Control".

Not reading information buttons

Failure to read and follow all content in ⓘ buttons throughout the IBT Control Application could result in injury or damage to Glide and/or the prosthesis due to inappropriate use.

Please read all of the content in the ⓘ buttons before using a feature in the IBT Control Application.

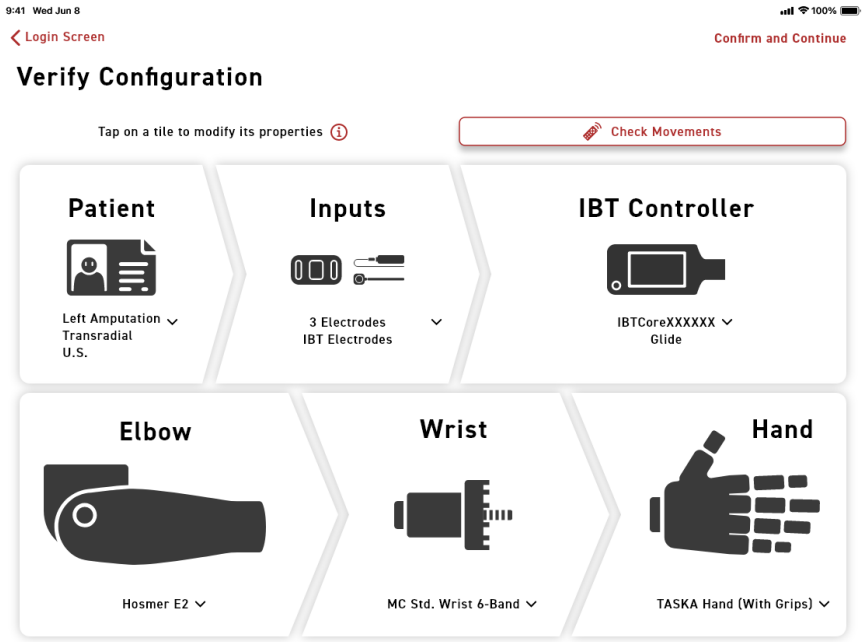
Connecting the Core2 Controller to the IBT Control Application



Under "Login as:", tap Practitioner and enter the password (provided separately) to use practitioner access.

Note: Practitioner accounts have access to several features that will not be enabled for patient accounts, who will login as User. User login does not require a password. The app will be in "View Only" mode for the patient unless unlocked for remote support by the practitioner.

Verify Correct Configuration



Use “Check Movements” to test the prosthesis connections and components.

Under the ‘Patient’ section, select the ‘US’ or ‘EU’ patient region depending on where the user will use their prosthesis.

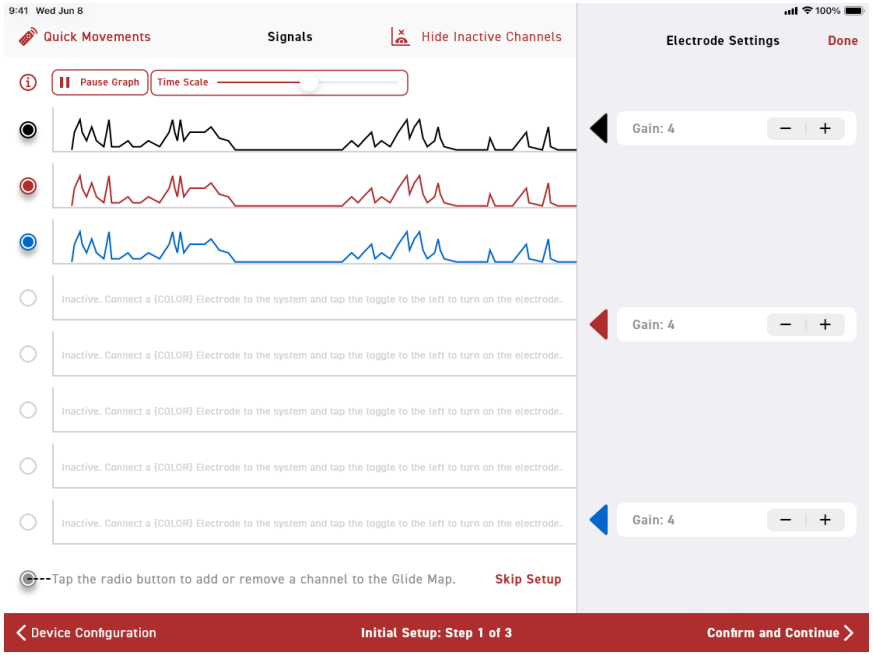
Tap “Confirm and Continue” to proceed.

Setup Glide

If Glide is being used for the first time, the IBT Control Application will commence the Glide Initial Setup.

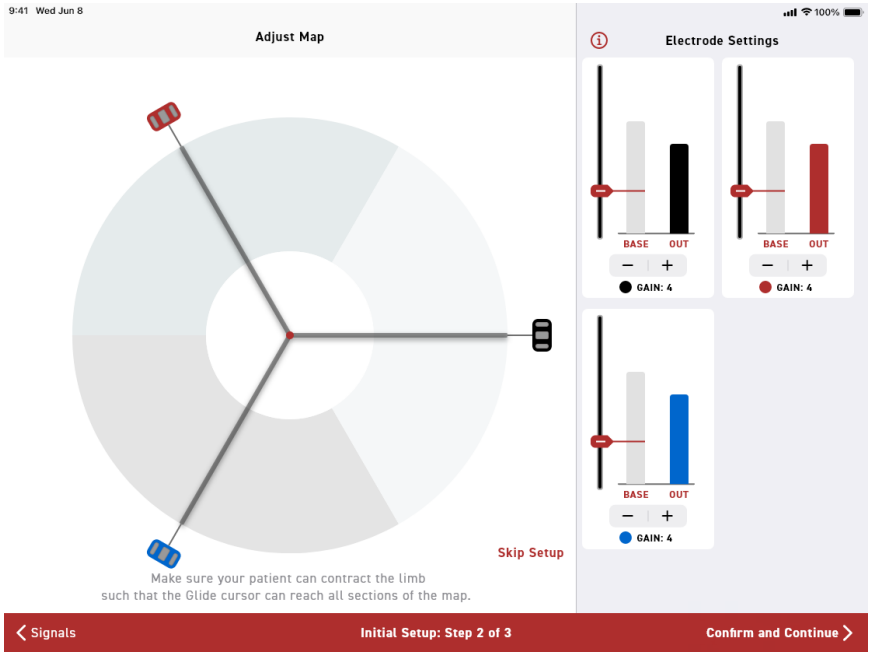
Step 1: Check Signals

Confirm that the correct color and number of electrodes are selected. Have the user contract each muscle site to confirm contact and muscle activation. Turn off disconnected or unused electrodes by tapping the circle buttons.



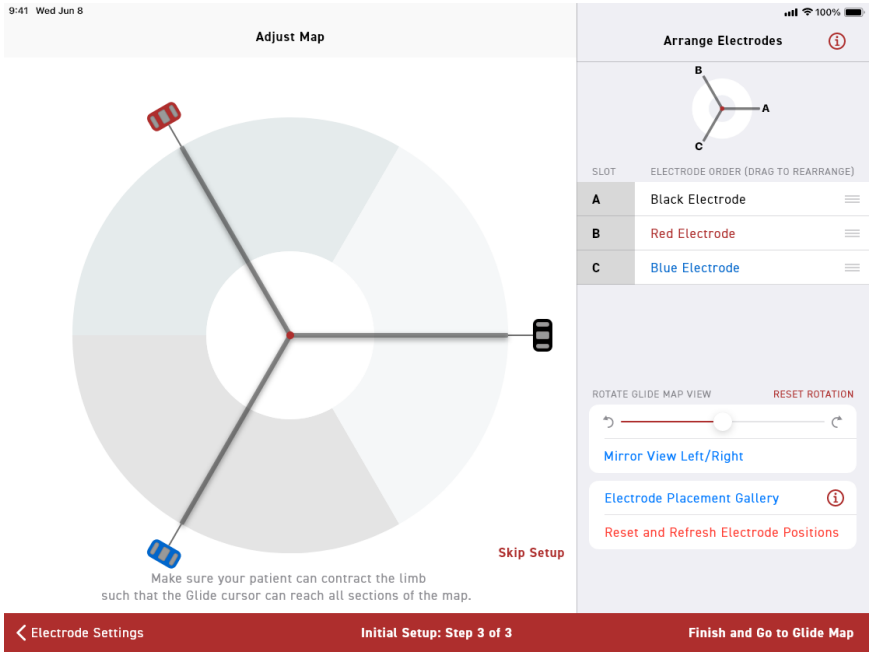
When the signals appear satisfactory, tap Confirm and Continue on the bottom.

Step 2: Adjust electrode gains and thresholds

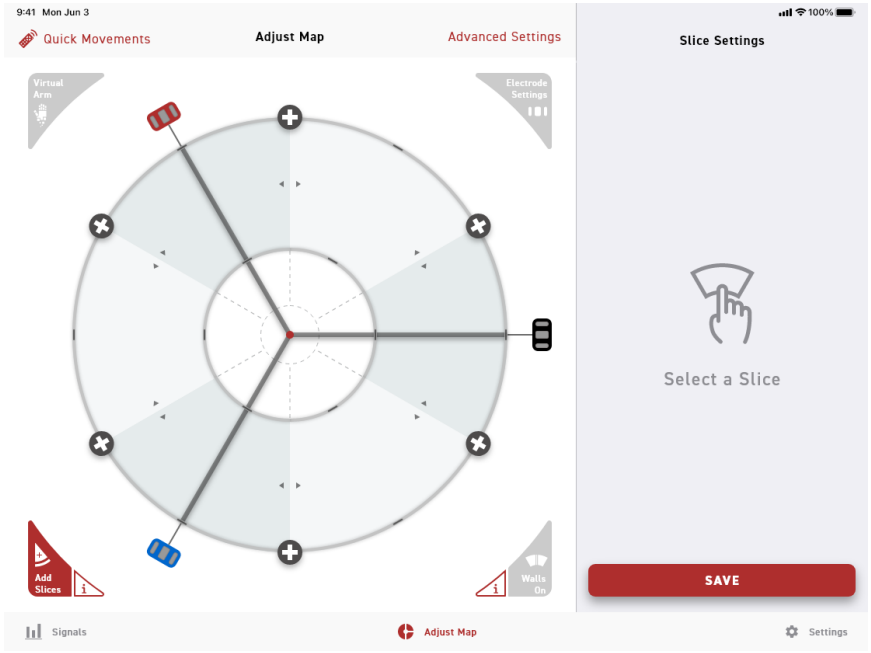


Adjust each gain and threshold to isolate the signals in the various sectors of the Glide map.

Step 3: Arrange Electrodes



Drag the ☰ to arrange the electrodes within the Glide Map to match the sequence of colors of the physical electrodes on the residual limb. The Glide Map should represent a cross section of the limb, with antagonist muscle activation on opposite sides of the map.



Once Initial Setup has finished, the Glide Map can be freely changed. After adding movements, try adjusting the slice borders and adding secondary actions. Turn on walls to prevent accidental movements.

Inadequate patient training

Failure to train the patient may lead to injury or damage to Glide and/or the prosthesis during use.

The patient must be instructed in the operation of Glide and must first use the device in the presence of a trained practitioner.

6 Maintaining Glide

PREVENTATIVE INSPECTION

All Glide systems undergo extensive quality assurance inspections prior to shipping. No additional inspection is required or advised.

MAINTENANCE

Cleaning Electrode Domes

Please follow the electrode dome cleaning instructions provided by the manufacturer.

Exposure to excessive liquids, moisture, vibration, dust, or impact

Exposure to these environments so may cause injury due to device malfunction and unintended prosthesis movement or faulty control.

» Do not expose Glide to excessive liquid, moisture, vibration, dust, or impact. User should not submerge their prosthesis or expose their prothesis to wet environments.
» Ensure connectors are free of debris and material before connecting components.

IBT Electrode Replacements

IBT Electrodes can be easily replaced if they are damaged or stop working. If you need to replace the electrodes, simply unplug the electrode and follow the instructions in Section 3 to reform the electrode chain. For any abnormal issues, discontinue use and contact IBT for support.

DISPOSAL

Do not throw away Glide components with common household waste. Dispose them by either returning the unit to IBT or taking the unit to an official electronics disposal site.

REPAIRS, RETURNS, AND WARRANTY

Please contact IBT at support@i-biomed.com regarding repairs and returns. Glide come with a 1-year manufacturer's defect warranty. Details of the warranty are enclosed separately.

7 Safety and Warnings

Not following safety instructions

Failure to read and follow all safety instructions could result in injury or damage to Glide and/or the prosthesis due to inappropriate use.

Please read all of the included safety literature before operating Glide.

Operating a motor vehicle

Unintended prosthesis movement may lead to serious injury or death.

Please do not use Glide to operate a motor vehicle.

Operating a firearm

Unintended prosthesis movement may lead to accidental or negligent discharge, and as a result, serious injury or death.

Please do not use Glide to handle firearms.

Use near medical devices critical for safety

Life-sustaining medical devices (e.g. pacemakers, defibrillators, other certain implantable devices, heart-lung machines, etc.) may experience Electromagnetic Interference (EMI) by being in proximity of Glide and malfunction.

Follow all operating conditions (including minimum distances) for both the life-sustaining medical devices and Glide and verify with a medical professional.

Operating machinery including, but not only, industrial machines, heavy equipment, motor-driven equipment, power tools, and sharp objects

Unintended prosthesis movement may result in serious injury or death.

» Do not use Glide to operate machinery.
» Do not use Glide to handle sharp objects such as knives or blades.

Unauthorized modification or disassembly of Glide

Unauthorized modification may cause injury due to device damage and malfunction. A risk of increased emissions or decreased immunity may result if any additional cables are attached. Changes or modifications not expressly approved by Infinite Biomedical Technologies, LLC could also void the user's warranty as well as authority to operate the equipment.

» Do not perform any disassembly procedures or modifications.
» Please contact IBT regarding any repairs and returns.

Use of the product for unusual activities and safety-critical tasks

The Glide system must not be used for unusual activities such as, sports with excessive strain and/or shocks to the wrist unit (pushups, downhill mountain biking) or extreme sports (free climbing, paragliding, etc.). Serious injury or death may result in any of these scenarios due to unintended prosthesis movement.

» Do not use Glide for unusual activities.
» Do not use Glide for safety-critical tasks.

Use of the product in proximity of a high electromagnetic emitting source or a source with untested emission characteristics

Exposure to a high electromagnetic emitting source or a source with untested emission characteristics may result in device malfunction and user frustration.

Do not use Glide in such surroundings.

Proximity to sources of strong magnetic or electrical such RF Emitters like X-ray, Metal Detectors, Electrosurgical Equipment, Diathermy Equipment, 5G Cellular, NFC, WPT, or Electronic Article Surveillance (EAS) devices

Glide may face interference in internal data communication which may cause unexpected behavior and result in user frustration.

» Avoid being in proximity of devices that emit strong magnetic or electrical fields.
» If proximity to these fields is unavoidable, watch for unexpected behavior of Glide. Do not stack Glide with other electronic devices during operation.
» Glide requires special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in these accompanying documents.

Exposure to extreme mechanical forces

Exposure may cause permanent damage to the device and cause malfunctions or unintended prosthesis movement, resulting in minor user injury.

» Do not drop, smash, or crush Glide components.
» Do not use excessive force or impact when installing or removing Glide components.
» If damage is suspected, inspect all of the Glide components and either replace components or have them repaired by IBT.

Long-term damage, wear and tear

Injury may occur due to faulty control or device malfunction.

» Ensure that all connections are tight and secure.
» Inspect all components for visible damage (e.g. cracks, broken pieces) before each use.
» If damage or malfunction is suspected, contact IBT.

Use of the product in hazardous workplaces and environments

Minor injury may result due to damage to Glide in hazardous workplaces resulting in device malfunction and unintended prosthesis movement.

» Do not use Glide near or directly over an open flame, or it may exceed safe temperature limits.
» Do not expose Core2 to excessive amounts of corrosive substances, such as salt water or sweat.
» Do not use harsh corrosive chemicals such as acetone, bleach, kitchen cleaners, etc. to clean the electrode domes.
» Switch off Glide before working in hazardous workplaces.

Insufficient skin contact of electrode domes

Injury may occur due to faulty control or device malfunction.

Ensure that the socket fits the residual limb well.

Use of inappropriate or incompatible components

Use of incompatible components may cause damage to the device, increase electromagnetic and RF emissions or decrease electromagnetic and RF immunity of Glide, and cause malfunctions or unintended prosthesis movement, resulting in minor user injury.

Use only prosthetic parts and accessories recommended by the manufacturer.

Use of damaged electrodes and domes

Injury may occur due to faulty control or device malfunction.

Replace the electrode or domes by following instructions in Section 3.

Exposure to temperature outside allowable range

Temperatures outside of the ranges specified in Section 2 may cause damage to the system and result in unintended prosthesis movement and minor injury.

» Do not expose prosthesis to temperatures outside the recommended range.
» Remove the prosthesis if it begins to feel hot.

Insufficient space for electrode domes because the distance between them is too small

Injury may occur due to unexpected prosthesis behavior.

Ensure that electrode domes do not contact each other by using appropriate dome size and spacing, or reducing the number of electrode domes in the prosthesis if necessary.

Use of the product in areas prone to electrostatic discharge

Repeat exposure to electrostatic discharge may damage Glide, resulting in device malfunction and user frustration.

Do not use Glide in an environment prone to building up static electricity.

Unrecognizable electrode input data due to muscle fatigue

Injury may occur due to faulty control or device malfunction.

If any part of your limb is tired, take a break from using the prosthesis.

Incorrect system requirements for the IBT Control Application

Faulty control or device malfunction may result.

Ensure your device meets the system requirements described in Section 5 before installation.

Use of non-biocompatible electrode domes

Skin rash or irritation may result.

Use industry standard domes.

Improper battery connection

Improper wiring, reversed polarity connection, and/or installation of an unsuitable battery may cause device malfunction or permanent damage to Glide, leading to minor injury.

» Closely follow the device connections guide during installation.
» Ensure that the battery meets all component manufacturer's requirements for input voltage.

Use of heat guns during fabrication

Excessive heat may damage Glide, leading to device malfunction and minor injury to the user.

» Do not use a heat gun or other heating devices in close proximity to Glide and its components.
» Use provided dummies during fabrication.

Compression of cabling

Compression of cabling may cause damage to the cable jacketing, leading to device malfunction, and may result in minor user injury.

Follow the instructions in the fabrication guide.

Use of sharp objects or tools during fabrication

Lack of caution may lead to accidental incisions, piercings or severing of Glide components, resulting in device malfunction and minor injury to the user.

Use caution when using sharp objects or tools during fabrication.

Use of the prosthesis while charging

Do not use the prosthesis while it is charging.

Use of an electrically conductive material for the socket

Carbon fiber laminate (and similar materials) may cause electrode signal interference when in contact with the electrode dome posts. This can result in minor injury due to device malfunction and unintended prosthesis movement.

Ensure that the electrode dome posts and associated wiring are electrically isolated from the socket material.

Use of a duplicate color electrode

System will malfunction if any two (or more) electrodes of the same color are connected. This can result in minor injury due to device malfunction and unintended prosthesis movement.

All connected electrodes should be of a distinct color.

Use near Portable RF communications equipment (Including peripherals such as antenna cables and external antennas)

Use of RF equipment can lead to degradation of the performance of Glide and cause malfunctions or unintended prosthesis movement, resulting in user frustration.

Do not use RF equipment within 30 cm (12 inches) of any part of Glide.

8 Regulatory Info

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, and (2) this device must accept any interference received, including interference that may cause undesired operation.

This device complies with Industry Canada license-exempt RSS standard(s). 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 the device. (Continued on next page).

Le présent appareil est conforme aux CNR d'Industrie Canada applicables aux appareils radio exempts de licence. L'exploitation est autorisée aux deux conditions suivantes : (1) l'appareil ne doit pas produire de brouillage, et (2) l'utilisateur de l'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement.

This product has been tested and verified to ensure that there are no issues or concerns regarding reciprocal interference. This includes EMI, EMC and RF.

This product has been certified and tested by 3rd party testing facilities to the following standards:

IEC 60601-1, 3rd Edition
IEC 60601-1-2, 3rd and 4th Edition
IEC 60601-1-11, 1st Edition
IEC 61000: See next page

Also compliant as per CISPR 11:2015

Guidance and Manufacturer's Declaration - Electromagnetic Emissions		
Glide is intended for use in the electromagnetic environment specified below. The customer or the user of Glide should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic Environment - Guidance**
RF Emissions CISPR 11	Group 1	Glide uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class B	Glide is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic Emissions IEC 61000-3-2	Class A	
Voltage Fluctuations IEC 61000-3-3	Complies	

Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
Glide is intended for use in the electromagnetic environment specified below. The customer or the user of Glide should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment - Guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 15 kV air	±8 kV contact ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines	± 2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% U_T; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315° 0% U_T; 1 cycle and 70% U_T; 25/30 cycles Single phase: at 0° 0% U_T; 250/300 cycles	0% U_T; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315° 0% U_T; 1 cycle and 70% U_T; 25/30 cycles Single phase: at 0° 0% U_T; 250/300 cycles	Mains power quality should be that of a typical commercial or hospital environment. If the user of Glide requires continued operation during power mains interruptions, it is recommended that Glide be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: U_T is the A.C. mains voltage prior to application of the test level.			

Guidance and Manufacturer's Declaration - Electromagnetic Immunity

Glide is intended for use in the electromagnetic environment specified below. The customer or the user of Glide should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance level	Electromagnetic Environment - Guidance
Conducted RF IEC 61000-4-6	3 Vrms 0,15 MHz - 80 MHz 6 Vrms in ISM and amateur radio bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz	3 Vrms 0,15 MHz - 80 MHz 6 Vrms in ISM and amateur radio bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz	Portable and mobile RF communications equip-ment should be used no closer to any part of Glide System, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d=\left[\frac{0.35}{10}\right]\sqrt{P}$ 80 MHz to 800 MHz $d=\left[\frac{7}{10}\right]\sqrt{P}$ 800 MHz to 2,7 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m).
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2,7 Ghz	10 V/m 80 MHz to 2,7 Ghz	Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey [a] Should be less than the compliance level in each frequency range. [b] Interference may occur in the vicinity of equipment marked with the following symbol:

NOTE 1: At 80 MHz and 800 MHz, 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.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which Glide is used exceeds the applicable RF compliance level above, the Glide should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating Glide.

Guidance and Manufacturer's Declaration - Electromagnetic Immunity

Glide is intended for use in the electromagnetic environment specified below. The customer or the user of Glide should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level			Compliance Level			Electromagnetic Environment - Guidance
	MHz	Modulation	Field Strength	MHz	Modulation	Field Strength	Portable and mobile RF communications equip-ment should be used no closer to any part of Glide System, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $E=\left[\frac{6}{d}\right]\sqrt{P}$ $d=\left[\frac{6}{E}\right]\sqrt{P}$ where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manu-facturer, d is the recommended separation distance in meters (m), and E is the field strength in V/m. Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol:
Immunity to proximity fields from RF wireless commu-nications equipment	385	18 Hz	27 V/m	385	18 Hz	27 V/m	
	450	18 Hz	28 V/m	450	18 Hz	28 V/m	
	710	217 Hz	9 V/m	710	217 Hz	9 V/m	
	745	217 Hz	9 V/m	745	217 Hz	9 V/m	
	780	217 Hz	9 V/m	780	217 Hz	9 V/m	
	810	18 Hz	28 V/m	810	18 Hz	28 V/m	
	870	18 Hz	28 V/m	870	18 Hz	28 V/m	
	930	18 Hz	28 V/m	930	18 Hz	28 V/m	
	1720	217 Hz	28 V/m	1720	217 Hz	28 V/m	
	1845	217 Hz	28 V/m	1845	217 Hz	28 V/m	
	1970	217 Hz	28 V/m	1970	217 Hz	28 V/m	
	2450	217 Hz	28 V/m	2450	217 Hz	28 V/m	
	5240	217 Hz	9 V/m	5240	217 Hz	9 V/m	
	5500	217 Hz	9 V/m	5500	217 Hz	9 V/m	
	5785	217 Hz	9 V/m	5785	217 Hz	9 V/m	
	0.1342	2.1 kHz	65 A/m	0.1342	2.1 kHz	65 A/m	
	13.56	50 kHz	7.5 A/m	13.56	50 kHz	7.5 A/m	
	0.030	CW	8 A/m	0.030	CW	8 A/m	

NOTE: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Recommended separation distances between portable and mobile RF communications equipment as well as RF wireless communications equipment and Glide				
Glide is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of Glide can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and Glide 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			
	80 kHz to 800 MHz $d=\left[\frac{3.5}{10}\right]\sqrt{P}$	800 MHz to 2.7 GHz $d=\left[\frac{7}{10}\right]\sqrt{P}$	710, 745, 780, 5240, 5500, 5785 MHz $d=\left[\frac{6}{9}\right]\sqrt{P}$	385, 450, 810, 870, 930, 1720, 1845, 1970, 2450 Mhz $d=\left[\frac{6}{28}\right]\sqrt{P}$
0,01	0,035	0,070	0,067	0,021
0,1	0,110	0,221	0,211	0,070
1	0,350	0,700	0,667	0,214
10	1,107	2,213	2,108	0,700
100	3,500	7,000	6,670	2,143
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (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.				

9 MR Safety Information

MR UNSAFE

Glide is MR unsafe.
This device presents a projectile hazard.

This person carries Glide.
Do not enter an MRI scanner room or an MR system.
Doing so may result in serious injury.

www.i-biomed.com/support.html
+1 (443) 451-7175

Use of the product in proximity to an MR system

Device may malfunction and user can be injured if the system is used in proximity of an MR system.

» Do not use Glide near an MR system (e.g., MRI system)

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