Steeper Configuration Device
Technical Manual

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Creating life's turning points, together

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Contents

To be used in conjunction with STPPR102 Steeper Configuration Device - Myo Kinisi Programming Guide.

Box Contents

- Steeper Configuration Device
- Male Power Supply Cable
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- Technical Manual
- Programming Guide for the Myo Kinisi

Product Information

The Steeper Configuration Device is a programming hub, designed for programming compatible Steeper myoelectric components. Used in combination with the Myo Kinisi hand; this device allows a clinician to customise the standard hand settings to fit each individual patient, features such as Auto-Grip can be enabled/disabled, the control strategy changed and thresholds or maximum speeds adjusted.

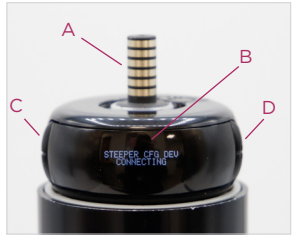
The Steeper Configuration Device is compatible with EQD and Short Wrist options, with supplementary cables provided to allow for short wrist connections.

The Configuration Device is an Accessory for a Class I Medical Devices which meet the general safety and performance requirements in MDR 2017/745 Annex I.

Features

- Offers 13 adjustable parameters to the terminal device
- Selection of control modes, using a variety of industry standard inputs
- Real-time adjustment of parameters
- Simple 3 button operation
- Compact design
- Easy-read screen
- Bluetooth connection for software updates
- Standard EQD fitting, with alternative method of connection via cables provided
- Short Wrist connection via cables provided
- Inline configuration

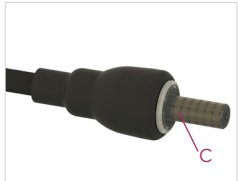
Operating Functions



A - EQD connection (male)
B - Easy-Read Display Screen
C - Decrease Button (left of screen)
D - Increase Button (right of screen)
E - Select Button. Press to move through each programming menu. (The select button is located at the rear of the Steeper Configuration Device).

Note: To scroll back through the menu, press and hold the ‘Select’ button.

Steeper Configuration Device Connections



A - EQD male connection
B - EQD female connection
C - EQD male connection of the Short Wrist Cable, supplied with the Steeper Configuration Device.

Connecting to an EQD Wrist

1. Connect the female EQD of the Steeper Configuration Device to the male connection within the forearm or demonstration cone.
2. Connect the male EQD connection of the Steeper Configuration Device to the female EQD connection of the Steeper Myoelectric Hand.
3. Gently push all three devices together with the power on, to power the Steeper Configuration Device.

Note: The devices must be in line, in a vertical 'stack' to ensure the Steeper Configuration Device does not disconnect from the power source or terminal device.

Position the patient's forearm to a vertical position and hold the terminal device in place with one hand whilst operating the Steeper Configuration Device with your other hand.

For alternative connection via cable please see next page.

Alternative Connection to EQD Wrist

1. Connect the male connection on the patient's EQD Wrist to the female EQD connection of the 'Wrist Connection Cable'.
2. Connect the 4-pin plug of the 'Male Power Supply Cable' into the female 4-pin socket of the 'Wrist Connection Cable'.
   Note: The 3-pin plug of the 'Wrist Connection Cable' (circled) is not required in this set up.
3. Connect the male EQD connection of the 'Male Power Supply Cable' into the female EQD connection of the Steeper Configuration Device.
4. Connect the male EQD connection of the Steeper Configuration Device to the female EQD connection of the Steeper Myoelectric Hand. This should allow for a secure connection between the devices, reducing instability between the Steeper Configuration Device and the patient's forearm.

Connecting to a Short Wrist

1. Connect the forearm power supply (female 4-pin connection) to the ‘Male Power Supply Cable’ provided.
2. Connect the ‘Male Power Supply Cable’ (provided) to the female EQD connection in the configuration device.
3. Connect the male EQD on the configuration device to the female EQD connection on the ‘Wrist Connection Cable’ supplied.
4. Connect the female 4-pin connector of the ‘Short Wrist Connection Cable’ to the male 4-pin connector of the cable emerging from the base of the Myo Kinisi.
5. Connect the male 3-pin connector of the ‘Short Wrist Connection Cable’ to the female 3-pin connection within the base of the Myo Kinisi Short Wrist Unit.

Operating the Configuration Device

When the Steeper Configuration Device is connected to a forearm with the power switched on and no terminal device is connected, the screen will display “STEEPER CFG DEV CONNECTING”.

When the Steeper Configuration Device is connected to a forearm with the power switched on, and the terminal device connected, the screen will display “CONFIG MODE HAND”.

Note: To scroll back through the menu, press and hold the ‘Select’ button located at the rear of the device.

Terminal Device Control

The Steeper Configuration Device is used to program terminal devices. From the Steeper Configuration Device you can:

- Adjust the control mode of the terminal device
- Customise the behaviour of the terminal device
- View the software version of the terminal device
- View the control mode of the terminal device
- Update the software

Configuration Device Parameters

Config Mode - Hand Menu
Menu of parameters for configuring the Myo Kinisi hand to a patient's individual abilities.

Hand Mode Menu
Menu of modes available in the Myo Kinisi hand, including both single and dual site, proportional and threshold control options for a variety of inputs. See the description of the 'Myo Kinisi Modes' that follow for more details.

Flip Electrodes
Reassigns Input 1 and Input 2 within the terminal device without the need to manually rewire the inputs. If Input 1 performs an 'open' command and Input 2 performs a 'close' command; 'Flip Electrodes' reassigns Input 1 to 'close' and Input 2 to 'open'.

Download Update
This feature allows any software updates to be provided remotely via a Bluetooth connection to a PC. Software updates may occasionally be required for the Steeper Configuration Device and/or any compatible terminal devices, such as the Myo Kinisi.

Calibrate
Performs calibration of the terminal device, for use only when instructed by a Steeper Product Manager or Steeper representative.

Config Mode - Options
Menu of servicing/updates for occasional use only.

Config Mode - Factory Reset
Returns parameters to the default settings of the mode in use.

Terminal Device Control Parameters

E-1 Threshold
Selects the threshold control strategy for input 1.

E-1 Proportional
Selects the proportional control strategy for input 1.

E-1 ON Level Threshold
Allows the adjustment of the EMG signal strength at which the signal elicited through input 1 will cause the hand to move. This is a sliding scale allowing real-time adjustment. Raising the level will make it easier for someone who produces multiple noise signals, or finds it hard to relax, to control the terminal device without accidental operation due to a higher, deliberate signal strength being required to initiate movement.

E-1 MAX Level Threshold
Allows adjustment of the EMG signal strength at which the signal is elicited through input 1 will cause a maximum opening/closing speed of the terminal device. This function dictates the boundary at which a signal strength changes from a low to a high signal strength. Once reached, this 'Max Level' threshold elicits movement in the connected terminal device at a programmed maximum speed. This is a sliding scale allowing real-time adjustment. Raising this level will provide easier speed control for those who have difficulty varying signal strength in a controlled manner, due to a larger change in the signal strength being required to provide the same change in operating speed.

E-2 Threshold
Selects the threshold control strategy for input 2.

E-2 Proportional
Selects the proportional control strategy for input 2.

E-2 ON Level Threshold
Allows adjustment of the EMG signal strength at which the signal elicited through input 2 will cause the hand to move. This is a sliding scale allowing real-time adjustment. Raising the level will make it easier for someone who produces multiple noise signals, or finds it hard to relax, to control the terminal device without accidental operation due to a higher, deliberate signal strength being required to initiate movement.

E2- MAX Level Threshold
Allows adjustment of the EMG signal strength at which the signal elicited through input 2 will produce maximum opening/closing speed of the terminal device. This function dictates the boundary at which a signal strength

changes from a low to a high strength. Once reached, this 'MAX Level' threshold elicits movement in the connected terminal device at a programmed maximum speed. This is a sliding scale allowing real-time adjustment. Raising the level will provide easier speed control for those who have difficulty varying signal strength in a controlled manner, due to a larger change in signal strength being required to provide the same change in operating speed.

Max Open Speed
The maximum speed at which the device will open.

In a threshold control strategy, the selected 'Maximum Open Speed' will occur as the corresponding EMG signal passes the E-*ON Level' threshold; so that above this level, the terminal device will travel at a constant maximum opening speed.

In a proportional control strategy, the selected 'Maximum Opening Speed' will occur at the E-*MAX Level' threshold; when the EMG signal sits beneath this level, and above the 'ON level' threshold, the terminal device opening speed will vary with the strength of the signal from the corresponding input E-* (* indicates input number).
Adjusting this parameter limits the achievable Maximum Opening Speed. This is a sliding scale that allows adjustment in real-time. Lowering this would improve speed control for those who participate in activities requiring fine movements due to each unit of each signal strength providing a smaller change in opening speed.

Info: Maximum Open Speed and Maximum Close Speed are independent of one another.

Max Close Speed
The maximum speed at which the device will close. In a threshold control strategy, the selected 'Maximum Closing Speed' will occur as the corresponding EMG signal passes the E-*ON Level threshold; so that above this level, the terminal device will travel at a constant maximum closing speed.
In a proportional control strategy, the selected 'Maximum Closing Speed' will occur at the 'E-*MAX Level' threshold; when the EMG signal sits beneath this level, and above the 'ON Level' threshold, the terminal device closing speed will vary the strength of the signal (from the corresponding input E-*).

Adjusting this parameter limits the achievable maximum closing speed. This is a sliding scale that allows adjustment in real time. Lowering this would improve speed control for those who participate in activities requiring fine movements due to each unit of signal strength providing a smaller change in closing speed.

Info: Maximum Close Speed and Maximum Open Speed are independent of one another.

Auto-Grip
For use in applications where grip must be maintained, Auto-Grip ensures that if the object being gripped moves or slips within the grasp of the terminal device, the hand will close by a degree to maintain the grip. This feature can be enabled or disabled during configuration.

Electrode Mode
The electrode mode is the method used to determine which signal elicits movement where the signals are not clearly distinct. There are three modes to choose from:

- Highest
  The highest signal will dictate the response in the terminal device when both signals are above the 'On Level' threshold.
- First Signal
  The first signal to cross the 'ON Level' threshold will dictate the response in the terminal device, regardless of the strength of the subsequent signal.
- Close Priority
  Where both signals are above the 'ON Level' threshold, the signal generated by the 'close' input will be prioritised and the hand will close.

Maximum Pulses
This setting dictates how the maximum grip is achieved. 1, 2, or 3 pulses can be selected; meaning that after fully closing onto an object, providing 1, 2 or 3 further pulse signals will increase the grip to maximum.

Invert
This feature allows the function of the signal patterns to be changed; for example, the signal pattern previously used to 'open' the device can be used to 'close' the device; and vice-versa. The inputs remain assigned as they were originally, only the signal patterns change function.

Alt Delay
This parameter dictates the length of time following a signal within which a new signal elicits the same direction of movement. Outside of the Alt Delay time, a new signal will have a new effect.
This is a timer, increased between 500 milliseconds (ms) to 1000ms; in increments of 25ms. Used for the related single site mode, for example all signals within a 500ms period of each other will open the terminal device. Outside of this period, the next signal will close the terminal device, all subsequent signals within a 500ms period of each other will close the hand and so on.

Pulse Period
The Pulse Period defines a period of time within which a signal rising above and falling below the 'ON Level' threshold' will be considered a Short Pulse. A signal rising above the 'ON Level' threshold' for longer than a Pulse Period will be considered a Long Pulse. The signal must rise above the 'ON Level' threshold to a strength exceeding 400% of the 'ON Level' threshold, and fall below the 'ON Level' threshold again within the Pulse Period to be considered a successful Short Pulse.

This is a timer scale, used for the related single site mode, a short pulse will move the terminal device in one direction, and a long pulse will move it in the other. Reducing the Pulse Period will reduce the likelihood of accidental operation of the terminal device.

Configuring the Myo Kinisi

The Myo Kinisi hand offers five mode options. Each mode provides a different variety of characteristics allowing mode selection based on the need of the user. The table adjacent illustrates the key attributes of each of the five control modes.

Info: The modes cannot be selected without the use of the Steeper Configuration Device. The Myo Kinisi default mode is Mode 1.

Control Parameters Table - Myo Kinisi

Control Mode	No. of Sites		Compatible Inputs				Control Strategy				Auto Grip
							Opening		Closing		
	Single	Dual	AC/DC Electrode	Force Sensitive Resistor (FSR)	Switch	Linear Transducer	Threshold	Proportional	Threshold	Proportional	
0	•		•	•	•	•	•	•			
1		•	•	•	•	•	•	•	•	•	•
2	•		•	•		•	•	•	•	•	
3	•		•	•	•	•	•	•	•	•	
4	•		•	•	•	•			•	•	

Adjustable Parameters of the Myo Kinisi

The parameters available for use with each of the five Myo Kinisi hand modes are illustrated in the tables opposite.

Control Mode	Invert	Flip Electrodes	Auto-Grip	Electrode Mode		
				Highest	First	Close priority
0	•					
1		•	•	•	•	•
2						
3						
4	•					

Control Mode	Input 1		Input 2		Control Parameters				
	ON Level	MAX Level *	ON Level	MAX Level*	Max Open Speed	Max Close Speed	Pulse Period	Alt Delay	Max Pulses
0	•	•			•	•			•
1	•	•	•	•	•	•			•
2	•	•			•	•			•
3	•	•			•	•		•	•
4	•	•			•	•	•		•

*Only available when using a Proportional mode

Quick Guide Process for Myo Kinisi

1. CHOOSE MODE
   Config Hand > Mode
   Select mode 0 - 4, based on the number of available inputs and the user's signal integrity.

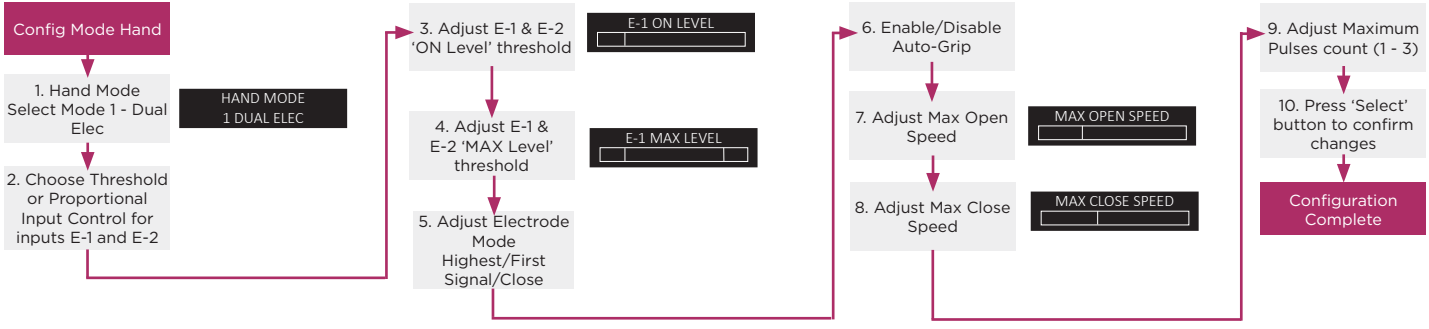
2. CHOOSE CONTROL STRATEGY
   Select threshold or proportional control strategy to suit the user's signals and adjust the ON Level threshold (and MAX Level threshold in proportional).

3. CUSTOMISE PARAMETERS
   Adjust Speed, Auto-Grip, Pulse Period etc to suit patient requirements. If required to scroll back up through the menu, press and hold the 'Select' button (located at the rear of the Steeper Configuration Device).

4. FINISH
   Once satisfied with adjustments made, press the 'Select' button to confirm changes and disconnect the Steeper Configuration Device from the hand and power supply.

Info: as the device has no power, once disconnected the screen will appear blank. Any changes made on the Steeper Configuration Device are made in real-time and are automatically uploaded to the hand, therefore they will remain if the device is accidentally disconnected.

Example of Mode 1 Configuration Process



Updating the Steeper Configuration Device

The Steeper Configuration Device is Bluetooth enabled and can be connected via Bluetooth to a Windows 10 PC for update purposes to both the Steeper Configuration Device and compatible terminal devices. To update:

1. Ensure Bluetooth is enabled on your Windows 10 PC.
2. Connect the Steeper Configuration Device to an SDU Cone or other power source and ensure the power is on.
3. Navigate to 'Download Update' within the Steeper Configuration Device menu structure and confirm with a right press.
4. The device will enter Bluetooth mode and wait for the Myo.Updater.exe program to send a header to update the Steeper Configuration Device or terminal device software.
5. On the PC; in the 'Bluetooth Devices' menu, pair the 'KINISI-CFG-1234' (numbers shown will vary as are device specific), then select this device name and click 'done'.
6. The latest software and updater can be found at: https://www.steepergroup.com/home/kinisi-updates/

Info: Save the updater program and software file in the same folder on your PC to allow the programs to run correctly.

7. Run the Myo-updater.exe program on your PC and select the Steeper Configuration Device from the drop down menu. When the required file is selected, hit 'update' and progress of the upload is shown in the bar beneath. The display on the Steeper Configuration Device will note the serial number and 'Receiving Data'.

8. On completion, the software is uploaded to the Steeper Configuration Device and the unit will automatically update and reset itself. DO NOT DISCONNECT THE FROM POWER SOURCE DURING THIS PROCESS.

For more information about updating the Steeper Configuration Device, please visit **www.steepergroup.com**

Updating the Myo Kinisi Software

If a newer version of the Myo Kinisi software is available from the Steeper Configuration Device; the Configuration Device will display ‘Upgrade Hand’ followed by the current version installed and the upgrade version available.

When you have confirmed the selection of the upgrade, the Myo Kinisi will power cycle and load the new file. A notification will appear on the Steeper Configuration Device ‘Do Not Power Off’ and a progress bar will appear.

Info: Interrupting the power to the hand during an update may cause an error. Do not disconnect from the power source until completed.

On successful completion of the update, the Configuration Device screen will return to ‘Config Hand Mode’.

Important Safety Information

Caution: The Steeper Configuration Device should only be used by a suitably qualified Prosthetic clinician or technician and should never be given to the end user.

Caution: The Steeper Configuration Device must only be used with compatible terminal devices and the cables provided.

Caution: The Steeper Configuration Device is not waterproof.

Info: If the Steeper Configuration Device is not performing as expected, check the connection between the terminal device and the Steeper Configuration Device.

Info: If a serious incident occurs relating to the device, full details must be reported to the Manufacturer and competent authority of the Member State where the user/patient is established.

Returns

If items are to be returned for any reason, please contact Steeper Customer Services or your local Steeper distributor quoting the part number and serial number (which can be found on the base of the device).

An RA (Returns Authorisation Number) and a complete 8.2.1 FRM 028 Product Concern Report must be submitted with the product return. These can be obtained from Customer Services.

Warranty Terms

The warranty term for the Steeper Configuration Device is two years. Warranty covers design and manufacturing faults only.

Where a claim is made under warranty, this claim must be supported by appropriate documentation. Photographs of any failed products must be provided in lieu of the product itself. If applicable, please do not send faulty batteries back to Steeper.

The warranty will be void on all system components if any components have been subject to abuse, modification, neglect, deliberate damage, loads beyond those for which the product was designed, or repair or maintenance by an uncertified person.

This product should only be used in combination with authorised Steeper products, as intended by Steeper, and as described in this document

The service life of the Steeper Configuration Device is two (2) years.

Disposal

The Steeper Configuration Device is an electrical device and should not be mixed with general household waste. For proper treatment, recovery and recycling, please take this product(s) to a designated collection point(s).

Disposing of this product correctly will help save valuable resources and prevent any potential negative effects on human health and the environment, which could otherwise arise from inappropriate waste handling. Please contact your local authority for further details regarding your nearest designated collection point.

Penalties may be applicable for incorrect disposal of the waste, in accordance with your national legislation.

Environment and Operational Conditions

Storage transport and operation	-20°C (-4°F) to +50°C (+122°F)
Operational	-5°C (-23°F) to +40°C (+104°F)
Pressure range	700-1060hPA
Maximum 80% relative humidity, above non-condensing.	
Do not expose to EM emissions above 8kV contact, 15kV air.	

Test Certification

The Configuration Device and its associated components listed within this document have been tested and certified to the following standard and requirements:

Medical Safety Testing:
IEC 60601-1:2005/A1:2012
IEC 60601-1-11: 2015: Includes meeting requirements
ISO 14971: 2019
IEC 60601-2:2014

Includes meeting requirements of ISO 14971:2019

Quality Assurance

Steeper/SteeperUSA operate a UKAS approved quality management system and fully complies with the requirements of BS EN ISO 13485:2016. This certifies that Steeper/SteeperUSA meet the appropriate international quality standards for the design, manufacture and supply of prosthetic products.

Steeper is registered with both the Medicines and Healthcare Regulatory Authority in the UK, and the Food and Drugs Administration of the United States Government for the manufacture and supply of prosthetic and orthotic products.
MHRA Registration N°: 0000006617
FDA Registration N°: 9612243
Model No: STP-RP633

Continued compliance with the standard is monitored by a program of internal and external audits.
The design and manufacture of Steeper equipment and components are subject to a policy of continuous reappraisal. The company therefore reserves the right to introduce changes and withdraw products without notice.

This device is CE marked which indicates that the device meets EU safety, health and environmental requirements. It also indicates device's compliance with EU legislation and free movement within the European market.

This device is UKCA marked which indicates that the device meets safety, health and environmental requirements. It also indicates

the device's compliance with the legislation of Great Britain (England, Wales, Scotland) and free movement within the market of Great Britain.

Certifications

Bluetooth
The Bluetooth declaration ID for BT121 hardware is: D027374. The Bluetooth declaration ID for Bluetooth Dual Mode software is: D027373.

CE
BT121 is in conformity with the essential requirements and other relevant requirements of the R&TTE Directive (1999/5/EC). The official DoC is downloadable from the product websites (www.silabs.com).

FCC
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.
The Steeper Configuration Device STP -RP633, complies with Part 18 of the FCC Rules (Section 18.212)

Any changes or modifications not expressly approved by Bluegiga Technologies could void the user's authority to operate the equipment.

FCC RF Radiation Exposure Statement:
This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment. End users must follow the specific operating instructions for satisfying RF exposure compliance. This transmitter meets both portable and mobile limits as demonstrated in the RF Exposure Analysis.

This transmitter must not be co-located or operated in conjunction with any other antenna or transmitter except in accordance with FCC multi-transmitter product procedures.

As long as the condition above is met, further transmitter testing will not be required. However, the OEM integrator is still responsible for testing their end-product for any additional compliance requirements required with this module installed (for example, digital device emissions, PC peripheral requirements, etc.).
OEM Responsibilities to comply with FCC Regulations
The BT121 Module has been certified for integration into products only by OEM integrators under the following conditions:

- The antenna(s) must be installed such that a minimum separation distance of 7 mm is maintained between the radiator

(antenna) and all persons at all times.
- The transmitter module must not be co-located or operating in conjunction with any other antenna or transmitter except in accordance with FCC multi-transmitter product procedures.

As long as the two conditions above are met, further transmitter testing will not be required. However, the OEM integrator is still responsible for testing their end-product for any additional compliance requirements required with this module installed (for example, digital device emissions, PC peripheral requirements, etc.). IMPORTANT NOTE: In the event that these conditions cannot be met (for certain configurations or co-location with another transmitter), then the FCC authorisation is no longer considered valid and the FCC ID cannot be used on the final product. In these circumstances, the OEM integrator will be responsible for re-evaluating the end product (including the transmitter) and obtaining a separate FCC authorisation.

End Product Labelling
The BT121 module is labelled with its own FCC ID. If the FCC ID is not visible when the module is installed inside another device, then the outside of the device into which the module is installed must also display a label referring to the enclosed module. In that case, the final end product must be labelled in a visible area with the following:

Contains Transmitter Module FCC ID: QOQBT121 or Contains FCC ID: QOQBT121

The OEM integrator has to be aware not to provide information to the end user regarding how to install or remove this RF module or change RF related parameters in the user manual of the end product.

IC
This radio transmitter (IC: 5123A-BGTBT121) has been approved by Industry Canada to operate with the embedded chip antenna. Other antenna types are strictly prohibited for use with this device.

This device complies with Industry Canada's license-exempt RSS standards. 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

RF Exposure Statement
Exception from routine SAR evaluation limits are given in RSS-102 Issue5. BT121 meets the given requirements when the minimum separation distance to human body is less than equal to 20mm. RF exposure or SAR evaluation is not required when the separation distance is 20mm or more. If the separation distance is less than 20mm the OEM integrator is responsible for evaluating the SAR.

OEM Responsibilities to comply with IC Regulations
The BT121 Module has been certified for integration into products only by OEM integrators under the following conditions:
- The antenna(s) must be installed such that a minimum separation distance of 20mm is maintained between the radiator (antenna) and all persons at all times.
- The transmitter module must not be co-located or operated in conjunction with any other antenna or transmitter.

As long as the two conditions above are met, further transmitter testing will not be required. However, the OEM integrator is still responsible for testing their end-product for any additional compliance requirements required with this module installed (for example, digital device emissions, PC peripheral requirements, etc.).

IMPORTANT NOTE: In the event that these conditions cannot be met (for certain configurations or co-location with another transmitter), then the IC authorisation is no longer considered valid and the IC ID cannot be used on the final product. In these circumstances, the OEM integrator will be responsible for re-evaluating the end product (including the transmitter) and obtaining a separate IC authorisation

End Product Labelling

The BT121 module is labelled with its own IC ID. If the IC ID is not visible when the module is installed inside another device, then the outside of the device into which the module is installed must also display a label referring to the enclosed module. In that case, the final end product must be labelled in a visible area with the following:

Contains Transmitter Module IC: 5123A-BGTBT121 or Contains IC: 513A-BGTBT121

The OEM integrator has to be aware not to provide information to the end user regarding how to install or remove this RF module or change RF related parameters in the user manual of the end product.

IC (français)

Cet émetteur radio (IC : 5123A-BGTBT121) a reçu l'approbation d'Industrie Canada pour une exploitation avecl'antenne puce incorporée. Il est strictement interdit d'utiliser d'autres types d'antenne avec cet appareil.

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;
2) l'utilisateur de l'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement.

Déclaration relative à l'exposition aux radiofréquences (RF)

Les limites applicables à l'exemption de l'évaluation courante du DAS sont énoncées dans le CNR 102, 5e édition. L'appareil BT121 répond aux exigences données quand la distance de séparation minimum par rapport au corps humain est inférieure ou égale à 20mm. L'évaluation de l'exposition aux RF ou du DAS n'est pas requise quand la distance de séparation est de 20mm ou plus. Si la distance de séparation est inférieure à 20mm, il incombe à l'intégrateur FEO d'évaluer le DAS.

Responsabilités du FEO ayant trait à la conformité avec les règlements IC

Le module BT121 a été certifié pour une intégration dans des produits uniquement par les intégrateurs FEO dans les conditions suivantes :

- La ou les antennes doivent être installées de telle façon qu'une distance de séparation minimum de 20mm soit maintenue entre le radiateur (antenne)

et toute personne à tout moment.

- Le module émetteur ne doit pas être installé au même endroit ou fonctionner conjointement avec toute autre antenne ou émetteur.

Dès lors que les deux conditions ci-dessus sont respectées, d'autres tests de l'émetteur ne sont pas obligatoires. Cependant, il incombe toujours à l'intégrateur FEO de tester la conformité de son produit final visà-vis de toute exigence supplémentaire avec ce module installé (par exemple, émissions de dispositifs numériques, exigences relatives aux matériels périphériques PC, etc).

REMARQUE IMPORTANTE: S'il s'avère que ces conditions ne peuvent être respectées (pour certaines configurations ou la colocation avec un autre émetteur), alors l'autorisation IC n'est plus considérée comme valide et l'identifiant IC ne peut plus être employé sur le produit final. Dans ces circonstances, l'intégrateur FEO aura la responsabilité de réévaluer le produit final (y compris l'émetteur) et d'obtenir une autorisation IC distincte.

Étiquetage du produit final

L'étiquette du module BT121 porte son propre identifiant IC. Si l'identifiant IC n'est pas visible quand le module est installé à l'intérieur d'un autre appareil, l'extérieur de l'appareil dans lequel le module est installé doit aussi porter une étiquette faisant référence au module qu'il contient. Dans ce cas, une étiquette comportant les informations suivantes doit être collée sur une partie visible du produit final :

« Contient le module émetteur IC : 5123A-BGTBT121 » ou « Contient IC : 5123A-BGTBT121 »

L'intégrateur FEO doit être conscient de ne pas fournir d'informations à l'utilisateur final permettant d'installer ou de retirer ce module RF ou de changer les paramètres liés aux RF dans le mode d'emploi du produit final.

Symbols Used on Product and Packaging

Symbol	Definition	Source
	Indicates the medical device manufacturer.	ISO 15223- 1:2016 Reference no. 5.1.1. (ISO 7000-3082)
	Indicates the authorized representative in the European Community / European Union.	ISO 15223-1:2016 Reference no 5.1.2
	The requirements for accreditation and market surveillance relating to the marketing of products; Medical Device Regulations.	765/2008/EC, 768/2008/EC MDR 2017/745 (Articles 2, 13, 14, 20, 21, 22, 74 and Annex V)
	Certification mark that indicates conformity with the applicable requirements for products sold within Great Britain (England, Wales, Scotland).	https://www.gov.uk/guidance/using-the-ukca-marking
	Indicates a carrier that contains Unique Device Identifier information.	MDR 2017/745 23.2(h) ISO 15223-1:2016
	Indicates the manufacturer's batch code so that the batch or lot can be identified.	ISO 15223- 1:2016 Reference no. 5.1.5. (ISO 7000-2492)

	Indicates a medical device that has not been subjected to a sterilisation process.	ISO 15223- 1:2016 Reference no. 5.2.7. (ISO 7000-2609)
	WEE marking indicates that this electronic product should not be disposed of in unsorted waste.	IS EN 50419:2006 Reference no. Fig. 1
	Mobius logo indicates that the marked item or its material is part of a recovery or recycling process.	ISO 704, ISO/IEC 13251, ISO 10987-1, ISO 9687 (Reference no. ISO 7000 -1135)
	Packaging is covered by Forest Stewardship Council assurance that it is made with, or contains, forest-based materials from FSC-certified forests or reclaimed sources.	FSC Certification
	Bluetooth device fitted - Bluetooth Symbol.	Trademarks of Bluetooth Special Interest Group (SIG)
	Meets FCC requirements per 21 CFR Part 15.	Federal Communications Commission.

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