

CUE1+

FOR PARKINSON'S

INSTRUCTIONS FOR USE



CHARCO
NEUROTECH



CUE1+ for people with Parkinson's
www.charconeurotech.com

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About Us

Charco Neurotech is a British medical device company dedicated to enhancing the quality of life for individuals living with Parkinson's disease.

www.charconeurotech.com.

Designed and manufactured
in South Korea

Intended Use and Product Description

The CUE1+ for Parkinson's is intended to deliver focused vibrotactile and cued stimulation, and can be tuned by the optional mobile application, to reduce slowness, stiffness, rigidity and freezing of gait in Parkinson's disease, for use by adults diagnosed with Parkinson's disease over the age of 18 years old.

The CUE1+ is a battery-powered wearable therapeutic medical device, designed to be worn on the sternum of people with

Parkinson's. The device is attached to the skin over the sternum using medical-grade adhesive patches. Once in place, the device is turned on and off using a simple push button.

The CUE1+ is intended to be worn daily for a minimum of 8 hours per day. The frequency and intensity of the vibrotactile stimulation can be adjusted using the companion mobile application.

Refer to further details within these instructions on how to use the CUE1+.

Safety Information

Please read all instructions for use before using the CUE1+, as it contains essential information.



WARNING

A WARNING statement provides important information about a potentially hazardous situation which, if not avoided, could result in death or serious injury.



CAUTION

A CAUTION statement provides important information about a potentially hazardous situation which, if not avoided, could result in death or serious injury to user or patient, or in damage to the equipment or other property.

Safety Considerations

The most common side effect associated with the use of the CUE1+ relates to the adhesive patch worn on the skin. Some users report skin irritation at the adhesive site. If you do experience skin irritation, remove the body-side patch, discontinue use of the CUE1+ and contact our community support team.

⚠ WARNING: The safety and effectiveness of the CUE1+ have NOT been evaluated in patients with an active implantable medical device such as a pacemaker or deep brain stimulator.

Contraindications

⚠ WARNING: The CUE1+ device is not indicated to be used by people with hypersensitivity to vibrotactile stimulation.

⚠ WARNING: The body-side patch is not intended to be used on open wounds, broken, inflamed or infected skin.

Warnings and Precautions

A warning statement provides essential information about a potentially hazardous situation which, if not avoided, could result in death or serious injury.

⚠ WARNING: DO NOT use a body-side patch on an open wound.

⚠ WARNING: DO NOT use the CUE1+ if the device appears to be damaged.

⚠ WARNING: DO NOT use the device and remove it immediately if you feel it getting warm.

⚠ WARNING: DO NOT rely on the CUE1+ when operating machinery, driving, or handling items that may cause injury.

⚠ WARNING: If an unexpected reaction occurs, or if anything does not feel right while using the device, immediately discontinue use of the CUE1+, seek medical attention if required, and contact our community support team.

⚠ WARNING: The CUE1+ should be kept out of reach of children and anyone who might swallow this item or otherwise cause injury to themselves.

⚠ WARNING: Remove the CUE1+ before X-ray, CT/MR/PET scanning, electrotherapy, surgery, etc., as your device may be damaged when exposed to strong electromagnetic fields.

⚠ WARNING: The user must avoid exposing the CUE1+ device to extreme heat, e.g. left inside a parked car in the sun.

⚠ WARNING: The CUE1+ must not be dried in microwave ovens or other ovens.

⚠ WARNING: Do not modify this equipment without the authorisation of the manufacturer.

⚠ CAUTION: Before charging, the underside of the device (including the device-side patch) should be cleaned by wiping off sweat and debris using a general cloth.

⚠ CAUTION: Only place the CUE1+ device on the skin over the sternum. Do not place anywhere else on the body.

⚠ CAUTION: Please do not use the device if you have a known history of allergies to Thermoplastic Polyurethane.

⚠ CAUTION: Do not wear the device during water activities, such as swimming, playing water sports, taking a shower, or while visiting spa or sauna facilities. Doing so can damage the device.

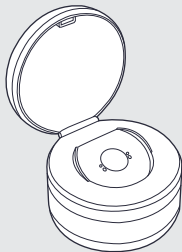
What's In the Box

- ❖ CUE1+ Device
- ❖ Docking Station
- ❖ Body-Side Patches x 6
- ❖ Device-Side Patch (already fitted to your CUE1+)
- ❖ USB-C Charging Cable
- ❖ Instructions For Use (IFU)
- ❖ Quick Start Guide (QSG)



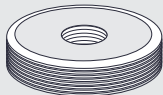
❖ CUE1+

Wearable device that attaches to your body using adhesive-backed hook-and-loop patches and delivers vibrotactile stimulation and cueing to you with a single press of the central button.



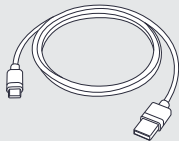
❖ DOCKING STATION

Securely hold and charge CUE1+ and store body-side patches in a built-in drawer.



❖ BODY-SIDE PATCHES

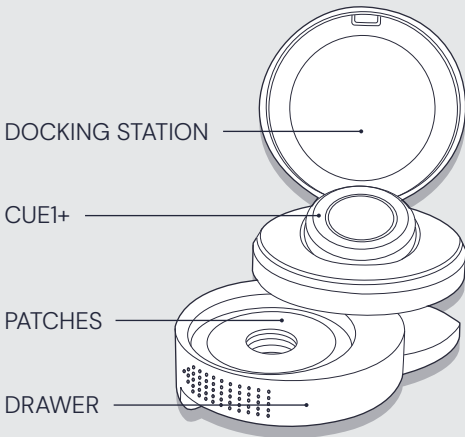
Wear your CUE1+ via these adhesive-backed loop body-side patches.



❖ USB-C CHARGING CABLE

Connect to a power source when charging the CUE1+

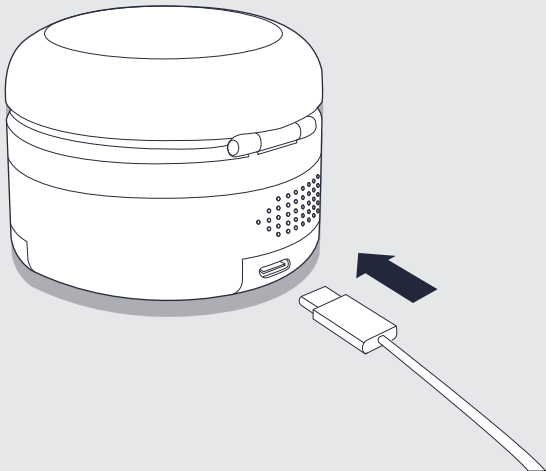
Overview



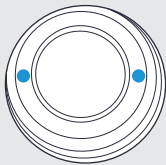
Body-side patches are stored in the drawer, accessed by rotating the middle section of the docking station. Please use the bumps to guide the direction of rotation.

Replacements are available from our website at www.charconeurotech.com/shop/.

Setting Up Your CUE1+



To charge your CUE1+, connect the USB-C charging cable provided to your docking station and an appropriate 5V USB plug. Place your CUE1+ on the docking station with the alignment dots ● on the face of the device in a horizontal position. Your CUE1+ will light up amber when charging and will turn green when fully charged.



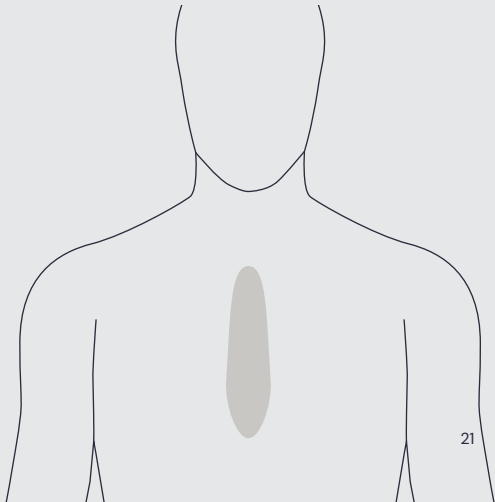
⚠ WARNING: Please do not use the adapter in a place where it is difficult to disconnect the power supply when charging the product.

⚠ WARNING: Immediately disconnect the docking station from the power supply if you suspect a fault or dangerous situation, such as a burning smell or sparks, if it is safe to do so.

⚠ WARNING: Please do not touch the two charging pins in the docking station simultaneously when it is connected to a power supply unit.

📖 NOTE: The CUE1+ should be charged regularly to maintain the battery life.

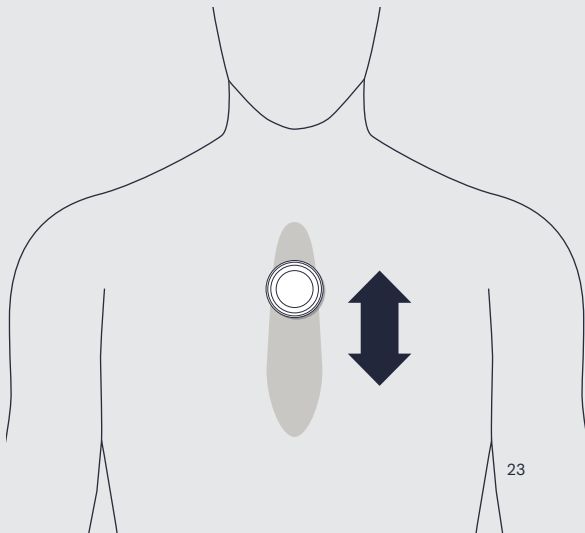
Wearing Your CUE1+

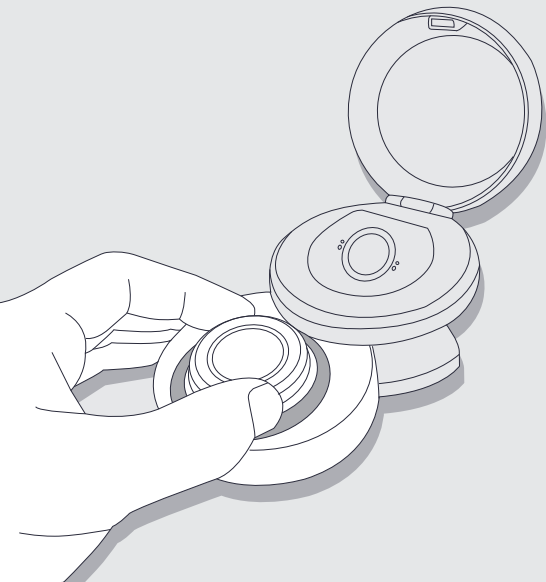


Please stand in front of a mirror and locate your sternum (breastbone).

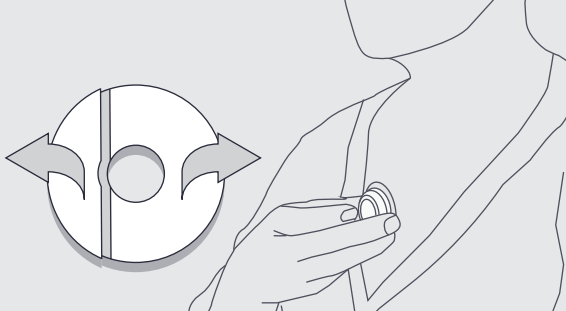
Gently run your hand down the centre of your chest area, along the breastbone (sternum). Find a position where the CUE1+ can sit completely flat against your skin, resting on a firm, bony area.

 **NOTE:** Ensure the area where you place the CUE1+ device is clean, hair-free, and dry.





Place your CUE1+ into the drawer where the body-side patches are stored, so that the device picks up one body-side patch.



Holding the device, gently peel off the body-side patch backing paper and apply the patch to the preferred location on your skin. Ensure the edges of the patch are fully adhered to the skin by applying pressure to the edge of the patch with your finger.

When applying the adhesive, avoid touching the sticky side with your hands. If the adhesive comes off, please do not reattach the adhesive, as it will no longer adhere as well.

The adhesive hook-and-loop patch system of the CUE1+ allows for secure attachment to the skin and convenient removal without causing discomfort. Please wait around 30 minutes after applying the patch before removing the CUE1+.

Using Your CUE1+



Turn the CUE1+ on with a single press of the big central button. You should be able to feel it vibrating. Press the button again to turn it off.

 **NOTE:** Do not expose the device to running water.

 **NOTE:** Do not wear the device during water activities, such as swimming, playing water sports, taking a shower, or while visiting spa or sauna facilities. Doing so can damage the device.

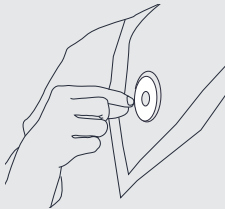
 **NOTE:** Do not expose the device and docking station to excessively dusty environments.

Your CUE1+ can be removed and replaced from the body as required. The body-side patch should stay adhered to your chest so you can easily place the CUE1+ back on when needed.

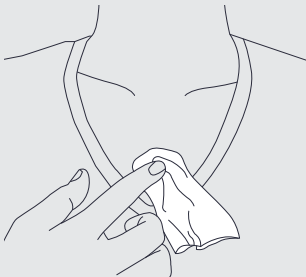
 **NOTE:** To help the body-side patch last longer, gently pat it dry with a towel after taking a shower. Avoid rubbing, as this may loosen the patch.

Replacing Your Body-Side Patch

Please replace the patch on your skin when it starts to show signs of wear within 14 days.



- ❖ Peel away the old adhesive from your skin using a fingernail to lift the edges.



- ❖ Clean and dry the area where the adhesive was attached.
- ❖ Refer to Page 21 for instructions on how to attach a new Body-Side Patch.

 **NOTE:** Body-side patches have been designed to be sweatproof and waterproof. Each patch is single-use only and can be worn for up to 14 days.

 **NOTE:** If any adhesive residue remains on your skin after removing the patch, you can gently wash it off with warm, soapy water.

 **NOTE:** The body-side patch has been tested for skin safety (biocompatibility). However, if you use the body-patch for longer than 14 days, you may experience skin discomfort. If you notice any itching, redness, irritation, burning, swelling, or discomfort, please remove the patch right away and contact us for support.

Replacing Your Device-Side Patch

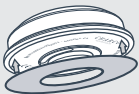
You should replace the device-side patch on the underside of your CUE1+ when it starts to show signs of wear, such as excess lint or fibres on the patch, or if the device feels less secure on the body.



- ❖ Peel away the old device-side patch from the CUE1+, using a fingernail to lift the edges.



- ❖ Remove the protective backing from a new device-side patch.



- ❖ Place the new device-side patch onto the CUE1+'s underside, taking care not to cover the metal contacts during placement.

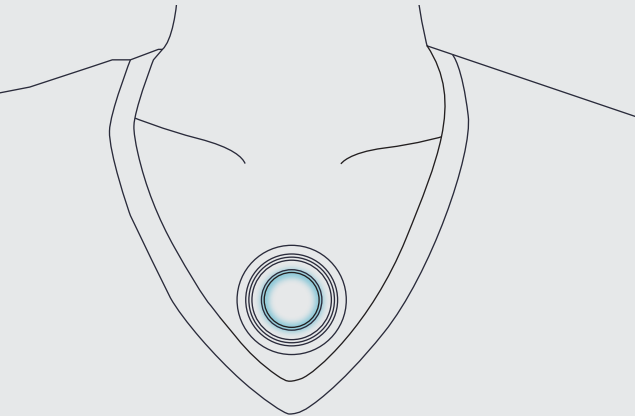


- ❖ Use your finger to press the device-side patch into place firmly. Smooth out any air bubbles to ensure full contact and a secure fit.

NOTE: The adhesive of the device-side patch is very strong, so please handle it with care when replacing it.

NOTE: Device-side patches can last up to 3 months but can be replaced sooner.

Lighting Guides





GREEN Fully Charged



AMBER Charging



RED Low Battery



BLUE Bluetooth Connected



**BLUISH
WHITE** Medication Reminder
(Continuous until button pressed,
or 10 seconds have passed)

BATTERY DEPLETION

Activated while the button is pressed.



More than
80%



More than
65%



More than
50%



More than
30%



More than
15%



Less than
15%

TIME ERROR STATE

Short, repeated blinking lights (Red-Blue-Red-Blue)



If you need further assistance, we are here for you.

The CUE1+ is a sternum-worn, non-invasive vibrotactile and cueing device designed for use in people (adults) with Parkinson's Disease.

No special training is required to use the device. However, if further assistance is needed, please get in touch with us through our support page at www.charconeurotech.com/support/ or email us at support@charconeurotech.com.

Mobile Application



CUE APP

Charco CUE APP for iOS and Android devices offer a user-friendly and discreet way to manage your CUE1+ device. The Charco CUE APP enables you to monitor the battery level, support firmware updates, adjust the vibrotactile stimulation settings, and set medication reminders.

 **NOTE:** It is not mandatory to download our mobile application, as the CUE1+ device can be used without the CUE APP.

 **NOTE:** Your iPhone or Android device needs to support Bluetooth Low Energy (BLE, also called Bluetooth Smart) to work with this product.

To get started, go to the App Store (for iPhone) or Google Play Store (for Android) and search for “CUE APP”.



 **NOTE:** To connect your CUE1+ to the CUE APP, press the centre button on your CUE1+ to restart the vibration, or charge your CUE1+ using the docking station, and open the CUE APP on your mobile device and follow the directions in the app.

The Bluetooth connection between the CUE1+ and your iPhone or Android device will disconnect if either one is turned off or if there is no activity for 5 minutes.

Stimulation Settings

Your CUE1+ comes pre-installed with the default stimulation settings. All our clinical trials have been conducted with the device on these default settings. We strongly advise that you do not change the stimulation setting within the first 3 months of use of your device, and before speaking to our Community Support team.

- ❖ The default vibration strength is set to 80%
- ❖ The default pulse time is set to 800 msec
- ❖ The default rest time is set to 800 msec

Device stimulation settings can be changed using the CUE APP.

- ❖ The strength of the vibration can be adjusted to be lower or higher than the default settings (range: 40-100%)
- ❖ The duration of the pulse and rest phases can be adjusted to be slower or quicker than the default settings (range: 100-2000 msec)

 **NOTE:** We recommend adjusting one setting at a time and waiting at least a week between making further adjustments.

For more information on the CUE APP,
please visit our website

[https://charconeurotech.com/
using-the-cue-app](https://charconeurotech.com/using-the-cue-app).

Setting Medication Reminders

Medication reminders can be set through the CUE APP. Navigate to the 'Medication' section in the CUE APP and add your medication details.

Multiple medication reminder times can be set, but they must be the same every day. Fill in the section with the requested data, save and apply those changes.

Your CUE1+ and smartphone will now vibrate and/or sound an alert to remind you to take your medication.

 **NOTE:** CUE1+ maintains a device time (its internal clock) to manage the medication reminder. To ensure accurate alerts, the device time must be adjusted by connecting the CUE1+ to the CUE APP on your smartphone in the following situations:

- When setting up the device for the first time.
- When your time zone changes due to travel or daylight-saving time.
- When the device is reset.

Updating Device Firmware

To ensure optimal performance of your CUE1+ device, keep the firmware up to date. When a new version of the device firmware is available, you will receive a notification via the CUE APP. Follow the on-screen instructions in the app to update the device firmware.

Before starting the firmware update, please ensure the device is sufficiently charged or placed on the docking station for charging. The firmware update may take several minutes to complete.

 **NOTE:** Do not turn off the device or disconnect Bluetooth during the firmware update.

Troubleshooting

If at any point your CUE1+ is not working as expected, resetting the device may resolve the problem.

RESETTING THE CUE1+:

A reset can be performed by pressing and holding down the centre button continuously for over 20 seconds, then releasing it.

A successful reset will reboot the device system, which is indicated by the bluish white LED lights rotating clockwise twice, blinking twice, and then turning off.

 **NOTE:** A reset may occur automatically when the device with an empty battery is connected to the docking station for charging.

 **NOTE:** If the device is reset, the clock inside it will go back to the starting time. This means your medication reminders will stop working. To fix this, open the CUE APP on your smartphone and reconnect the device. This will set the correct time and turn the reminders back on.

 **NOTE:** Resetting the device will not erase your vibration or medication settings. These are safely saved inside the CUE1+, even when it is turned off.

TIME ERROR STATE:

If you see quick, repeating flashes in red-blue-red-blue (see Lighting Guide), your device has incurred a time error.

If your CUE1+ displays the time error state, please reconnect it to the CUE APP. This will automatically adjust the device time to match your smartphone's time, resolving the issue.

If the problem continues, please visit our support page at www.charconeurotech.com/support/.

Cleaning

We recommend cleaning the CUE1+ device periodically with a clean, soft and dry cloth.

 **NOTE:** Turn off the CUE1+ before cleaning.

 **NOTE:** Do not use any cleaning solutions since this may damage the device.

Disposal

Please dispose of the CUE1+ according to national, state, and local regulations, as the device contains a Lithium-ion polymer battery.

Used or expired patches should be disposed of in regular household waste.

Symbols

	Warning
	Note
	Serial number
	Lot number
	Catalogue number
	Manufacturer
	Date of manufacture
	Single patient multiple use
	Medical device



Waste electrical and electronic equipment



European Authorised Representative



Temperature limitation



Keep dry



Refer to instruction manual/booklet



Do not use if package is damaged

IP XY

Ingress protection Code per IEC 60529, X - Solid Foreign Objects level protection, Y- Water Level protection



Type BF applied part



Unique Device Identifier

Technical Specification

Bluetooth Specifications

Bluetooth Module	ISP1807-LR-RS Bluetooth® low energy module.
Transmit Power	+8 dBm (typical), +8.5 dBm (max)
Receiver Sensitivity	-95 dBm at BLE 1 Mbps, -103 dBm at BLE 125 kbps
Frequency Range	2.402 – 2.480 GHz

Electrical Power

Source	Rechargeable Lithium-ion polymer battery
Nominal Capacity	110mAh
Nominal Voltage	3.7V
Maximum Charge Voltage	4.2 V
Charging Power Input	5V – 110mA

Essential Performance

Loss or degradation of the device vibration does not result in any unacceptable risk to the user.

Environmental Conditions

Temperature	5°C to 40°C
Relative Humidity	15% to 90%
Atmospheric Pressure	70 kPa to 106 kPa

Transport Conditions

Temperature	-10°C to 35°C
Relative Humidity	Less than or equal to 90%
Atmospheric Pressure	70 kPa to 106 kPa

Storage Conditions

Temperature	-10°C to 35°C
Relative Humidity	Less than or equal to 90%
Atmospheric Pressure	70 kPa to 106 kPa

IP Classification

CUE1+	IP47
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Docking Station	IP31
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Dimensions

Weight	18 g
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Height	12 mm
--------	-------

Diameter	40 mm
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Case Docking Station Power

Input Rating	5V – 0.5A (USB-C spec)
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Output Rating	5V – 0.11A (Device Charging Current)
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Charger Power	USB Powered
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Charging Supply Requirements

To charge the device through the docking station, we provide you with a USB-C charging cable. This USB-C charging cable must only be plugged into an IEC-62368-1 certified 5V power source.

Shelf-Life

CUEI+	1 Year (battery inside)
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Adhesive Patches	2 Years
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 **NOTE:** The device has a shelf life of one year if not periodically charged during storage. Its shelf life will increase proportionally with consistent periodic charging.

Expected Service Life

CUEI+	2 Years
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Case Docking Station	3 Years
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USB-C Charging Cable	3 Years
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FCC

This device complies with part 15 of the FCC rules. Operation is subject to the following two conditions.

- This device may not cause harmful interference.
- This device must accept any interference received, including interference that may cause undesired operation.

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

The FCC ID for Integrated ISP-1807 BLE module: 2AAQS-ISP1807

Disclosure: As of December 2021, the CUE1+ device is in the process of registering with the FCC. It has been tested and found to comply with the limits for Class B digital device, pursuant to part 15 of the FCC rules. We are in the process of establishing a US based responsible party as part of the FCC requirements. Please refer to any enclosed corrigenda in case of an update to this status or statement.

Electromagnetic Compatibility Declaration

The CUE1+ is intended for use in the electromagnetic environment specified below. The user should ensure that it is used in such an environment.

Emission Test	Compliance
RF emissions; CISPR 11	Group 1
RF emissions; CISPR 11	Class B
Harmonic emissions IEC 61000-3-2	Not applicable
Voltage fluctuations and flicker emissions IEC 61000-3-3	Not applicable

Immunity test	Test level IEC 60601
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air
Radiated RF; IEC 61000-4-3	10 V/m 80 MHz – 2.7 GHz 80 % AM at 1 kHz
Electric Fast Transient Burst Immunity IEC 61000-4-4	± 2 kV 100 kHz repetition frequency
Fast Surge Immunity IEC 61000-4-5	± 0.5 kV, ± 1 kV, ± 2 kV
Radio Frequency Common Mode Immunity IEC 61000-4-6	3 VRMS (80% AM at 1 kHz); 150 kHz to 80 MHz
Power frequency (50/60 Hertz) magnetic field IEC 61000-4-8	30 A/m (50/60 Hz)

If a serious incident occurs concerning the CUE1+, it must be reported to the manufacturer and the competent authority of the country in which you are located.

The report should contain the following information:

- What happened, when and where it occurred, how it happened, and why they think it occurred.
- Was the incident related to the instructions for use of the product?
- Was the outcome affected by a user's pre-existing condition?

Please go to the last page for contact details.



Charco Neurotech hereby declares that the device CUE1+ conforms with the general safety and performance requirements.



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CUE1+ FOR PEOPLE WITH PARKINSON'S

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