Patch Transcutaneous Electrical Applicator (Patch-TEA)

Model: TEA-21

Transtimulation Research Inc

Instructions for Use

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Intended use

Transcutaneous Electrical Applicator (TEA) device uses transcutaneous electrical nerve stimulation (TENS) to stimulate nerves for therapeutic purposes. Depending on the parameters of the electrical impulses (pulse frequency, ON and OFF durations, total session duration), different therapeutic effects can be produced.

Indications for Use

Patch-TEA device is intended to be used in adult patients only for temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back, neck, arm, and leg, due to strain from exercise or normal household work activities and suitable for home use.

Safety guidelines

It is important that you read all contraindications, warnings, and precautions below because they are intended to keep you safe, prevent injury and avoid a situation that could result in damage to the device.

1. Contraindications

- Do not use this device, if you have a cardiac pacemaker, implanted defibrillator, implanted neurostimulator, metallic stent, cerebrospinal fluid shunt, implanted pump, or other implanted metallic device. Such device use could cause electric shock, burns, electrical interference, or death. In addition, an implanted medical device can be subjected to magnetic interference from this device.

- Do not use this device, if you have a body-worn electro-mechanical medical device, such as insulin pump
- The electrode should not be placed over skin lesions.
- The electrode should not be placed over swollen, infected, inflamed areas or skin eruptions (e.g. phlebitis, thrombophlebitis, varicose veins, etc.).
- The electrode should not be placed on the front or sides of the neck.

- The electrode should not be placed on the head.
- The electrode should not be placed on the chest to avoid cardiac rhythm disturbances.

- The electrode should not be placed over abdominal or inguinal hernia.
- The electrode should not be placed over the surgical area after a recent surgery.
- The electrode should not be placed on the legs, if you have critical ischemia or other serious arterial circulatory problem in the legs.
- Do not use this device, if you have any undiagnosed pain syndromes.
- Do not use this device, if you are pregnant.

2. ⚠ Warnings

- If you have had medical or physical treatment for your pain, consult with your physician before using this device.
- If your pain does not improve, becomes more than mild, or continues for more than 4 weeks, stop using the device and consult with your physician.
- if you feel discomfort during use, discontinue and do not increase the intensity level.
- Do not apply the stimulator in the presence of electronic monitoring equipment (such as cardiac monitors), which may not operate properly when electrical stimulation device is in use.
- Do not apply stimulation while connected to high-frequency surgical equipment, which may cause burn injuries on the skin under the electrode pad, as well as problems with the stimulator.
- Do not apply the stimulator in the vicinity of shortwave or microwave therapy equipment, since this may affect the output power of the stimulator.
- Contact the manufacturer of the electrical stimulator or recording device if you do not know if the electrode can be used with the stimulation or recording device.
- Do not apply stimulation when in the bath or shower.
- Do not apply stimulation while sleeping.
- Do not apply stimulation while driving, operating machinery, or during any activity in which electrical stimulation can put you at risk of injury.
- Apply stimulation only to normal, intact, clean, healthy skin.
- The long-term effects of chronic electrical stimulation are unknown.
- Consult with your physician before using this device, because the device may cause lethal rhythm disturbances to the heart in susceptible individuals.
- Do not apply stimulation over the front or sides of the neck, because this could cause severe muscle spasms resulting in airway closure, difficulty in breathing, or adverse effects on heart rhythm or blood pressure.
- Do not apply stimulation over the front or top of the head, as the effects of stimulation of the brain are unknown.
- Do not apply stimulation across the chest, because the introduction of electrical current into the chest may cause heart rhythm disturbances, which could be lethal.
- Do not apply stimulation over skin lesions, open wounds or rashes, or over swollen, red, infected, or inflamed areas or skin eruptions (e.g., phlebitis, thrombophlebitis, varicose veins).
- Do not apply stimulation over, or in proximity to, cancerous lesions.
- Do not apply stimulation near the genitals.
- Incorrectly applying or using the electrode pad could result in discomfort or skin burns.

- Keep the stimulator out of reach of children.
- Do not use the device on children.
- Consult your doctor if you are in any doubt whatsoever.
- Use this device only with the electrode pad provided by the manufacturer, as its size, shape, and type may affect the safety and effectiveness of electrical stimulation.
- Do not share the use of electrode pad with other persons because of risks of adverse skin reactions and disease transmission.
- Do not modify or alter the Patch-TEA device or Patch-TEA app as it may result in a hazardous situation.
- The Patch-TEA device should not be brought into the Magnetic Resonance (MR) environment, as the device is MR Unsafe and may present a projectile hazard.

3. ⚠ Precautions

- Federal (United States) law restricts this device to sale by or on the order of a physician or properly licensed practitioner (prescription only).
- TENS is not effective for pain of central origin including headache.
- TENS is not a substitute for pain medications and other pain management therapies.
- TENS devices have no curative value.
- TENS is a symptomatic treatment and, as such, suppresses the sensation of pain that would otherwise serve as a protective mechanism.
- TENS effectiveness is highly dependent upon pain origin.
- The long-term effects of TENS are unknown.
- TENS safety during pregnancy has not been established.
- You may experience skin irritation or hypersensitivity due to the electrical stimulation or application of electrically-conductive gel.
- If you have suspected or diagnosed heart disease, you should follow precautions recommended by your physician,
- If you have suspected or diagnosed epilepsy, you should follow precautions recommended by your physician.
- Proceed with caution if stimulation is applied to areas of the skin that lack normal sensation.
- Use caution if you have a tendency to bleed internally, such as following an injury of fracture.
- Consult with your physician prior to using the device after a recent surgical procedure, because stimulation may disrupt the healing process.

- Use caution if stimulation is applied over the menstruating or pregnant uterus.
- For single patient use only.
- Any improper use may be dangerous.
- Isolated cases of skin irritation may occur at the site of the electrode placement following long-term application.
- Do not use this device at the same time as other equipment which sends electrical pulses to your body.
- Do not use sharp objects such as pencil point or ballpoint pen to operate the buttons on the control panel.
- To check the electrode connections before each use.
- Electrical stimulators should be used only with the electrode pad provided by the manufacturer.

4. Adverse reactions

- Possible skin irritation or burn under the electrode pad may occur.
- On rare occasions, first-time users of TENS have reported feeling light-headed or faint. We recommend that you use the device while seated until you become accustomed to the sensation.
- If the stimulation levels are uncomfortable or become uncomfortable, reduce the stimulation Intensity to a comfortable level and contact your physician if problems persist.
- You should stop using the device and should consult with a physician if you experience adverse reactions from the device.

Chapter 1: Patch-TEA device and accessories

1.1 List of included parts

Part Name	Quantity	Part no.
Patch-TEA device	1	DE-TEA21
Patch-TEA charging case	1	CA-TEA21
USB charging cable	1	CC-TEA21
USB power adapter	1	PA-TEA21
Electrode pad	4	EP-TEA21

1.2 Patch-TEA device

As shown on Figure 1, the front of Patch-TEA device has the buttons for setting the device operations. A magnetic snap connector is located on the back of Patch-TEA device. The Patch-TEA device can be connected to the charging case and to the electrode pad.

Figure 1: Patch-TEA device

Patch-TEA device is powered using an internal rechargeable lithium polymer battery. As shown on table below, once the device is turned on, the operating mode is indicated by the LED color. When the battery is fully charged and is in standby mode, the LED color is green; when it is in in stimulation mode, the LED color is white. The LED is flashing, when the Bluetooth is not connected and turns solid, when the Bluetooth connection with the smartphone is established. The stimulation treatment can be provided for up to 4 hours under normal operating conditions. When the device battery is discharged, the LED color changes to a flashing orange.

LED color	Patch-TEA device operating mode
flashing green	The device is in standby mode, Bluetooth is not connected
solid green	The device is in standby mode, Bluetooth is connected
flashing white	The device is in stimulation mode, Bluetooth is not connected
solid white	The device is in stimulation mode, Bluetooth is connected
flashing yellow	low battery
solid yellow	device is charging

1.3 Charging case with USB charging cable

When Patch-TEA device is not in use, it is recommended to store it in the charging case (Figure 2). Since the charging case contains an internal battery, it can charge the stimulator, when charging is required. There is an LED on the front of the charging case. When the cover of the charging case is opened, the LED indicates the charging case status. When the charging case battery is fully charged and is ready for charging the Patch-TEA device, the LED is a solid blue. When the charging case battery is low, the Patch-TEA device cannot be charged, and the LED is a flashing yellow.

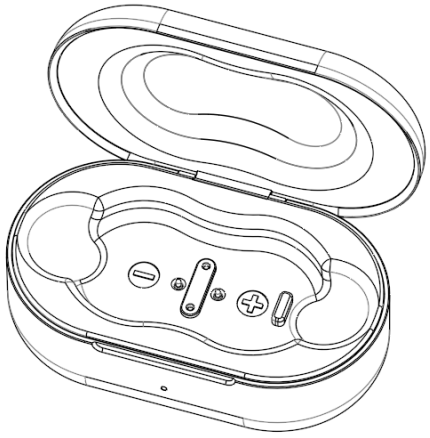


Figure 2: Inside view of the charging case with USB charging cable

To charge the charging case battery, connect it to the USB power adapter through the USB charging cable, as shown on Figure 3. Make sure to use the USB power adapter that is approved for use in the US (120 V, 60 Hz) and supports the required current/power (1A/5W). When the charging case is charging, the LED is solid yellow; and when the battery is fully charged, the LED turns solid blue.

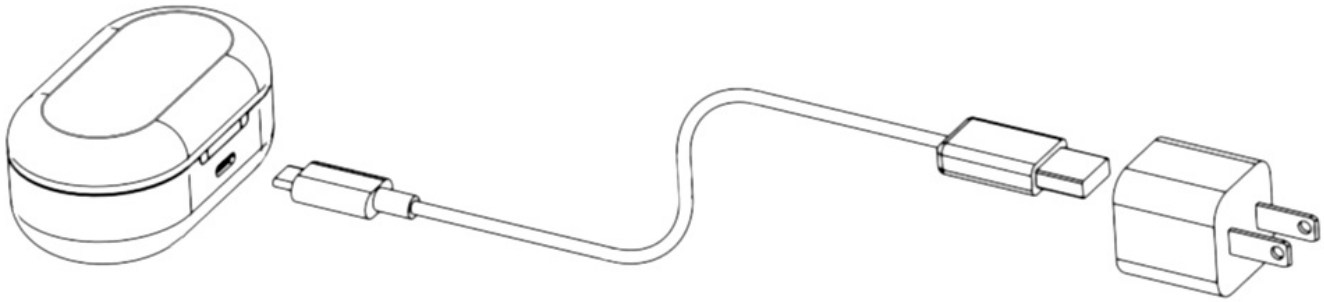


Figure 3: Charging case with USB charging cable and USB power adapter.

⚠ Caution

1. When using a wrong or poor-quality USB power adapter, the device's safety is compromised, resulting in possible damage to your property and health. Please purchase the medical-grade adapter that meets the IEC 60950-1 or IEC 62368-1 standard.

2. After fully charging the battery, if the working time of battery is shorter than before and you want to replace it, don't try to replace the rechargeable battery by yourself. Please contact the manufacturer or distributor for replacement. Self-disassembly and replacement the battery may cause damage to the device and battery.

3. When the device is not used for a long time, the battery will discharge slowly. In order to avoid battery damage, please charge the device and charging case at least once every three months.

1.4 Electrode pad

1.4.1. Electrode pad placement

As shown on Figure 4, the Patch-TEA device is inserted inside the electrode pad until it snaps in the electrode pad's buckle. After removing the protective film for the bottom surface, place the electrode pad firmly on the skin. Please, make sure the skin is clean and dry before applying the electrode pad and ensure the electrode pad is well-adhered to the skin. If the skin is oily or wet, please wipe it with a dry soft cloth. If necessary, it can be disinfected by gently wiping with a cotton round dipped in sterilized alcohol.

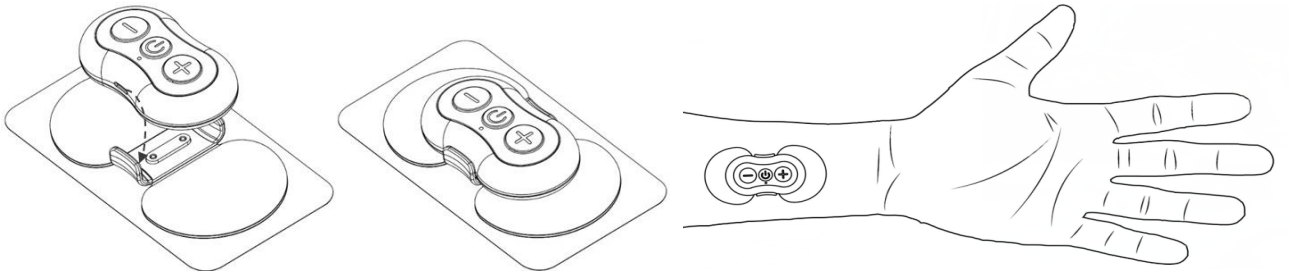


Figure 4: Electrode pad placement on the skin

As shown on Figure 5, the electrode pad is commonly placed on the following skin locations to achieve the best treatment results.

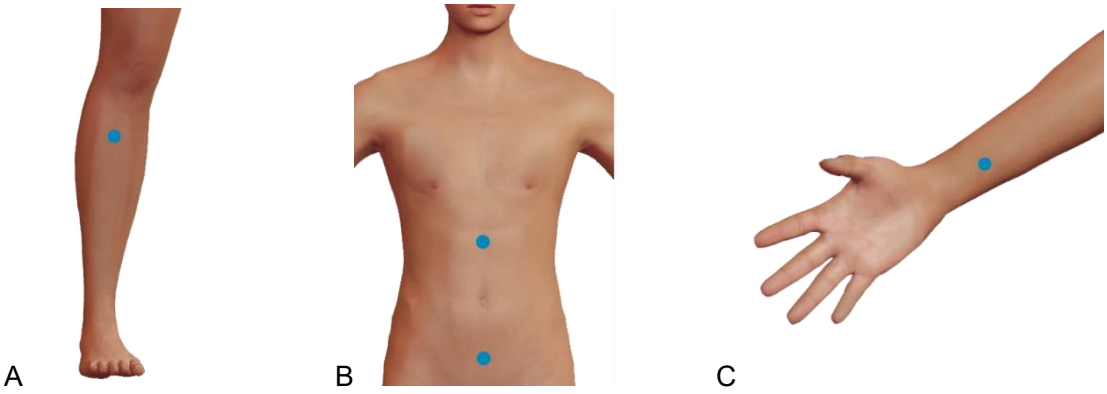


Figure 5: Skin locations for placement of the electrode pad: A) ST36 (Zusanli), B) CV4 (Guanyuan) and CV12 (Zhongwan), and C) PC6 (Neiguan)

1.4.2 Proper usage of the electrode pad

a. The Patch-TEA device may only be connected with the electrode pad provided by the manufacturer, as their size, shape, and type may affect the safety and effectiveness of electrical stimulation. Order the electrode pad replacements only on the official company web page: https://www.transtimulation.com/home/products

b. Make sure that the Patch-TEA device is turned off when attaching or removing the electrode pads.

c. If you want to reposition the electrode pad during the application, turn the device off first.

d. The use of electrode may lead to skin irritations. If you experience such skin irritations, e.g. redness, blistering or itching, discontinue use of them and see your physician if the irritation persists.

e. Electrode pads are intended for single-person use. Please avoid their use by different persons.

f. The electrode pad must connect entirely to the skin surface to prevent hot spots, which may lead to skin burns.

g. After a single use of the electrode pad, through it away, as adhesion between the electrode pad and the skin may deteriorate depending on the skin properties and duration of stimulation. If the electrode pad contact to skin becomes loose, its contact area decreases and can cause a skin burn.

⚠ Caution

1. *Before applying the electrode pad, it is recommended to wash/degrease and dry the skin.*
2. *Do not turn on the device when the electrode pad is not positioned on the skin.*
3. *Do not remove the electrode pad from the skin while the device is still on.*
4. *Always remove the electrode pad from the skin with a moderate pull in order to avoid injury in the event of highly sensitive skin.*
5. *Only use the electrode pads provided by the manufacturer. Use of electrode pads from another company could result in injuries to the user.*

⚠ *Warning*

The provided electrode pad can reach current densities exceeding 2.0 mA/cm^2 that may cause skin burns or irritation under the electrode pad during use. Please, check the skin under the electrode pad following each stimulation session for skin burns or irritation. If you notice such skin burns or irritation, then apply stimulation at a different site, reduce the stimulation intensity to a level where the skin burns or irritation does not occur or discontinue use of the device and consult with your doctor. When increasing the stimulation intensity, please adjust it gradually from minimal level to maximal tolerable level. If you are not sure, please consult your doctor and follow doctor's advice. In addition, it is suggested that the stimulation

time should not exceed 120 min per use. If you encounter discomfort, please stop treatment immediately.

1.5 Patch-TEA app

The keys on Patch-TEA device allow the user to perform only basic operations, including starting and stopping treatment and adjusting the stimulation intensity. In order to perform advanced operations, users have to install and use the companion Patch-TEA app on the Android smartphone. Use of the Patch-TEA app is described in 2.7.

Chapter 2: Directions for use

2.1 Preparing the device

Before using Patch-TEA device for treatment, confirm the charging case LED indicates that the device if fully charged. Remove the device from the charging case, and connect it to the electrode pad, while the pad is attached to the skin, as described in 1.4. The charging instructions are in 1.3.

2.2 Description of the device buttons

The following table describes the functions of three buttons on the device:

Button	Description
⏻	ON/OFF power and treatment button: Short press to turn on the device; Long press to turn off the device In standby mode, short-press to start the treatment; In treatment mode, short-press to stop the treatment
+	Increase the stimulation intensity by 0.5 mA
—	Decrease the stimulation intensity by 0.5 mA

2.3 Turning the device ON and OFF

To turn the device on, short-press the Power button ⏻. Patch-TEA device goes into Standby mode (green LED color). While in the Treatment or Standby modes, long-press the Power button ⏻ for 3 seconds to power off the device. Automatic shutdown: The device will automatically shut down, if there is no operation within 5 minutes in the standby state.

2.4 Initiating treatment

Short-press the Power button ⏻ to start the treatment process (white LED color). In order to avoid sudden unpleasant sensation of stimulation, the initial current should be set to 0.5 mA.

2.5 Adjusting stimulation intensity

Short-press + and — keys to adjust the stimulation intensity. The — key reduces the stimulation intensity to a minimum level of 0.5 mA. The + key increases the stimulation intensity to a maximum level of 10 mA. the LED will flash quickly, once the minimal or maximal level is reached.

2.6 Terminating treatment

While in the Treatment mode, press the Power button ⏻ to terminate the treatment process and enter

Standby mode.

2.7 Using the Patch-TEA app

2.7.1 To install the Patch-TEA app on your Android smartphone, please go to the official company web page https://www.transtimulation.com/home/products and then tap “Download .apk file”. You may see a pop-up warning you that this file may harm your device. Tap “Download anyway” to continue with the download. Then, tap “App installation instructions” link on the same web page and follow the instructions. Once the installation is complete, you will see the Patch-TEA app icon on the smartphone, as shown on Figure 6.

Figure 6: Patch-TEA app icon

2.7.2 Launch the Patch-TEA app, as shown on Figure 7. When launching the Patch-TEA app for the first time, you might be asked to allow the app permissions, please tap “Allow” to agree to these permissions.

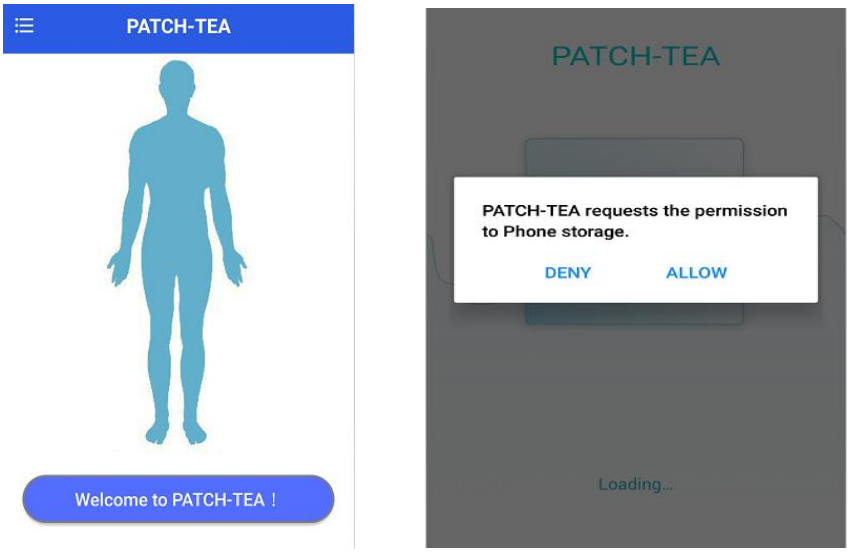


Figure 7: Launch screens

2.7.3 Registration screen. If using the Patch-TEA app for the first time, you will need to register new user account by tapping " Register a new account" and fill out the registration fields, as shown on Figure 8.

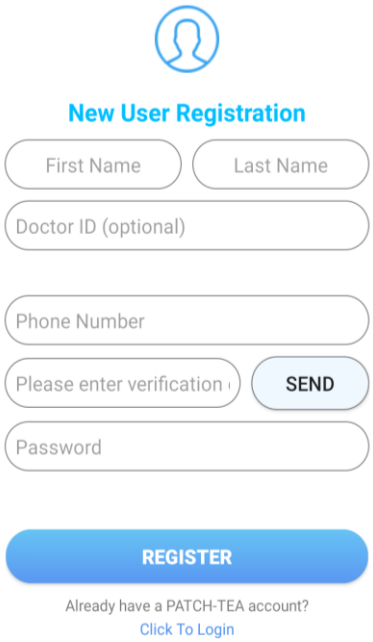


Figure 8: Registration screen

2.7.4 Log-in screen. Please enter user phone number and password on the login screen and then tap “Log In” to enter the app, as shown on Figure 9.

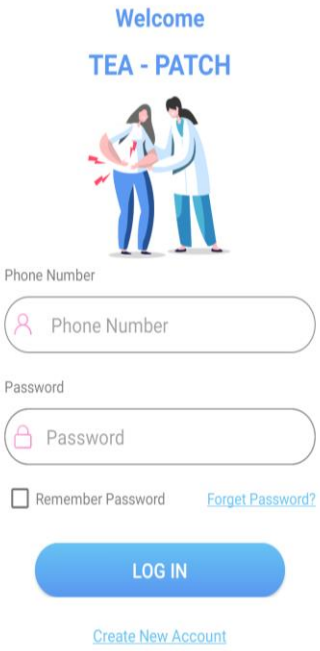


Figure 9: Login screen

If you forgot the account password, please tap "Forgot password" to proceed to the next screen, where you can enter the registered phone number, tap “Send” to receive the one-time password (OTP) by SMS, and enter the OTP for verification to see the account password, as shown on Figure 10.

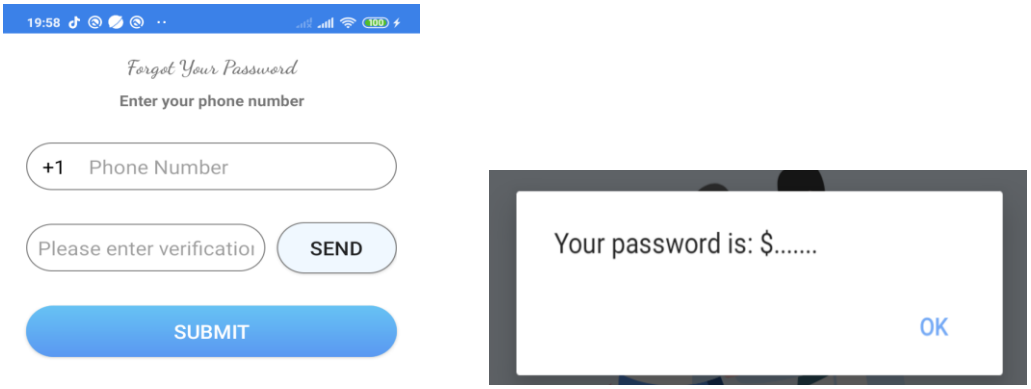


Figure 10: Forgot password screens

2.7.5 Home page

Home page has a menu in the left-top corner with the following menu items, as shown on Figure 11:

- Treatment
- Device Usage
- Reports
- Daily Symptoms
- Help and Feedback
- Logout

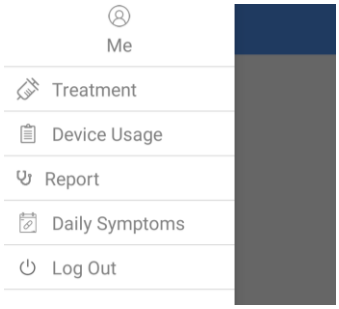


Figure 11: Home page menu

2.7.5 Treatment screen. On this screen, you have the following Treatment options for controlling the Patch-TEA treatment, as shown on Figure 12.

- tap “Search Bluetooth” icon to list all devices are connected to android phone. Once the search is completed, if the Patch-TEA device is connected to the phone, it will be listed below the “Search Bluetooth” icon
- tap “Connect” icon once the listed device to connect
- when connected to the device, you may tap “Delete” icon to disconnect the device

- tap “Download” icon to download the data from the device to phone
- when the electrode pad is attached to the appropriate skin location and connected to the Patch-TEA device, tap ⏻ icon to turn on/off the stimulation (you will see the rainbow above the device icon, when the stimulation is turned on). Each treatment is automatically stopped at specified completion time (60 minutes by default).
- tap ＋ or － icons to increase or decrease the treatment intensity

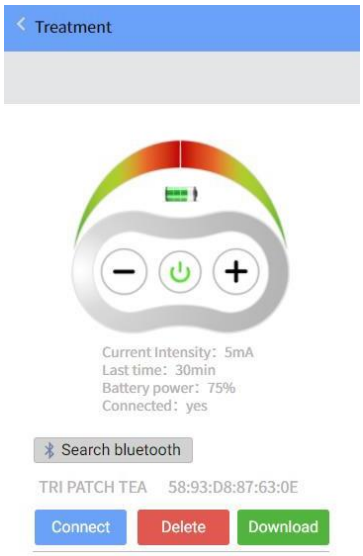


Figure 12: Treatment screen

Adjustments to the frequency, pulse width, and duration of stimulation require consultation with your physician.

Once the treatment is completed, you can exit the app, detach the electrode pad, and place the Patch-TEA device in the charging case for storage and charging.

2.7.6 Device usage screen shows when the device was used and an average current during that usage time. You can specify the device usage range by typing Start time and End time, as shown on Figure 13.

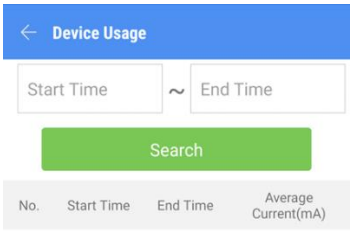


Figure 13: Downloading the treatment log in the app

2.7.7 Reports screen lists all questionnaires that were completed on the Daily Symptoms screen, as shown on Figure 14:

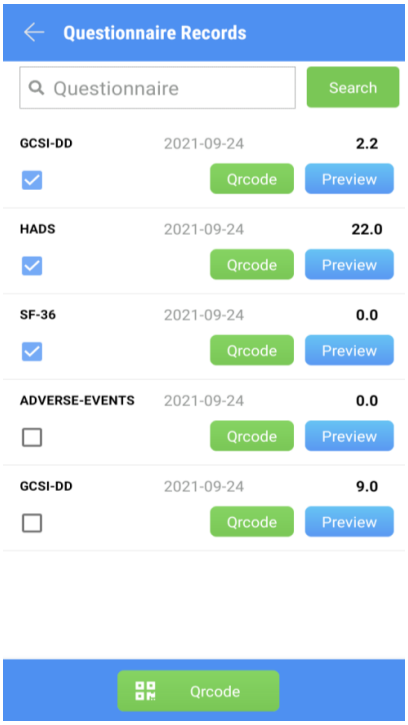


Figure 14: Reports screen

The Reports screen includes the following buttons:

- Search
- QR code
- Preview

- Search button

Tap “Search” to search for previously-entered questionnaires after entering a part of the questionnaire name, as shown in Figure 15.

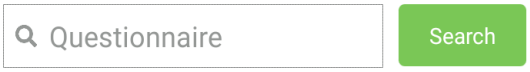


Figure 15: Search button

- QR code button

Tap “QR code” to display the QR code corresponding to a particular questionnaire, as shown in Figure 16. The doctor can scan that QR code using the doctor’s tablet to upload the questionnaire data to that tablet.

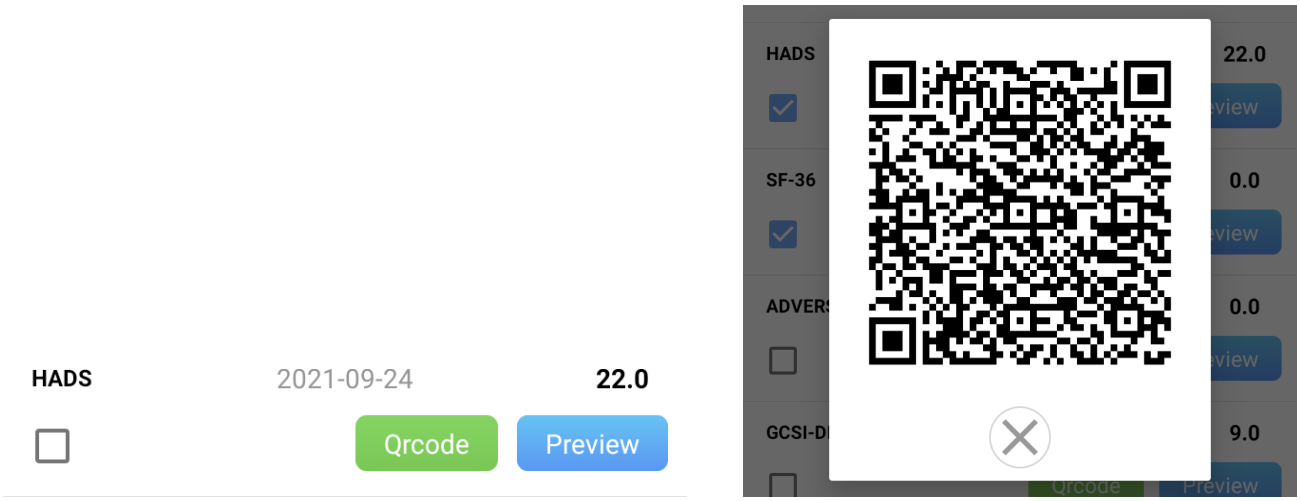


Figure 16: QR code button and the QR code for sending a particular questionnaire

You can send multiple questionnaires to the doctor by ticking the checkboxes next to these questionnaires and tapping “QR code” button at the bottom of the screen, as shown on Figure 17.

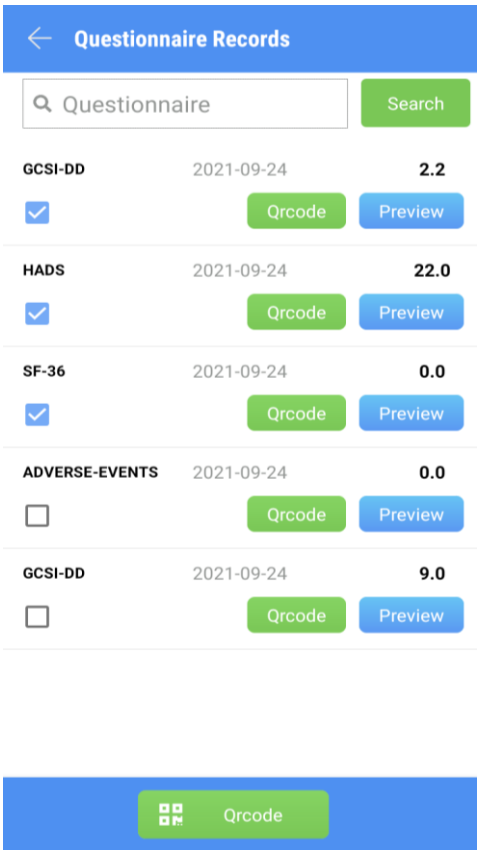


Figure 17: QR code button for sending multiple questionnaires

- Preview button

You can review the questionnaire answers by tapping “Preview” next to the QR code button, as shown on

Figure 18.

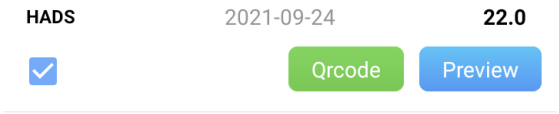


Figure 18: Preview button

2.7.8 Daily Symptoms screen allows selecting the start date for monitoring therapy progression by completing the symptom questionnaires according to the schedule. The start date cannot be modified once the first questionnaire is submitted. The start date is selected, as shown on Figure 19.

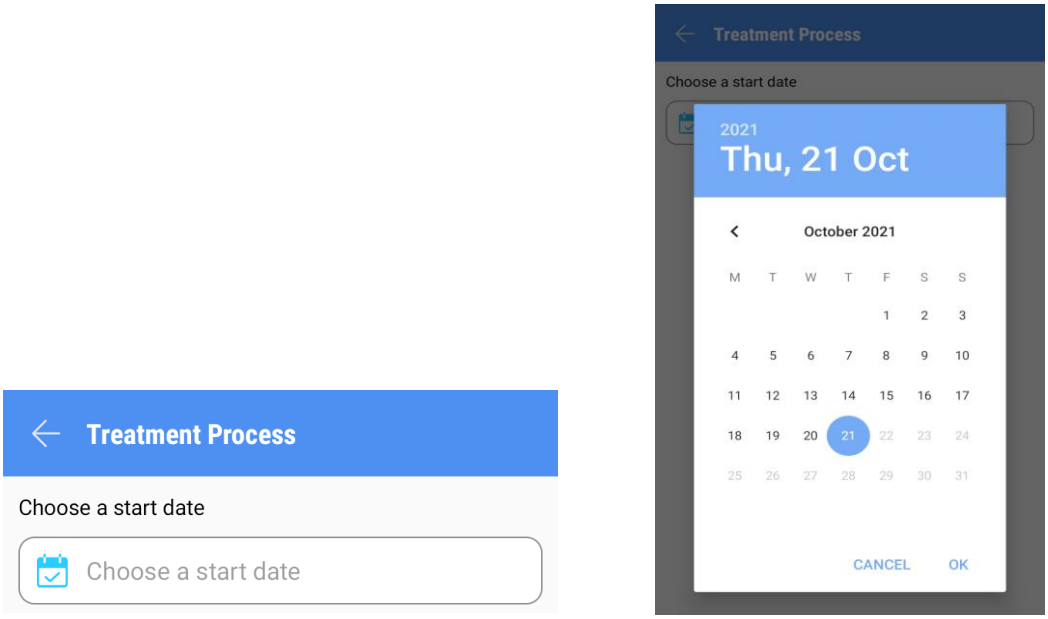


Figure 19: Selecting the start date on Daily Symptoms screen

After selecting the date, the list of upcoming dates (up to 56, beginning from the start date) with corresponding questionnaires is displayed, as shown on Figure 20.

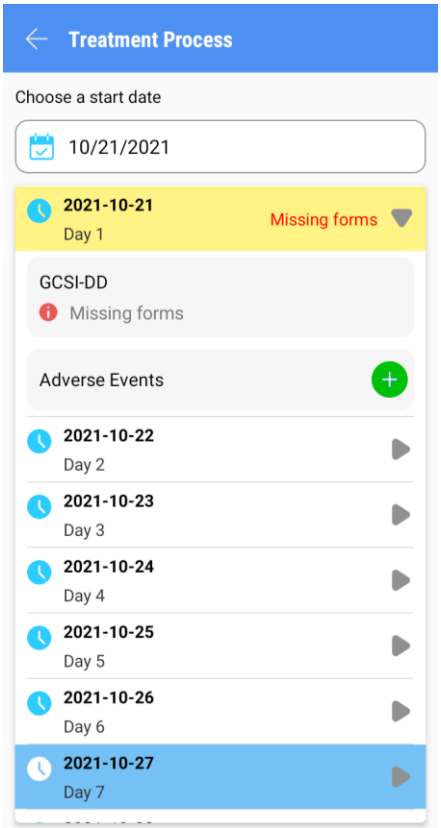


Figure 20: List of dates with corresponding questionnaires on Daily Symptoms screen

In the displayed list of dates, some of them are displayed in yellow to warn you about incomplete questionnaire forms, as shown on Figure 21.

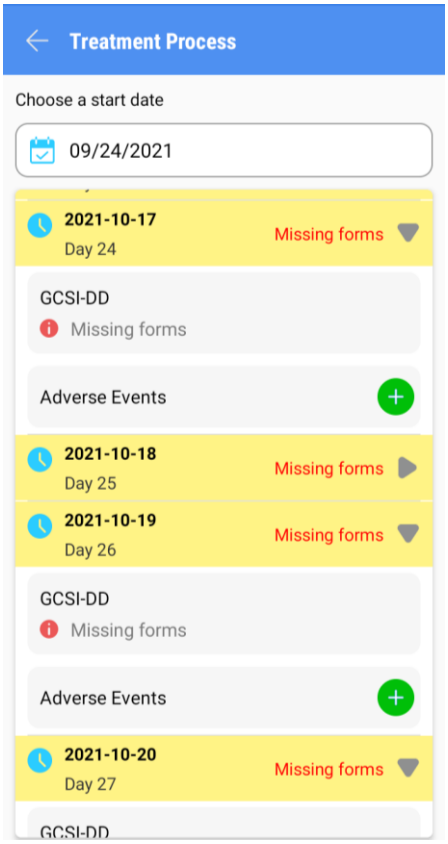


Figure 21: List of dates with incomplete questionnaire forms on Daily Symptoms screen

You can tap on any incomplete questionnaire and finish completing it, then tap “Submit”, as shown on Figure 22.

Figure 22: Submit button for completed questionnaire forms on Daily Symptoms screen

You can also review and re-submit your previously submitted questionnaire by tapping “Preview”, as shown on Figure 23.

Figure 23: Preview and Submit buttons for previously completed questionnaire forms on Daily Symptoms screen

2.7.9 Help and Feedback screen has three tabs: “Patch-TEA Procedure”, “Troubleshooting” , and “About”, as shown on Figure 24. Tap “About” to see the current Patch-TEA app version. Tap “Check for update” and the app will automatically check for the latest app version. If the installed version is the latest version, you will see the message “Your software is up to date”. Otherwise, you will see a message indicating to go to the official

company web page https://www.transtimulation.com/home/products to install the latest version.

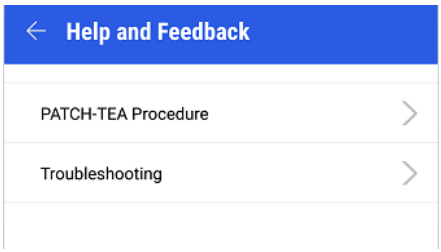


Figure 24. Help and Feedback screen

2.7.10 Tap “Logout” on the Home page menu to exit the app, as shown on Figure 25.

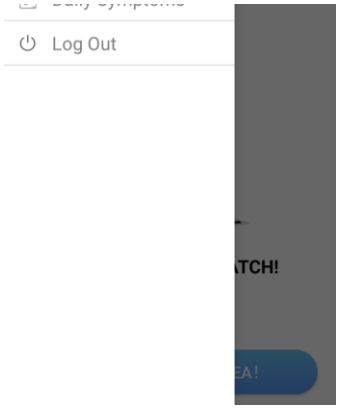


Figure 25: Logout item on the Home page menu

2.7.11 ⚠ ***Cybersecurity warnings***

- *To avoid cybersecurity risks, download the app only from the official company web page https://www.transtimulation.com/home/products.*
- *If a cybersecurity event is suspected to take place, please stop using the app and contact the manufacturer or distributor for technical assistance.*
- *The Patch-TEA device has no ability to automatically restore or recover the settings and access log information in the event of a device (software or hardware) failure or security event. For restoring/resetting the settings and account information, please contact the manufacturer or distributor*.

2.8 Bluetooth wireless technology

2.8.1 Bluetooth Summary

The Patch-TEA device uses Bluetooth communications. Bluetooth is a wireless communications protocol that is designed to operate in short-range wireless personal area networks (WPAN).

The Patch-TEA device supports the Smart (Low Energy) Bluetooth protocol (BLE). BLE, Wireless LAN, and

IEEE 802.15.4/ZigBee protocols share the same 2.4 GHz Industrial Scientific Medical (ISM) band. Within that band, data is transmitted inside one of 40 channels spaced 2 MHz apart.

BLE specification	*Value or value range*
Protocol version	4.2
Class	Class 2
Transmission Distance	Up to 2 m
Frequency Band	2.402 - 2.480 GHz
Data Bandwidth	1 Mbps
Cybersecurity	Signature authentication key for establishing BLE connection using the Elliptic Curve Digital Signature Algorithm (ECDSA) with 256-bit key length and the Cyclic Redundancy Check CRC16; data encryption during BLE transmission using the hardware-accelerated Advanced Encryption Standard (AES) block cypher with 128-bit length; database uses the hardware-accelerated Secure Hash Algorithm SHA256 cypher.
Interference Robustness	Adaptive frequency hopping, Lazy Acknowledgement, 32-bit message integrity check using packet checksum
Modulation	Gaussian frequency shift keying (GFSK)
Latency (from non-connected state)	1000 ms
Transmission Power	Maximal 1 mW
Receiver Sensitivity	Typical -91 dbm, Maximal -94 dbm

2.8.2 Cybersecurity protection

Signature authentication key for BLE connection using the Elliptic Curve Digital Signature Algorithm (ECDSA); data encryption during BLE transmission using the 128-bit Wi-Fi Protected Access-2 Advanced Encryption Standard (WPA2-AES) key with dedicated WPA2-AES-128 processor on DA14580 system-on-a-chip from Dialog Semiconductor; database uses a SHA256 hash algorithm. Users should not share their login details with others. All events are logged to an internal event log. Once the device is returned to the manufacturer, the log can be interpreted and analyzed for possible cybersecurity events. In a case of a detected or suspected cybersecurity event, the cybersecurity incident response plan is activated, which includes capturing and preserving forensic evidence; discovering potential vulnerabilities and finding solutions for mitigating these vulnerabilities; contacting the users with the instructions how to mitigate the discovered vulnerabilities; and potentially also contacting relevant local, state, and federal authorities.

2.8.3 Quality of Service (QoS)

The wireless QoS needed for to assure effective product communication in the Patch-TEA app is optimized for Bluetooth when the product and connected smartphone with Android 6.0 (or later) are within 10 m from each other. The wireless QoS needed for to assure effective product communication for transfer of data to

the Patch-TEA device is optimized when the connected device has adequate Bluetooth connection. If the wireless signal is lost, the data transmission may be interrupted. Data latency and/or the probability of loss of service creates an inconvenience only and does not affect operation of the product or user’s treatment.

2.8.4 User actions and wireless communication delay or failure

The function of the product is not impacted if disruption of the app wireless communication occurs. If the app becomes disconnected from the product during use, remove the product from the radio frequency (RF) field and wirelessly reconnect to their device. Should the user be concerned about the Bluetooth connection for any reason, the user can close the App on the smartphone.

2.8.5 Warning: possible effects from RF sources in the vicinity of the device

When using Patch-TEA device with a smart device, relocate the devices away from sources that may interfere with the Bluetooth connection. The presence of other devices that may create radio frequency interference (RFI) may result in loss of Quality of Service of the Bluetooth connection. Device may cause RFI include but are not limited to the following: other cellular telephones, wireless PC and tablets, pagers, Bluetooth devices, device with remote controls, electromagnetic security systems, RFID or other in-band transmitters.

Chapter 3: Product Maintenance

3.1 Maintenance

If the device and electrode pad are not cleaned according to the requirements, or the electrode pad is not used as required, cross infection between different users may be caused.

After use, the device surface should be thoroughly cleaned.

List of cleaning supplies

- Hand sanitizer (The dosage is enough for you to clear your hands once);
- 70% isopropyl alcohol (About 100 mL);
- Sterile water (About 100 mL);
- Dry and clean soft cloth

Cleaning of Patch-TEA device

Clean the device at room temperature (15-25℃) as described below.

3.1.1 Before performing this cleaning procedure, wash your hands with hand sanitizer.

3.1.2 Remove all residual foreign matters from the device using clean soft cloth immediately after use.

3.1.3 Take a piece of clean soft cloth soaked with 70% isopropyl alcohol to swab on the surface of the device until no visible contaminants remain. Care should be taken not to clean the electrode pad connectors.

3.1.4 Use a piece of clean soft cloth soaked with sterile water to wipe off the cleaning reagent on the surface of the device, until no visible cleaning agent remain. Care should be taken not to clean the electrode pad connectors.

3.1.5 Wipe off with a dry and clean soft cloth to remove residual moisture.

3.1.6 The device should be thoroughly cleaned, inspect the device surface to ensure the device has no visible dirt. If there is still dirt, repeat the steps from 5.1.3 to 5.1.5 until the device is free of dirt.

3.1.7 Check whether there are cracks on the device surface. Don’t try to repair the device, if any damage is observed. Instead, contact the manufacturer or distributor.

Warning:

- Do not use abrasive cleaning reagent, do not use diluent, gasoline, volatile oil and so on to wipe.

- Don’t use other non-recommended methods to perform cleaning.
- Don’t use the abrasive cleaner to clean the device, don’t drop the device in the water or other liquids.
- Ensure that no water penetrates into the device. Should this happen, use the device again only when it is completely dry.
- Do not clean the device during treatment. Be sure that the device is turned off before cleaning.

Cleaning of electrode pads

The electrode pad cannot be cleaned or decontaminated between the uses, If the electrode pad is dirty or contaminated, please replace it with a new one.

For proper maintenance, please place the electrode pad back on the protective film after use and then put it into the zip bag for storage.

Warning: For reasons of hygiene, each electrode pad should be used for single person. If you do not comply with correct cleaning methods and the use of cleaning solutions, the device may be damaged.

3.2 Waste Disposal

Patch-TEA device does not produce any waste during normal use.

Patch-TEA device and its accessories can be treated as electronic medical products in accordance with relevant national environmental protection requirements for treatment and waste disposal.

3.3 Storage

1. Turn the device off and disconnect from the electrode pad.

2. Remove the electrode pad from your skin.

3. Place the electrode pad on the protective film for storage.

4. Keep the Patch-TEA device in the charging case

5. Keep the Patch-TEA device, charging case, and electrode pad in a cool, dry place, at 5-40^{o}C and 25-80% relative humidity.

Please do not store the device in the following places:

- a place of high temperature, humidity, non-ventilation, direct sunlight, dust, or salty air;
- a place where it can be subjected to tilt, vibration, or shock;
- a place that can be easily reached by children;

- chemical storage sites and places where corrosive gases are produced.

Chapter 4: Technical Specifications

General specifications:

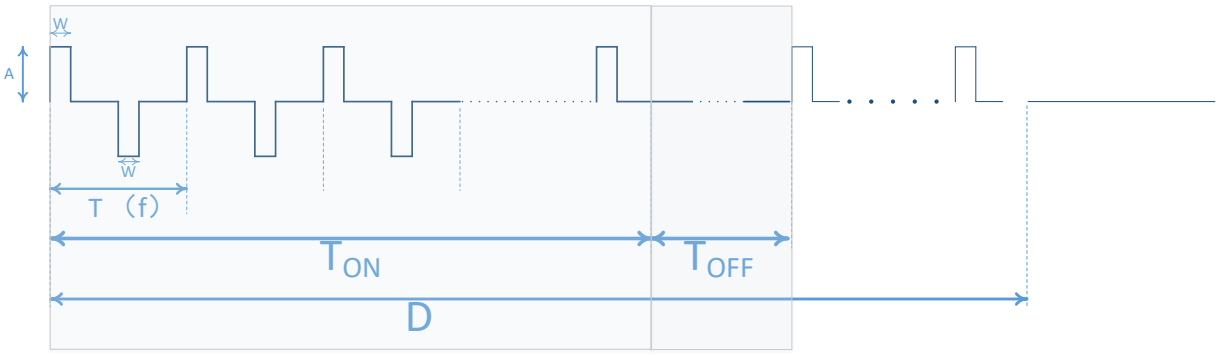
Name	Patch Transcutaneous Electrical Applicator (Patch-TEA)
Model	TEA-21
Power supply	
Power	Internal battery in the Patch-TEA device and charging case
Patch-TEA device battery type	Rechargeable 3.7 V Lithium-Polymer Battery 110 mAh
Patch-TEA device battery life	500 Charge Cycles (≥80% Nominal capacity)
Charging case battery type	Rechargeable 3.7 V Lithium-Polymer Battery 850 mAh
Charging case charging Input	5 V through USB-C connector (USB charging cable is included)
Charging case battery life	500 Charge Cycles (≥80% Nominal capacity)
Stimulation specifications	
Stimulation channels	1
Stimulation waveform	Rectangular alternating
Stimulation modes	Continuous, Burst
Maximum output voltage	5 V @ 500 Ω, 20 V @ 2 kΩ, 55 V @ 10 kΩ
Maximum output current	10 mA @ 500 Ω, 10 mA @ @ 2 kΩ, 5.5 mA @ 10 kΩ
Current or voltage regulation	Current regulation
Stimulation pulse width range	50 – 500 μs
Stimulation frequency range	1 – 100 Hz
Treatment time range	5 – 240 min (default 60 min)
Device service life	5 years
Automatic shutoff	300 ± 10 s
Electrode pad physical specifications	
Type	Self-adhesive (single-use)
Inter-electrode spacing	30 mm
Electrode shape and size	Round, diameter 10 mm
Connector type	Proprietary
Patch-TEA device physical specifications	
Dimensions	50 × 28 × 11 mm
Weight	13 g
Housing	ABS plastic

Charging case physical specifications	
Dimensions	76 × 44 × 31 mm
Weight	60 g
Housing	ABS plastic
Environment	
Operating/storage/transport temperature	5 to 40℃
Operating/storage/transport humidity	25% to 80% RH
Storage/transport atmospheric pressure	70 to 106 kPa
Electric shock	Internally Powered Equipment, type BF Applied Parts
IP Rating	IP22
Classification of safety levels	Not suitable in the presence of flammable mixtures
Running mode	Continuous Operation
EMC	Group 1, Class B
Smartphone compatibility	
Google Android	Android 9.0 (or later) smartphone with Bluetooth 4.2 (or higher)
Apple iOS	Not supported
Bluetooth specifications	
Protocol version	4.2
Class	Class 2
Transmission Distance	Up to 2 m
Frequency Band	2.402 - 2.480 GHz
Data Bandwidth	1 Mbps
Cybersecurity	Signature authentication key for establishing BLE connection using the Elliptic Curve Digital Signature Algorithm (ECDSA) with 256-bit key length and the Cyclic Redundancy Check CRC16; data encryption during BLE transmission using the hardware-accelerated Advanced Encryption Standard (AES) block cypher with 128-bit length; database uses the hardware-accelerated Secure Hash Algorithm SHA256 cypher.
Interference Robustness	Adaptive frequency hopping, Lazy Acknowledgement, 32-bit message integrity check using packet checksum
Modulation	Gaussian frequency shift keying (GFSK)
Latency (from non-connected state)	1000 ms
Transmission Power	Maximal 1 mW
Receiver Sensitivity	Typical -91 dbm, Maximal -94 dbm

Stimulation pulse parameters

Parameter	Value			
	Minimum	Maximum	Factory Defaults	Unit
Stimulation pulse frequency	1	100	25	Hz
Stimulation pulse width (PW)	50	500	500	μs
Output current	0.5	10.0	0.5	mA
Treatment time	5	240	60	min
Stimulation mode	Continuous and Burst modes		Burst mode (2s on, 3s off)	-

Waveform:



Chapter 5: Electromagnetic Compatibility Statement

Patch-TEA device has been tested and found to comply with the limits for both immunity and emissions of the medical device standard IEC 60601-1-2:2014. It is suitable for use in professional healthcare facility and home environments. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation.

For the purpose of its operation, this device has wireless communication function, including RF transmitter and receiver at 2.4 GHz with pulse modulation that radiate RF energy and, if not installed and used in accordance with the instructions, may cause harmful interference to RF communications of other equipment in the vicinity. However, there is no guarantee that interference will not occur in a particular installation. If this device does cause harmful interference to radio or television reception, which can be determined by turning the device off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Use of this device adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is unavoidable, this device and the other equipment should be observed to verify that they are operating normally.
- The use of accessories, transducers and cables other than those specified or provided by the manufacturer or distributor could result in increased electromagnetic emissions or decreased electromagnetic immunity of this device and result in improper operation.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the device, including cables specified by the manufacturer. Otherwise, degradation of the performance of this device could result.
- When the AC power supply is unplugged, the battery charging will stop; and when the AC power supply is plugged back, the battery charging will resume automatically. These operations are normal risks and it will not result in risks to basic safety or essential performance.
- If the use location is near (e.g. less than 1.5 km from) AM, FM or TV broadcast antennas, before using this device, it should be observed to verify that it is operating normally to assure that this device remains safe with regard to electromagnetic disturbances throughout the expected service life.

⚠ **Caution**

Security, radiofrequency identification (RFID) devices, electromagnetic anti-theft systems in stores and libraries (e.g. tag deactivation devices), and metal detectors at entrances/exits of stores, libraries, and other public places, and airport security screening devices may affect the Patch-TEA device. Please do not use Patch-TEA device near these places. If you have to use one of these devices, turn off your Patch-TEA device beforehand.

Using Computed Tomography (CT), diathermy, and electrocautery procedures near Patch-TEA device may cause its malfunction or damage. Please do not use Patch-TEA device during these procedures. The Patch-TEA device should not be brought into the Magnetic Resonance (MR) environment, as the device is MR Unsafe and may present a projectile hazard.

Before each usage, check the status of your Patch-TEA device to ensure it can operate normally.

Patch-TEA device is intended for use in the electromagnetic environment specified in Tables 1 and 2; and the user should assure that it is used in such an environment. When your Patch-TEA device is operated within the specified electromagnetic environment, it will remain safe and provide the following essential performance: stimulation output in accordance with set parameters (no erroneous output).

Table 1: Guidance and manufacture's declaration – Electromagnetic Emission

Emission test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	Patch-TEA device 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	Patch-TEA device is suitable for use in all environments including professional healthcare facility and home environment
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations and flicker emissions; IEC 61000-3-3	Complies	

Table 2: Guidance and manufacture's declaration – Electromagnetic Immunity

Immunity test	**IEC 60601-1-2 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge IEC 61000-4-2:2008	±8kV contact; ±2kV, ±4kV, ±8kV, ±15 kV air	±8kV contact; ±2kV, ±4kV, ±8kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Radiated RF Electromagnetic fields IEC 61000-4-3:2006 + A1:2007 + A2:2010	10 V/m, 80MHz – 2.7GHz 80% AM at 1kHz	10 V/m, 80MHz – 2.7GHz 80% AM at 1kHz	Professional healthcare facility and home environment
Proximity fields from RF wireless communications equipment IEC 61000-4-3:2006 + A1:2007 + A2:2010	See Table 3	Complies	Professional healthcare facility and home environment
Electrical Fast Transients and Bursts IEC 61000-4-4:2012	±2 kV, 100kHz for power supply line	±2 kV, 100kHz for power supply line	The quality of power supply should be that of a typical professional healthcare facility and home environment

Surges IEC 61000-4-5:2005	±0.5 kV, ±1 kV line to ground	±0.5 kV, ±1 kV line to ground	The quality of power supply should be that of a typical professional healthcare facility and home environment
Conducted disturbance Induced by RF Fields (150kHz to 80MHz) IEC 61000-4-6:2013	3V for full spectrum and 6V for ISM bands 80% AM at 1kHz	3V	The user can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF equipment (transmitters) and the device as described in Table 4.
Rated power frequency magnetic fields IEC 61000-4-8:2009	30 A/m 50 Hz and 60 Hz	30 A/m 50 Hz	Professional healthcare facility and home environment
Voltage Dips, Short Interruptions and Voltage Variations IEC 61000-4-11:2004	0% UT at 0.5T, 1T, 250T 70% UT at 25T	0% UT at 0.5T, 1T, 250T 70% UT at 25T	The quality of power supply should be that of a typical professional healthcare facility and home environment

Table 3: Proximity fields from RF wireless communications equipment

Recommended minimum separation distance is 30 cm (12 inch) in the professional healthcare facility and home environment.

Frequency (MHz)	**Band** (MHz)	**Modulation**	**Maximum power** (W)	**Test Level** (V/m)
385	380 – 390	Pulse modulation 18 Hz	1.8	27
450	430 – 470	FM ± 5 kHz deviation, 1 kHz sine	2	28
710	704 – 787	Pulse modulation 217 Hz	0.2	9
745				
780				
810	800 – 960	Pulse modulation 18 Hz	2	28
870				
930				
1 720	1700 – 1990	Pulse modulation 217 Hz	2	28
1 845				
1 970				

2 450	2400 – 2570	Pulse modulation 217 Hz	2	28
5 240	5100 – 5800	Pulse modulation 217 Hz	0.2	9
5 500				
5 785				

Table 4: Recommended separation distances between portable and mobile RF communication equipment and Patch-TEA device

The Patch-TEA device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the devices can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Patch-TEA device 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/		
	150kHz ～80MHz $d = 1.2\sqrt{P}$	80MHz ~ 800MHz $d = 1.2\sqrt{P}$	800MHz～2.5GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0. 23
0.1	0. 38	0. 38	0. 73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

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

Note 1: At 80MHz and 800MHz, the separation distance for the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people

Table 5: Manufacturer's declaration of electromagnetic immunity

Patch-TEA devices are intended for use in the electromagnetic environment specified below. The customers or the users of these Patch-TEA devices should assure that it is used in such electromagnetic environment at professional healthcare facility and home environment.

Immunity test	**IEC 60601 Test level**	**Compliance level**	**Electromagnetic environment – guidance**
Conducted RF IEC 61000-4-	3Vrms	3Vrms	Portable and mobile RF communications equipment should be used no closer to any part of Patch-TEA devices, than the recommended separation distance

6 Radiated RF IEC 61000-4-3	150KHz to 80MHz 10 V/m 80 MHz to 2.7 GHz	 10 V/m 80 MHz to 2.7 GHz	calculated from the equation appropriate to the frequency of the transmitter. **Recommend separation distance** d = $1.2\sqrt{P}$ 150KHz-80MHz d = $1.2\sqrt{P}$ 80MHz-800MHz d = $2.3\sqrt{P}$ 800MHz-2.5GHz 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 meters (m). 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: 
Note1: At 80 MHz and 800 MHz, the higher frequency range applies. Note2: 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 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 Patch-TEA devices are used exceeds the applicable RF compliance level above, Patch-TEA device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Patch-TEA device. [b] Over the frequency range 150 kHz to 80MHz, field strengths should be less than 3 V/m.			

Table 6: EMC reference information for two Patch-TEA device cables

Cable	Max. cable length, shielding		Quantity	Cable classification
USB charging cable	0.4 m	Unshielded	1	DC Power

Chapter 6: FCC Statement

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

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the manufacturer or distributor for assistance.

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

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

Modifications not expressly approved by the manufacturer could void the user’s authority to operate the equipment under FCC rules.

Chapter 7: Fault analysis and troubleshooting

Fault	Possible causes	Possible solutions
Patch-TEA device unable to start	Battery is depleted	Charge the battery and then try again
	Software failure	Reset Patch-TEA device to default parameters
Patch-TEA device produces no stimulation	Stimulation intensity is too low	Adjust the stimulation intensity
	Electrode pad damage	Replace the electrode pad
	Software failure	Reset Patch-TEA device to default parameters
Battery module cannot be charged	USB power adapter or USB charging cable failure	contact the customer service for replacement of the USB power adapter or USB charging cable
	Battery does not hold charge	contact the customer service for replacement of the battery
Bluetooth device cannot connect to the Patch-TEA device	Tea app is not correctly installed	Download and reinstall the Patch-TEA app
	Smartphone does not support Patch-TEA app	Refer to the system requirements for the list of compatible smartphones
	Bluetooth use for the Patch-TEA app is not authorized	Go to the Bluetooth Device Settings on the smartphone and authorize Bluetooth use for the Patch-TEA app
	Smartphone and Patch-TEA device are too far away from each other	Reduce the distance between Patch-TEA device and the smartphone and try connecting again
	Software failure	Reset Patch-TEA device to default parameters
Skin redness	Poor adhesion of the electrode pad	Ensure proper adhesion of the electrode pad
	The electrode pad is dirty	Clean or replace the electrode pad

Chapter 8: Product Warranty

Patch-TEA device is covered by a one-year warranty from the date of purchase (proof of purchase is required).

Warranty applies to the Patch-TEA device itself and does not cover the USB charging cable or electrode pads.

Within that period, the manufacturer or distributor will replace your faulty Patch-TEA device at no charge (except shipping & handling fees), provided that the device:

- has been used for the intended purpose and in the manner described in these Instructions for Use
- has not been connected to an unsuitable power source
- has not been subjected to misuse or neglect
- has not been modified or disassembled
- has not been damaged by accidental fall

Legal rights are not affected by this warranty.

To request the warranty service, please contact the manufacturer or distributor.

Chapter 9: Applied Standards

Standard number	Description
IEC 60601-1: 2005+A1:2012	General requirements for basic safety and essential performance
IEC 60601-1-2: 2014	Collateral standard: Electromagnetic disturbances - Requirements and tests
IEC 60601-1-6: 2010+A1:2013	Collateral standard: Usability
IEC 60601-1-11: 2015	Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in homecare environment
IEC 60601-2-10: 2012	Particular requirements for the basic safety and essential performance of nerve and muscle stimulators
IEC 62133-2: 2017	Secondary cells and batteries containing alkaline or other non-acid electrolytes
IEC 62304: 2006+A1:2015	Medical device software - Software life cycle processes
ISO 15223-1: 2016	Symbols to be used with medical devices labels, labeling and information to be supplied
ANSI/AAMI EC12: 2000/(R)2015	Disposable ECG Electrodes
FCC 47 CFR Part 15 Subpart C	Radio Frequency Devices: Intentional Radiators
ISO 10993-5: 2009/(R)2014	Biological Evaluation of Medical Devices: Tests for in vitro cytotoxicity
ISO 10993-10: 2010/(R)2014	Biological Evaluation of Medical Devices: Tests for irritation and skin sensitization
ISO 14971: 2007	Application of Risk Management to Medical Devices

Chapter 10 Reporting adverse events

MedWatch is the Food and Drug Administration's (FDA) program for reporting serious reactions, product quality problems, therapeutic inequivalence/failure, and product use errors with human medical products, including drugs, biologic products, medical devices, dietary supplements, infant formula, and cosmetics.

If you think you or someone in your family has experienced a serious reaction to a medical product, you are encouraged to take the reporting form to your doctor. Your health care provider can provide clinical information based on your medical record that can help FDA evaluate your report.

However, we understand that for a variety of reasons, you may not wish to have the form filled out by your health care provider, or your health care provider may choose not to complete the form. Your health care provider is NOT required to report to the FDA. In these situations, you may complete the Online Reporting Form yourself.

You will receive an acknowledgement from FDA when your report is received. Reports are reviewed by FDA staff. You will be personally contacted only if we need additional information.

Submitting Adverse Event Reports to FDA

Use one of the methods below to submit voluntary adverse event reports to the FDA:

1) **Report Online** at: www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home

2) **Consumer Reporting Form FDA 3500B**. Follow the instructions on the form to either fax or mail it in for submission. For help filling out the form, see MedWatch*Learn*. The form is available at: www.fda.gov/downloads/aboutFDA/reportsmanualsforms/forms/ucm349464.pdf

3) **Call FDA at 1-800-FDA-1088** to report by telephone

a) **Reporting Form FDA 3500** commonly used by health professionals. The form is available at: www.fda.gov/downloads/aboutFDA/reportmanualsforms/forms/ucm163919.pdf

Manufacturer information

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