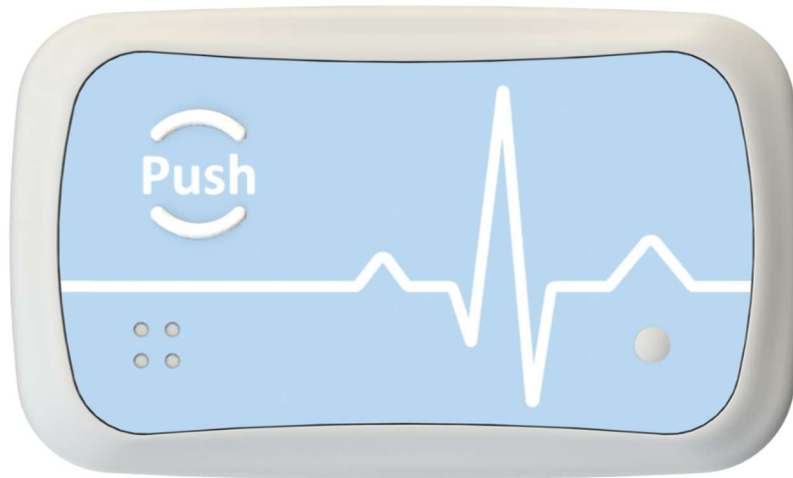


Trident® 30M

Mobile Patch Monitor



Operator Manual

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Description

Caution: US Federal law restricts this device to sale by or on the order of a physician.

The Trident® 30M is an accurate, reliable, and user-friendly ambulatory electrocardiograph recorder for use in mobile cardiovascular telemetry. It is capable of continuously recording 3 channels of patient ECG data using either a single patch electrode or 3 surface electrodes adhered to the body while operating for over 7 days. Recording durations up to 30 days are possible by providing the patient with a recharging cable. The Trident® 30M employs a rechargeable lithium polymer battery to achieve such an extended recording duration. Its compact and stylish design is discreet and comfortable to wear.

The Trident® 30M provides the ability to automatically detect and record pacemaker activity as well as several common arrhythmias in accordance with the applicable standards of the International Electrotechnical Commission (IEC).

The Trident® 30M contains an internal Wi-Fi modem to allow access to the patient ECG data and analysis results. Any piece of data recorded on the device may be queried wirelessly during the course of the study. Additionally, data transmissions may be triggered automatically or manually as a result of arrhythmia analysis, or manual patient input, respectively.

The Trident® 30M provides a multitude of options to control recording parameters such as sampling rate, frequency response, and analysis parameters such as heart rate thresholds. These settings may be updated wirelessly during the course of a study to allow the device to dynamically adapt to the needs of the operator.

Note: The Trident® 30M does not provide interpretive or diagnostic statements. Interpretation and diagnosis are the responsibilities of a trained healthcare professional or physician.

Indications for Use

The Trident® 30M is intended for acquiring ambulatory ECG signals from patients who either are at risk of having cardiac disease or have intermittent symptoms indicative of cardiac disease and who have demonstrated a need to be monitored on a continuing basis.

Patients include, but are not limited to:

- Patients requiring monitoring for non-life-threatening arrhythmias such as supraventricular tachycardias (e.g. atrial fibrillation, atrial flutter, PACS, PSVT) and ventricular ectopy.
- Patients requiring monitoring for evaluation of brady arrhythmias and intermittent bundle branch block including after cardiovascular surgery and myocardial infarction.
- Patients requiring monitoring for arrhythmias associated with co-morbid conditions such as hyperthyroidism or chronic lung disease.

Patients with symptoms that may be due to cardiac arrhythmias in which arrhythmias are suspected or need to be excluded. These may include, but are not limited to, symptoms such as:

- a. syncope of unknown etiology.
 - b. dyspnea (shortness of breath).
- Patients with palpitations with or without known arrhythmias to obtain correlation or arrhythmias with symptoms.
 - Patients who require monitoring of the effects of drugs to control ventricular rate in atrial arrhythmias (e.g. atrial fibrillation).
 - Patients recovering from cardiac surgery who are indicated for outpatient arrhythmia monitoring.
 - Patients with diagnosed sleep disorders, including sleep apnea (obstructive central) to evaluate possible nocturnal arrhythmias.
 - Patients requiring arrhythmia evaluation of etiology of stroke or transient cerebral ischemia, possibly secondary to atrial fibrillation or flutter.

Data from this device may be used by another device to analyze, measure or report QT interval. The device is not intended to sound any alarms for QT interval changes.

Contraindications

The Trident® 30M is not intended for use under the following conditions:

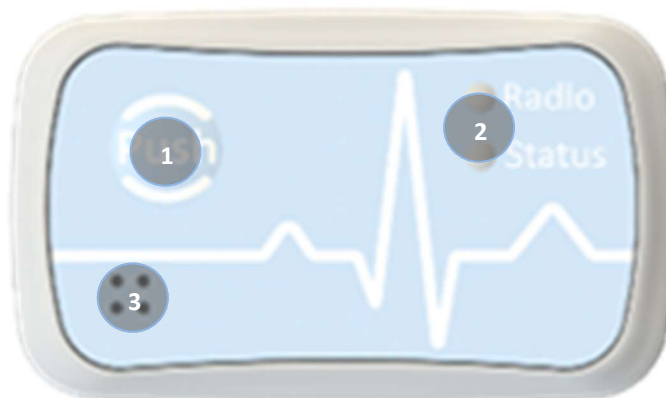
- Patients with potentially life-threatening arrhythmias who require inpatient monitoring.
- Patients who the attending physician thinks should be hospitalized.

Note:

The Trident® 30M system does not provide interpretive or diagnostic statements. Interpretation and diagnosis are the responsibility of a trained healthcare professional or physician.

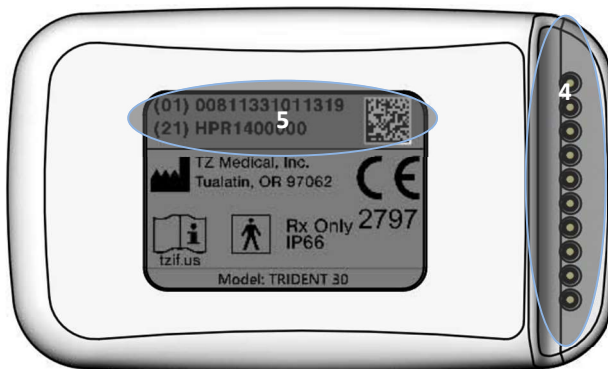
Recorder Components

1. Event Button
2. Indicator LEDs
3. Speaker



Front view of the Trident® 30M.

4. Electrode Patch Connector
5. Serial Number



Back view of the Trident® 30M.

Equipment Symbols

	Atmospheric Pressure Limitation
	Caution
	CE Mark
	Consult the electronic Directions for Use
	Country of Manufacture
	Electrically Isolated
	Temperature Limit
	Humidity Limitation
	Manufacturer Info
	Medical Device
Rx Only	Prescription Only
	Type BF device

Device Overview



Device has ingress rating of IP66 in accordance with IEC 60529



Recycling Symbol - Do not dispose of this product as unsorted municipal waste. Prepare this product for reuse or separate collection as specified by Directive 2002/96/EC of the European Parliament and the Council of the European Union on Waste Electronic and Electrical Equipment (WEEE). If this product is contaminated, this directive does not apply.

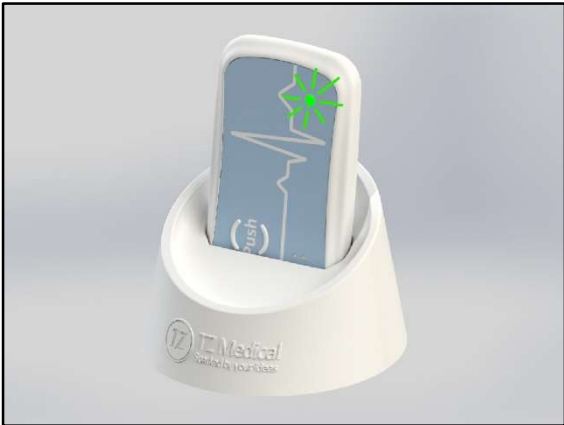
Precautions

- Use only patch electrodes or lanyard cables provided by TZ Medical with the Trident® 30M.
- Re-using accessory items labeled “Single-Use” is not recommended and may increase the risk of patient cross-contamination.
- Disconnect patient leads before defibrillation.
- To reduce the risks of strangulation or asphyxiation do not leave electrode cables accessible to infants or children. Carefully route the electrode cables to reduce the possibility of entanglement or strangulation during use.
- False positive and false negative pacer pulse detects may occur when using Pacemaker Pulse Detection.
 - False positives – may result from poor electrode connection to the patient or a large amount of electrical interference from nearby source.
 - False negatives – may occur with pacemakers that are bipolar because of a weak pacemaker pulse signal at the patient’s skin.
- When viewing the ECG data, the presence of pacemaker signals in the ECG trace should not be considered true representations of the actual pacemaker stimulus amplitude.
- To receive the best recording results, instruct patients to stay away from heavy electrical equipment or other sources of electromagnetic interference. This includes equipment such as electric blankets and heating pads.
- Do not expose device to extreme temperatures (beyond the limits shown in the environmental specifications).
- Do not allow conductive parts of the Trident® 30M patient electrodes to contact other conductive parts including earth.
- Allow 2 hours for the Trident® 30M to warm from the minimum storage temperature or cool from the maximum storage temperature before operating the device.
- The Trident® 30M device should only be connected to a PC certified to IEC 60950-1 when using the Trident® Nano Single-Bay USB Dock (PN: HPR-0055).
- The disposable patient electrode uses medical adhesives approved for long term skin contact. Consult with a physician to ensure your skin can support long term adhesive contact prior to wearing the Trident® 30M device.
- Patients’ skin integrity shall be evaluated by healthcare professional prior to electrode application.
- Patients with delicate or sensitive skin may prefer to use the alternate Trident® Nano 3-Electrode Patient Cable with Lanyard (PN: HPR-0057) or Trident Nano 3-Electrode Patient Cable with Lead Clip (PN: HPR-0130), which allows the device to be used with a variety of off-the-shelf medical grade patient electrodes.
- Selecting an aggressive adhesive patch can result in increased skin damage or irritation if skin integrity is not evaluated before selection.
- Changes or modifications made to this equipment not expressly approved by TZ Medical may void the FCC authorization to operate this equipment.
- Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

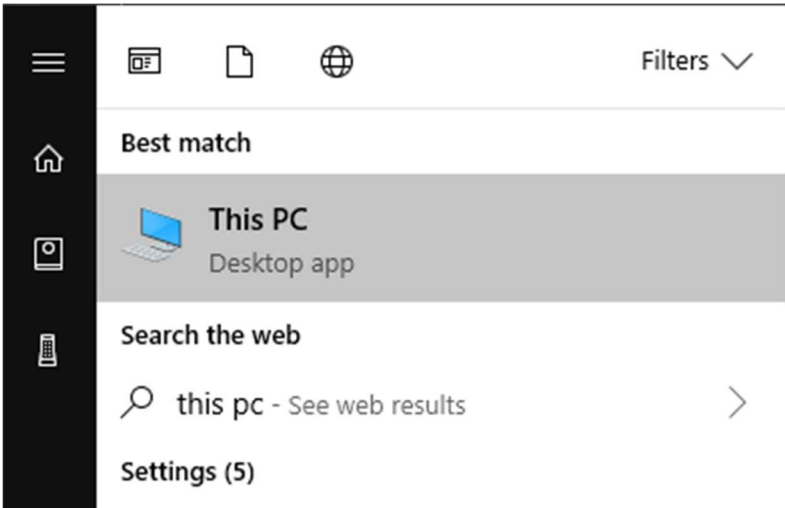
Format and Configure

To prepare a device for patient hookup you will need to format the drive storage and properly configure the settings.

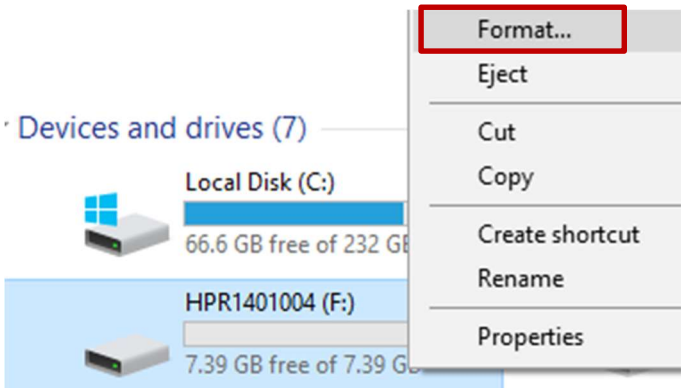
Plug the device into a USB dock attached to a computer running Windows 7 or newer.



Navigate to This PC using the windows start menu.

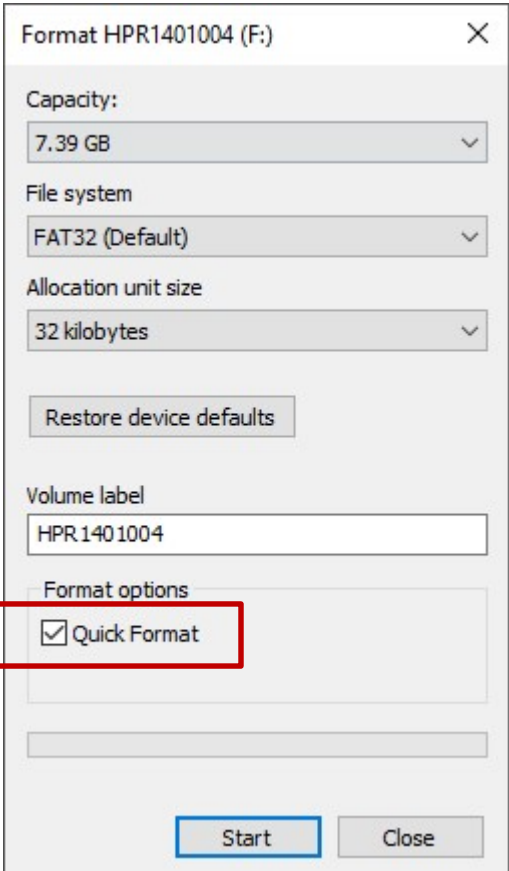


Right-click the device's drive name and select Format.

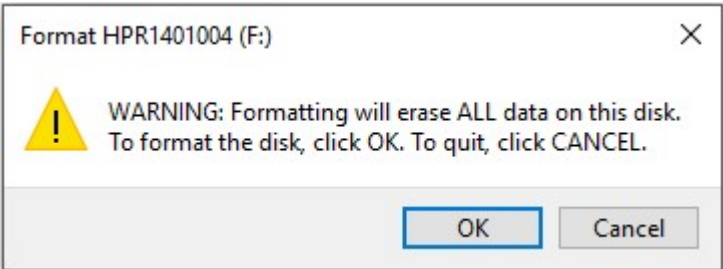


Prepare Device

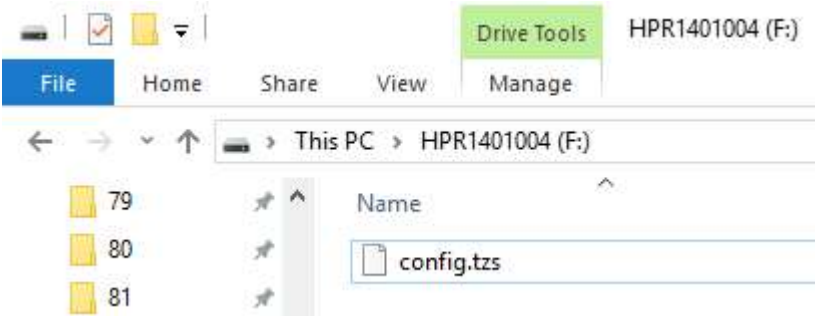
Select Quick Format and click start.



Click OK to the warning. **This will completely erase any patient data on the device.**



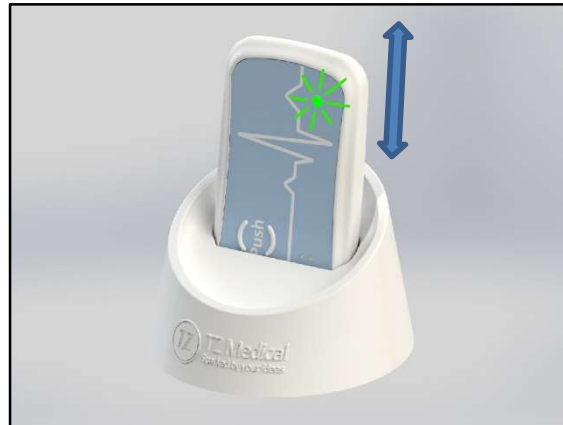
When the format is complete, load the desired configuration file (config.tzs) onto the device.



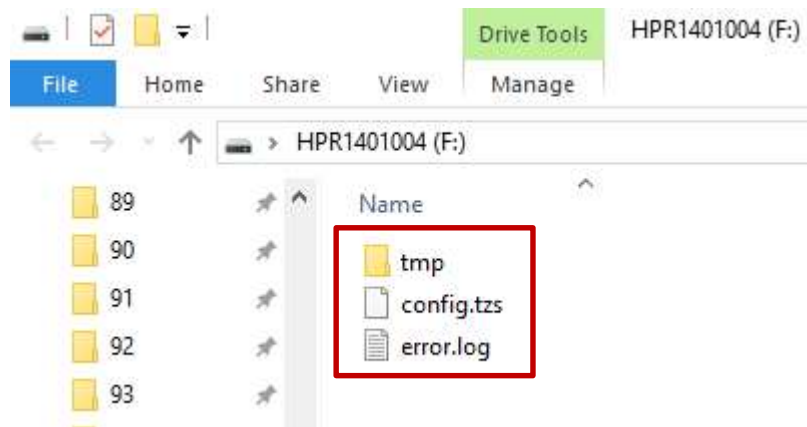
**There are no settings that may be directly modified using the patch module.*

Prepare Device

Reboot the device by briefly removing it from the USB dock and plugging it back in.



Check the device boots with no errors, the drive has no remaining patient data, and the new base structure has been generated.



Check Battery Status

Check that the device has a sufficient battery level for the next study. When plugged into a charger or USB dock, a fully charged device with no data will emit a solid green light. If there is still data on the device and the study is incomplete, it will emit a solid yellow light, and if the study is complete with data, it will emit a solid red light.



Wireless Connections

Connecting to BLE

To connect to the Trident 30M via BLE you will need to pair with the device.

Plug the device into a charging dock



Once the device is finished with bootup press the button to enter ble pairing mode. The Radio LED should begin slowly pulsing blue to indicate pairing mode active



When a successful pair has occurred the Radio LED will turn solid blue for 1 second while playing a tone and then turn off.



Wireless Connections

If no successful pairing occurs within 2 minutes, the device will automatically exit pairing mode. In this case the Radio LED will alternate between solid red and solid blue 5 times over about 1 second while a pairing failed tone is played.



Electrode Patch Application

Preparing the Area

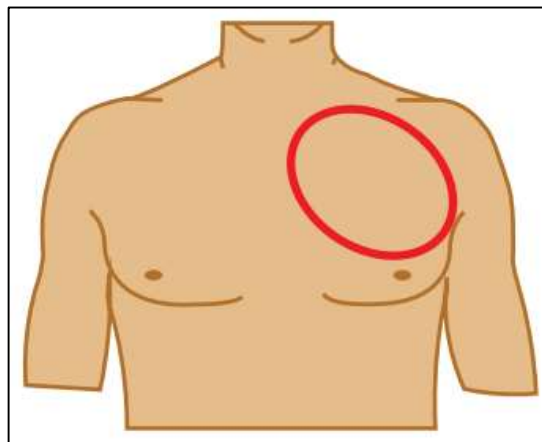
Healthcare Professionals: Evaluate patient skin integrity prior to preparation.

CAUTION: Inappropriate skin preparation can damage the skin or cause irritation.

CAUTION: Selecting an aggressive adhesive patch can result in increased skin damage or irritation if skin integrity is not evaluated before selection.

Prepare the skin where the electrode will be placed:

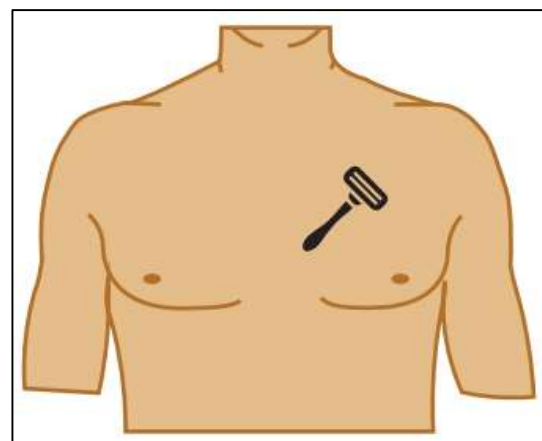
- a. The Trident® 30M Electrode Patch is designed to be worn on the upper left chest.



- b. Shave the application area with a razor to remove hair.
- c. Abrade the area with recommended tool or equivalent to remove dead skin cells

10 abrasive passes each direction with a min. of 50 passes (left---right; right---left; up---down; down---up; diagonal)

Recommended Tool: 3M Red Dot Trace Prep 2236

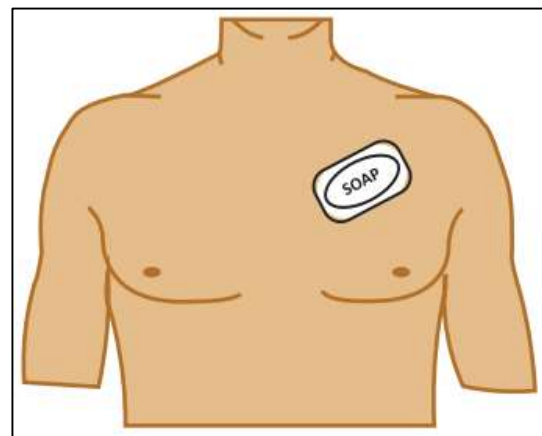


- d. Clean the area with soap and water mixture or isopropyl alcohol to remove natural skin oil.

NOTE: Soap must be oil and fragrant free.

NOTE: Excessive isopropyl alcohol may dehydrate skin.

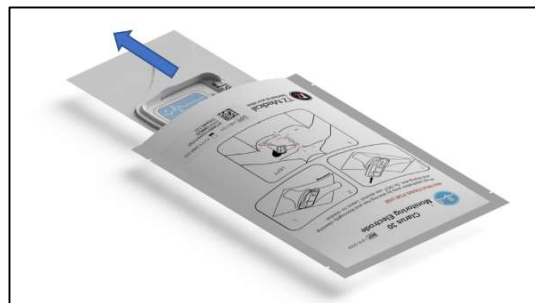
- e. Dry the area with a dry cloth or gauze.



Electrode Patch Application

Starting a Study

Tear open the pouch and remove the electrode.



Slide the recording device into the electrode ensuring the orientation of the device matches the picture on the electrode. The device will power on automatically. After several seconds, the light on the front of the device will turn off.

*(*If the device continually blinks yellow or red, an error has been encountered. Contact your service provider.)*



Peel the release liner from the electrode.

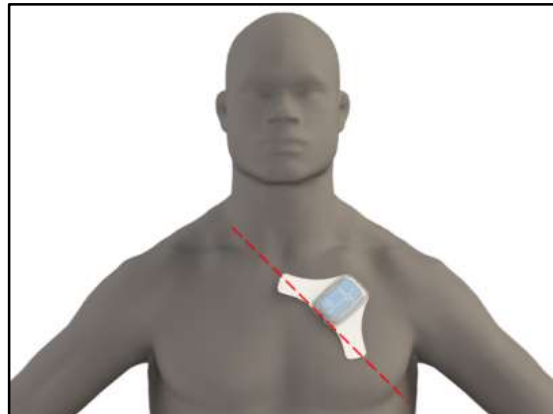


Electrode Patch Application

Place the electrode patch on the chest at a 45° angle. The “wings” of the electrode should span between the sternum and left nipple with the main body towards the left shoulder.

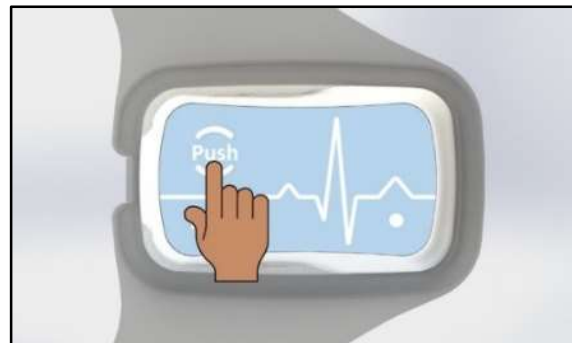
Press down firmly on all parts of the electrode for a minimum of 90 seconds to ensure proper adhesion to the skin.

NOTE: For best practice, have the patient stand with their back against the wall while pressing firmly on the electrode.



Check the recording status by briefly pressing the button and observing the light on the device.

This can easily be done by briefly pressing the button while standing in front of a mirror.



The device should blink green 5 times to indicate everything is functioning properly.

If the device blinks yellow instead, the electrode was not properly adhered. To fix this, remove the device and press down firmly on all parts of the electrode to ensure proper adhesion to the skin.

If the device blinks red, the device was improperly configured. Remove the device and then follow the steps in Prepare Device section.

If the device alternates between green and yellow, the device has low battery. Remove the device and then follow the steps for Charging.

If the device alternates between green and red, the electrode wear time has been exceeded. Remove the device and then follow the electrode application steps with a new electrode.



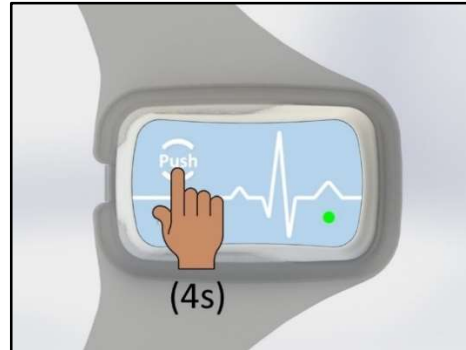
Recording

Electrode Patch Application

During a Study

If the patient feels a symptom while wearing the electrode, they must hold the button for 4 seconds to record the event.

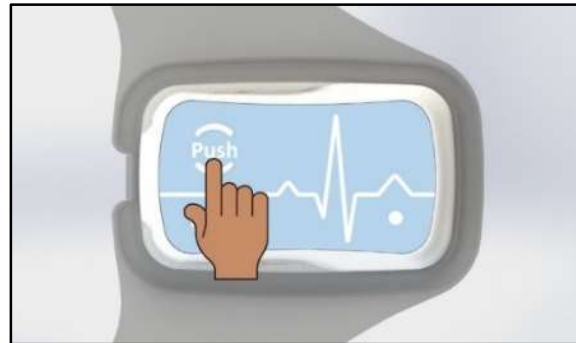
The LED will blink green and an “Event Recorded” tone will play.



Hold the event button for 4 seconds to mark an event.

The patient should check the status of the device every morning to ensure it is working properly. To do so, press the button and observe the light on the device.

This can easily be done by briefly pressing the button while standing in front of a mirror.



The device should blink green 5 times to indicate everything is functioning properly.

If the device blinks yellow instead, the electrode is not properly adhered. To fix this, either press down firmly on all parts of the electrode or remove the module and replace the electrode by following the steps for removal.

If the device blinks red, the recording is complete and the device should be returned for analysis.

If the device alternates between green and yellow, the device has low battery. If a charging dock is provided, the device should be charged before continuing the study. Otherwise, continue the study as normal as long as possible.

If the device alternates between green and red, the electrode wear time has been exceeded. Follow the steps for Extended Studies.



Recording

Electrode Patch Application

Extended Studies

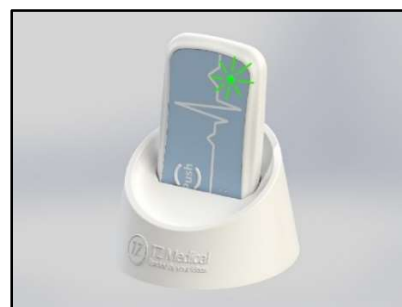
If an extended study has been prescribed to the patient, it may be necessary to replace the electrode and recharge the device after 3-4 days depending on various factors including physical activity, perspiration, skin condition. At this time, it is also recommended to charge the device for 30-40 minutes to provide the highest quality recording.

Before removing the adhesive electrode from the skin, eject the device by firmly pressing on front edge near the power button, and slide until device pops out of place.

Once the device has been removed, slowly peel the electrode from the skin and discard.



Plug the device into the included wall charger and let the device charge until the light on the device no longer blinks.

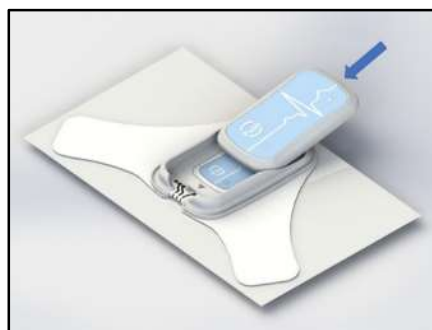


Module charging in a charging dock.



Module fully charged in a charging dock.

Apply a new electrode following the same steps described in Starting a Study above.

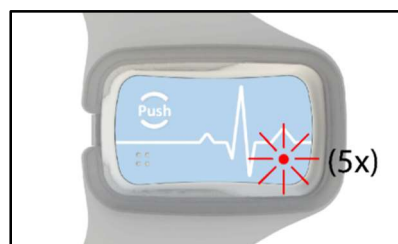


Electrode Patch Application

Ending a Study

The study is ended once the required study time has been reached. It can also be ended early by connecting the device to a PC via USB at any time. Once a study has been ended, the device cannot be used for recording until the data has been removed as described in the Prepare Device section.

The device will blink red 5 times when checking the device's status to indicate the recording is complete



Recording is complete

Once the recording is complete, eject the device by firmly pressing on front edge near the push button, and slide until device pops out of place.

The device should then be returned to the service provider for data retrieval and analysis.



Once the device has been removed, slowly peel the electrode from the skin and discard.

3-Lead Cable Application

Preparing the Area

The Trident® Nano Patient Cable accessory is designed to be worn around the neck and connect to the body via standard snap electrodes.

Justification for Snap Electrodes: TZ Medical does not design or manufacture the standard off-the-shelf medical grade snap electrodes to be used with the Trident® 30 3-Lead Cable. Testing for biocompatibility and functionality has been done by the manufacture for the off-the-shelf medical grade snap electrode.

Prepare the skin where the electrode will be placed:

- If hair is present, shave the area with a razor.
- Clean the area with soap and water, making sure all soap residue is removed afterwards.

Starting a Study with Lanyard

Place the lanyard around the neck.



Snap each lead onto a standard, off-the-shelf medical grade ECG electrode (such as a 3M Red Dot as shown).



Peel the release liners from the electrodes and attach to body as shown making sure to press down firmly to ensure proper adhesion to the skin.



3-Lead Cable Application

Starting a Study with Lead Clip

Ensure the Lead Clip is snapped onto the black lead.



Snap each lead onto a standard, off-the-shelf medical grade ECG electrode (such as a 3M Red Dot as shown).



Peel the release liners from the electrodes and attach to body as shown making sure to press down firmly to ensure proper adhesion to the skin.



3-Lead Cable Application

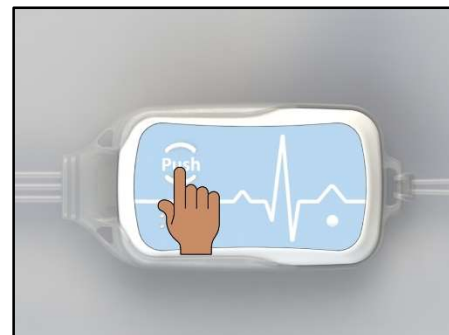
Electrode Color	Application Placement
Black	LA
White	RA
Red	LL

Slide the recording device into the patient lanyard cable. The device will power on automatically. After several seconds, the light on the front of the device will turn off.

*(*If the device continually blinks yellow or red, an error has been encountered. Contact your service provider.)*



Check the recording status by briefly pressing the button and observing the light on the device.

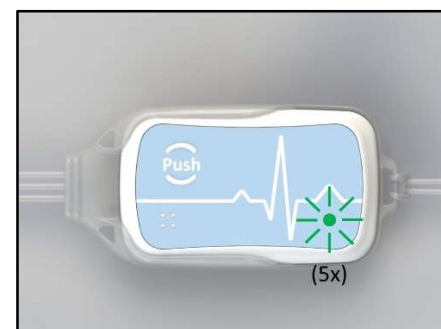


The device should blink green 5 times to indicate everything is functioning properly.

If the device blinks yellow instead, one of the electrodes was not properly adhered. To fix this, press down firmly on each of the electrodes to ensure proper adhesion to the skin.

If the device blinks red, the device was improperly configured. Follow the steps in Prepare Device above.

If the device alternates between green and yellow, the device has low battery. Remove the device and then follow the steps for Charging.

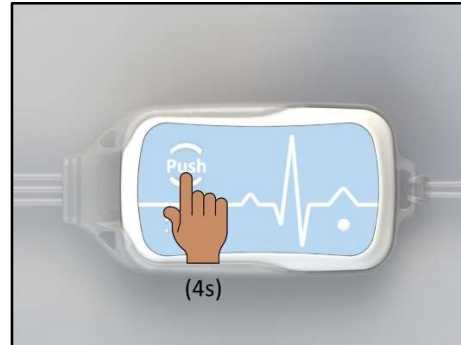


3-Lead Cable Application

During a Study

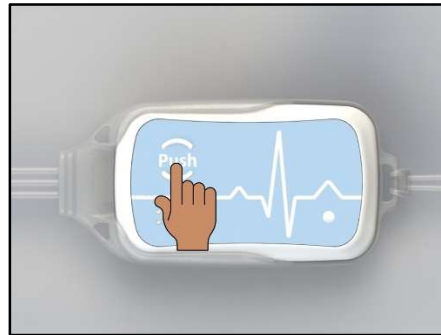
If the patient feels a symptom while wearing the electrode, they must hold the button for 4 seconds to record the event.

The LED will blink green and an “Event Recorded” tone will play.



Hold the event button for 4 seconds to mark an event.

The patient should check the status of the device every morning to ensure it is working properly. To do so, press the button and observe the light on the device.



The device should blink green 5 times to indicate everything is functioning properly.

If the device blinks yellow instead, at least one of the electrodes is not properly adhered. To fix this, press down firmly on each of the electrodes to ensure proper adhesion to the skin.

If the device blinks red, the recording is complete and the device should be returned for analysis.

If the device alternates between green and yellow, the device has low battery. Remove the device and then follow the steps for Charging.



Recording

3-Lead Cable Application

Extended Studies

If an extended study has been prescribed to the patient, the device may need to be recharged.

Eject the device by firmly pressing on front edge near the power button, and slide until device pops out of place.



Plug the device into the included wall charger and let the device charge until the light on the device no longer blinks.



Module charging in a charging dock.



Module fully charged in a charging dock.

Reinsert the device into the cable. It should power on automatically.

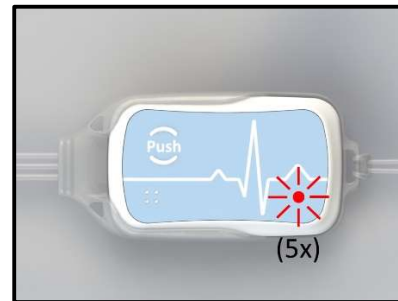


3-Lead Cable Application

Ending a Study

The study is ended once the required study time has been reached. It can also be ended early by connecting the device to a PC via USB at any time. Once a study has been ended, the device cannot be used for recording until the data has been removed as described in the Prepare Device section.

The device will blink red 5 times when checking the device's status to indicate the recording is complete.



Recording is complete

Once the recording is complete, eject the device by firmly pressing on front edge near the power button, and slide until device pops out of place.

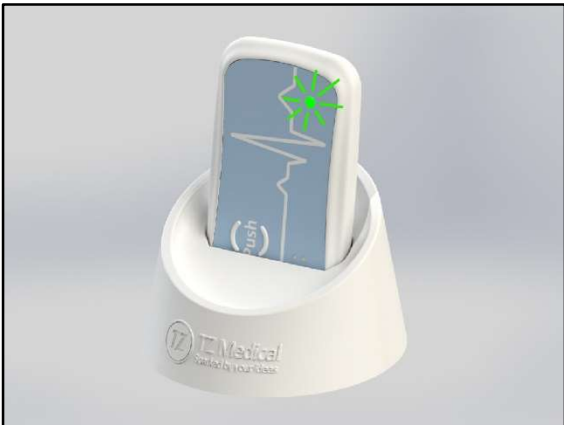
The device and cable should then be returned to the service provider for data retrieval and analysis.



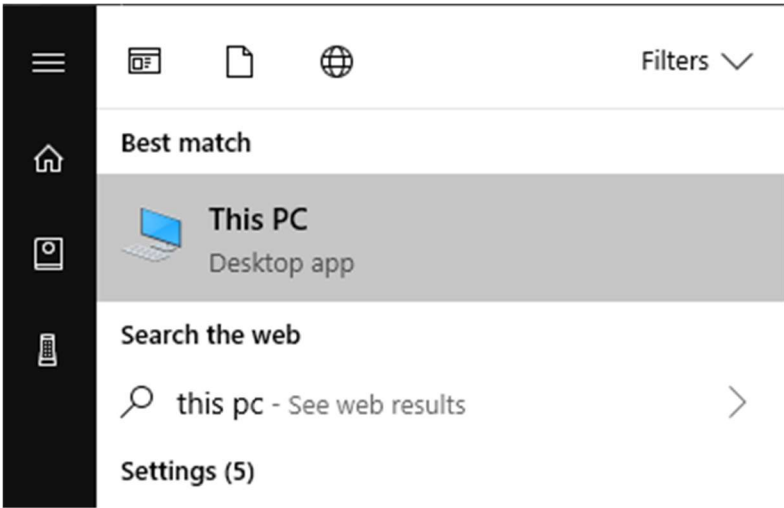
Retrieving Patient Data

Patient data may be retrieved at any time by connecting the module to a PC using the Trident® Nano Single-Bay USB Dock accessory (HPR-0055).

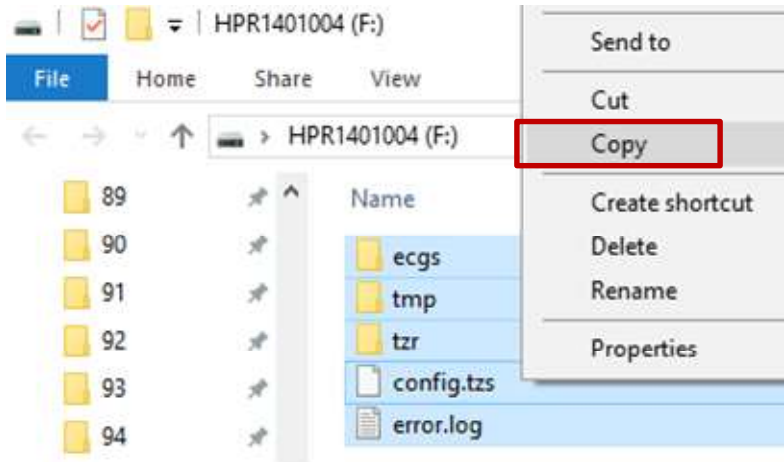
Plug the device into a USB dock attached to a computer running Windows 7 or newer.



Navigate to This PC using the windows start menu.

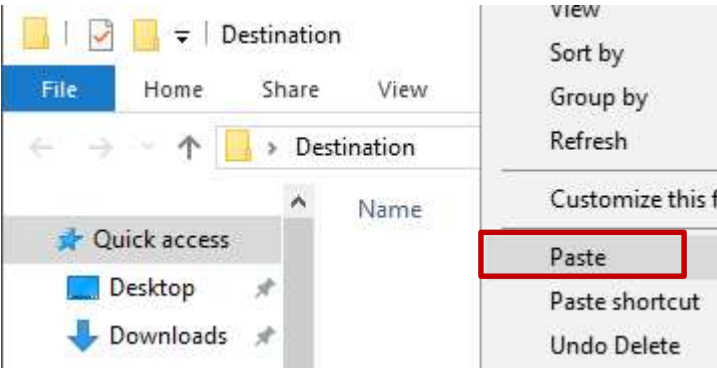


Navigate to the device drive; select everything from the device then right click and select Copy.



After a Study

Navigate to the desired location for the data, then right click and select Paste.

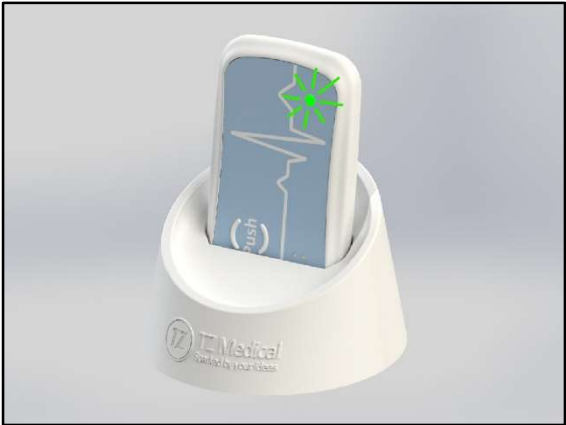


Note: No special steps are required when terminating a study early. Once the device has been connected via USB, it will not record additional ECG data until the patient data has been removed from the device.

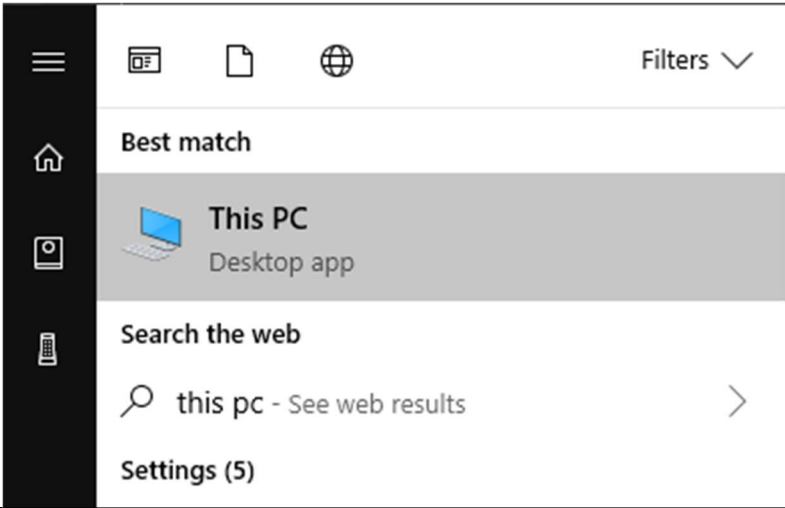
Removing Patient Data

In order to prepare the device for a new study, or if there was a mistake in setting up the device, the Trident® 30M can be easily reformatted.

Plug the device into a USB dock attached to a computer running Windows 7 or newer.

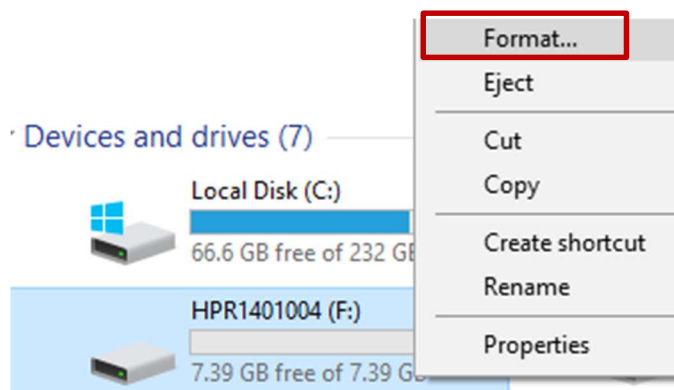


Navigate to This PC using the windows start menu.

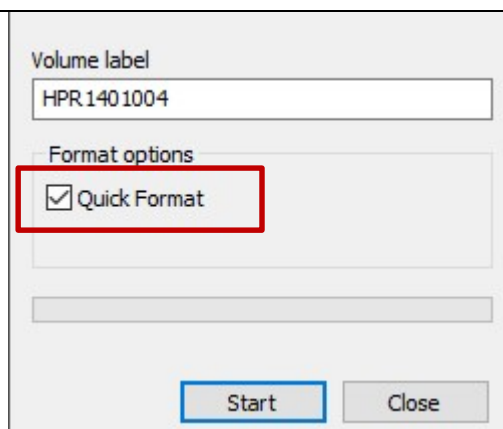


After a Study

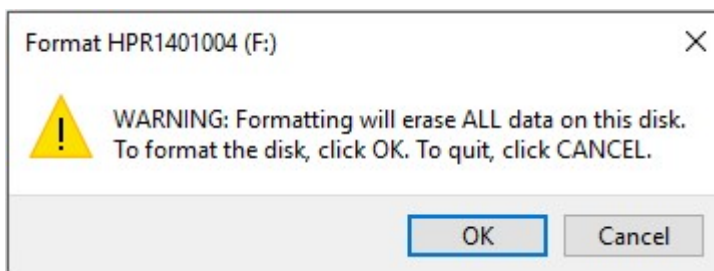
Right-click the device's drive name and select Format.



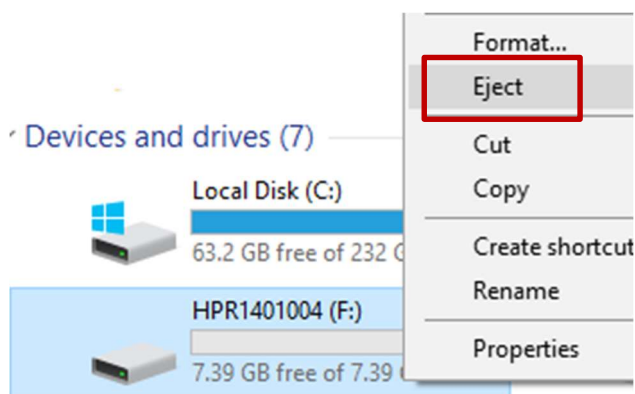
Select Quick Format and click start.



Click OK to the warning*. **This will completely erase any patient data on the device.**



After the device finishes formatting, right click the device's drive name and select Eject to safely remove the device from the computer.

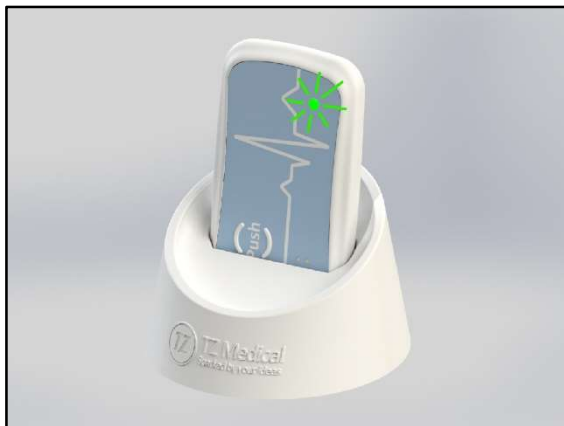


***NOTE:** Make sure that any recording has been uploaded to a computer before reformatting, or else the data will be lost.

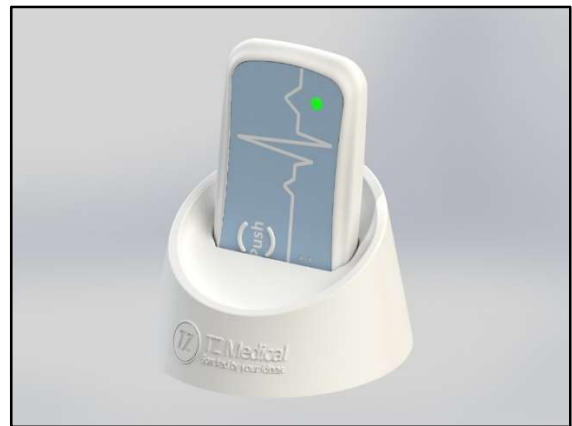
Charging

The Trident® 30M employs a rechargeable lithium-ion battery to meet the demanding power requirements of continuous monitoring. The battery cannot be recharged without interrupting the data recording.

To charge the battery, disconnect the module from the patient electrode patch or lanyard cable and connect the Trident® Nano Single-Bay Charge-Only Dock (HPR-0056). To charge the device between studies, you may either connect the device to the Trident® Nano Single-Bay USB Dock (HPR-0055) or insert the Trident® device into the Trident® Patch 10-Device Charging Dock (HPR-0036). The single bay USB dock also provides USB access to device data. While the Trident® 30M is charging, the green LED on the front of the module will blink once every two and a half (2.5) seconds if the device has no patient data. If any patient data is present, the device will instead blink the red LED on the front. When charging has been completed, the LED on the front of the module will become solidly lit to indicate charging is complete.



Module charging in a charging dock.



Module fully charged in a charging dock.

Patient Use Precautions

The Trident® 30M contains sensitive electronic circuitry. Please observe the following precautions while using the Trident® 30M. Failure to do so may result in serious damage to the device.

Avoid Sharp Impacts

While the Trident® 30M has been designed to survive minor drops, it is possible to damage the internal structure, or outer casing, if the device suffers a sharp impact or is otherwise traumatized. Such use may irreparably damage the Trident® 30M and void its warranty.

Avoid Pulling on Wires

Always disconnect lanyard cables from the device by grasping the plastic cradle connector, not by pulling directly on the wires. Yanking on the wires may result in irreparable damage to the lanyard cables.

Patient Responsibilities

As the patient, you will need to fulfill the following responsibilities while using the Trident® 30M in order to ensure proper detection and analysis of your heart's symptoms.

Keep Electrodes Connected

The Trident® 30M can only record data when it is properly connected to the electrode locations on your body. The device will emit a "Disconnect tone" when the status is checked by the patient and one or more of the electrodes has poor connectivity. If too many of the electrodes become disconnected, the Trident® 30M will be unable to record useful data.

Report Any Heart-Related Events

Hold the button on the front of the device for 4 seconds to mark when you feel any heart-related symptoms.

Showers Only

The electronics module has been designed to be water resistant. You may leave it in place while showering. However, the electrode and module should be dried immediately afterwards.

****DO NOT FULLY SUBMERGE THE DEVICE (SWIMMING, BATHING, ETC.)****

Storage

When not being used for recording data, the Trident® 30M should be stored outside of any electrode patch or lanyard cables to limit battery self-discharge. To wake the Trident® 30M after it has been stored simply install the module into a patient electrode patch or lanyard cable to begin recording. To maximize battery life, it is recommended that for long periods of storage that the device be stored at 50% battery charge in a cool environment.

Cleaning

Do not attempt to submerge, autoclave, or steam clean the Trident® 30M or the patient cable.

Do not use solvents to clean the device. Examples include:

- Ketones or Esters (Acetone, Methyl Ethyl Ketone [MEK], Ethyl Acetate, Benzyl Acetate)
- Strong Bases (Ammonium Hydroxide, etc.)
- Benzene
- Mineral Spirits
- Bleach (chlorine or hypochlorite)

Observe the following procedure to clean the Trident® 30M between patient uses (not applicable to single-use or disposable items):

1. Disconnect the patient cable.
2. Wipe the exterior of the Trident® 30M and its accessories with a damp cloth. Use mild detergent diluted in water or surface wipes such as PDI Super Sani-Cloth® Germicidal Disposable Wipes (“purple top”). Take care not to allow water or moisture to enter the Trident® 30M, especially around the cable contacts. Other acceptable cleaning agents: up to 97% isopropyl alcohol, up to 3% benzyl ammonium chloride.
3. Dry with a clean cloth or paper towel.
4. Clean the patient cable in the same manner before each procedure.

Testing

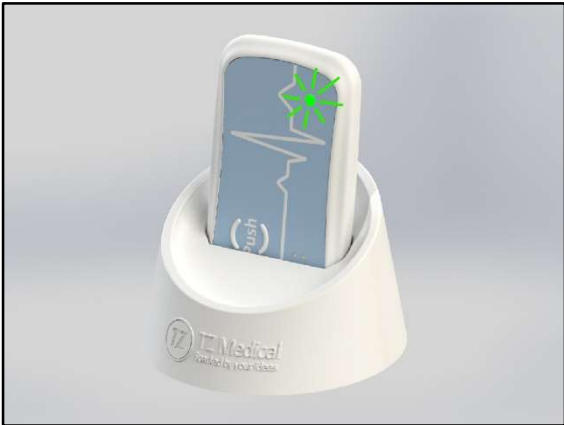
The Trident® 30M recorder performs a comprehensive self-test each time it is powered on. This test is designed to detect any potential problems prior to starting a recording session. In the unlikely event that an error occurs please contact your service provider for further instructions.

To verify the ECG signal path prior to deploying on a patient, simply start a recording then connect a patient lanyard cable between a patient simulator and the device. Remove the module from the lanyard cable, download a portion of the data to ECG reporting software and verify the expected signal shape.

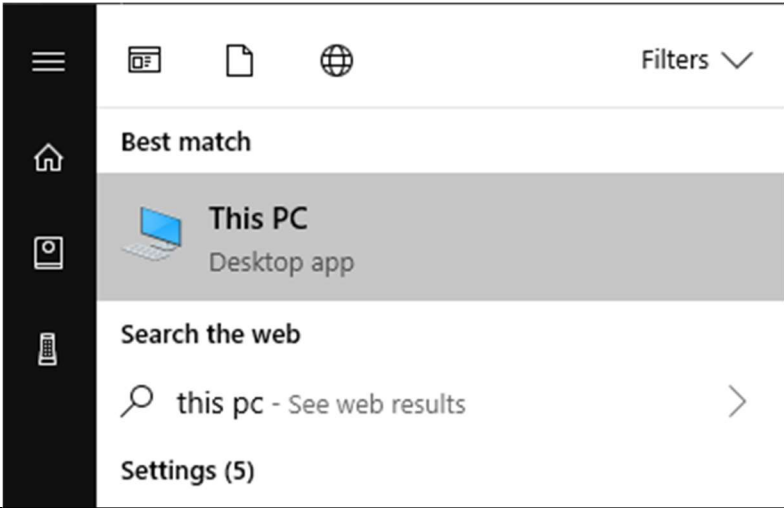
Updating Firmware

To ensure that you have access to the latest features and greatest device stability, it is recommended that the latest version of the Trident® 30M firmware be used. The latest firmware file can always be obtained from BitRhythm.

Plug the device into a USB dock attached to a computer running Windows 7 or newer.

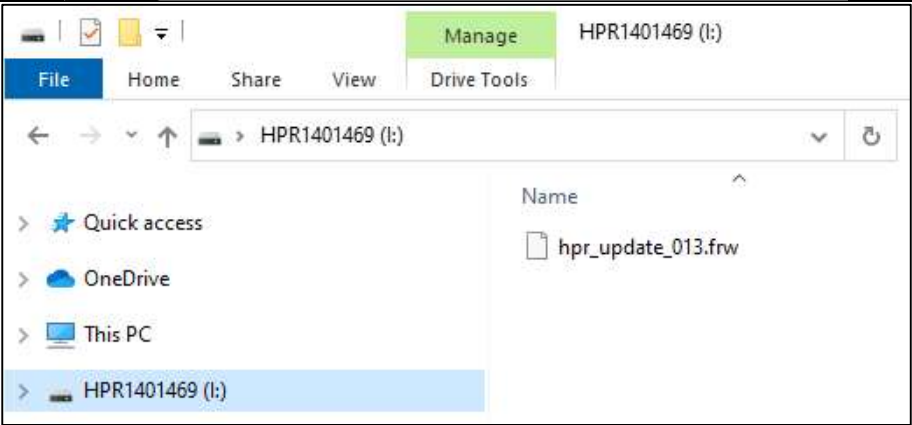


Navigate to This PC using the windows start menu.



Select the device drive, then copy the firmware file onto the device.

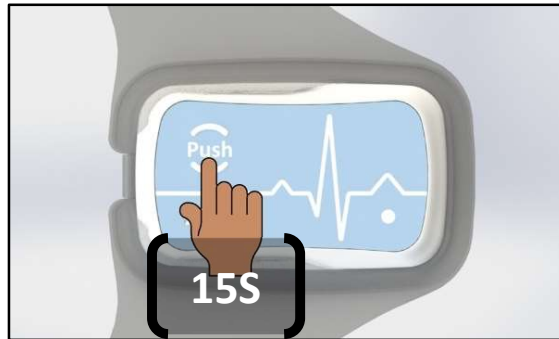
Remove the device from the PC. The next time the device is connected to an accessory or cable, the device will read the new firmware file and update.



Power Cycling the Device

The installed device may be power cycled by pressing and holding the power button for approximately fifteen seconds or until the indicator LED displays the startup sequence.

Note: this method is not preferred but may be needed if the device becomes unresponsive.



Error Alerts

The Trident® 30M has been designed to detect and recover from most error conditions automatically. There are situations that may occur where the device simply cannot recover on its own. In such cases, the Trident® 30M will display an error alert to the user using the indicator LEDs and audible tones.

State	Visual Indication	Audio Indication
Insufficient Battery for Recording	Status LED blinks Yellow slowly (every 2.5 seconds)	None
Insufficient Battery for Bootup	Status LED shows bootup sequence for a short time before abruptly stopping	Power-on tone (<1s)
Generic Error Encountered	Status LED blinks Red rapidly (every 0.3 seconds)	None

Checking the device recording status during a study will sometimes report important information for the user:

State	Visual Indication	Audio Indication
Recording Impaired (Lead Disconnected)	Status LED blinks Yellow 5 times over 2.5 seconds	Lead Disconnect tone (<3s)
Electrode Wear Time Exceeded	Status LED alternates Green and Red 5 times over 2.5 seconds	Wear Time Exceeded tone (<3s)

If the error indicates a problem with electrode lead connectivity, verify all electrodes are properly adhered to the body. Insufficient battery is often reported when a longer study is requested and the device is not fully charged, in which case charging the device should remedy the error. If these two steps do not work, these errors can often be resolved through connecting the Trident® 30M to a computer, and reformatting the device (removing patient data) which erases the recording memory. In the unlikely event the error message persists, please contact your service provider as the device may need to be returned to TZ Medical Inc. for service. See the Warranty section of this manual for instructions on returning a device for service.

Comprehensive LED Indications

If the device was recently plugged into an accessory, the device may be in bootup:

State	Visual Indication	Audio Indication
Power Received	Status LED solid Green	None
Bootup in Progress	Status LED blinks Green rapidly (every 0.42 seconds)	Power-on tone (<1s)
Passed Self-Test	Status LED turns off	Bootup Complete tone (<1s)

If the device is plugged into a Charging Dock, USB Dock, or Multi-Bay USB Dock, refer to the following table:

State	Visual Indication	Audio Indication
Full Charge no Study	Status LED solid Green	None
Full Charge Incomplete Study	Status LED solid Yellow	None
Full Charge Complete Study	Status LED solid Red	None
Charging no Study	Status LED blinking Green slowly (once every 2.5 seconds)	None
Charging Incomplete Study	Status LED blinking Yellow slowly (once every 2.5 seconds)	None
Charging Complete Study	Status LED blinking RED slowly (once every 2.5 seconds)	None
USB data connection terminated	Status LED fades Yellow slowly (once every 2.5 seconds)	USB Disconnect tone (<1s)

If the device is plugged into a recording accessory, the device may be configured to automatically notify of the need to check the device status. In this case, the device will repeat the notification every N seconds as set in the configuration.

State	Visual Indication	Audio Indication
Status Check Needed	Status LED fades Yellow over 1.5 seconds every N seconds	Status Check Needed tone (<1s)

Troubleshooting

If pressing the button results in the Status LED indicating state, refer to the following table:

State	Visual Indication	Audio Indication
Recording in Progress	Status LED blinks Green 5 times over 2.5 seconds	Recording in Progress tone (<1s)
Recording Complete	Status LED blinks Red 5 times over 2.5 seconds	Recording Complete tone (<1s)
Recording Impaired (Lead Disconnected)	Status LED blinks Yellow 5 times over 2.5 seconds	Lead Disconnect tone (<3s)
Low Battery	Status LED alternates Green and Yellow (G-Y-G-Y-G) over 2.5 seconds	Low Battery tone (<3s)
Electrode Wear Time Exceeded	Status LED alternates Green and Red (G-R-G-R-G) over 2.5 seconds	Electrode Wear Time tone (<3s)
Un-Serialized Device	Status and Radio LEDs blink through Green, Yellow, Red, Magenta, Blue, Cyan, and White over 2.3 seconds, repeating 3 times.	Demo Mode tone (<4s))

If pressing the button results in the Radio LED indicating state, refer to the following table:

State	Visual Indication	Audio Indication
Bluetooth Pairing Mode	Radio LED fades Blue 5 times over 2.5 seconds	None
Bluetooth Connected, no events	Radio LED blinks Blue 3 times slowly over 2.5 seconds	None
Bluetooth Connected, with events	Radio LED blinks Blue 10 times rapidly over 2.5 seconds	None
Wifi Searching	Radio LED fades Green 5 times over 2.5 seconds	None
Wifi Connected, no events	Radio LED blinks Green 3 times slowly over 2.5 seconds	None
Wifi Connected, with events	Radio LED blinks Green 10 times rapidly over 2.5 seconds	None
Wifi and Bluetooth disconnected	Radio LED blinks Yellow 3 times slowly over 2.5 seconds	None

Troubleshooting

Otherwise refer to the following table for additional LED codes:

State	Visual Indication	Audio Indication
Insufficient Battery for Recording	Status LED blinks Yellow slowly (every 2.5 seconds)	None
Error Encountered	Status LED blinks Red rapidly (every 0.3 seconds)	None
Invalid Clock	Status LED fades from Yellow to Red rapidly, repeating every 2.1 seconds	None
Format in Progress	Status LED blinks Yellow rapidly (every 0.42 seconds)	None
Firmware Update in Progress	Status LED fades through Green -> Yellow -> Red over 1.5 seconds repeatedly	None
Patient Event Recorded	Status LED solid Green for 1 second	Recorded Event tone (<1s)
Insufficient Battery for Bootup	Status LED shows bootup sequence for a short time before abruptly stopping	Power-on tone (<1s)
Device in Demo Mode	Status LED blinks through Green -> Yellow -> Red over 1 second 5 times at conclusion of bootup sequence	Demo Mode tone (<4s)
Device Powering Down	Upon module removal from accessory, Status LED fades Red over 0.7 seconds repeatedly for a short period.	Power-down tone (<2s)
Un-Serialized Device	Status LED fades back and forth between Red and Green rapidly (every 0.5 seconds)	Un-Serialized tone (<4s)

Specifications

Functional

ECG Channels	Up to 3 bipolar channels
Sample Rate	200 -1600 Hz
User Interface	Tactile button with LED indication

Memory

Total Recording Time	Up to 30 days, up to 7 days continuous (from full charge)
Media	8GB internal
Data Retention	Over 10 years

Physical

Dimensions	2.60 x 1.55 x 0.33 inches (66.0 x 39.5 x 8.5 mm)
Weight	1.0 oz. (28g)

Electrical

Input Impedance	> 10M Ohms
CMRR	> 60 dB
Signal Range	± 400 mV
Resolution	(24 bits)
Frequency Response	0 to 150 Hz
Pacemaker Detection	ANSI/AAMI/IEC 60601-2-47:2012

Environmental

Operating Temperature	0 C (32 F) to 45 C (113 F)
Storage Temperature	-25 C (-13 F) to 70 C (158 F)
Storage Humidity	5% to 95%, non-condensing
Atmospheric Pressure	70 kPa to 106 kPa

Battery

Type	Single Cell, Lithium Polymer Rechargeable
Life	Up to 7 days, from full charge

External Power Requirements

Output Voltage	5.0 VDC +/- 5% measured at the output
Output Current	500 mA minimum

Wireless Transmission

Service (Model: H30M)	Multi Band Wi-Fi, and Multi Band Bluetooth Low Energy
Bands (Model: H30M)	IEEE 802.11 b/g/n Wireless, Bluetooth Low Energy 5.0

Specifications

Projected service life

The projected service life of the Trident® 30M and Trident® Nano 10-bay Charging Dock is approximately 2 years based on the following assumptions:

- Typical 60-day shelf storage duration
- Battery charge and discharge does not exceed 500 cycles for the service life of the device
- Proper cleaning and maintenance per the operator manual
- Trident® Nano patient electrodes are single-use disposable items.
- Lanyard cables are intended to last the duration of a single study
- Electrode contact duration will be affected by external factors. These include but are not limited to:
 - Skin Type
 - Concentration of oils in skin
 - Activity level
 - Frequency of exposure to water
 - Intensity of exposure to water
 - Placement
 - Skin preparation prior to placement
 - Aggressive contact from patient garments

Additional equipment classification information as required in EN 60601-1

EQUIPMENT not suitable for use in the presence of a FLAMMABLE ANAESTHETIC MIXTURE WITH AIR or WITH OXYGEN OR NITROUS OXIDE

IP66 - The EQUIPMENT allows no ingress of dust; complete protection against contact; Water projected in powerful jets (12.5mm nozzle) against the enclosure from any direction has no harmful effects.

Internally Powered Equipment

Mode of Operation – Continuous

Conformance to Regulatory Standards

ANSI/AAMI/IEC 60601-2-47:2012

 Manufactured by TZ Medical, Inc. 20497 SW Teton Ave Ste A Tualatin, OR 97062	 EU Authorized Representative: CEPartner4U Esdoornlaan 13 3951 DB Maarn The Netherlands www.cepartner4u.eu	 2797
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Limited Warranty

This TZ Medical product is warranted to be free from manufacturing and material defects for a period of two (2) years from the date of shipment from TZ Medical to the original purchaser ("Warranty Period"). If a hardware defect arises and a valid claim is received within the Warranty Period, TZ Medical will either repair or replace the defective product free of charge for parts or labor.

Excluded from this warranty are expendable supply items including, but not limited to, electrodes, patient cables, charging adapters, and batteries. This warranty does not apply to any product which TZ Medical determines has been modified or which has been damaged due to customer abuse or misuse (e.g. corrosion from water ingress or cracking of the LCD glass).

Except for the express warranties stated above, TZ Medical disclaims all warranties including implied warranties of merchantability and fitness. The stated express warranties are in lieu of all obligations of liabilities on the part of TZ Medical for damages, including but not limited to, special indirect or consequential, arising out of or in connection with the use or performance of TZ Medical products.

Any action for breach of warranty shall be commenced within one (1) year of said breach or be forever barred. Any repairs made to the product that are not covered by the warranty shall be billed to the customer.

Unauthorized modifications to TZ Medical products could void your warranty and alter the regulatory status of the device. Any resulting service required is not covered under our service agreements. Such modifications can affect the performance or safety of your device in unpredictable ways, and TZ Medical is not responsible for equipment that has been modified.

Obtaining Warranty Service

To obtain repairs, the device should be shipped pre-paid to TZ Medical at the address shown below. Units that are repaired under warranty will be returned postage paid. Any device serviced by TZ Medical will be factory reset, removing all custom device settings and formatting all data storage devices.



TZ Medical
Sparked by your ideas

TZ Medical, Inc.
20497 SW Teton Ave Ste A
Tualatin, OR 97062

Phone: 800.944.0187
Fax: 503.639.0239

Accessories

The following accessories are available for use with the Trident® 30M:

Part Number	Description
HPR-0055	Trident® Nano Single-Bay USB Dock
HPR-0056	Trident® Nano Single-Bay Charge-Only Dock
HPR-0075	Trident® Nano 10-Bay Charging Dock Kit
HPR-0057	Trident® Nano 3-Electrode Patient Cable with Lanyard
HPR-0130	Trident® Nano 3-Electrode Patient Cable with Lead Clip
HPR-0132	Trident® Nano 3-Channel Sport Electrode
HPR-0150	Trident® Nano 3-Channel Pediatric Sport Electrode

Wireless Compliance

FCC ID: ZIMH30M

FCC Compliance Statement

NOTICE:

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

- (1) this device may not cause harmful interference, and
- (2) this device must accept any interference received, including interference that may cause undesired operation.

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

- *Reorient or relocate the receiving antenna.*
- *Increase the separation between the equipment and receiver.*
- *Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.*
- *Consult the dealer or an experienced radio/TV technician for help.*

Changes or modifications made to this equipment not expressly approved by TZ Medical Inc. may void the FCC authorization to operate this equipment.

Wireless Compliance

IC ID: 9647A-H30M

License Exempt (Canada)

NOTICE:

This device contains license-exempt transmitter(s)/receiver(s) that comply with Innovation, Science and Economic Development Canada's license-exempt RSS standard(s).

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.

L'émetteur/récepteur exempt de licence contenu dans le présent appareil est conforme aux CNR d'Innovation, Sciences et Développement économique Canada applicables aux appareils radio exempts de licence.

L'exploitation est autorisée aux deux conditions suivantes:

- (1) l'appareil ne doit pas produire de brouillage, et*
- (2) l'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement.*

EMC Precautions

The Trident® 30M needs special precautions regarding EMC and needs to be installed and put into service according to the following EMC information.

List of all cables and maximum lengths of cables, transducers and accessories:

Transducer / Accessories	Maximum Cable Length
Trident® 3-Electrode Lanyard Cable	12.3 in (312 mm)
Trident® USB Data Retrieval Dock	59.5 in (1511 mm)

Warnings:

- The use of accessories and cables other than those specified, with the exception of transducers and cables sold by the manufacturer of the Trident® 30M as replacement parts for internal components, may result in increased emissions or decreased immunity of the Trident® 30M.
- The Trident® 30M should not be used adjacent to or stacked with other equipment and if adjacent or stacked use is necessary, the Trident® 30M should be observed to verify normal operation in the configuration in which it will be used.
- The Trident® 30M may be interfered with by other equipment, even if that other equipment complies with CISPR emission requirements.
- The Trident® 30M does not have life supporting function
- The Trident® 30M does not provide functionality the loss of which would cause unacceptable risk.
- Portable and mobile RF communications equipment can affect the Trident® 30M and should be kept at a minimum distance of 30cm (12 inches) from any part of the system, including lead cables.

Guidance and Manufacturer's Declaration - Emissions		
The Trident® 30M is intended for use in the electromagnetic environment specified below. The customer or user of the Trident® 30M should ensure that it is used in such an environment.		
Emissions Test	Compliance	Electromagnetic Environment – Guidance
RF Emissions CISPR 11	Group 1, Class B	The Trident® 30M is suitable for use in all establishments, including domestic establishments and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes.
Harmonics EN 61000-3-2	Class A	
Flicker EN 61000-3-3	Complies	

EMC Precautions

Guidance and Manufacturer's Declaration – Immunity			
The Trident® 30M is intended for use in the electromagnetic environment specified below. The customer or user of the Trident® 30M should ensure that it is used in such an environment.			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
ESD IEC 61000-4-2	±8kV Contact ±15kV Air	±8kV Contact ±8kV Air	Floors should be wood, concrete or ceramic tile. If floors are synthetic, the r/h should be at least 30%
EFT IEC 61000-4-4	±2kV Mains ±1kV I/Os	±2kV Mains Not Applicable ¹	Mains power quality should be that of a typical home environment.
Surge IEC 61000-4-5	±1kV Differential ±2kV Common	±1kV Differential Not Applicable ²	Mains power quality should be that of a typical home environment.
Voltage Dips/Dropout IEC 61000-4-11	0% for 0.5 Cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315° 0% for 1 Cycle and 70% for 25/30 Cycles 0% for 250/300 Cycles	0% for 0.5 Cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315° 0% for 1 Cycle and 70% for 25/30 Cycles 0% for 250/300 Cycles	Mains power quality should be that of a typical home environment. If the user of the Trident® 30M requires continued operation during power mains interruptions, it is recommended that the Trident® 30M be powered from an uninterruptible power supply or battery.
Power Frequency 50/60Hz Magnetic Field IEC 61000-4-8	30A/m	30A/m	Power frequency magnetic fields should be that of a typical home environment.

¹ Holter Monitor System kit does not include I/O cables of sufficient length for standard to apply.

² Holter Monitor System kit does not include protected common ground wire.

EMC Precautions

Guidance and Manufacturer's Declaration – Immunity			
The Trident® 30M is intended for use in the electromagnetic environment specified below. The customer or user of the Trident® 30M should ensure that it is used in such an environment.			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
Conducted RF IEC 61000-4-6	3 V/m general 6 V/m ISM and amateur radio bands	3 V/m general 6 V/m ISM and amateur radio bands	Field strengths from fixed transmitters, as determined by an electromagnetic site survey, should be less than the compliance level Interference may occur in the vicinity of equipment containing a transmitter.
Radiated RF IEC 61000-4-3	10 V/m	10 V/m	Field strengths from fixed transmitters, as determined by an electromagnetic site survey, should be less than the compliance level. Interference may occur in the vicinity of equipment containing a transmitter.