TEKTELIC Communications Inc.
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eDoctor

Instructions for Use

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Revision History

Revision	Issue Date	Editor	Comments
0.1	Nov 4, 2020	Reza Nikjah	• Initial release.
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0.3	June 6, 2023	Shania Stewart	• Updated product name and product code. • Expanded on product specifications and added product images. • Updated the instructions for use and added troubleshoot information.
1.0	Aug 4, 2023	Shania Stewart	• Updated product code to support Rev C modules. • Corrected T-code in document footer. • Added additional setup information and safety precautions. • Added regulatory compliance statements.
1.1	Aug 22, 2023	Shania Stewart	• Minor edits.
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1.3	Aug 23, 2023	Shania Stewart	• Added tool requirement.
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1.5	Nov 30, 2023	Emma Tholl	• Added technical description. • Reformatted document. • Updated setup/operational instructions. • Added cleaning instructions, disposal instructions, maintenance.
1.6	Jan 9, 2024	Emma Tholl	• Implemented comments from RookQS and Tektelic.
1.7	May 3, 2024	Emma Tholl	• Updated roles to match actual implementation.
1.7	May 13, 2024	Andrii Bondarenko	• Updated user guide for eDoctor mobile and web applications.
1.8	October 21, 2024	Emma Tholl	• Fixed links in troubleshooting section • Updated device introduction. • Updated the IFU to reflect TEKTELIC offering the network operator role as a service. • Added Essential Performance as a section. • Made changes based on UL findings list.
1.9	November 13, 2024	Emma Tholl	• Added link to the quick start guide and eDoctor introduction video.

2.0	September 19, 2025	Andrii Shtepa	• Updated device specifications (dimensions and weight). • Updated renders to reflect revised modules and labels. • Updated App Store links to English-language versions. • Clarified measurement frequency (“every 5 minutes when worn”). • Refined and restructured instructions for patient addition, editing, and information display for improved clarity and consistency. • Improved clarity and flow in troubleshooting and setup sections by removing redundancies and rewording content.
2.1	February 25, 2026	Shania Stewart	• Fixed minor formatting issues. • Edited skin temperature time constant.
2.2	March 12, 2026	Shania Stewart	• Added sources to the symbols glossary. • Added additional radio specifications. • Added MR safety information. • Updated and added additional EMC information.
2.3	March 31, 2026	Ali Mekawy	• Added additional warning regarding device FW updates • Updated section 3.6.1 to include notification regarding FW and SW updates. • Updated service life statement to address cybersecurity risks due to continued use after end of service life • Updates table 4-1 to included “Suspected cybersecurity incident” • Updated table 5-1 to discuss FW update • Updated sections 5.4.1.1 - 5.4.1.3 to describe cybersecurity techniques used in the system
2.4	April 17, 2026	Tania Rizwan, Anna Suprunova	• Updated Section 5 to add definition of Non-clinical Performance • Updated Section 5.8 to add description of acceptable performance degradation, and added note about compliance to IEC 60601-4-2 • Updated the following sections to align with cybersecurity labeling requirements: • Table 2-2: Minimum Browser Versions • Table 2-3: Minimum Mobile Operating Systems • Table 5-4: eDoctor Server Application Security Specifications

			• Section 3.11: Expected Service Life • 5.6.1.1: Network Ports • Table 4-1: Troubleshooting Problems and Options (General Troubleshooting)
2.5	May 1, 2026	Tania Rizwan, Shania Stewart	• Updated contraindications to remove statement regarding health conditions and diagnosis. • Clarified the FCC's definition of harmful interference.

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1. Glossary

1.1. Warnings and Cautions

⚠ **WARNING** – A **WARNING** statement indicates a potentially harmful situation, which if not avoided, may result in serious harm or death.

⚠ **CAUTION** – A **CAUTION** statement indicates a potentially harmful situation, which if not avoided, may result in minor or moderate harm.

⚠ **WARNING** – For proper use of this device, read and follow these instructions for use.

⚠ **WARNING** – Adhere to all WARNINGS and CAUTIONS in these instructions for use to maintain patient safety.

⚠ **WARNING** – The chest strap may pose a choking hazard. Do not chew or place in mouth.

⚠ **CAUTION** – The eDoctor contains a lithium coin cell battery. Do not burn or puncture battery. Please ensure disposal instructions are followed.

⚠ **CAUTION** – Do not ingest battery, Chemical Burn Hazard. Even used batteries can cause severe injury or death. Call a local poison control center for treatment information.

⚠ **CAUTION** – This product contains a coin cell battery. If the coin cell battery is swallowed, it can cause severe internal burns in just 2 hours and can lead to death. Even used batteries can cause severe injury or death.

⚠ **CAUTION** – Keep new and used batteries away from children. If the battery compartment does not close securely, stop using the product and keep it away from children. If you think batteries might have been swallowed or placed inside any part of the body, seek immediate medical attention.

⚠ **CAUTION** – Risk of fire or explosion if battery is replaced by an incorrect type.

⚠ **WARNING** – No modification of this equipment is allowed.

⚠ **WARNING** – Do not modify this equipment without authorization of the manufacturer.

⚠ **WARNING** – If this equipment is modified, appropriate inspection and testing must be conducted to ensure continued safe use of the equipment.

⚠ **WARNING** – The eDoctor device and chest band are MR Unsafe. Do not expose the device or the chest band to a magnetic resonance (MR) environment. The device and chest band present projectile hazards. Patients should not receive an MR exam while the device and chest band are fastened to the patient.

⚠ **WARNING** – Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

⚠ **WARNING** – Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

⚠ **WARNING** – 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 TEKTELIC eDoctor Device, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

⚠ **WARNING** – Do not wear if sensitive to nylon, spandex, or stainless-steel.

⚠ **CAUTION** – To avoid damage to the device, do not allow fluids to come in contact. If fluids do come into contact, remove the device from service immediately and contact the manufacturer.

⚠ **CAUTION** – Review all cleaning instructions carefully before cleaning the device.

⚠ **WARNING** – Please ensure device has been cleaned before returning to manufacturer for repair and/or maintenance to lessen risk of infection.

⚠ **WARNING** – Please ensure device has been cleaned before disposal to lessen risk of infection.

⚠ **WARNING** – Do not remove the enclosure, current-carrying components are present. Maintenance must only be completed by the manufacturer.

⚠ **WARNING** – Service or repair of device must only be completed by the manufacturer.

⚠ **WARNING** – Device failure may occur due to use-life exceeded. Perform regular inspection of the device and chest strap.

⚠ **WARNING** – Remove this device before patient defibrillation.

⚠ **WARNING** – Only wear device on intact skin. Do not apply over broken skin.

⚠ **CAUTION** – Remove device if irritation occurs.

⚠ **WARNING** – Inspect the area of contact with the device and strap every 24 hours. If any irritation has occurred, remove immediately.

⚠ **WARNING** – Care provider users should ensure that their hospital network has firewalls, network security protections, data security protections, and anti-virus protections subject to HIPAA compliance within their network.

⚠ **WARNING** – TEKTELIC strongly advises the user NOT to modify, alter, or reset the software without consent from TEKTELIC. Exceptions to this are when the App instructs the user to perform a software update or if a TEKTELIC technical assistance representative instructs/guides the user through maintenance and/or troubleshooting.

⚠ **WARNING** – Do not force discharge, recharge, disassemble, heat above 70°C or incinerate. Doing so may result in injury due to venting, leakage, or explosion resulting in chemical burns.

⚠ **CAUTION** – Remove and immediately recycle or dispose of used batteries according to local regulations and keep away from children. Do NOT dispose of batteries in household trash or incinerate.

⚠ **CAUTION** – Do not attempt to recharge non-rechargeable batteries.

⚠ **CAUTION** – It will take 25 minutes for the device to warm to 20°C from the minimum storage temperature.

⚠ **CAUTION** – It will take 25 minutes for the device to cool to 20°C from the maximum storage temperature.

⚠ **CAUTION** – Please wait for the skin temperature readings to stabilize after putting the device on or if there have been changes in environmental conditions.

⚠ **CAUTION –** Damage to the device may degrade sensor and electrode performance.

⚠ **CAUTION –** The device should not be near or in contact with high temperatures (i.e., Fireplace).

⚠ **CAUTION –** The device should be kept out of range from pets and children. Strap can pose a choking hazard. Device should not be put in mouth as it contains electrical components and a battery.

⚠ **CAUTION** – Remove and immediately recycle or dispose of batteries from equipment not used for an extended period according to local regulations.

⚠ **CAUTION** – Do not mix old and new batteries, different brands or types of batteries, such as alkaline, carbon-zinc, or rechargeable batteries.

⚠ **CAUTION** – Device and strap must make direct contact with intact skin.

⚠ **CAUTION** – Ensure the batteries are installed correctly according to polarity (+ and -).

⚠ **CAUTION** – Mobile devices and PCs used to access the eDoctor web app or the eDoctor mobile app should be secured when not in use.

⚠ **CAUTION** – Users should regularly apply/allow security updates to your device's operating system (OS).

⚠ **CAUTION** – TEKTELIC does not make any commercial use of or disclose any private information of eDoctor users

⚠ **CAUTION** – Users should follow their hospital's data backup process where applicable to ensure data can be recovered in the event of an emergency. TEKTELIC Technical support can also be contacted to assist with disaster recovery.

⚠ **CAUTION** – Safeguard your login information with the utmost care. Never share your username and password with any third party.

⚠ **CAUTION** – Exercise prudence when installing mobile applications. Only install apps from trusted sources, such as official app stores. Avoid downloading and installing applications from unverified or unofficial sources.

⚠ **CAUTION** – Use strong, unique passwords for your web accounts. Combine a mix of upper and lower-case letters, numbers, and symbols. Consider using a reputable password manager.

⚠ **CAUTION** – Users should ensure that data from the web and mobile application is periodically backed-up to ensure availability of information in the event of a disaster.

⚠ **CAUTION** – TEKTELIC personnel will never request your password or login information. Notify TEKTELIC immediately if you receive unexpected or confusing emails, phone calls, or other forms of communication

⚠ **CAUTION** – Federal law restricts this device to sale by or on the order of a physician.

⚠ **CAUTION** – Do not share login information (e.g. password) of your eDoctor account.

⚠ **CAUTION** – Do not touch the battery and the patient at the same time during battery replacement.

⚠ **CAUTION** – Do not touch the gateway/smart phone/computer and patient at the same time.

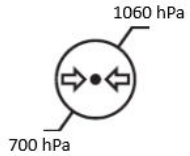
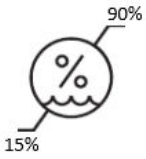
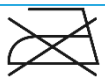
California Proposition 65:

⚠ **WARNING** – This product can expose you to chemicals including lead, nickel, and carbon black, which are known to the State of California to cause cancer, birth defects or other reproductive harm. For more information, go to www.P65Warnings.ca.gov.

1.2. List of Symbols

Table 1-1: Symbols and Meaning

Symbol	Meaning	Source of Symbol
	Warning/Caution	ISO 15223-1: 2021, Symbol 5.4.4
	Type BF Applied Part	ANSI/AAMI ES60601-1:2005 & A1:2012 & A2:2021, Table D.1, Symbol 20
	MR Unsafe	ASTM F2503-23, Fig. 9
	Consult Instructions for Use	ISO 15223-1:2021, Symbol 5.4.3
	FCC Declaration of Conformity	47 CFR § 2.1074 (b)
	Ingestion hazard. This product contains a button cell or coin battery	ANSI/UL 4200A-2023, Fig. 7B.1

Symbol	Meaning	Source of Symbol
	Temperature Limitation. (5°C to 40°C)	ISO 15223-1:2021, Symbol 5.3.7
	Atmospheric Pressure Limitation (700 hPa to 1060 hPa)	ISO 15223-1:2021, Symbol 5.3.9
	Humidity Limitation (15% to 90%)	ISO 15223-1:2021, Symbol 5.3.8
	Date of Manufacture (YYYY-MM-DD)	ISO 15223-1:2021, Symbol 5.1.3
	Manufacturer	ISO 15223-1:2021, Symbol 5.1.1
	Serial Number	ISO 15223-1:2021, Symbol 5.1.7
	Unique Device Identifier	ISO 15223-1:2021, Symbol 5.7.10
Rx ONLY	Prescription Use Only	21 CFR § 801.109 (b)(1)
IP22	IP Rating	ANSI/AAMI ES60601-1:2005 & A1:2012 & A2:2021, Table D.3, Symbol 2
	Do Not Iron (Chest Strap)	ISO 7000, Symbol 3113
	Do Not Dry Clean (Chest Strap)	ISO 7000, Symbol 3114
	Do Not Bleach (Chest Strap)	ISO 7000, Symbol 3124
	Dry Flat (Chest Strap)	ISO 7000, Symbol 3080
	Hand Wash Normal (Chest Strap)	ISO 7000, Symbol 3125

1.3. List of Terms and Acronyms

- **BPM** - Beats per minute.
- **RPM** - Respirations per minute.
- **Device** - TEKTELIC eDoctor sensor supported by the eDoctor application.

- **Device EUI** - A 16-letter/digit globally unique Extended Unique Identifier (EUI-64) is assigned by the manufacturer, or the owner, of the end-device (ex. 647FDA00000XXXXX).
- **Serial Number** - A 9-letter/digit unique identifier which is assigned by TEKTELIC for each gateway and device models that contains manufactory information (ex. 0000X0000).
- **T-code** - An 8-letter/digit unique identifier which is assigned by TEKTELIC for each gateway and device models according to its region or specification (ex. T000XXXX).
- **Gateway** - IoT based device that connects other appliances to a wider network. They act as a bridge between these devices and the wider network, allowing them to communicate with each other and exchange data.
- **Gateway ID** - A 16-letter/digit unique gateway identifier, which is assigned by the manufacturer (ex. 647FDAFFFE0XXXXX).
- **Setup Wizard** - simple and intuitive onboarding procedure for new users of eDoctor application.
- **IoT** – Internet of Things.
- **LoRaWAN** – Long Range Wide Area Network.
- **Patient** – Adult wearing the TEKTELIC eDoctor Device.
- **Healthcare Professional** – Adult responsible for viewing the applications and setting up patients.
- **Network Operator** – Adult responsible for setting up a LoRaWAN network. This role is offered as a service by TEKTELIC Communications Inc.
- **WARNING** – A **WARNING** statement indicates a potentially harmful situation, which if not avoided, may result in serious harm or death.
- **CAUTION** – A **CAUTION** statement indicates a potentially harmful situation, which if not avoided, may result in minor or moderate harm.

2. Product Description

2.1. Device Introduction

TEKTELIC eDoctor is the ideal solution for monitoring health, tracking activity levels, stress, physical readiness, heart health, and overall well-being. This wearable device has a battery life of 2-3 months and is designed to monitor vital and wellness parameters including skin temperature, respiration rate, pulse rate, chest expansion, activity level, and position. The device is worn on an adjustable chest strap and wirelessly transmits data to be displayed on a mobile and/or web application.

Normal use of the device includes three roles, the network operator, the healthcare professional and the patient. The network operator is responsible for the configuration of the gateway(s) and device(s) on the mobile and web applications. This role is offered as a service by TEKTELIC Communications Inc. The healthcare professional is the main viewer of the data displayed on the mobile and web applications and will configure patients on the applications (i.e. Add new patients, pair a patient with a device, add patient information, remove patients, etc.). The patient is responsible for simply wearing the device.

2.2. Indications for Use

The TEKTELIC eDoctor Device is intended for reusable bedside, mobile and central multi-parameter, physiologic patient monitoring of adult patients in professional healthcare facilities, such as hospitals or skilled nursing facilities, or their own home. It is intended for monitoring of patients by trained healthcare professionals. The TEKTELIC eDoctor Device is intended to be reused on single or multiple patients. It has been designed for prolonged use and is transit-operable, meaning it is intended to be worn on the body and is operable during movement.

The TEKTELIC eDoctor Device is intended for intermittent monitoring of the following parameters in adults:

- Pulse rate
- Skin temperature
- Respiration rate
- Chest expansion
- Activity Level
- Position

2.3. Contraindications

The eDoctor Device is not intended for use in high-acuity environments, such as ICU or operating rooms.

The eDoctor Device is not for emergency use or emergency situations.

The eDoctor Device is not a substitute for an ECG monitor. The eDoctor Device is not intended for use on acutely ill cardiac patients where continuous ECG monitoring is more appropriate.

The eDoctor Device is not suited for adults who are sensitive to contact with stainless steel, nylon, or spandex.

2.4. Device Description

This section will describe the hardware components and software components of the TEKTELIC eDoctor Device. A diagram representing the eDoctor system can be seen in Figure 2-1 below.

The system consists of:

- An eDoctor Device
- An adjustable chest strap
- A coin cell battery (3.0 V non-rechargeable CR2477 battery)
- A TEKTELIC LoRaWAN Gateway (not included)
- eDoctor Mobile Application
- eDoctor Web Application
- Mobile device (not included)

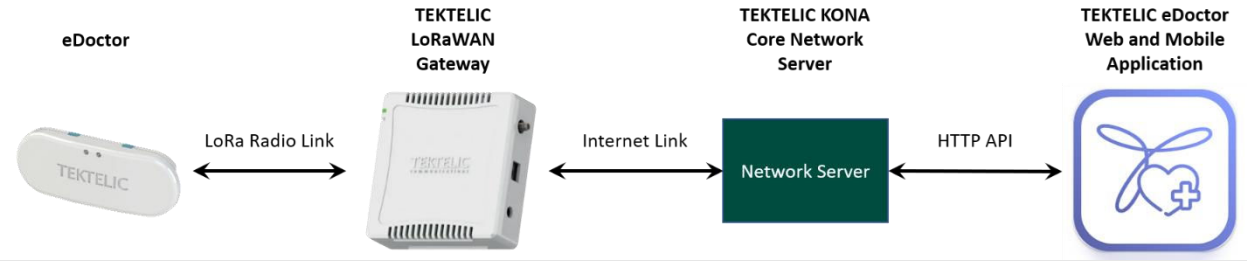


Figure 2-1: eDoctor System Diagram

2.4.1. Hardware Components

⚠ **WARNING** – Use only recommended accessories supplied by TEKTELIC.

⚠ **WARNING** – No modification of this equipment is allowed.

⚠ **WARNING** – Do not modify this equipment without authorization of the manufacturer.

⚠ **WARNING** – If this equipment is modified, appropriate inspection and testing must be conducted to ensure continued safe use of the equipment.

Figures 2-2 and 2-3 show the enclosure and external interfaces of the eDoctor. Two light indicators (one green and one orange) are present on the front of the enclosure, while two push buttons (both blue) are accessible on the top of the enclosure.
The eDoctor has an IP classification of IP22. This classification means the enclosure protects against solid foreign objects of 12.5 mm and greater and is protected against vertically falling water drops when the enclosure is tilted up to 15’.

There are two strap snaps on the back of the enclosure so that the device can be attached to an adjustable strap for different chest sizes. The adjustable chest strap, shown in Figure 2-4, is made up of nylon and spandex with conductive ECG pads that are intended to touch the skin. The skin temperature probes go through the two small holes in the chest strap to contact the wearers skin.

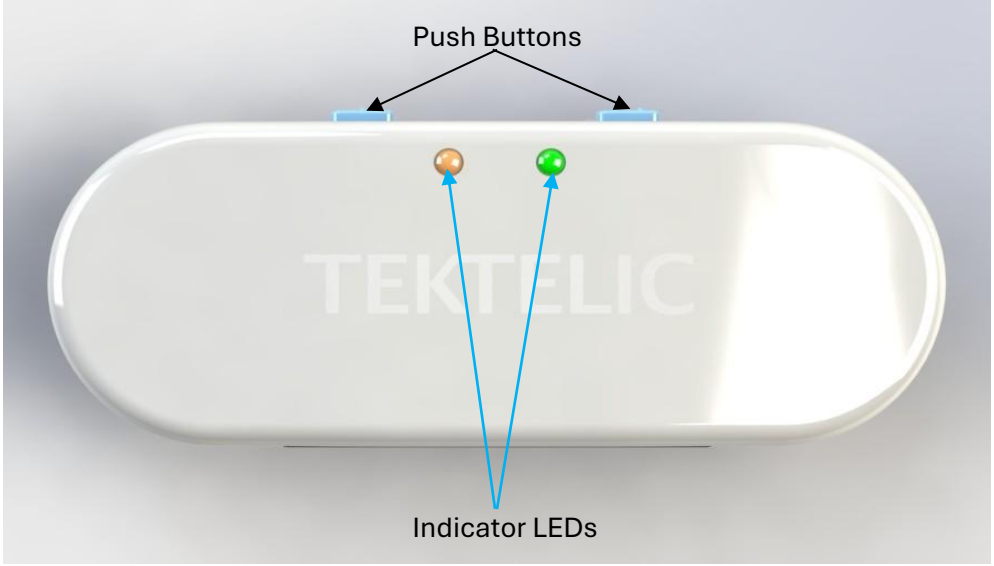


Figure 2-2: Front View of eDoctor External Interfaces

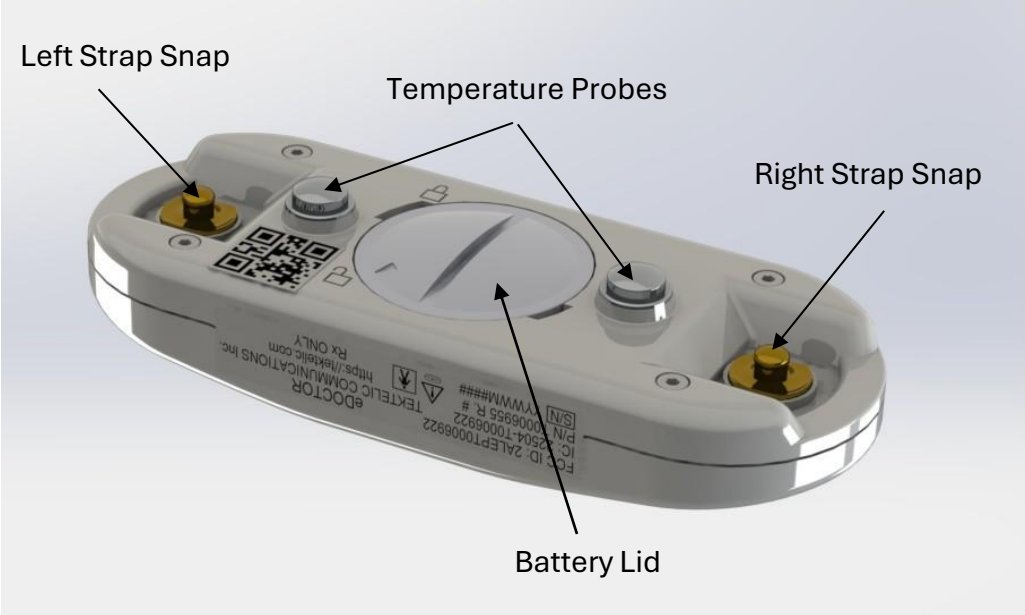


Figure 2-3: Back View of eDoctor External Interfaces

Figure 2-4: eDoctor Chest Strap

The eDoctor specifications are listed in Table 2-1.

Table 2-1: eDoctor Specifications

Parameter	Specification
Use Environment	Indoor professional healthcare facilities
Medical Device Classification	USA FDA Class II Device
Size	eDoctor: 107.5 mm x 40.9 mm x 22.8 mm Small Chest Strap: Minimum: 603.2 mm x 1.7 mm x 30.0 mm Maximum: 838.2 mm x 1.7 mm x 30.0 mm Large Chest Strap: Minimum: 844.5 mm x 1.7 mm x 30.0 mm Maximum: 1320.8 mm x 1.7 mm x 30.0 mm
Weight	eDoctor: 68.0 g (with battery) Small Chest Strap: 25.3 g Large Chest Strap: 33.3 g
Power Source	Battery operated (one 3.0 V non-rechargeable CR2477 battery)
Network Technology, Frequency Band, and Bandwidth (BW)	LoRaWAN using North American Region: US902-928 Transmit (Tx): 902 MHz – 915 MHz, 125 or 500 kHz BW Receive (Rx): 923 MHz – 928 MHz, 500 kHz BW
Maximum Transmit Power (ERP)	14 dBm
Air Interface	LoRa (Chirp Spread Spectrum)
Battery Lifetime	> 2 months
Number of Visual Indicators	2 (one orange and one green)
Number of Push Buttons	2 (both blue)
Sensing Functions	Skin temperature, pulse rate, respiration rate, chest expansion, activity level, and position
IP Classification	IP22
Use Life	eDoctor Device: 2 years Chest Strap: 2 years
Temperature Range	Operating: 5°C (41°F) to 40°C (104°F) Storage: -25°C (-13°F) to 70°C (158°F)
Applied Parts of the System	BF Applied parts. Probes, ECG contacts, strap fabric

2.4.2. Software Components

The eDoctor is designed to operate with the TEKTELIC eDoctor Web and Mobile Applications.

The TEKTELIC eDoctor Application is an easy-to-use tool used to store up to three months worth of data and display the latest measurements from the eDoctor Device.

The Mobile Application allows the network operator to create a LoRaWAN network by adding gateways and devices. Once the network has been established, the healthcare professional can

assign devices to patients. When the device is worn by a patient, their reported parameters will be visualized on both the Web and Mobile Applications.

The TEKTELIC eDoctor Mobile Application is available for download on the App Store and Google Play.

To access the TEKTELIC eDoctor Web Application, click the link and log in to the TEKTELIC eDoctor Web Application.

Please ensure the following minimum system requirements are met:

Table 2-2: Minimum Browser Versions

Browser Name	Minimum Version
Google Chrome	Version 120+
Mozilla Firefox	Version 120+
Safari	Version 17+

Table 2-3: Minimum Mobile Operating Systems

Mobile Operating System	Minimum Version
Android	Version 7+
iOS	Version 15.1+

Table 2-4: Minimum Desktop Operating Systems

Desktop Operating System	Minimum Version
Windows	Version 10

3. Operating Information

⚠ **WARNING** – The chest strap may pose a choking hazard. Do not chew or place in mouth.

⚠ **WARNING** – Do not modify this equipment without authorization of the manufacturer.

⚠ **WARNING** – Firmware updates must only be performed by TEKTELIC Communications Inc. Unauthorized attempts to modify or update the device firmware may result in device malfunction, compromised security, or loss or performance.

⚠ **WARNING** – Only wear device on intact skin. Do not apply over broken skin.

⚠ **CAUTION** – Remove device if irritation occurs.

⚠ **WARNING** – Inspect the area of contact with the device and strap every 24 hours. If any irritation has occurred, remove immediately.

⚠ **CAUTION** – Remove and immediately recycle or dispose of used batteries according to local regulations and keep away from children. Do NOT dispose of batteries in household trash or incinerate.

This section describes the included product, required equipment for setup, unpacking and inspection instructions, setup instructions, and operating instructions.

For concise operating information, please refer to the eDoctor Quick Start Guide included in the device packaging or visit the TEKTELIC website for an introductory video.

3.1. Required Equipment

To onboard and configure the TEKTELIC gateway(s), eDoctor device(s), and patient(s), please download the TEKTELIC eDoctor mobile application from the App Store or Google Play.

A flat tool (e.g., a coin) is required to lock/unlock the battery lid located on the back of the device. No other special equipment or tools are required to power or operate the eDoctor.

3.2. Unpacking and Inspection

The following should be considered during the unpacking of a new eDoctor:

1. Inspect the shipping carton and report any significant damage to TEKTELIC.
2. Unpacking should be conducted in a clean and dry location.
3. Do not discard the shipping box or inserts as they will be required if a unit is returned for repair or maintenance.

3.3. Setup Instructions

The setup procedure is to be completed by the network operator in an indoor environment. This procedure includes setting up the LoRaWAN network, creating the application account, as well as onboarding the gateways and devices. This setup is offered as a service by TEKTELIC Communications Inc.

The device can be powered on by either the network operator or the healthcare professional, depending on what is most convenient.

3.3.1. Gateway Setup

To turn on the gateway, follow the steps below:

1. Connect power cable from the gateway to an outlet.
2. Connect the gateway to either ethernet or cellular.
    a. For ethernet, connect the ethernet cable from the gateway to the ethernet socket.
    b. For cellular, insert a SIM card into the specified SIM port on the gateway. Please refer to Kona Gateway Cellular Backhaul FAQ for additional support.
3. Once steps 1 and 2 have been completed, the gateway should be begin flashing green.

Further setup for onboarding and configuring the gateway on the app will be described in Section 3.6.3.1. below.

3.3.2. Powering on the device/replacing the battery

⚠ **CAUTION** – Do not touch the battery and the patient at the same time during battery replacement.

⚠ **CAUTION** – Do not touch the gateway/smart phone/computer and patient at the same time.

The eDoctor is shipped with a battery installed and an insulating sticker on the negative terminal of the battery to prevent device operation. Removing the sticker and re-inserting the battery will activate the device. After the sticker has been removed, the battery must be removed to turn off the device.

Before each use, visually check the battery to ensure no corrosion has occurred. If corrosion is noticed or the equipment has not been used for an extended period, replace the battery with a **new** CR2477, 3V Lithium Manganese Dioxide coin cell. Remove and immediately recycle or dispose of batteries according to the local regulations. **Recommended battery brand:** Panasonic.

Do not mix old and new batteries, different brands or types of batteries, such as alkaline, carbon-zinc, or rechargeable batteries.

To activate the unit or to replace the battery when required, follow these steps:

Note: Ensure the device has been onboarded to the mobile application by the network operator before proceeding.

1. Locate the battery lid on the back of the eDoctor. Rotate the lid counterclockwise using a flat tool (e.g., a coin) to unlock it, and then remove the battery lid from the device.

Figure 3-1: Unlocking battery lid

2. Remove the battery from the battery holder. For activation of a newly received device, peel the sticker off the negative terminal of the battery. For battery replacement, use only a **new** CR2477, 3V Lithium Manganese Dioxide coin cell. **Recommended battery brand:** Panasonic.

Figure 3-2: Removing battery sticker for use

3. Place the battery inside the eDoctor battery compartment ensuring the battery is installed correctly according to polarity (+ and –). The positive terminal of the battery must be visible after insertion. Align the battery lid so that the arrow is pointing to the bottom left, and turn the lid clockwise with a flat tool (e.g., a coin) until there is a click and noticeable resistance to further rotation to lock it in.

Figure 3-3: Placing battery in device

Figure 3-4: Locking battery lid

4. After a few seconds, the visual indicators on the eDoctor should start blinking, showing that the eDoctor is trying to join the LoRaWAN network. The visual indicators will stop blinking once the eDoctor has joined the LoRaWAN network.

Note: Time from device powering on until ready for normal use may take up to 5 minutes. The device will only report measurements while it is being worn.

3.4. Checkout Procedure

Once the patient has completed using the device, the healthcare professional can assist in removing the strap and device from the patient. Afterward, the healthcare professional is expected to follow the cleaning procedures outlined in the Cleaning Instructions section.

3.5. Operating Instructions

The following operating instructions assume the setup procedure has already been followed. This means the LoRaWAN network has been fully setup, the gateways and devices have been onboarded, and the device has been powered on.

The following sections will describe how to wear the device, how to use the push buttons, as well as how to navigate and use different features on the mobile and web applications.

3.5.1. Wearing the device

⚠ **CAUTION** – It will take 25 minutes for the device to warm to 20°C from the minimum storage temperature.

⚠ **CAUTION** – It will take 25 minutes for the device to cool to 20°C from the maximum storage temperature.

⚠ **CAUTION** – Please wait for the skin temperature readings to stabilize after putting the device on or if there have been changes in environmental conditions.

⚠ **WARNING** – Do not wear if sensitive to nylon, spandex, or stainless-steel**.**

⚠ **WARNING** – Only wear device on intact skin. Do not apply over broken skin.

⚠ **CAUTION** – Remove device if irritation occurs.

⚠ **WARNING** – Inspect the area of contact with the device and strap every 24 hours. If any irritation has occurred, remove immediately.

1. Attach the eDoctor to the adjustable chest strap using the snaps located on both the device and the strap. Make sure that the two metal probes in the middle of the device go through the holes in the strap.

Figure 3-5: Device and strap not connected

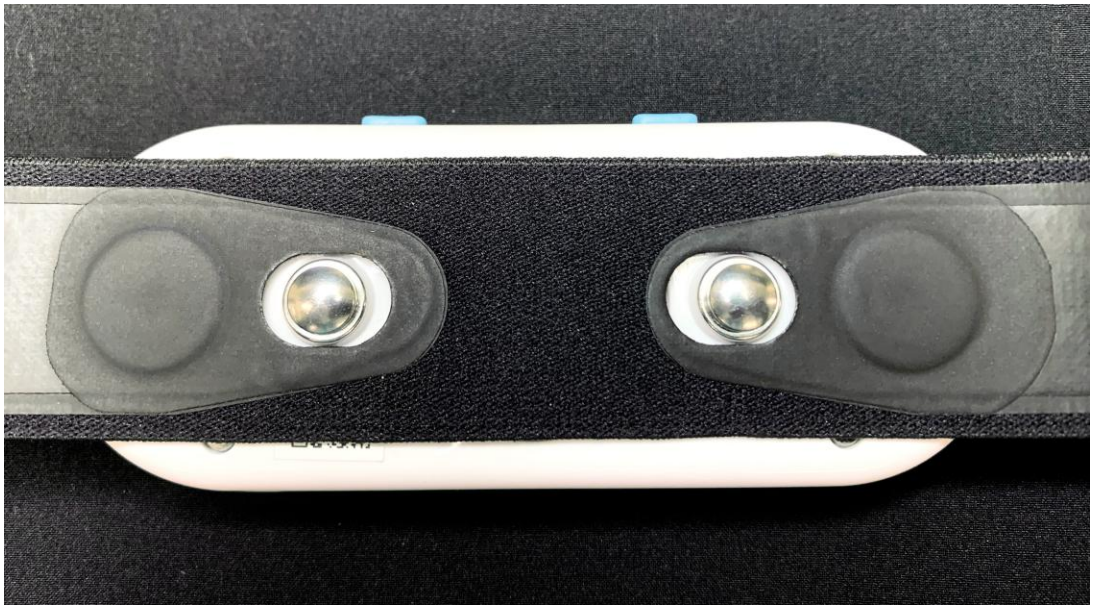


Figure 3-6: Device and strap connected via snaps

Figure 3-7: Device and strap ready to wear

2. Adjust the relaxed chest strap to a length that is 8-10 cm shorter than your chest circumference (i.e., if your chest circumference is 90 cm, adjust the chest strap to be 80-82 cm in length). Place the eDoctor strap and device in direct contact with the skin, under clothing and centered on the chest, as shown in Figure 3-8 below. Stretch the two ends of the strap gently towards each other and clip them together. **Make sure to wear the device so that the two push buttons face upwards and the TEKTELIC logo is the right way up.**

Note: The eDoctor device and strap should sit comfortably without sagging. Try taking shallow and deep breaths to ensure that the strap is adjusted properly.

Figure 3-8: Device and strap being worn correctly

Note: Inspect the chest strap to ensure it is not displaying any signs of deteriorations from prolonged use such as loose fabric, rips, holes, etc. If the strap displays any of these signs, please dispose the strap and use a new strap instead.

3. After a few minutes, the device will begin reporting data to the application. By default, the device will report data every 5 minutes when worn.

Note: For accurate monitoring, ensure the device is worn snugly and correctly positioned. The temperature contacts must make direct contact with the skin and the strap should not sag. Improper fit or loose contact, particularly during sleep, may result in inconsistent readings or temporary data gaps.

3.5.2. Push-button functionality

1. To change the reporting period from 5 minutes to every 1-minute, also known as Enhanced Reporting mode, toggle the button on the application or hold either one (not both) of the push buttons for more than 3 seconds and then release. If this procedure is done correctly, the device will flash an orange light.
2. To exit Enhanced Reporting mode, press and release either one (not both) of the push buttons 3 times within 3 seconds. If the procedure is done correctly, the device will flash a green light. This will switch the device to report every 5 minutes.
3. To restart the device, press and hold both push buttons for at least 5 seconds and then release.

3.6. TEKTELIC eDoctor Mobile Application Functionality

TEKTELIC eDoctor mobile application is an easy-to-use tool for monitoring patients' vital signs in real time. This app is a perfect choice for remote health monitoring and tracking any changes in medical conditions. eDoctor will significantly improve operational processes in the medical sphere, reducing time wasted on regular checks and filling out the forms with updated measurements. With this app, users can access measurements from eDoctor device.

3.6.1. TEKTELIC eDoctor Mobile Application Download and Registration

The creation of an eDoctor Mobile Application account is offered by TEKTELIC Communications Inc. To create an account, please reach out to the TEKTELIC Support Portal.

In order for TEKTELIC Communications Inc. to create an eDoctor Mobile Application account for you, they will require the following information:

- An email account that the eDoctor Mobile Application account can be created under
- The gateway ID (GWID) of the gateway(s) that should be added to the account. The GWID can be found on the bottom label of the gateway.
- The device EUI (DevEUI) of the device(s) that should be added to the account. The DevEUI can be found on the bottom label of the device.

From here, you will be sent an email at the email address provided to TEKTELIC that asks you to change the password to your eDoctor Mobile Application account. Once the password has been

changed, you will gain access to the eDoctor Mobile Application account. This email address and newly created password will also provide access to the eDoctor Web Application.

For instructions on how to add a patient, please refer to the Adding new patient section.

If you are setting up the TEKTELIC eDoctor mobile application on your own, please follow the steps described in the following sections:

1. Download the TEKTELIC eDoctor mobile application from the App Store or Google Play and then open it.
2. Tap on the "Sign Up" button to begin the registration process.

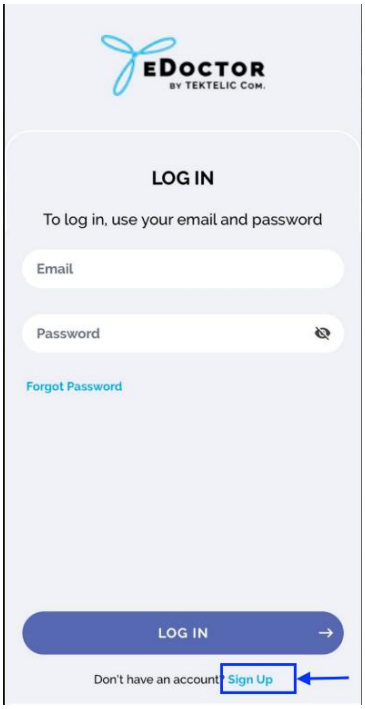


Figure 3-9: Starting the registration process

3. Enter your email address and password in the designated fields. Make sure to provide a valid and accessible email address. Password should be at least 8 characters long with a mix of letters, numbers and symbols.
4. Please read the privacy policy carefully by clicking on "Privacy Policy". After reading and agreeing to the rules, click on the checkbox.
5. Once you have entered your email address and password, tap on the "Register" button.
6. Check your email and find a message with confirmation code. If you do not see the email in your inbox, please check your spam or junk folder. If you don’t see the code in your spam or junk folder, click “Resend code” to receive a new code.

7. Return to the App, enter confirmation code and tap on the "Continue" button.

- If the code matches, a confirmation message will appear, indicating that your registration is successful.
- If the code doesn't match, an error message will appear, asking you to enter the correct confirmation code. Please double-check the code or click “Resend code” to receive a new code.

3.6.2. Authorization

To log in to the application:

1. Open the app to access the login screen.
2. Enter the email and password you used during registration.
3. Tap the "Log in" button.

Once logged in and your profile is set up, you can begin using the app’s features.

If login fails, double-check your email and password and try again.

3.6.3. Setup wizard

After registering and logging in for the first time, you'll be guided through the Setup Wizard.

The Setup Wizard is a step-by-step process that helps you connect and configure your gateways and devices. It’s designed to simplify the initial setup and ensure a smooth start with the application.

To begin, tap **"GET STARTED"** to add your first gateway.

3.6.3.1. Adding a Gateway

To add a gateway, tap the **“ADD GATEWAY”** button. You can either scan the QR code on the device or enter the details manually, including the Gateway ID, Serial Number, Revision, and T-Code.

Figure 3-10: Setup wizard start view

3.6.3.1.1. Adding Gateway using QR Code

To add a gateway using a QR code, use the in-app camera to scan the QR code on your gateway.

Make sure camera permission is enabled for the app. If you previously denied it, you can allow it by going to your phone's settings:
Settings → Apps → eDoctor → Permissions → Camera.

Figure 3-11: Scan QR gateway

3.6.3.1.2. Adding Gateway manually using gateway ID

To add a gateway manually by entering the gateway ID you should click on “Don’t have the QR code or can't scan?”.

Figure 3-12: Adding gateway using ID view

After scanning the QR code (or choosing manual entry), a screen will appear prompting you to enter the Gateway ID.

Note: The Gateway ID must be 16 characters long and start with “647FDAFFFE”.

Once entered, click the **"Submit"** button. You’ll then be taken to the internet connection setup screen.

3.6.3.1.3. Adding gateway manually using T-code, Revision and Serial number

If you have forgotten your gateway ID or it is damaged, you can add a gateway using Serial number and T-code. If this happens, click on “Add gateway with T-code, Revision and Serial number”. After this, a screen will appear prompting the user to enter the T-code, Revision and Serial number.

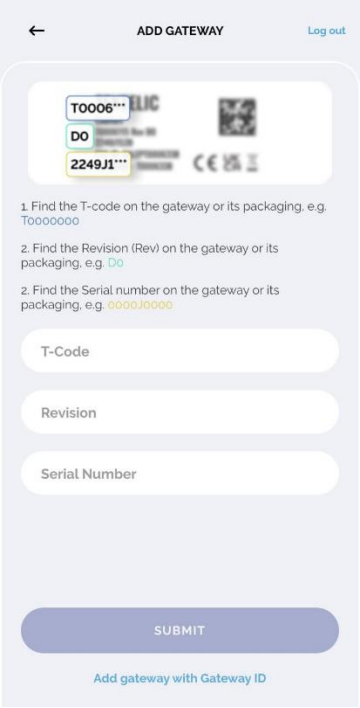


Figure 3-13: Adding gateway using serial number, revision and T-code

Note: The T-code should be 8 characters long and start with “T”.

Note: The Revision should have up to 4 characters (Latin letters and digits only).

Note: The Serial Number should be 9 characters long and contain a letter in the middle.

Click on the "Submit" button after entering T-code, Revision and Serial number. After submit your entering, you will be taken to the internet connection setup.

3.6.3.1.4. Editing gateway

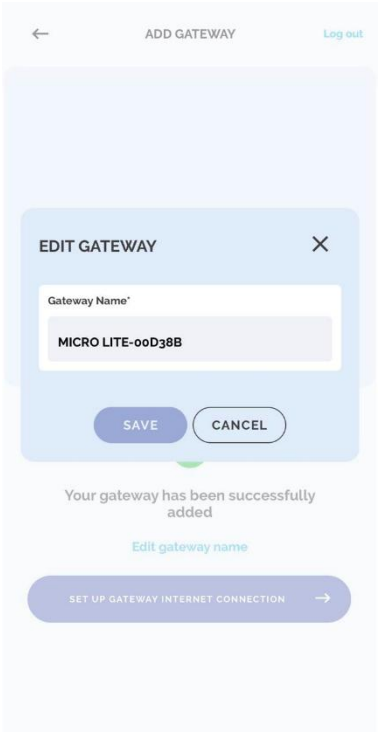


Figure 3-14: Edit gateway view

After you successfully add a gateway, you can change its name by clicking on "**Edit gateway name**".

To save the entered name, click "Save" button, and to cancel and return to the previous name, click "Cancel".

Note: The Gateway Name should be minimum 3 and maximum 255 characters long.

Note: The Gateway Name should only contain Latin letters, numbers and special characters: e.g., ! @ # ?].

3.6.3.1.5. Gateway Connection

Go further to the internet connection setup by clicking on the "**SET UP GATEWAY INTERNET CONNECTION**" button.

Connect the Ethernet cable to the gateway and wait while the gateway is connecting. It may take up to 5 minutes. After completing the setup of the Internet connection, you will receive an

“The Internet connection has been established” message and you can add a device by clicking on the "**ADD DEVICE**" button.

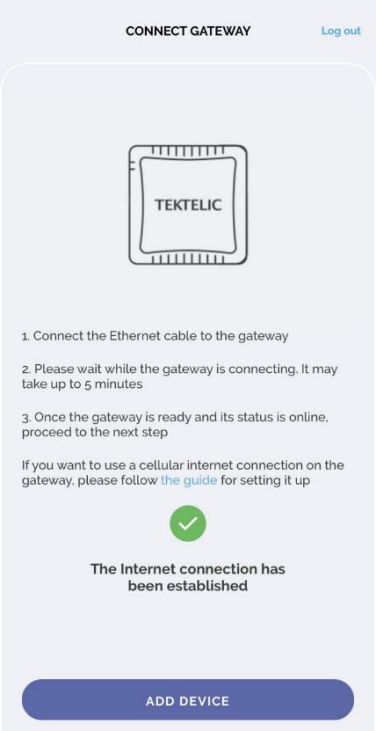


Figure 3-15: Successful internet connection view

If after 5 minutes the gateway does not pass the Internet connection stage, you will receive an error screen and can restart the process by clicking on the "TRY AGAIN" button.

If you want to use a cellular internet connection on the gateway with LTE, please follow the guide for setting it up - Cellular Configuration.

3.6.3.1.6. Skip Gateway Connection

If you do not want to complete the Internet connection setup at this step, you can skip the gateway connection process and proceed directly to adding a device. To do this, click on the **"ADD DEVICE"** button.

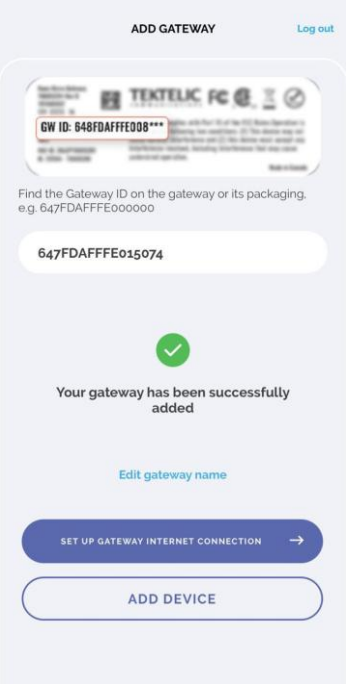


Figure 3-16: Skip gateway internet connection view

You will be redirected to the device setup screen without establishing the Internet connection for the gateway.

Please note that if you skip the gateway connection setup, you will still be able to configure the Internet connection later in the application when needed.

3.6.3.2. Adding Device

To add a device, click **"ADD DEVICE":**

To add a device, need to scan the QR code from it or add it manually by entering its serial number, revision and t-code or device EUI.

3.6.3.2.1. Adding device using QR

To add a device using QR you should scan with the camera window in the app, the QR code of your device.

Figure 3-1738: Scan QR on device

3.6.3.2.2. Adding device manually using T-code, Revision and Serial number

To add a device manually by entering the T-code, Revision and Serial number you should click on “Don’t have the QR code or can't scan?”. After this, a screen will appear prompting you to enter the T-code, Revision and Serial number.

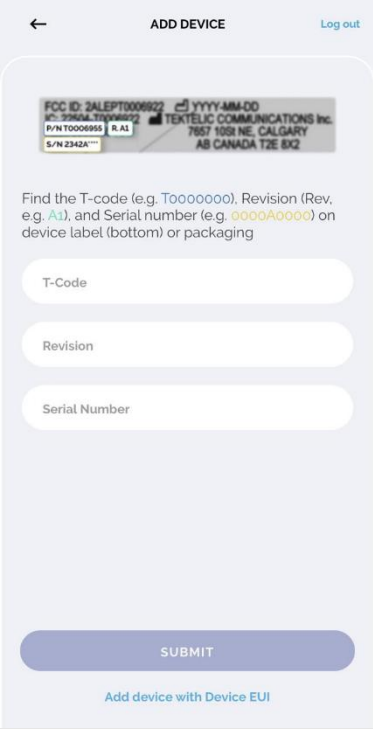


Figure 3-1839: Adding device using serial number, revision and T-code view

Note: The T-code should be 8 characters long and start with “T”.

Note: The Revision should have up to 4 characters (Latin letters and digits only).

Note: The Serial Number should be 9 characters long and contain a letter in the middle.

Click on the "Submit" button after entering your device T-code, revision and Serial number. After submit your entering, you will be taken to the device establishing connection.

3.6.3.2.3. Add device manually using device EUI

Click on “Add device with Device EUI” if you only know the Device EUI of the device. After this, a screen will appear prompting you to enter the Device EUI.

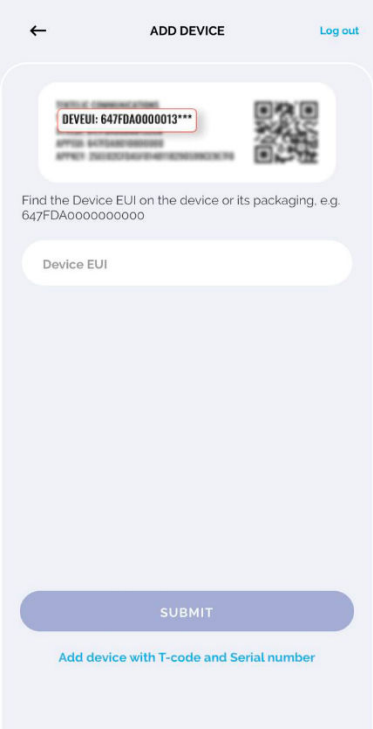


Figure 3-19: Adding device using device EUI

Note: The Device EUI should be 16 characters long and start with “647FDA”.

Click on the "Submit" button after entering your Device EUI. After submit your entering, you will be taken to the device establishing connection.

3.6.3.2.4. Editing device

After successfully add a device, can change its name by clicking on "**Edit device name**" or go further to the activate device by clicking on the "**ACTIVATE DEVICE**" button.

Note: The Device Name should be minimum 3 and maximum 255 characters long.
Note: The Device Name should only contain Latin letters, numbers and special characters: e.g., ! @ # ?].

3.6.3.3. Activate device and complete setup wizard

For device activation:

1. Open the device case and take out the battery.
2. Remove the battery tab.
3. Reinsert the battery and close the device case.
4. Wait for the device to start collecting the data. It may take up to 5 minutes. After completing the device activation, will receive an “The connection has been established”

message and you can complete setup wizard by clicking on the "**COMPLETE SETUP WIZARD**" button.

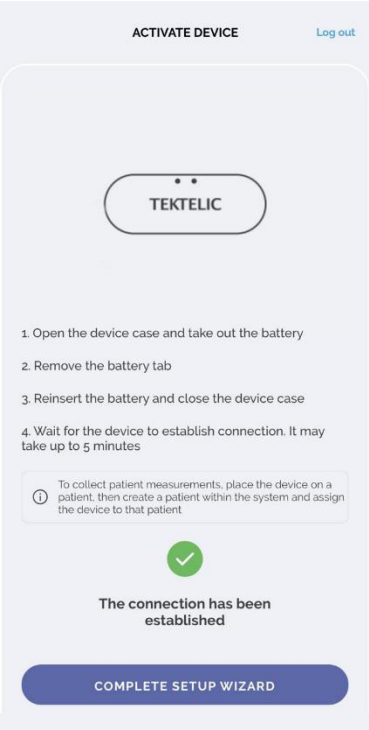


Figure 3-20: Successfully activate device view

⚠ If after 5 minutes the device does not pass the Internet connection stage, you will receive an error screen and can restart the process by clicking on the "TRY AGAIN" button.

After successfully completing all the steps and by clicking on the "**COMPLETE SETUP WIZARD**", will proceed to the main functionality of the application.

3.6.3.3.1. Skip Device Connection

If you do not want to activate the device during this step, you can skip the device activation and complete the Setup Wizard. To do this, click on the **"COMPLETE SETUP WIZARD"** button.

You will finish the Setup Wizard without activating the device. This option allows you to complete the setup process and return later to activate the device when needed.

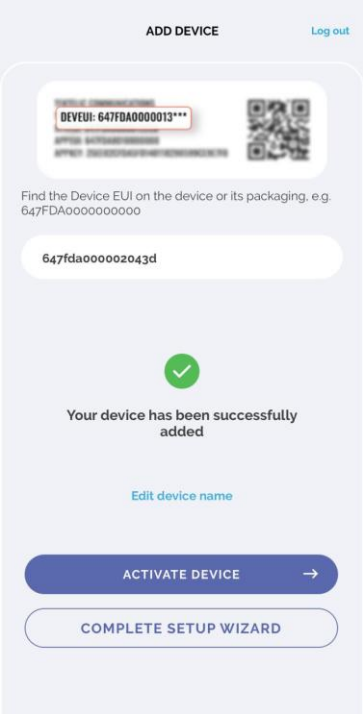


Figure 3-21: Skip device internet connection view

Please note that if you skip the device activation, the device will not start transmitting data until you perform the device activation.

3.6.4. Manage Patient

The "**Patient**" page allows the user to manage patients (view device data, change patient information and delete patients).

3.6.4.1. Adding new patient

To add a new patient in the app, follow these 4 simple steps:

1. Tap the "+" icon
Tap the **"+"** icon in the lower right corner of the screen to begin.

2. Scan or enter the patient's ID
Scan the patient's QR code, or tap "QR is not available" to manually enter the patient's Medical ID (an internal identifier used in your organization), then tap "Next".
https://support.tektelic.com/**Note**: The Patient QR code may contain any combination of letters and/or numbers that uniquely identifies the patient. The specific format may vary depending on the hospital or healthcare system.

3. Scan or select a device
Scan the QR code of the device, or tap "QR is not available" and select a device from the dropdown list of previously added ones. Tap "Next" to continue.

4. Enter patient details
Enter the first name, last name, age, and gender. Optionally, set threshold values for measurements.
Note:
Pulse and Respiration Rate thresholds must be entered as whole numbers. Skin Temperature thresholds can include decimal values; use a dot (.) as the decimal separator.

If everything is correct, tap "Submit" to complete patient creation. If changes are needed, tap "Back" to edit the information.

Note: The device data screen updates every minute. Please wait at least one minute for the data to appear.

3.6.4.2. Editing patient information

To edit patient information such as the first name, last name, or measurement thresholds:

1. Select the patient's card.
2. Go to the "Information" section.
3. Tap the edit icon in the lower right corner of the screen.

Make the necessary changes and click the "SAVE" button to apply the updates.

3.6.4.3. Delete Patient

To delete a patient:

1. Select the patient's card.
2. Click on the corresponding trash can icon in the right-top corner of the screen.
3. Confirm deleting by clicking on "OK".

Note: The history of data for patient after its removal will also be deleted.

3.6.4.4. Patient Device Data

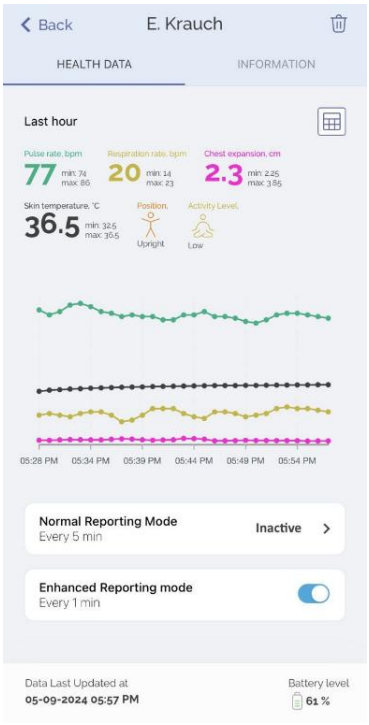


Figure 3-22: View of patient data reported from the eDoctor device

After creating a patient, you can view their device-reported data by selecting the patient's card.The screen will automatically update to reflect new values reported by the device.

Above the graph, the most recently received value for each parameter within the past hour is shown. Next to each parameter, the minimum and maximum values received during that hour are also displayed.
The status for Position and Activity Level is shown based on the latest received values.

If a reported value for Pulse Rate, Skin Temperature, or Respiration Rate falls outside the set thresholds, it will be highlighted in red in the Last Hour view.

Also, the corresponding values outside the established thresholds are highlighted in red in table view screen.

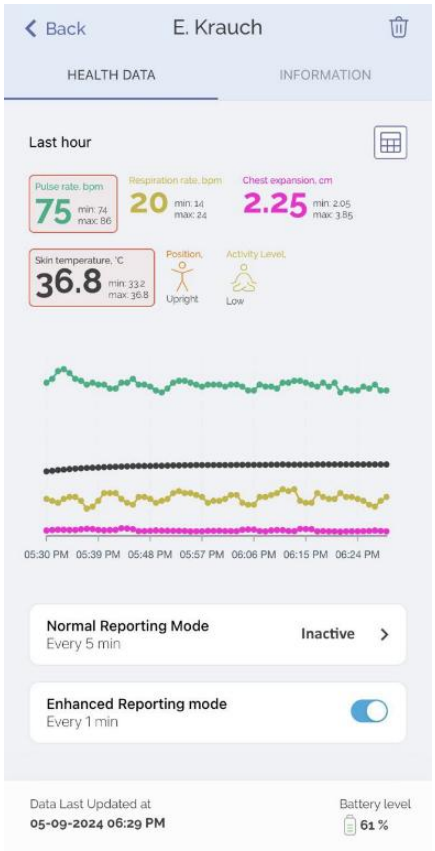


Figure 3-23310: Highlighting patient's thresholds

3.6.4.4.1. View device data

After the patient card is opened, you can view the latest data from the device. The eDoctor device reports skin temperature, pulse rate, respiration rate, chest expansion, position, activity level, last report time, as well as the battery level of the device itself. To view data for a certain period, you must click on the table icon in the upper right corner of the last measurement data. In Figure 3-22 below, skin temperature is used as an example.

Figure 3-24: Data history screen

Clicking on the desired parameter will take you to the data history screen for that parameter. You can customize the period of data display using the dropdown selector in the upper right corner of the screen. You can select two main periods – last hour (which is set by default after opening the history screen) and last 24 hour.

You can also customize measurement display using the dropdown selector in the upper left corner of the screen. You can select six measurements – Pulse Rate (which is set by default after opening the history screen), Skin temperature, Respiration rate, Chest Expansion, Position, Activity level.

Position and Activity level measurements display the corresponding status depending on the received parameter.
Position measurement can take the parameters Upright and Horizontal.
Upright: This parameter is displayed when the patient's body position value received from the

device exceeds 30 degrees.
Horizontal: This parameter is displayed when the patient's body position value received from the device equals 30 degrees or lower.

For return to viewing measurement data for last hour, click on chart icon in the upper right corner above the selection period of data display.

3.6.4.4.2. Reporting mode setting

New data from the device will be received after the period set in the device settings. By default, normal mode is set with a reporting period of 5 minutes.
The user can change it by clicking on the configuration icon and enter the desired reporting period from 2 to 60 minutes.

1. Click on the corresponding icon.
2. Set the report value in minutes (minimum value 2, maximum value 60).
3. Confirm the selected value clicking "Save" button.

The user can increase the device data reporting speed by switching on the enhanced reporting mode (clicking on the “Enhanced Reporting Mode button”, turning it purple).

3.6.5. Manage Gateways

The "**Gateways**" page allows you to manage gateways (view details, add new gateway, change gateway name and delete gateways).
You can open the “**Gateways”** page by clicking on the corresponding icon in the top menu.

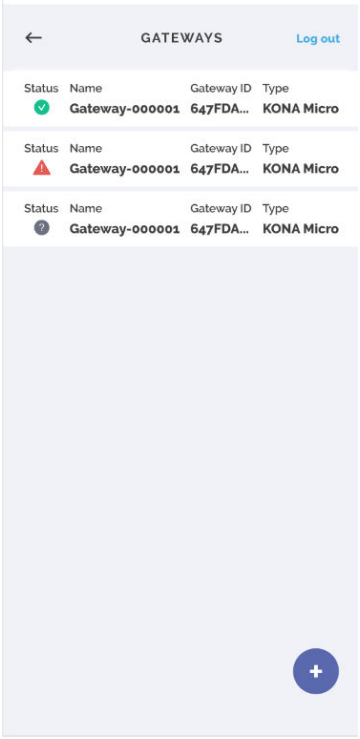


Figure 3-25311: Gateway page view

3.6.5.1. View Gateway details

To check the detailed information about your gateway, simply click on gateway in the table and the system will open the detailed view where you can see the gateway details, its ID, model and name.

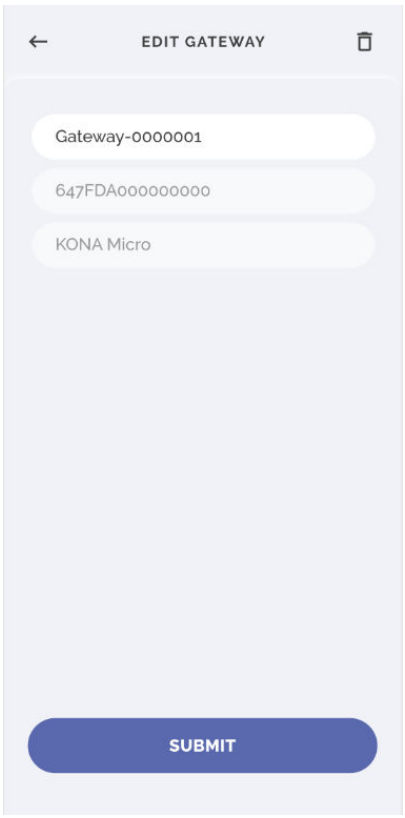


Figure 3-26: Gateway details view

3.6.5.2. Gateway editing

For editing gateway name:

1. Click on name field.
2. Enter new gateway name that does not repeat with an already existing name.
3. Click on the "**SUBMIT**" button. After changing the name of the gateway, a pop-up message will appear.

Note: The Gateway Name should be minimum 3 and maximum 255 characters long.
Note: The Gateway Name should only contain Latin letters, numbers and special characters: e.g., ! @ # ?].

3.6.5.3. Add new gateway

To add a new gateway, click on the plus icon (in the lower right corner of the screen) and follow the instructions in the Adding a Gateway section, described above. Unlike adding a gateway using the setup wizard, you cannot immediately set up the Internet connection for your

gateway. Instead, you can add another existing gateway by clicking on 'Add one more gateway +' or finish and return to the gateways page by clicking the 'Finish' button.

3.6.5.4. Gateway deleting

To delete a gateway that already exists, simply select the corresponding icon in the right-top angle on gateway details screen you would like to delete.

⚠ After gateway deleting, all data transmissions from devices that were in coverage of the gateway, will be disrupted.

3.6.6. Manage devices

The "**Manage Devices**" page allows the user to manage devices (view details, change device name, add new device and delete devices).
You can open the "**Manage Devices"** page by clicking on the corresponding icon in the top menu.

3.6.6.1. View device details

To check the detailed information about your device, simply click a record in the table and the system will open the detailed view where you can see the device details, its id, type and name.

3.6.6.2. Device editing

For editing device name:

1. Click on name field.
2. Enter new device name that does not repeat with an already existing name.
3. Click on the "**SUBMIT**" button. After changing the name of the device, a pop-up message will appear.

Note: The Device Name should be minimum 3 and maximum 255 characters long.
Note: The Device Name should only contain Latin letters, numbers and special characters: e.g., ! @ # ?].

3.6.6.3. Add new device

To add a new device, click on the plus icon (in the lower right corner of the screen) and follow the instructions in the Adding Device section described above. Unlike adding a device to the setup wizard, you cannot immediately set up the connection of your device but add another existing device clicking on "Add one more device +" or finish and return to the devices list by clicking on "Finish" button.

3.6.6.4. Device deleting

To delete a device that already exists, simply select the corresponding icon in the right-top angle on device details screen you would like to delete.
To delete a device, you must delete the patient to which this device is attached.

⚠ The history of data from the device after its removal will also be deleted.

3.6.7. Account Settings

You can also change and customize your account settings, such as setting/changing your account name and password and also account disabling.
You can open the Account settings by clicking on the corresponding icon in the top menu.

3.6.7.1. Forgot Password

To recover your password in the application, you must:

1. Proceed to login screen by opening the app.
2. Click on the "Forgot Password" button.
3. Enter the email address that you previously used to create an account.
4. Click on the "Reset password" button.
5. Check your email and find a message with confirmation code. If you do not see the email in your inbox, please check your spam or junk folder.
6. Return to the App, enter confirmation code and tap on the "Continue" button.
7. Enter password and confirm password in the designated fields and click on "Submit" button to set new password for your account.
   Password should be at least 8 characters long with a mix of letters, numbers and symbols.
8. If the code matches, a confirmation message will appear, indicating that your password reset is successful.
9. Click "OK" button and log in to the application using your email and new password.

3.6.7.2. Change Name

To change the account name setting, click on "Not Specified" if the account name is not yet set, or click on the previously entered name to change it.

3.6.7.3. Change Password

To change the account password:

1. Click on the "Change password" option.
2. Enter the old password, new password, and confirm the new password.
3. After clicking the "Save" button, your account password will be updated.

Note: Password should be at least 8 characters long with a mix of letters, numbers and symbols.

3.6.7.4. Application settings

To select the appropriate units of measurement according to your preferences:

1. Select the desired unit (Metric or Imperial).
2. Click on the “Save” button.

Note: Metric unit is the default value when creating an account.

The Metric system uses degrees Celsius (°C) to measure skin temperature and centimeters (cm) to measure chest expansion. The Imperial system uses degrees Fahrenheit (°F) and inches (in), respectively.

3.6.7.5. Logout

To logout from an app, click on the corresponding icon in the upper right corner of the screen. You can re-login to your account by entering your email and password.

3.7. TEKTELIC eDoctor Web Application Functionality

TEKTELIC eDoctor Web is a user-friendly solution for real-time monitoring of patients' vital signs and an ideal choice for remote health monitoring and tracking any changes in medical conditions. The eDoctor Web is designed to streamline access to eDoctor measurements, offering users continuous control over their health parameters.

TEKTELIC eDoctor Web is your way to facilitate routine medical processes, make healthcare accessible, and increase patients' safety in remote areas. To use the web application, go to the TEKTELIC eDoctor web and log in.

3.7.1. User authorization

For authorization in the eDoctor web, you should:

1. Enter the email and password in the appropriate fields from a previously created account in the mobile application.
2. Click on the "Log in" button.

Note: Once you have completed the profile setup, you can start exploring and using the eDoctor web features and functionalities.
Note: In case of unsuccessful login to the web application, try to recheck and re-enter your email and password.

3.7.2. Manage Patient

The "**Patient**" page allows you to manage patients (view patient data, change patient information and delete patients).

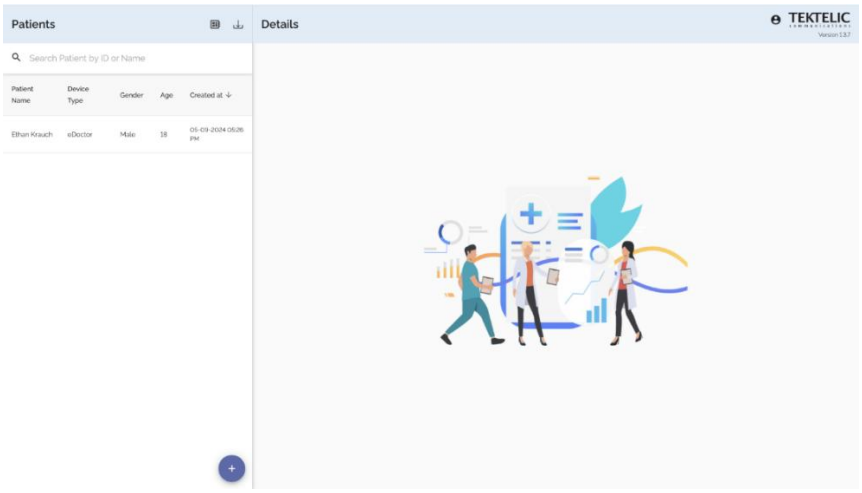


Figure 3-27: Patient page view

3.7.2.1. Adding new patient

1. For adding a new patient, you need to follow 4 simple steps:
2. Click on the "**+**" icon in the bottom of the screen.
3. Fill in the patient's information (first name, last name, age, gender), fill in the threshold fields for measurements (optional) and click "Next" button.
   Note: Thresholds for Pulse rate and Respiration rate measurements can only contain integer values, and thresholds for Skin temperature measurement can contain both integer and decimal values. To fill a decimal value, you should use only the dot symbol
4. Assign device for patient, selecting available device from dropdown list.
5. Carefully review the patient information you entered and if everything is correct and click the “Submit” button to finish creating the patient. If you see that you have entered incorrect data, then edit the patient's info.

3.7.2.2. Editing patient information

For editing patient information (first name, last name and measurements thresholds) select the patient's card, then go to the "Details" block and click on the edit icon.

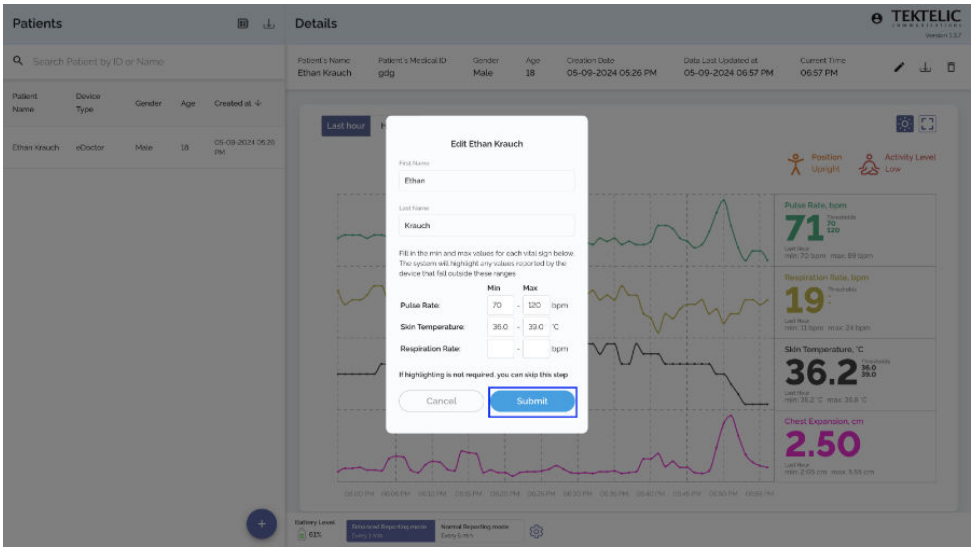


Figure 3-28: Editing patient info view

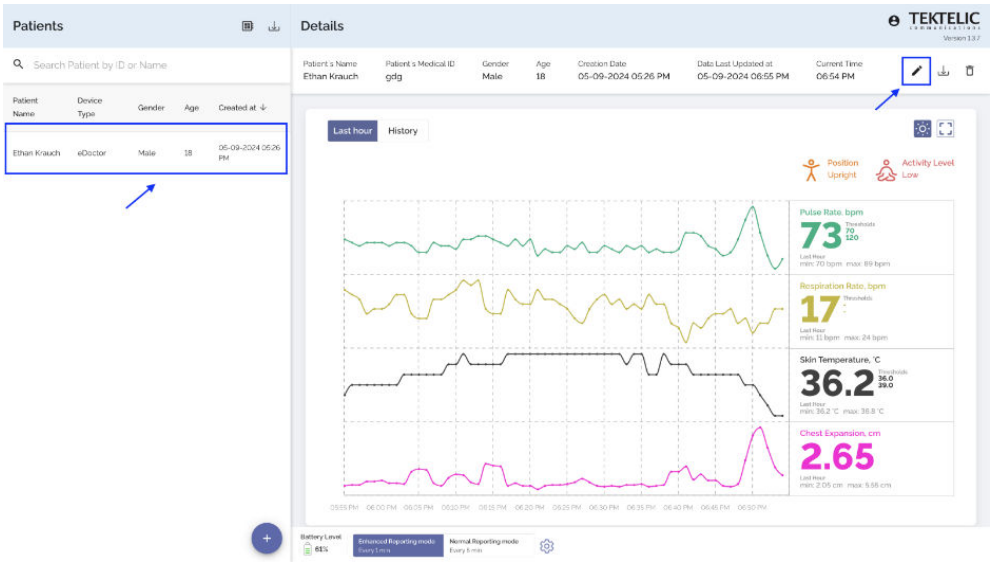


Figure 3-29: Selecting patient editing info view

Change first name, last name or measurements thresholds and click on "**Submit"** button.

3.7.2.3. Delete patient

To delete patient, simply select the patient's card, click on the corresponding icon in the right-top corner of the screen and confirm deleting by clicking on "Submit".

3.7.2.4. Patient device data

After creating a patient, will opens a Last Hour screen with data from the device. You can see the main report data for eDoctor device.
eDoctor device report skin temperature, pulse rate, respiration rate, chest expansion, position, physical activity, last report time, as well as the battery level of the device itself.

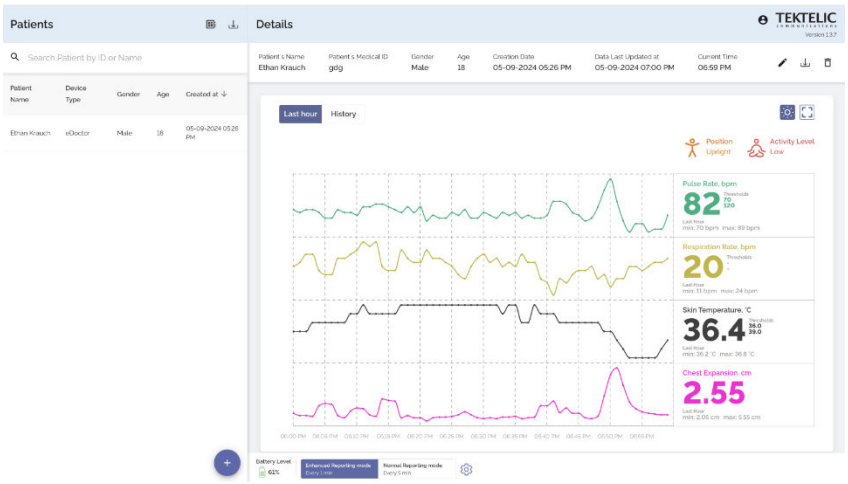


Figure 3-30: Patient data from eDoctor device view

The Last Hour screen displays data received over the last hour. The data will be updated on the screen every minutes.

To the right of the graph, you can see the last received value of a specific parameter for the last hour. Also, next to each parameter its minimum and maximum value obtained over the last hour and the set threshold values are displayed.

Position and Activity level measurements display the corresponding status depending on the received parameter.
Position measurement can take the parameters Upright and Horizontal.
Upright: This parameter is displayed when the patient's body position value received from the device exceeds 30 degrees.
Horizontal: This parameter is displayed when the patient's body position value received from the device equals 30 degrees or lower.

Activity level measurement can take the parameters Low, Medium, High.
Low: A level of activity characterized by the absence of significant physical activity. For example, sitting or lying down.
Medium: A level of activity that includes moderate physical activity, such as walking or standing.
High: A level of activity indicating intense physical activity or increased activity. For example, running or exercising.

If the obtained value for Pulse rate, Skin Temperature or Respiration Rate measurements is outside the established thresholds, the corresponding value is highlighted in red on the Last Hour screen.

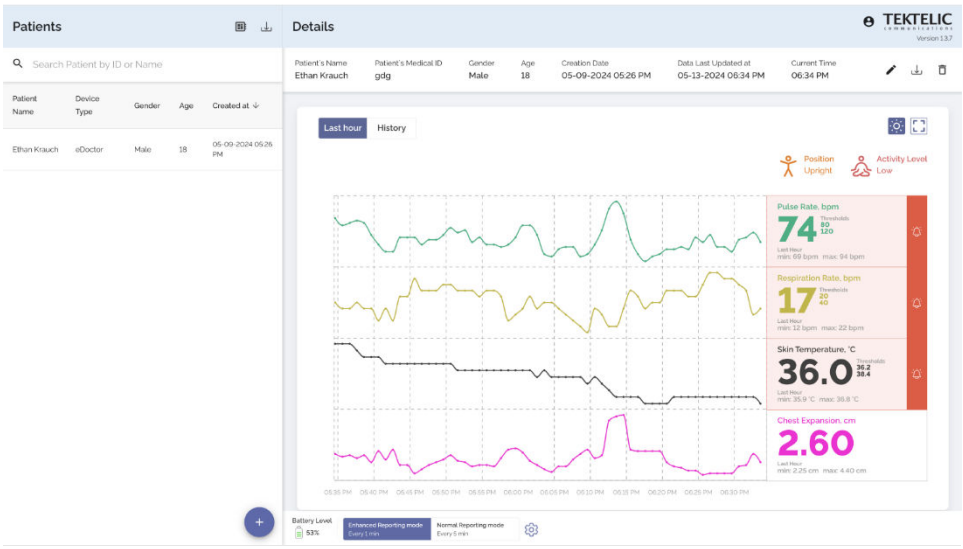


Figure 3-31312: Highlighting patient's thresholds

Also, the corresponding values outside the established thresholds are highlighted in red in table view screen.

3.7.2.4.1. View device data

To view detailed information for the last three months, you need to go to the History screen.

To customize the information on the chart, select up to two measurements, the desired date range for the last three months and the aggregation option.

Note: Position and Activity Level are not available on the chart.

Three aggregation options are available: by minutes, hourly, daily.
Per-minute aggregation displays all values of the selected measurement for the selected period.
Hourly aggregation displays the average received value per hour for the selected measurement over the selected period.

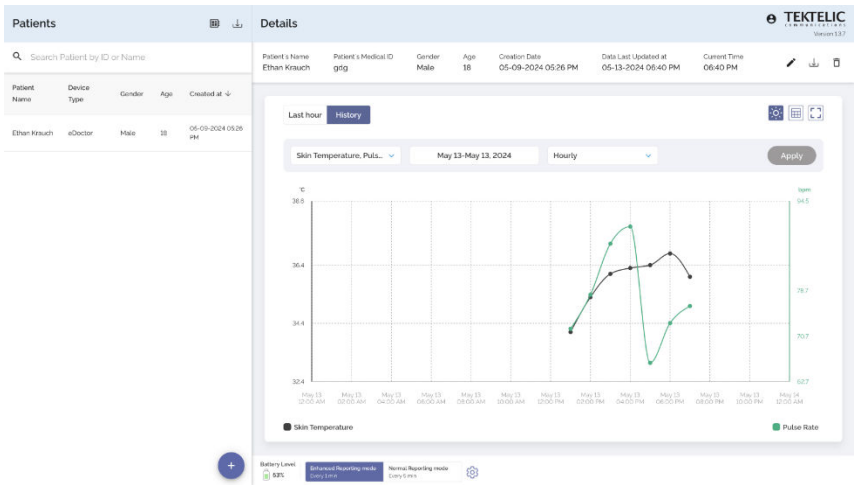


Figure 3-32: Data history screen

Daily aggregation displays the average received value per day for the selected measurement for the selected period.

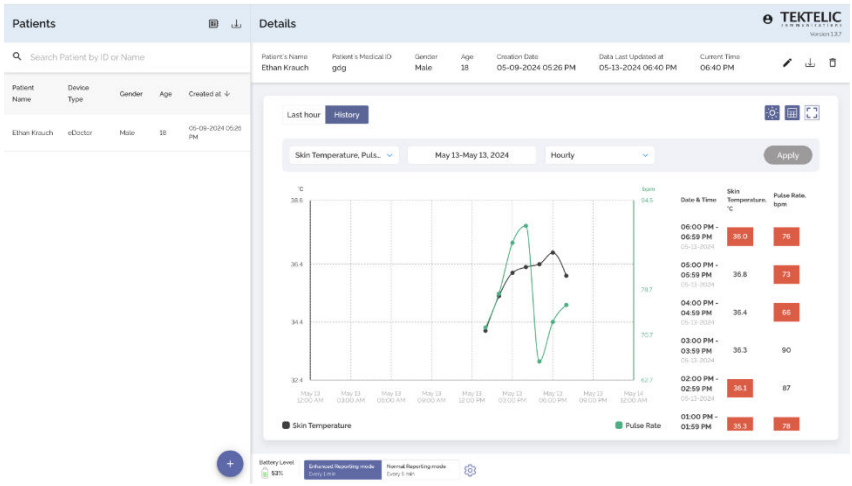


Figure 3-33: Table view

Data history for the selected parameter display in table and chart view.
You can see the aggregation average (Avg) values for the selected period in the table view or by hovering on the data point on the chart line.
You can turn table view display on and off using the "Table View" button.

Note: Position and Activity Level are available on the table view

3.7.2.4.2. Reporting mode setting

New data from the device will be received after the period set in the device settings. By default, normal mode is set with a reporting period of 5 minutes when worn.

The user can change it by clicking on the “Normal Reporting Mode” field and enter the desired reporting period from 2 to 60 minutes.

1. Click on the corresponding block.
2. Set the report value in minutes (minimum value 2, maximum value 60).
3. Confirm the selected value clicking "Save" button.

The user can increase the device data reporting speed by switching on the enhanced reporting mode (clicking on the “Enhanced Reporting Mode button”, turning it purple).

3.7.2.4.3. Change theme for data visualization

To switch between light and dark themes for the visualized data, click on the corresponding icon above the graph.

The theme change will be applied to the account in the web application.

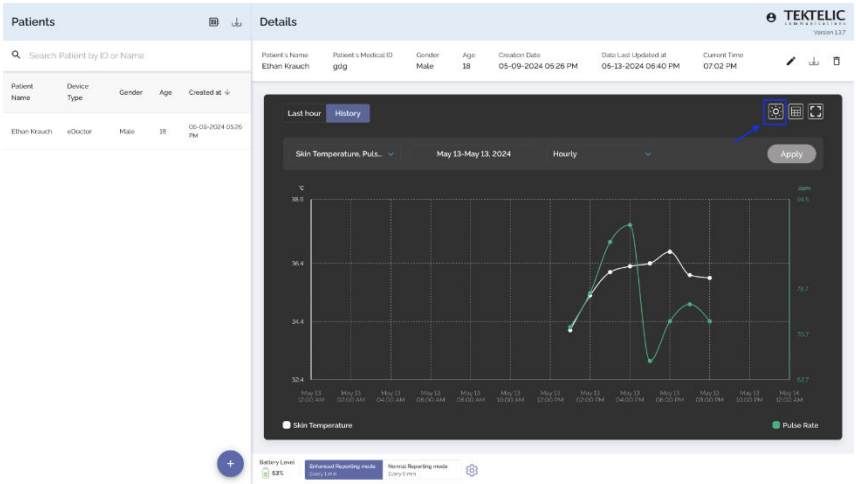


Figure 3-34313: Change theme for data visualization

3.7.2.5. Application settings

To select the appropriate units of measurement according to your preferences:
1. Click on the corresponding icon in the upper right corner of the screen and select “Application settings”.

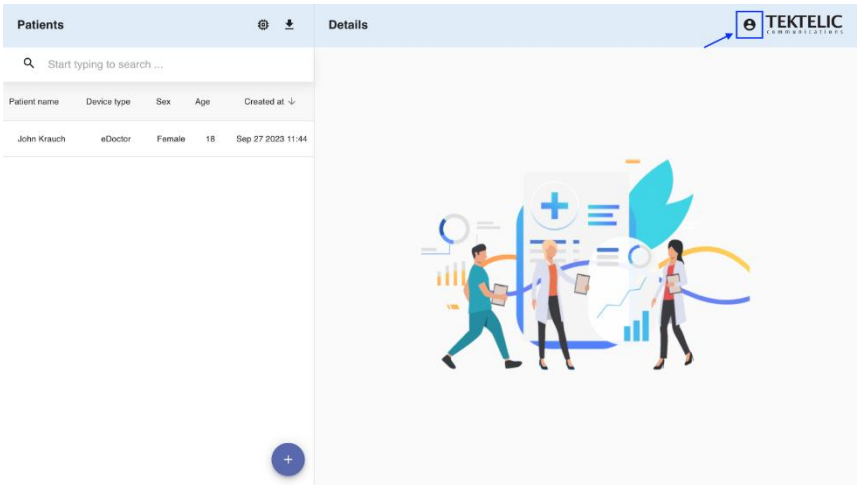


Figure 3-35: Account settings icon view

2. Select the desired unit (Metric or Imperial).
3. Click Save button.

Note: Metric unit is the default value when creating an account.

The Metric system uses degrees Celsius (°C) to measure skin temperature and centimeters (cm) to measure chest expansion. The Imperial system uses degrees Fahrenheit (°F) and inches (in), respectively.

3.7.2.6. Full screen mode

To open the full screen mode, you need to click on the corresponding icon above the graph. Full screen mode can be used for both Last Hour and History screens

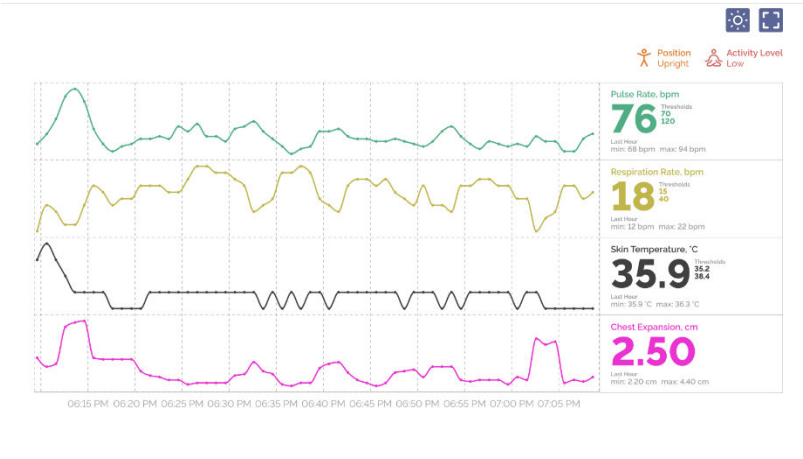


Figure 3143-36: Full screen mode

3.7.2.7. Export patient's data

To obtain a table with patient/patients' data, you can use data export to a csv file. This file contains the history of the data from the patient's device and the patient's personal data.

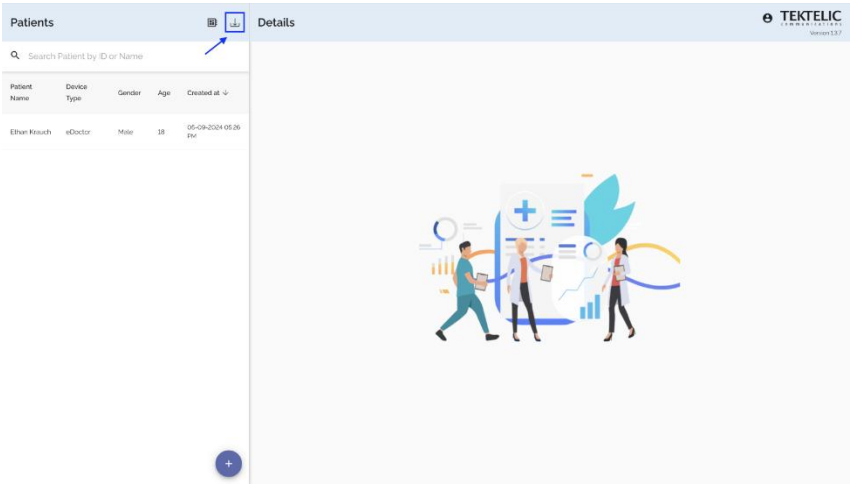


Figure 3-37: Export csv file with all patient's data view

To download the data of all patients into a csv file, use the corresponding icon above the list of all patients.

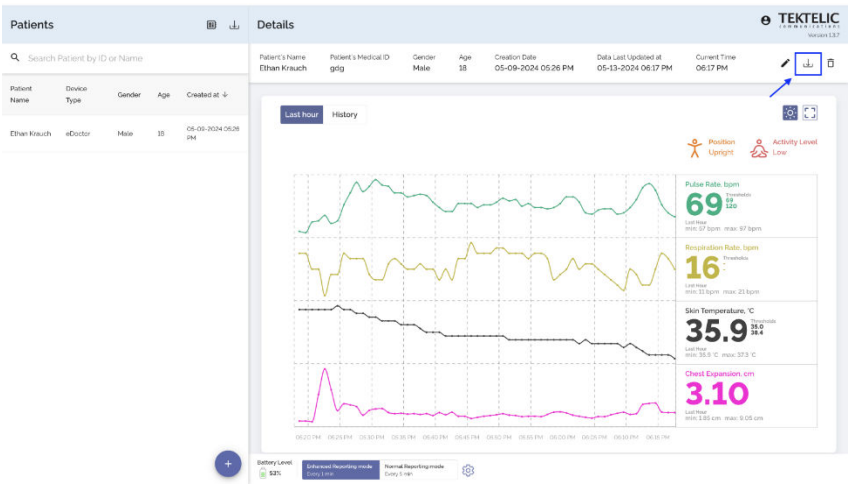


Figure 3-38: Export csv file of the specific patient's data view

To download the data of a specific patients into a csv file, select the needed patient's card and use the corresponding icon in the patient details block.

3.7.3. Manage Devices

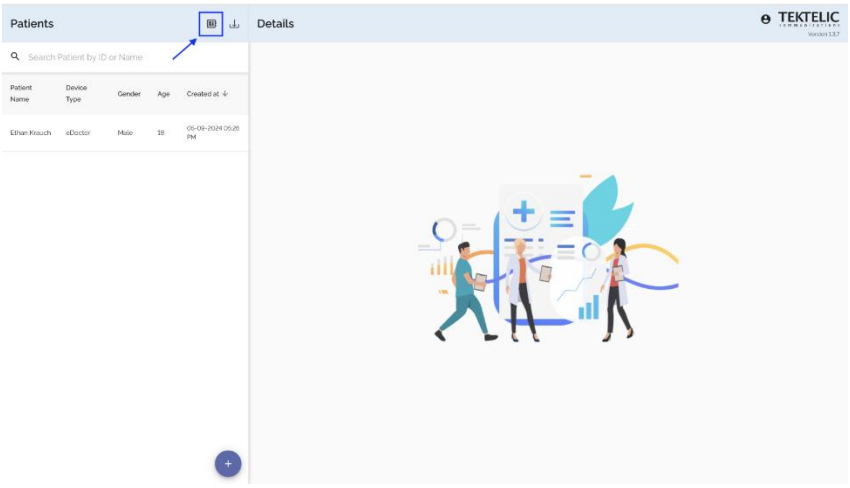


Figure 3-39: Devices list view

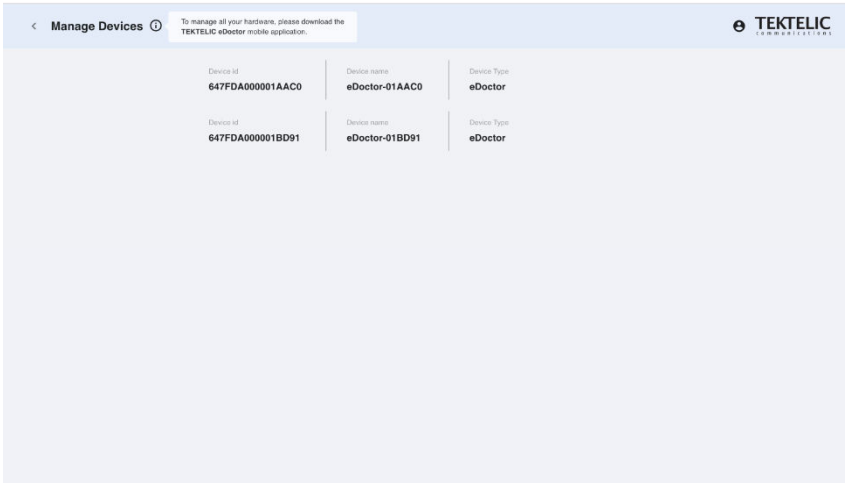


Figure 3-40: Manage devices page navigator icon

The "**Manage Devices**" page allows you to view devices on account.
To manage all your hardware, please download the TEKTELIC eDoctor mobile application.
You can open the "**Manage Devices"** page by clicking on the corresponding icon in the top menu.

3.7.4. Forgot Password

To recover your password in eDoctor web, you must:

1. Proceed to login screen by opening the web application.
2. Click on the "Forgot Password" button.
3. Enter the email address from the account you are trying to log in to.

4. Click on the “Reset password” button.
5. Check your email and find a message with confirmation code. If you do not see the email in your inbox, please check your spam or junk folder.
6. Return to the web application and enter verification code.
7. Enter new password and confirm password in the designated fields and click on “Submit new password” button to set new password for your account.

Note: Password should be at least 8 characters long with a mix of letters, numbers and symbols.

8. After entering all fields correctly, the password will be successfully changed, and you will be redirected to eDoctor web login screen.
9. If the verification code entered was incorrect, a corresponding pop-up notification will appear.

3.7.5. Logout

To logout from eDoctor web, click on the corresponding icon in the upper right corner of the screen (see Figure 3-39 below).
You can re-login to your account by entering your email and password.

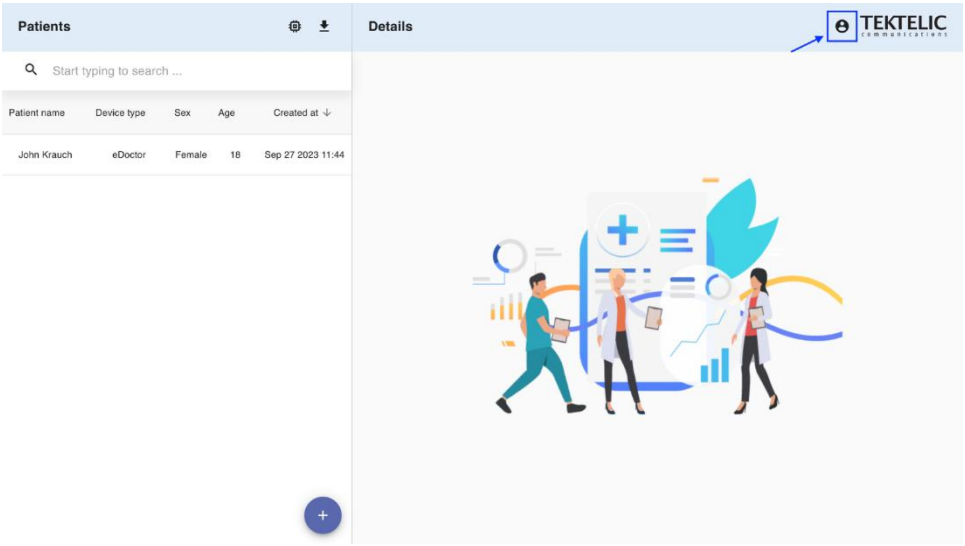


Figure 3-41 Logout from eDoctor web

3.8. Software and Firmware Updates

TEKTELIC Communications Inc. notifies users when software or firmware updates are available. Notifications are sent via email to the address associated with the user's registered account.

In addition, for mobile applications, update availability may be indicated through the respective mobile operating system's application store mechanisms. On iOS devices, the App Store may display a badge indicating available updates after a new version has been approved and published. On Android devices, the Google Play Store may generate system notifications indicating that application updates are available.

Users are responsible for maintaining accurate and up-to-date contact information and for ensuring that application updates are applied in accordance with their organization's policies.

3.9. Cleaning Instructions

⚠ **CAUTION** – To avoid damage to the device, do not allow fluids to come in contact. If fluids do come into contact, remove the device from service immediately and contact the manufacturer.

⚠ **CAUTION** – Review all cleaning instructions carefully before cleaning the device.

Table 3-1: Cleaning Supplies Required

Item Number	Equipment / Applications
1	TEKTELIC eDoctor Device
2	TEKTELIC eDoctor Chest Strap
3	Hospital-Grade Decontamination Wipes
4	Bowl of Cold Water
5	Mild Detergent (Dishwashing Liquid)

The TEKTELIC eDoctor Device and chest strap are both non-sterile, reusable, and can be used on multiple patients.

The TEKTELIC eDoctor Device and chest strap must be decontaminated between uses on different patients and before being returned to the manufacturer for maintenance or repair. This practice will limit the risk of infection and help ensure safety.

Cleaning Procedure for the eDoctor Device:

1. Remove the eDoctor device from the chest strap.

2. Ensure the battery lid is securely locked on the device before beginning to clean it with a disinfecting wipe.
3. Wipe down all surfaces of the eDoctor device with a new, unused, hospital-grade disinfecting wipe. If the wipe dries out while cleaning, continue the cleaning with another new, unused disinfecting wipe.
4. Once the eDoctor device has been fully wiped down with a disinfecting wipe, set it in a clean area to dry.

Cleaning Procedure for the Chest Strap:

1. Remove the eDoctor device from the chest strap.
2. Place the strap in a bowl full of cold water with a small amount of a mild detergent, such as dishwashing liquid.
3. Handwash the chest strap and allow it to air dry lying flat.

It is the responsibility of the healthcare professional to ensure this cleaning procedure is completed correctly. Additional infection control precautions should be followed as directed by your local operating institution's guidelines.

Healthcare professionals and/or patients should regularly inspect the TEKTELIC eDoctor Device and chest strap for cleanliness and decontaminate as needed.

3.10.Maintenance

Maintenance must **ONLY** be completed by TEKTELIC staff.

⚠ **WARNING** – Please ensure device has been cleaned before returning to manufacturer for repair and/or maintenance to lessen risk of infection.

⚠ **WARNING** – Do not remove the enclosure, current-carrying components are present. Maintenance must only be completed by the manufacturer.

⚠ **WARNING** – Service or repair of device must only be completed by the manufacturer.

⚠ **WARNING** – Device failure may occur due to use life exceeded. Perform regular inspection of the device and chest strap.

3.11. Expected Service Life

The expected service life of the TEKTELIC eDoctor Device and chest strap is 2 years. During this expected service life, the device may require battery changes every 2-3 months depending on use.

The expected service life is defined as the length of time at which the device and chest strap are suggested to be replaced to prevent performance degradation.

When the expected service life of the device is reached, the device may no longer meet the pulse rate, respiration rate, and/or skin temperature accuracy specifications. Security updates, patches, and vulnerability mitigations may no longer be available. Devices used beyond their supported service life may be subject to increased cybersecurity risk. Exceeding the expected service life will not pose an electrical safety hazard.

The eDoctor applications are maintained and supported through regular software updates, including security patches.

At the end of support, security updates may no longer be provided. Continued use of unsupported versions may increase cybersecurity risks.

Users are advised to upgrade to supported versions to maintain security and performance.

3.12. Medical Device Disposal

⚠ **WARNING** – Please ensure device has been cleaned before disposal to lessen risk of infection.

⚠ **CAUTION** – The eDoctor contains a lithium coin cell battery. Do not burn or puncture battery. Please ensure disposal instructions are followed.

⚠ **CAUTION** – Remove and immediately recycle or dispose of batteries from equipment not used for an extended period according to the local regulations.

When the TEKTELIC eDoctor device has reached its expected service life, remove and immediately recycle or dispose of used batteries according to local regulations and keep away from children. Do NOT dispose of batteries in household trash or incinerate.

When the TEKTELIC eDoctor device and/or chest strap has reached its expected service life, please dispose of it in the garbage.

4. Troubleshooting Information

Table 4-1: Troubleshooting Problems and Options

Basic Feature	Problem	Options
General Troubleshooting	Difficulty with set-up, operation, or application(s).	• Refer to the "Setup Instructions" section of the IFU. • Refer to the "Operating Instructions" section of the IFU. • Refer to the "TEKTELIC eDoctor Mobile Application Functionality" section of the IFU. • Refer to the "TEKTELIC eDoctor Web Application Functionality" section of the IFU.
Accessory Troubleshooting	Fitting/attaching the chest strap.	• Refer to the "Wearing the device" section of the IFU.
General Troubleshooting	Powering on the device or replacing the battery.	• Refer to the "Powering on the device/replacing the battery" section of the IFU.
General Troubleshooting	Device remains blinking for more than five minutes.	• Ensure the device is provisioned on the Network Server. • Ensure the local LoRaWAN Gateway has also been provisioned on the eDoctor Mobile Application. • Ensure the local LoRaWAN Gateway is online and within range of the device.
Health-Data	Health metrics are not displaying correctly.	• Refer to the "Wearing the device" section of the IFU. Ensure the strap has been adjusted correctly.
General Troubleshooting	Setting up the gateway with cellular backhaul (SIM card).	• Refer to the Kona Gateway Cellular Backhaul FAQ.
General Troubleshooting	Suspected cybersecurity incident (e.g. unauthorized access, abnormal behavior)	• Disconnect the affected system(s) from the network • Notify your organization's IT/security team • Follow the procedures outlined in the TEKTELIC

		Vulnerability Disclosure Policy
General Troubleshooting	Detected security event (e.g., unauthorized login attempts, unauthorized configuration changes, abnormal system or application behavior)	Security events are logged by the system. Users are notified of security events through application interfaces.

For further technical support, please visit the TEKTELIC Support Portal.

If any malfunctions or mistakes occur, please contact your TEKTELIC local representative on the TEKTELIC Website.

5. Technical Description

5.1. Software Bill of Materials (SBOM)

TEKTELIC Communications Inc. maintains a machine-readable SBOM for the eDoctor device and associated applications.

The SBOM includes a list of software components and dependencies to support cybersecurity risk management.

The SBOM is available to authorized users upon request. Please refer to the TEKTELIC Support Portal for access.

5.2. Essential Performance

Essential performance for the eDoctor device is defined as: “The device shall report accurate pulse rate, respiration rate, and skin temperature values.” To ensure essential performance the following conditions should be considered:

⚠ **CAUTION** – To avoid damage to the device, do not allow fluids to come in contact. If fluids do come into contact, remove the device from service immediately and contact the manufacturer.

⚠ **CAUTION** – Damage to the device may degrade sensor and electrode performance.

⚠ **CAUTION** – The device should not be near or in contact with high temperatures (i.e., Fireplace).

⚠ **CAUTION** – Device and strap must make direct contact with intact skin.

For more information on the pulse rate, respiration rate, and skin temperature accuracy specifications please refer to the Pulse Rate, Respiration Rate, and Skin Temperature monitoring specification sections.

5.3. Non-clinical Performance

Non-clinical performance refers to functions of intended use that are not related to basic safety or essential performance, as per IEC TS 60601-4-2.

This can be summarized as the eDoctor device's ability to boot and remain in the typical operating state while powered, transmit and receive data, flash the LEDs, recognize push button presses, determine when the device is worn or not worn, measure and report data as expected when worn, and stay in sleep mode when not worn.

5.4. Use Environments

The TEKTELIC eDoctor Device is designed for ideal use in indoor environments. The storage temperature conditions range from -25°C to 70°C. The operational conditions range from 5°C to 40°C. The most common use environments would include in professional healthcare facilities, such as hospitals or skilled nursing facilities, or their own home.

Remove the strap from the device while not in use. This will ensure the device goes to sleep and preserves its battery. It will stop reporting after 1 minute of not being worn.

5.5. Monitoring Specifications

This section will describe the security specifications for the eDoctor device, web application, mobile application, and server application. It also describes the transducer, measurement range, accuracy (if applicable), and resolution of all reported parameters. Reported parameters without accuracy are considered wellness parameters.

5.5.1. Device/System Security

Table 5-1: eDoctor Device Security Specifications

eDoctor Device Security Specifications	
Encryption Standard	AES 128 encryption as per the LoRaWAN Specification
Data Storage	Data stored in the device flash memory includes: • Parameter settings. • Calibration data, set at the factory.

	• LoRaWAN settings, including secure keys.
Data Exchange	HTTPS protocol, transferred through TLS connection, encrypted by algorithm RSA 2048
Firmware Update Control	Firmware updates for the TEKTELIC eDoctor device are restricted and can only by performed by TEKTELIC Communications Inc. at authorized facilities.

Table 5-2: eDoctor Web Application Security Specifications

eDoctor Web Application Security Specifications	
Encryption Standard	User-related data is stored in an AWS Cognito user pool
Data Storage	PostgreSQL database hosted on AWS cloud server
Data Exchange (Between User and Software)	HTTPS protocol, transferred through TLS connection, encrypted by algorithm RSA 2048

Table 5-3: eDoctor Mobile Application Security Specifications

eDoctor Mobile Application Security Specifications	
Encryption Standard	User-related data is stored in an AWS Cognito user pool
Data Storage	Temporarily stores information the user works with in the application
Data Exchange (Between User and Software)	HTTPS protocol, transferred through TLS connection, encrypted by algorithm RSA 2048

Table 5-4: eDoctor Server Application Security Specifications

eDoctor Server Application Security Specifications	
Encryption Standard	Amazon RDS
Data Storage	User data is stored in AWS Cognito. Information about devices, gateways, patients, and patients' parameters, user account settings, and device configurations are stored in the PostgreSQL 14.7 database.
Data Exchange (Between User and Software)	HTTPS protocol, transferred through TLS connection, encrypted by algorithm RSA 2048
Data Retention and Recovery	Application configuration recovery mechanisms are not available to end users.

	Configuration and user data are maintained on backend systems and are associated with authenticated user accounts. In the event of a data loss incident, system data may be restored by TEKTELIC technical personnel from backend backups. Backups are retained for a defined period (7 days) and may be extended if required for recovery purposes.

5.5.1.1. Network Ports

The TEKTELIC eDoctor Web and Mobile Applications use the following network interfaces for communication:

HTTPS (TCP port 443) — outbound communication from web browsers and mobile applications to backend services for user authentication, data access, and system interaction. The destination endpoints are the eDoctor backend services hosted in a controlled server environment.

No inbound network ports are required to be opened within the user's or healthcare facility's network for normal system operation.

All communications are initiated by client components toward designated backend endpoints over secure channels.

5.5.1.2. Protection of Critical Functionality

The TEKTELIC eDoctor system incorporates security features intended to safeguard the device, its core functionality, and associated user data. These protections are implemented by TEKTELIC and are enabled as part of normal system operation.

Communications between the eDoctor device, LoRaWAN gateway, and backend infrastructure are secured using industry-standard encryption methods. Each device uses unique identifiers and cryptographic keys to ensure that data is exchanged only with authorized system components.

Data transmitted across system elements, including cloud services and user-facing applications, is protected through secure communication protocols (such as TLS). These protections help prevent unauthorized access to system data and help ensure that device operation is not altered or interfered with.

5.5.1.3. Data Flow and Security Controls

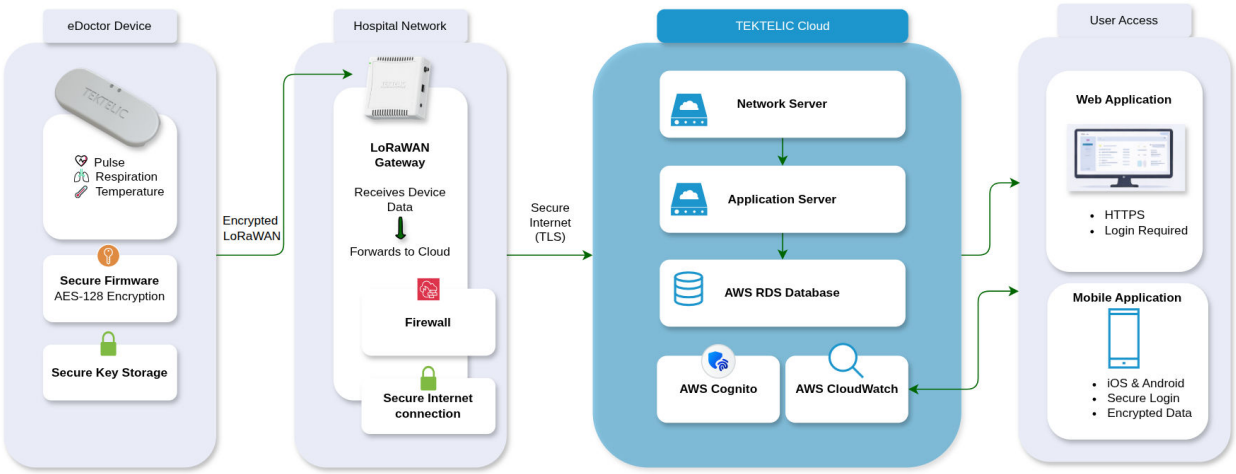


Figure 5-1: Data Flow and Security Controls

5.5.2. Pulse Rate

The unit of measurement for pulse rate is beats per minute (bpm).

Table 5-5: Pulse Rate Specifications

Pulse Rate Specifications	
Transducer	ECG measurement integrated circuit
Measurement Range	30 bpm to 200 bpm
Resolution	1 bpm
Accuracy	+/- 3 bpm

Measurements falling outside the measurement range are reported as invalid.

In the last 15 seconds of every minute, the pulse rate is sampled multiple times. The pulse rate reported is the rounded statistical average of the per-minute pulse rate over the last three minutes.

5.5.3. Respiration Rate

The unit of measurement for respiration rate is respirations per minute (rpm).

Table 5-6: Respiration Rate Specifications

Respiration Rate Specifications	
Transducer	Piezo element
Measurement Range	4 rpm to 80 rpm
Resolution	1 rpm
Accuracy	+/- 2 rpm

Measurements falling outside the measurement range are reported as invalid.

The respiration rate is derived from the voltage samples taken from the piezoelectric element over one minute. The respiration rate reported is the rounded statistical average of the per-minute respiration rates calculated every minute over the past three minutes.

5.5.4. Chest Expansion

Table 5-7: Chest Expansion Specifications

Chest Expansion Specifications	
Transducer	Piezo element
Measurement Range	0.0 cm to 12.7 cm
Resolution	0.05 cm

Measurements falling outside the measurement range are reported as invalid.

The chest expansion value reported is the rounded statistical average of the per-minute chest expansions calculated every minute over the past three minutes.

5.5.5. Skin Temperature

⚠ **CAUTION** – Please wait for the skin temperature readings to stabilize after putting the device on or if there have been changes in environmental conditions.

To ensure the accuracy stated in the table below is achieved, please allow for the skin temperature readings to stabilize.

Table 5-8: Skin Temperature Specifications

Skin Temperature Specifications	
Transducer	Thermistor – Direct mode thermometer
Measurement Range	30°C to 43°C
Resolution	0.05°C
Accuracy	+/- 0.3°C

A thermistor is a type of resistor whose resistance changes significantly with temperature, allowing it to be used as a temperature sensor.

Measurements falling outside the measurement range are reported as invalid.

Skin Temperature Time Constant: The eDoctor may take up to 8 minutes to respond to a 2°C change in skin temperature. This value reflects the sensor's response characteristics under controlled test conditions and is provided to illustrate typical performance.

Skin temperature is measured by two thermistors once every minute while being worn. The reported skin temperatures are the skin temperature measurements performed in the last minute by each thermistor. The eDoctor mobile and web application shows one skin temperature value, which is the maximum value between the two most recently reported skin temperature values.

5.5.6. Position

Table 5-9: Position Specifications

Position Specifications	
Transducer	Accelerometer
Measurement Range	Sitting/Standing (90°), Lying down (0°)

Position will be reported as upright for values of 30° to 90°. Less than 30° will be considered laying down.

5.5.7. Activity Level

Table 5-10: Activity Level Specifications

Activity Level Specifications	
Transducer	Accelerometer
Measurement Range	Low, medium, high

Activity level values correspond to the following movements:

- Low: Still/stationary
- Medium: Turning/shifting
- High: Exercising/running

5.6. Electrical Safety

⚠ **CAUTION** – Do not touch the battery and the patient at the same time during battery replacement.

⚠ **CAUTION** – Do not touch the gateway/smart phone/computer and patient at the same time.

The TEKTELIC eDoctor Device has been tested for and complies with electrical safety and IEC 60601-1:2005, AMD1:2012, AMD2:2021, IEC 60601-1-11:2015 and AMD1:2021 for devices intended for home use.

5.7. MRI Safety Information

⚠ **WARNING** – The eDoctor device and chest band are MR Unsafe. Do not expose the device or the chest band to a magnetic resonance (MR) environment. The device and chest band present projectile hazards. Patients should not receive an MR exam while the device and chest band are fastened to the patient.

5.8. Electromagnetic Compatibility (EMC)

⚠ **WARNING** – Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

⚠ **WARNING** – Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

⚠ **WARNING** – 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 TEKTELIC eDoctor Device, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

The TEKTELIC eDoctor Device has been tested for and complies with IEC 60601-1-2:2014 + AMD1:2021 and is FCC qualified as a portable device. The TEKTELIC eDoctor device has also been tested according to the recommendations of IEC TS 60601-4-2:2024 Medical electrical equipment – Part 4-2: Guidance and interpretation – Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems.

Electromagnetic Emissions Declaration:

The eDoctor device is designed for use in the specified electromagnetic environment outlined below. Users must ensure that the eDoctor device is operated within this environment.

Table 5-11: Emissions Test Compliance and Guidance

Emissions Test	Compliance	Electromagnetic Environment Guidance
Electromagnetic Radiation Disturbance (Radiated Emissions) CISPR 11	Group 1	The eDoctor uses RF energy only for its internal function.
Electromagnetic Radiation Disturbance	Class B	The eDoctor is intended for use in domestic establishments.

(Radiated Emissions) CISPR 11		
Conducted Disturbances (Conducted Emissions) CISPR 11	N/A	Device is battery powered with no AC or DC power port.
Harmonic Current Emissions IEC 61000-3-2	N/A	Device is battery powered with no AC or DC power port.
Voltage Changes, Voltage Fluctuations and Flicker Emissions IEC 61000-3-3	N/A	Device is battery powered with no AC or DC power port.

Electromagnetic Immunity Declaration:

The eDoctor device is designed for use in the specified electromagnetic environment outlined below. The compliance levels represent the levels at which the eDoctor has been tested to ensure that it maintains basic safety, essential performance, and non-clinical performance. Users must ensure that the eDoctor device is operated within this environment.

The eDoctor may be unable to provide accurate results when subject to noise or interference affecting the measurement quality. Ensure that the environment is free from potential sources of interference to minimize the risk of inaccurate measurements. Examples of potential sources of interference include, but are not limited to, other electronic devices or strong electromagnetic fields. Radiated RF EM fields between 134 – 186 MHz may cause temporary interruption in data transmission.

Electrostatic discharge could cause the eDoctor to restart. If this occurs, the eDoctor is expected to recover and continue operation within 30 seconds. This has no impact on the essential performance of the eDoctor.

The operator (i.e., the healthcare professional) should take appropriate measures to minimize the impacts of potential interference by following the guidance below.

Table 5-12: Immunity Test Compliance and Guidance

Immunity Test	Compliance	Electromagnetic Environment Guidance
Electrostatic Discharge IEC 61000-4-2	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Radiated RF EM fields IEC 61000-4-3	10 V/m (Essential Performance), 3 V/m (Non-clinical Performance)	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

	80 MHz – 2.7 GHz 80% AM at 1 kHz (see Note below)	the TEKTELIC eDoctor Device, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
Proximity fields from RF wireless communications equipment IEC 61000-4-3	See Table 5-13.	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 TEKTELIC eDoctor Device, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
Rated power frequency magnetic fields IEC 61000-4-8	N/A	Device and chest strap do not contain any magnetically sensitive components.
Proximity Magnetic Fields IEC 61000-4-39	N/A	Device and chest strap do not contain any magnetically sensitive components.
Conducted disturbances induced by RF fields IEC 61000-4-6	N/A	Patient coupling points do not have conducting cables.
Electrical fast transients/bursts IEC 61000-4-4	N/A	Device is battery powered with no AC or DC power port.
Surges IEC 61000-4-5	N/A	Device is battery powered with no AC or DC power port.
Voltage dips IEC 61000-4-11	N/A	Device is battery powered with no AC or DC power port.
Voltage interruptions IEC 61000-4-11	N/A	Device is battery powered with no AC or DC power port.
Electrical transient conduction along supply lines ISO 7637-2	N/A	Device is battery powered with no AC or DC power port.

Note: Non-clinical performance degradation at 10 V/m was observed between 134.2 MHz and 186.4 MHz. Non-clinical performance degradation at 3 V/m did not occur, maintaining compliance.

Table 5-13: Proximity Fields from RF Wireless Fields Immunity Test Compliance

Test Frequency (MHz)	Modulation	Immunity Test Level (V/m)
385	Pulse Modulation: 18 Hz	27
450	FM: ±5 kHz deviation, 1 kHz sine	28
710, 745, 780	Pulse Modulation: 217 Hz	9
810, 870, 930	Pulse Modulation: 18 Hz	28
1720, 1845, 1970	Pulse Modulation: 217 Hz	28
2450	Pulse Modulation: 217 Hz	28
5240, 5500, 5785	Pulse Modulation: 217 Hz	9

5.9. FCC Compliance Statements

Federal Communications Commission

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.

To comply with FCC exposure limits for general population / uncontrolled exposure, this device has lowered its maximum power to comply with SAR limits for wearable devices and must not be co-located or operating in conjunction with any other transmitter.

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

NOTE: "Harmful interference" is defined in 47 CFR §2.1 by the FCC as follows: Interference which endangers the functioning of a radionavigation service or of other safety services or seriously degrades, obstructs, or repeatedly interrupts a radio communication service operating in accordance with the [ITU] Radio Regulations.

6. Precautions

In the interest of ensuring a secure and enjoyable experience with our mobile and web application, we strongly recommend the following precautions:

⚠ **CAUTION** – Mobile devices and PCs used to access the eDoctor web app or the eDoctor mobile app should be secured when not in use.

⚠ **CAUTION** – Users should regularly apply/allow security updates to your device's operating system (OS).

⚠ **CAUTION** – TEKTELIC does not make any commercial use of or disclose any private information of eDoctor users

⚠ **CAUTION** – Users should follow their hospital's data backup process where applicable to ensure data can be recovered in the event of an emergency. TEKTELIC Technical support can also be contacted to assist with disaster recovery.

⚠ **CAUTION** – Safeguard your login information with the utmost care. Never share your username and password with any third party.

⚠ **CAUTION** – Exercise prudence when installing mobile applications. Only install apps from trusted sources, such as official app stores. Avoid downloading and installing applications from unverified or unofficial sources.

⚠ **CAUTION** – Use strong, unique passwords for your web accounts. Combine a mix of upper and lower-case letters, numbers, and symbols. Consider using a reputable password manager.

⚠ **CAUTION** – Users should ensure that data from the web and mobile application is periodically backed-up to ensure availability of information in the event of a disaster.

⚠ **CAUTION** – TEKTELIC personnel will never request your password or login information. Notify TEKTELIC immediately if you receive unexpected or confusing emails, phone calls, or other forms of communication

⚠ **CAUTION** – Do not share login information (e.g. password) of your eDoctor account.

By adhering to these precautions, you contribute to a safer and more secure experience while using our mobile and web applications.

7. Warranty

Products sold hereunder are covered by a warranty against defects in material and workmanship provided the Products and services are subjected to normal use and service. The applicable warranty period is twelve (12) months plus two weeks from the date of shipment. The foregoing warranty shall not apply to:

1) Products that have been modified by anyone other than TEKTELIC without TEKTELIC's prior written consent and/or subjected to improper handling, storage, installation, operation or maintenance;

2) Any item of the Products which is furnished by Purchaser as a component part of a purchased Product, or any equipment that is not manufactured by TEKTELIC and is purchased by TEKTELIC on behalf of Purchaser. For the removal of doubt, components selected or sourced by TEKTELIC shall be covered by the warranty;

3) Models or samples which are furnished to Purchaser as illustrations only of the general properties of TEKTELIC's products and workmanship;

4) Damage to Products caused by abrasive materials, corrosion due to aggressive fluids, lightning, improper voltage supply, mishandling or misapplication.

Except as expressly set forth herein, TEKTELIC expressly disclaims any and all representations, warranties, conditions, covenants, guarantees and/or assurances, whether express or implied, relating to or arising out of Products or services and/or this contract, including without limitation, any implied representations, warranties, conditions, covenants and/or guarantees as to merchantability, merchantable quality, non-infringement, fitness for a particular purpose, those arising by statute or otherwise, or from a course of dealing or usage or trade. To the extent permitted by applicable law, all warranties, representations, terms and conditions other than as expressly contained herein are excluded. Each party acknowledges that it has not relied on any other term, condition, representation, warranty, matter, statement or conduct in entering into this contract.

Purchaser's sole remedy for a breach of this limited warranty, for any other liability under this contract, or for any liability that cannot be excluded as provided by applicable law, shall be limited (at TEKTELIC's sole option) the repair, replacement or refund to Purchaser's account for any such Products which are returned by Purchaser during the applicable warranty period, provided that (i) TEKTELIC is promptly notified in writing during such warranty period upon discovery by Purchaser that the Products failed to conform to the express warranties set forth above, (ii) such Products are returned to TEKTELIC Incoterms 2010 DDP TEKTELIC's plant shipping costs covered by the Purchaser, and (iii) TEKTELIC's examination of such Products shall

disclose to TEKTELIC's satisfaction that such alleged deficiencies actually exist and were not caused by accident, misuse, neglect, alteration, improper installation, unauthorized repair or improper testing as set forth above. If TEKTELIC elects to repair or replace such Products, TEKTELIC shall have a reasonable time to make such repairs or replace such Products. The Products shall be returned to Purchaser location Incoterms 2010 DDP, cost covered by TEKTELIC. The repaired or refurbished units will receive a ninety (90) day warranty, or the remainder of the original product warranty, whichever is longer.

8. Contact Us

For questions or comments about the device and its application, or other issues related to the eDoctor solution requiring assistance, please contact your TEKTELIC local representative which can be found on the TEKTELIC Website.

For technical support please refer to the Troubleshooting section or visit the TEKTELIC Support Portal.

To contact our local United States of America representative, please refer to the following name and address:

Rook Quality Systems
1155 Mount Vernon Hwy
Suite 800
Dunwoody GA 30338

Table 8-1: Manufacturer Symbol and Description

Symbol	Manufacturer
	Tektelic Communications Inc. 7657 10 St NE, Calgary, AB T2E 8X2