THE VITLS PLATFORM

INSTRUCTIONS FOR USE

Wireless.Connected.Healthcare

Contents

Introduction

The Vitls Platform user manual is intended to provide information for the correct operation of the Tégo VSS Sensor, the Vitls Mobile, and the Vitls Monitor. Do not operate these products before reading the instructions.

The Vitls Platform was developed for intended use by clinicians and medically qualified personnel. The Vitls Platform is not intended to be a replacement for good clinical judgment. The Vitls Platform is for prescription use only.

The Vitls Platform Introduction

The Vitls Platform is a wireless multi-parameter physiological monitoring system. The Vitls Platform was developed to include an Application Programming Interface (API) which is intended to allow development of user interface applications, enabling clinicians and medically qualified personnel to access recorded physiological data. The Vitls Platform consists of:

- Wearable device with multiple sensors (the Tégo VSS Sensor – An Adhesive Patch with integrated Sensors)
- The Secure Server Library (Cloud-based, including an API)
- The Vitls Monitor (accessible via web application after being verified and enrolled into a specific admission center)
- The Vitls Mobile (mobile application for iOS and Android that allows caretakers and patients to connect to a Vitls Tégo device over Bluetooth Low Energy)

The Tégo VSS Sensor Description

The Tégo VSS Sensor is a battery-operated adhesive patch with integrated sensors and wireless transceiver which is worn on the upper body and records heart rate (HR), respiration rate, blood oxygen levels (SpO_2), and body temperature. There are two different sizes (one for adult and one for pediatric patients) that differ in the length of the flexible portion of the sensor. The Tégo VSS Sensor continuously gathers multi-parameter physiological data from the person being monitored and then transmits the encrypted data via bi-directional communication to a third-party connectivity relay or the Vitls Mobile when in range. When not in range, the collected data is stored on the Tégo VSS Sensor (for a maximum of 3 hours) and transmitted when a connection with the third-party connectivity relay or the Vitls Mobile has been restored. The encrypted wireless data recorded by the Sensor is

sent, by the third-party connectivity relay, such as Aruba 340 series, or Vitls Mobile to the Secure Server. The data may be downloaded from the Secure Server Library or integrated into a Third-Party Application via the APIs of the Secure Server Library. In addition, the wireless data may be transferred to an optional Secure Server Library where it may be stored for future analysis.

During usual operation, data is collected by the Tégo VSS Sensor and transmitted to the third-party connectivity relay or Vitls Mobile immediately (when in range). A continuous Bluetooth connection is required between the Sensor and the third-party connectivity relay or Vitls Mobile, and a continuous Internet connection between the Secure Server Library and the third-party connectivity relay or Vitls Mobile, in order to facilitate continuous data transmission. The continuous wireless transmission of the data occurs with a delay or latency of seconds between continuous data collection and transmission.[1] The recorded data can be stored and downloaded from the third-party connectivity relay or Vitls Mobile. Recorded data can continue to be transferred to the Secure Server Library if there is an active server connection. Should the Secure Software Library (i.e. Medable) not receive a notification for one minute, data will be stored on the Tégo sensor and the secure software library will push a notification to reconnect the Tégo sensor to the Vitls Monitor.

The Tégo VSS Sensor is applied with an acrylic-based adhesive that is bio-compatible. The clinically proven adhesive provides reliable adhesion in humid environments, during physical activity, fever, and perspiration. The adhesive is also waterproof.

Indications for Use

The Vitls Platform is a wireless remote monitoring system intended for use by clinicians and medically qualified personnel for continuous collection of multi-parameter vital signs data in healthcare and home settings. This includes heart rate (HR), respiration rate (RR), blood oxygen levels (SpO_2), and body temperature. The data, which is transmitted wirelessly from the Tégo VSS Sensor, is stored and made available for review by clinicians and medically qualified personnel.

The Tégo VSS Sensor is intended for use on patients who are 2 years of age or older as a general patient monitor, which provides multi-parameter vital signs

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[1] Note that though the data is continuously transferred from the Tégo VSS Sensor to the third-party connectivity relay or Vitls Mobile, the SpO_2 data represents an average of the collected data points.

information. The data from the Vitls Platform is intended for use by clinicians and medically qualified personnel as an aid to diagnosis and treatment of patients.

Federal law restricts this device to be sold by or on the order of a physician.

Contraindications

The Vitls Platform:
- is not recommended for use in the presence of mechanically induced high frequency ventilation,
- is not intended for use on users who have implanted defibrillators or pacemakers,
- is not intended as a stand-alone diagnostic monitor, but the data may be applicable for use in diagnosis,
- is not intended for use on users on cardio-pulmonary bypass, and
- is not intended during an MRI scan or in a location where it will be exposed to strong electromagnetic forces.

⚠ Warnings
- Depending on wireless connectivity, a temporary interruption of data transmission is possible, which may impact continuous monitoring. Data will be stored on the Tégo VSS Sensor for transfer once connectivity is reestablished.
- The nature of Long Wear (Acrylic) adhesive may cause adverse skin reactions. Clinicians and medically qualified personnel should advise patients to seek medical attention should an allergic reaction occur and persist beyond 2-3 days. There is an increased probability of occurrence of skin reactions the longer the duration of contact the device has with the skin.
- Histories of skin irritations should be considered before placing the Tégo VSS Sensor on a patient.
- Do not place the Tégo VSS Sensor on broken skin.
- The Tégo VSS Sensor is not intended to replace appropriate medical supervision and safe practices.
- Clinical validation has not been performed on patients who are pregnant or breastfeeding.
- The use of any software other than those specified in this manual will violate the safety, effectiveness and design controls of the Tégo VSS Sensor and such use may result in an increased risk to users and patients.
- If, after basic troubleshooting, the Tégo VSS Sensor is still not connected to the third-party connectivity relay or Vitls Mobile, discard and replace with a new Sensor.

- Should the Tégo VSS Sensor fall off, discard and replace with a new one. The Sensor cannot be reapplied.
- The Tégo VSS Sensor can store data for up to 3 hours, after which a connection with the third-party connectivity relay or Vitls Mobile has to be re-established.
- Do not use the Tégo VSS Sensor in an oxygen-rich environment.
- The Tégo VSS Sensor is not intended to be used during an MRI scan or in a location where it will be exposed to strong electromagnetic forces.

Precautions

CAUTION: Federal Law restricts this device to sale by or on the order of a physician
- For vital signs data to be sent to a clinician and medically qualified person for review:
  - The battery of the Tégo VSS Sensor must have sufficient power to enable data transmission. A notification will alert the clinician or medically qualified person that the battery power is low.
  - The Tégo VSS Sensor must be attached to the patient. A notification will alert the clinician/medically qualified person if the sensor is not properly attached or falls off.
  - The user must remain in range of the third-party connectivity relay or Vitls Mobile. A notification will alert the clinician/medically qualified person when the sensor has disconnected from the third-party connectivity relay or Vitls Mobile.
- Clinicians and medically qualified personnel must be aware that if uninterrupted continuous data monitoring is necessary for patient safety, treatment in the home setting may not be appropriate. If considered medically necessary, additional measures may be taken to ensure appropriate care and monitoring is provided to meet the clinical need.
- If connected to other devices/systems through the same user interface (i.e. mobile phone) whilst connected to the Vitls Platform via a Bluetooth connection, please note that performance of either or both Bluetooth connected devices/system could potentially be affected.
- Similar devices may cause signal interference during data transmission. If you experience this effect, steer clear of interfering devices.
- Do not use the Tégo VSS Sensor if the packaging has been opened, or appears used, damaged, or expired.
- Do not attach the Tégo VSS Sensor over body hair on the chest/under arm area. Body hair should be removed before application.
- The Tégo VSS Sensor will remain intact in moist environments. It will not be damaged or compromised during bathing or showering. Minimize exposure directly under the shower head, excessive contact with soap, or scrubbing. Gently dab the Tégo VSS Sensor dry after bathing or showering. Submerging

the Tégo VSS Sensor or using in a sauna is not recommended. If submersion occurs, the duration must be less than 5 minutes and less than 18 inches (45cm) in depth.

- If discomfort or irritation occurs, the Tégo VSS Sensor should be removed immediately. Wear only one sensor at a time. The probability for skin irritation increases with the duration of contact with the skin. Do not wear for longer than the recommended time and remove immediately if irritation occurs.
- If the patient experiences mild soreness, redness or irritation after removing the Tégo VSS Sensor, do not apply a new sensor in the same location. Choose another recommended location.
- If the Tégo VSS Sensor becomes twisted, unattached, or falls off the user, whether from normal use, exposure to excessive vibrations, improper device positioning, or submersion in water, previously acquired readings for respiration rate, pulse oximetry, and heart rate will be displayed on the Vitls Monitor dashboard along with a notification to reconnect the Tégo VSS Sensor.
- Incorrect handling, excessive force, or dropping the Tégo VSS Sensor may cause malfunction or permanent damage.
- Changes in the ME equipment or the environment may cause inaccurate readings by the Tégo VSS Sensor. Exposure of the Tégo VSS Sensor to temperatures outside of ambient conditions may cause inaccurate readings.
- If application of the device is applied on skin or in an environment at temperatures above 41°C, adhesive properties may be altered and unable to maintain grip. In addition, measurements taken by the device are at a higher risk of inaccuracy.
- Keep the Tégo VSS Sensor away from children under 2 years old and pets. The sensor may be a choking hazard and may be harmful if swallowed.
- If any component of the Vitls Platform fails to operate after attempting all suggested troubleshooting methods, contact your clinician or a medically qualified person immediately.
- Dispose of all Tégo VSS Sensors as per local laws, care facility laws or hospital laws for routine/nonhazardous electronic waste.

Platform Description

The Vitls Platform consists of the Tégo VSS Sensor, the Secure Server Library, the Vitls Monitor, and the Vitls Mobile. The Secure Server Library is accessible via an application program interface (API) that allows authorized persons to receive data and notifications generated by the system. The Tégo VSS Sensor is a battery-operated adhesive patch with integrated sensors and wireless transceiver, which is worn on the upper body and records heart rate, respiration rate, blood oxygen levels (SpO_2), and body temperature at rest. The sensor continuously gathers multi-

parameter vital signs and then transmits the data via bi-directional communication to a central server controlled by the Secure Server Library, where the data is stored for analysis by clinicians, medically qualified personnel and researchers.

1. Tégo VSS Sensor
    a. The Sensor is designed as a low-cost disposable self-adhesive interface to the body. The enclosure is constructed of a froth able foam with a PU film coating. Residing within the enclosure, the Sensor module performs processing functions related to the capture of multi-parameter vital signs data and also performs bi-directional communication with the third-party connectivity relay or Vitls Mobile App.
2. Vitls Secure Server Library is installed on a cloud server, it manages the upload, processing and storage of sensor data.
3. The Vitls Monitor displays patient vital signs data to clinicians and medically qualified personnel. The Vitls Monitor must be used for pairing of the Tégo VSS sensor and to make notes in a patient's profile.[2]
4. The Vitls Mobile is an optional tool for clinicians or remotely monitored patients to connect to the Tégo VSS sensor over Bluetooth and obtain vital signs data.

Cybersecurity

As a wireless, connected vital sign monitoring system, the Vitls Platform has controls implemented to mitigate risks under cybersecurity vulnerabilities. The platform is configured to provide prompt notifications to the Provider (i.e. Physician or Hospital system) when such suspected incident occurs. Vitls, requires the Provider to notify Vitls immediately when suspected incident occurs, and provide information regarding the incident. This can include but is not limited to aberrant system behavior and affected platform components(s). Vitls strongly advises the Provider NOT to modify, alter, or update the platform so to return the platform to fully functional capability without consent from Vitls. The following describes the cybersecurity vulnerability procedure if an incident report is received:

- Confirmation letter on receiving a report will be provided to the Provider within 24-hours from the date of the incident report.
- Suggested actions will be provided to the Provider within 15-days from the date of incident report.
- Disclose incident vulnerability to Information Sharing and Analysis Organizations (ISAOs) within 30-days from the date of incident report.

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[2] Note that the device can be used without the Vitls Mobile and data can be fed into the EMR of the hospital.

- Submit Medical Device Report to the FDA within 30-days from the date of the incident report.

Storage and Handling

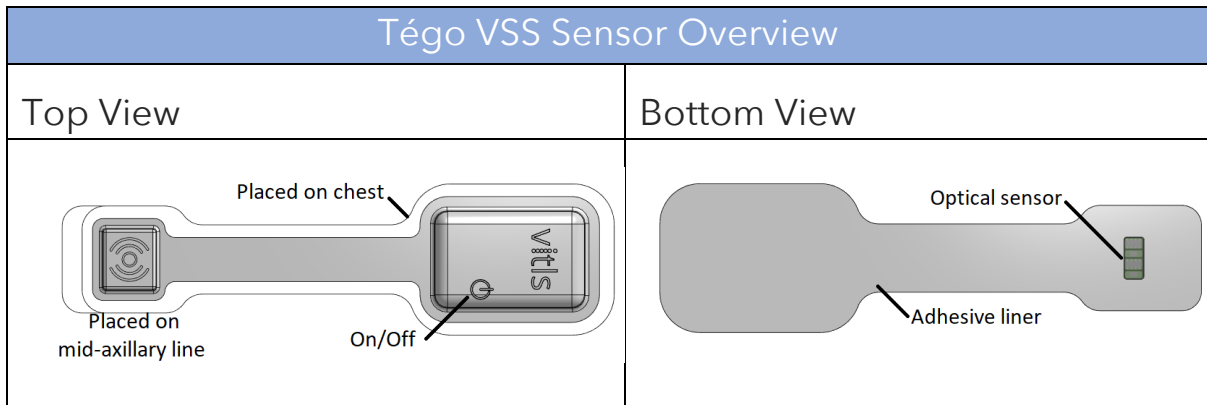Storage temperature range: 5°C - 41°C

Storage relative humidity range: 10 - 93% RH

Storage barometric pressure range: 70 - 102 kPa

Ensure your hands are clean and dry before handling the Tégo VSS Sensor. Gloves are recommended for clinicians and medically qualified personnel when handling the Sensor.

Vitls Platform Operating Instructions

Tégo VSS Sensor Overview	
Top View	**Bottom View**

Skin Preparation and Application
1. **Prepare the skin:** The Sensor can be applied to the Left or Right chest. Select a side for the sensor placement. Shave the area where the sensor will be applied if necessary (armpit and chest). Use a sterile prep pad to clean the skin and allow the area to dry completely.

2. **Remove from packaging:** Tear the packaging open along the indicated line and remove the Tégo VSS Sensor carefully. ALWAYS INSPECT THE DEVICE BEFORE USE. DO NOT USE A DAMAGED DEVICE.	
3. **Power on Test:** Locate and press the power button. Look for a blue light illuminating twice to confirm the device is powered on and connected to the third-party connectivity relay or is discoverable by the Vitls Mobile (see the Vitls Mobile Overview for more information). Turn off the device by holding down the power button for three seconds.	

4. <u>Placement of the Sensor:</u> Pull the adhesive backing off **(retain packaging containing DeviceID)**, first on the Temperature Image side and place firmly under the arm, directly in the armpit (axilla) on the mid-axillary line. Now ask the patient to lower their arm, pull off the adhesive on the Vitls Logo side and place comfortably (not too loose and not too tight) on the chest. Press down on both ends of the patch to ensure it is well adhered to the skin. Avoid exercise for at least 30 minutes after patch application.	
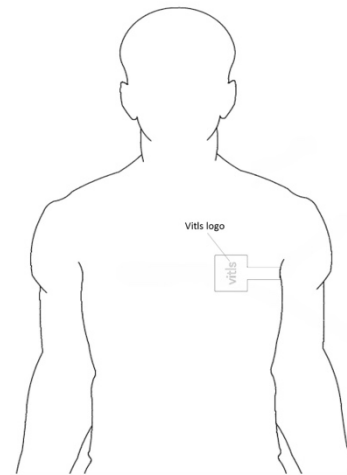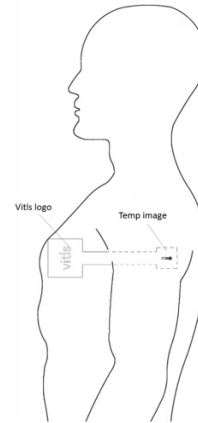
Pairing the Tégo VSS Sensor during a Patient Admission (Healthcare Provider Only)
1. Turn on the Tégo VSS Sensor and make sure the blue light appears, indicating a successful connection to the third-party connectivity relay or the Vitls Mobile app. On the Vitls Monitor, go to the Add Patient screen and complete the necessary fields (see Vitls Monitor Overview for more information). For the Device ID field, enter the Device ID located on the adhesive backing **(previously retained)** and click/press Add Patient. If the Tégo VSS Sensor is flashing blue 2 consecutive times, every 10 seconds, vitals data should be appearing on the Dashboard page of the Vitls Monitor for that patient.
2. Once the Sensor has been paired with the patient admission on the Vitls Monitor, retain the adhesive backing in the patient's file.

3. It is recommended that clinicians and medically qualified personnel replace the Tégo VSS Sensor after 144 hours (6 days) of use. To preserve data, the Tégo VSS Sensor must be connected to the third-party connectivity relay or Vitls Mobile prior to the end of battery life (144 hours/6 days).

Indicators	
Indicator	**Description**
Blue LED	• Indicates the device is connected to the third-party connectivity relay or Vitls Mobile. Two flashes of the light every 10 seconds indicate pairing with App is successful.
Red LED	• 2 Flashes, every 8 seconds, indicates the device is disconnected from the third-party connectivity relay or Vitls Mobile. • Shining for 2 seconds indicates battery low.
Low Battery	Low battery indicator on the Vitls Monitor indicates the time remaining and alerts the user when there is 10% left of battery life.
– –	This is the Potentially Incorrect indicator on the Vitls Monitor, which indicates that a vitals measurement may be incorrect.

Removal and Re-application
Use of adhesive remover pads are recommended to remove the Sensor. Gently sweep the swab pad under the patch as you pull away from the skin. The Tégo VSS Sensor cannot be reapplied. For application of a new patch, it is recommended to use the opposite side of the upper body.

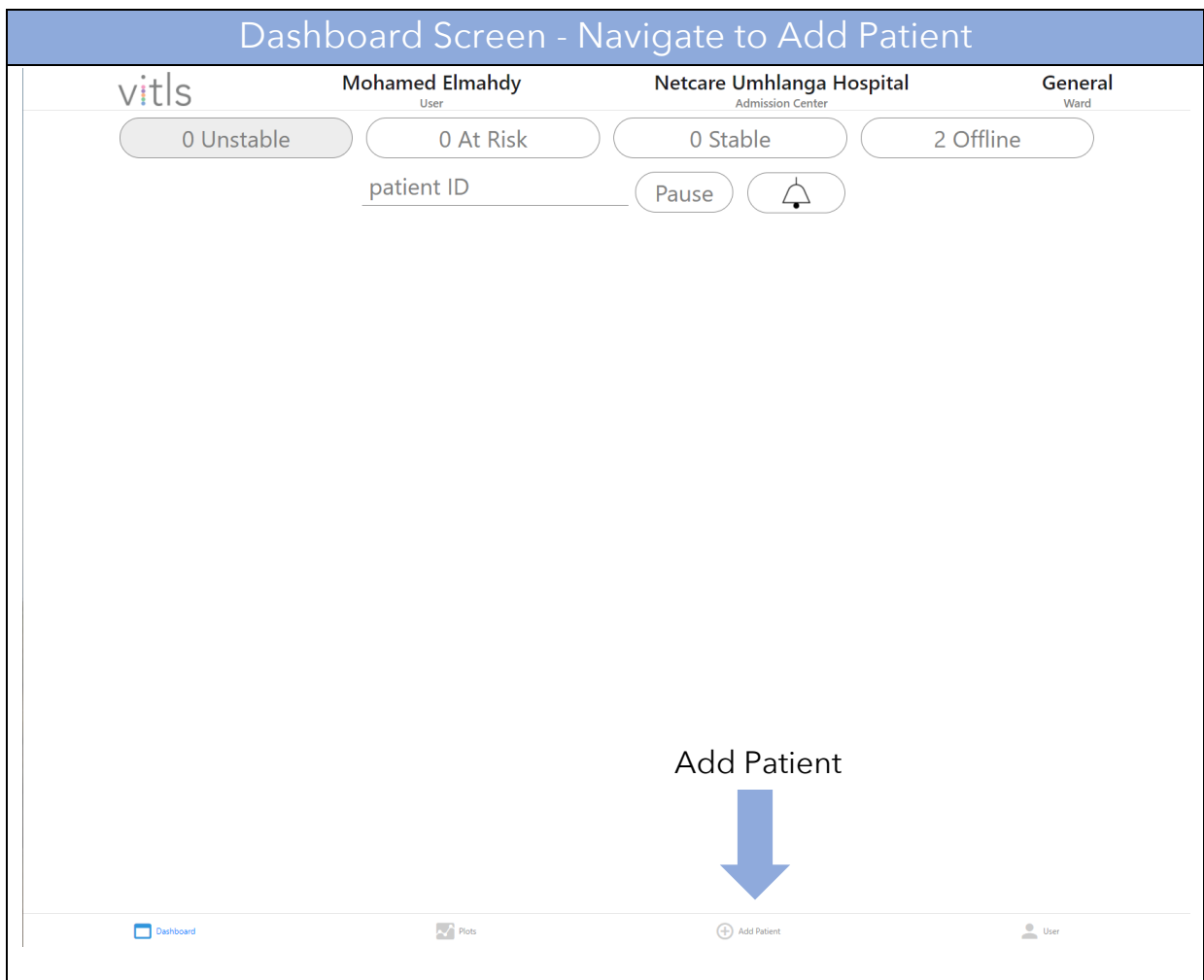| Disposal |
|---|
| Please observe local laws for disposal of battery-operated electronic products. Dispose of all Tégo VSS Sensors as per local laws, care facility laws or hospital laws for routine/nonhazardous electronic waste. |

Troubleshooting

Basic troubleshooting includes the following:
- Make sure that the "Tégo VSS Operating Instructions" have been followed.
- If the Tégo VSS Sensor is lifting from the skin's surface, press down firmly on the areas of the sensor that lifted in order to reattach it to the skin. If the problem persists, use a new sensor.
- For loss of connection between the Tégo VSS Sensor and the third-party connectivity relay or Vitls Mobile, attempt the following:
  - Restart the third-party connectivity relay or Vitls Mobile and allow software to reconnect to the Tégo VSS Sensors. Or if that does not resolve the issue, then
  - Restart the Tégo VSS Sensor by holding down on the power button for at least three seconds, and then pressing the power button once
  -
  - Review each patient's profile in the app to ensure their Sensor has reconnected.
  - If the problem persists, replace the disconnected patient's Sensor with a new one.
  - For any messages such as "Battery low", "Bad Battery", "Sensor Failure", replace the patient's Sensor with a new one.

If you are still experiencing device issues after troubleshooting, contact your local representative for further assistance.

Vitls Monitor Overview (Healthcare Provider Only)

1. The Vitls Monitor will be accessible via a web browser.
2. Open the Vitls Monitor from a web browser at monitor.vitlsinc.com.
3. Login with your credentials if you already have an account, otherwise register for an account by clicking on the Signup button below.
4. Follow the below instructions to add a patient, pair a device and view patient data.
5. Click/press "Add Patient" at the bottom of the screen.

Dashboard Screen - Navigate to Add Patient

vitls

Mohamed Elmahdy
User

Netcare Umhlanga Hospital
Admission Center

General
Ward

| 0 Unstable | 0 At Risk | 0 Stable | 2 Offline |

patient ID   Pause   🔔

Add Patient

⬇

🖵 Dashboard   📈 Plots   ⊕ Add Patient   👤 User

6. Complete all required (*) fields.

Patient On-boarding

7. Enter the DeviceID found on the adhesive backing, click Add Patient. If successful, you will be directed to the Dashboard Screen. If not, check to see if you completed all of the required text fields.
8. Tap on the patient's panel/card in the Dashboard Screen to view the Individual Patient Screen displaying patient admission info, vital sign threshold bounds, vital sign alert summary and logs, notes, and the vital sign plots. Patient's panel/card will be located in either the Stable, At-Risk or Unstable category depending on their latest vital sign values measured and the threshold bounds set.
9. View patient details and adjust the vital sign Unstable threshold bounds in the Threshold card as needed. Vital sign upper and lower bounds for heart rate, respiration rate and temperature can be set using the +/- buttons beside the upper and lower threshold values. The oxygen saturation lower bound can be set, and 100 is the fixed upper bound. These values set the threshold values for determining if patient is Unstable (high priority). At-Risk (low priority), is 10% less/more than the upper/lower Unstable vital sign threshold bounds. Make sure to not set these bounds to extreme and unrealistic values, that will render the alarms ineffective (i.e. oxygen saturation set to 50%, or temperature upper bound set to 50°C/122°F).
10. View and add notes about the patient's admission, such as treatment updates and Tégo repositioning, using the Notes card. All notes will be automatically timestamped when added.

11. View vital sign alert logs in the Vitals Alerts card. An overview of the alerts captured for each vital sign at the At-Risk and Unstable alert category is provided as a percentage of all vital sign values measured for the patient. For example, if 10 out of 100 temperature values were in the Unstable range defined by the threshold bounds for temperature, the overview value would be 10% for Unstable temperature.
12. Click on each vital sign alert log overview value to see a pop-up (modal) containing the vital sign value log listed, and an option to download the log in CSV format.
13. Tap on a specific vital sign to view the plot (bottom of screen). Choose a date and time range to view vital sign data for in the plot using the Date Range selector. A date and time range selection can also be on the plot by clicking in one area of the plot, dragging the mouse to another area, and then releasing the mouse click. Hover over each data point to see vital sign value, timestamp, and an index value from first vital sign value measured.

Individual Patient Screen

Individual Patient Screen

vitls — **Mohamed Elmahdy** (User) — **Netcare Umhlanga Hospital** (Admission Center) — **General** (Ward)

Patient Info

Patient ID:
VITL037

Device ID:
VITL037

Room:
1

Bed:
1

Age (years):
1

Height:
1

Weight:
1

Gender:
u

Diagnosis:

Admitted:
10/15/2020, 1:03:34 PM

Last Vitals Obtained:
10/16/2020, 8:22:02 AM

Discharge

Thresholds

+ 101 High	Heart Rate (BPM)	59 Low +
+ 200 High	HRV (ms)	50 Low +
+ 100 High	Temperature (°F)	96 Low +
+ 20 High	Respiration (BrPM)	10 Low +
100 High	Pulse Ox (%SPO₂)	92 Low +

Update

Notes

2020-10-15T18:03:34.331Z

Patient dosage note

note

View patient admission details

Adjust vital sign Unstable threshold bounds

Dashboard — Plots — Add Patient — User

---

vitls — **Mohamed Elmahdy** (User) — **Netcare Umhlanga Hospital** (Admission Center) — **General** (Ward)

Discharge   Update

Notes

2020-10-15T18:03:34.331Z

Patient dosage note

note

Add Note

Vitals Alerts

	Unstable		At-Risk
Heart Rate:	0%	Heart Rate:	51%
%SPO₂:	0%	%SPO₂:	0%
Respiration Rate:	0%	Respiration Rate:	0%
Temperature:	0%	Temperature:	56%

Latest Vitals:

PULSE	HRV	SATS	RESP	TEMP
85	--	97	12	99.0
BPM	ms	%SPO₂	BrPM	°F

View and add notes on patient admission/treatment/progress

View vital sign alert logs. Click on Summary

Dashboard — Plots — Add Patient — User

Individual Patient Screen

Log of vital sign alerts can be downloaded in CSV format.

Heart Rate Alert Log

10/16/2020, 8:22:02 AM--93
10/16/2020, 8:21:56 AM--93
10/16/2020, 8:21:46 AM--92
10/16/2020, 8:21:41 AM--92
10/16/2020, 8:21:30 AM--93

Download
Close

View latest vital sign values

Latest Vitals:

PULSE	HRV	SATS	RESP	TEMP
83	--	93	12	99.9
BPM	ms	%SPO₂	BrPM	°F

Define date and time range for plot

Adjust plot x- and y-axis position. Click on Eye icon to zoom back out to default view.

Change which vital sign value is plotted

Heart Rate   SATS   Respiration   Temperature

Download all vital sign values in CSV format

Download Vitals

Vitals Obtained:
130
Download

Individual Patient Screen

vitls

Mohamed Elmahdy
User

Netcare Umhlanga Hospital
Admission Center

General
Ward

Latest Vitals:

PULSE	HRV	SATS	RESP	TEMP
85	--	97	12	99.0
BPM	ms	%SPO₂	BrPM	°F

Hover over a data point to see value, timestamp, and index from first vital sign measured

Date Range

2020/10/15 – 2020/10/16

DD/MM/YYYY

value : 84 BPM
Date : 10/16/2020, 8:31:07 AM
index from start : 18

Time (HH:mm:ss)
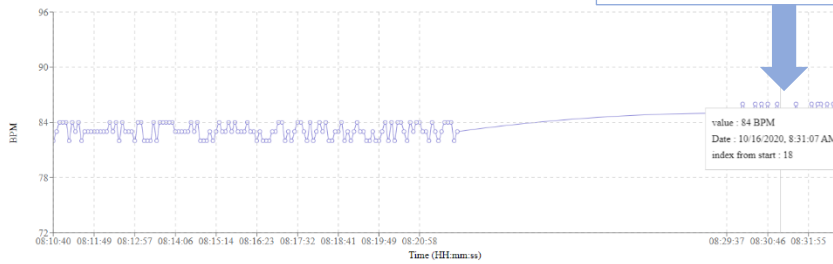
Heart Rate   SATS   Respiration   Temperature

Download Vitals

Vitals Obtained:

166

Download

Dashboard   Plots   Add Patient   User

14. In the Dashboard Screen, patient cards showing latest vital sign values, Tégo battery level, and patient info can be viewed for each vital sign alert category and Tégo status category. The categories are located at the top of the Dashboard Screen, and contain a value representing the number of patients within that category, along with the name of the category. Click a category to view patients within that category. Patients with an online Tégo will have their patient cards located in one of the vital sign alert categories: Unstable, At Risk, or Stable. Patients with an offline Tégo will have their patient cards located in the Offline Tégo status category.
15. The Dashboard screen will update every 10 seconds. Automatic updates can be paused to search for a patient by clicking on the Pause button below the categories and to the right of the search text field input. Once clicked, the pause button will turn into the Update button. To return to automatic updates, click on the Update button. The pause will automatically be timed-out after 30 seconds, and after which will return to automatic updates.
16. Search for a patient by their patient ID using the text field input with "patient ID" as a place holder. As the patient ID name is entered, the patient cards will be filtered to what is being typed. The search will be performed on the category that is currently being viewed.
17. If a patient is classified as Unstable, an audible alert will sound and a visual alert will be displayed as a red border around the Unstable category. The audible and visual alerts will continue if a patient, or several patients, are in the Unstable category. The audible alert can be muted by clicking on the Mute button.

Dashboard Screen - View Patients

Vital sign alert and Tégo status

Patient in Stable vital sign category

vitls   **Mohamed Elmahdy** User   **Netcare Umhlanga Hospital** Admission Center   **General** Ward

| 0 Unstable | 1 At Risk | 1 Stable | 0 Offline |

patient ID   Pause   🔔

● 1 of 2 At Risk

| Battery | Room | Bed | Patient ID/Name |
| 97% | 1 | 1 | VITL038 |

PULSE	HRV	SATS	RESP	TEMP
95	--	93	13	98.8
BPM	ms	%SPO₂	BrPM	°F

Visual alert if patient vital sign in At Risk category. Vital sign value and unit turns yellow.

Patient in At Risk vital sign category

📋 Dashboard   📈 Plots   ⊕ Add Patient   👤 User

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vitls   **Mohamed Elmahdy** User   **Netcare Umhlanga Hospital** Admission Center   **General** Ward

| 1 Unstable | 0 At Risk | 1 Stable | 0 Offline |

patient ID   Pause   🔔

● 1 of 2 Unstable

| Battery | Room | Bed | Patient ID/Name |
| 90% | 1 | 1 | VITL038 |

PULSE	HRV	SATS	RESP	TEMP
96	--	91	14	98.8
BPM	ms	%SPO₂	BrPM	°F

Visual alert if patient(s) in Unstable category. Unstable category button border turns red.

Patient in Unstable vital sign category

Visual alert if patient vital sign in Unstable category. Vital sign value and unit turns red.

📋 Dashboard   📈 Plots   ⊕ Add Patient   👤 User

vitls — Mohamed Elmahdy (User) — Netcare Umhlanga Hospital (Admission Center) — General (Ward)

1 Unstable   0 At Risk   1 Stable   0 Offline

patient ID   Pause   🔕

● 1 of 2 Stable

Battery	Room	Bed	Patient ID/Name
93%	1	1	VITL037

PULSE	HRV	SATS	RESP	TEMP
84	--	95	14	99.3
BPM	ms	%SPO₂	BrPM	°F

Dashboard   Plots   Add Patient   User

Mute the audible alarm if patient(s) in Unstable category

vitls — Mohamed Elmahdy (User) — Netcare Umhlanga Hospital (Admission Center) — General (Ward)

0 Unstable   1 At Risk   1 Stable   0 Offline

patient ID   Update   🔔

● 1 of 2 At Ris

Battery	Room	Bed	Patient ID/Name
93%	1	1	VITL038

PULSE	HRV	SATS	RESP	TEMP
95	--	92	14	98.6
BPM	ms	%SPO₂	BrPM	°F

Dashboard   Plots   Add Patient   User

Pause the automatic every 10 second updates for latest patient vital sign values. Pause will timeout after 30 seconds. Pause button will change to Update if paused. Click on Update to resume automatic vital sign value updates.

18. Ability to switch admission center or ward, change measurement units (i.e. temperature from Fahrenheit to Celsius), and logout from Vitls Monitor is located in the User info page.
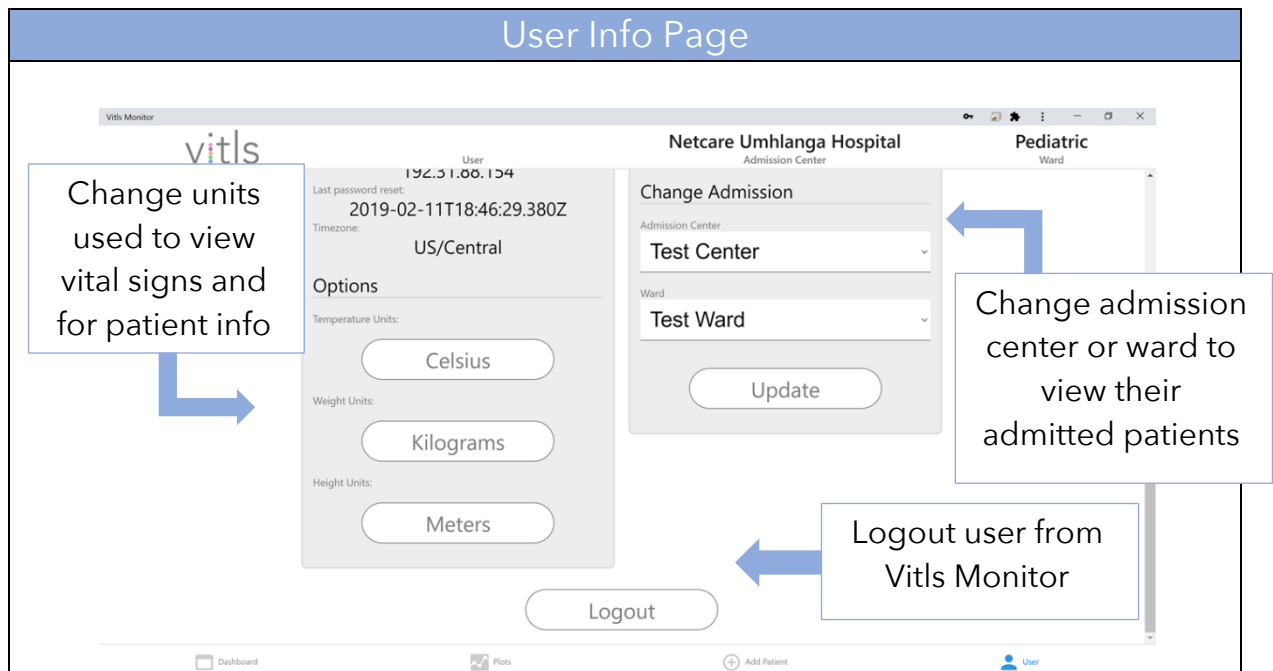

Vitls Monitor Alarms

Alarms are delivered to users on Vitls Monitor, and encompass one of the following events:

1. Disconnection of Tégo from third-party connectivity relay or Vitls Mobile (Low priority)
2. One of the patient(s) vital sign values are within the At-Risk category bounds (Low priority)
3. One of the patient(s) vital sign values are within the Unstable category bounds (High priority

All alarms are presented with a visual alert. To properly view the visual alerts, make sure to maximize the Internet Browser window that is running Vitls Monitor, and to sit no more than 2 meters away from the screen. Also, a PC monitor larger than 22 inches and with a refresh rate of 60Hz or higher is recommended. The high priority alarm will be accompanied with a burst of 10 0.2-second long tones with a peak at 1605 Hz, which is triggered every 10 seconds. Be sure to check that the volume of the device that is running the Vitls Monitor is at an audible level. This auditory

alarm can be silenced by clicking on the Mute button ⟨bell icon⟩ or on the Unstable
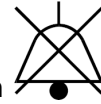
category button. The mute button will change to the Unmute button ![mute icon]. Clicking on the Unmute button will play auditory alarm, if any are required, and change Unmute button back to the Mute button. If a new patient enters the Unstable category, the alarm sound will automatically play again, and if the Unmute button is visible, it will change to the Mute button.

The maximum delay for alarm condition and generation is under 10 seconds and the mean delay for alarm condition and generation is under 5 seconds. Since Vitls Monitor Dashboard screen will update patient vital sign values every 10 seconds and the Tégo will collect and transmit measurements every 2 seconds, the typical vital sign value on Vitls Monitor has a 2 +/- 2 second delay. The 2 second deviation is based on the network latency for transmitting data from third-party connectivity relay or Vitls Mobile to the Secure Server Library, and for receiving data from the Secure Server library by Vitls Monitor. The alarm conditions are computed at user's Vitls Monitor session. The delay of alarm condition computation by the Vitls Monitor script, and presentation of the alarm should be no more than 1 second. The delay of an alarm or vital sign value update can be determined by the user by clicking on the Patient card and viewing the latest vital sign value timestamp.

The thresholds for Unstable are adjustable and the At-Risk thresholds are set to ~10% less/more than the Unstable upper/lower values. The table below shows the default threshold bounds for the Stable, At-Risk, and Unstable conditions.

| Vital Sign Threshold Bounds for Stable, At-Risk and Unstable Conditions			
Vital Sign	Stable	At-Risk (Low)	Unstable (High)
Temperature	35.9 - 37.4 °C Tégo(96.8 - 97.7 °F)	36 – 36.5 °C (96.8 - 97.7 °F) 37.5 – 38 °C (99.5 - 100.4 °F)	< 36 °C (< 96.8 °F) > 38 °C (< 100.4 °F)
Heart Rate	58 - 90 BPM	59 – 65 BPM 91 – 101 BPM	< 59 BPM > 101 BPM
Oxygen Saturation	94 - 100%	92 – 94%	< 92%
Respiration Rate	9 - 17 BrPm	10 – 11 BrPM 18 – 20 BrPM	< 10 BrPM > 20 BrPM

When patients shift to the At-Risk or Offline categories, the border of the respective category button will be highlighted orange until the category is selected to view the patient card that was shifted. When patients shift to Unstable, the border of the Unstable category button will flash red at a frequency of 1.5Hz until the Unstable category is selected to view the patient card that was shifted. For all cases above, if the category is already viewed, the behavior will still act the same and the current view's category button will need to be selected again. If patient is in Offline category, check on Tégo connectivity to third-party connectivity relay or Vitls Mobile. The Tégo VSS Sensor should be blinking red if disconnected.

All alarm activity, acknowledging and silencing alarms, will be stored on the Secure Server Library and history can be viewed by the admission center's administrator. The vital sign alert log can be viewed by the user, and is dynamic since it is based on the current threshold values set for that patient. The vital sign alert log is located in each patient's screen, as shown in the Vitls Monitor description above.

Vitls Mobile Overview

1. The Vitls Mobile can be obtained by searching for Vitls Mobile in the Google Play or Apple App store.
2. After downloading and installing the app, launch the app from the mobile device's home screen or application list.
3. Grant the Vitls Mobile permission to use Location and Bluetooth of the mobile device. Location information is not collected; however, Location Service permissions are required to utilize mobile device's Bluetooth functionality.

Grant Permission for Bluetooth Functionality
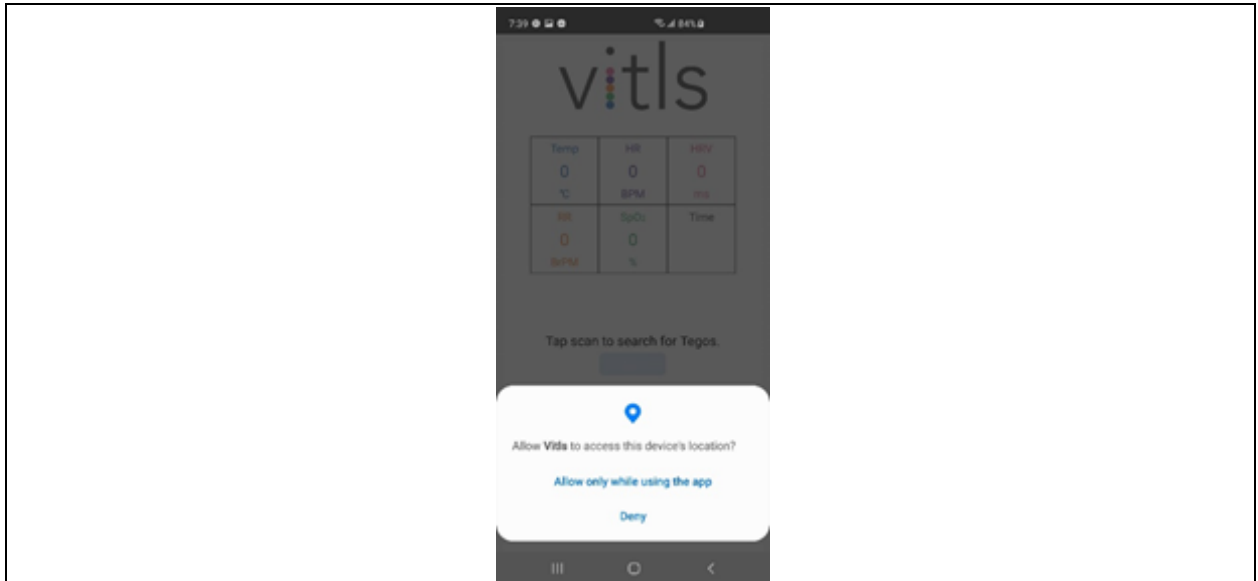
4. Seek help on application of the Tégo VSS Sensor (Tégo) by pressing on Help.
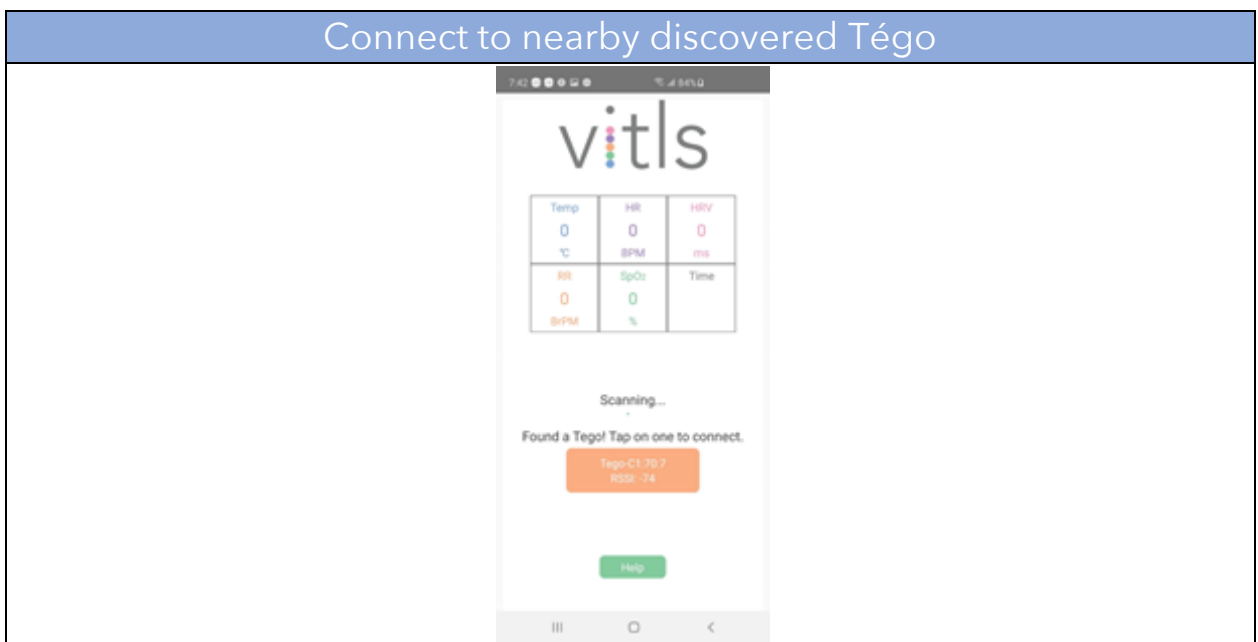
Help/Guide Page
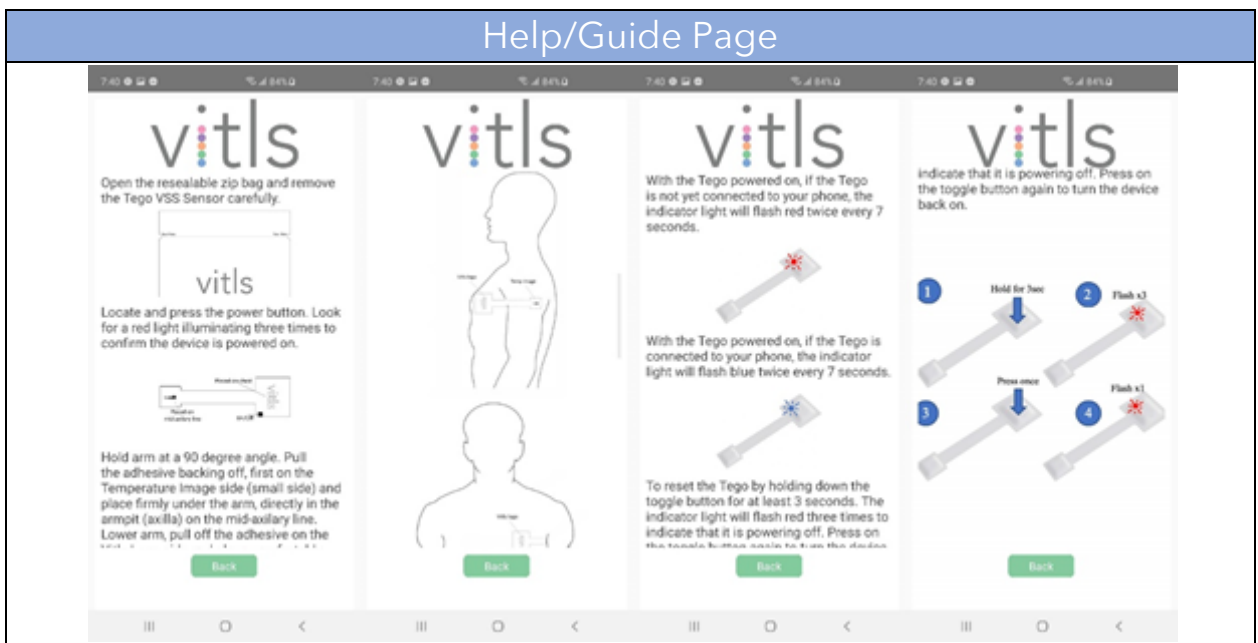
5. Apply and power on the Tégo nearby
6. Press Scan to search for the nearby Tégo

Scan for nearby Tégos

7. Press on the nearby Tégo listed in the discovered device list

Connect to nearby discovered Tégo

8. If pairing is complete, vital sign data from nearby connected Tégo and a connected icon will appear on the VMA. If Tégo disconnects from mobile device, a notification will be delivered on the mobile device and a disconnect icon will appear.

Receive Vital Sign Data from Connected Tégo

Vitls Contact Information

For questions or comments about the device and its application, or other issues related to the Vitls platform requiring assistance, please contact your local representative using the information provided below.

USA

Vitls Inc.
Texas Medical Centre Innovation Institute
2450 Holcombe Avenue
Houston, TX 77021
USA
Phone: +1 (415) 949-9963
www.vitlsinc.com

Product Specifications	
Measurements	Specifications
PPG	Wavelength 525 nm to 950 nm (Infrared, Red and Green emitter with detector)
Heart Rate (stationary and ambulatory)	30 - 200 Beats per Minute (root-mean-square difference <±5 or 10% Beats per Minute, whichever is greater)
Respiration Rate	4-42 Breaths per Minute with a mean absolute error of less than 1.5 Breaths per Minute, validated by simulation studies.
SpO_2 (Pulse Ox, functional oxygen saturation)	0% - 100% (≤ ± 4.0% between 70 and 100%)[3]
SpO_2 Wavelength of Peak Emission	Infrared Emitter - 950 nm Red Emitter - 660 nm Green Emitter - 530 nm **Note**: The range of wavelengths associated with the Pulse Ox can be especially useful to clinicians upon evaluation
Optical Sensor Maximum Output Power	645 mW
Body Temperature	25°C – 45°C (≤ ± 0.3°C) 77°F – 113°F (≤ ± 0.54°F)
Thermometer Transient Response (Direct Mode)	25 s to go from 35°C to 37°C 50 s to go from 35°C to 33°C
Minimum Measurement Time	60 seconds

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[3] Because Pulse Ox equipment measurements are statistically distributed, only about 2/3 of the measurements can be expected to fall within ± 4.0% of the measured value.

System Specifications	
Communications	
Bluetooth (BT4.1)	Max. 15 Meters (50 Feet Line of Sight) between sensor and relay
Radio Modulation	FSK (Frequency-shift Keying)
Radio Frequency	2.4GHz
Transmit power	-20 to +4 dBm
Security	AES-ECB 128 Bit Encryption or AES-CCM 128 Bit Encryption (Advanced Encryption Standard)
Battery	
Battery Type	Lithium
Battery Voltage	3V
Battery Life	144 Hours
Shelf Life	6 months
Operating Conditions	
Thermometer Operating Mode	Direct
Ambient Temperature	5.0°C – 41.0°C 41.0°F – 105.8°F
Humidity	10 – 93% RH
Altitude	<3000 m
Barometric Pressure	70 kPa to 102 kPa
Material Specifications	
Enclosure Material	VOLEXTRA Foam - Blue 52720-2 (Top Layer) I-807 (Bottom Layer)

Aruba 340 Specifications	
Wi-Fi Antennas	AP-344 External antenna

	AP-345 Internal antennas
Wi-Fi Radio	Indoor, dual radio, 5 GHz 802.11ac 4x4 MIMO and 2.4 GHz 802.11n 4x4 MIMO Support for up to 256 associated client devices per radio, and up to 16 BSSIDs per radio
Supported frequency bands	2.400 to 2.4835 GHz 5.150 to 5.250 GHz 5.250 to 5.350 GHz 5.470 to 5.725 GHz 5.725 to 5.850 GHz
Supported radio technologies	802.11b: Direct-sequence spread-spectrum (DSSS) 802.11a/g/n/ac: Orthogonal frequency-division multiplexing (OFDM)
Supported modulation types	802.11b: BPSK, QPSK, CCK 802.11a/g/n/ac: BPSK, QPSK, 16-QAM, 64-QAM, 256-QAM, 1024-QAM (proprietary extension)
Transmit power	Configurable in increments of 0.5 dBm
Maximum (aggregate, conducted total) transmit power	2.4 GHz band: +24 dBm (18dBm per chain) 5 GHz band: +24 dBm (18 dBm per chain) Note: Conducted transmit power levels exclude antenna gain. For total (EIRP) transmit power, add antenna gain.
Supported data rates (Mbps):	802.11b: 1, 2, 5.5, 11 802.11a/g: 6, 9, 12, 18, 24, 36, 48, 54 802.11n: 6.5 to 600 (MCS0 to MCS31) 802.11ac: 6.5 to 1,733 (MCS0 to MCS9, NSS = 1 to 4 for VHT20/40/80, NSS = 1 to 2 for VHT160) 802.11ac: 1,950 and 2,166 (MCS10 and MCS11, NSS = 1 to 4 for VHT20/40/80, NSS = 1 to 2 for

	VHT160)5
	802.11n high-throughput (HT) support: HT20/40
	802.11ac very high throughput (VHT) support: VHT20/40/80/160
	802.11n/ac packet aggregation: A-MPDU, A-MSDU

Technical Description
Summary of test methods to establish SpO$_2$ accuracy, reference method for pulse rate accuracy

SpO$_2$ and pulse rate accuracy were determined in accordance with Medical electrical equipment – IEC 80601-2-61:2017 *Particular requirements for basic safety and essential performance of pulse oximeter equipment*. A clinical trial was conducted in accordance with ISO 14155:2011 *Clinical investigation of medical devices for human subjects – Good clinical practice*. The results of the trial and accuracy findings are listed in the Product Specifications section.

Electromagnetic Emission Declaration		
The Tégo VSS Sensor is intended for use in the electromagnetic environment specified below. The end user of the Tégo VSS Sensor should ensure that it is used in such an environment.		
Emission test	Compliance	Electromagnetic environment
RF emissions CISPR 11	Group 1	The Tégo VSS Sensor uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The Tégo VSS Sensor is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.

FCC Compliance
FCC ID: 2ASYD-VT-F-010-V2

- This Tégo VSS Sensor components comply with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This sensor may not cause harmful interference, and (2) This sensor must accept any interference received, including interference that may cause undesired operation (FCC Title 47, Subpart A, Part 15.19(3)).

- Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment (FCC Title 47, Subpart A, Part 15.21) Note: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures (FCC Title 47, Subpart B, Part 15.105(b)):

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

Guidance and declaration – electromagnetic immunity (For ME equipment ME system that are not life-supporting)			
The Tégo VSS Sensor is intended for use in the electromagnetic environment specified below. The end user of the Vitls Platform (including the Tégo VSS Sensor) should ensure that it is used in such an environment.			
Immunity test	IEC 60601 Test Level	Compliance level	Electromagnetic environment- guidance
Radiated RF IEC 61000-4- 3	3 V/m 80 MHz to 2.5 GHz	3 V/m (Professional healthcare environment) 10 V/m (Home healthcare environment) 80 MHz to 2.7 GHz	Portable and mobile RF communications equipment should be used no closer to any part of the Vitls Platform than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.17\sqrt{P}$ 80 MHz to 800 MHz $d = 2.33\sqrt{P}$ 800MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a] should be less than the compliance level in each frequency range[b]. Interference may occur in the vicinity of equipment marked with the following symbol:

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.			
Guidance and declaration – electromagnetic immunity (For ME equipment ME system that are not life-supporting)			
The Tégo VSS Sensor is intended for use in the electromagnetic environment specified below. The end user of the Vitls Platform (including the Tégo VSS Sensor) should ensure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment- guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 8 kV contact ± 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 %.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: U_T is the A.C. mains voltage prior to application of the test level.			

Recommended separation distance between portable and mobile RF communications equipment and the Vitls Platform (For ME equipment ME system that are not life-supporting)

The Tégo VSS Sensor is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The end user of the Vitls Platform (including The Tégo VSS Sensor) can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Tégo VSS Sensor as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m	
	80 kHz to 800 MHz $d = 1.17\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.33\sqrt{P}$
0.01	0.17	0.23
0.1	0.37	0.74
1	1.17	2.33
10	3.69	7.38
100	11.67	23.33

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.
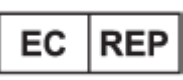
Note 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

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

Manufacturer's declaration-electromagnetic immunity
Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment

The Tégo VSS Sensor is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The end user of the Vitls Platform (including The Tégo VSS Sensor) can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Tégo VSS Sensor as recommended below, according to the maximum output power of the communications equipment.

Test frequency (MHz)	Pulse modulation 50% DC (Hz)	IEC 60601 test level	Compliance level
385	18	27	27
450	18	28	28
710	217	9	9
745	217	9	9
780	217	9	9
810	18	28	28
870	18	28	28
930	18	28	28
1720	217	28	28
1845	217	28	28
1970	217	28	28
2450	217	28	28
5240	217	9	9
5500	217	9	9
5785	217	9	9

General Symbols	
Symbol	Title
	IP Rating: • IP27 - protected against submerging in water (up to 1 meter for 5 minutes)
	Do not re-use
	Consult instructions for use
	Properly dispose of EEE (Electrical and Electronic Equipment)
	Non-ionizing radiation
	Defibrillation proof type CF applied part
	MR Unsafe
	Manufacturer
	Caution
	Do not use if package is damaged
EC REP	Authorized Representative in the European Community
SN	Serial number

General Symbols	
Symbol	Title
LOT	Batch code
	Bell cancel
	Use by date
	Pressure limits (Storage)
	Temperature limits (Storage)
	Humidity limits (Storage)
NON STERILE	Non-sterile
	Radio Emission
IR	Infrared Light Emission
	Direct Current
	Thermometer
	Bluetooth

General Symbols	
Symbol	Title
	Avoid Prolonged Exposure to Sunlight
	Refer to Manual
– –	Potentially Incorrect indicator on the Vitls Mobile, which indicates that a vitals measurement may be incorrect.