THE VITLS PLATFORM

INSTRUCTIONS FOR USE

Contents

Introduction

The Vitls Platform user manual is intended to provide information for the correct operation of the Tego VSS Sensor, the BaseStation and the Vitls App. 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 vital signs 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 vital signs information in real-time. The Vitls Platform consists of:

- Wearable device with multiple sensors (the Tego VSS Sensor – An Adhesive Patch with integrated Sensors)
- The BaseStation Software Library
- The BaseStation
- The Secure Server Library (Cloud-based, including an API)
- The Vitls App (accessible on a smartphone, tablet, PC or monitor that displays the data and configures the Tego VSS Sensor)

The Tego VSS Sensor Description

The Tego 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, Heart rate variability (HRV), respiration rate, blood oxygen levels (SpO_2), body temperature, and activity (including fall detection). The Tego VSS Sensor continuously gathers multi-parameter vital signs data from the person being monitored and then transmits the encrypted data via bi-directional communication to the BaseStation Software Library, contained on the BaseStation, when in range. When not in range, the collected data is stored on the Tego VSS Sensor (for a maximum of 3 hours) and transmitted when a connection with the BaseStation has been restored. The encrypted wireless data recorded by the Sensor is sent, by the BaseStation Software Library, to the Secure Server. The data may be downloaded from the Secure Server Library or integrated into a Third-Party BaseStation Application via the APIs of the Secure Server Library. In addition, the wireless data may be transferred to an optional Secure Server Library where they may be stored for future analysis.

During usual operation, data is collected by the Tego VSS Sensor and transmitted to the BaseStation Software Library immediately (when in range). A continuous connection is required between the Sensor and the BaseStation Software Library 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 BaseStation. Recorded data can continue to be transferred to the Secure Server Library if there is an active server connection. Should the BaseStation lose the connection to the Secure Server Library, data will be stored on the BaseStation until the connection with the Secure Server Library has been restored.

Authorized clinicians and medically qualified personnel can configure the system parameters via the API to generate notifications of changes in measured data. With the connection to the Secure Server, a notification is triggered when configured vital signs data parameters are exceeded. Notifications are transmitted to a generic display device (i.e. smartphone, tablet, PC or monitor).

The Tego VSS Sensor is applied with a silicone-based adhesive that is bio-compatible. The clinically proven adhesive provides improved 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, Heart rate variability (HRV), respiration rate, blood oxygen levels (SpO_2), body temperature and activity (including fall detection). The data which is transmitted wirelessly from the Tego VSS Sensor, is stored and made available for review by clinicians and medically qualified personnel. The Vitls Platform includes the ability to notify clinicians and medically qualified personnel when vital signs data fall outside configured ranges, for selected parameters.

The Tego VSS Sensor is intended for use on patients of any age as a general patient monitor, which provides multi-parameter vital signs 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 sale 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,

[1] Note that though the data is continuously transferred from the Tego VSS Sensor to the BaseStation Software Library, the SpO_2 data represents an average of the collected data points.

- 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 or real-time monitoring. Data will be stored on the Tego 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 Tego VSS Sensor on a patient.
- Do not place the Tego VSS Sensor on broken skin.
- The Tego 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 Tego VSS Sensor and such use may result in an increased risk to users and patients.
- If, after basic troubleshooting, the Tego VSS Sensor is still not connected to the BaseStation, discard and replace with a new Sensor.
- Should the Tego VSS Sensor fall off, discard and replace with a new one. The Sensor cannot be reapplied.
- The Tego VSS Sensor can store data for up to 3 hours, after which a connection with the BaseStation has to be re-established.
- Do not use the Tego VSS Sensor and BaseStation should not be used in an oxygen-rich environment.

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 Tego 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 Tego 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 BaseStation. A notification will alert the clinician/medically qualified person when the sensor has disconnected from the BaseStation.
    - The BaseStation must remain connected to a power source/charged and functional for data transmission. Wireless connectivity must be active for transmission of data from the BaseStation to the server.
- 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/system 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 affect, steer clear of interfering devices.
- Do not use the Tego VSS Sensor if the packaging has been opened, or appears used, damaged, or expired.
- Do not attach the Tego VSS Sensor over body hair on the chest/under arm area. Excessive body hair should be removed before application.
- The Tego 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 Tego VSS Sensor dry after bathing or showering. Submerging the Tego 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 Tego 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 Tego VSS Sensor, do not apply a new sensor in the same location. Choose another recommended location.
- If the Tego VSS Sensor becomes twisted, unattached, or falls off of the user, whether from normal use, exposure to excessive vibrations, improper device positioning, or submersion in water, inaccurate respiration rates, pulse oximetry, and heart rate will display on the dashboard.
- Incorrect handling, excessive force, or dropping the Tego VSS Sensor may cause malfunction or permanent damage.
- Changes in the ME equipment or the environment may cause inaccurate readings by the Tego VSS Sensor. Exposure of the Tego 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 Tego VSS Sensor away from children 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 Tego 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 Tego VSS Sensor, the BaseStation Software Library, the BaseStation, and the Secure Server Library. 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 Tego 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, Heart rate variability (HRV), respiration rate, blood oxygen levels (SpO_2), body temperature and activity (including fall detection). The sensor continuously gathers multi-parameter vital signs and then transmits the data via a bi-directional BaseStation to a central server controlled by the Secure Server Library, where the data is stored for analysis by clinicians, medically qualified personnel and researchers. Authorized clinicians and medically qualified personnel can configure the system parameters in the Secure Software Library via API through the Mobile App/Web Dashboard to generate notifications of changes in measured parameters. A notification is triggered when configured vital signs parameters are exceeded. Notifications are transmitted to a generic display device (i.e. Smartphone, Tablet, PC or Monitor). The Vitls Platform is made up of the following:

1. Tego 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 BaseStation.
2. The BaseStation Software Library manages bi-directional communication between the Sensor and the Secure Software Library and is installed on the BaseStation.
3. The BaseStation is an AC-powered device that receives and transmits data. It contains a Rechargeable Battery, a Microprocessor, Storage, AC Power Connection, BLE Module, Wi-Fi Module and Ethernet Port.
4. Vitls Secure Software Library is installed on a cloud server, it manages the upload, processing and storage of sensor data, as well as real-time configuration of and notifications from the Vitls Platform.
5. The App displays patient vital signs data to clinicians and medically qualified personnel. The App must be used for paring of the Tego VSS sensor, setting up of alert limits, addressing of alerts and to make notes in a patient's profile.[2]

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. Hospital/ Physician 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

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

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

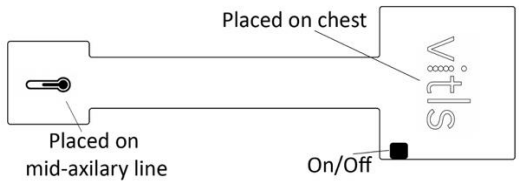
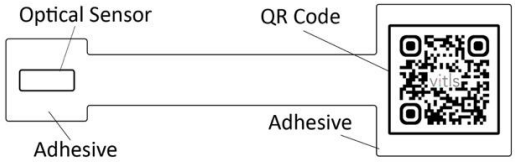
Storage and Handling

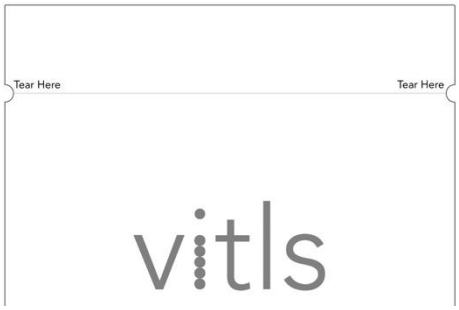
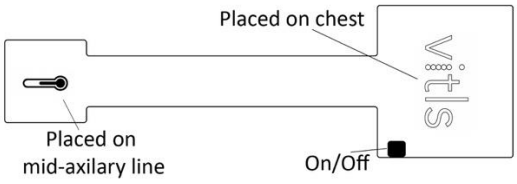
Storage temperature range: 10℃ - 45℃

Storage relative humidity range: 10 - 93% RH

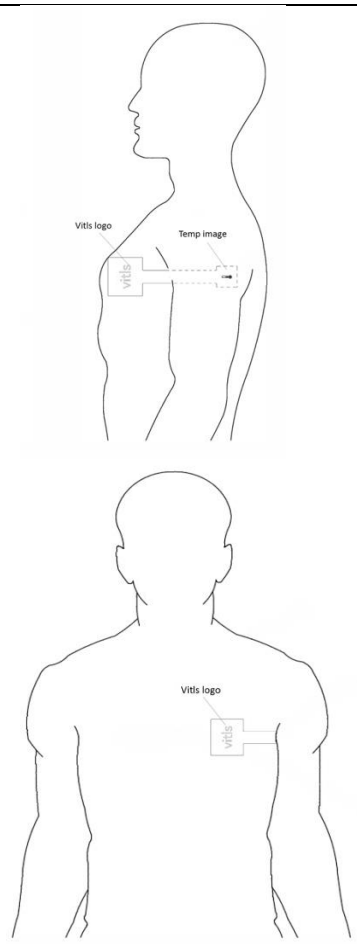
Storage barometric pressure range: 70 - 102 kPa

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

Tego VSS Sensor Overview	
Top View	Bottom View
	

Skin Preparation and Application	
1. <u>Prepare the skin:</u> 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.	
2. <u>Remove from packaging:</u> Tear the packaging open along the indicated line and remove the Tego VSS Sensor carefully.	
3. <u>Power on:</u> Locate and press the power button. Look for a red light illuminating three times to confirm the device is powered on.	

4. <u>Placement of the Sensor:</u>
   Pull the adhesive backing off **(retain backing containing QR Code)**, first on the Temperature Image side and place firmly under the arm, directly in the armpit (axilla) on the mid-axilary 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.



5. <u>Pairing the Tego VSS Sensor with the Vitls App:</u>
   Important: After completing Patient Onboarding in the Vitls App, you will be prompted by the Device Paring Screen. Scan the QR Code located on the adhesive backing **(previously retained).**, and wait for a green tick (✅) that will appear when pairing was successful. A blue light on the Tego VSS Sensor will flash 2 consecutive times, every 10 seconds, when pairing has been successful. For further guidance, please refer to the Vitls App Overview on page 13.

6. Once the Sensor has been paired with the Vitls App, retain the adhesive backing in the patient's file.

7. It is recommended that clinicians and medically qualified personnel replace the Tego VSS Sensor after 144 hours (6 days) of use. To preserve data, the Tego VSS Sensor must be connected to the BaseStation prior to the end of battery life (144 hours/6 days).

Indicator Lights	
Indicator	**Description**
Blue LED	Indicates the device is connected to the BaseStation. Two flashes of the light indicate pairing with App is successful.
Red LED	• Three flashes of the Red light indicates the device has been switched on. • 2 Flashes, every 8 seconds, indicates the device is disconnected from the BaseStation. • Shining for 2 seconds indicates battery low.
Low Battery	Low battery indicator on the Vitls App indicates the battery level is low and power will soon be lost.
– –	This is the Potentially Incorrect indicator on the VItls App, which indicates that a vitals measurement may be incorrect.

Removal and Re-application

Use of sterile prep pads are recommended to remove the Sensor. Gently sweep the swab pad under the patch as you pull away from the skin. The Tego 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 Tego VSS Sensors as per local laws, care facility laws or hospital laws for routine/nonhazardous electronic waste.

Troubleshooting

Basic troubleshooting includes the following:

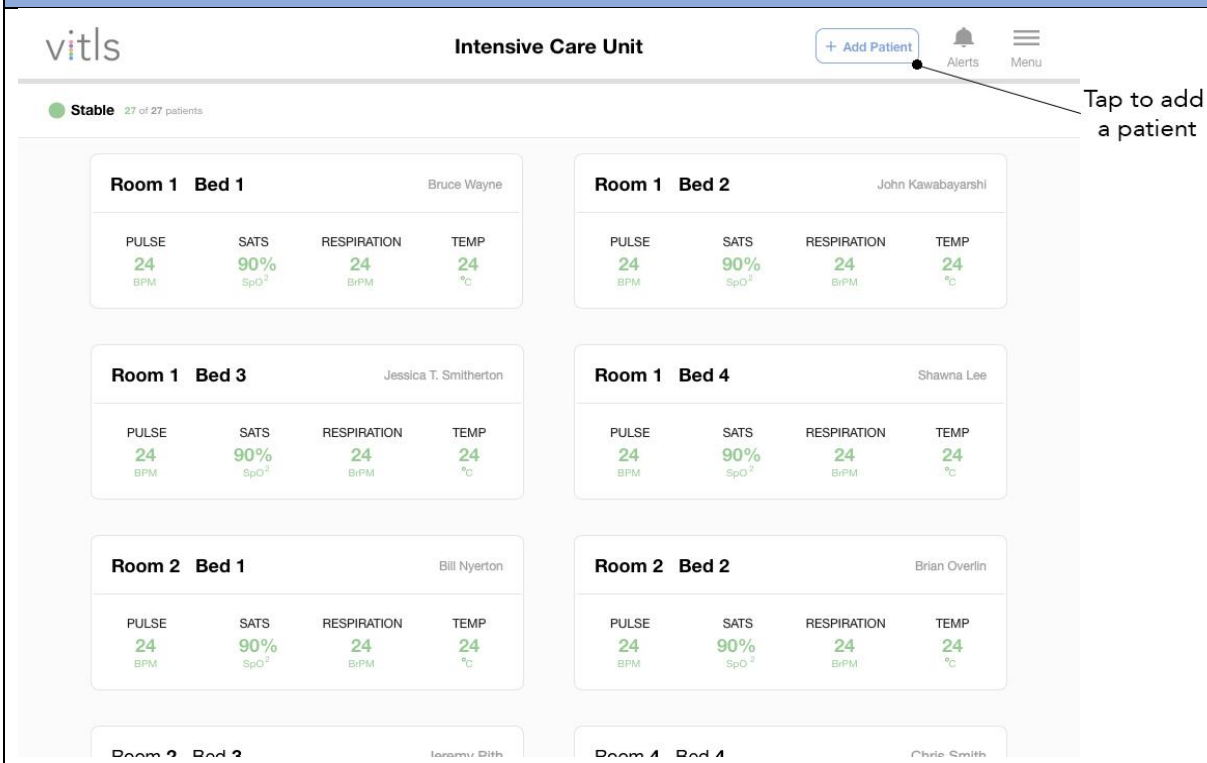
- Make sure that the “Tego VSS Operating Instructions” have been followed.
- If the Tego VSS Sensor is lifting from the skin’s surface, press down firmly on the areas of the sensor that lifted in order to reattach it to the skin. If the problem persists, use a new sensor.
- For loss of connection between the Tego VSS Sensor and the Application, attempt the following:
    - Restart the Application and allow software to reconnect to the Tego VSS Sensors. Or if that does not resolve the issue, then
    - Turn off Wi-Fi and turn Wi-Fi back on. Restart the application and allow software to reconnect to the Tego VSS Sensors. Or if that does not resolve the issue, then
    - Reboot the BaseStation via the Vitls Mobile App on the tablet. Wait for the BaseStation to reboot and allow BaseStation to pair with the Tego VSS Sensors.
    - Review each patient’s profile in the app to ensure their Sensor has reconnected with the App.
    - If the problem persists, replace the 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.

App Overview

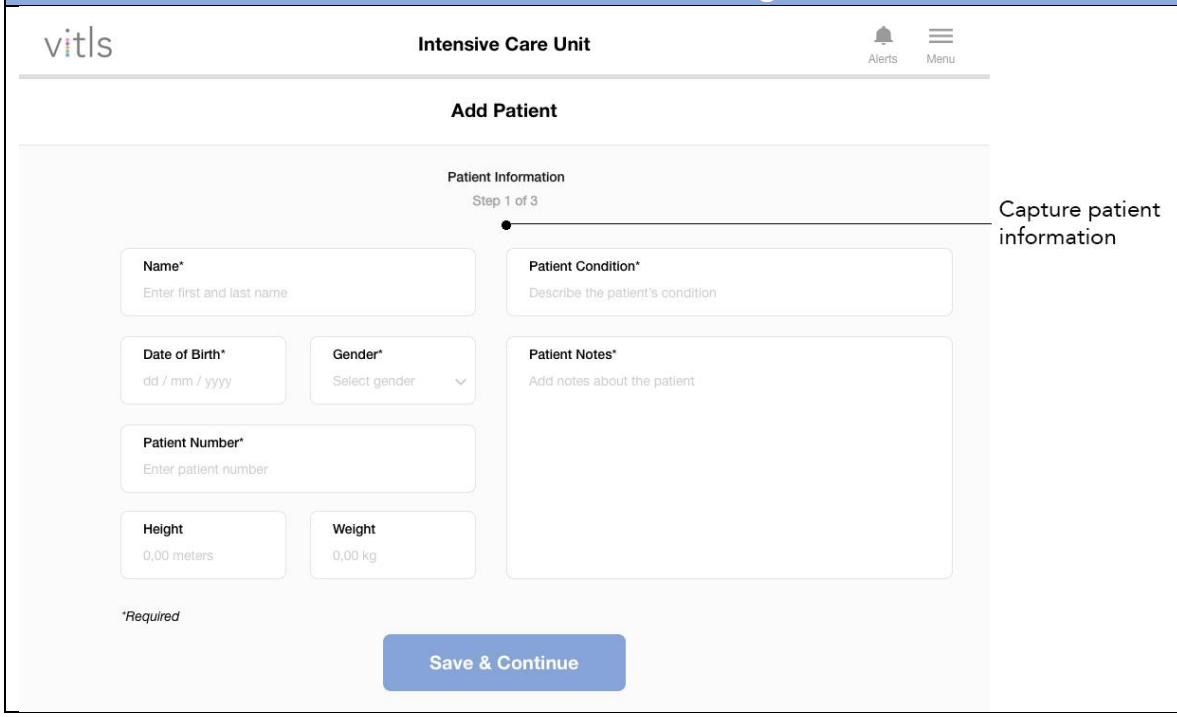
1. The Vitls App will be pre-loaded on the display device (i.e. smartphone, tablet etc.).
2. Open the Vitls App from the home screen of the tablet.
3. Follow the below instructions to add a patient, pair a device and view patient data.
4. Tap “Add Patient” at the top of the screen.

Add a Patient



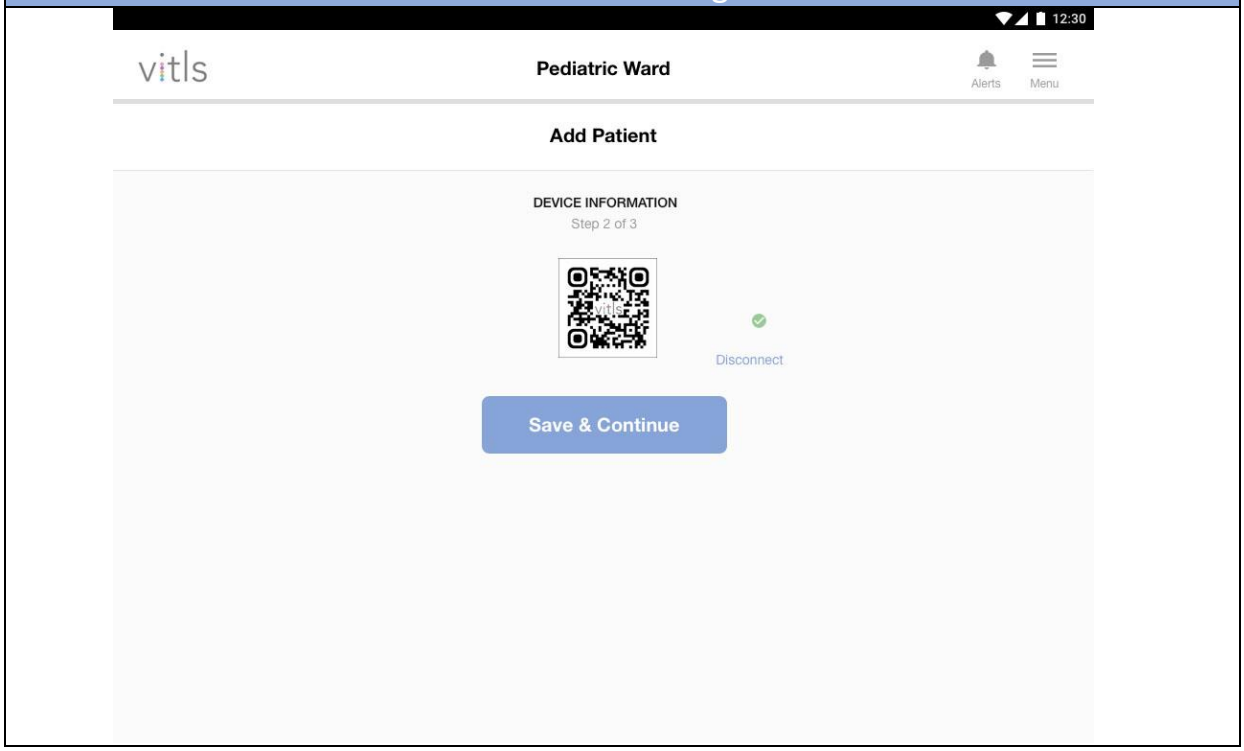
5. Complete all required (*) fields. Tap “Save & Continue”.

Patient On-boarding



6. Scan the QR Code found on the adhesive backing and wait for a green tick (✅) indicating pairing successful.

Device Pairing

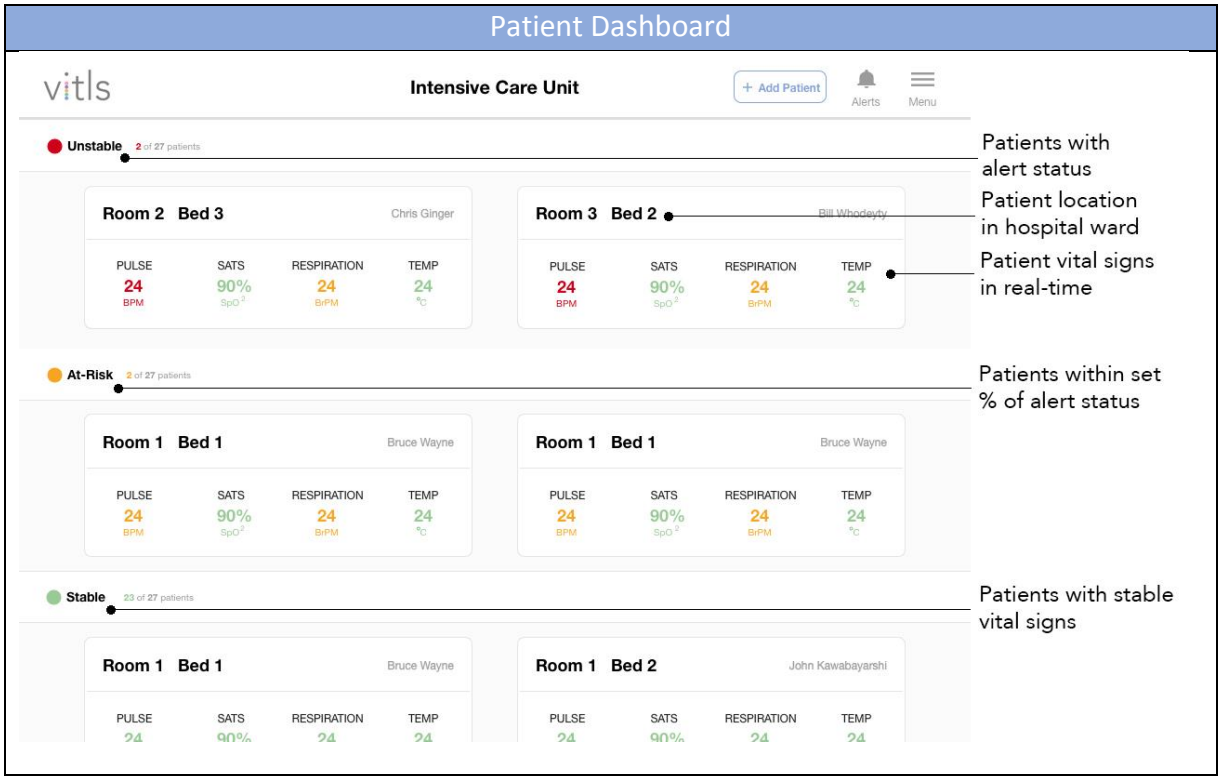


7. Select the bed that the patient has been allocated to. Tap “Save & Finish”.

Setting Patient Location

8. The Dashboard will display the status of all the patients wearing a Tego VSS Sensor that has been paired with the App.

Patient Dashboard



9. Tap on the patient’s name in the Patient Dashboard Screen to view the Individual

Patient Screen displaying all the vital signs, graphs and notes.

10. Tap on a specific vital sign to view the graph (bottom left).

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

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Phone: +1 (415) 949-9963
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Product Specifications	
Measurements	Specifications
PPG	Wavelength 525nm to 950nm (Infrared, Red and Green emitter with detector)
Heart Rate (stationary and ambulatory)	30 - 200 Beats per Minute (<±5 or 10% Beats per Minute, whichever is greater)
Heart rate variability (HRV)	20 - 200 Milliseconds (Measured by the variation in the beat-to-beat interval.)
Respiration Rate	10-30 Breaths per Minute with a mean absolute error of less than 2 Breaths per Minute, validated by clinical studies 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] **Note:** There are no SpO_2 alarm conditions or indicators for SpO_2 inaccuracy.[4]
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	255 Analog V
Body Temperature	15°C – 50°C (≤ ± 0.3°C) 59°F – 122°F (≤ ± 32,54°F)

[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.

[4] Vitls cannot be used to assess the exact accuracy of the Pulse Ox monitor. There is no industry accepted method of verifying the correct calibration of the monitor other than testing on human beings.

Fall Detection	Fall or No Fall (> 90% Sensitivity and > 98% Specificity)
Step Count	< 5% Absolute Error Compared to Manual Count. Step count is reset to 0 after step 65535 is reached.
System Specifications	
Communications	
Bluetooth (BT4.1)	Max. 15 Meters (50 Feet Line of Sight)
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
Operating Conditions	
Ambient Temperature	10°C– 45°C 50°F– 113°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) MED 5567A (Bottom Layer)

Technical Description
Summary of test methods to establish SpO2 accuracy, reference method for pulse rate accuracy

SpO2 and pulse rate accuracy were determined in accordance with Medical electrical equipment — IEC 80601:Part 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.

Clinical Study
Summary of clinical study reports used to assess SpO2 accuracy, patient information (whether test subjects were sick/healthy, describe skin color, age, gender, etc)

Electromagnetic Emission Declaration		
The Tego VSS Sensor is intended for use in the electromagnetic environment specified below. The end user of the Tego VSS Sensor should ensure that it is used in such an environment.		
Emission test	Compliance	Electromagnetic environment
RF emissions CISPR 11	Group 1	The Tego 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 Tego 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

- This Tego 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)):

    - Reorient or relocate the receiving antenna.
    - Increase the separation between the equipment and the receiver.
    - Connect the equipment to 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.

Guidance and declaration – electromagnetic immunity (For ME equipment ME system that are not life-supporting)			
The Tego VSS Sensor is intended for use in the electromagnetic environment specified below. The end user of the Vitls Platform (including the Tego 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	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√P 80 MHz to 800 MHz d = 2.33√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 Tego VSS Sensor is intended for use in the electromagnetic environment specified below. The end user of the Vitls Platform (including the Tego 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	± 6 kV contact ± 8 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	3 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 Tego 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 Tego VSS Sensor) can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Tego 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√P	800 MHz to 2.5 GHz d = 2.33√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.

General Symbols	
Symbol	Title
	IP Rating: • IP24 - protected against splashing water • IP27 - protected against submerging in water (up to 1 meter for 15 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
	Authorized Representative in the European Community
	Serial number

General Symbols	
Symbol	Title
	Batch code
	Use by date
	Pressure limits (Storage)
	Temperature limits (Storage)
	Humidity limits (Storage)
	Non-sterile
	Radio Emission
	Direct Current
	Thermometer
	Bluetooth
	Avoid Prolonged Exposure to Sunlight