# Teladoc Health™ VITA<sup>®</sup>

**User Guide** 

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# **Safety Instructions**

Trained healthcare professionals are the intended users of Teladoc Health Patient Access devices. Users of the system require clinical judgment and experience to review and interpret the patient data transmitted.

## Notes, Cautions, and Warnings

The types of safety instructions are provided below.

**NOTE:** Supplementary information for facilitating operation of the system.

**CAUTION:** Instructions for avoiding damage to the system.

**WARNING:** Disregarding this information may prove hazardous to the safety of a person near the Teladoc Health Patient Access Device.

#### Safety Symbols

#### Symbols appearing on the Patient Access device and other equipment include:

| Attention: Consult accompanying documents for description of intended use.  |        |
|---|--------|
| Warning Dangerous Voltage:Touching exposed contacts may cause<br>electrical shock. Safety features designed into the device do not allow<br>exposed live AC contacts until the Patient Access Device is fully engaged with<br>its docking station. When fully engaged, contacts are not accessible. |        |
| Wireless Transmitter Notification: Non-ionizing electromagnetic radiation.<br>This device communicates over the 802.11 ac/a/b/g/n standard for wireless<br>communication.   | ((••)) |
| <b>Body Float</b> : Type B. A Type B piece of equipment is one that provides a particular degree of protection against electric shock, particularly regarding allowable leakage current and reliability of the protective earth connection (grounding).   | Ť      |



**Consult Operator's Manual**: Operating Instructions are contained in a separate instruction manual. Some Patient Access Devices utilize a Class II laser which complies with 21 CFR Chapter 1, subchapter j. Maximum laser radiation output is less than one milliWatt. Refer to the appropriate Patient Access Device User Manual to determine the specific wavelength (color) employed by the laser pointer.





The VITA utilizes a Class II Laser which complies with 21 CFR Chapter 1, Sub-Chapter J. Maximum Laser radiation output is less than one milli-watt at a wavelength of 635 nanometers.

**CAUTION:** Provider Access Software users should not direct the laser beam at persons or at reflective surfaces that may cause disturbances. Dazzle, flash-blindness, and afterimages may be caused by a beam from a Class II laser product, particularly under low ambient light conditions. This may have indirect general safety implications resulting from temporary disturbance of vision or from startle reactions. Such visual disturbances could be of particular concern when performing safety-critical operations.



## **Safety Warnings and Cautions**

#### WARNINGS

• Teladoc Health requires all users to first be trained in the proper use of the VITA. The VITA stands approximately 5.5 ft. tall (168 cm) and weighs about 180 lb. (82 kg). An untrained operator could potentially bring about a collision, possibly causing damage or injury.

#### **CAUTIONS:**

- Teladoc Health does not support the addition of third party software to an VITA. Adding third party software (especially for video conferencing) to the computer can cause the VITA to malfunction. Please be advised to check with Technical Service PRIOR to installing any third party software.
- The VITA should be plugged in or docked whenever it is possible so it is fully charged and ready for a consult.
- There are no user-serviceable components. Refer servicing and repair to qualified personnel only.
- DO NOT IMMERSE the VITA. DO NOT ALLOW any cleaning solution inside the VITA. Avoid excess solution which may enter the VITA through its openings.
- Keep the VITA free from moisture and extreme temperatures.
- Teladoc Health has not performed safety and efficacy testing for many peripheral USB devices being used with the VITA. Customers must test and validate medical peripherals for their own use cases and environments
- Ensure external USB devices are disconnected prior to moving the VITA.

**NOTE**: The VITA utilizes a Class II Laser Pointer which complies with 21 CFR Chapter 1, sub-chapter j. Maximum Laser radiation output is less than one milliwatt at a wavelength of 635 nanometers.

**CAUTION**: Dazzle, flash-blindness, and afterimages may be caused by a beam from a Class II laser product, particularly under low ambient light conditions. This may have indirect general safety implications resulting from temporary disturbance of vision or from startle reactions. Such visual disturbances could be of particular concern connected with performing safety-critical operations. Users should not stare at the beam and perform active protective reactions by moving the head or closing the eyes to avoid continued intrabeam viewing.



#### WARNINGS

- The VITA is not MRI safe nor MRI compatible and should only be used in locations where the presence of metal is not controlled.
- Flammable Anesthetics: The VITA is not suitable for use in the presence of flammable anesthetic mixture with air, or in the presence of a flammable anesthetic mixture with oxygen or nitrous oxide.



# Virtual Care System

Health systems view virtual care as an extension of their services; relying on a combination of software, hardware, networks, systems, and people to work together to deliver improved access and care to their patients.

Enabling healthcare's only integrated virtual care platform, Teladoc Health powers virtual encounters at clinics, healthcare facilities, and patient homes for an integrated experience across a multitude of use cases. Built on our cloud-based network, Solo™ is the backbone to delivering care anywhere at anytime. It provides users with everything they need to streamline their telehealth needs for fast user adoption.

## Designed for healthcare, security, and reliability

Our cloud-based, patented network ensures the industry's highest standards for protecting and securing sensitive healthcare information. Our downloadable and web-based platform allows users to access virtual care across a broad range of consumer and telehealth devices in a variety of clinical environments.





# **Intended Application**

The VITA is intended to provide high quality HIPAA compliant audio and video sessions between a provider and a patient over the Teladoc Health Telehealth Network.

The VITA is HIPAA compliant and can be used for audio and video telecommunications in a variety of clinical environments.



# **VITA Overview**





| Chest Display                                     | Touch-screen used for local control of VITA.   |
|---|--|
| Collision Avoidance<br>Sensors                    | VITA's collision avoidance sensors consist of 3D near-IR depth sensors and sonars to provide for detection of obstructions.  |
| Directional<br>Microphone                         | Captures audio for playback on the Provider Access Software.   |
| Docking Charger<br>Interface                      | Used to connect to Dock (allows charging and automated Docking).   |
| Emergency Stop<br>Button                          | Stops VITA's (base) movements by disengaging its motors. Also, used to disengage wheels, when needing to quickly move VITA manually. See " <u>VITA Emergency Stop" on page 17</u> ".                                 |
| Head Speakers                                     | Plays audio from Provider Access microphone on VITA.   |
| Leeen Deinten                                     | FDA Class II Laser Pointer fixed to the VITA pan/tilt Head.  |
| Laser Pointer                                     | Avoid exposure. Laser radiation is emitted from this aperture.   |
| LED Indicator                                     | VITA status indicators.  |
| Lights  | Refer to <u>"VITA Status Indicator Lights" on page 42</u> ".   |
| Power<br>Button/Power Cord<br>(inside cord bay    | The VITA power button turns on the computer and display.<br>Power cord used to recharge VITA without the Dock.   |
| Remote Display                                    | Displays remote user's face (video from the Provider Access) or recorded pictures and video from the Provider Access on VITA.  |
| Rocker Switch<br>(Main On <i>/</i> Off<br>Switch) | Removes power to the VITA computer systems.  |
| Storage / Expansion<br>Bays                       | An expansion bay is located on each side of the VITA. One side contains the Stethoscope and Headset, the other side contains the Privacy Handset and the Input/Output ports for connecting approved devices to VITA. |
| Virtually There<br>Cameras                        | Capture remote video for viewing at the Provider Access.   |
| Volume Control<br>Knobs                           | Used to adjust volume. See "Volume Adjustment Knobs".  |



# **VITA Basics**

## **Charging the VITA**

- VITA will charge to 80% in two hours.
- VITA will charge to 100% in six hours.

**NOTE**: Keep VITA docked whenever it is not in use.

The VITA can be sent to its Dock from the Provider Access Software or by hospital personnel using the Touch-Screen Chest Display. See <u>"VITA AutoDrive " on page 22</u>.

If Dock is not available for any reason and VITA needs to be charged, plug the VITA into a standard grounded outlet.

**NOTE**: The power plug has an internal light which lights when plugged into a live outlet. Ensure it is lit when charging with the power plug.

**CAUTION**: The VITA contains high capacity rechargeable, Lithium-Ion batteries. The VITA should be plugged in when not in use so it is fully charged and ready for the next consult and to avoid deep discharge cycles that can shorten the battery's useful life. Other than keeping the batteries charged by keeping the VITA plugged in, no user maintenance of the batteries is required.

#### **Charging Status Indicator Lights**

The VITA Dock has an LED indicator light located on the top of the Dock. In addition, the power plug contains a light which turn on when plugged into a live AC outlet.

| Dock                                 | LED State     | Indicator Light |
|--------------------------------------|---------------|-----------------|
| No AC power applied                  | Off           |                 |
| AC power applied, not mated to robot | On            |                 |
| AC power applied, mated to robot     | On - blinking |                 |
| VITA Power Plug                      | Light State   |                 |
| Plugged in and powered               | On            |                 |
| Unplugged or not powered             | Off           |                 |



## **VITA Power Controls**

The VITA has two power controls:

- the Rocker Switch (main On/Off switch), that removes power from torso and base.; and
- the VITA computer power button does graceful shutdown of the VITA.

The Rocker Switch is located just below the skirt on the base, above the Docking Charger Interface.

The Rocker Switch, which remains in either the Off or On position, controls the power to the VITA. If the VITA is neither plugged in nor docked, the power is provided from the battery. The VITA Rocker Switch should stay On, except during storage, service, transport, or to avoid depleting the battery.

#### **Power On Sequence**

- 1. Switch the Rocker Switch to the On position.
- 2. Plug the VITA in at its docking station or plug the power cord into an approved wall socket.
- 3. Turn On the power to the computer:

Press and hold in the Computer Power Button for about half of a second.

Check to ensure the display powers up successfully.

After a period of self-testing (1-2 minutes), the screen saver should appear on the display.

**NOTE**: Keep the VITA docked (or plugged in) and left powered on at all times.

#### CAUTIONS:

- To ensure system readiness, connectivity, and charged batteries, power on the VITA at least two hours before its intended use.
- The VITA checks for and installs any available and scheduled updates automatically when it is docked.







#### **Power Off Sequence**

**CAUTION**: When powering down the VITA for any reason, always ensure that the Computer Power Button is powered off first and that the VITA Display screen turns off (turns black) before turning off the Rocker Switch. It will take approximately 30-45 seconds for the Display screen to turn off.

- 1. Turn Off the Power to the computer:
  - Press the Computer Power Button.
  - Check to ensure that the display screen turns off (turns black).

#### NOTES:

- It will take approximately 30-45 seconds for the screen to turn off.
- If the computer does not shut down following the above step, you can force a shut down by holding the Computer Power Button in for several seconds until the VITA Display screen turns black.
- 2. Turn Off the Rocker Switch.

## **VITA Emergency Stop**

#### To disable VITA movement:

Press the red Emergency Stop Button.

- The VITA will stay on, but cannot be driven.
- The VITA can now be pushed where needed.

#### To enable VITA movement again:

 Twist the red Emergency Stop Button clockwise approximately 1/4 turn until it pops out.





## VITA Volume Adjustment Knobs

The VITA has two volume controls: one on each side of the Touch-screen Display.

• Turn either dial to control the volume of the VITA speakers.





## **VITA Head and Chest Display**



- The VITA Head Display is used for display and status.
- The VITA Chest Display is a touchscreen and is used for input.
- A remote provider can connect to the VITA using Teladoc Health Provider Access Software. VITA automatically accepts the connection request if the provider is authorized.
- When remote practitioner actively connects to VITA using the Provider Access software, the practitioner's video will be displayed on the VITA Head Display and the practitioner's name will be shown on the Chest Display.
- When the VITA is NOT actively connected to Provider Access Software, it is considered Idle. When the VITA is idle, an animation will be displayed. Screen savers selected by the customer may optionally be shown; to do so, consult your Teladoc Health representative or Technical Support.



The VITA Touch-Screen Chest Display provides In Session information and local controls of the VITA. Whenever the VITA is powered on, you can tap the Chest Display to interact.





## VITA Information Screen

Select the **i**con to display the Diagnostic Information for the VITA.

| P R | eady                               |                     |  | 9/2/202  | 21 🛃           |
|-----|------------------------------------|---------------------|--|--|----------------|
|     |                                    | Diagnost            | ic Information   |  |                |
|     | Teladoc Health \<br>Ready          | /ita                | Vetwork Detai  | ls   |                |
|     | Battery charge                     | 92%                 | Connection type  | ₩iFi   |                |
|     | Bus voltage                        | 35.94               | WiFi SSID  | ENG  |                |
|     | Serial Number                      | Robot-9139          | Signal strength  | 100%   |                |
|     | Location                           | SQA: Vita v2 (9139) | External IP  | 170.176.184.241  |                |
|     | Subtype                            | RP-8                | Internal IP  | 192.168.128.49   |                |
|     | Software version                   | 10.43.122           | Environment  | Staging  |                |
|     | Build date                         | August 31 2021      |  |  |                |
|     | Autodrive status                   | Available           | Connectivity S   | tatus  |                |
|     | Base status                        | Connected           |  |  |                |
|     |                                    |                     | SIP  | Registered   |                |
|     |                                    |                     | FMS  | Registered   |                |
|     |                                    |                     | Devices Api  | Registered   |                |
|     |                                    |                     |  |  |                |
|     |                                    |                     |  |  |                |
|     |                                    |                     |  |  |                |
|     |                                    |                     |  |  |                |
| O   | Customer and Tech<br>(877) 484-911 | nical Services<br>9 | This software uses libraries fror<br>This software uses libraries fror | n the FFmpeg project under the LGF<br>n the libusb project under the LGPLv | PLV2.1<br>/2.1 |



#### **VITA AutoDrive**

| Auto Drive Destinations | Q |
|-------------------------|---|
| Charging Station        |   |
| • os-test-office        |   |
| e sqa-big-door-entrance |   |
| • sqa-big-window        |   |
| • sqa-entrance          |   |
|                         |   |
|                         |   |
|                         | i |

To send VITA to a predefined location, tap the AutoDrive button, then tap the desired destination location button.

While in motion, tap the Chest Display to halt VITA.



• When stopped, the Chest Display shows Resume and Cancel buttons.





• Tap the Resume button to allow VITA to continue on to its destination. If not resumed or canceled, the navigation will time out.

The VITA's Chest Display will report when it reaches its destination or if it fails to reach its destination.

#### Docking the VITA

To initiate automated docking, when it is available, tap the AutoDrive button, then the Dock button

**NOTE:** Dock will always appear at the top of the list.

#### Change AutoDrive Map

The VITA has Multi-Map capabilities that allow it to utilize AutoDrive on different floors. During installation, please ask the Product Specialist to create a new map and install a new dock for the map..



| ← Change Map             |            |
|--------------------------|------------|
| building3-sqa            |            |
| BLG2-Vita Map-QA-Patrol  |            |
| DHA DHA                  | $\bigcirc$ |
| MHSRS2                   |            |
| NEW_TIC_ICUDock_12_16_16 |            |
| <b>1</b> PATH_9-30-18MF  |            |
|                          | -          |
| O Ø 🖳 🔅                  | i          |

Follow these steps to switch floor maps on the VITA:

CAUTION: Make sure to check destinations before and after the map change.

- 1. Tap anywhere on the chest display of the VITA. Tap Settings on the Tool bar.
- 2. Tap on Change Map.
- 3. Tap on the new map under Available Maps that corresponds to the new location of the VITA.
- 4. The VITA will prompt you to confirm that you want to switch maps. Tap Acceptto confirm.



5. Dock the VITA on the newly selected map.



• The highlighted floor name under Available Maps is the current map on the VITA.

## **VITA Video Settings Screen**

To select a different video option,

- 1. Tap the Video Settings icon 🔽 on the chest display.
- 2. Select the option to display on the head display.

**NOTE**: An approved device must be connected to the corresponding input before selecting.





## **VITA In Session Screens**

When a session is active on the VITA, the head and chest display change to show the specialist and available controls.





## Active Session Screen Navigation

When a Virtual Care session is in progress, a toolbar similar to the one below is displayed.

| ζ Ψ 💌 | PIP End •••  |
|-------|--|
| Icon  | Function   |
| Ç     | Toggles the device's privacy handset on or off. While the<br>handset is active, the device's speakers and microphone will<br>be inactive.                                      |
| Ļ     | Tap to mute the device's microphone, tap again to un-mute.   |
|       | Mutes the video.   |
| PIP   | Toggle the Picture-in-Picture.   |
| End   | Tap to end the current remote session. A confirmation box will display before the remote session is ended.   |
|       | Battery charge status is located in the upper right hand<br>corner of the display on the Diagnostic Information screen. A<br>lightning bolt indicates the battery is charging. |
| •••   | Opens More Options screen.   |



#### **Device Audio and Video Mute**

The video can be paused by either the practitioner or on the device.

#### **Practitioner Mute Icons**



#### **Device Mute Icons**





## VITA More Options Screen

The More Options screen allows the patient side operator to change in-session viewing settings or to select an AutoDrive destination.





## **VITA Settings Screen**

Tap 🖸 on the VITA's chest display to show the available settings.





#### **VITA Wi-Fi Connection Setup**





- 1. Select Wifi Setup from the Settings screen
  - 2. Select the desired secure, clinical wireless SSID network.

| ← Wifi Se                    | etup C |
|------------------------------|--------|
| Connected                    |        |
| Conference Bots<br>Secured   |        |
| SQA_ROBOT_NETWORK<br>Secured |        |
|                              |        |
| Vita<br>Secured              |        |
| SQA-IPv6<br>Secured          |        |
|                              |        |
| <b>O O N</b>                 | a 🔅 🔅  |

CAUTION: Guest, Staff, and VIP type networks are not suitable for connection of a medical device peripheral.



#### 3. Enter the network security key.

| ÷     |                |       |   |   |   |   |   |       |   |   |   |   |       |   |
|-------|----------------|-------|---|---|---|---|---|-------|---|---|---|---|-------|---|
|       | Enter password |       |   |   |   |   |   |       |   |   |   |   |       |   |
|       | 1              | 2     | 3 | 4 | 5 | 6 | 7 | 8     | 9 | 0 |   | = | ×     |   |
| t     | ab             | q     | w | е | r | t | у | u     | i | ο | Р | [ | 1     | ١ |
| Ca    | aps            | а     | s | d | f | g | h | j     | k | I |   |   | 0     |   |
|       | shift          | 2     | z | x | c | v | b | n     | m |   |   | / | shift |   |
| clear |                | space |   |   |   |   |   | clear |   |   |   |   |       |   |
|       | cancel         |       |   |   |   |   |   |       |   |   |   |   |       |   |

4. Use the **Information Icon** () on the lower right corner of the screen and ensure that the status is **Ready** before attempting to make a connection.

NOTES:

- The Diagnostic Information page will display current WiFi status.
- The VITA will automatically connect to known Wi-Fi profiles. For stored WiFi profiles, the password can be changed by selecting it and editing the password.



#### **Device Network Checkup**

The Network Checkup screen runs and displays the results of a test of the device's current network connection.

- The checkup will automatically run when the screen opens.
- A green check-mark appears for each past item.
- An orange X appears for any failed item with contact information on how to resolve any issues.







## Stethoscope Setup

The **Stethoscope Setup** settings screen allows the user to select the stethoscope during a virtual encounter.



| ÷     | Stethoscope Setup |            |  |   |  |
|-------|-------------------|------------|--|---|--|
| 1 💿   | None              |            |  |   |  |
| • F   | PCP (USB)         |            |  |   |  |
| • • • | PCP (Tethered)    |            |  |   |  |
|       |                   |            |  |   |  |
|       |                   |            |  |   |  |
|       |                   |            |  |   |  |
|       |                   |            |  |   |  |
|       |                   |            |  |   |  |
|       |                   |            |  |   |  |
|       |                   |            |  |   |  |
|       | ~                 |            |  |   |  |
| •     | Ø                 | <b>≻</b> ₀ |  | i |  |



## **Device Session Start Sound**

The Session Start Sound settings screen allows the user to change start sound volume on the device at the start of a virtual encounter.



| ÷ | Ses                         | sion Start Sound           |
|---|-----------------------------|----------------------------|
| 5 | Sounds                      | Volume                     |
|   | o Science Fiction (Default) | <ul> <li>Normal</li> </ul> |
|   | Calm Bell                   | Ouieter (50%)              |
|   | Cheerful Chimes             | Ouietest (15%)             |
|   | Knock Knock                 | Silent                     |
|   |                             |                            |
|   |                             |                            |
|   |                             |                            |
|   |                             |                            |
|   |                             |                            |



#### **Date and Time Settings**

Tap Settings then Date and Time , to adjust how the date and time are displayed on the VITA during a session.

Tap to return to the Settings screen. 4 **Date and Time** Date ( L) Clock Show clock Show date Show 12 hour clock Format YYYY/MM/DD **Display seconds** MM/DD/YYYY Session DD.MM.YYYY Show session timer i



## **Device Cleaning Mode**

The VITA has a screen-cleaning mode, so that no functionality is inadvertently called upon when cleaning.







#### VITA Change Map



- 1. Tap the from the Settings screen to select different, preprogrammed maps.
- 2. Scroll through the available maps to locate the appropriate one.
- 3. Tap the appropriate map to select it.
- 4. Tap 🖸 to return to the idle screen.

| ←  | Change Map               |   |  |  |  |  |  |
|----|--------------------------|---|--|--|--|--|--|
| D  | building3-sqa            |   |  |  |  |  |  |
|    | BLG2-Vita Map-QA-Patrol  |   |  |  |  |  |  |
|    | DHA                      |   |  |  |  |  |  |
| IJ | MHSRS2                   |   |  |  |  |  |  |
|    | NEW_TIC_ICUDock_12_16_16 |   |  |  |  |  |  |
|    | ратн_9-30-18мг           |   |  |  |  |  |  |
|    |                          |   |  |  |  |  |  |
|    | o 🤗 🖛 🜣                  | i |  |  |  |  |  |



## VITA Edit Badge

This feature allows the information found on the Chest Display name badge.



1. Tap Edit Badge from the Settings screen to edit the information on the VITA's Chest Display's badge.





- 2. Tap the field to change the text.
- 3. Use the onscreen keyboard to enter the revised text.



- 4. Tap **I** to accept the new text.
- 5. Select a different icon, if available, by tapping the left or right arrows.
- 6. Tap 🖸 to return to the home screen.



## **Device Settings - More Options**

From the **Settings** screen, select the icon to display additional device settings.



| Application                  |  |  |  |  |
|------------------------------|--|--|--|--|
| Enable Passcode To Unlock    | Enables a passcode to unlock the device. The Passcode is the Device's Serial Number. You will be prompted to confirm activation of the Passcode.                           |  |  |  |
| Hide Screensaver Top Text    | When toggled on, the text, <b>Please keep this device on at all times</b> is not displayed on the screensaver.   |  |  |  |
| Hide Screensaver Bottom Text | When toggled on, the text, <b>Touch to interact</b> is not displayed on the screensaver.   |  |  |  |
| Hide In-Session Controls     | Hides the In-Session controls on the bottom of the screen.   |  |  |  |
|                              | <ul> <li>While in-session, use the icon to un-hide the In-Session Controls.</li> <li>See <u>"Active Session Screen Navigation" on page 27</u> for more details.</li> </ul> |  |  |  |



## **VITA Status Indicator Lights**

VITA has LED light strips that indicate its operational status and condition. Lights are located on all four sides under the base and on the left and right sides just above the base. The Head and Chest Displays will also display the color. The meaning of the indicator lights is described in the following table. See "VITA Anatomy and Components" for the location of the LED indicator lights.

| VITA Status                | LED Color, Animation   | Example |
|----------------------------|--|---------|
| Start Up                   | <ul> <li>Crey Base lights</li> <li>No Head or Chest display</li> </ul>   |         |
| Idle (not charging)        | <ul> <li>White/Cray color pallet</li> <li>IDLE badge displayed</li> <li>Badge displays greeting</li> </ul>                     |         |
| Idle (charging)            | <ul> <li>White/Cray color pallet</li> <li>Idle badge displayed</li> <li>Badge displays greeting - Base lights pulse</li> </ul> |         |
| Message–See "Message Mode" | <ul> <li>Magenta color pallet</li> <li>Message badge displayed</li> <li>Notification shows error</li> </ul>                    |         |



| VITA Status   | LED Color, Animation  | Example |
|---|---|---------|
| Mission–AutoDrive command from the Chest Display other than Dock. | <ul> <li>Blue color pallet</li> <li>Mission badge displayed</li> <li>Badge displays destination</li> </ul>                              |         |
| Session   | <ul> <li>Teal color pallet</li> <li>Session badge displayed</li> <li>Badge displays User name</li> </ul>                                |         |
| Fault   | <ul> <li>Yellow/previous color pallet</li> <li>Previous badge displayed</li> <li>Notification shows error - Yellow LED light</li> </ul> |         |

**NOTE**: If VITA is going to its Dock and is not currently in a session, the LED colors will be static white. This can occur as a result of VITA being sent to the Dock from the Chest Display, a disconnected session, or losing its Wi-Fi signal, or because of an idle or low battery timeout.



# **Cleaning and Maintenance**

## **Approved Disinfectants**

The following disinfectants have been tested for compatibility with Teladoc Health devices:

- PDI bleach wipes
- OxyCide
- Ethyl Alcohol
- Isopropol Alcohol
- Sodium Hypochlorite (5.25%-6.15% household bleach diluted 1:500 provides >100 ppm available chlorine).
- Iodophor Germicidal Detergent Solution (follow product label for use dilution).
- Quaternary Ammonium Germicidal Detergent Solution (follow product label for use dilution).

## WARNINGS:

- Do not attempt to open or remove any parts of the VITA.
- Do not remove any covers to reduce the risk of electric shock. There are no userserviceable components inside.
- Refer servicing and repair to qualified personnel only.
- Wear safety glasses when handling solution prior to dilution.
- Wear rubber or nitrile gloves, if in contact with liquid.
- Avoid contact with eyes, skin and clothing.
- Wash hands after cleaning device.
- Do not wear product-contaminated clothing for prolonged periods.
- Always follow manufacturer's instructions on product labels when mixing chemicals.



#### CAUTIONS:

- DO NOT USE phenolic germicidal detergent solutions on any parts of the device. Contact Teladoc Health Technical Support for approved cleaning solutions.
- Severe contamination, especially of the undercarriage may require some disassembly and this should only be done by an Teladoc Health representative.
- DO NOT IMMERSE the device.
- DO NOT ALLOW any cleaning solution inside the device.
- Keep the device from moisture and extreme temperatures.
- Avoid excess solution that could enter the device through its openings.



## **Cleaning Instructions**

Clean the outer surfaces of the Device when visibly soiled or after contact with any contaminates. All surfaces, such as display monitors or sensor windows may be disinfected using the following procedure. Use a commercial LCD screen cleaner to prevent craze, staining, or discoloration of the display monitors and use optical lens cleaners to clean the camera lenses.

**NOTE**: For devices with touch screens, go to Settings > Cleaning Mode, to temporarily disable the touch interface for 30-seconds to enable cleaning. See <u>"Device Cleaning Mode"</u> on page 37

- Soak a lint-free cloth in a hospital grade disinfectant solution of sodium hypochlorite 6.15%, e.g., dilution 1:500 (1/4 oz. per gallon water) and wring out the cloth so that drips do not appear when wiping surfaces.
- 2. Wipe surfaces that have become soiled or contaminated. Avoid applying excess solution which may enter the device through its openings.
- 3. Allow to air dry.

## **Cleaning Sensor Windows (VITA)**

Keep the sensor windows clean to ensure dirt or foreign particles are not interpreted as objects to avoid when the device is moving.

- Clean all three windows of the waist sensor.
- Clean the entire 270° extent of the sensor located under the skirt at the front of the device.



#### VITA Maintenance

The VITA contains no user serviceable parts and requires no maintenance. For further information regarding preventive maintenance, maintenance or assistance with troubleshooting, customers should contact Teladoc Health Technical Support at +1 (877) 484-9119.

## VITA Inspecting the ESD Cable

The Electric Static Discharge (ESD) cable is located on the underside of the VITA to dissipate any static charges that arise. The cable should be checked periodically to ensure that it is





present and remains in contact with the floor.

**CAUTION**: Do not tilt VITA onto its bumpers or attempt to place VITA on its back. The bumpers located on the bottom edge of VITA may be damaged.

- Tilt the VITA toward the back on its roller wheels so that the static cable can be viewed.
- As shown in the photograph, the cable should be relatively straight and not kinked.
- Verify that the cable reaches the floor when the VITA is upright.

Contact Teladoc Health at +1 (877) 484-9119 if the ESD cable appears damaged or is missing.





# **Privacy Handset**

## **NOTE**: Always place the Privacy Handset on the hook after use.

The Privacy Handset is for use in conversations that require privacy or understandability in a loud environment.

When the Privacy Handset is enabled from the Provider Access Software, the standard Patient Access Device audio system is disabled. This means the Patient Access Device microphone is not active, and the Patient Access Device speaker is not active.

When the Privacy Handset is disabled, the audio system is transferred from the phone, back to the standard Patient Access Device audio system.

It is important to return the Privacy Handset to the hook on the Patient Access Device. Ask someone on the Patient Access Device-side to return the Privacy Handset to the hook if necessary.

## Activating the Privacy Handset from the VITA

Select the **I** icon from the device's screen to activate the Privacy Handset.

- The icon changes to 💟.
- Activating the Privacy Handset deactivates the VITA's main speakers and microphone.

**NOTE**: The provider has the ability to deactivate the Privacy Handset and reactivate the VITA's main speakers and microphone.

## **Deactivating the Privacy Handset from the VITA**

Select the 🔯 icon from the device's screen to activate the Privacy Handset.

- The icon changes to 🕻 .
- The VITA's main speakers and microphone will again be active..

**NOTE**: The provider also has the ability to activate the Privacy Handset from their Provider Access Software.





# VITA Aux Video Ports

The VITA's expansion bay includes both video input ports and a VGA output port. The USB ports can also serve to capture video from approved USB cameras. This allows the remote physician to view multiple video inputs through the Provider Access Software.

The VGA output allows the video from the Provider Access (shown on the VITA remote display) to be shown on a different screen or on a projector.

#### WARNINGS:

- The video images transmitted to and displayed on the VITA and Provider Access may not contain all of the information in the original scene. Video information from the camera is captured, compressed, transmitted, and redisplayed remotely at a different resolution. As a result information in the original scene may be lost.
- Color reproduction in the transmitted video is not guaranteed. It should not be assumed that the colors on the display are an exact replication of the actual colors in the scene.
- Clinical judgment and experience are required to review and interpret images and information transmitted via the VITA and Provider Access.



**CAUTION**: Always push the Emergency Stop button in when connecting video equipment to the Auxiliary Video Input. Disconnect the equipment when ending a session and before pulling the Emergency Stop button out to enable the VITA's (base) movements. The VITA has Autonomous drive modes that will be commanded when it is not in session. For example, the VITA will return to its Dock when its battery charge is running low. The VITA and/or attached equipment may be damaged if the VITA is driven with equipment connected to its Inputs.



# **VITA Physical Specifications**





## **VITA Technical Specifications**

| erformance   |   |  |  |  |
|--|---|--|--|--|
| Pan range: +/- 170° max  | Tilt range: 127° max  |  |  |  |
| Pan speed: 90°/sec max   | Tilt speed: 90°/sec max   |  |  |  |
| Maximum speed: 3.36 mph (forward)  |   |  |  |  |
| Locomotion: holonomic drive system   |   |  |  |  |
| Multiple center and base-mounted cameras and sensors                                   |   |  |  |  |
|  | FDA Class 1 Laser sensors detect obstructions up to 98 ft. (30m) within a 270 degree range centered about the front of the robot.   |  |  |  |
| Microphone: Mono, directional (hyper-cardioid), 50Hz-19kHz, Speakers: two 5 W mono     | 16 kHz sampling rate,   |  |  |  |
| speakers in the head and a sub-woofer in the base. Capable of 100dB sound (1KHz @ 1m). | 16-bit audio  |  |  |  |
| Camera: 120X equivalent zoom, remote zoom & focus                                      | Display: 15" LCD, 1024x768 px, 400 Nits   |  |  |  |
| Video: 30 fps, 648x480 px resolution, 24-bit color                                     |   |  |  |  |
| Display: 15 in LCD, 1024x768   |   |  |  |  |
| Touch-screen: 8.4 in. LCD, 1024x760  |   |  |  |  |
| 802.11 a, b, g, or n   |   |  |  |  |
| 4-5 hrs (depending on usage)   |   |  |  |  |
|  |   |  |  |  |
| 2 hours from 0% to 80% (6 hours to 100%)   |   |  |  |  |
| Related to the range of the wireless network in use                                    |   |  |  |  |
|  | Pan range: +/- 170° max         Pan speed: 90°/sec max         Maximum speed: 3.36 mph (forward)         Locomotion: holonomic drive system         Multiple center and base-mounted cameras and sensors         Microphone: Mono, directional (hyper-cardioid), 50Hz-19kHz, Speakers: two 5 W mono speakers in the head and a sub-woofer in the base. Capable of 100dB sound (1KHz @ 1m).         Camera: 120X equivalent zoom, remote zoom & focus         Video: 30 fps, 648x480 px resolution, 24-bit color         Display: 15 in LCD, 1024x768         Touch-screen: 8.4 in. LCD, 1024x760         802.11 a, b, g, or n         4-5 hrs (depending on usage)         2 hours from 0% to 80% (6 hours to 100%)         Related to the range of the wireless network in use |  |  |  |

## **VITA System Input Power Requirements**

|           | North America | International |
|-----------|---------------|---------------|
| Voltage   | 115 VAC       | 230 VAC       |
| Frequency | 60 Hz         | 50 Hz - 60 Hz |
| Current   | 10 Amps       | 5 Amps        |

## **VITA Classification**

- Internally Powered /Class I while in Charging Mode
- Type B applied parts Headset and Handset



## **VITA Environmental Specifications**

## Operating

Designed to operate in an indoor environment suitable for human personnel.

(10° to 30° C, 30 to 75% RH, 700 hPa to 1,060 hPa)

## Non-operating / Storage / Transport

Designed to travel to installations in commercial and cargo airliners and standard ground transportation.

(-40° to +70° C, 10 to 100% RH, 500 hPa to 1,060 hPa)



# Patient Access Device - Error Messages

## These text messages may appear in the lower right of the VITA's Display.

| Message Explanation  |   | Action   |  |
|--|---|--|--|
| "Internet connection<br>failure." "Internet con-<br>nection slow."   | Very high round-trip latency at Provider Access or<br>Patient Access Device. Possible cause: poor internal net-<br>work conditions, low Quality of Service Internet con-<br>nection or excessive bandwidth usage.   | These error messages represent non-optimal<br>Internet connection conditions. They may hap-<br>pen periodically on many networks under nor-<br>mal conditions. However, if they persist, contact |  |
| "Internet failure:<br>Severe loss."  | Packets lost. May see jumpy video with lower frame<br>rates at Provider Access or Patient Access Device. Poss-<br>ible cause: poor internal network conditions, low Quality<br>of Service Internet connection or excessive bandwidth<br>usage.                      | the nospitals in department.   |  |
| "Internet failure:<br>Severe loss remotely."   | Problem was detected on reverse side (i.e., at the Pro-<br>vider Access). These messages are shown if problem is<br>only being detected in one direction.   |  |  |
| "Internet failure: Audio<br>lost."   | Packets containing audio data lost, therefore user may<br>notice loss of audio at Provider Access or Patient Access<br>Device. Possible cause: poor internal network con-<br>ditions or low Quality of Service Internet connection or<br>excessive bandwidth usage. |  |  |
| "Internet failure: Audio<br>lost remotely."  | Problem was detected on reverse side (i.e., at the Pro-<br>vider Access). These messages are shown if problem is<br>only being detected in one direction.   |  |  |
| "No stethoscope<br>audio. Power cycle it<br>next to the device."   | Physician cannot auscultate because the stethoscope<br>audio is no longer connected to the Provider Access<br>Software.   | Restart stethoscope and try again.   |  |
| "Stethoscope disabled<br>due to critically low<br>battery (10%). Please<br>replace battery for nor-<br>mal operation." | Battery needs to be charged or replaced by the nurse<br>on the Patient Access side.   | Charge or replace battery.   |  |
| "Stethoscope battery<br>is critically low (10%).<br>Sound degradation<br>expected. Please<br>replace battery soon."    | Battery is critically low. Consider charging or replacing<br>the battery soon.  | Charge or replace battery.   |  |



# **Network Configuration**

**NOTE:** For the best performance from the device in terms of Device Optimization and connection success, utilize the information found in these two documents:

- MB-15513 Network Configuration for Teladoc Health Devices
- MB-14011 Teladoc Health Telehealth Network Specifications

Contact your Teladoc Health representative for copies of these documents.

The Teladoc Health System is comprised of a Remote Presence Patient Access Device and a minimum of one Provider Access Software Device. The Provider Access and Patient Access Devices are linked via the Internet over a secure connection.

## **Configuring the VITA Wireless Connection**

The VITA Control Core uses a Windows computing environment and a wireless network card.

For the VITA, basic Wireless Network connections can be made using the touch-screen, under Settings.

## **Non-Overlapping Channels**

In order to achieve a smooth transition from one wireless access point (WAP) to the next it's important to configure each WAP on a non-overlapping channel.

## **Transmitting Power**

The WAPs may be configured to provide the wireless signal at different power transmission levels. Setting the WAP to the maximum power transmission will deliver the maximum coverage area.

## Interference

If WAPs are co-located in the same environment, radio frequency interference may be generated. Too many WAPs transmitting on overlapping channels may also degrade the wireless signal quality.

WAPs placed too close to one another may also produce RF congestion. In this case, the WAP transmission power should be reduced; therefore, reducing the coverage area and limiting the overlap between adjacent WAPs.

## **Security Options**

Each wireless network must be configured with security to prevent unauthorized access to the net-work. The ADU provides multiple features to configure the VITA to access as well as secure the wireless network. Domain membership is not supported, but all other current security configurations can be configured. WPA2/AES-PSK is preferred.



## **Network Installation**



## **Network Requirements**

#### **Provider Access User Authentication**

Users launch the Provider Access Software from their desktops and login to begin consults. Users have a unique username and password for their Provider Access accounts, which is created at registration.



Enterprise login allows users to use their company credentials to login to the Provider Access Software. If your system is configured to use Enterprise login, your system may automatically login to the Provider Access Software.

Users should make sure to comply to HIPAA standards by ensuring that they log off when away from their computers for extended periods of time. Users must log into Provider Access Software using their Teladoc Health username and password. After a period of inactivity, users are logged out automatically as a security feature.

#### **Firewall Requirements**

The Teladoc Health Telehealth System uses bidirectional communication under TCP and/or UDP. The Teladoc Health Telehealth Network consists of connections made through either our SharedComm or SIP servers. For optimal connections using SharedComm, Patient Access Devices and Provider Access Software require outgoing UDP access on ports 9000-9101 with reflexive UDP access ('UDP Replies') enabled. (Note: UDP replies are enabled by default on most firewalls). For optimal connections using SIP, Patient Access Devices and Provider Access Software require outgoing UDP access on ports 35000-35500 with reflexive UDP access ('UDP Replies') enabled.

For training and support purposes (including software upgrades), Teladoc Health routinely makes use of remote desktop applications (Kaseya, GoToAssist & GoToMyPC). Teladoc Health requires access to all Patient Access Devices and Provider Access Software via one of these applications.

For a detailed list of IP addresses and ports to white list, please refer to the document: Network Configuration for Teladoc Health Devices (MB-15513). Additional modifications may be necessary for use with a Web Filter and /or Stateful Packet Inspection.

#### Video Information

**Frame rate:** Video is captured at 30 frames per second but can be reduced for low bandwidth connections.

Codec (video and audio compression): Teladoc Health uses the standards-based H.264 AVC codec for video and the Opus or Speex codec for audio.

Dynamic Video Quality provides the ability to dynamically adjust resolution and video quality during a live session without user interaction. Advanced users can specify preferences for adjusting resolution. Video quality depends on factors such as robot motion, available bandwidth, and user preference.

#### **Bandwidth Requirements**

The ideal bandwidth required is 700 kbps in both directions from any Provider Access Software or Patient Access Device. For Provider Access Software located in homes, lower bandwidths such as home cable broadband can be configured with good performance



effectively utilizing 300 kbps. For installations where higher audio and video quality is desired, higher bandwidths above 700 kbps can be allocated.

For HD video, your Provider Access Device must be configured to allow 2000-3000 kbps.

## **Line Quality Requirements**

Network performance is critical to maintaining a responsive Provider Access Software to Patient Access Device session. Metrics cover a range of network characteristics which impact delivery of complete correct data in the proper order in a timely fashion. Teladoc Health runs tests using proprietary and third party software tools to determine if a broadband connection meets a sufficient level of network performance to maintain a session. Teladoc Health can provide these tools to customers upon request.

**NOTE**: During any particular session, quality may be degraded or the session may be disconnected if the network performance limits described below are exceeded, even though performance measurements were within limits at another point in time.

There are five important network characteristics affecting connectivity:

**Data rate**: A connection must have the required up-stream and downstream bandwidth, as discussed above.

Latency (delay): Average network latency on a connection should not exceed 300ms.

**Maximum Transfer Unit:** The Maximum Transfer Unit (MTU) must not be set below 1400 bytes.

**Reliability**: A connection must be reliable, without significant packet loss. A connection should experience no more than 3% packet loss.

**Jitter**: Jitter is variability in latency. Jitter on a connection should not exceed +/- 50ms during 95% of the duration of a session.

**NOTE**: Teladoc Health's software is fully capable of dealing with the normal variability of data over the Internet. It is the quality of the endpoint connections which is critical and must be tested.

#### **Wireless Network Requirements**

The Teladoc Health System is compatible with 802.11 ac, a, b, g, and n protocols. The Maximum Handoff Threshold time must be less than 150ms.

In environments which experience network congestion, the Teladoc Health application requires Quality of Service (QoS) or priority of traffic to ensure a successful connection.

#### Satellite Networks

The network characteristics detailed above (bandwidth requirements, packet loss, jitter, and MTU) are strongly recommended to achieve an audio/video session of functional quality over a



satellite network. The one notable exception is the expected latency typical of satellite networks.

The Teladoc Health System can maintain an audio/video session of functional quality with latency up to 900 ms if all other network characteristics are met. Please note that this delay will be evi-dent on both sides of any audio/video/command communication as is typical of satellite net-works.

If utilizing a satellite network with latency above 600 ms, the delay in drive commands may hinder the operator from maintaining safe control over the movement of mobile devices. Teladoc Health therefore does not recommend utilizing mobile devices, such as the Teladoc Health 7i, on a satellite net-work.

#### Encryption

The Teladoc Health System incorporates encryption methodology utilizing a combination of RSA public/private key and 256-bit AES symmetric cryptography. The following is a brief summary:

Each time a Provider Access session is initiated, a symmetric key is created using AES 256-bit cryptography. The encrypted data is then transmitted using RSA 4096-bit public-private key cryp-tography. PHI and other sensitive health information is further secured using SSL/TLS and other different forms of authentication.

## **Virus Protection**

TrendMicro's OfficeScan is installed on every system. This software automatically updates as soon as new virus definitions are available. Teladoc Health staff monitor software updates as they be-come available. Teladoc Health staff install all necessary security updates on Patient Access De-vices.



## **HIPAA Procedures**

As a business associate, Teladoc Health is subject to compliance of the law under §164.308 (Administrative Safeguards), under §164.310 (Physical Safeguards), and under §164.312 (Technical Safeguards) to maintain and transmit health information in electronic form in connection with transactions performed by the customer (covered entity).

The policy of this organization is to ensure, to the greatest extent possible, that Protected Health Information (PHI) is not intentionally or unintentionally used or disclosed to violate the HIPAA Privacy Rule or any other federal or state regulations governing confidentiality and privacy of health information.

There are a number of safeguards implemented into the telehealth system that ensure that it complies with the latest HIPAA regulations. One of the key requirements is Teladoc Health's ongoing implementation and updating of its HIPAA security policies and procedures to ensure for the availability, security, and privacy of telehealth connections and ePHI (electronic protected health information). Teladoc Health maintains a policy to ensure workforce HIPAA compliance and training. Teladoc Health additionally maintains HIPAA security policies and procedures, a data destruction policy, and security incident response procedures.

## **Guidelines for Compliance**

The telehealth system allows hospitals and medical professionals to be in compliance with HIPAA regulations. Teladoc Health is providing the following to assist with HIPAA privacy regulations as they pertain to the telehealth system.

HIPAA requires all healthcare organizations to have policies and procedures, and the guidelines below, but they may not cover all situations for a specific organization. For example, from time to time, automatic software upgrades may be downloaded which may contain new features. Teladoc Health will inform users of significant features added, their impact and how they may affect HIPAA policies, procedures, and safeguards.

## **Access to Provider Access**

The computer using the Provider Access should be placed in a location that is only accessible to individuals who have authorized access to Protected Health Information (PHI). It is recommended that Provider Access be password protected via a Windows or iOS user account.



Only authorized users should have passwords, and users should safeguard passwords according to hospital policies and procedures. Passwords should be treated as highly confidential information. If you believe your password may have been compromised, it should be changed as soon as possible. Change your password by clicking on the "Forgot Password" link on the login screen of the Teladoc Health Provider Access.

The Auto Logout feature is set to log out of the Teladoc Health Provider Access when the system is inactive for 30 minutes. Also, all users should be trained to log out of Windows, iOS or the Virtual Private Network (VPN), when away from the system for any period of time. This is important for security reasons, so that any person attempting access to the Provider Access will be required to enter a password for secure access.

## **Discussion and Display of PHI**

From time to time a physician will likely engage in remote communications with patients and medical staff in which patient information (records, images and video) will be discussed or displayed. In general, the same care should be exercised as though the physician were physically present. For example:

- Use Head rotation to look around and see who else is nearby and might see or hear the sensitive information, and use appropriate discretion.
- Use the microphone mute button when conversing with someone alongside the Teladoc Health Provider Access to avoid the inadvertent conferencing of patient-related conversation.
- The Teladoc Health Provider Access screen should be positioned to point away from public areas, so as not to be visible to passersby.

## **Images and Video**

By default when saved, all captured images and video files are stored encrypted files; viewable only by the Provider Access user who captured them. All files are saved in the user's Teladoc Health Media Vault to provide added protection.

For convenience, these files may be saved in common formats, e.g., JPEG for still images. These files are no longer encrypted and therefore are viewable by any user who can access them. As such, there are a few recommended techniques for safeguarding PHI contained in these images and video:

• Ensure all personnel who have access to the Provider Access Software also have full permission to access stored images and videos under the hospital's policies and



procedures;

- Make sure to store captured images and videos only on removable media (e.g., recordable CD-ROMs) which can be taken with each user or on secure network drives;
- Do not save to disk any captured images and video clips. Use these images and video segments only while logged in for a virtual encounter.

## **Disclosure of PHI**

If the physician plans to transmit or copy stored images or video to other individuals or organizations, e.g., to a healthcare operator, the physician needs to abide by standard HIPAA codes governing who may receive PHI and under what conditions. The hospital's HIPAA compliance officer should be consulted for details.



## Electromagnetic Compatibility - Guidance and Manufacturer's Declaration

The VITA system complies with IEC 60601-1-2, General Requirements for Safety – Collateral standard: Electromagnetic compatibility. Performance of the device is unaffected by exposure to the compliance levels described in Tables 1, 2, 3 and 4 in the following section.

Special precautions and installation information for the VITA for electromagnetic compatibility (EMC) are provided below:

- Equipment in hospital environments, including the VITA and other portable or mobile communications equipment, can produce Electromagnetic Interference (EMI), that may affect the function of these devices. Such effects are prevented by use of equipment with EMI characteristics proven below recognized limits, as identified in the tables below.
- In the event of suspected interference from other equipment, which prevents the proper functioning of the VITA, contact Teladoc Health and discontinue use of the system until the problem can be remedied.

The following tables contain the Manufacturer's declaration and additional information required by IEC 60601-1-2.

**WARNING:** Leakage current from interconnected electrical equipment may exceed safe levels. In order to maintain patient and user safety, it is important to interconnect only with devices in compliance with IEC 60601-1-1 requirements. It is the responsibility of the user to ensure that any interconnected equipment not supplied by Teladoc Health maintains compliance with IEC 60601-1-1 requirements.

## **Table 1: Electromagnetic Emissions**

| The VITA is intended for use in the electromagnetic environment specified below. The customer or the user of the VITA should assure that it is used in such an environment. |            |   |  |  |  |
|---|------------|---|--|--|--|
| Emissions Test  | Compliance | Electromagnetic Environment   |  |  |  |
| RF Emissions CISPR 11   | Group 1    | The VITA 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 A    | The VITA is suitable for use in all establishments other than domestic and those  |  |  |  |
| Harmonic Emissions<br>IEC 61000-3-2   | Class A    | buildings used for domestic purposes.   |  |  |  |
| Voltage Fluctuations /<br>Flicker Emissions IEC<br>61000-3-3  | Complies   |   |  |  |  |



## **Table 2: Electromagnetic Immunity**

The VITA system is intended for use in the electromagnetic environment specified below. The customer or the user of the VITA should assure that it is used in such an environment.

| Immunity Test   | EC 60601 Test Level   | Compliance<br>Level   | Electromagnetic Environment - Guidance   |
|---|---|---|--|
| Electrostatic Dis-<br>charge (ESD) IEC<br>61000-4-2   | ±6 kV Contact<br>±8 kV Air  | ±6 kV Contact<br>±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%.  |
| Electrical Fast Tran-<br>sient /Burst IEC<br>61000-4-4  | ±2 kV for Power Supply<br>Lines<br>±1 kV for Input /<br>Output Lines  | ±2 kV for Power<br>Supply Lines<br>±1 kV for Input /<br>Output Lines  | Mains power quality should be that of a typical commercial or hospital environment.  |
| Surge IEC 61000-4-5   | ±1 kV Line(s) to Line(s)<br>±2 kV Line(s) to Earth  | ±1 kV Line(s) to<br>Line(s)<br>±2 kV Line(s) to<br>Earth  | Mains power quality should be that of a typical commercial or hospital environment.  |
| Voltage Dips, Short<br>Interruptions, and<br>Voltage Variations<br>on Power Supply<br>Input Lines IEC<br>61000-4-11 | <5% UT (>95% dip in<br>UT) for 0.5 cycle<br>40% UT (60% dip in UT)<br>for 5 cycles<br>70% UT (30% dip in UT)<br>for 25 cycles<br><5% UT (>95% dip in<br>UT) for 5 sec | <5% UT (>95%<br>dip in UT) for 0.5<br>cycle<br>40% UT (60% dip<br>in UT) for 5<br>cycles<br>70% UT (30% dip<br>in UT) for 25<br>cycles<br><5% UT (>95%<br>dip in UT) for 5<br>sec | Main power quality should be that of a typical commercial or<br>hospital environment. If the user of the requires continued<br>operation during power mains interruptions, it is recommended<br>that the VITA be powered from an uninterruptible power supply<br>(UPS) or a battery. |
| Power frequency<br>(50 /60 Hz)<br>Magnetic Field<br>IEC 61000-4-8   | 3 A/m   | 3 A/m   | Power frequency magnetic fields should be at levels characteristic<br>of a typical location in a typical commercial or hospital<br>environment.  |
|   | U <sub>T</sub> is the a.c   | . mains voltage pric  | pr to application of the test level.   |



## **Table 3: Electromagnetic Immunity**

VITA is intended for use in the electromagnetic environment specified below. The customer or the user of an VITA should assure that it is used in such an environment.

| Immunity Test                                | Conducted RF  |                    |  |
|--|---|--------------------|--|
|  | IEC 61000-4-6 Radiated FR   |                    |  |
|  | IEC 61000-4-3   |                    |  |
| EC 60601 Test                                | 3 Vrms 150 kHz to 80 MHz  |                    |  |
| Lever  | 3 V/m 80 MHz to 2.5 GHz   |                    |  |
| Compliance Level                             | 3 Vrms 150 kHz to 80 MHz  |                    |  |
|  | 3 V/m 80 MHz to 2.5 GHz   |                    |  |
| Electromagnetic<br>Environment -<br>Guidance | Portable and mobile RF communications equipment should be used no closer to any part of the VITA, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance:<br>d=1.2   |                    |  |
|  |   |                    |  |
|  | d= 1.2 <b>V</b> P   | 80 MHz to 800 MHz  |  |
|  |   | 800 MHz 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 <sup>a</sup> , should be less than the compliance level in each frequency range <sup>b</sup> . |                    |  |
|  | Interference may occur in the vicinity of equipment marked with the following sym   | ıbol:              |  |



## NOTES:

- At 80 MHz and 800 MHz, the higher frequency range applies.
- These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.
- a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the VITA is used exceeds the applicable RF compliance level above, the VITA should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the VITA.
- b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [3] V/m.



## **Table 4: Recommended separation distances**

# Recommended separation distances between portable and mobile RF communications equipment and the VITA.

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

| Rated Maximum Output Power of<br>Transmitter<br>(W) | Separation distance according to frequency of transmitter<br>(m) |               |                |
|---|--|---------------|----------------|
|   | 150 kHz to 80 MHz  | 80 MHz to 800 | 800 MHz to 2.5 |
|   | d =1.2 √P  | MHz d =1.2 √P | GHz d= 2.3     |
| 0.01  | 0.12   | 0.12          | 0.23           |
| 0.1   | 0.38   | 0.38          | 0.73           |
| 1   | 1.2  | 1.2           | 2.3            |
| 10  | 3.8  | 3.8           | 7.3            |
| 100   | 12   | 12            | 23             |

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

#### NOTES

- 1. At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
- 2. These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.



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#### About Teladoc Health

Teladoc Health is the global virtual care leader, helping millions of people resolve their healthcare needs with confidence. Together with our clients and partners, we are continually modernizing the healthcare experience and making high-quality healthcare a reality for more people and organizations around the world.

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