# Teladoc Health<sup>®</sup> Mini™ User Guide

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https://teladochealth.com/patents/

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# **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 any time. 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.





# **Safety Instructions**

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:

NOTE: Supplementary information to facilitate the operation of the system.

CAUTION: Instructions for avoiding damage to the system.

WARNING: 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 are defined in the table below.

Wireless Transmitter Notification: Non-ionizing electromagnetic radiation. This device communicates over the 802.11 ac/a/b/g/n standard for wireless communication.	
Pinch Point: Avoid the labeled pinch point on the rear of the display of your device.	
Do Not Dispose of in Household Waste: This symbol explains that you should not place the electrical item in the general waste.	
FCC: The FCC mark is a voluntary mark employed on electronic products manufactured or sold in the United States which indicates that the electromagnetic radiation from the device is below the limits specified by the Federal Communications Commission and the manufacturer has followed the requirements of the Supplier's Declaration of Conformity authorization procedures.	FC



<b>Manufacturer</b> : This symbol shall be accompanied by the name and address of the manufacturer.	
Country of Manufacture: To identify the country of manufacture of products. CN = China as country of manufacture.	<b>CN</b>
Consult Operator's Manual: Operating Instructions are contained in a separate instruction manual.	
Do not push or lean: Do not push on cart when it is prevented from lateral movement by an obstruction.	
CE Label: On commercial products, the letters CE mean that the manufacturer or importer affirms the good's conformity with European health, safety and environmental protection standards.	CE

**Proposition 65: State of California**: The law requires California to publish a list of chemicals known to cause cancer or reproductive toxicity, and for businesses with 10 or more employees to provide warnings when they knowingly and intentionally cause significant exposures to listed chemicals.



**WARNING**: This product can expose you to chemicals including Diisononyl Phthalate, which is known to the State of California to cause cancer, and Bisphenol A, which is known to the State of California to cause birth defects or other reproductive harm. For more information go to www.P65Warnings.ca.gov.



# **Definition of "Device"**

Use of the word "device(s)" in this User Guide refers to Teladoc Health telehealth products, not medical devices as defined in Section 201(h) of the Federal Food, Drug, and Cosmetic Act (FD&C) Act.

In addition, the term "mobile devices" refers to smartphones and tablets.



# **Mini Overview**

The Mini is a remote presence device with a , full motion head that includes a zoom camera, directional microphone, and speaker system.

## **Intended Application**

The Mini is intended to provide high quality Privacy compliant audio and video sessions between a provider and a patient over the Teladoc Health Telehealth Network in a variety of clinical environments.



# **Mini Available Options**

The Mini is available in different configurations depending on the environment.

The available configurations are:

Mini Cart	
Wall Mounted	
Tabletop	



# **Mini Anatomy and Components**

## **Mini Cart**





## **Mini Cart's Storage Compartment**

The Mini Cart's storage compartment provides a location for storing peripherals used with the Mini.

**Mini Cart's Storage Compartment's Measurements** 

• Door: 7.6" tall x 5.6" wide

• Mini Storage Compartment's Interior Volume: 300 cubic inches

• Safe Working Load: 2.2lbs (1kg)





#### **Expansion Ports**

#### **CAUTION:**

 Adding third party software or hardware to the Mini may cause it to malfunction or operate erratically; excluding those devices designed for connection through existing hardware ports. Teladoc Health does not support the addition of third party software or hardware to the Mini. Please check with Technical Service PRIOR to installing any third party devices.

#### **Mini Cart**

The Mini Cart has two USB 3.0 ports that can be used to connect a variety of medical device peripherals for use during consults.





#### **Mini Wall Mounted**

The Mini Wall Mounted has one USB 3.0, one Ethernet and AC port located at the base of the unit.





# Mini Tabletop

The Mini Tabletop has one USB 3.0, one Enternet, and AC port located near the base of the unit.





# **Getting Started**

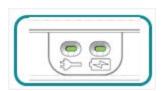
## **Unpacking and Charging the Mini**

WARNING: Plug the Mini into a grounded "Hospital Grade" electrical outlet to minimize the risk of electrical shock.

- 1. Carefully remove the Mini from its packaging, take care not to cause damage.
- 2. Plug the Mini into grounded "Hospital Grade" AC outlet and allow the system to charge for at least 2 hours to reach a full charge.



# **Mini Power and Charging Indicator**



Unit Status	Power plug LED	Battery LED
	\$	4
Unplugged	Off	Off
Plugged in, charging	On	On, Blinking
Plugged in, fully charged	On	On



## **Moving the Mini Cart**

The Mini Cart is designed to be moved by hospital staff into a broad array of locations such as clinics, emergency rooms, rural hospitals, long-term care communities and more. The requirement for operation is a grounded, hospital grade electrical outlet supplying a minimum of 100-240 VAC, 50/60 Hz, 1.3A for the Mini Cart.

Prior to moving the Mini Cart, and when moving the Mini Cart, do the following:

- Ensure any auxiliary devices attached to the Mini Cart are unplugged.
- Ensure the power cord is unplugged and hung on the Mini Cart's handle.
- Ensure the wheels are unlocked before moving.
- Exercise caution when encountering thresholds and doorways.
- Move to the desired location.
- Lock the wheels.
- Plug in the power cord.



# **Hanging Mini Wall Mounted**

Use these instructions to mount the Mini Wall Mounted to a predetermined location.

Step	Action	Image
1.	<ul> <li>a. Use the Wall Mounting Plate as a guide to mark installation locations for the wall anchors.</li> <li>b. Use either the supplied anchors or other anchors deemed suitable by facilities personnel.</li> <li>c. Use the bubble level as a reference to ensure the Wall Mounting Plate is level prior to marking hole locations.</li> <li>d. Drill holes and install anchors.</li> </ul>	
2.	Fasten the Wall Mounting Plate to the anchors.	
3.	Position the Mini Wall Mount assembly over the Wall Mounting Plate.	



4.	Slide the Mini Wall Mount down over the Wall Mounting Plate until the locating pins on the top of the Mini Wall Mounting Plate are fully engaged.	
5.	Secure the Mini Wall Mount assembly to the Wall Mounting Plate using the supplied M3 Socket Head Cap screws.	
6.	Plug in the supplied AC cord into the bottom of the Mini Wall Mount assembly.	



#### Mini Power On

**Powering On the Mini** 

Press and hold the power button for 2-3 seconds until the device powers on.

NOTE: It is recommended that the Mini remain powered on to receive updates and to be available for use.





## **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 Mini Wireless Connection**

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

For the Mini, 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.

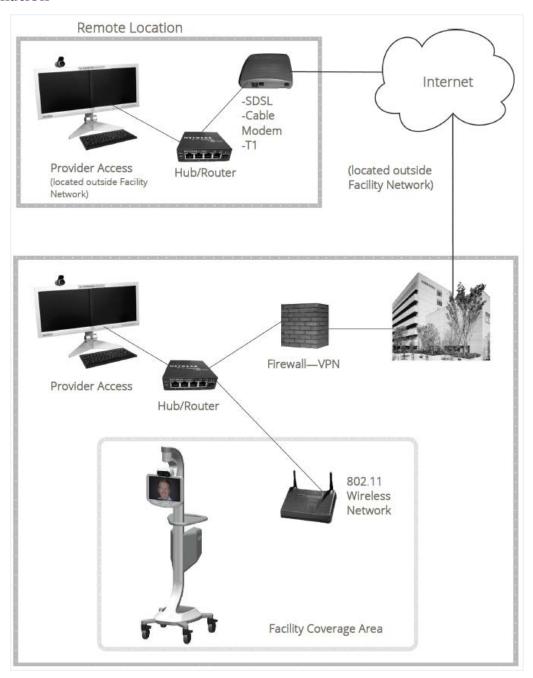
WAPs placed too close to one another may also produce RF congestion. In this case, the WAP transmission power should be reduced; therefore, reducing the coverage area and limiting the overlap between adjacent WAPs.

#### **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 Mini 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**





#### **Mini Features**

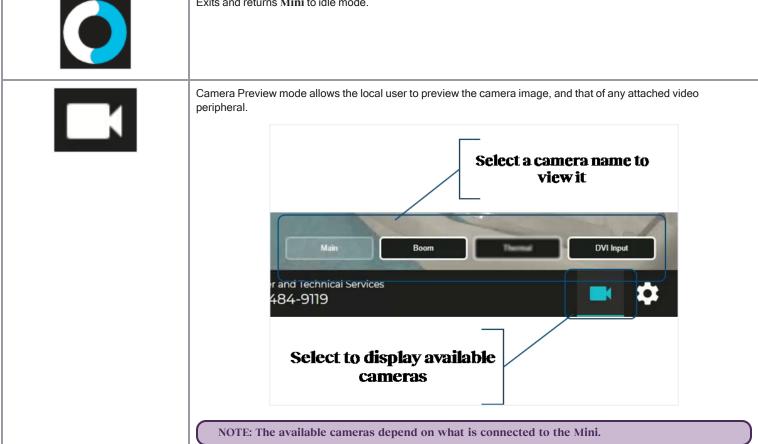
## **Out of Session Screen Navigation**

When the Mini is not actively connected to the Provider Access Software, it is considered idle, and an animation will be displayed.

NOTE: Screensavers chosen by the customer may optionally be shown; to do so, consult your Teladoc Health representative or Technical Support.

Tap anywhere on the Mini's screen to access the available idle features.









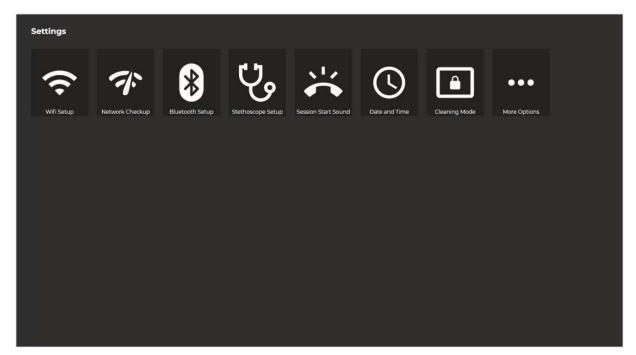
Icon	Function
	<ul> <li>Wifi Setup - allows user to establish a WiFi connection on the Mini.</li> <li>Network Check - runs a diagnostic of the current network connection.</li> <li>Bluetooth Setup - allows user to connect or remove Bluetooth devices to the Mini.</li> <li>Stethoscope Types-select an optional stethoscope (if desired).</li> <li>Session Start Sound - allows the level of the session start sound to be adjusted.</li> <li>Date and Time - allows user to choose date and time display on the device in and out of the virtual encounter.</li> <li>Cleaning Mode - turns off the touchscreen to allow cleaning.</li> <li>More Options - other device display settings.</li> </ul>
<b>Q</b>	Opens an online version of the <b>Mini</b> 's User Guide.
•	Displays Diagnostic Information Includes useful technical information such as:  • Serial number  • Location  • Battery charge  • Wireless Network (SSID) and signal strength  • IP addresses  • Teladoc Health Telehealth Network connectivity  • Device status



# **Mini Settings Screens**

## Tap the screen and then tap the Settings icon



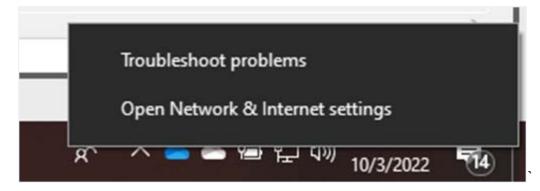


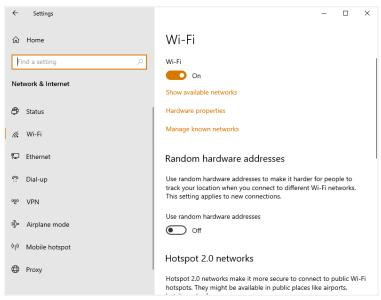


#### Mini Wi-Fi Connection Setup

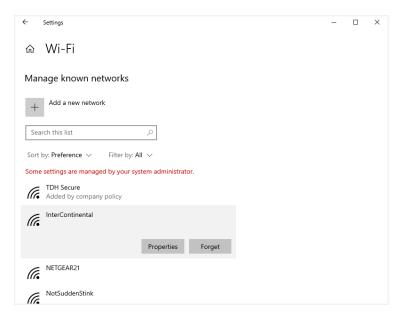
#### **NOTES:**

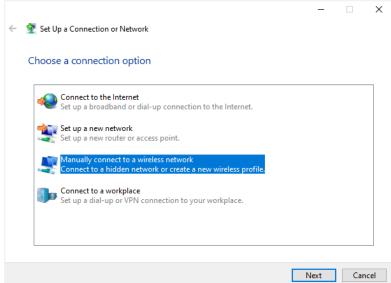
- Advanced Wi-Fi set up should be done only by a trained technician.
- 1. Press "Ctrl Shift Space" on the keyboard to bring up Debug mode.
- 2. Click the "X" at the top-right of the window to close the Robot software.



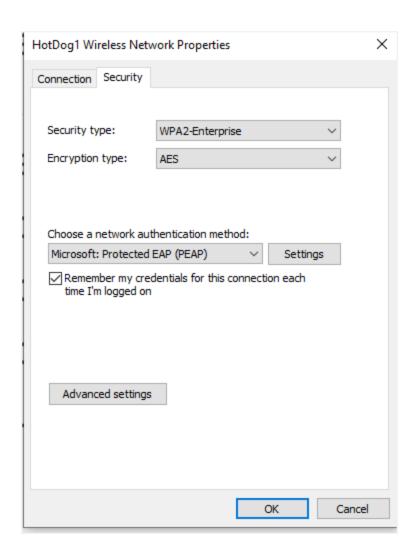












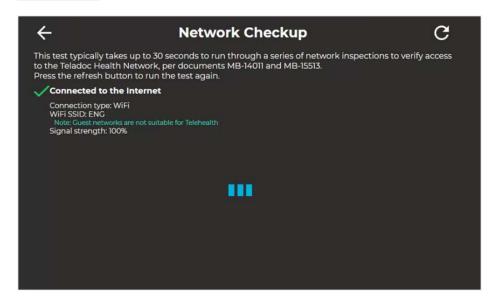


#### **Device Network Checkup**

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.







#### **Device Settings Bluetooth Setup**



Use to connect or disconnect Bluetooth devices to the Mini.





#### **Stethoscope Setup**

The Stethoscope Setup settings screen allows the user to select the optional third-party stethoscope during a virtual encounter.

See "PCP-USB Stethoscope" on page 1 for more details.



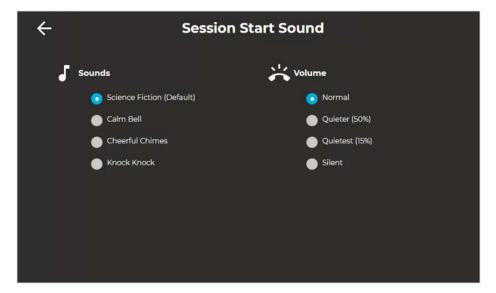




#### **Device Session Start Sound**

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



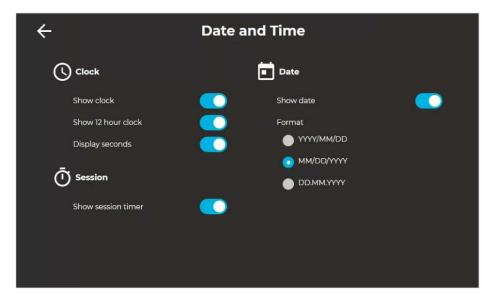




#### **Date and Time Settings Screen**

The Date and Time settings screen allows the user to change how and if time is displayed on the device.





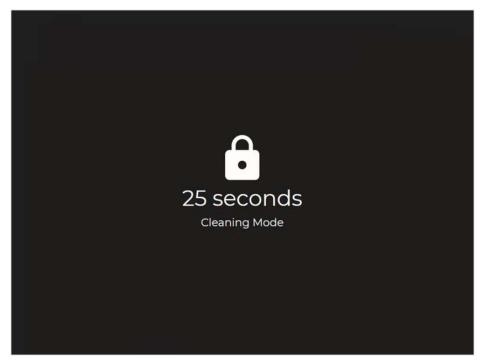


#### **Device Cleaning Mode**

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

• See "Cleaning and Maintenance" on page 38 for more details.

Tap Settings Cleaning Mode , to disable the screen for 30-seconds to allow cleaning.

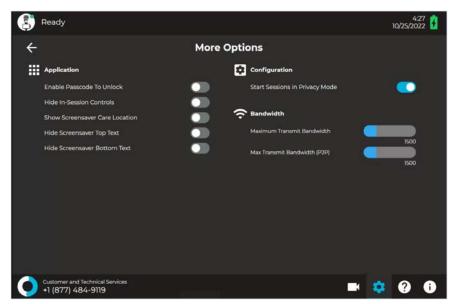




#### **Device Settings - More Options**

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





Application		
Hide In-Session Controls	Hides the In-Session controls on the bottom of the screen.	
	• While in-session, use the icon to un-hide the In-Session Controls.	
	See <u>"Active Session Screen Navigation" on the next page</u> for more details.	
Show Screensaver Care Location	Shows the device's location in the upper-left corner of the screensaver screen.	
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.	
Disable User Input	Disables all user input on the Mini. User can still access settings to reenable user input.	
Hide Screensaver Top Text	When toggled on, the text, Please keep this device on at all times is not displayed on the screensaver.	
Hide Screensaver Bottom Text	When toggled on, the text, Touch to interact is not displayed on the screensaver.	
Configuration		



Start Sessions in Privacy Mode	When enabled, when a session starts, the device's camera will be disabled until the physician is told to activate the camera.  • See "Privacy Mode" on page 1 for more details.	
Bandwidth		
Maximum Transmit Bandwidth	Displays the current maximum transmit bandwidth setting	
Max Transmit Bandwidth (P2P)	Displays the current maximum transmit bandwidth (P2P) setting	

# **Active Session Screen Navigation**

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

<b>(</b> ) <b>∢</b> × <b>(</b> )	PIP End V
Icon	Function
	Volume control: Move slider to adjust device's volume.
<b>→</b> ×	Mute the local volume by dragging the slider to the left or pressing the left-most speaker icon.
<b>Q</b>	Mutes the device's microphone; tap again to unmute.
	Turns off the video.
PIP	Toggles the Picture-in-Picture.
End	Ends 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 corner of the display on the Diagnostic Information screen. A lightning bolt indicates the battery is charging.
~	Toggles the tool bar between show and hide.



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

The video can be paused by either the remote specialist or on the patient-side device.

#### **Practitioner Mute Icons**



#### **Device Mute Icons**





### **Cleaning and Maintenance**

### **Device Cleaning**

#### **Approved Cleaners**

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

- PDI Bleach Wipes
- OxyCide
- Ethyl Alcohol
- Isopropyl 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 Mini.

N'essayez pas d'ouvrir ou de retirer des pièces du TV Pro 300.

• Do not remove any covers to reduce the risk of electric shock. There are no user-serviceable components inside.

ne retirez aucun couvercle pour réduire le risque de choc électrique. Il n'y a aucun composant réparable par l'utilisateur à l'intérieur.

• Wear safety glasses when handling solution prior to dilution.

Porter des lunettes de sécurité lors de la manipulation de la solution avant la dilution.

• Wear rubber or nitrile gloves if in contact with liquid.

Porter des gants en caoutchouc ou en nitrile en cas de contact avec un liquide.

• Avoid contact with eyes, skin and clothing.

Evitez le contact avec les yeux, la peau et les vêtements.

Wash hands after cleaning device.

Se laver les mains après avoir nettoyé l'appareil.



- Do not wear product-contaminated clothing for prolonged periods.
   Ne pas porter de vêtements contaminés par le produit pendant des périodes prolongées.
- Always follow manufacturer's instructions on product labels when mixing chemicals.
   Suivez toujours les instructions du fabricant sur les étiquettes des produits lorsque vous mélangez des produits chimiques.
- Ensure a power cord is connected to the AC wall outlet with protective earthing connection.

A Cordon d'alimentation connecté à une prise de courant avec mise à la terre.



#### **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 may require some disassembly, and this should only be done by a 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.

NOTE: Refer to the TV manufacturer for details about cleaning the TV attached to the Mini.

#### **Pre-cleaning**

- 1. Contact Teladoc Health Technical Support (TAC) at TAC@teladochealth.com or +1 (877) 484-9119 before powering down the device so they can pause monitoring the device.
- 2. Wear gloves.
- 3. Power off the Mini.

#### **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 "Device Cleaning Mode" on page 34

- 1. Power down and unplug the device.
- 2. 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.
- 3. Wipe surfaces that have become soiled or contaminated. Avoid applying excess solution, which may enter the device through its openings.
- 4. Allow to air dry.



#### **Post-cleaning**

- 1. Power on the Mini.
- 2. Contact Technical Support (TAC) to let them know cleaning is complete so they can resume monitoring the device.

### **Maintenance and Inspection**

#### **Mini Maintenance**

The Mini 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.

### Mini Recycling and Disposal

#### **Leased Units**

- Teladoc Health leased Mini units must be returned at the conclusion of their lease contract for recycling or reuse.
- Contact Teladoc Health Technical Support at +1 (877) 484-9119 for details on returning the Teladoc Health Mini.

#### **Purchased Units**

- If the equipment was purchased, it is the responsibility of the customer to make sure any electronic waste or equipment is properly disposed of when necessary.
- For more information about where you can drop off your waste for recycling, please contact your local authority.



# **Mini Technical Specifications**

### **Mini Performance Specifications**

Microphone	Directional (hyper-cardioid), 10Hz-40kHz		
Speakers	2X 5W mono		
Camera	High Definition (HD) Camera:10x optical zoom & 1.9 digital zoom (19x effective zoom), 30 fps, 1920 x 1080p resolution, 24-bit color		
PC	MS Surface Pro 7+ i7 8GB RAM, 128 GB SSD, Windows 10 LTSC		
Display	12.3" Diagonal Touchscreen 2736 X 1824 pixels		
Hood	Pan Range: 266 degrees		
Head	Tilt Range: 92 degrees		
USB Ports	2 - USB 3.0 - Cart		
	1 - USB 3.0 - Wall Mounted and Tabletop		
Wireless Network	Wi-Fi 6: 802.11ax compatible		
	Bluetooth 5.0		
Wired Network	1 x Gigabit Ethernet (Wall Mounted and Tabletop only)		
Battery Life	2 Hours in session		
Charging Time	3 Hours from fully discharged to 80% charge		

## **Mini System Input Power Requirements**

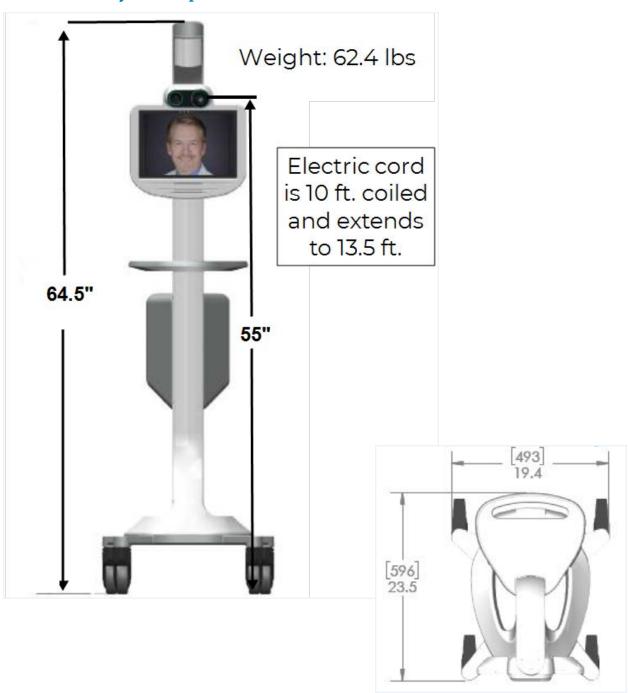
Voltage	100-240 VAC
Frequency	50/60 Hz
Current	1.3 Amps

### **Mini Classification**

Mini - Class I, Type B, Continuous Operation

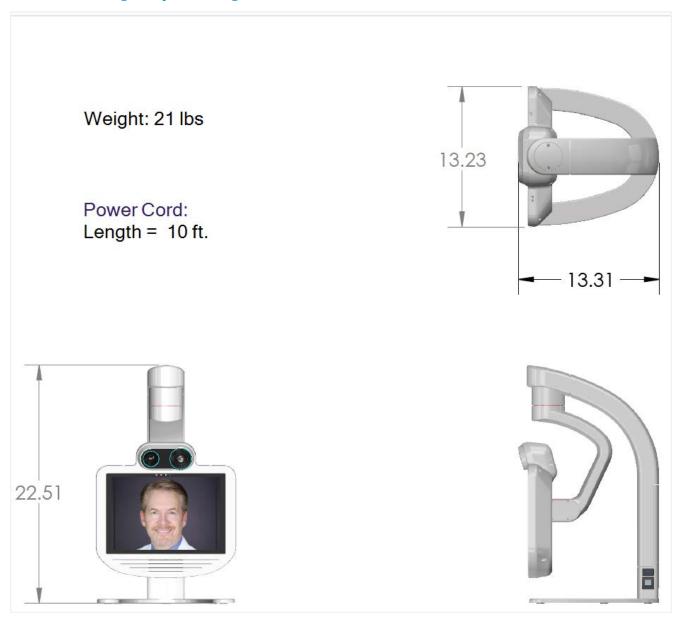


# **Mini Cart Physical Specifications**



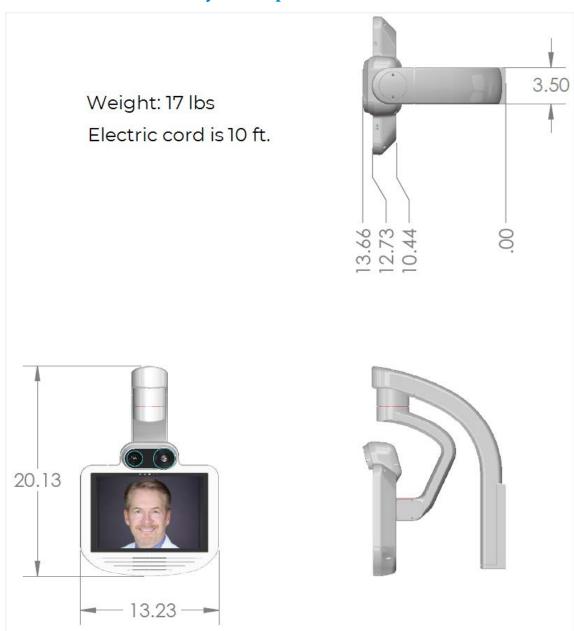


# **Mini Tabletop Physical Specifications**





# **Mini Wall Mounted Physical Specifications**





### **Medical Electrical Equipment Test Standards**

- IEC 60601-1-2:2014 Ed.4 Medical Electrical Equipment Part 1-2: General Requirements for Safety Collateral Standard: Electromagnetic Compatibility Requirements and Tests
- IEC 60601-1-6 Ed: 3.1 Medical Electrical Equipment Part 1-6: General Requirements for Basic Safety and Essential Performance Collateral Standard: Usability
- IEC 60601-1:1988 Ed.2 +A1;A2;C1 Medical Electrical Equipment Part 1: General Requirements For Basic Safety And Essential Performance
- AAMI ES 60601-1:2005+A1 Medical Electrical Equipment Part 1: General Requirements For Basic Safety And Essential Performance
- CSA C22.2#60601-1:2014 Ed.3 Medical Electrical Equipment Part 1: General Requirements For Basic Safety And Essential Performance
- IEC 60601-1:2005 Ed.3 +A1;C1:2014 Medical Electrical Equipment Part 1: General Requirements For Basic Safety & Essential Performance
- IEC 60601-1-2 ed.2.1 (2005) Medical electrical equipment Part 1-2: General requirements for safety Collateral standard: Electromagnetic compatibility Requirements and tests
- IEC 60601-1-6:2010 Ed.3 Medical electrical equipment Part 1-6: General requirements for basic safety and essential performance Collateral standard: Usability
- IEC 60601-1:2005, COR1:2006, COR2:2007, AMD1:2012 Medical electrical equipment Part 1: General requirements for basic safety and essential performance
- IEC 60601-1:2012 (Edition 3.1) Medical electrical equipment Part 1-6 General requirements for safety Collateral Standard: Usability
- IEC 60601-1-2 ed 4.0 (2014-02) Medical electrical equipment Part 1-2: General requirements for basic safety and essential performance Collateral Standard: Electromagnetic disturbances Requirements and tests
- IEC 60601-1-2 Ed. 2.0 Medical electrical equipment Part 1-2: General requirements for safety Collateral standard: Electromagnetic compatibility Requirements and tests
- IEC 62366-1:2015 Ed.1 Medical Devices Part 1: Application Of Usability Engineering To Medical Devices
- AAMI 62366-1: 2015 Medical devices Part 1: Application of usability engineering to medical devices
- CAN/CSA/IEC 62366-1: 2015 Medical devices Part 1: Application of usability engineering to medical devices
- CENELEC EN 62366-1: 2015 Medical devices Part 1: Application of usability engineering to medical devices



- EN 55035:2017 Electromagnetic Compatibility Of Multimedia Equipment Immunity Requirements
- CENELEC EN 55032:2012 Electromagnetic Compatibility of Multimedia Equipment, Emission Requirements
- IEC 60601-1:2005Ed.3+A1 Medical Electrical Equipment Part 1: General Requirements For Basic Safety & Essential Performance

### **Information and Communication Technology Equipment Test Standards**

- IEC 60950-1:2005 (Second Edition) + A1:2009 + A2:2013 Information Technology Equipment Safety Part 1: General requirements
- IEC 62368-1: 2014 Ed.2 +C1 Audio/Video, Information And Communication Technology Equipment Part 1: Safety Requirements
- IEC 62368-1:2018 Ed.3 Audio/Video, Information And Communication Technology Equipment Part 1: Safety Requirements
- AS/NZS 62368.1:2018 Audio/Video, Information and Communication Technology Equipment Safety Requirements (Australia / New Zealand)
- DS/EN 62368-1:2014 Audio/Video, Information and Communication Technology Equipment
   Part 1: Safety Requirements (Denmark)
- EN 62368-1:2014+A11:2017 Audio/Video, Information and Communication Technology Equipment. Safety Requirements (British Standard)
- CEI EN 62368-1:2016 Audio/Video, Information and Communication Technology Equipment Part 1: Safety Requirements (Europe)
- J 62368-1 (H30) Audio/Video, Information and Communication Technology Equipment Safety Requirements (Japan)
- CSA/UL 62368-1:2014 Audio/Video, Information and Communications Technology Equipment Part 1: Safety Requirements (Canada)
- UL 62368-1:2014 Ed.2 Audio/Video, Information And Communication Technology Equipment Part 1: Safety Requirements
- CSA C22.2#62368-1:2014 Ed.2 Audio/Video, Information And Communication Technology Equipment Part 1: Safety Requirements
- IEC 60065:2014 (Eighth Edition) Audio, video and similar electronic apparatus Safety requirements
- EN 61000-3-2:2014 Electromagnetic Compatibility (Emc) -- Part 3-2: Limits Limits For Harmonic Current Emissions (Equipment Input Current <= 16 A Per Phase)



- EN 61000-3-3:2013 Electromagnetic Compatibility (Emc) -Part 3-3: Limits -Limitation Of Voltage Changes, Fluctuations & Flicker In Public Low-Voltage Supply Systems For Equipment With Rated Current <=16 A Per Phase & Not Subject To Conditional Connection
- EN 55032: 2012/AC: 2013 Electromagnetic compatibility of multimedia equipment Emission requirements (CISPR 32:2012 (EQV)) Class A
- EN 55035:2017 Electromagnetic Compatibility Of Multimedia Equipment Immunity Requirements Class A
- ETSI EN 301 489-1 V2.2.3 (2019-11) ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 1: Common technical requirements; Harmonised Standard for ElectroMagnetic Compatibility
- ETSI EN 301 489-17:2017Ed.V3.1.1 Electromagnetic Compatibility (EMC) Standard For Radio Equipment And Services; Part 17: Specific Conditions For Broadband Data Transmission Systems; Harmonised Standard Covering The Essential Requirements Of Article 3.1(B) Of Directive 2014/53/Eu
- IC ICES-003:2016 (Ed. 6) Information Technology Equipment (Including Digital Apparatus) Limits and Methods of Measurement
- ETSI EN 301 489-9 Issued:2002/04/01 EMC and ERM; (EMC) Standard for Radio Equipment and Services; Part 9: Specific Conditions for Wireless Microphones, Similar Radio Frequency (RF) Audio Link Equipment, Cordless Audio and In-Ear Monitoring Devices-V1.3.1
- IEC 60950-1:2005Ed.2+A2012;C2012 Information Technology Equipment Safety Part 1: General Requirements
- AS/NZS CISPR 32:2015 Electromagnetic Compatibility Of Multimedia Equipment Emission Requirements
- CISPR 32:2015 Ed.2.0 Electromagnetic Compatibility Of Multimedia Equipment Emission Requirements



### **Mini Environmental Specifications**

### **Operating:**

Designed to operate in an indoor environment suitable for human personnel. ( $10^{\circ}$  to  $35^{\circ}$  C, 30 to 75% RH, 700 hPa to 1,065 hPa)

### **Non-operating:**

Designed to travel to installations in commercial and cargo airliners and standard ground transportation. (0 $^{\circ}$  to +50 $^{\circ}$  C, 10 to 95% RH, 700 hPa to 1,065 hPa)



# **Electromagnetic Compatibility - Guidance and Manufacturer's Declaration**

The Teladoc Health system complies with IEC 60601-1-2 4th edition, 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 Mini for electromagnetic compatibility (EMC) are provided below:

- Equipment in hospital environments, including the Mini and other portable or mobile communications equipment, can produce Electromagnetic Interference (EMI), which 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 Mini, 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.

#### **WARNINGS:**

• Use of accessories, transducers and cables other than those specified or provided by Teladoc Health could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation."

### **Table 1: Electromagnetic Emissions**

an environment.  Emissions	Compliance	Electromagnetic Environment
Test		
RF Emissions CISPR 11	Group 1	The <b>Mini</b> 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 <b>Mini</b> is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
RF Emissions CISPR 32	Class A	NOTE: The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which
Harmonic Emissions IEC 61000-3-2	Class A	CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.
Voltage Fluctuations / Flicker Emissions IEC 61000-3-3	Complies	WARNING: This equipment is compliant with Class A of CISPR 32. In a residential environment this equipment may cause radio interference.



### **Table 2: Electromagnetic Immunity**

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

CAUTION: An ESD event may cause the system to lose functionality for a short amount of time. If the event does not recover automatically, power cycle the device.

Immunity Test	EC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Electrostatic Discharge (ESD) IEC 61000-4-2	±8 kV Contact ±15 kV Air	±8 kV Contact ±15 kV Air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical Fast Transient / Burst IEC 61000-4-4	±2 kV for Power Supply Lines ±1 kV for Input / Output Lines	±2 kV for Power Supply Lines ±1 kV for Input / 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) ±2 kV Line(s) to Earth	±1 kV Line(s) to Line(s) ±2 kV Line(s) to Earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage Dips, Short Inter- ruptions, and Voltage Vari- ations on Power Supply Input Lines IEC 61000- 4-11	<5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 sec	<5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the <b>Mini</b> be powered from an uninterruptible power supply (UPS) or a battery.
Power Frequency (50/60 Hz) Magnetic Field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

U<sub>T</sub> is the a.c. mains voltage prior to application of the test level.



### **Table 3: Electromagnetic Immunity**

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

Immunity Test	EC 60601 Test Level	<b>Compliance Level</b>	Electromagnetic Environment - Guidance		
Conducted RF IEC 61000-4-6 Radiated FR IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 6V in ISM bands between 150kHz and 80MHz	3 Vrms 150 kHz to 80 MHz  6V in ISM bands between 150kHz and 80MHz	Portable and mobile RF communications equipment should be used no closer to any part of the <b>Mini</b> , including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance:  d= 1.2		
	3 V/m 80		d= 1.2 √P  80 MHz to 800 MHz  800 MHz to 2.5 GHz		
	MHz to 2.5	3 V/m 80 MHz	800 MHz to 2.5 GHz		
	GHz	to 2.5 GHz	d= 2.3 <b>V</b> P		
			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 symbol:		

#### NOTES:

- 1. At 80 MHz and 800 MHz, 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.

#### **CAUTIONS:**

- Momentary video loss may occur in the presence of a 380MHz wireless signal.
- Audible tones may be heard when the device is in close proximity with equipment emitting 24-30MHz electromagnetic radiation. In this case, please move the device to another location, or call technical support for assistance.
- 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 Mini is used exceeds the applicable RF compliance level above, the Mini should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Mini.
- 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 Mini.

The Mini is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Mini can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Mini 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)			
	150 kHz to 80 MHz	80 MHz to 800	800 MHz to 2.5	
	d =1.2 <b>√</b> P	MHz d =1.2 <b>√</b> P	GHz d= 2.3 <b>√</b> P	
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.



## **HIPAA Compliance**

The Teladoc Health Provider Access platform is a main component of Teladoc Health's telehealth system and are developed with HIPAA compliant safeguards for use in healthcare. They are available as a pre-loaded Windows Desktop or Laptop, a Software Install, or as an app for iOS. Connections are supported by the Teladoc Health Telehealth Network; a cloud-based server infrastructure that provides secure connectivity and unprecedented flexibility and scalability.

### **Guidelines for Compliance**

The telehealth system helps hospitals and medical professionals comply with HIPAA regulations. The tabs to the left describe some of the ways the telehealth system supports HIPAA compliance.

HIPAA requires all healthcare organizations to have policies and procedures, and the guidelines to the left. However, these 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 a passerby.

### **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 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.



# **Contact Information**

24/7 Live Technical Support

1-800-484-9119

24/7 Live Remote Technical Support & Live Chat

https://intouchhealth.com/contact-us/

**Email Support** 

ITHSupport@intouchhealth.com

Website

www.InTouchHealth.com

**Teladoc Health User Manuals** 

https://manuals.intouchcustomer.com

Sales & Product Demos

1-805-562-8686



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www.TeladocHealth.com

InTouch Health and InTouch Technologies are now a Teladoc Health company, and InTouch Health is a registered trademark of Teladoc Health.

#### **LEARN MORE**

TeladocHealth.com | engage@teladochealth.com



#### **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.