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Patent(s): http://www.intouchhealth.com/patents

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<tr>
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<th>Author/Contributor</th>
</tr>
</thead>
<tbody>
<tr>
<td>Copyright 2002-2008</td>
<td>Xiph.org Foundation</td>
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<tr>
<td>Copyright 2002-2008</td>
<td>Jean-Marc Valin</td>
</tr>
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<td>Analog Devices Inc.</td>
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<tr>
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<td>Jutta Degener, Carsten Bormann</td>
</tr>
</tbody>
</table>

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Last updated: December, 2019
Safety Instructions

User Profile
Trained healthcare professionals are the intended users of any InTouch Health Patient Access Device. Users of the system require clinical judgment and experience to review and interpret the patient data transmitted.

Notes, Cautions, and Warnings

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

Information in **ORANGE BOLDFACED TYPE** throughout this User Guide should be interpreted in the following context:

- **NOTE:** Provides supplementary information for facilitating operation of the system.
- **CAUTION:** Presents instructions for avoiding damage to the system.
- **WARNING:** Disregarding this information may prove hazardous to the safety of a person near the InTouch Health Patient Access Device.

| **Wireless Transmitter Notification** | ![Wireless Transmitter Notification Icon] |
|____________________________________|------------------------------------------|
| - Non-ionizing electromagnetic radiation. This device communicates over the 802.11 ac/a/b/g/n standard for wireless communication. |

<table>
<thead>
<tr>
<th><strong>Pinch Point</strong></th>
<th>![Pinch Point Icon]</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Avoid the labeled pinch point on the rear of the display of the InTouch Lite 4.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Body Float</strong></th>
<th>![Body Float Icon]</th>
</tr>
</thead>
<tbody>
<tr>
<td>- 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).</td>
<td></td>
</tr>
</tbody>
</table>
Electromagnetic Compatibility - Guidance and Manufacturer's Declaration

The InTouch Lite 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 InTouch Lite for electromagnetic compatibility (EMC) are provided below:

- Equipment in hospital environments, including the InTouch Lite 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 InTouch Lite, contact InTouch 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.
Table 1: Electromagnetic Emissions

<table>
<thead>
<tr>
<th>Emissions Test</th>
<th>Compliance</th>
<th>Electromagnetic Environment</th>
</tr>
</thead>
<tbody>
<tr>
<td>RF Emissions CISPR 11</td>
<td>Group 1</td>
<td>The InTouch Lite 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.</td>
</tr>
<tr>
<td>RF Emissions CISPR 11</td>
<td>Class A</td>
<td>The InTouch Lite 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.</td>
</tr>
<tr>
<td>Harmonic Emissions IEC 61000-3-2</td>
<td>Class A</td>
<td></td>
</tr>
<tr>
<td>Voltage Fluctuations / Flicker Emissions IEC 61000-3-3</td>
<td>Complies</td>
<td></td>
</tr>
</tbody>
</table>
Table 2: Electromagnetic Immunity

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

<table>
<thead>
<tr>
<th>Immunity Test</th>
<th>EC 60601 Test Level</th>
<th>Compliance Level</th>
<th>Electromagnetic Environment - Guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Electrostatic Discharge (ESD) IEC 61000-4-2</td>
<td>±8 kV Contact ±15 kV Air</td>
<td>±8 kV Contact ±15 kV Air</td>
<td>Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.</td>
</tr>
<tr>
<td>Electrical Fast Transient / Burst IEC 61000-4-4</td>
<td>±2 kV for Power Supply Lines ±1 kV for Input / Output Lines</td>
<td>±2 kV for Power Supply Lines ±1 kV for Input / Output Lines</td>
<td>Mains power quality should be that of a typical commercial or hospital environment.</td>
</tr>
<tr>
<td>Surge IEC 61000-4-5</td>
<td>±1 kV Line(s) to Line(s) ±2 kV Line(s) to Earth</td>
<td>±1 kV Line(s) to Line(s) ±2 kV Line(s) to Earth</td>
<td>Mains power quality should be that of a typical commercial or hospital environment.</td>
</tr>
<tr>
<td>Voltage Dips, Short Intermittence, and Voltage Variations on Power Supply Input Lines IEC 61000-4-11</td>
<td>&lt;5% UT (&gt;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 &lt;5% UT (&gt;95% dip in UT) for 5 sec</td>
<td>&lt;5% UT (&gt;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 &lt;5% UT (&gt;95% dip in UT) for 5 sec</td>
<td>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 Patient Access Device be powered from an uninterruptible power supply (UPS) or a battery.</td>
</tr>
<tr>
<td>Immunity Test</td>
<td>EC 60601 Test Level</td>
<td>Compliance Level</td>
<td>Electromagnetic Environment - Guidance</td>
</tr>
<tr>
<td>-------------------------------------------</td>
<td>---------------------</td>
<td>------------------</td>
<td>----------------------------------------</td>
</tr>
<tr>
<td>Power Frequency (50/60 Hz) Magnetic Field</td>
<td>30 A/m</td>
<td>30 A/m</td>
<td>Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.</td>
</tr>
<tr>
<td>IEC 61000-4-8</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

\(U_T\) is the a.c. mains voltage prior to application of the test level.
Table 3: Electromagnetic Immunity

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

<table>
<thead>
<tr>
<th>Immunity Test</th>
<th>EC 60601 Test Level</th>
<th>Compliance Level</th>
<th>Electromagnetic Environment - Guidance</th>
</tr>
</thead>
</table>
| Conducted RF IEC 61000-4-6  | 3 Vrms 150 kHz to 80 MHz | 3 Vrms 150 kHz to 80 MHz | Portable and mobile RF communications equipment should be used no closer to any part of the InTouch Lite, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance:
| Radiated FR IEC 61000-4-3  | 6V in ISM bands between 150kHz and 80MHz | 6V in ISM bands between 150kHz and 80MHz | d = 1.2 \sqrt{P}  
80 MHz to 800 MHz |
|                             | 3 V/ m 80 MHz to 2.5 GHz | 3 V/ m 80 MHz to 2.5 GHz | d = 2.3 \sqrt{P}  
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, should be less than the compliance level in each frequency range.

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.
<table>
<thead>
<tr>
<th>Immunity Test</th>
<th>EC 60601 Test Level</th>
<th>Compliance Level</th>
<th>Electromagnetic Environment - Guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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 InTouch Lite is used exceeds the applicable RF compliance level above, the InTouch Lite should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the InTouch Lite.

b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than \([3] \text{ V/m}\).
Table 4: Recommended separation distances

**Recommended separation distances between portable and mobile RF communications equipment and the InTouch Lite.**

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

<table>
<thead>
<tr>
<th>Rated Maximum Output Power of Transmitter (W)</th>
<th>Separation distance according to frequency of transmitter (m)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>150 kHz to 80 MHz</td>
</tr>
<tr>
<td>0.01</td>
<td>1.2 $\sqrt{P}$</td>
</tr>
<tr>
<td>0.1</td>
<td>0.38</td>
</tr>
<tr>
<td>1</td>
<td>1.2</td>
</tr>
<tr>
<td>10</td>
<td>3.8</td>
</tr>
<tr>
<td>100</td>
<td>12</td>
</tr>
</tbody>
</table>

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.
Virtual Care System Overview

Health systems now 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, quality, and care to their patients.

Enabling healthcare’s only integrated virtual care platform, InTouch Health powers virtual visits within your clinics, healthcare facilities, or even your patients’ home for an integrated experience across a multitude of use cases, environments, and budgets.

Built on our cloud-based network, Solo™ by InTouch, our next generation software platform, is the backbone to delivering care anywhere, anytime. Solo by InTouch provides users with everything they need to streamline their telehealth needs for fast user adoption and program growth.
With Solo by InTouch as your virtual care foundation, connect people, healthcare systems, HIT systems, devices, and third-party software applications to enable telehealth solutions across the patient care journey. Whether launching a scheduled visit from your EMR, providing care for patients at home or in a clinic, Solo by InTouch provides a core set of tools to easily deliver virtual care and provide users with an immersive, patient-centric view of their clinical workflows.

**Purpose-built for healthcare. Designed with the security and reliability you need**

Our cloud-based, patented network ensures the industry’s highest connection success rate and meets industry-defined requirements 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 any clinical setting. Within a single platform, users are in control of their virtual experience with a configurable dashboard to meet the unique set of preferences for every user. Layer Solo by InTouch into your existing HIT system investments or use it as the foundation to close your workflow gaps with our software modules, creating a solution unique to you.

24/7 Technical Support (877) 484-9119
InTouch Lite 4 and Its Intended Application

The InTouch Lite 4 is a clinical communications tool that provides a means of transmitting, receiving, and storing real-time audio, video and patient data. InTouch Lite 4 may also be used in conjunction with 510(k)-cleared devices that transmit patient biometric data including vital signs information. The InTouch Lite 4 transmits and receives information over a high-speed connection between patients and health professionals. The InTouch Lite 4 can be used for communications in both low and high acuity clinical environments, e.g. pre-, peri-operative and post-surgical, cardiovascular, neurological, prenatal, psychological and critical care assessments and examinations. Clinical judgment and experience are required to review and interpret the information transmitted.

InTouch Lite 4 Indications for Use

The InTouch Lite 4 is used in telecommunications for a variety of clinical applications. These applications include, but are not limited to: cardiovascular, neurological, behavioral health, neonatal, etc., use cases. The InTouch Lite 4 does not diagnose health care conditions but instead provides the means for the remote physician to administer his or her assessments and examinations. The InTouch Lite 4 is intended for use in both low and high acuity use cases.
# InTouch Lite 4 Anatomy and Components

<table>
<thead>
<tr>
<th></th>
<th>Description</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Directional Microphone</td>
<td>Used to pick up audio in a narrow zone.</td>
</tr>
<tr>
<td>2</td>
<td>Dual High-Definition Cameras</td>
<td>Captures remote video for viewing on the Provider Access Software.</td>
</tr>
<tr>
<td>3</td>
<td>InTouch Thermal Camera (Optional)</td>
<td>The InTouch Thermal Camera™ is intended for adjunctive use in audio and video telemedicine consultations.</td>
</tr>
<tr>
<td>4</td>
<td>Touch Sensitive Display</td>
<td>Enables local controls and shows Provider Access Software user’s face.</td>
</tr>
<tr>
<td>5</td>
<td>Battery Charging Status</td>
<td>Displays the power and charging status of the InTouch Lite 4.</td>
</tr>
<tr>
<td>6</td>
<td>Expansion Panel</td>
<td>Includes ports for approved USB peripheral devices, HDMI output, optional HDMI input, and Ethernet.</td>
</tr>
<tr>
<td>7</td>
<td>Tray</td>
<td>Work surface for a laptop or other items.</td>
</tr>
<tr>
<td>8</td>
<td>Handle</td>
<td>Easily maneuver the InTouch Lite 4.</td>
</tr>
</tbody>
</table>

---

24/7 Technical Support (877) 484-9119
<p>| | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>9</td>
<td>Power Cord</td>
<td>Used to power the InTouch Lite 4 and recharge the battery.</td>
</tr>
<tr>
<td>10</td>
<td>Storage Compartment</td>
<td>Holds miscellaneous items.</td>
</tr>
<tr>
<td>11</td>
<td>Wheel Locks</td>
<td>Locks each wheel in place when stationary (four wheels).</td>
</tr>
<tr>
<td>12</td>
<td>Air Vents</td>
<td>Air vents help maintain a safe operating temperature for the device.  (Do not cover)</td>
</tr>
<tr>
<td>13</td>
<td>Back of Touch Display</td>
<td>Power button and additional USB ports.</td>
</tr>
<tr>
<td>14</td>
<td>Device Nameplate</td>
<td>Nameplate detailing the device's serial number and regulatory information.</td>
</tr>
<tr>
<td>15</td>
<td>Power Button</td>
<td>Used to toggle the power for the InTouch Lite 4.</td>
</tr>
<tr>
<td>16</td>
<td>Privacy Handset</td>
<td>Used for conversations requiring privacy or intelligibility in loud environments.</td>
</tr>
<tr>
<td>17</td>
<td>Serial Number Plate</td>
<td>Contains the device's serial number and support contact phone number.</td>
</tr>
<tr>
<td>18</td>
<td>Neck</td>
<td>Can be raised from 54” to a height of 75” by way of lifting or lowering the display.</td>
</tr>
<tr>
<td>19</td>
<td>Speakers</td>
<td>Used during sessions to hear the person connected to the device.</td>
</tr>
</tbody>
</table>
InTouch Lite 4 Features

Adjusting the Head Height on an InTouch Lite 4

The InTouch Lite 4 head can be placed between 54" and 75" off the floor by raising or lowering the head up or down to the desired height.
Moving the InTouch Lite 4

The InTouch Lite 4 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 standard grounded AC outlet supplying a minimum of 100-240 VAC, 50/60 Hz, 6.5A (US and International) for the InTouch Lite 4.

- Ensure the Lite is set at its lowest position.
- Ensure any auxiliary devices attached to the Lite are unplugged.
- Ensure the power cord is unplugged and hung on the Lite 4’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.
InTouch Lite 4 Main Power - Recharging the InTouch Lite

The battery charge indicator is located on the InTouch Lite 4 on the side of the storage compartment.

Another battery charge indicator is located in the upper right hand corner of the display and includes the percentage of the battery's charge.

- Fully charged = 100%
- A lighting bolt indicates the battery is charging

If the InTouch Lite 4 is not plugged in, the power is provided from the battery. The Battery charge lights will be lit indicating the remaining percentage of battery life whenever the InTouch Lite 4 is plugged in or turned on.

If the battery charge drops below the alarm threshold, the sound-byte “Please plug me in” will be played at intervals until the InTouch Lite 4 is plugged into AC power. Plug in the device as soon as possible.
Keep the InTouch Lite 4 plugged in and left powered on at all times. Plug the Lite into a grounded “Hospital Grade” electrical outlet to minimize the risk of electrical shock during the battery charging cycle.

- The system will charge to 85% in four hours.
- The system will charge to 100% in six hours.

**WARNINGS:**

- If the power plug of the Lite is damaged, the InTouch Lite 4 can be operated using the on-board battery system. Report this condition to Technical Service immediately for repair.
- The InTouch Lite 4 contains a sealed, rechargeable, lead-acid, gel-type battery. The InTouch Lite 4 should always be plugged in to avoid deep discharge cycles that can shorten the battery’s useful life. Other than keeping the battery charged by keeping the InTouch Lite 4 plugged in, no user maintenance of the battery is required.
InTouch Lite 4 Head Display

The InTouch Lite 4 is equipped with a touch-screen. This allows the user to access the many features available on the InTouch Lite 4. For example:

- Check device status
- Manage settings
- Access the User Guide
- Consult Request – A Service feature to summon a remote provider (optional)
- Personalizing the patient side user experience
- Natural consult with the articulating head display

InTouch Lite 4 Idle Features (Out of Session)

When the InTouch Lite 4 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 InTouch Health representative or Technical Support.

Tap anywhere on the InTouch Lite 4's screen to access the available idle features.
<table>
<thead>
<tr>
<th>Icon</th>
<th>Function</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image" alt="Icon" /></td>
<td>Exits and returns InTouch Lite 4 to idle mode.</td>
</tr>
<tr>
<td>Icon</td>
<td>Function</td>
</tr>
<tr>
<td>------</td>
<td>----------</td>
</tr>
<tr>
<td><img src="image" alt="Camera Icon" /></td>
<td>Camera Preview mode allows the local user to preview the camera image, and that of any attached video peripheral.</td>
</tr>
<tr>
<td><img src="image" alt="Gear Icon" /></td>
<td>Settings</td>
</tr>
<tr>
<td></td>
<td>- <strong>Wifi Setup</strong> - allows user to establish a WiFi connection on the InTouch Lite 4.</td>
</tr>
<tr>
<td></td>
<td>- <strong>Cleaning Mode</strong> - turns off the touchscreen to allow cleaning.</td>
</tr>
<tr>
<td></td>
<td>- <strong>Date and Time</strong> – allows user to choose date and time display on the device in and out of session.</td>
</tr>
<tr>
<td></td>
<td>- <strong>More Options</strong> - other device display settings.</td>
</tr>
<tr>
<td><img src="image" alt="Question Mark Icon" /></td>
<td>Opens an HTML version of the InTouch Lite 4’s User Guide.</td>
</tr>
<tr>
<td><img src="image" alt="Information Icon" /></td>
<td>Displays Diagnostic Information -- Includes useful technical information such as:</td>
</tr>
<tr>
<td></td>
<td>- Serial number</td>
</tr>
<tr>
<td></td>
<td>- Battery charge</td>
</tr>
<tr>
<td></td>
<td>- Wireless Network (SSID) and signal strength</td>
</tr>
<tr>
<td></td>
<td>- IP addresses</td>
</tr>
<tr>
<td></td>
<td>- InTouch Telehealth Network (SIP) connectivity</td>
</tr>
<tr>
<td></td>
<td>- Device status</td>
</tr>
</tbody>
</table>
InTouch Lite 4 Settings Screens
Tap the screen and then tap the Settings icon

InTouch Lite 4 Wi-Fi Connection Setup

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

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

3. Enter the network security key.

3. Use the Information Icon (i) 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.
- InTouch Lite 4 will automatically connect to known Wi-Fi profiles. For stored WiFi profiles, the password can be changed by selecting it and editing the password.

Connectivity Details

The InTouch Lite 4 can connect to the Internet using cellular broadband through MiFi or other devices capable of creating WiFi hotspots. The cellular service provider and/or signal strength may change from area to area. Customers should contact InTouch Health Technical Service for further information.

- Wireless Network Signal Strength Indicator is located on the Diagnostic Information page
  - If Indicator states Fair user may experience video problems.
  - When Indicator states Weak the Robot may lose the connection—it is best to return to a stronger signal area immediately.

Device Cleaning Mode

The InTouch Lite 4 has a screen-cleaning mode, so that no functionality is inadvertently called upon when cleaning.

- See "Cleaning Instructions" on page 51 for more details.

Tap Settings > Cleaning Mode to disable the screen for 30-seconds to allow cleaning.
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 Settings - More Options

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

Messages

- Hide Screensaver
- Top Text
- Hide Screensaver
- Bottom Text
Active Session Screen Navigation

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

<table>
<thead>
<tr>
<th>Icon</th>
<th>Function</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image" alt="Volume Control Icon" /></td>
<td><strong>Volume control</strong> - Move slider to adjust device's volume.</td>
</tr>
<tr>
<td><img src="image" alt="Mute Icon" /></td>
<td>Mute the local volume by dragging the slider to the left, or pressing the left-most speaker icon.</td>
</tr>
</tbody>
</table>

24/7 Technical Support (877) 484-9119
<table>
<thead>
<tr>
<th>Icon</th>
<th>Function</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image" alt="Microphone Icon" /></td>
<td>Tap to mute the device's microphone, tap again to un-mute.</td>
</tr>
<tr>
<td><img src="image" alt="Camera Icon" /></td>
<td>Mutes camera on both Provider and Patient sides.</td>
</tr>
<tr>
<td><img src="image" alt="PIP Icon" /></td>
<td>Toggle the Picture-in-Picture.</td>
</tr>
<tr>
<td><img src="image" alt="End Icon" /></td>
<td>Tap to end the current remote session. A confirmation box will display before the remote session is ended.</td>
</tr>
<tr>
<td><img src="image" alt="Battery Icon" /></td>
<td>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.</td>
</tr>
<tr>
<td><img src="image" alt="Tool Bar Icon" /></td>
<td>Toggles the tool bar between show and hide.</td>
</tr>
</tbody>
</table>
Privacy Handset

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.

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

The InTouch Lite 4’s expansion panel includes:

- 1 - HDMI output port
- 1 - HDMI input (optional)
- 2 - USB 3.0 ports
- 1 - Ethernet port

**NOTE:** If you wish to view streaming video from external inputs in 720p HD quality, please ask Technical Support to configure the bandwidth settings on your account.

**WARNINGS:**

- The video images transmitted to and displayed on the Patient Access Device and Provider Access Software 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. Color reproduction in a video system is a complicated combination of lighting, cameras, and display technology. 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 Lite and Provider Access Software.
CAUTIONS:

- Adding third party software or hardware to the Lite may cause it to malfunction or operate erratically. Excluding those devices designed for connection through existing hardware ports, InTouch Health does not support the addition of third party software or hardware to the Lite. Please check with Technical Service PRIOR to installing any other third party devices.

- Do not leave video equipment connected to the Auxiliary Video Input. The equipment or the Patient Access Device may be damaged if the Patient Access Device is moved with equipment connected to the Input.
Lite 4 Power On

1. Locate the rocker battery switch on the front-bottom of the device.
2. Flip the rocker battery switch to the right.
   - Pressing the rocker battery switch to the left will disconnect the batteries, and pressing to the right will connect the batteries.
3. Plug the Patient Access Device into a standard grounded AC outlet and allow the system to charge for at least 6 hours to reach a full charge.
4. Power on the InTouch Lite 4 by pressing the power button located on the back of the head.
Lite 4 Power Off

Follow these steps to power off an InTouch Lite 4:

1. Press power button on back of the head.

2. Confirm the power off with InTouch Patient Access Software by pressing power button a second time.

3. Unplug from wall.

Do Not Turn Off

Turning off disables 24/7 patient care.

Press the power button again to confirm shutdown.
4. Flip the battery switch to the off position (press left side of switch down).
InTouch Thermal Camera Overview (Optional)

InTouch Thermal Camera Indications for Use

The InTouch Thermal Camera is only for use in addition to other medical devices (i.e. Thermometer, Ultrasound, Mammography). It does not provide any absolute measurement of temperature and should not be used for sole screening or diagnosis for any disease or condition.

InTouch Thermal Camera Statement of Intended Use

The InTouch Thermal Camera is intended to view, measure and record heat patterns and variations. It is intended for use as adjunctive diagnostic imaging for thermally significant indications stemming from heat emitted from the human body. The significance of these thermal patterns and variations is determined by professional investigation. This device is intended for use by qualified technical personnel trained in its use. Clinical judgment and experience are required to review and interpret the information transmitted.

WARNING: The InTouch Thermal Camera should not be used as the sole device to diagnose or screen for breast cancer or any other condition. The InTouch Thermal Camera should not be used in place of mammography and is only for use in addition to other diagnostic or screening devices. Incorrect use of the InTouch Thermal Camera carries the risks of a delayed or missed diagnosis, or unnecessary additional tests.

Intended Environment

Environments anticipated are Hospitals, Ambulatory Care Clinics, Skilled Nursing Facilities, and other professional healthcare facilities.

NOTES:

- The InTouch Thermal Camera must be connected to the InTouch device before starting a session.
- Do not hold the InTouch Thermal Camera in your hands while using, as the heat from your hand may affect the thermal images provided by the InTouch Thermal Camera.
- Any thermal measurement provided by the InTouch Thermal Camera is not intended as an absolute measurement of temperature and is intended to be used in conjunction with other temperature measuring devices.
The InTouch Thermal Camera is not intended for use in Home Healthcare or Special Environments, as defined in IEC 60601-1-2:2014.

- The emissions characteristics of this equipment make it suitable for use in hospitals (CISPR 11 Class A). If it is used in a residential environment (for which 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 reorienting the equipment.

Using the InTouch Thermal Camera View

Locally - Using Camera Preview

1. Tap the image preview icon.
2. Select Thermal Camera from the list of available devices.
3. Tap the image preview icon to end the preview session.
Check Thermal Differences

Use this feature to gather additional information on temperature asymmetries and hotspots. To see the thermal difference between the two spots represented in degrees Celsius.

1. Click and hold on one part of the patient image,
2. Drag the mouse to other parts of the image.
   - The thermal difference displays in Celsius.
   - In the below example, point B is 3.1° Celsius greater than point A.

Thermal Map Palettes

Each Thermal Map Palette offers a different range of colors to represent variations in thermal differences.
Cleaning the InTouch Thermal Camera Lens

As excessive cleaning of the lenses may damage the anti-reflective coating, do not clean the lenses frequently. In most cases blowing dust off is sufficient. Finger prints should be removed as soon as possible.

**CAUTION:** DO NOT clean with ammonia-based solutions. This will degrade the special coating on the lens.

To clean:

1. Remove dirt from the lens surface by blowing with clean air before using a soft cotton or wool cloth to wipe the lens surface.
2. Soak cloth with 96% isopropyl alcohol or commercial lens cleaner containing more than 30% isopropyl alcohol.
3. Twist it to remove excess liquid
4. Clean the lens one time only and discard the cloth.
   - Use new cloth each time.
Thermal Camera Specifications

<table>
<thead>
<tr>
<th>Imaging</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Sensor technology</td>
<td>Uncooled VOx microbolometer</td>
</tr>
<tr>
<td>Array format</td>
<td>320x256</td>
</tr>
<tr>
<td>Effective frame rate</td>
<td>Up to 30Hz depending on available bandwidth</td>
</tr>
<tr>
<td>Thermal Sensitivity</td>
<td>&lt;40 mK (Industrial); &lt;50 mK (Professional); &lt;60 mK (Consumer)</td>
</tr>
<tr>
<td>Field of view</td>
<td>24°</td>
</tr>
<tr>
<td>Accuracy</td>
<td>+/- 1.1 °C (for temperature difference)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Electrical</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Input power</td>
<td>5V</td>
</tr>
<tr>
<td>Power dissipation</td>
<td>As low as 500 mW</td>
</tr>
<tr>
<td>Video channels</td>
<td>USB</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Mechanical</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Size</td>
<td>21 x 21 x 11 mm</td>
</tr>
<tr>
<td>Weight</td>
<td>7.5g</td>
</tr>
</tbody>
</table>
### Environmental

<table>
<thead>
<tr>
<th></th>
<th>Designed to operate in an indoor environment suitable for human personnel. (-40° to 80° C, 30 to 75% RH, 700 hPa to 1,065 hPa)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non-Operating</td>
<td>Designed to travel to installations in commercial and cargo airliners and standard ground transportation. (-50° to 105° C, 10 to 95% RH, 700 hPa to 1,065 hPa)</td>
</tr>
<tr>
<td>Service Life</td>
<td>6 years</td>
</tr>
</tbody>
</table>

#### InTouch Thermal Camera Summary of Accuracy

The InTouch Thermal Camera temperature difference accuracy was calculated and verified to be +/- 1.1 °C at 99% confidence with a measurement bias within +/- 0.1 °C. To determine these values, data was collected over multiple cameras, multiple users, and multiple temperatures ranging from 22-48 °C. Traceable certified reference black body calibrators and thermocouples were employed in order to establish the temperature difference accuracy and bias, and a Gage Repeatability & Reproducibility was run to assess the variation of the measurement system. The root sum of squares method was employed to compute the overall uncertainty of the system at the given confidence interval.

**WARNING**: The InTouch Thermal Camera must be calibrated at least once a year based on usage. Calibration of the InTouch Thermal Camera must be done by InTouch Health.

### InTouch Thermal Camera FDA Clearance

**FDA Clearance - K181716: InTouch Thermal Camera 510(k)**
Patient Access Device - Error Messages

These text messages may appear in the lower right of the Patient Access Device's Display.

<table>
<thead>
<tr>
<th>Message</th>
<th>Explanation</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>“Internet connection failure.”</td>
<td>Very high round-trip latency at Provider Access or Patient Access Device. Possible cause: poor internal network conditions, low Quality of Service Internet connection or excessive bandwidth usage.</td>
<td>These error messages represent non-optimal Internet connection conditions. They may happen periodically on many networks under normal conditions. However, if they persist, contact the hospital’s IT department.</td>
</tr>
<tr>
<td>“Internet connection slow.”</td>
<td></td>
<td></td>
</tr>
<tr>
<td>“Internet failure: Severe loss.”</td>
<td>Packets lost. May see jumpy video with lower frame rates at Provider Access or Patient Access Device. Possible cause: poor internal network conditions, low Quality of Service Internet connection or excessive bandwidth usage.</td>
<td></td>
</tr>
<tr>
<td>“Internet failure: Severe loss remotely.”</td>
<td></td>
<td></td>
</tr>
<tr>
<td>“Internet failure: Audio lost.”</td>
<td>Packets containing audio data lost, therefore user may notice loss of audio at Provider Access or Patient Access Device. Possible cause: poor internal network conditions or low Quality of Service Internet connection or excessive bandwidth usage.</td>
<td></td>
</tr>
<tr>
<td>“Internet failure: Audio lost remotely.”</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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- 49 -
<table>
<thead>
<tr>
<th>“No stethoscope audio. Power cycle it next to the device.”</th>
<th>Physician cannot auscultate because the stethoscope audio is no longer connected to the Provider Access Software.</th>
<th>Restart stethoscope and try again.</th>
</tr>
</thead>
<tbody>
<tr>
<td>“Stethoscope disabled due to critically low battery (10%). Please replace battery for normal operation.”</td>
<td>Battery needs to be charged or replaced by the nurse on the Patient Access side.</td>
<td>Charge or replace battery.</td>
</tr>
<tr>
<td>“Stethoscope battery is critically low (10%). Sound degradation expected. Please replace battery soon.”</td>
<td>Battery is critically low. Consider charging or replacing the battery soon.</td>
<td>Charge or replace battery.</td>
</tr>
</tbody>
</table>
Cleaning and Maintenance

Cleaning Instructions

Clean the outer surfaces of the Device when visibly soiled or after contact with any contamines. 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 30

1. Power off 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.
Approved Disinfectants

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

- 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).

**NOTE:** the following agents are for the exterior, not the lens or screen.

**WARNINGS:**

- Do not attempt to open or remove any parts of the InTouch Lite.
- Do not remove any covers to reduce the risk of electric shock. There are no user-serviceable 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 InTouch 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 InTouch 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.

Maintenance and Inspection

InTouch Lite 4 Maintenance

The InTouch Lite 4 contains no user serviceable parts and requires no maintenance. For further information regarding preventive maintenance, maintenance or assistance with troubleshooting, customers should contact InTouch Health Technical Service.
InTouch Lite and Network Installation

Unpacking and Charging the Patient Access Device

1. Carefully remove the Patient Access Device from its packaging, taking care not to cause damage.
2. Flip the battery switch to the right.
   - Pressing the button to the left will disconnect the batteries, and pressing to the right will connect the batteries.
3. Plug the Patient Access Device into a standard grounded AC outlet and allow the system to charge for at least 6 hours to reach a full charge.
4. Power on the InTouch Lite 4 by pressing the power button located on the back of the head.

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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 InTouch Devices
- MB-14011 - InTouch Telehealth Network Specifications

Contact your InTouch Health representative for copies of these documents.

The InTouch Telehealth 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. The optimal configuration is determined during installation.

Configuring the InTouch Patient Access Device Wireless Connection
The InTouch Lite Control Core uses a Windows computing environment and a wireless network card.

For the InTouch Lite 4, 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 network. The ADU provides multiple features to configure the InTouch Lite 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

Remote Location

Internet

Provider Access (located outside Facility Network)

Hub/Router

SDSL
Cable Modem
T1

(located outside Facility Network)

Provider Access (located outside Facility Network)

Hub/Router

Firewall—VPN

802.11 Wireless Network

Facility Coverage Area

InTouch Health

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### Performance

<p>| | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Head</strong></td>
<td>Pan range: +/- 170°</td>
<td>Tilt range: +27° / -65° max</td>
</tr>
<tr>
<td><strong>Audio</strong></td>
<td>Microphone: directional (hyper-cardioid), 10Hz-40kHz</td>
<td>16 kHz sampling rate, 16-bit audio</td>
</tr>
<tr>
<td></td>
<td>Speakers: 4X 5W mono</td>
<td></td>
</tr>
<tr>
<td><strong>Video</strong></td>
<td>High Definition (HD) Cameras: 45X equivalent zoom, 30 fps, 1920 x 1080p resolution, 24-bit color</td>
<td>Display: 15” LCD, 1024x768 px, 500 nit, projected-capacitive touch-screen</td>
</tr>
<tr>
<td><strong>Network</strong></td>
<td>802.11 ac/a/b/g/n Bluetooth 4.1 + HS Gigabit Ethernet</td>
<td></td>
</tr>
<tr>
<td><strong>Battery Life</strong></td>
<td>5 hrs (depending on use)</td>
<td></td>
</tr>
<tr>
<td><strong>Charging Time</strong></td>
<td>4 hrs from 100% discharge to 80% charge (6 hrs to 100% charge)</td>
<td></td>
</tr>
</tbody>
</table>
System Input Power Requirements

<table>
<thead>
<tr>
<th></th>
<th>InTouch Lite 4</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>US and International</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Voltage</strong></td>
<td>100-240 VAC</td>
</tr>
<tr>
<td><strong>Frequency</strong></td>
<td>50/60 Hz</td>
</tr>
<tr>
<td><strong>Current</strong></td>
<td>6.5 Amps</td>
</tr>
</tbody>
</table>

Classification

| InTouch Lite 4 | Class I, Type B, Continuous Operation |

General Specifications

InTouch Lite 4
IEC 60601-1:2005Ed.3+A1 Medical Electrical Equipment - Part 1: General Requirements For Basic Safety & Essential Performance
IEC 62366:2007Ed.1+A1 Medical Devices - Application Of Usability Engineering To Medical Devices
IEC 62304:2006 Ed.1 +A1 Medical Device Software - Software Life Cycle Processes
AAMI ES60601-1:2005+A1 Medical Electrical Equipment
CSA C22.2#60601-1:2014Ed.3 Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance

EMC Classifications

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


InTouch Lite 4

**Environmental Specification for InTouch Lite 4**

Operating:
Designed to operate in an indoor environment suitable for human personnel. (10° to 38° 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° to +50° C, 10 to 95% RH, 700 hPa to 1,065 hPa)

24/7 Technical Support (877) 484-9119
Contact Information

24/7 Live Technical Support
(877) 484-9119

24/7 Live Remote Technical Support & Live Chat
https://intouchhealth.com/contact-us/

E-mail Support
ITHSupport@intouchhealth.com

Website
www.InTouchHealth.com

InTouch Health User Manuals
https://intouchhealth.com/manuals/

Sales & Product Demos
(805) 562-8686

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