iPad
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TM
C3 WAVE
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GTIN: 00884908114607

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*Note: For use with software 1.0.*

## 1. SYMBOL TABLE

| | |
|---|---|
| | On / Off |
| | Read Accompanying Documents for important safety-related information |
| | Rated type CF patient protection |
| | Date of Manufacture |
| SN | Device serial Number |

## 2. IMPORTANT NOTICES

| | |
|---|---|
| | Before using C3 Wave, the user must thoroughly understand the contents of this manual, in addition to the iPad manual, including all warnings, cautions, contraindications, and intended use. |
| **Warning** | This device is only intended for use by qualified and trained medical professionals. Before using this device, the user must be qualified for placement of Peripherally Inserted Central Catheters [PICC] and trained in the proper use of this device. |
| **Caution** | Before starting a new procedure, verify the C3 Wave application does not require updating. Do this by launching the App Store and selecting the Updates tab. If a C3 Wave update is required, the user must fully understand the updates prior to starting a new procedure. The What's New section details the revisions to the application. After reviewing the updates, select Update, and wait for the new application to load. |

## 3. INTRODUCTION

C3 Wave is designed to provide a continuous display of electrocardiograph [ECG] waveform to be used as a guide in placement of peripherally-inserted central catheters [PICC] in peripheral veins leading to the heart of the patient. The principle for operation of this system uses three ECG leads placed on the patient's chest and generates a third ECG lead by switching from RA to PICC stylet. The ECG waveform is wirelessly transmitted to a tablet which allows the operator to view and record changes to the ECG waveform as the tip of the catheter approaches the heart. As the PICC catheter approaches the atrium of the heart, the P wave in the ECG waveform shows substantial changes. This system is designed to aid the visualization of changes in P wave amplitude.

The C3 Wave system must only be operated by a skilled nurse, physician, or trained medical professional who has been qualified in placement of PICC's and trained in the proper use of this device.

| | |
|---|---|
| **Warning** | Never use C3 Wave if dropped or visibly damaged. Remove damaged device from service and return to Medcomp for service. |
| **Warning** | Do not immerse C3 Wave in water or other fluids. Serious damage may occur, possibly resulting in injury to the user or patient. |

## 4. INDICATION FOR USE/INTENDED USE

### 4.1 Indications for Use

C3 WAVE is indicated for use as a supplemental aid in positioning for Peripherally Inserted Central Catheters (PICC) in adult patients. It provides real-time catheter tip location information by using the patient's cardiac electrical activity. Confirmation of tip placement should be verified according to clinical judgment and established hospital protocol, (e.g., Chest X-ray, Flouroscopy).

Note: Limiting, but not contraindicated, situations for this technique are patients where cardiac rhythms may change presentation of the P-wave:

-Atrial fibrillation

-Atrial flutter

-Severe tachycardia
-Pacemaker-driven rhythm
-Chronic obstructive pulmonary disease (COPD)

Such patients are easily identified prior to PICC insertion. Use of an additional confirmation method is necessary to confirm catheter tip location.

**4.2 Intended Use**

C3 WAVE is intended to provide real time tip location information of a central venous catheter by utilization of ECG to observe P-wave changes as the tip approaches the right atrium of the heart via the superior vena cava.

| | |
|---|---|
| **Warning** | C3 WAVE works with the normal sinus rhythm of the heart. Do not rely on ECG signal detection for catheter tip positioning when interpretation of the external or intravascular ECG P-wave is difficult. For example, when:<br>-P-Wave is not present<br>-P-Wave is not identifiable<br>-P-Wave is intermittent |
| **Warning** | This device is not intended for use as a diagnostic ECG device as the system is designed to aid the visualization of changes in P wave amplitude. |
| **Warning** | Do NOT use this device in the presence of flammable anesthetics, oxygen-enriched atmospheres, or explosive gases. |
| **Warning** | This device has not been tested for use near electrosurgical devices. It is not recommended for use in operating rooms. |

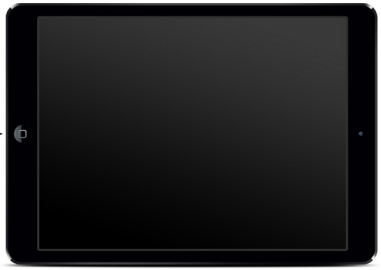
## 5. FEATURES and CONTROLS

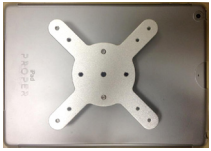
The C3 Wave system is composed of an iPad, Hub, Power Supply, Charging Base, Remote, a disposable ECG Clip Cable and ECG Snap Lead Set.

**5.1 iPad**

The iPad receives the patient information wirelessly transmitted from the Hub. The interactive application displays the information guiding the user during PICC placement. The application also allows the user to save information pertaining to the procedure to the patient's file. The iPad can be operated in a non-sterile environment using the touch screen or during a sterile procedure by placing the remote inside the sterile bag.

*Note: It is recommended that the iPad be mounted with the included VESA mount to prevent drops or other damage.*

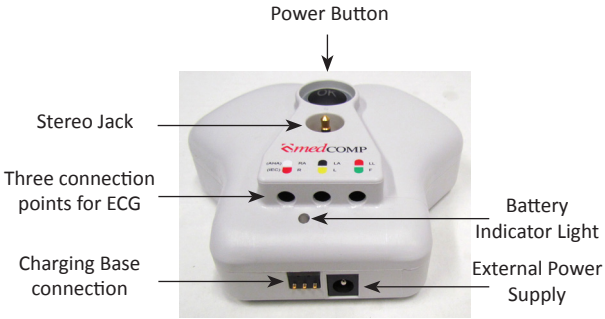


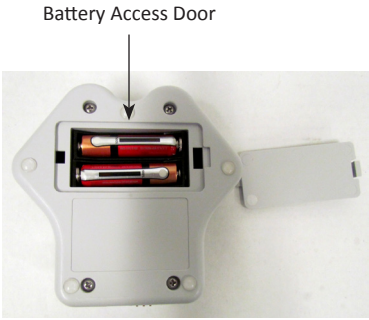




| | |
|---|---|
| Multi-Touch Display | Color graphic display with capacitive touch screen. |
| Sleep/Wake Button | Pressing once will put the iPad in Sleep or Wake mode. Pressing and holding for a few seconds will turn the iPad On or Off. |
| VESA Mount | Four mounting points in VESA standard 75mm square pattern. |

**5.2. Hub**

The Hub allows the user to set up a standard three-lead ECG connection to the patient prior to the start of the PICC location procedure. During the PICC location procedure two leads [Red and Black] from this Hub are used together with the ECG clip [White] lead on the stylet wire to create the guidance ECG wave form. The Hub is non-sterile and requires the use of the provided drape to create the sterile field.



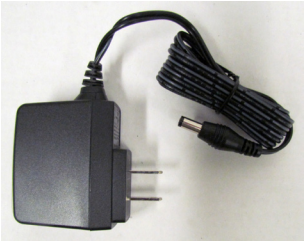

| | |
|---|---|
| Power Button | Press and hold for two seconds to turn Hub ON. Power Button will flash blue while connecting with iPad. Once connected the Power Button will illuminate solid blue. Press and hold for five seconds to turn Hub OFF. Power Button will not illuminate when Hub is OFF. Pressing and holding for ten seconds will break the wireless connection with the Hub. |
| Stereo Jack | Connection point for ECG Clip cable. |

| | |
|---|---|
| Battery Indicator LED | Battery test: Press and release the Power Button to illuminate Hub battery indicator LED. Red flash indicates charging is required. Yellow flash indicates partially discharged. Green flash indicates fully charged. |
| | Charging: When hub is charging the Battery Indicator LED will continuously flash. Red flash indicates charging is required. Yellow flash indicates partially discharged. Green flash indicates fully charged. |
| DIN connections | Connection points for ECG snap leads. |
| Battery Door | Battery access door. Removing the screw allows the user to change battery. |

### 5.3. Hub Power Sources

#### 5.3.1 Power Supply

The medical grade power supply [5VDC, 10W] is used to charge or operate the hub during use if the battery is low or discharged.

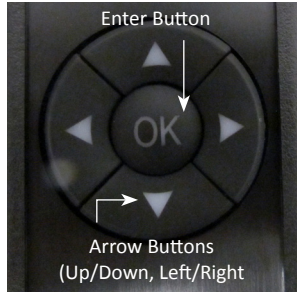


### 5.3.2 Charging Base

When not in use the Hub can be charged while resting in the Charging Base. Plug the medical grade power supply [5VDC, 10W] into the Charging Base and verify the Hub Battery Indicator LED is flashing.

### 5.4. Remote

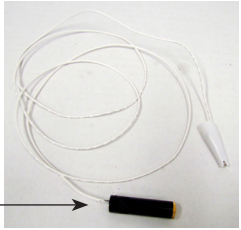
The Remote provides a wireless connection between user and iPad. The remote is non-sterile and requires the use of the provided bag to create the sterile field.



| | |
|---|---|
| **Up/Down/Left/ Right Buttons** | Allows the user to wirelessly highlight icons on the iPad. |
| **Enter Button** | Allows the user to wirelessly make selections on the iPad. |
| **Front Cover** | Removing the four screws from the front cover allows the user to change battery. |

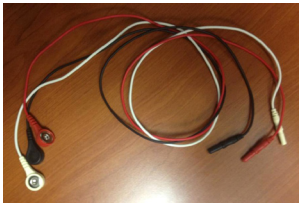
### 5.5. ECG Clip Cable

The ECG Clip Cable is part of the sterile disposable kit. It transmits the patients ECG waves by connecting the PICC stylet to the Hub. Connections are made using the alligator clip and stereo jack.




### 5.6. ECG Snap Lead Set

The red, white and black ECG snap leads plug into the DIN ports on the hub. The snaps fit standard disposable ECG pads. The ECG Snap Lead Set is non-sterile and requires the use of the provided drape to create the sterile field.




| | |
|---|---|
| **Warning** | Do not immerse the external power supply in water or other fluids, as this may create a dangerous shock hazard to the patient and user. |
| **Warning** | Use only the medical grade external power supply provided with the device. Use of unapproved power supply may compromise patient safety or damage the unit. |
| **Warning** | Never use a visibly damaged external Power Supply. Return to Medcomp for Service. |
| **Warning** | If the Hub requires the use of the external power supply during a procedure, do not place the Hub on the patient's chest. Position the Hub on a flat surface next to patient. |
| **Warning** | To avoid risk of electric shock, this equipment must only be connected to a supply mains with protective earth. |

| | |
|---|---|
| **Warning** | To disconnect power to the Hub when using the external power supply, remove the external power supply from the supply mains. |
| **Warning** | Use only the IEC approved batteries provided with C3 Wave. Use of unapproved batteries may compromise patient/user safety or damage unit. |
| **Warning** | Use of cables or accessories, other than those packaged with C3 Wave, may negatively affect EMC performance. |

## 6. TECHNICAL SPECIFICATIONS

### 6.1 iPad

See iPad owner's manual for technical specifications.

### 6.2 Hub

| | |
|---|---|
| Dimensions | 4.15" wide x 4.0" high x 1.6"deep |
| Weight | 0.35 lb [0.16 kg] |
| Internal Battery Capacity at 77°F [25°C] | 800mAh |
| Internal Battery Voltage at 77°F [25°C] | 1.2V |
| External Power Supply | Input: 100-240VAC, 50-60Hz, 0.3A<br>Output: 5VDC, 10W |
| Normal Operating Conditions | +32° to +95°F [0° to +35°C]<br>5 to 95% non-condensing relative humidity |
| Storage Conditions | -4° to +113°F [-20° to +45°C]<br>5 to 95% non-condensing relative humidity |
| Hub Rating | Rated type CF patient protection |
| External Power Supply Rating | Class II, medical grade external power supply |

| | |
|---|---|
| Rx Frequency | 2402-2480MHz |

**6.3 Remote**

| | |
|---|---|
| Dimensions | 5.5" long x 2.0" wide x 0.8" thick |
| Weight | 0.18 lb [0.08 kg] |
| Internal Battery Capacity at 77°F [25°C] | 230mAh |
| Internal Battery Voltage at 77°F [25°C] | 3V |
| Normal Operating Conditions | +32° to +95°F [0° to +35°C]<br>5 to 95% non-condensing relative humidity |
| Storage Conditions | -4° to +113°F [-20° to +45°C]<br>5 to 95% non-condensing relative humidity |
| Rx Frequency | 2402-2480MHz |

| | |
|---|---|
| **Caution** | Do not operate cell phones or portable radio transmitters when C3 Wave is in use. These devices may interfere with normal operation of the system. |
| **Caution** | Never use C3 Wave near high intensity magnetic fields, e.g. an MRI scanner. Strong magnetic fields may damage the system. |
| **Caution** | C3 Wave may be interfered with by other equipment even if that equipment complies with CISPR emission requirements. |
| **Caution** | If significant interference [noise] is observed in the ECG waveform, then operate the Hub on battery power [disconnect AC adapter] to isolate the Hub from the disruptive environment. |
| **Caution** | Federal Law in the United States restricts this system to sale by or on the order of a physician. |

## 7. APPLICATION AND IPAD OPERATION

### 7.1. Power On iPad

Turn on iPad using Sleep/Wake button.

### 7.2 LAUNCH APPLICATION

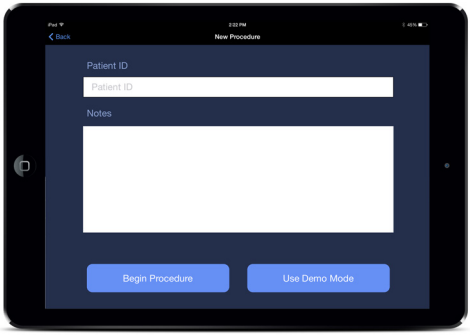
Using the touch screen, tap the C3 wave application to open.

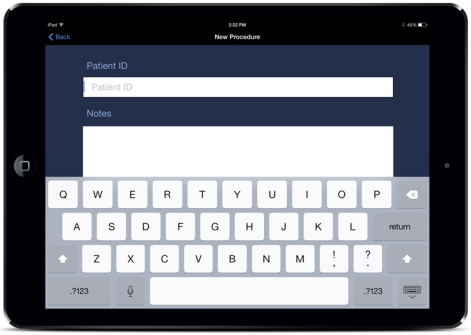
### 7.3 NEW PROCEDURE

Using the touch screen, tap “New Procedure” to begin.

## 7.4 ENTER PATIENT ID/NOTE

Use touch keypad to enter Patient ID. If Notes are required enter them now. When finished, tap Begin Procedure.




## 7.5 POWER ON HUB

Press and hold the Power Button for two seconds. The button will illuminate blue when power is ON.

### 7.5.1 Wirelessly Connect Hub to iPad

The wireless connection is automatic. When the Hub is turned ON the Power Button will initially flash blue. When the Power Button illuminates solid blue the connection to the iPad has been made.

### 7.5.2 Internal Test

The internal test window will pop up after the wireless connection has been made. If the test was successful, tap OK on the touch screen. If service is required, tap Service and return unit to Medcomp.

Power Button

Internal Test
Image Place Holder

**7.6 Connect 3 Patient Snap Leads**

Connect the ECG Snap Leads to the corresponding color of the Hub. Snap the disposable ECG Adhesive Electrodes from the kit to the ECG snap leads.

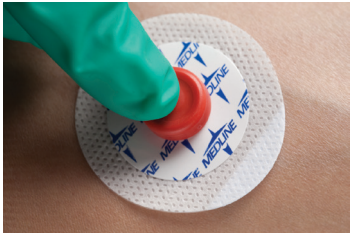
**7.7 Apply the ECG Adhesive Electrodes to Patients Chest**

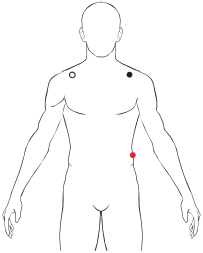
Clean the patient's skin. Remove the ECG Adhesive Electrodes clear backing and apply to patient's skin. Note: Avoid areas with excessive hair.

Follow color codes/lettering on Hub: RA (White) = Right Arm, LA (Black) = Left Arm, LL (Red) = Left Leg.

*Note: For international use the ECG Snap Lead connections are: R (Red) = Right Arm, L (Yellow) = Left Arm, F (Green) = Left Leg.*

*Note: It is recommended that the Medcomp supplied ECG pads be used.*





### 7.8 Verify Surface ECG Signal

Verify patient's ECG waveform is acceptable for use in guiding PICC location.

*Note: Patient and PICC must be still while reading wave forms*

*Note: If lead is incorrectly positioned or not connected the Lead OFF alert will appear.*

### 7.9 Collect a Baseline ECG Snapshot During Surface Mode

Use Remote to highlight Camera icon. Press Enter to select image. If using touch screen tap Camera icon to select image.

**7.9.1**

If image is correct use Remote to highlight Accept icon. Press Enter to save image. If using touch screen tap Accept icon to save image.

**7.9.2**

If image is incorrect use Remote to highlight Refresh icon. Press Enter to generate new image. If using touch screen, tap Refresh icon to generate new image.

**7.9.3**

To quit without saving image, use Remote to highlight Cancel icon and press Enter. If using touch screen tap Cancel icon.

**7.10 Enter Surface Measurement**

When a snapshot is accepted the Surface Measurement screen will pop-up. Use Remote or touch screen to scroll to correct measurement. The current selection will be highlighted in the blue box. Press enter to Accept measurement or tap Accept if using the touch screen.

**7.11 Enter Internal Mode**

Use the Remote to highlight the Surface icon. Press the Enter button to slide the Surface icon to the Internal icon. If using the touch screen tap the Internal icon.

*Note: Verify the ECG trace changes from yellow with yellow scroll bar to a blank trace with a blue scroll bar. The PICC OFF alert will also appear on the screen. A white trace will resume when the ECG Clip Cable is connected.*

**7.12 Prep Sterile Field**

**7.12.1 Remote**

Place Remote in sterile bag. Secure end of bag with supplied rubber bands.

**7.12.2 Hub**

Place Drape over Hub on patient's chest. Ensure Hub is centered in Drape window.

*Note: If Hub requires charging during a procedure, position the Hub next to the patient rather than on their chest.*

**7.13 Connect ECG Clip Cable to Hub**

Connect the stereo jack on the ECG Clip Cable to the stereo jack on the Hub by carefully piercing the sterile drape window.

### 7.14 Connect ECG Clip Cable to PICC

Squeeze alligator clip and place on the metal portion of stylet wire. When alligator clip connection is made a PICC OFF alert will appear. This warning will be cleared in Section 7.15.

*Note: C3 Wave only works with conductive [metal] stylets.*

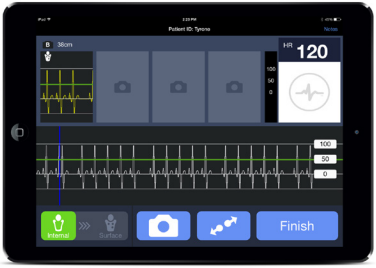
PICC Off Alert
Image Place Holder

### 7.15 Verify PICC ECG Signal

Advance PICC catheter as normal into patient. As the PICC advances past the introducer the ECG connection will be completed. The PICC OFF alert will automatically clear and the patients ECG waves will appear on the iPad.

*Note: Patient and PICC must be still while reading wave forms.*

*Note: Verify the ECG trace is white with blue scroll bar.*



**7.16 Collect ECG Snapshot of Deflection and Maximum P-wave**

Use Remote to highlight Camera icon. Press Enter to select image.

**7.16.1**

If image is incorrect use remote to highlight Refresh icon. Press Enter to generate new image.

**7.16.2**

If image is correct use Remote to highlight Accept icon. Press Enter to save image.

**7.16.3**

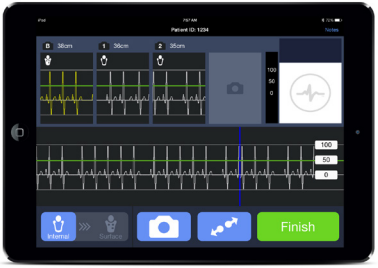
To quit without saving image highlight Cancel icon and press Enter.

### 7.17 Enter Implant Depth

When a Snapshot is accepted the Internal Measurement screen will pop-up. Use Remote to scroll to correct measurement. The current selection will be highlighted in the blue box. Press enter to Accept measurement.

### 7.18 Finish Procedure

When the last Snapshot is saved use the Remote to highlight Finish. Press Enter to make selection. This will launch the Bundle Protocol screen.



**7.19 Bundle Protocol Parameters**

Read the bundle protocol questions to verify all parameters have been met. If you can answer Yes to all questions tap Yes and then tap OK. If you cannot answer Yes to all questions tap No then tap OK. After OK is selected the Patient File Screen will pop up.

*Note: the field will no longer be sterile when using the touch screen.*

## 7.20 Save, Print or Replay Patient Files

### 7.20.1 Save

Use the touch screen to highlight the Patient File you wish to save. On the right hand side of the screen the patient information preview will be displayed. The ECG snapshots will be checked which indicates they will be saved. If one or more snapshots are not required, deselect them by tapping on the snapshot to remove the check mark. To save the file and selected snapshots, tap on the Launch EMR icon.

### 7.20.2 Print

Use the touch screen to highlight the Patient File you wish to print. On the right hand side of the screen the patient information preview will be displayed. The ECG snapshots will be checked which indicates they will be printed. If one or more snapshots are not required, deselect them by tapping on the snapshot to remove the check mark. To print the file and selected snapshots, tap on the Print icon.

| | |
|---|---|
| **Caution** | If using Medcomp specified Air Printer then do not print while in the patients room. |

### 7.20.3 Replay

Use the touch screen to highlight the Patient File you wish to replay. To replay the procedure, tap on the Replay icon. While the procedure is replaying the Pause and Play icon will be displayed in the bottom left hand corner. Tap the Pause icon to temporarily stop the procedure. Tap the Play icon to restart the procedure. To fast forward or rewind drag the time bar which will be displayed across the bottom of the screen.

## 7.21 Power Off

### 7.21.1 iPad

Press and hold the Sleep/Wake button to Power off the iPad. Remove any external sources of power connected to the iPad.

### 7.21.2 Hub

Press and hold the Hubs Power Button. The Power Button will no longer be illuminated when power is OFF. Remove any external sources of power connected to the Hub.

## 7.22 Clean-up

### 7.22.1 Disposables

Follow your facilities procedure for the proper disposal of the ECG pads, ECG Clip Cable, Remote Bag and Drape when the procedure is completed.

### 7.22.2 Reusables

The iPad, Remote, Hub and ECG Leads should be cleaned when the procedure is completed.

# 8. ADDITIONAL APPLICATION CONTROLS

## 8.1 ECG Wave Zoom

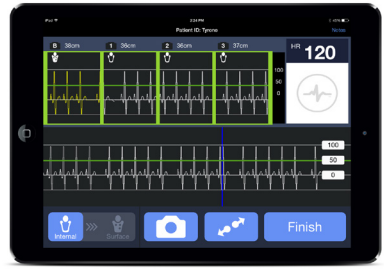
When the patient's ECG wave is difficult to read or when more detail is preferred, use the [zoom] icon to change the size of the ECG trace. Use the Remote to highlight the Zoom icon. Press the Enter button to display the sliding scale. The Up and Down buttons will increase or decrease the size of the ECG trace. When the desired scale has been reached press the Enter button to hide the sliding scale.

If the user has not prepped the sterile field the touch screen can be used. Tap on the Zoom icon to display the sliding scale. Drag the sliding scale up or down to increase or decrease the size of the ECG trace. Tap the Zoom icon a second time to hide the sliding scale.

**8.2 Scroll Through Snapshots**

Four Snapshots can be displayed at any one time. When five or more Snapshots have been selected the user will need to scroll to view them. Using the remotes Up button, highlight the Snapshots. Once highlighted, the left and right buttons allow the user to scroll through the images.

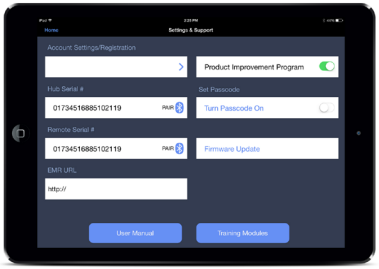
If the user has not prepped the sterile field the touch screen can be used to scroll through the snapshots. Tap the Snapshots. Drag left or right to display the hidden Snapshots.



## 8.3 Delete Patient Files

To delete a Patient file, tap the File Manager icon on the home screen. A list of Patient Files will appear on the left hand side of the screen. Scroll through the list by dragging up or down . Tap the file you wish to delete. The contents of the file will be displayed on the right hand side of the screen. Tap the Delete icon and the Delete Patient File window will appear. Tap Delete to confirm and delete the file. Tap Cancel to return to the File Manager screen.

## 8.4 Settings and Support



**8.4.1 Account Settings/Registration**
**8.4.2 Hub Serial #**
**8.4.3 Remote Serial #**
**8.4.4 EMR URL**
**8.4.5 Product Improvement Program**
**8.4.6 Set Passcode**
**8.4.7 Firmware Update**

## 9. CLEANING

The Hub, Remote, and associated cables [excluding disposables] may be cleaned using a soft cloth or wipe in combination with the following using your institutions guidelines or disinfectant manufacturer's recommendations. Prior to cleaning, disconnect all power sources and turn OFF power. (Reference iPad user manual for cleaning instructions).

Mild detergent and water.
Bleach 10% solution with water.
Isopropyl alcohol 70% solution.
Surface disinfectants compatible with plastic materials.

| | |
|---|---|
| **Caution** | Never use organic solvents [acetone, kerosene, strong acids, or strong bases] to clean the Hub, Remote, or associated cables as damage will result. |
| **Caution** | Never steam sterilize or autoclave the Hub, Remote, or associated cables as damage will result. |

# 10. PARTS and ACCESSORIES

## 10.1. Parts

| Description |
|---|
| Hub |
| Hub Battery, 1.2V, 800mAh, NiMh |
| Remote |
| Remote Battery, 3V, 230mAh, LiMn |
| ECG Accessory Pack [ECG Clip Cable & Bag; 25-box] |
| ECG Snap Leads Set, USA |
| ECG Snap Leads Set, IEC |
| Power Cord, USA |
| Power Cord, UK |
| Power Cord, EU |

## 10.2 Accessories

HP Envy 5530 [Office use only, NOT for patient bedside use.]

# 11. TROUBLESHOOTING GUIDE

## 11.1. Alarms , Alerts & Informational Messages

| Alarm | Priority | Description | Corrective Action |
|---|---|---|---|
| System Failure Alarm<br>[power-on self-test]<br>“Power Supply Failure”<br>“I2C Communication Failure”<br>“Watchdog Failure”<br>“Software Image Failure” | High<br>[Red] | System self-test failure detected at power-on. | Remove monitor from service for repair by qualified biomedical engineer. [Note: button is provided to enter service screen which allows user to recover patient files.] |
| System Failure Alarm<br>[while operating]<br>“Power Supply Failure”<br>“I2C Communication Failure” | High<br>[Red] | System failure detected while running. | Remove monitor from service for repair by qualified biomedical engineer. [Note: button is provided to enter service screen which allows user to recover patient files.] |
| Battery Warning:<br>“Extremely Low Battery” | High<br>[Red] | Internal battery is almost fully depleted. | Plug monitor into AC power and continue use. Alarm may be cleared by pressing enter on remote control or by touching “OK” on the screen. |
| Alert Message:<br>“PICC Off” | Moderate<br>[Yellow] | Patient lead is disconnected. | Check ECG Alligator Clip and connection to Remote Cable. |
| Alert Message:<br>“RA Off”<br>“LL Off”<br>“LA Off”<br>“Leads Off” | Moderate<br>[Yellow] | Patient Lead shows poor electrical connection . | Check connections from patient cable to ECG pads on patient. Consider replacing ECG pad if excessive noise or wander in ECG waveform. |

| | | | |
|---|---|---|---|
| Informational Message: "…confirm entry…" | Low [Grey] | Confirm selected action, such as "Finish Case", or "Delete File" | None. |

*Note: High priority alarms can be reviewed from settings/service screen by pressing the "LOG" button on the settings service screen. This displays the system log file [with date/time stamp] which shows the results of all power-up tests and high priority alarms.*

## 12. STANDARDS, DECLARATIONS AND LICENSING

**12.1**

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

*Note: This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at his own expense.*

**12.2**

This device complies with Industry Canada license-exempt RSS standard(s). Operation is subject to the following two conditions: (1) this device may not cause interference, and (2) this device must accept any interference, including interference that may cause undesired operation of the device.

*Le présent appareil est conforme aux CNR d'Industrie Canada applicables aux appareils radio exempts de licence. L'exploitation est autorisée aux deux conditions suivantes : (1) l'appareil ne doit pas produire de brouillage, et (2) l'utilisateur de l'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement.*

**12.3**

This device is certified by Underwriters Laboratories, Control Number E468297, to comply with General Medical Equipment requirements for Electrical Shock, Fire and Mechanical Hazards only, in accordance with ANSI/AAMI ES60601-1 AMD 1 (2012), CAN/CSA-C22.2 No. 60601-1 (2014).

**12.4**

This device has no essential performance as intended by IEC60601-1 AM1.

Table 1

| **Guidance and Manufacturer's Declaration – Electromagnetic Emissions** | | |
|---|---|---|
| The C3 Wave System is intended for use in the electromagnetic environment specified below.<br>The customer or the user of the C3 Wave System should assure that it is used in such an environment. | | |
| **Emissions Test** | **Compliance** | **Electromagnetic Environment – Guidance** |
| RF Emissions<br>CISPR 11 | Group 1 | The C3 Wave System 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<br>CISPR 11 | Class A | The C3 Wave System 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. |
| Harmonic Emissions<br>IEC 61000-3-2 | Class A | |
| Voltage Fluctuations/<br>Flicker Emissions<br>IEC 61000-3-3 | Complies | |

Table 2

| Guidance and Manufacturer's Declaration – Electromagnetic Immunity | | | |
|---|---|---|---|
| The C3 Wave System is intended for use in the electromagnetic environment specified below. The customer or the user of the C3 Wave System should assure that it is used in such an environment. | | | |
| **IMMUNITY Test** | **IEC 60601 Test Level** | **Compliance Level** | **Electromagnetic Environment – Guidance** |
| Electrostatic discharge (ESD)<br>IEC 61000-4-2 | ± 6 kV contact<br>± 8 kV air | | Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%. |
| Electrical fast transient/ burst<br>IEC 61000-4-4 | ± 2 kV for power supply lines<br>± 1 kV for input/output lines | | Mains power quality should be that of a typical commercial or hospital environment. |
| Surge<br>IEC 61000-4-5 | +1 kV differential mode<br>+2 kV common mode | | Mains power quality should be that of a typical commercial or hospital environment. |
| Voltage dips, short interruptions and voltage variations on power supply input lines<br>IEC 61000-4-11 | <5 % UT<br>(>95 % dip in UT)<br>for 0.5 cycle<br>40 % UT<br>(60 % dip in UT)<br>for 5 cycles<br>70 % UT<br>(30 % dip in UT)<br>for 25 cycles<br><5 % UT<br>(>95 % dip in UT)<br>for 5 sec | | Mains power quality should be that of a typical commercial or hospital environment. If the user of the C3 Wave System requires continued operation during power mains interruptions, it is recommended that the C3 Wave System be powered from an uninterruptible power supply or a battery. |
| Power frequency (50/60 Hz) magnetic field<br>IEC 61000-4-8 | 3 A/m | | Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment. |
| *NOTE: $U_T$ is the a.c. mains voltage prior to application of the test level.* | | | |

Table 4

| Guidance and manufacturer's Declaration – Electromagnetic Immunity | | | |
|---|---|---|---|
| The C3 Wave System is intended for use in the electromagnetic environment specified below. The customer or the user of the C3 Wave System should assure that it is used in such an environment. | | | |
| **IMMUNITY TEST** | **IEC 60601 TEST LEVEL** | **Compliance Level** | **Electromagnetic Environment – Guidance** |
| Conducted RF<br>IEC 61000-4-6 | 3 Vrms<br>150 kHz to 80 MHz | [*3*] V | Portable and mobile RF communications equipment should be used no closer to any part of the C3 Wave System, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.<br><br>**Recommended separation distance**<br>$d = \left[\frac{3.5}{3}\right]\sqrt{P}$ |
| Radiated RF<br>IEC 61000-4-3 | 3 V/m<br>80 MHz to 2.5 GHz | [*3*] V/m | $d = \left[\frac{3.5}{3}\right]\sqrt{P}$ 80 MHz to 800 MHz<br><br>$d = \left[\frac{7}{3}\right]\sqrt{P}$ 800 MHz to 2.5 GHz<br><br>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).<br><br>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b]<br><br>Interference may occur in the vicinity of equipment marked with the following symbol: |

| | |
|---|---|
| *NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.*<br><br>*NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.* | |
| a | Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the C3 Wave System is used exceeds the applicable RF compliance level above, the C3 Wave System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the C3 Wave System. |
| b | Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [3] V/m. |

Table 6

| Recommended separation distance between portable and mobile RF communications equipment and the model ____ | | | |
|---|---|---|---|
| The C3 Wave System is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the C3 Wave System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the C3 Wave System as recommended below, according to the maximum output power of the communications equipment. | | | |
| Rated maximum output power of transmitter<br>W | Separation distance according to frequency of transmitter<br>m | | |
| | 150 kHz to 80 MHz<br>$d = \left[\frac{3.5}{3}\right]\sqrt{P}$ | 80 MHz to 800 MHz<br>$d = \left[\frac{3.5}{3}\right]\sqrt{P}$ | 800 MHz to 2.5 GHz<br>$d = \left[\frac{7}{3}\right]\sqrt{P}$ |
| 0.01 | | | |
| 0.1 | | | |
| 1 | | | |
| 10 | | | |
| 100 | | | |
| 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 rating of the transmitter in watts (W) according to the transmitter manufacturer.<br><br>*NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.*<br><br>*NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.* | | | |

# 13. MAINTENANCE and SERVICE REQUIREMENTS

## 13.1 Routine Maintenance

**13.1.1**

Verify the electrical connections are clean and free from foreign matter prior to each procedure.

**13.1.2**

Clean and disinfect the Hub, Remote and associated cables before and after each procedure.

**13.1.3**

Hub batteries should be charged when Hub battery indicator LED lights orange.

**13.1.4**

Remote battery is not rechargeable and should be replaced as needed.

**13.2**

Semi-Annual Maintenance

**13.2.1**

Rechargeable batteries should be removed from the Hub and stored separately when not in use for three months or more.

**13.2.2**

Rechargeable batteries should be charged every four months when in storage.

**13.3**

Annual Maintenance

**13.3.1**

Coin cell battery should be checked or replaced annually.

**13.3.2**

Replace Hub battery when it no longer holds a charge.

**13.3.3**

C3 Wave should be tested annually in demo mode by a trained clinician to verify proper functionality.

**13.4 Service Assistance**
Contact the Technical Service Department for assistance.
Medical Components, Inc
Phone +1 215.256.4201

When calling please have the following information available: Model of unit, serial number, date of purchase, and description of problem.

**13.5 Training**
Contact your local sales representative to schedule training.

**13.6 Returning Unit for Repair**
If it becomes necessary to return C3 Wave for repair, contact the Technical Service Department. You will be issued a Return Authorization [RA] number.
Clean and decontaminate the components prior to returning for repair. Package the components in a manner equivalent to the way they were purchased. Mark the RA number on the outside of the package. Returns will not be accepted for service without a RA number.

Ship components to USA service at: Medical Components, Inc
1499 Delp Drive
Harleysville, PA 19438 USA

**13.7 Disposal of Unit**
C3 Wave meets all RoHS standards and does not present any hazards for disposal. C3 Wave batteries must be recycled or disposed of in accordance with your local laws and regulations. See iPad owner's manual for iPad disposal instructions.

| | |
|---|---|
| **Warning** | Never disassemble or attempt to repair C3 Wave. Call the Technical Service Department or return components for repair. |
| **Warning** | Never attempt to alter or modify C3 Wave. Serious damage may occur, possibly resulting in injury to the user or patient. |
| **Warning** | Never perform unauthorized modifications to the monitor hardware or software. This could result in serious injury to the patient or the user. |
| **Warning** | Never attempt to service or maintain C3 Wave while in use. |
| **Warning** | Changes or modifications made to this equipment not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment. |

## 14. LIMITED WARRANTY

Medical Components, Inc. warrants to the purchaser that the C3 Wave System shall be free from defects in material and workmanship for a period of one year from the date of purchase. This warranty is expressly in lieu of any other express or implied warranties, including, but not limited to, any implied warranty of merchantability or fitness for a particular purpose.

Purchaser's remedy for a breach of warranty shall be limited to, at the option of Medical Components, Inc., repair or replacement of the C3 Wave System. Purchaser shall be responsible for return shipping charges.

The aforesaid warranty does not apply when any single component has been dissembled, altered, misused, neglected, or operated outside of the perimeters specified within this manual.