C-Trak Apollo

Wireless/Wired Gamma Probe
for radio guided surgery

User Manual

CareWise
EXPERIENCE & EXPERTISE

Contents

IMPORTANT INFORMATION

WARNING: No modification of this equipment is allowed.

1.0 Introduction

1.1 C-Trak® Analyzer and Probe Introduction

The C-Trak® Apollo system has been designed to detect and quantify the nuclear radiation from gamma emitting isotopes ranging in energy emissions between 27-600 keV. A clear display of numeric quantities and an audible signal convey an increase or decrease in radiation detection allowing the surgeon to localize radiolabeled tissue for excision. The latest model of the Apollo system presents maximum flexibility for the User in being able to operate in one of three modes:

1) Wired gamma probe.
2) USB wired connection of the OmniProbe via the Apollo handset.
3) Wireless connection of OmniProbe via the Apollo handset using bluetooth technology.

The system is comprised of the C-Trak® Apollo touchscreen analyzer and one or more of the OmniProbe® family of probes. The OmniProbe® and OmniProbe®-EL are capable of detecting gamma ray energies up to 364 keV. The OmniProbe®-PET is capable of detecting gamma ray energies up to 600 keV. The analyzer is designed for operation with Care Wise designed gamma probes. The analyzer may also be supplied with the Apollo Wireless handset and/or foot pedal.

C-Trak® probes have special collimation and shielding that allow highly directional detection of radiation from sites of interest, along with greatly reduced detection of background radiation.

The analyzer is designed to operate the probe, display the data from the detected radiation, and display and control the system's operating parameters. The result is optimum performance in measuring gamma radiation from the photopeak of isotopes such as Technetium-99m (Tc-99m), Indium-111 (In-111), Iodine-125 (I-125) and Fluorine-18 ([F-18]-FDG) while minimizing detection of Compton-scattered radiation.

The C-Trak® Apollo system meets ANSI/AAMI ES60601-1: A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012, CSA CAN/CSA-C22.2 NO. 60601-1:14, IEC 60601-1 Edition 3.1 (2012) / EN 60601-1:2006 + A1:2013 + A12:2014 medical safety testing and certification requirements. Its comprehensive shielding of high voltage sites within the instrument eliminates the possibility of significant electrical current leakage to patient or user under normal operating conditions. The C-Trak® Apollo system has excellent electrical safety; the system is designed to turn off the high voltage if the current exceeds 10 µA, or if any short circuit is detected. The system has been designed and manufactured for safe operation in an operating room environment, as long as flammable anesthetic gases are not used and the system is not physically abused.

The C-Trak® Apollo CW4000 System is CE certified and is fully compliant with FDA (21 CFR Part 820), MDD (93/42/EEC) and CMDR (SOR/98-282) requirements.

CE CE 1434

1.2 C-Trak® Getting Started Guide

(1) Attach the Monitor to the Stand. Place the stand on a flat, stable surface. Slide computer onto stand carefully until the 'Quick Release' bracket on the back of the computer locks into the bracket on the stand.

(2) Connect the Care Wise provided Power Cord. Check that the power supply cables are free of any nicks, cuts, exposed wires or other damage. Connect the power supply to the computer and to an AC outlet. An indicator light on top of the power supply should glow.

(3) Connect the Probe. Check that probe cable is free of any nicks, cuts, exposed wires or damaged connectors. Connect the probe to the monitor and then turn the power on using the power button on the front of the monitor. [Reminder: The OmniProbe® is a Type B Applied Part .]

The C-Trak® Apollo system takes a few minutes to start up (boot) completely. Once the system displays the Count Screen, (described in section 2.4-1), it is ready for use.

NOTE: To verify or reset the clock time if the system has been relocated, press 'Main Menu', then 'Setup', then 'Select Time Zone' to choose the time zone for your area.

Assembly of the C-Trak® Apollo System

Slide computer monitor quick release bracket over stand bracket until the tab locks into place.

(4) Connecting the OmniProbe to the Apollo Wireless Handset if not using the wired option.

To attach an OmniProbe to an Apollo Handset, first ensure that the Apollo Handset is turned off; no LEDs will be illuminated on the keypad:

Unscrew the probe clamp nut in an anti- (counter) clockwise direction until the nut is loose but still engaged with the thread:

Carefully insert the OmniProbe through the clamp so that the base of the probe comes into contact with the LEMO connector mounted on the handset.

Tighten the nut in a clockwise direction until the base of the nut compresses the O-ring at the bottom of the threaded section.

The Apollo Handset and OmniProbe many now be powered on via pressing the 'Power' button located on the Apollo keypad. The top LED will flash blue until the handset is connected in the Apollo software (see Section 2.4-14). Once connected, the top LED will be illuminated with a steady blue light:

1.3 C-Trak® Quick Reference for Surgical Use

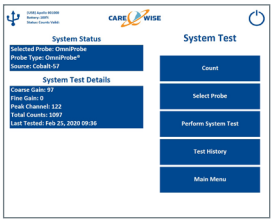
Before use the system should be calibrated using the supplied test source. (See page 12)

To calibrate the system

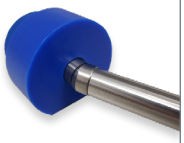
This should be performed each day, before surgery.

The system should be properly connected up and allowed to run for 5 minutes to warm up.

1. On the 'SYSTEM TEST' main screen, ensure that the correct probe is selected (choose 'SELECT PROBE'). Note: Not using the correct probe will result in the system storing the calibration data against the wrong probe's serial number, so please select the correct probe from the list, or add a new one if your probe is not in the list.

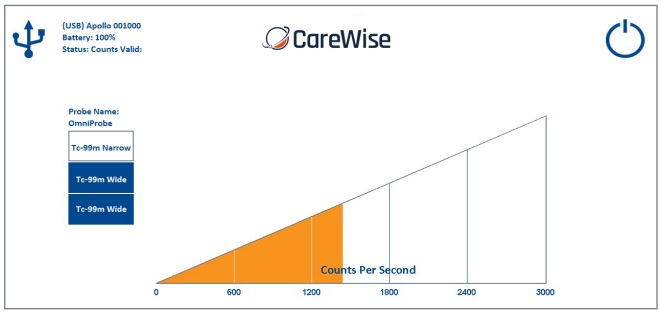


2. Using the supplied radioactive source holder with the correct source inside (<18 months old for Co-57), insert the probe fully into the source holder until it reaches the end.



3. On the system test menu screen choose 'PERFORM SYSTEM TEST'. Follow the instructions given on the screen to perform the system test (calibration).
4. Upon successful completion, (if no errors have shown) the system is now ready for use.

Note: Ensure the probe and source holder are not moved during the test. If the probe or source is moved during the test, please repeat the test again.



C-Trak® Apollo Count Screen

1. Ensure that the Apollo Analyzer is securely attached to the stand. Check that the power cable and probe cable are free of any nicks, cuts, exposed wires or damaged connectors. Ensure that the power box is on. Connect probe, and then turn the Apollo power on, as in steps 1-3 in Section 1.2 If not using the wired probe connection, ensure that an Apollo wireless handset has been connected, powered on and connected in the software.
2. Ensure that:
   a. The probe connected to the analyzer is the probe listed on the Count Screen [Image bottom left on this page].
   b. The Isotope shown on the Count Screen is the isotope that will be used.
3. Set RANGE at desired setting based on the expected level of activity. A range of 0-100 is often preferred for the initial survey [Figure 1].
4. Check VOLUME setting to ensure a comfortable level [Figure 1].
5. Take background test [Section 4.2] to ensure probe is free of contamination.
6. Use the probe to locate the area of greatest radiation uptake of clinical interest before making the first incision.
7. In sentinel node procedures, always remain conscious of the location of the injection site in order to differentiate between very high levels of radiation coming from the injection site and radiation coming from the desired tissue; e.g., sentinel lymph node itself. It can be helpful to mark the patient's skin to show the boundary of the very high level radiation coming from tissue immediately surrounding the injection site.
8. Move the probe slowly and avoid jerky movements. With experience the user will develop a 'feel' for the appropriate speed.
9. Detected count rates drop with the square of the distance from tissue being viewed. Stay very close to the tissue plane. While performing the initial survey, be careful not to push the probe into the skin while moving it, as this will also move the skin relative to the lymphatics.

The 5 µCi Co-57 check source should be replaced every 18 months. Na-22 check source should be replaced every 5 years. Check sources may be purchased through Care Wise or your Care Wise distributor. See Product List, Appendix F, for Product Codes.

Call Care Wise on +1-813-626-6848 (US & Canada) +44 (0)1273 497600 (Europe & Worldwide) or e-mail support@carewise.com with any inquiry.

2.0 Getting acquainted with the C-Trak® System

2.1 Front Panel [Figure 1]

(1) **Display Screens** – Depending on the specific screen selected, displays the data on radiation detected by the system, the specific configuration of the system when in use, or the information needed to calibrate or reconfigure the system as desired.

(2) **Brightness Controls** – Adjust the brightness of the system's display screen.

(3) **Power Switch** – Turns the system on. To shut down press icon on top right hand side of the screen

(4) **Volume Controls** – Adjust the system volume.

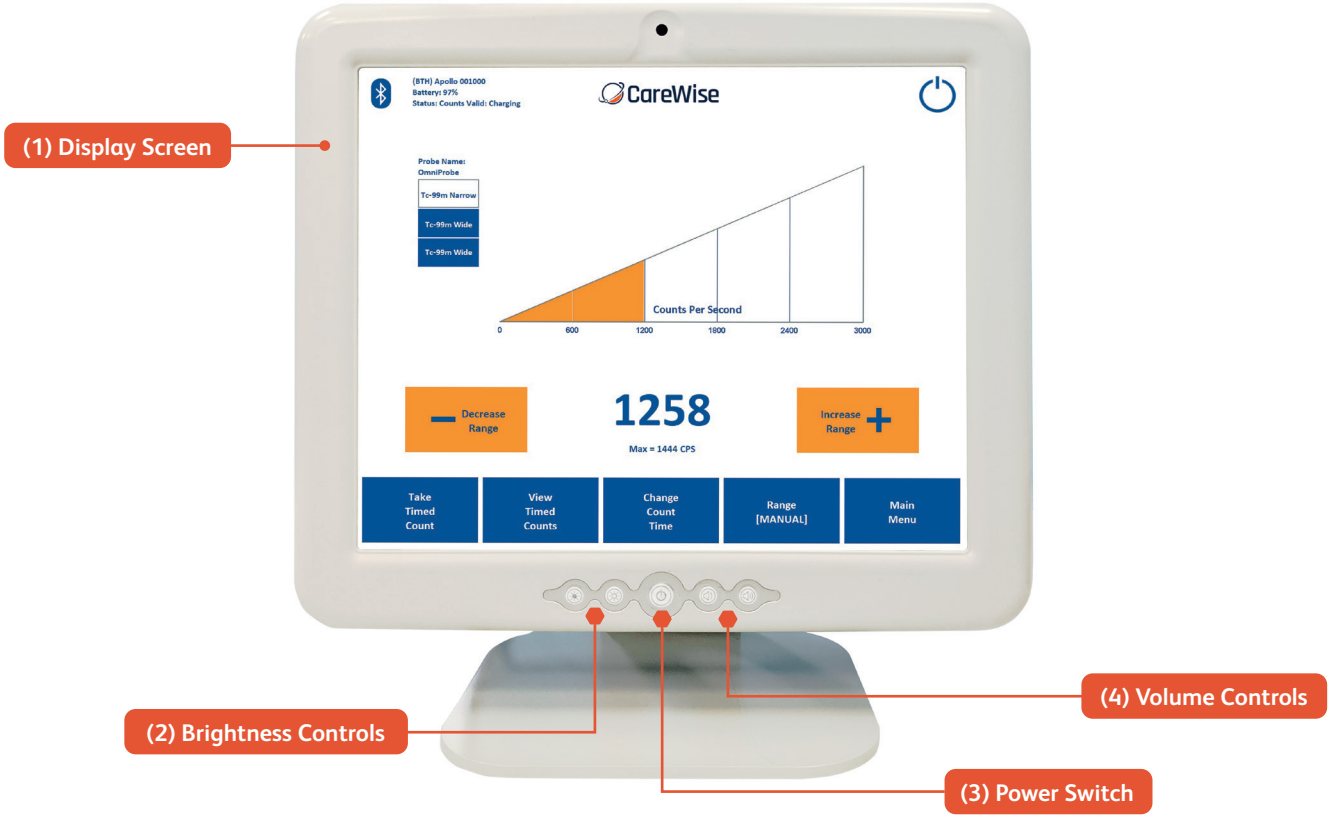


Figure 1 – Front Panel of C-Trak® Apollo System

2.2 Bottom Panel [Figure 2]

(1) **Power** – DC In Connection

- External, Universal AC input (100-240 vac 47-63 Hz), 100 watts, DC-out: 12 V, 8.33 A.
- For U.S. applications, the AC mains plug is Hospital Grade, NEMA 5-15P-HG.
- Contact Care Wise or your Care Wise distributor to supply or replace the proper AC mains plug/cable for your application.

(2) **USB Connectors** – These are ONLY for use with Care Wise approved peripherals (e.g. Care Wise approved accessory printer, Apollo charging dock and foot pedal' [Section 8]). Attaching any devices not explicitly approved by Care Wise (including keyboards, mice, other printers, etc.) can lead to loss of functionality and system damage. DO NOT PLUG ANY UNAPPROVED DEVICES INTO THE C-TRAK® Apollo SYSTEM!

Unused ports will be blanked off with port covers which must not be removed.

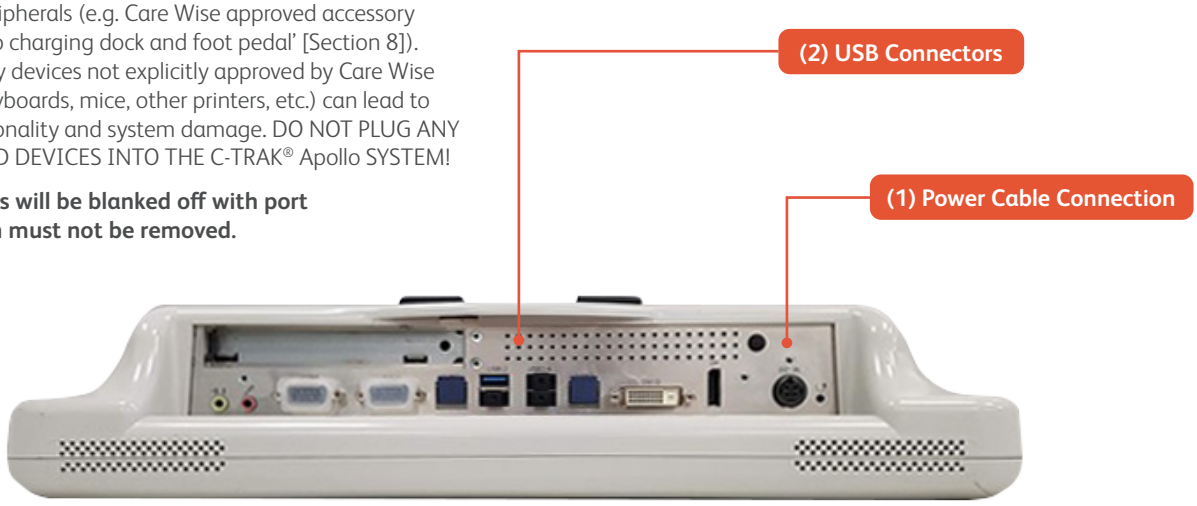


Figure 2 – Bottom Panel of C-Trak® Apollo System

2.3 Right panel [Figure 3]

Probe Connector – The analyser connection is a MHV style high-voltage connector for all Care Wise probes.
(**NOTE:** This is not a "BNC" connector.)

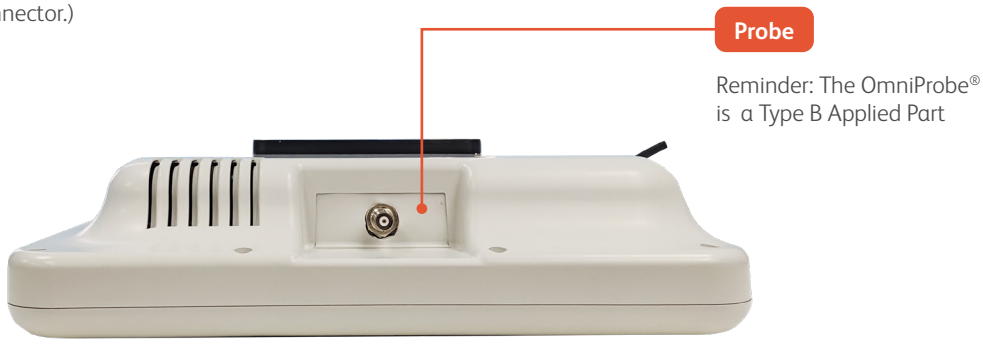


Figure 3. – Right Panel of C-Trak® Apollo System

2.4 Accessing the screens

The C-Trak® Apollo is a touchscreen system. To change screens or input data, select the desired field by touching the corresponding 'button' with your finger. The screen will respond to bare or gloved fingers or other stylus and solid instruments. Please use caution when using anything other than your finger. The screen can be damaged. You may wish to use a clear plastic 'screen protector' product.

Note: 'Greyed out' buttons indicate options that are unavailable based on current settings.

Note: There may be differences in the screen on your analyzer from those presented here due to revisions to the system software over time.

2.4-1 Count Screen

The first screen to appear when the system starts up is the Count Screen, which displays feedback about the amount of radiation the probe detects [Figure 4]. The features of this screen are described below. Refer to Figure 4 and the numeric reference for details.

(1) Rate Meter Display

- There are three versions of the RATE METER DISPLAY. The default, shown in Figure 4, uses a wedge-shaped indicator to show the amount of radiation detected. The other two versions of the RATE METER DISPLAY are an analog indicator and a histogram of counts per second over time. These are shown in Figures 5 and 6 respectively.
- ***NOTE:** Tap the graphical indicator to change the display type.

(2) Counts per Second Display – This numerical display indicates the number of photons detected by the gamma probe per second. Underneath the varying measured count rate value, the maximum number of counts detected (in cps) is displayed; this value is updated every 30 seconds. Tapping this area allows you to change this to 5,10,15,20 or 25 seconds. When a new maximum count rate is reached during a measurement, the Counts per Second numerals will change from blue to red temporarily.

(3) Range Controllers – The DECREASE RANGE and INCREASE RANGE controllers are used to adjust the range of counts per second displayed. Ranges of 0-100, 0-300, 0-600, 0-1000, 0-3000, 0-6000, 0-10000, 0-30000, 0-60000, 0-100000 are available.

(4) Take Timed Count Button – Pressing this button begins a timed count for the current duration. While timed counts are underway, they are viewed on the TAKE TIMED COUNTS SCREEN. Details are in 2.4-2. The Timed Count operation may also be started by pressing the Timed Count 'Egg Timer' button on the Apollo Handset keypad or by pressing the foot pedal accessory.

(5) View Timed Counts Button – Pressing this button allows the user to view any data for timed counts already taken. Details are in 2.4-3.

(6) Change Count Time Button – Pressing this button allows the user to change the duration of timed counts. Details are in 2.4-4.

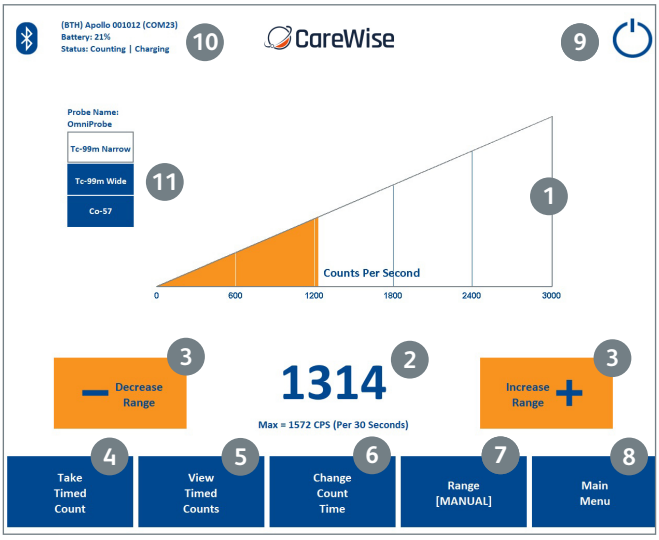


Figure 4 – Count Screen with Wedge Meter

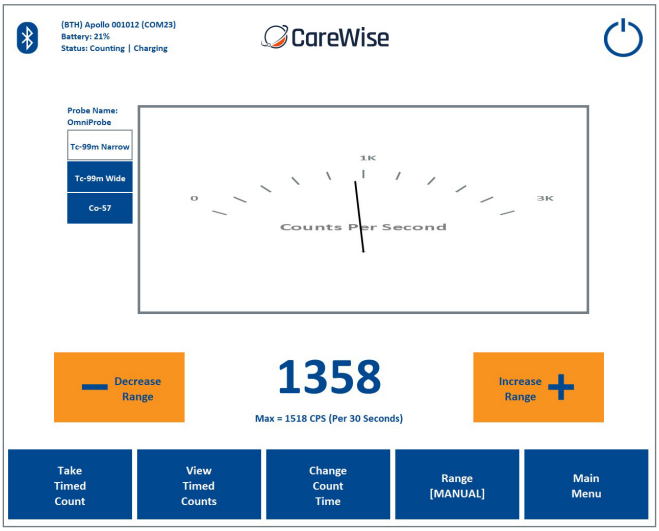


Figure 5 – Count Screen with Analog Meter

(7) Toggle between manual and auto-range – When the [AUTO] ranging option is selected, the software will automatically change the measurement range and associated sound pitch to the optimal setting for the quantity of radioactivity being detected at that point in time. The optimisation process typically takes no more than five seconds.

(8) Main Menu Button – Pressing this button directs the user to the MAIN MENU [Figure 11], described in 2.4-6.

(9) System Shutdown

(10) Probe Connection – (see section 2.4-14).

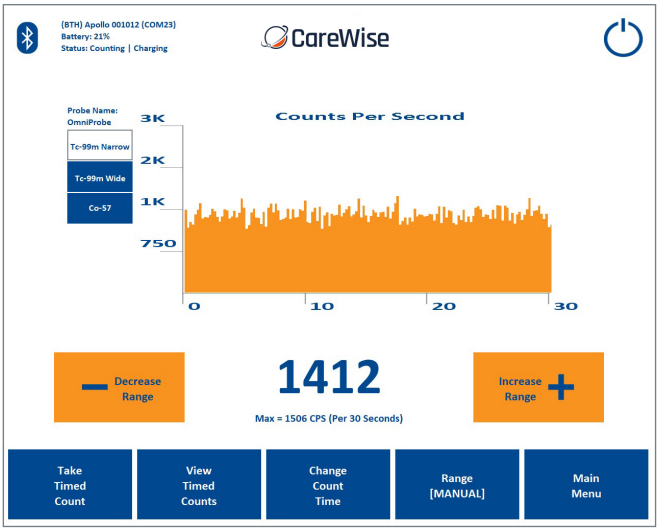


Figure 6 – Change Count with Histogram

(11) Surgical Information Window – This area of the screen displays information about the current surgical procedure including which probe and isotope are in use and what detection range is selected.

Note: Three buttons on the main Counts screen allow the isotope detection range to be toggled. The top button sets the clinical isotope, the middle is the Tc-99m wide setting which increases sensitivity but at a compromise of directionality and the bottom the customer User isotope. Details on setting these isotopes can be found in Section 2.4-10.

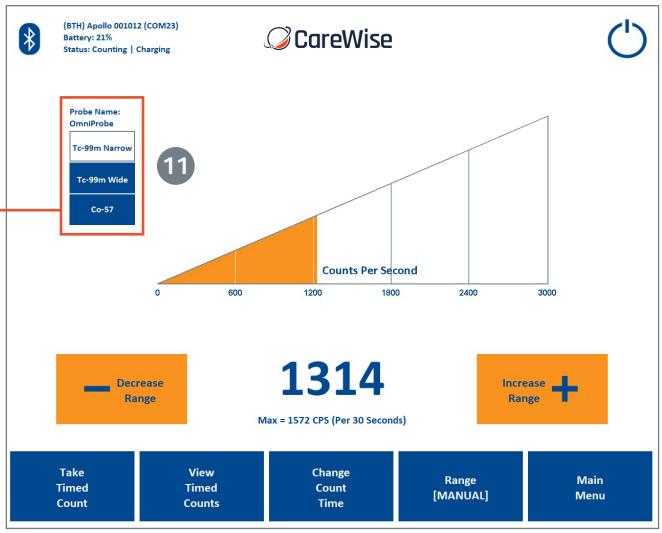


Figure 4 (Duplicated from page 8) **– Count Screen with Wedge Meter and highlighted Surgical Information Window (Probe Information and Isotope Window Settings)** (If probe has not been calibrated in 30 days it will prompt calibration).

2.4-2 Take Timed Counts Screen

On the Take Timed Counts Screen [Figure 7], a user can collect information about how much radiation is detected over time. In the lower corner is a countdown timer, which starts with the duration of the timed count selected in 2.4-4; the default duration is 10 seconds. Three seconds after the countdown is complete, the user will be returned to the Counts Screen in 2.4-1.

The user can exit from the Take Timed Counts Screen by pressing the "Exit" button. If the user chooses to exit while a count is being taken, counting is interrupted and no data are saved. If the user exits after the count is completed but before the 3-second automatic return to the Counts Screen, the data from the current timed count are saved.

NOTE: ID information entered on the View Timed Counts Screen will be displayed above the timed counts list.

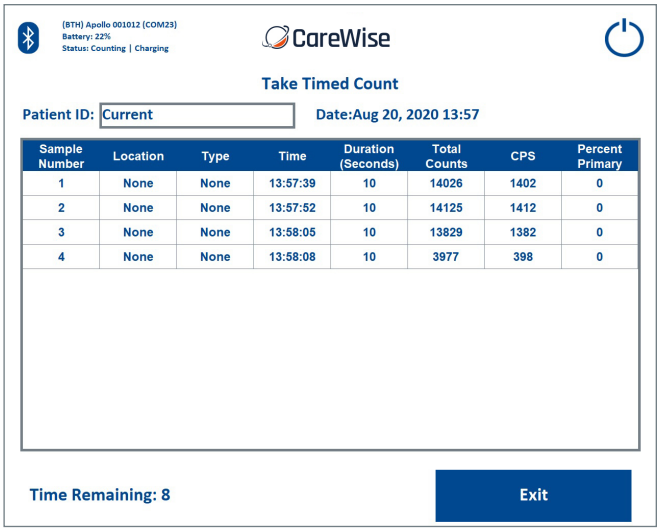


Figure 7 – Take Timed Counts Screen

2.4-3 View Timed Counts Screen

On the View Timed Counts Screen [Figure 8], a user can see the results of any timed counts that have been taken, edit ID information for the data and print the results.

Viewing Timed Counts:

Each time a user presses the Take Timed Counts button on the Count Screen (described in 2.4-1), and the user does not interrupt the collection of timed count data by pressing the Exit button (described in 2.4-2), data are retained about the amount of radiation collected during that timed count. Data about timed counts are retained on the View Timed Counts Screen until the system is shut down, or until the user presses the "Clear" button in the lower left corner, and confirms the choice in the dialog box that appears.

Arranging Timed Count Fields:

There are eight fields on the View Timed Counts Screen which the user can rearrange by touching the field name and sliding to the left or right: Sample Number, Location, Type, Timestamp, Duration, Total Counts, Counts per Second, and Percent Primary.

Figure 8 – View Timed Counts Screen

2.4-3 View Timed Counts Screen (Continued)

Locking Timed Count Fields:

The user can lock the changeable fields by pressing the lock icon in the upper, right-hand side. When the image of the padlock is "open" [as in Figure 8], the fields can be rearranged. When the image of the padlock is "closed", the fields are locked in place.

Editing Timed Count Fields:

There are three user-editable fields in the View Timed Counts Screen: ID, Location and Type. The user can edit the ID field by pressing within the white area and, using the popup keyboard, enter any defining ID to correspond with this data set. To set Location and Type, select an entry to display a pop-up menu. Select the appropriate option from the menu. For Location, the options include: In Vivo – Left and Right, Ex Vivo – Left and Right and Background Left and Right. For Type, the options include: Sentinel, Primary, Tumor, and Other.

The 'Primary' option in the Type field should be selected for the sentinel node with the highest amount of radioactivity in a given set of timed count data. The C-Trak® Apollo system will automatically calculate the percentage of the Primary's activity for all other timed counts, and display these percentages in the "Percent Primary" field. Note that only one timed count can be set as "Primary"; if another timed count is set to "Primary", the count previously labeled "Primary" will be relabeled "Other".

Saving Timed Count Data:

On the C-Trak® Apollo system, the user can manually save a Timed Count data set by pressing the "Save" button and entering an appropriate and unique name for the data set. The user can restore a previously saved set of timed count data by pressing the "Load" button and selecting the appropriate file name.

NOTE: If the system is shut down without saving the Timed Count data, all current data will be lost. If the system suffers an unexpected shut down (e.g. due to power failure), the option to restore the Timed Count data will be presented the next time the system is powered on. Pressing 'Yes' will restore the Timed Count data to the summary table, accessible via the 'View Timed Counts' button. Pressing 'No' will remove the Timed Count data from the system memory.

Printing Timed Count Data:

To print from the C-Trak® Apollo system, ensure that the printer cable is plugged into the USB port and the printer is turned on, then press print on the screen.

Please note only printers purchased from Care Wise will work with the system.

Figure 8 – View Timed Counts Screen

2.4-4 Change Count Time Screen

On the Change Count Time Screen [Figure 9], a user can set the duration of timed counts. The default is 10 seconds. The default can be restored quickly by pressing the "Default" button.
The duration for timed counts can range from
1 second to 999 seconds.

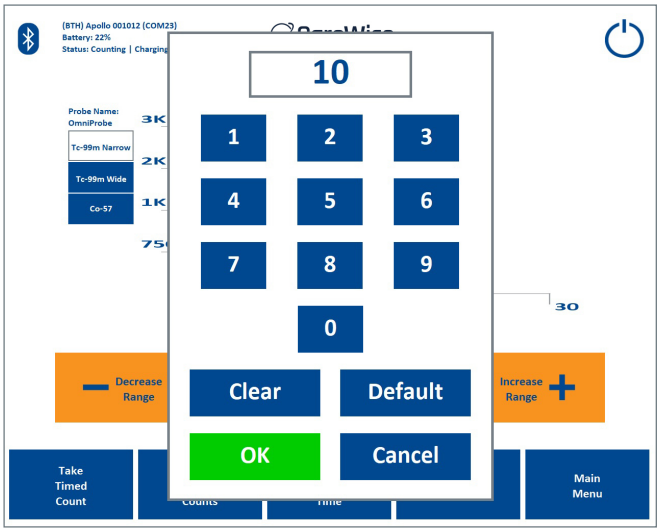


Figure 9 – Change Count Time Screen

2.4-5 Big Counts Screen

On the Big Count Screen [Figure 10], a user can receive enlarged numerical feedback about the amount of radiation the probe is detecting. To show the Big Counts Screen, press the numerical measured count rate value on the Main Count Screen. To exit from the Big Counts Screen, press any area on the screen.

Figure 10 – Big Counts Screen

2.4-6 Main Menu

'The Main Menu [Figure 11], allows the user to navigate to the Count Screen (described in 2.4-1), System Test Screen (described in 2.4-7), and Setup Screen (described in 2.4-8), and also allows the user to change the audible count rate sound type and turn off the C-Trak® Apollo System's power using the "Shutdown" power icon, (described in 2.4-13).

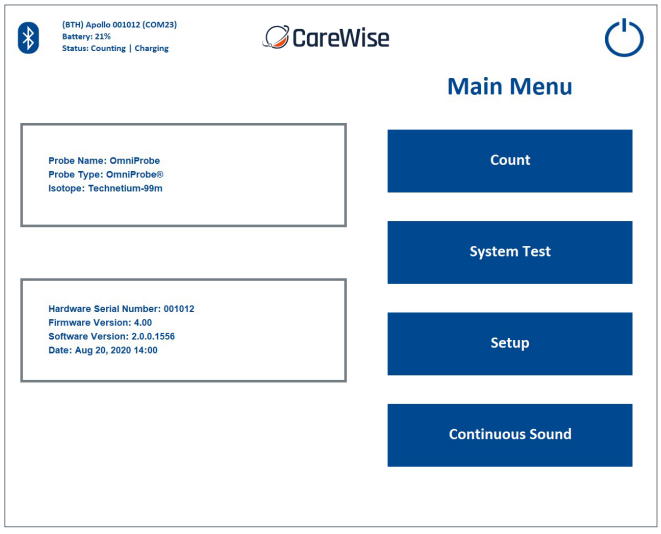


Figure 11 – Main Menu Screen

2.4-7 System Test Screen

On the System Test Screen [Figure 12a], reached from the Main Menu [Figure 11], a user can calibrate and test all functionality of the Apollo system. When a user presses SYSTEM TEST, the Apollo system will both calibrate and test the system.

IT IS ESSENTIAL THAT THE CORRECT PROBE BE SELECTED FOR THIS PROCESS. If the wrong probe is selected, the system test data will be inaccurate, because they will pertain to the wrong probe. The probe must be inserted into a fresh (within 18 months for Co-57; within 5 years for Na-22) check source and held still to perform the test.

The C-Trak® Apollo system creates a database and stores calibration data for each probe used. For a first-time calibration, or to change to a different probe, select the probe to be used through the SELECT PROBE button, as described in 2.4-9.

When a system test is performed, the C-Trak® Apollo system compares the current performance of the selected probe with the saved results of previous performances, to see if any undesirable changes have occurred. A warning message will appear if there are any issues with the probe or analyser. If a particular OmniProbe and Apollo Handset (where the latter is being used) has not undergone a System Test for a period of 30 days, an indication will appear in the Main Counts screen [Figure 12b]. A System Test should be performed as soon as possible if this notification appears. Once the System Test has been performed, the notification will disappear. See Appendix C for Error Messages.

Note: For newly-selected OmniProbes or newly-paired handsets, an initial System Test must be performed. A warning message [Figure 12c] will appear in the main counting screen until such a test is performed.

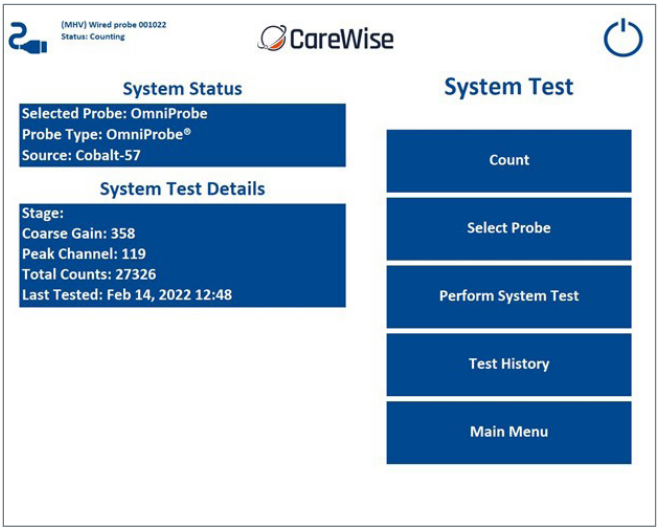


Figure 12a – System Test Screen.

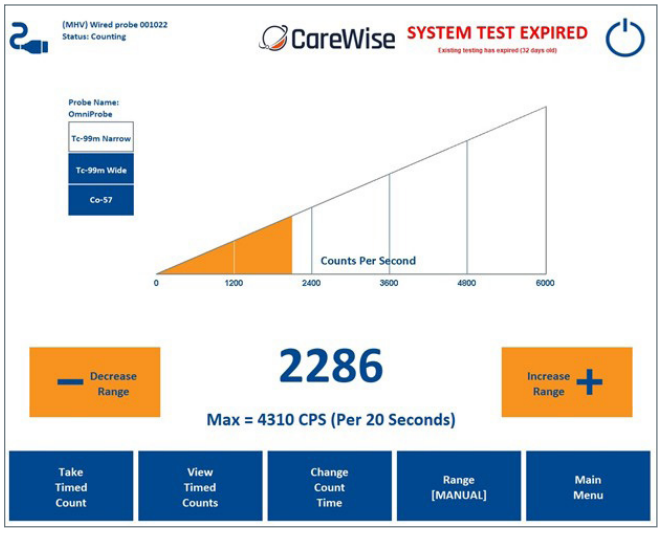


Figure 12b – System Test Expiry Warning.

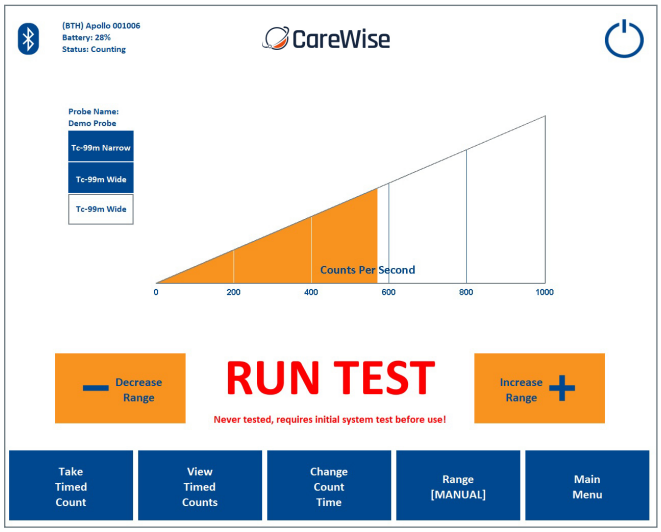


Figure 12c – Main Counts screen showing indication for running a System Test if a new OmniProbe or Apollo handset is selected and has never had a System Test before.

The System Test procedure for the OmniProbe® PET differs from the OmniProbe® Standard and OmniProbe® EL. As outlined in Section 3.1, it is recommended that the System Test is performed using a 20 µCi (740 kBq) 57Co source to define the gain parameters for each PET probe and then a 5 µCi (185 kBq) 22Na source is used with the Fluorodeoxyglucose-18 (FDG) counting window set to confirm the correct response to 511 keV gammas associated with PET-emitters. The following steps should be followed:

The 57Co check source should be placed in the PET probe source holder (Figure 12d) with the orange surface facing outwards, towards the PET probe.

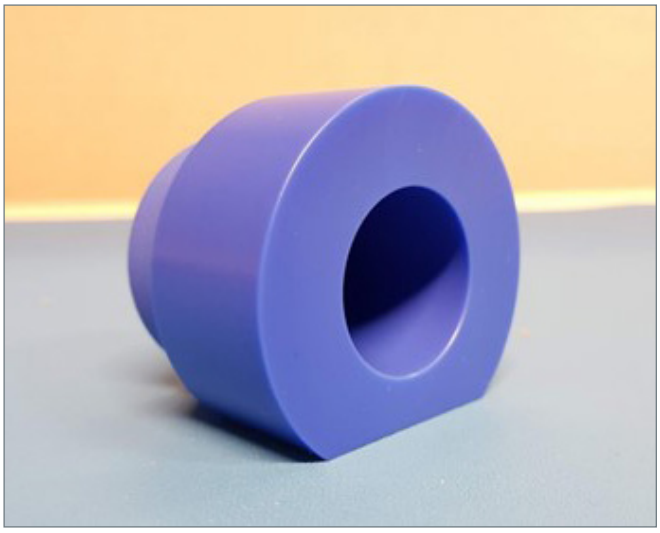


Figure 12d – PET Probe Holder

Insert the PET Probe into the source holder.

Add the PET Probe to the Probe List in the Select Probe screen (Section 2.4-9). **DO NOT** select the probe as an OmniProbe PET; instead, select the probe as a **standard OmniProbe**. Record the Name as 'PET' and add the appropriate Serial Number (Figure 12e).

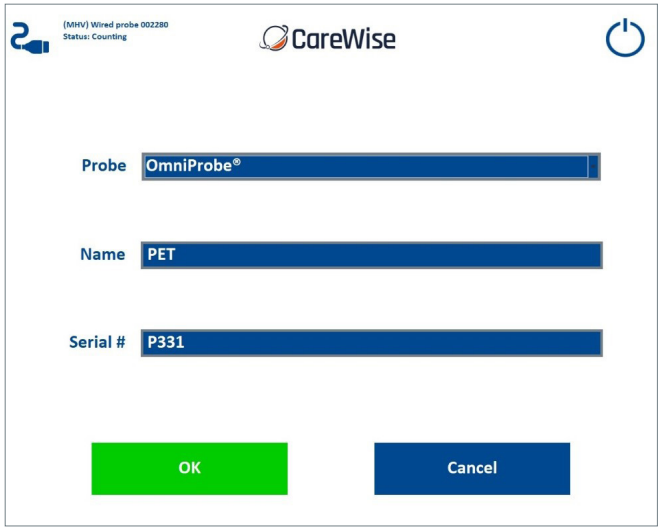


Figure 12e – PET Probe details – note selection as standard OmniProbe

Perform the System Test on the PET Probe. Once completed, the System Test parameters will be recorded as normal (Figure 12f).

Remove the PET probe from the source holder and then remove the ^{57}Co source from the source holder and store in a suitable container and location.

Place the ^{22}Na source in the source holder, ensuring the orange surface is pointing outwards, towards the probe and re-insert the PET probe.

Change the counting window to Fluorodeoxyglucose-18 (FDG) and observe the measured count rate in the main Counts screen. Depending on the age of the source, the measured count rate should be in the range ~400-600 cps.

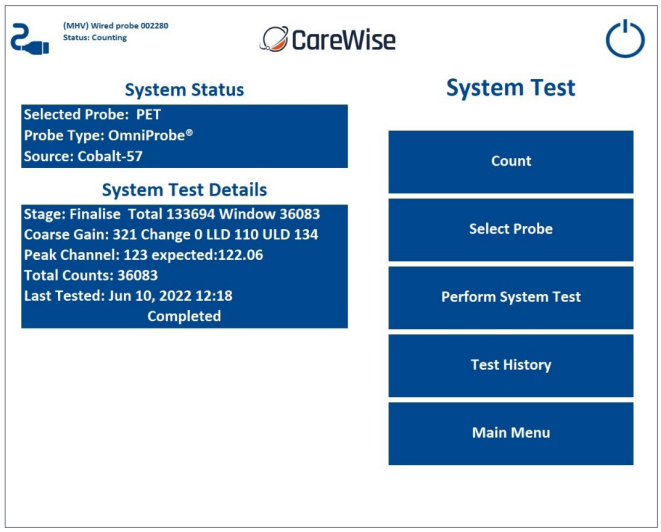


Figure 12f – Example of a completed System Test for a PET Probe with the 57Co source.

2.4-8 Setup Screen

The Setup Screen [Figure 13], allows the user to navigate to various screens used to set up or customize the C-Trak® Apollo system. Users can navigate from here to the Select Probe, Select Isotope, Set Time Zone, and Main Menu Screens.

The Setup Screen also displays important information about the hardware, firmware, and software serial numbers and version numbers, as well as information about the probe and isotope currently selected.

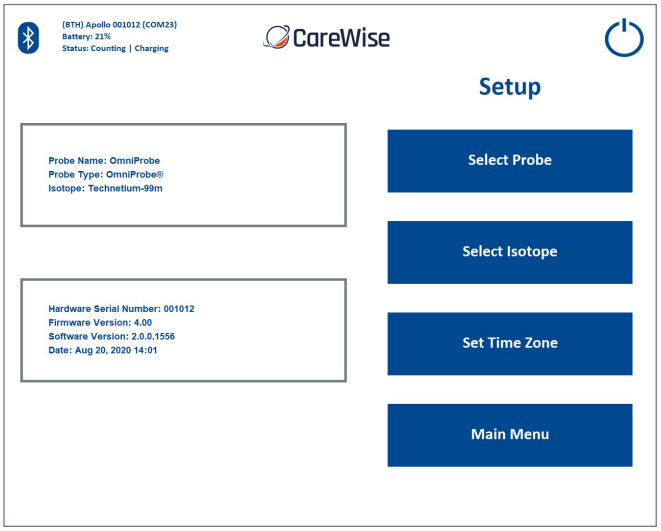


Figure 13 – Setup Screen

2.4-9 Select Probe Screen

The Select Probe Screen [Figure 14], can be reached from the SYSTEM TEST Screen or the SETUP Screen. Select Probe allows users with multiple probes to select which C-Trak® gamma probe to use. Users can create new probe entries by selecting NEW or choose a different probe with SELECT. All probe information can be edited using the EDIT option.

To edit an existing probe profile, select the probe to be edited and press "Edit". Both creating a new probe entry and editing an existing one will bring up the Edit/Create Probe Screen, shown in Figure 15 below. When finished, touch the "select" button in the lower left corner of the screen. This will navigate back to the System Test or Setup Screens.

Adding a New Probe or Editing Existing Probe Information

To create a new entry, select the Probe Type from the drop down menu. Then select "Name" or "Serial #" to generate an on screen keyboard and type in the new information. Press OK to save the probe data. Multiple probe entries may be saved/retrieved on the Apollo system along with the calibration data for each.

Pressing the OK button saves the changes and returns to the Select Probe Screen above.

If a probe is no longer used with the system, Users can remove this from the list by using the DELETE button.

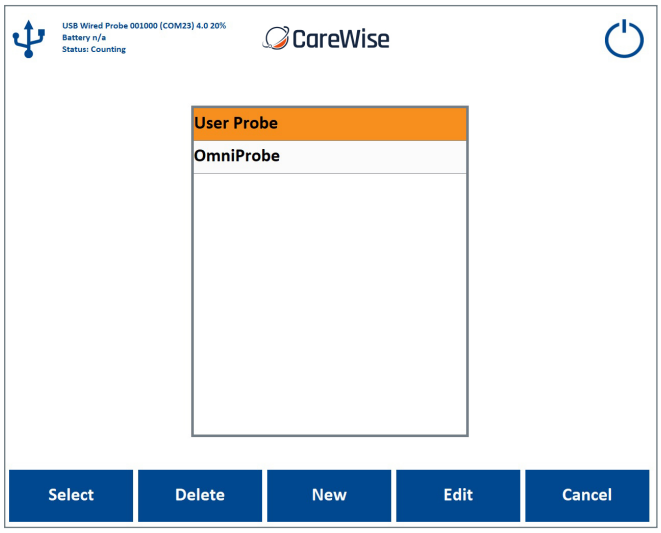


Figure 14 – Select Probe Screen

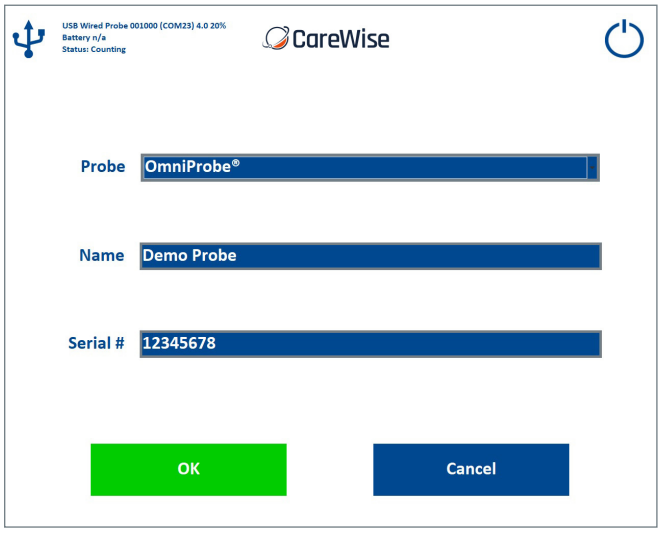


Figure 15 – Edit/Create Probe Screen

2.4-10 Select Isotope Screen

The Select Isotope Screen [Refer to Figure 16] allows the user to quickly choose from a list of commonly used isotopes, based on the type of probe currently selected.

(1) Clinical Isotope – Pressing this button brings up the Count Screen preset to detect the most commonly used clinical isotope associated with the type of probe selected. The default settings for OmniProbe® and OmniProbe®-EL devices, the clinical isotope is Tc99m. For OmniProbe®-PET devices, the clinical isotope is 18F-FDG.

(2) Calibration Isotope – Pressing this button brings up the Count Screen preset to detect the calibration isotope associated with the type of probe selected. The default calibration isotope for the OmniProbe® and OmniProbe® EL devices is Co-57. For OmniProbe® PET devices, the calibration isotope is Na-22. It is not necessary to select a calibration isotope before performing a System Test, as the C-Trak® Apollo System will automatically select the appropriate calibration isotope for the selected probe.

(3) User Isotope – This button brings up the Count Screen preset to detect the secondary isotope assigned by the user. By default, it will display "User Isotope" and be greyed out (unusable) until the user assigns an isotope to this shortcut button by pressing the LIBRARY button and selecting an isotope from the list. Press ASSIGN to save the isotope as the User Isotope. Press SELECT to bring up the Count Screen preset to detect the selected User Isotope.

(4) Isotope Library – Pressing this button brings up the ISOTOPE LIBRARY, a list of commonly used isotopes, described in 2.4-10.1.

(5) Main Menu – Pressing this button allows the user to navigate to the MAIN MENU, described in 2.4-6.

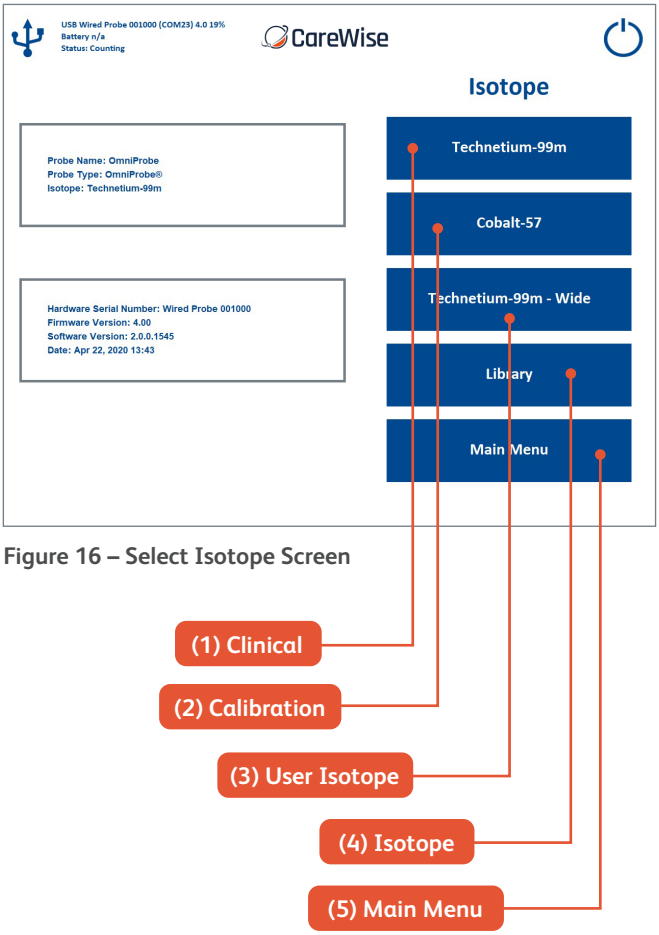


Figure 16 – Select Isotope Screen

2.4-10.1 Isotope Library Screen

The Isotope Library [Figure 17] comes pre-installed with commonly used isotopes. Users can freely create, edit and delete their own isotope entries. The isotopes that come pre-installed, (shown in red on the Isotope Library Screen) cannot be edited or deleted. To create a new isotope entry, press NEW. To edit or delete an existing (user-created) isotope entry, select the entry then press EDIT or DELETE respectively.

To select an isotope, highlight the entry and press SELECT. The isotope chosen will become the active isotope.

To assign an isotope to the USER ISOTOPE button, select the entry from the list and press ASSIGN. Assigning a user isotope allows the user to quickly select a commonly used isotope without having to navigate to the full isotope library.

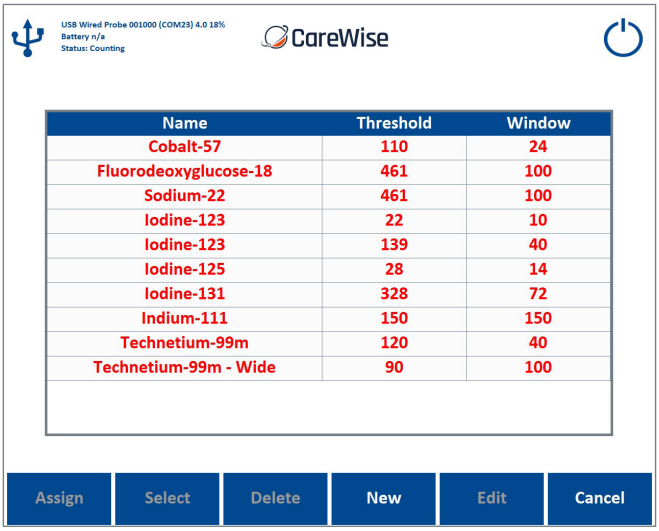


Figure 17 – Isotope Library Screen

2.4-10.2 Edit/Create Isotope Screen

To create or edit an isotope entry from the Isotope Library Screen (Section 2.4-10.1), selecting NEW will bring up the Edit/Create Isotope Screen [Figure 18]. The user can enter the isotope's full name, as well as a shortcut name, threshold setting, window setting, and primary photopeak using the on screen keyboard.

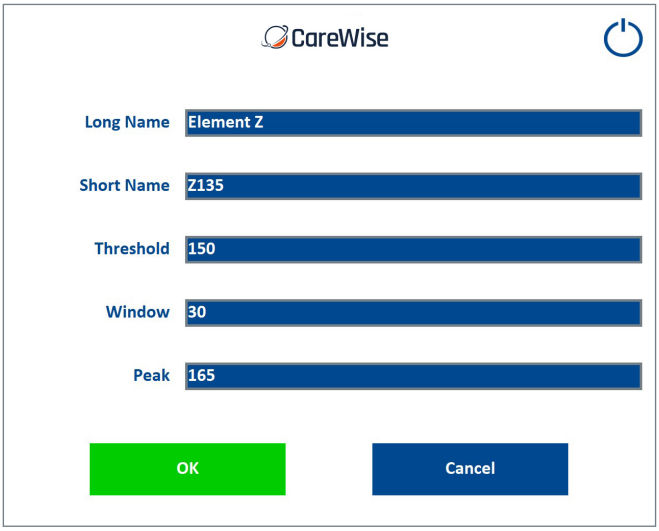


Figure 18 – Edit/Create Isotope Screen

2.4-11 Set Time Zone Screen

The Set Time Zone Screen [Figure 19], reached from the SETUP SCREEN [Figure 13], allows the user to select the appropriate time zone.

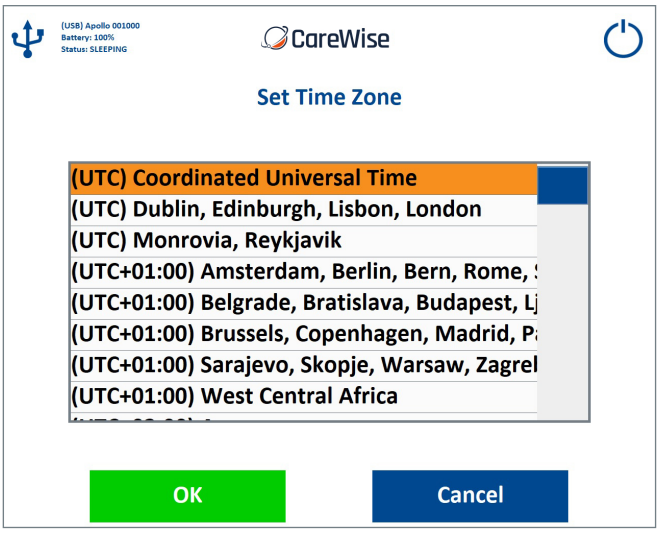


Figure 19 – Set Time Zone Screen

2.4-13 Shutdown Screen

The Shutdown Screen [Figure 20] appears if the 'power button' icon in the top right-hand corner is pressed and allows the user to turn off the Apollo System. Pressing 'No' will return the User to whichever screen was live before the power button icon was pressed. Pressing 'Yes' will shut down the system.

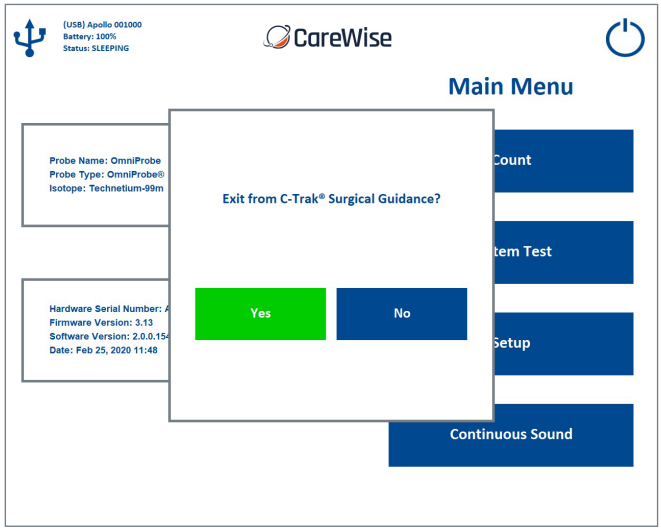


Figure 20 – Shutdown Screen

2.4-14 Probe Connection

Connecting to an Apollo wireless probe handset via USB or Bluetooth can be achieved by pressing the icon in the top left-hand corner of the main Counts screen (note icon may be Bluetooth, USB or No Connection).

Note: When using the wired OmniProbe connection, the icon will appear as per Figure 21c.

Important Note: When delivered, the system will already be paired to the supplied Apollo handsets. Please contact your local representative or Care Wise directly for further information.

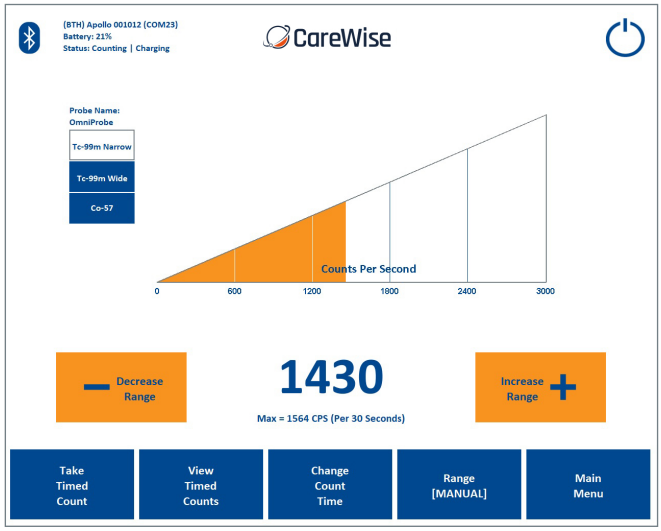


Figure 21a – Main Count Screen showing the Bluetooth icon for the active wireless Apollo handset mode of operation

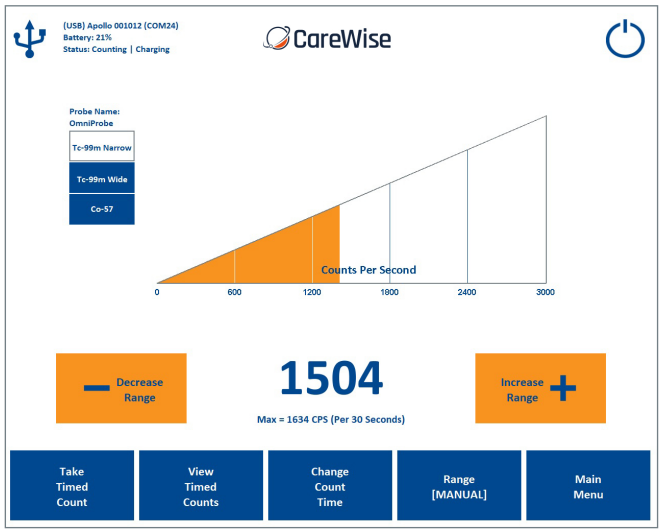


Figure 21b – Main Count Screen showing the USB icon for the active USB wired Apollo handset mode of operation

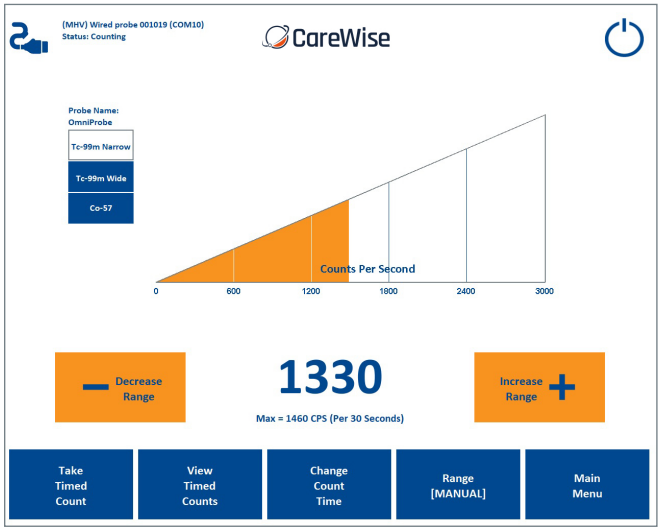


Figure 21c – Main Counts Screen showing the Cable icon for the active wired OmniProbe mode of operation

In order to pair a new Apollo handset with the system, press the Pair button in the Available Devices screen.

Enter that day's password (obtainable from Care Wise Support: support@carewise.com) [Figure 22b].

The system will search for devices automatically – when the device with the correct serial number (shown on the underside of the Apollo handset) appears, highlight the device and click 'Next' [Figure 22c]. The newly paired device will appear in the system device list once the list has been refreshed.

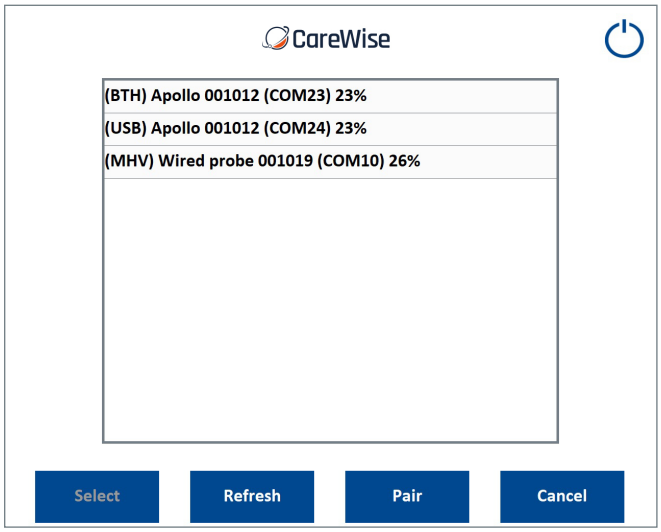


Figure 22a – The Pair button should be pressed to pair a new handset via Bluetooth

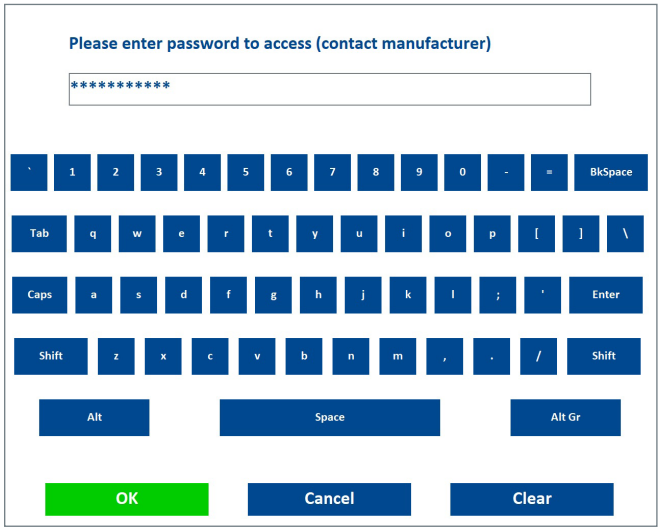


Figure 22b – Enter the password obtained from Care Wise Support using the on-screen keyboard

Figure 22c – Add Device window showing available devices that can be selected

Pressing the Icon will bring up the available connections screen which will list all of the available Apollo devices that have been previously linked to the Apollo system.

Each connection type is displayed in terms of six parameters:

Connection Type: Bluetooth (BTH)

Device Name: Apollo

Serial Number: S/N 001012

Connected COM port: COM23

Battery Charge Level: 21%

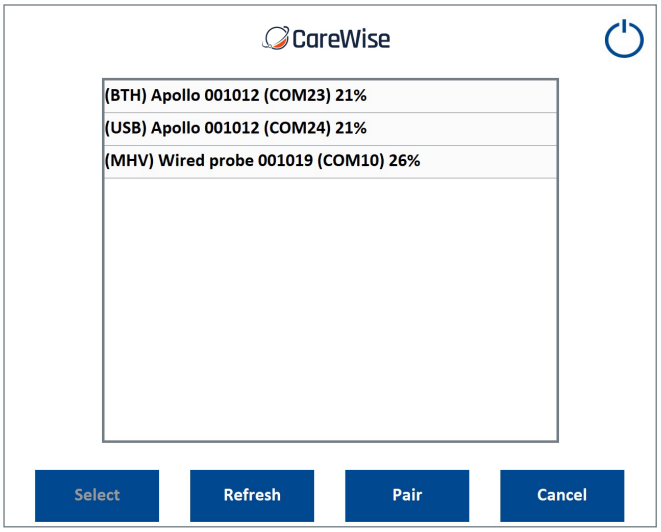


Figure 23 – Available connections screen showing the list of available devices

If the paired device is not listed, click 'Refresh' and the system will scan for all available paired devices. Note: The OmniProbe must be connected to the Apollo Handset and the latter be powered on via the on/off button on the handset keypad before the system scans for devices; the top blue LED on the handset keypad will flash blue when looking for a connection.

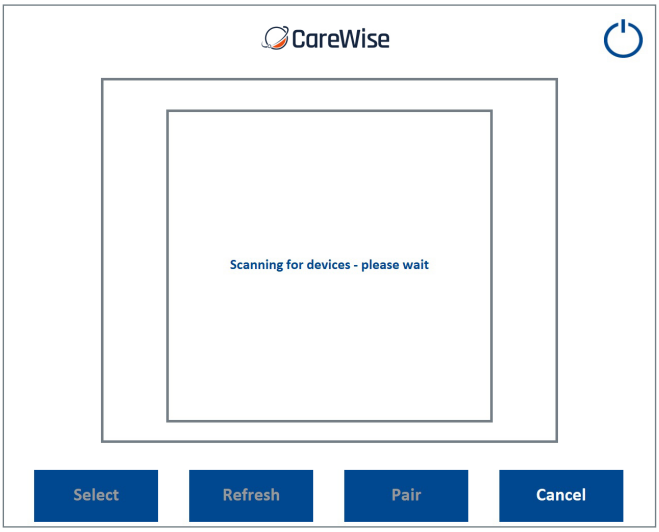


Figure 24 – Information shown on screen when the list of available devices is being scanned after pressing the Refresh button

Once the desired Apollo device has been listed, press the corresponding line in the Available Devices table; this will cause the line to be highlighted in orange:

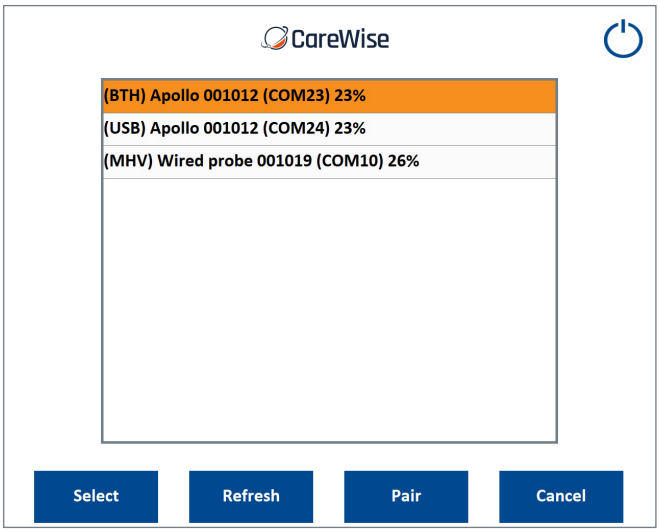


Figure 25 – Highlighted available device after it has been pressed

Click 'Select' to connect the software to the selected Apollo Handset device.

Figure 26 –Information shown on screen when the highlighted available device has been selected after pressing the Select button

Once connected, the software will return to the main Counts screen and the top LED on the Apollo Handset keypad will be illuminated in steady blue (not flashing).

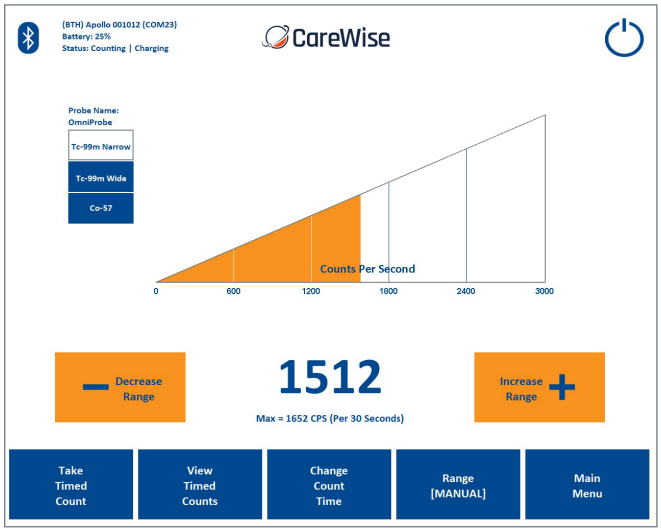


Figure 27 – Main Counts Screen showing the summary information related to the connected device

The Apollo Handset will enter 'Sleep' mode after a period of inactivity (five minutes) [Figure 28a]. The handset can be woken up by moving it, after which it will start counting again. Note that a timed count cannot be started whilst the handset is in sleep mode. After an additional 15 minutes of inactivity, the handset will shut down automatically to save power [Figure 28b]. To resume using the system after this period, the handset will require switching on via the handset power button. Once the handset is active again, counting will resume automatically [Figure 29].

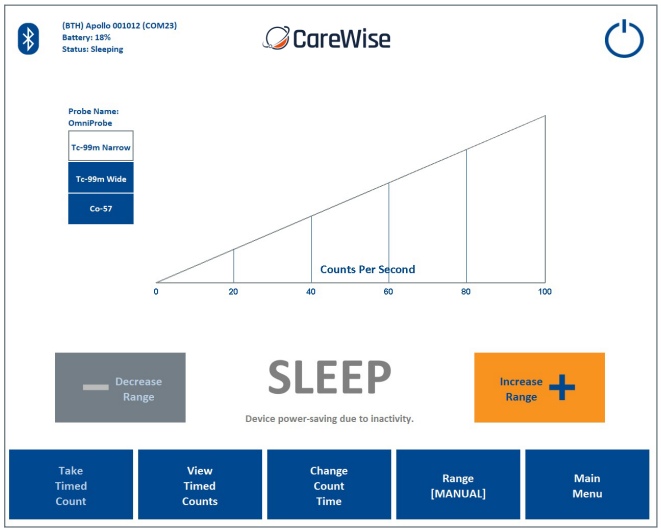


Figure 28a – On screen notification that the Apollo handset has entered a sleep mode after five minutes of inactivity

Low battery indication and charging:

For Low Battery indications, see Appendix C.

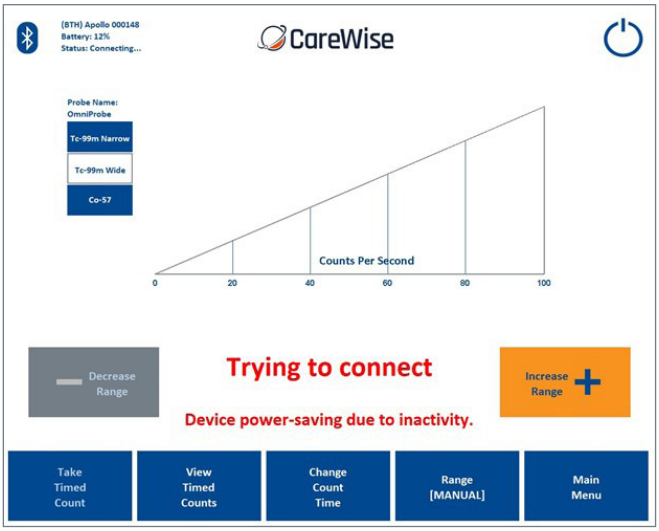


Figure 28b – System power-saving screen following 20 minutes' inactivity of the handset.

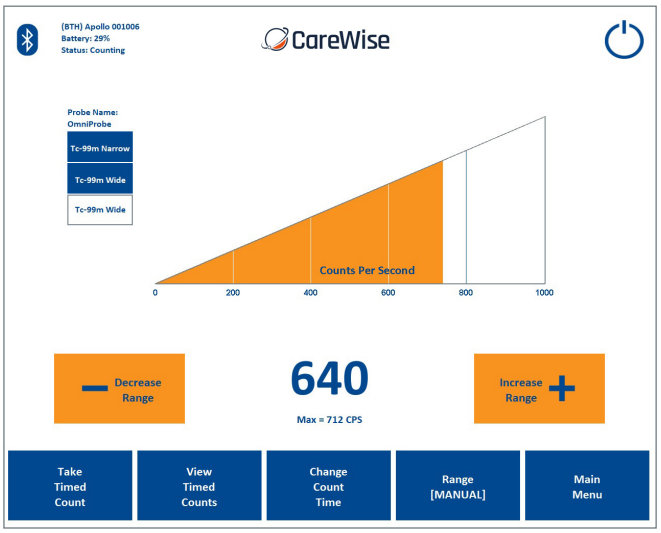


Figure 29 – Main Counts Screen showing Apollo handset has become active again after a Sleep period.

3.0 Calibration Guidelines

3.1 Isotope Check Source

The Apollo System is designed to warn the user when the check source is getting low. The date stamped on the Check Source disc is its "birth date" at which time the radioactivity was at the strength listed on the disc. For information on obtaining a check source contact Care Wise or your representative.

Check Source for C-Trak® OmniProbe® and OmniProbe® EL

A 5 µCi Cobalt 57 (Co-57) check source should be used to calibrate the system if an OmniProbe® is in use or a 10 µCi Cobalt 57 check source for the OmniProbe® EL.

The characteristics of Cobalt 57 are:

- Primary photo peak energy: 122 keV
- Half life (time it takes for activity to decay by one-half): 271 days (9 months).

The Co-57 check source should be replaced every 18 months. See Section 3.4 for guidance on renewing the source date within the software.

Check Source for C-Trak® OmniProbe® PET

A 20 µCi Co-57 check source should be used to calibrate the system if an OmniProbe® PET is in use. A 5 µCi Sodium 22 (Na-22) check source is also used to check the response in the correct isotope counting window.

The characteristics of Na-22 are:

- Primary photopeak energy: 511 keV
- Half life: 951 days (2.6 years)

The 5 µCi Na-22 check source (Product Code CW5-CTXX-10) should be replaced every five years.

See Appendix G for information on handling and disposal provided by the manufacturer of the Care Wise-supplied check sources.

3.2 Check Source Holder Use

A Source Holder is used for calibrating C-Trak® systems. Unscrew the two pieces of the source holder and place the source inside with the label facing downwards. Screw together. When performing a System Test [Section 2.4-7], insert the nose of the probe into the holder all the way and hold still for the duration of the test. When the System Test is complete, remove the probe from the source holder.

NOTE: If using the OmniProbe®, the collimator may sometimes pull off and stay in the holder. Unscrew the base and push the collimator with your finger or other soft object.

If using a C-Trak® OmniProbe®, have the standard Tc collimator on the probe for calibration. This allows it to fit properly into the Source Holder. If a sterile drape (sleeve) is on the probe, it must be removed before placing probe in the Source Holder.

The check source may be stored in the Source Holder unless your institutional policies specify otherwise.

3.3 Performing Calibration

The system should be calibrated frequently to ensure optimal sensitivity. Performing a System Test, in essence, performs a calibration. The System Test (described in section 2.4-7) will compare the test results from the current calibration to data stored from previous tests of the same probe. A System Test will ensure that all components are functioning properly.

Care Wise recommends that a System Test be performed each time it is first used on any given day. A System Test is also required if the OmniProbe is removed or replaced for any reason. The software will notify the User if an OmniProbe is connected which has never undergone a System Test.

3.4 Changing the Source Renewal Date

Upon the replacement of the check source, it is important to update the source renewal date in the software. Within the System Test screen select Test History [Figure 30a].

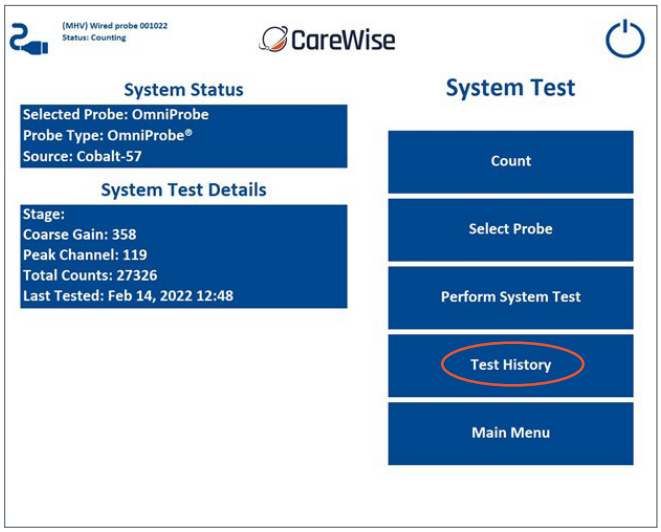


Figure 30a – System Test Screen showing the Test History button.

Press the New Source Button [Figure 30b] and select the calibration date of the check source from the calendar display [Figure 30c].

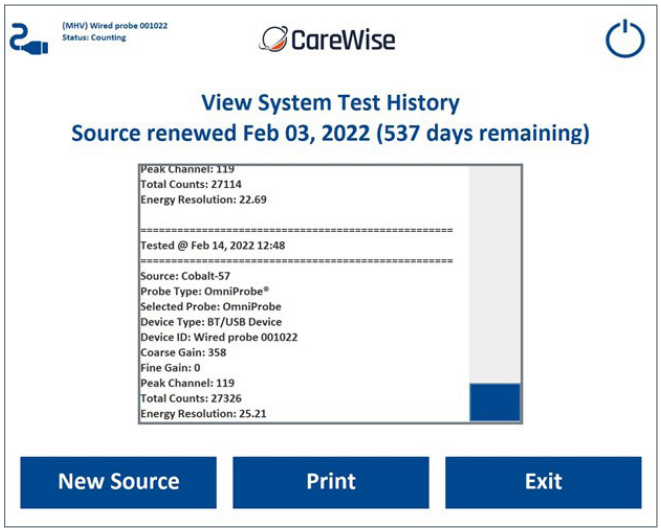


Figure 30b – System Test History summary showing the New Source button.

After selection, the number of days remaining for the source will be displayed.

Figure 30c – Calendar date selection for the new check source.

4.0 Pre-surgery Set Up

Before use the system should be calibrated using the supplied test source. (See page 4)

4.1 Before Power Is Turned On

If using the system in a wired mode, connect the probe cable to the Right Panel probe connector [Figure 3]. Check the probe cable for any significant nicks, cuts, exposed wires or damaged connectors. If not using the probe cable, ensure that the OmniProbe is connected to the Apollo handset and that the handset is turned on. Connect the handset to the USB cable if being used in that mode.

4.2 Background Test

A background test will determine if the equipment or the environment is contaminated with radioactive material. The background test should be conducted inside the operating room immediately prior to probe use and the results logged to establish the baseline or normal amount of radioactivity present.

1. Make sure the isotope that will be used in the surgery is selected.
2. Remove or shield all known sources of radioactivity from area. Point the probe up and away from all known sources.
3. Perform one or more 10-second counts with probe pointed straight up. Log the results.
4. If the results are elevated from the last log entry, decontaminate the probe in accordance with guidelines in section 5.3. If results are still elevated, the environment may be contaminated and the appropriate hospital personnel should be informed.

CAUTION: If the instrument indicates a high background when no radioisotope is present, the sterile disposable drape may be contaminated. If such is the case, removing the sterile drape from the probe should reduce the background to a normal reading (if no radioisotope is present). Continued indication of radioisotope after the sterile drape has been removed may indicate that the probe body has been contaminated. See section 5 for further information.

5.0 Sterile Practices, Cleaning and Disinfecting

Processing Instructions in accordance with ISO 17664:2017, Annex B

5.1 Care Wise C-Trak® OmniProbes

Manufacturer: Southern Scientific Limited

Device: Care Wise C-Trak® OmniProbes (Standard, EL and PET; standard and Lechner collimators) and Coaxial Probe Cable (includes probe cables with Würth Elektronik Ferrite Type 742 711 11)

Note: Serial Numbers P421 Onwards

WARNINGS	OmniProbes sold with the C-Trak system are sold as **non-sterile** devices and must always be used within a sterile drape. Sterilisation of the OmniProbes is possible, but optional, and can be used as an extra precaution if necessary; please see further information regarding the validated sterilisation methods in the table below. **DO NOT AUTOCLAVE** the gamma probe (OmniProbe). Steam or dry heat sterilisation will damage the gamma probe and cable, void the warranty and could result in injury to the operator or patient. **DO NOT IMMERSE** the analyser control unit or cable connections in liquids.
Limitations on processing	There are no known restrictions on number of processing cycles.

INSTRUCTIONS	
Initial treatment at the point of use	Cleaning before first use must be performed. Further details are given in the Cleaning: Manual section below.
Preparation before cleaning	The OmniProbe's collimator (standard or Lechner) should be removed prior to cleaning and processed separately.  **Important Note: The probe cable (when fitted) should also be removed prior to cleaning and cleaned separately.**

Cleaning: Automated	Automated cleaning should not be performed on the device.
Cleaning: Manual	**1) Before First Use and Routine Cleaning** The Apollo device and accessories should be regularly cleaned to prevent build-up of dirt and detritus and as part of pre- and post-operative processing. To clean the device, ensure it is switched off and wipe gently with a non-abrasive cloth with a mild detergent or IPA solution (70% v/v) or equivalent disposable wipes (e.g. Clinell Universal Wipes). When Cleaning the Omniprobe, make sure to remove the collimator and clean the nosepiece. **Note:** Do not use any cleaning solution on any connector or ports. Ensure the device is fully dry before use or reconnecting any accessory or probe. Refer to the warnings section above. **2) Cleaning to remove potential radioactive contamination** Potential contamination from radioactive material will be indicated by an increase in the measured background count rate (i.e. with no radioisotope in the region of the probe). a) Remove the sterile drape from the probe – the background count rate should return to normal levels (no greater than 1-2 cps). b) If, after removing the sterile drape from the probe, the system still indicates a high background, shut down the system. c) Use a disposable pan or vessel to contain the liquid required to complete the cleaning process The liquid, disposal wipes, and any other material that will contact the liquids used in the decontamination process must be assumed to be radioactive. These materials and liquids must be handled and disposed of as per your institution's licence agreements with national state or federal regulatory agencies. Consult with your radiation safety officer for guidance. d) Use a commercially-available decontaminating product (e.g. Bind-It™ Radioactive Decontamination products) to clean the probe. Rinse the probe several times with distilled water. **Note:** Make certain that the connector within the distal end of the probe handset is absolutely dry before inserting the cable connector into the probe handset. Never immerse the connector ends of the probe cable in liquid. e) Dry the probe thoroughly with a disposable wipe and leave to air dry. It is extremely unlikely that the probe cable will become contaminated; however, if it does, the same procedure as above can be followed. f) Reconnect the cable and probe and turn on the C-Trak Apollo System. If the system is still indicating a high background, turn the system off and repeat the steps above. If the system still indicates a high background, contact nuclear medicine or biomedical engineering for evaluation. The probe may have been damaged. **3) Cleaning prior to disinfection or sterilisation** **Tristel Trio Method (Step 1: Cleaning)** The Pre-Clean Wipe (CE Marked as a Class I Medical Device) is impregnated with a triple-enzymatic detergent and surfactant. a) Disinfect hands and wear gloves when handling disinfectants and medical devices. b) Take one Pre-Clean Wipe sachet. c) Remove the Wipe from its sachet and lay it out in the palm of your hand. d) Wipe the surface of the medical device until soil and organic matter have been visibly removed. In case of heavy soiling more than one Wipe may be used. e) Discard the used Wipe and gloves in accordance with local regulations. Do not reuse. Keep the empty Wipe sachet for traceability.
Disinfection	**1) General Disinfection** To disinfect the device, ensure it is switched off and wipe gently with a non-abrasive cloth with a mild disinfectant or IPA solution (70% v/v) or equivalent disposable wipes, e.g. Clinell Universal Wipes. The collimator should be removed from the OmniProbe body to allow the nosepiece to be disinfected. **Note:** Do not use any disinfectant solution on any connector or ports. Ensure the device is fully dry before use or reconnecting any cable, accessory or probe. Refer to the warnings section above.

Disinfection (continued)	**2) Tristel Trio Method** The OmniProbe and cable have been validated against the Tristel Trio Wipes System. Following Step 1: Cleaning described above, the following steps must be observed to obtain high-level disinfection: **Tristel Trio Method (Step 2: Activating and High-Level Disinfecting)** The second step in the decontamination procedure is the high-level disinfection of the medical device. The Sporicidal Wipe is CE Marked as a Class IIb Medical Device. a) Disinfect your hands and put on new gloves. b) Take one Sporicidal Wipe sachet. c) Remove the Wipe from its sachet and lay it out in the palm of your hand. **Note:** Activate the Sporicidal Wipe as soon as you have removed it from the sachet and use it immediately. d) Remove the lid from the Activator Foam bottle. • If you are using Trio Wipes System (50), apply two aliquots of Activator Foam onto the Sporicidal Wipe. • If you are using Trio Wipes System (5), apply four aliquots of Activator Foam onto the Sporicidal Wipe. **Note:** If the Activator Foam bottle is being used for the first time, depress the pump two to four times to prime it. The first output from the foam bottle can be left on the Wipe, to be followed by complete aliquots. The Activator Foam bottle is then primed for subsequent Wipes. e) Fold the wipe in on itself and scrunch together for 15 seconds to activate. Ensure that the Wipe is evenly covered with foam. Use the activated Wipe immediately. Presence of a chlorine-like odour confirms that the Wipe is ready to use. f) Wipe the surface of the medical device in one movement to cover it with foam, ensuring all areas come into contact with the Wipe. Pay special attention to edges, ridges and indentations. g) Observe a 30-second contact time. h) Discard the used Wipe in accordance with regulations. Do not reuse. Keep the empty wipe sachet for traceability. **Tristel Trio Method (Step 3: Rinsing)** The third and final step in the decontamination procedure is rinsing of the medical device. The Rinse Wipe is impregnated with de-ionised water and a low-level of antioxidant which removes chemical residues from a surface. Each Rinse Wipe sachet is packed and then sterilised by gamma-irradiation. The Rinse Wipe is CE Marked as a Class I Sterile Device. a) Take one Rinse Wipe sachet. b) Remove the Wipe from its sachet and lay it out in the palm of your hand. c) Wipe the surface of the device that has been decontaminated to remove excess foam. d) Discard the used Wipe and gloves in accordance with local regulations. Do not reuse. Keep the empty Wipe sachet for traceability.
Drying	For the Tristel Trio Wipes system, upon completion of the decontamination cycle, the device should be left to air dry. Store the device in accordance with hospital protocols to prevent damage or recontamination.
Maintenance, Inspection and Testing	See the C-Trak Apollo IFU for System Test information. Probes and cables should be inspected visually prior to any processing operation being undertaken for any signs of degradation, surface corrosion or damage.

Packaging	There are no specific methods for packaging or containing the medical device during and/or after processing. All probes in the C-Trak® family of probes are operated while sheathed in a sterile disposable sleeve such as those commonly used with ultrasound probes or laparoscopic cameras. **CAREFULLY FEED PROBE AND CABLE INTO SHEATH. DO NOT DROP PROBE INTO SHEATH AS THIS PLACES STRESS ON THE CABLE CONNECTIONS.**
Sterilisation	**Ethylene Oxide** Validated by Nelson Laboratories, Inc., Salt Lake City, UT, USA. **Preconditioning Parameters:** Temperature: 54 ± 2°C Relative humidity: 70 ± 5% Vacuum set point: 1.3 psia Steam partial pressure: 2.18 psia Preconditioning set point: 2.8 psia Preconditioning time: 1 hour **Sterilisation Parameters:** Temperature: 54 ± 2°C Relative humidity: 70 ± 5% Pressure set point: 9.3 psia Ethylene oxide concentration: 725 ± 25 mg/l Gas exposure time (full cycle): 2 hours Aeration time (full cycle): 12 hours Aeration temperature: 51 - 59°C **ASP Sterrad® 100S** A full cycle of ASP STERRAD® 100S Steriliser (from Advanced Sterilization Products, Inc.). Validated for 100 cycles by Advanced Sterilization Products, Inc., Irvine, CA, USA. **ASP Sterrad® 100NX** A full DUO cycle of Sterrad® 100NX Steriliser (from Advanced Sterilization Products, Inc.). Validated for 20 cycles by Advanced Sterilization Products, Inc., Irvine, CA, USA. **Note:** The device must be cleaned, rinsed and dried in accordance with the instructions for the use of the steriliser. Refer to the Sterrad® 100NX Operation Manual for proper operation of the unit and cycle selection. **Steris V-PRO®** Sterilisation can be performed in the following: • V-PRO® 1 Low temperature Sterilization System Standard Cycle. • V-PRO® 1 Plus Low Temperature Sterilization System Lumen and Non Lumen Cycles. • V-PRO® maX Low Temperature Sterilization System Lumen, Non Lumen and Flexible Cycles. • V-PRO® maX Low Temperature Sterilization System Lumen, Non Lumen, Flexible and Fast Non Lumen Cycles. • V-PRO® 60 Low Temperature Sterilization System Lumen, Non Lumen, and Flexible Cycles. • V-PRO® s2 Low Temperature Sterilization System Lumen, Non Lumen, Flexible and Fast Cycles. Validated for 50 cycles by STERIS Corp., Mentor, OH, USA. **Note:** The device must be cleaned, rinsed and dried in accordance with the instructions for the use of the steriliser. Refer to the STERIS Operation Manual for proper operation of the unit and cycle selection. **Note:** Sterilisation methods other than those described above could damage the probe and cable, void the warranty and could result in injury to the operator or patient.

Storage	**Storage Temperature:** 10 - 40˚ C (50˚ F to 104˚ F) **Storage Relative Humidity** 30% - 75%, non-condensing
Additional Information	**Important Note: THE CABLE AND PROBE SHOULD BE COVERED BY A STERILE DRAPE WHEN USED IN SURGERY.** The probe cable may be used in a sterile field after a sterile drape is placed over the probe and cable. Sterile drapes are available from medical supply companies that will allow use with a trocar sheath or cannula. The suggested installation sequence of a sterilised probe into a sterile drape is as follows: a) A professional in the sterile field (i.e. a scrub nurse) holds the sterilised OmniProbe® device and the sterile drape. b) A professional outside the sterile field (i.e. a circulating nurse) holds the cable. c) The scrub nurse inserts the probe into the drape and passes the rear end of the drape (without pulling it out to its full length) to the circulating nurse. d) The circulating nurse takes the rear end of the drape in one hand and the cable in the other hand, reaches into the un-extended drape with the cable and inserts the cable connector into the OmniProbe connector. e) The circulating nurse then pulls the drape up the cable to its full length, and connects the cable to the C-Trak Analyser.
Manufacturer Contact	Southern Scientific Ltd. (Europe and RoW) E-mail: info@southernscientific.co.uk Telephone: +44 1273 497600 LabLogic Systems, Inc. (USA) E-mail: sales@carewise.com Telephone: +1 813 626 6848

5.2 Apollo Handset

Manufacturer: Southern Scientific Limited **Device:** Care Wise C-Trak® Apollo Wireless Hanset and USB Cable	
WARNINGS	Apollo Wireless Handset accessories sold with the C-Trak system are sold as non-sterile devices and must always be used within a sterile drape. Sterilisation of the handsets is possible, but optional, and can be used as an extra precaution if necessary; please see further information regarding the validated sterilisation methods in the table below. **DO NOT AUTOCLAVE** the handset. Steam or dry heat sterilisation will damage the gamma probe and cable, void the warranty and could result in injury to the operator or patient. **DO NOT IMMERSE** the handset or cable connections in liquids. **IF STERILISED, THE HANDSET MUST BE PROCESSED WITH THE OMNIPROBE IN PLACE.**
Limitations on processing	There are no known restrictions on number of processing cycles.

INSTRUCTIONS	
Initial treatment at the point of use	Cleaning before first use must be performed. Further details are given in the Cleaning: Manual section below.
Preparation before cleaning	The handset USB cable (when fitted) should be removed prior to cleaning and cleaned separately. **Important Note: The handset MUST be processed with an OmniProbe attached and switched OFF.** 
Cleaning: Automated	Automated cleaning should not be performed on the device.
Cleaning: Manual	**1) Before First Use and Routine Cleaning** The Apollo device and accessories should be regularly cleaned to prevent build-up of dirt and detritus and as part of pre- and post-operative processing. To clean the device, ensure it is switched off and wipe gently with a non-abrasive cloth with a mild detergent or IPA solution (70% v/v) or equivalent disposable wipes (e.g. Clinell Universal Wipes). When Cleaning the Omniprobe, make sure to remove the collimator and clean the nosepiece. **Note:** Do not use any cleaning solution on any connector or ports. Ensure the device is fully dry before use or reconnecting any accessory or probe. Refer to the warnings section above. **2) Cleaning to remove potential radioactive contamination** Potential contamination from radioactive material will be indicated by an increase in the measured background count rate (i.e. with no radioisotope in the region of the probe). a) Remove the sterile drape from the probe/handset – the background count rate should return to normal levels (no greater than 1-2 cps). b) If, after removing the sterile drape from the probe/handset, the system still indicates a high background, shut down the system. c) Use a disposable pan or vessel to contain the liquid required to complete the cleaning process The liquid, disposal wipes, and any other material that will contact the liquids used in the decontamination process must be assumed to be radioactive. These materials and liquids must be handled and disposed of as per your institution's licence agreements with national state or federal regulatory agencies. Consult with your radiation safety officer for guidance. d) Use a commercially-available decontaminating product (e.g. Bind-It™ Radioactive Decontamination products) to clean the probe/handset. Rinse the probe several times with distilled water. **DO NOT** rinse the handset with distilled water. **Note:** Make certain that the connector within the distal end of the probe handle is absolutely dry before inserting the cable connector into the probe or the Apollo handset. **NEVER** immerse the connector ends of the probe cable in liquid. e) Dry the probe/handset thoroughly with a disposable wipe and leave to air dry. It is extremely unlikely that the probe cable will become contaminated; however, if it does, the same procedure as above can be followed. f) Reconnect the cable and probe and turn on the C-Trak Apollo System. If the system is still indicating a high background, turn the system off and repeat the steps above. If the system still indicates a high background, contact nuclear medicine or biomedical engineering for evaluation. The probe may have been damaged.

C-Trak Apollo

Disinfection	To disinfect the device, ensure it is switched off and wipe gently with a non-abrasive cloth with a mild disinfectant or IPA solution (70% v/v) or equivalent disposable wipes, e.g. Clinell Universal Wipes. The collimator should be removed from the OmniProbe body to allow the nosepiece to be disinfected. **Note:** Do not use any disinfectant solution on any connector or ports. Ensure the device is fully dry before use or reconnecting any cable, accessory or probe. Refer to the warnings section above.
Drying	For the Tristel Trio Wipes system, upon completion of the decontamination cycle, the device should be left to air dry. Store the device in accordance with hospital protocols to prevent damage or recontamination.
Maintenance, Inspection and Testing	See the C-Trak Apollo IFU for System Test information. Handsets and cables should be inspected visually prior to any processing operation being undertaken for any signs of degradation, surface corrosion or damage.
Packaging	There are no specific methods for packaging or containing the medical device during and/or after processing. All probes in the C-Trak® family of probes are operated while sheathed in a sterile disposable sleeve such as those commonly used with ultrasound probes or laparoscopic cameras. **CAREFULLY FEED PROBE/HANDSET AND CABLE (WHERE USED) INTO SHEATH. DO NOT DROP PROBE/HANDSET INTO SHEATH.**
Sterilisation	**ASP Sterrad® 100NX** A full DUO cycle of Sterrad® 100NX Steriliser (from Advanced Sterilization Products, Inc.). Validated for 50 cycles by Advanced Sterilization Products, Inc., Irvine, CA, USA. **Note:** The device must be cleaned, rinsed and dried in accordance with the instructions for the use of the steriliser. Refer to the Sterrad® 100NX Operation Manual for proper operation of the unit and cycle selection. **Steris V-PRO®** Sterilisation can be performed in the following: • V-PRO® 1 Low temperature Sterilization System Standard Cycle. • V-PRO® 1 Plus Low Temperature Sterilization System Lumen and Non Lumen Cycles. • V-PRO® maX Low Temperature Sterilization System Lumen, Non Lumen and Flexible Cycles. • V-PRO® maX Low Temperature Sterilization System Lumen, Non Lumen, Flexible and Fast Non Lumen Cycles. • V-PRO® 60 Low Temperature Sterilization System Lumen, Non Lumen, and Flexible Cycles. • V-PRO® s2 Low Temperature Sterilization System Lumen, Non Lumen, Flexible and Fast Cycles. Validated for 100 cycles by STERIS Corp., Mentor, OH, USA. **Note:** The device must be cleaned, rinsed and dried in accordance with the instructions for use of the steriliser. Refer to the STERIS Operation Manual for proper operation of the unit and cycle selection. **Note:** Sterilisation methods other than those described above could damage the probe and cable, void the warranty and could result in injury to the operator or patient.
Storage	**Storage Temperature:** 10 - 40° C (50° F to 104° F) **Storage Relative Humidity** 30% - 75%, non-condensing

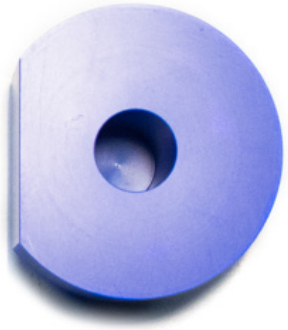
Additional Information	**Important Note: THE CABLE AND PROBE SHOULD BE COVERED BY A STERILE DRAPE WHEN USED IN SURGERY.** The probe cable may be used in a sterile field after a sterile drape is placed over the probe and cable. Sterile drapes are available from medical supply companies that will allow use with a trocar sheath or cannula. The suggested installation sequence of a sterilised probe into a sterile drape is as follows: a) A professional in the sterile field (i.e. a scrub nurse) holds the sterilised OmniProbe®/Apollo device and the sterile drape. b) A professional outside the sterile field (i.e. a circulating nurse) holds the cable. c) The scrub nurse inserts the probe into the drape and passes the rear end of the drape (without pulling it out to its full length) to the circulating nurse. d) The circulating nurse takes the rear end of the drape in one hand and the cable in the other hand, reaches into the un-extended drape with the cable and inserts the cable connector into the OmniProbe connector. e) The circulating nurse then pulls the drape up the cable to its full length, and connects the cable to the C-Trak Analyser.
Manufacturer Contact	Southern Scientific Ltd. (Europe and RoW) E-mail: info@southernscientific.co.uk Telephone: +44 1273 497600 LabLogic Systems, Inc. (USA) E-mail: sales@carewise.com Telephone: +1 813 626 6848

5.3 Apollo Check Source Holder

Manufacturer: Southern Scientific Limited **Device:** Care Wise C-Trak® Check Source Holder	
WARNINGS	Check Source Holders accessories sold with the C-Trak system are sold as non-sterile devices. Sterilisation of the check source holder is possible, but optional, and can be used as an extra precaution if necessary; please see further information regarding the validated sterilisation methods in the table below. **DO NOT AUTOCLAVE** the Check Source Holder. Steam or dry heat sterilisation will damage the holder, void the warranty and could result in injury to the operator or patient. **DO NOT PROCESS THE SOURCE – REMOVE FROM THE HOLDER.** 
Limitations on processing	There are no known restrictions on number of processing cycles.

INSTRUCTIONS	
Initial treatment at the point of use	Cleaning before first use must be performed. Further details are given in the Cleaning: Manual section below.

C-Trak Apollo

Preparation before cleaning	**Important Note: The Check Source Holder should be split into its two parts and the source removed and stored safely and securely prior to any cleaning or sterilisation operations being performed.**  
Cleaning: Automated	Automated cleaning can be performed on the check source holder but has not been validated against any particular system or process. **Important Note: The ^{57}Co source must be removed before any automated cleaning process.**
Cleaning: Manual	**1) Before First Use and Routine Cleaning** The Apollo device and accessories should be regularly cleaned to prevent build-up of dirt and detritus and as part of pre- and post-operative processing. To clean the source holder, the ^{57}Co check source must be removed from the source holder before it can be cleaned. Ensure that the source holder is fully dry before placing the ^{57}Co check source back inside. To clean, wipe gently with a non-abrasive cloth with a mild detergent or IPA solution (70% v/v) or equivalent disposable wipes (e.g. Clinell Universal Wipes). **2) Cleaning to remove potential radioactive contamination** Potential contamination from radioactive material will be indicated by an increase in the measured background count rate (i.e. with no radioisotope in the region of the probe/handset). a) Split the two halves of the Check Source Holder and store the ^{57}Co check source safely. b) Use a disposable pan or vessel to contain the liquid required to complete the cleaning process. The liquid, disposal wipes, and any other material that will contact the liquids used in the decontamination process must be assumed to be radioactive. These materials and liquids must be handled and disposed of as per your institution's licence agreements with, national, state or federal regulatory agencies. Consult with your radiation safety officer for guidance. c) Use a commercially-available decontaminating product (e.g. Bind-It™ Radioactive Decontamination products) to clean the Check Source. d) Dry the holder parts thoroughly with a disposable wipe and leave to air dry.
Disinfection	To disinfect the device, ensure that the ^{57}Co check source has been removed and wipe gently with a non-abrasive cloth with a mild disinfectant or IPA solution (70% v/v) or equivalent disposable wipes, e.g. Clinell Universal Wipes. **Note:** Ensure the device is fully dry before use or refitting the ^{57}Co check source. Refer to the warnings section above.
Drying	Upon completion of any cleaning/decontamination cycle, the device should be left to air dry. Store the device in accordance with hospital protocols to prevent damage or recontamination.
Maintenance, Inspection and Testing	See the C-Trak Apollo IFU for System Test information. The Check Source Holder parts should be inspected visually prior to any processing operation being undertaken for any signs of degradation, surface corrosion or damage.
Packaging	There are no specific methods for packaging or containing the holder accessory during and/or after processing.

Sterilisation	**ASP Sterrad® 100NX** A full DUO cycle of Sterrad® 100NX Steriliser (from Advanced Sterilization Products, Inc.). Validated for 50 cycles by Advanced Sterilization Products, Inc., Irvine, CA, USA. **Note:** The device must be cleaned, rinsed and dried in accordance with the instructions for the use of the steriliser. Refer to the Sterrad® 100NX Operation Manual for proper operation of the unit and cycle selection. **Steris V-PRO®** Sterilisation can be performed in the following: • V-PRO® 1 Low temperature Sterilization System Standard Cycle. • V-PRO® 1 Plus Low Temperature Sterilization System Lumen and Non Lumen Cycles. • V-PRO® maX Low Temperature Sterilization System Lumen, Non Lumen and Flexible Cycles. • V-PRO® maX Low Temperature Sterilization System Lumen, Non Lumen, Flexible and Fast Non Lumen Cycles. • V-PRO® 60 Low Temperature Sterilization System Lumen, Non Lumen, and Flexible Cycles. • V-PRO® s2 Low Temperature Sterilization System Lumen, Non Lumen, Flexible and Fast Cycles. Validated for 100 cycles by STERIS Corp., Mentor, OH, USA. **Note:** The device must be cleaned, rinsed and dried in accordance with the instructions for use of the steriliser. Refer to the STERIS Operation Manual for proper operation of the unit and cycle selection. **Note:** Sterilisation methods other than those described above could damage the probe and cable, void the warranty and could result in injury to the operator or patient.
Storage	**Storage Temperature:** 10 - 40˚ C (50˚ F to 104˚ F) **Storage Relative Humidity** 30% - 75%, non-condensing
Additional Information	The Check Source Holder may be used in a sterile field in conjunction with an OmniProbe and Apollo handset (latter where used) after a sterile drape is placed over the probe, handset and/or cable. Sterile drapes are available from medical supply companies that will allow use with a trocar sheath or cannula. The suggested System Test operation using a sterile Source Holder and probe/handset is as follows: a) The Check Source Holder will have been processed in two halves and held by a professional in the sterile field (e.g. scrub nurse). b) A professional outside the sterile field (i.e. a circulating nurse) holds the check source and places it into the blue section of the sterile holder. c) The scrub nurse screws the grey section of the holder into the blue section and can then insert the sheathed probe with cable or handset into holder well. d) The circulating nurse can then perform the System Test using the Apollo software. e) Once the System Test is complete, the Check Source Holder can be placed aside in a safe location. **Important Note: The Check Source Holder must be split and the source removed before any subsequent processing operation is undertaken**
Manufacturer Contact	Southern Scientific Ltd. (Europe and RoW) E-mail: info@southernscientific.co.uk Telephone: +44 1273 497600 LabLogic Systems, Inc. (USA) E-mail: sales@carewise.com Telephone: +1 813 626 6848

The instructions provided above have been validated by the manufacturer of the medical device as being capable of preparing a medical device for reuse. It remains the responsibility of the processor to ensure that the processing, as actually performed using equipment, materials and personnel in the processing facility, achieves the desired result. This requires verification and/or validation and routine monitoring of the process. **Date issued:** January, 2022

6.0 Safety Considerations

6.1 Error Messages

Appendix C describes the various error messages that may appear if the C-Trak® Apollo System detects any malfunction. In the event of an error message, select YES to continue use of the Apollo System. If the message continues to appear, call Care Wise for guidance.

6.2 Power Supply Requirements

The power supply included with the C-Trak® Apollo system is rated for 100 V-240 V AC. Do not attempt to use the Apollo system with any voltage below 100V or above 240 V. The power supply included with the Apollo system transforms the incoming AC current and provides the system with 12 V DC current at a maximum of 8.33 A.

CAUTION: Use only a power supply and power cord provided by Care Wise specifically for the C-Trak® Apollo System to prevent the occurrence of shock, fire or product damage.

6.3 Disassembly

Do not attempt to disassemble or otherwise service the probe, analyzer unit, or power supply. There are no user-serviceable parts.

DISASSEMBLY VOIDS THE WARRANTY AND TRANSFERS ALL CONTINGENT LIABILITY TO THE INDIVIDUAL AND INSTITUTION INVOLVED.

6.4 Lithium-Ion Battery Care and Maintenance

The Apollo wireless handset contains a rechargeable Lithium-Ion battery.

Lithium-Ion rechargeable batteries require routine maintenance and care in their use and handling. Please read and follow the guidelines in this section to safely use the Lithium-Ion batteries contained within the handset and hence achieve the maximum battery lifespan.

Overview

Do not leave Apollo handsets containing batteries unused for extended periods of time. When a handset has been unused for 6 months, check the charge status and charge accordingly. The charge status is indicated in the top, left-hand corner of each main screen in the Apollo software.

The typical estimated life of a Lithium-Ion battery is about two to three years or 300 to 500 charge cycles, whichever occurs first. One charge cycle is a period of use from fully charged, to fully discharged, and fully recharged again.

Rechargeable Lithium-Ion batteries have a limited life and will gradually lose their capacity to hold a charge. This loss of capacity (aging) is irreversible. As the battery loses capacity, the length of time it will power the Apollo handset decreases.

Lithium-Ion batteries continue to slowly discharge (self-discharge) when not in use or while in storage. Routinely check the battery's charge status via the Apollo software.

Maintenance

Routinely check the handset battery's charge status via the Apollo software – this will be displayed as a percentage value.

Use the supplied charging dock and wall-plug charger to charge the handset as the primary means of charging. The USB connection into the PC base unit should only be used to trickle-charge the handset battery in emergency situations and not to charge the battery fully.

Further details on low battery level indications may be found in Appendix C (Figure 36).

Please contact Care Wise Support to arrange for the handset battery to be replaced with a new one if you note either of the following conditions:

1) The battery run time drops below about 80% of the original run time (typically 4 hours' continuous use when new).
2) The battery charge time increases significantly (typically 2-4 hours, depending on the charge conditions).

Important Note: The handset battery cannot be changed by the user and must be performed by the manufacturer.

If a handset with battery is stored or otherwise unused for an extended period, be sure to follow the storage instructions in this section. If you do not follow the instructions, and the battery has no charge remaining when you check it, consider it to be damaged. Do not attempt to recharge it or to use it. Contact Care Wise Support as soon as possible to replace the battery.

Charging

When the system is not in use, the Apollo Handset can be charged via the supplied charging dock and wall-plug USB power supply. The handset may be placed into the dock with the keypad facing the front so that the micro-USB port on the base of the handset engages with the equivalent connector on the dock.

A flashing blue LED at the base of the handset will indicate that the charging status; when fully charged, the LED will illuminate steady blue.

A flashing blue LED at the base of the handset will indicate that the charging status; when fully charged, the LED will illuminate steady blue.

In an emergency situation, the handset can also be charged via a USB port on the underside of the PC base unit; however, this method should not be used as the default method of charging the handset.

Only the supplied charging devices should be used to charge the battery of the Apollo Handset. THIRD PARTY-SUPPLIED CHARGERS MUST NOT BE USED.

Storage

Charge or discharge the battery to approximately 66% of capacity before storage for prolonged periods.

Charge the battery to approximately 66% of capacity at least once every six months if the handset is not to be used for a prolonged period.

Store the handset including the battery at temperatures between 10 °C and 40 °C (50 °F and 104 °F).

Note: The battery self-discharges during storage. Higher temperatures (above 50 °C or 122 °F) reduce the battery storage life.

Handling Precautions

Do not disassemble, crush, or puncture a battery.

Do not short the external contacts on a battery if visible.

Do not dispose of a battery in fire or water.

Do not expose a battery to temperatures above 60 °C (140 °F).

Keep the battery away from children.

Avoid exposing the battery to excessive shock or vibration.

Do not use a damaged battery.

If a battery pack has visible leaking fluids from the handset, do not touch any fluids. Dispose of a leaking battery pack (see Disposal and Recycling).

In case of eye contact with fluid, do not rub eyes. Immediately flush eyes thoroughly with water for at least 15 minutes, lifting upper and lower lids, until no evidence of the fluid remains. Seek medical attention.

Disposal and Recycling

Lithium-Ion batteries are subject to disposal and recycling regulations that vary by country and region. Always check and follow your applicable regulations before disposing of any battery. In the UK and Europe, WEEE Regulations should be followed. Contact Rechargeable Battery Recycling Corporation (www.rbrc.org) for U.S.A. and Canada, or your local battery recycling organisation.

Many countries prohibit the disposal of waste electronic equipment in standard waste receptacles.

6.5 Radioactive Concerns

All radioactive isotopes and/or material, drapes, liquids, cleaning materials, etc., that come in contact with a radioisotope, or item that is contaminated with a radioisotope, must be handled as per your institution's radiation rules and regulations. Consult with your Radiation Safety Officer for guidance concerning the use and disposal of radioactive material. See Appendix G for disposal information provided by the manufacturer of the Care Wise provided Cobalt 57 and/or Sodium 22 Check Source.

6.6 Use of Electrosurgical Devices

Electrosurgical and other electrocautery devices can emit excess electromagnetic noise that may cause the C-Trak® analyzer to record false counts if these devices are used to cut or cauterize concurrent with the probe's use in surgical exploration.

6.7 Use of Accessory Equipment

Only the accessories as defined in Section 8 should be used with this device.

6.8 Probe Handling Guidelines

Treat the probe as you would any expensive, delicate, surgical instrument.

The probe is not a solid bar of metal. Inside are two crystals and a photomultiplier tube. If the probe is dropped or hit sharply against something hard, it can break.

PLEASE Handset THE PROBE CAREFULLY!

DO NOT PLACE C-TRAK® PROBES ON OR NEAR A MAGNETIC INSTRUMENT PAD OR MAT. The magnetic field can permanently degrade probe components and diminish performance.

CAUTION: The C-Trak® system is not intended for use in the presence of flammable anesthetics or other explosive gases. There is a risk of explosion if the Apollo System is used in the presence of flammable gases.

7.0 Technical Specifications

7.1 Power / Probe Overload Cutoff

The Apollo CW4000 system is classified by the U.S. Code of Federal Regulations as a Class I device. In Europe the Apollo system is classified as a Class IIa device. In Canada it is Class II.

Power is provided to the Apollo CW4000 system via a Hospital Grade external power supply included with the purchased system:

- External, Universal AC input (100-240 vac 47-63 hz), 100 watts, DC-out: 12 V, 8.33 A.
- For U.S. applications, the AC mains plug is Hospital Grade, NEMA 5-15P-HG
- Contact Care Wise or your Care Wise distributor to supply or replace the proper AC mains plug/cable for your application or governmental/country requirements.
- The guidelines set forth by your recognized National Certification Body (NCB) may require additional certification. If required, contact Care Wise or your Care Wise distributor for assistance.

CAUTION: Use only a power supply provided by Care Wise specifically for the C-Trak® Apollo System to prevent the occurrence of shock, fire or product damage.

Bias voltage supplied to the probe is generated by a stable, high voltage supply embedded within the C-Trak® Apollo system. The voltage is set at 900 vdc and the current is always less than 10 µA. Any current exceeding this threshold will immediately turn OFF this voltage. The system can only be turned back ON via direct user interaction as directed by the displayed error message. Unauthorized attempts to repair the probe, cable or the C-Trak® Apollo computer system can result in a minor electrical shock.

Neither the external power supply nor the power supply inside the computer are serviceable by the user.

CAUTION: Use only the hospital grade power supply and power cord provided by Care Wise. The use of any other power supply or power cord may cause harm to the user, damage the equipment and void the warranty. Contact Care Wise for repair or replacement parts.

Automatic shutoff is a safety feature of the C-Trak® Apollo system. Ten micro amperes (10 µA) is the international standard for the maximum allowable leakage current from a medical device operating off of an external power source that contacts a patient's body during use. If current greater than 10 µA were to flow to the probe, the C-Trak® Apollo system would immediately shut off all current to the probe to prevent any risk to patient or surgeon. A warning dialog would then appear on screen instructing the user how to proceed safely.

7.2 LCD Display

The 17" LCD Resistive Touch display is integral to the C-Trak® Apollo CW4000 System. The screen is sensitive to finger pressure and does not require a stylus. Resolution is 1280 x 1024.

7.3 Probe Connector

Series 'MHV' coaxial connector for ALL probes
[CAUTION: This is NOT a "BNC" style connector.]

7.4 Size

420 mm (W) x 360 mm (H) x 80 mm (D)

7.5 Weight

Approximately 7 kg (15.4 lbs).

7.6 Finish

Anti-bacterial coated plastic.

7.7 Mode of Operation

Continuous operation.

7.8 Serial Numbers

The serial number of the analyzer is located on the back of the unit on the Product Label. The serial number for the probe is engraved on the side of the probe at the base of the probe body, near the cable connection.

7.9 Environmental Limits

Operational Temperature	10-40° C (50° F to 104° F)
Storage Temperature	10-40° C (50° F to 104° F)
Operation Relative Humidity	30% - 75%, non-condensing
Storage Relative Humidity	30% - 75%, non-condensing
Atmospheric Pressure	700 hPa to 1060 hPa
Operational Altitude	less than 2000 meters (~6000 ft)

7.10 Label Legibility

In normal use, the operator of the CW4000 views the product from the front, facing the computer screen usually at a distance no greater than nine (9) feet. The ID/Serial Number Label is on the rear of the product and is intended to be viewed in a normal, room lighting environment (500 lux or greater) by a person with a visual acuity (corrected, if necessary) of 20/20 at a distance of approximately 12-18 inches (a normal reading distance). Aside from the serial number, the information included on this label is also available in the printed User's Guide (included with each product).

8.0 Use of Optional Accessories

8.1 Apollo Handset

The Apollo Wireless Handset has been designed to permit operation of the Apollo system without the need to have a physical cable between the OmniProbe and analyzer unit. The Apollo Handset processes the same count rate information as that processed within the analyzer. The handset contains all the necessary electronics to power the OmniProbe and operate for up to four hours continuously. The system has been designed such that the system may be operated between cabled and optionally non-cabled modes interchangeably. More information of setting up the Apollo Handset is given in Sections 1.2 and 2.4.

In addition to operation via Bluetooth® wireless technology, the Apollo Handset can also communicate with the analyzer via USB. The micro-USB cable can be inserted into the base of the Apollo Handset for the purposes of charging or to operate the probe communications with the PC via USB rather than Bluetooth.

Figure 31 – Probe Charger

8.2 Apollo Charging Dock and Plug-In Charger

When the system is not in use, the Apollo Handset can be charged via the supplied handset charging dock. The handset may be placed into the dock with the keypad facing the front so that the micro-USB port on the base of the handset engages with the equivalent connector on the dock. The charging dock USB plug may be placed in one of the available USB ports located on the bottom of the analyzer PC unit.

A wall-mounted charger is also supplied for charging the battery of the Apollo Handset if the charging dock is unavailable. If an Apollo wireless handset becomes fully discharged, the approximate charge times to achieve a fully charged battery are approximately four (4) hours if charged via the USB port on the control PC or two (2) hours if charged via the Apollo handset charging dock or plug-in charger.

WARNING! Only the supplied charging devices should be used to charge the battery of the Apollo Handset. THIRD PARTY-SUPPLIED CHARGERS MUST NOT BE USED.

8.3 C-Trak® Apollo System Cart

To ensure that all system components are neatly and securely stored, Care Wise offers a sturdy wheeled C-Trak® Apollo System Cart. The analyser is mounted directly onto the cart support plate. An accessory tray with foam insert is used to store the probes, check sources and holders; an optional shelf may be used to mount a printer if required.

IMPORTANT SAFETY NOTE: The system cart must only be manoeuvred using the rear-mounted handset and not pushed from other points in the system. The positions of the accessory tray and shelf (if fitted) are fixed and must not be modified. When the cart is in position, all four wheel brakes must be engaged.

Cart Specifications

Mass of cart (including printer shelf and accessory bin): 18.0 kg

Mass of cart (as above and including PC screen): 23.5 kg

Maximum permissible load for accessory bin:
1.5 kg (Apollo accessories only)

Maximum permissible load for printer shelf:
2.0 kg (recommended Apollo Printer only)

C-Trak® Apollo System with cart.

8.4 Foot Pedal

An optional USB Foot Pedal can be supplied with the analyzer which allows the timed counts operation [Section 2.4-2] to be started by depressing the foot pedal instead of pressing the touch screen button or the equivalent button on the keypad of the Apollo Handset.

8.5 Printer

Care Wise offers an optional printer for hardcopy output of results. Printer software is preloaded in the C-Trak® Apollo System. Attach the printer cable to any of the four USB ports on the bottom panel of the analyzer unit. [See Figure 2.] Use only Care Wise approved accessories in the USB ports. See Section 2.2.

The printer is powered from the AC mains and is supplied with a standard US style AC plug set. Contact Care Wise or your Care Wise distributor to supply or replace the proper AC mains plug/cable for your application or governmental/country requirements.

Printer supplies (ink cartridges) are available from your local computer/printer supply outlet, the printer manufacturer or from Care Wise.

8.6 Lechner Collimator

Care Wise provides a standard technetium collimator on the OmniProbe® with a 39° angled nose and a .270" aperture. The accessory Lechner collimator is designed with a 30° angled nose and a .200" aperture. The Lechner collimator is designed for conditions of high background radiation levels. Using the specialized Lechner collimator can be a major advantage in certain types of clinical cases.

The removable collimators add additional directionality but decrease sensitivity due to the narrower aperture. When a collimator is used, it must be firmly attached to the probe to avoid injury to the operator or patient. To attach, keep the nose aperture open to prevent air pressure that impedes installation and click the slide-on collimator firmly in place.

Other special collimators can be made available by special order. Call Care Wise on +1-813-626-6848 (US & Canada) +44 (0)1273 497600 (Europe & Worldwide) for e-mail support@carewise.com for information and advice as needed.

9.0 International Symbols

Information, Consult Accompanying Documents (User's Guide)

Equipment not suitable for use in the presence of a flammable mixture with air or with oxygen or nitrous oxide

Medical – General Medical Equipment as to electrical shock, fire and mechanical hazards only in accordance with ANSI/AAMI ES60601-1: A1:2012, CAN/CSA-C22.2 No. 60601-1:14 <48ZK>

CE 1434 Conformity with the MDD has been confirmed and approved by the Notified Body PCBC. Registration Number: 1434

CE The CE mark with the number applies to the PC unit only

Degree of protection against electric shock:
Type B Applied Part (OmniProbe® Family of Probes)

Protective Earth Ground Protection against Electric Shock:
Class 1 Equipment

Manufacturer's Site:
Southern Scientific

Date of Manufacture

NON STERILE Product is shipped in a non-sterile state

10° 40° Temperature Limits (°C)

30 75 Humidity Limits

700 10(Atmospheric Pressure (hPa)

"Man Reading Book"
Consult Accompanying Documentation for Mandatory Information

If you wish to discard electrical and electronic equipment (EEE), please contact the manufacturer or local distributor. This symbol is only valid in the European Union (EU). If you wish to discard this product, please contact your local authorities or distributor and ask for the correct method of disposal.

No pushing. System must only be moved when mounted on a cart using the fitted handset.

DANGER Contains HV Circuit.

EC REP Indicates the Authorised Representative in the EU.

Appendix A

Warranty

Care Wise warrants all new analyzers, probes, and related products addressed in this User Guide to be free of defects due to workmanship, materials and design for a period of twenty-four months from date of delivery. Refurbished products are warranted for one year. Repaired product is warranted for ninety days.

Damage resulting from misuse by the owner or its agent(s) will be the sole responsibility of the owner and is not covered under warranty.

In the event of instrument failure, the owner must notify Care Wise for repair or replacement. Liability of this warranty is limited to the purchase price of the instrument. Electrical safety must be periodically checked at the hospital in which this device is used in accordance with the Joint Commission standards and procedures.

User servicing or disassembly of any portion of this system voids the warranty. The individual performing unauthorized disassembly and the owner of the system assume sole liability for damage to the system and any consequential damages.

Receiving Condition Examination

Owner is responsible for inspecting the shipping carton for visible damage when it is delivered by the carrier. If damage to the shipping carton is visible the carrier should be notified immediately that the carton was received in damaged condition.

If damage to the equipment is visible, save the shipping container and the packing material and request an immediate inspection by the carrier.

Care Wise is not responsible for any damage that occurs during shipment. Please contact our office if we can be of assistance in resolving a damage claim with the carrier.

Return of Goods to Manufacturer

All equipment being returned for repair or evaluation, whether under warranty or not, must receive return authorization from Care Wise or your local international distributor prior to shipment and be assigned an RMA number. The C-Trak® instrument must be returned in the original shipping container (box) or in a container that will adequately protect the product. Do NOT ship in just the carrying case! All shipments should include documentation containing customer name, shipping address, telephone number and any other necessary information. Please call if there are any questions regarding the packing material and cartons.

A Purchase Order, signifying customer authorization, must be provided before repair or rework is performed.

Equipment being returned, for any reason, MUST be clean and disinfected. A completed copy of the Care Wise Proof of Cleaning Statement [Appendix E], must be signed and accompany any returned product. Items returned without this form, as well as any items deemed to be contaminated, may be returned at the expense of the party returning the equipment or be assessed a charge of £150 for cleaning/disinfecting by Care Wise.

Repair of C-Trak® Products Statement

New and/or manufacturer-refurbished C-Trak® Products are only available for sale directly from Care Wise or one of the Care Wise licensed distributors or sales representatives. Care Wise is also the sole source for authorized, proper, and responsive repair, rework, and remanufacture of the C-Trak® Products.

Care Wise, and only Care Wise, has a full understanding of the manufacture, operation and performance of the C-Trak® Products. Full working knowledge and understanding, including tolerances, specifications, performance requirements, and product history of each of the specific machined, molded, and assembled components and subassemblies of the C-Trak® Products, are known only to Care Wise, and are proprietary to Care Wise.

Care Wise will support the repair and maintenance of the Apollo product for seven years after purchase of the system. Care Wise will endeavor to satisfactorily repair these systems after this period, but cannot guarantee the availability of components or manufacturer support. Due to the nature of computer manufacturers, their product support history and in keeping with state-of-the-art design upgrades, the stated useful life of this product is seven years.

Any unauthorized servicing, disassembly, or attempted repair or rebuilding of a C-Trak® Product by the customer owning the Product, or a third party, voids the warranty of the entire C-Trak® System. Please see the Product Warranty.

Service Contracts

Care Wise offers Service Contracts that further assure the proper upkeep and performance of the C-Trak® products. The Service Contract includes a discount on repair charges, free loaners and one PM (Preventive Maintenance) per yearly subscription. Please contact Care Wise for further information.

Appendix B

Troubleshooting

The meter moves but there is no sound

1. The volume may be turned down. To adjust the volume on the system press the volume buttons located on the front panel.
2. The range selected does not detect the radioisotope present. Lower the Range using the Range Selections.

Connection error or no counts or sound

1. Check that probe connector is “turned and locked” in place. If not, re-connect, select “YES” on error message and try again.
2. Check that analyzer has the proper probe and isotope selected for use. If not, select proper probe and isotope and try again.
3. Check that you get counts with a known source of radiation (i.e. A valid Check Source) held against nose of probe. If yes, then problem may be with radiopharmaceutical administration or distribution. If no, the probe may be damaged. Call Care Wise for assistance.

Erratic counts or intermittent counts

1. There may be electrical interference. Remove offending sources of interference.
2. There may be magnetic interference. Do not use the gamma probe near a magnetic pad or mat.
3. The probe could be contaminated with radioactivity. Follow the instructions in Section 5.3 to decontaminate the probe.
4. The probe could be damaged. Call Care Wise for assistance.

Any other questions or concerns

Contact Care Wise on +1-813-626-6848 (US & Canada) +44 (0)1273 497600 (Europe & Worldwide) or e-mail support@carewise.com for information and advice as needed.

Appendix C

Error Messages

Probe or Apollo Device Disconnected – [Figure 32] Information: USB/Bluetooth communications have been disconnected; reconnect the Apollo Handset (Bluetooth or USB) and press 'OK'.

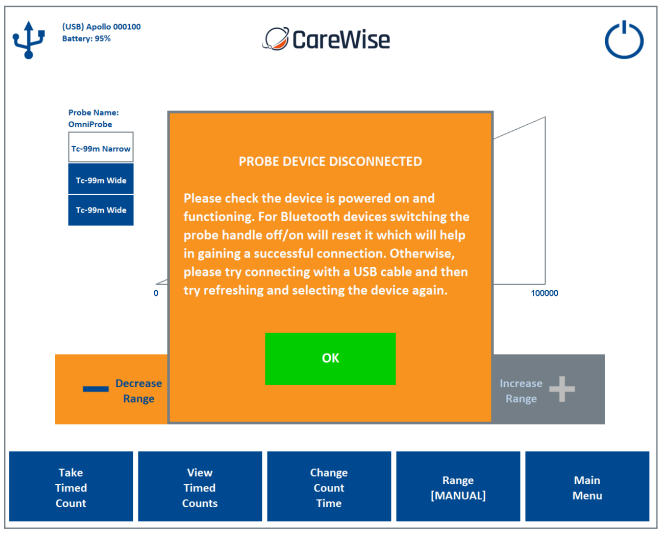


Figure 32 – Connection Error Message

Probe Disconnected – [Figure 33] Warning: The OmniProbe has become disconnected from the Apollo Handset or probe cable. The Probe Disconnection Error will appear if the probe or cable is disconnected from the analyzer. Reconnect the probe and select 'Yes' to continue.

If this error continues to appear, the probe may be damaged. Contact Care Wise on +1-813-626-6848 (US & Canada) +44 (0)1273 497600 (Europe & Worldwide) or e-mail support@carewise.com for assistance.

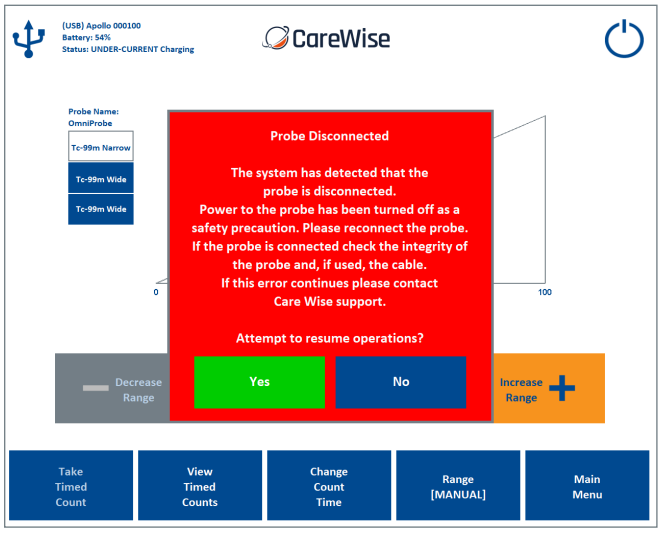


Figure 33 – Probe Disconnected

Current or High Voltage Errors – [Figures 34 and 35] These errors will appear if the system detects a short circuit in the probe or cable. Check the probe and cable for damage, and select 'Yes' to continue if there is no visible damage.

If these errors continue to appear, the probe may be damaged. Contact Care Wise on +1-813-626-6848 (US & Canada) +44 (0)1273 497600 (Europe & Worldwide) or e-mail support@carewise.com for assistance.

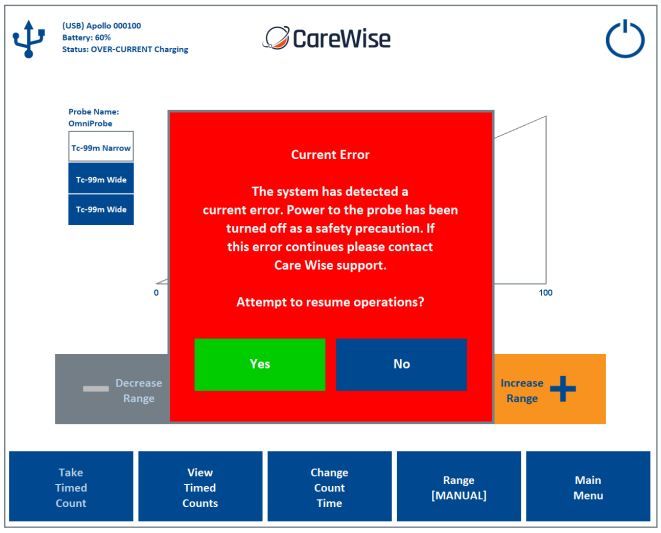


Figure 34 – Current Error

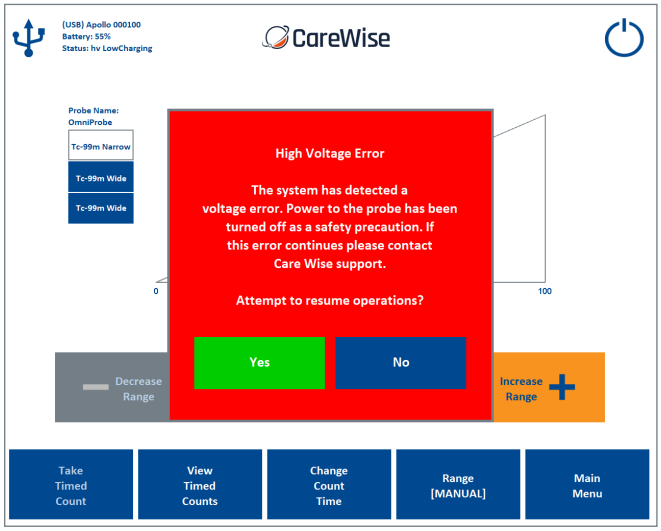


Figure 35 – High Voltage Error

Low Battery Indications – [Figure 36] If the system is being operated using an Apollo Handset in Bluetooth® wireless mode, the software will indicate if the battery level drops below a critical value. In the 'Battery Critical' phase, a coloured box will appear around the Bluetooth® symbol in the top, left-hand corner of the screen, which will alternate between green and red. An audible 'alarm' sound will also be generated by the system to indicate a critical battery level and 'Battery Critical' will be displayed in the instrument status. In this state, please connect the Apollo Handset to a USB cable attached to the analyser, charging dock or the wall mounted charger to ensure that the battery may be recharged.

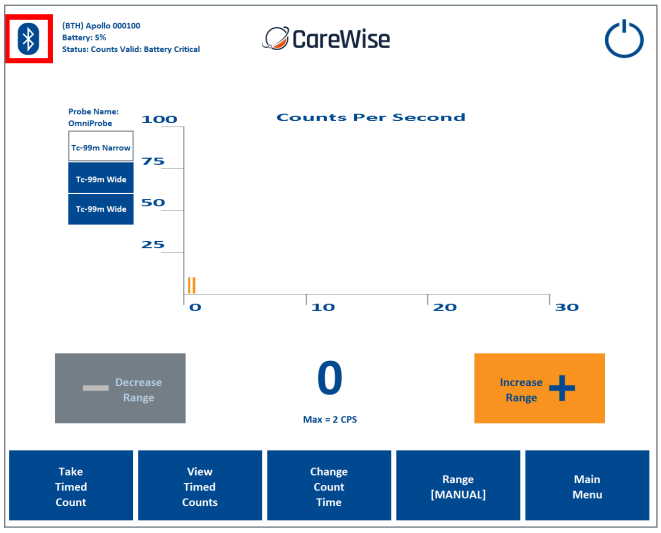


Figure 36 – Low Battery Indications

If the battery continues to lose charge, the Apollo Handset will enter a 'shutdown' state – [Figure 37 and 38].

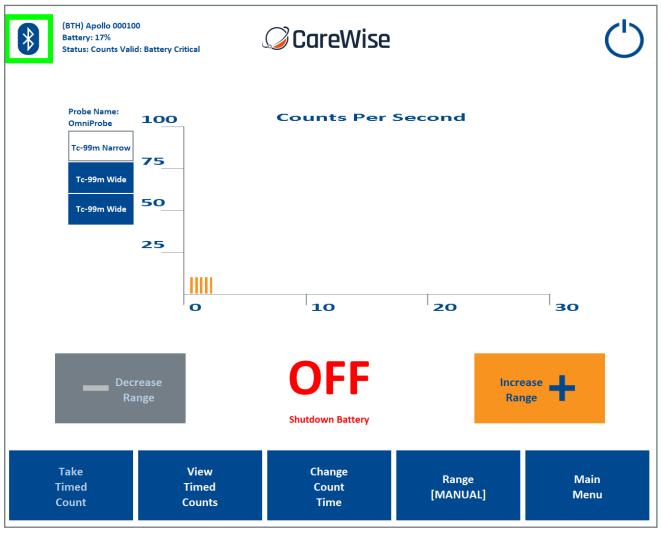


Figure 37 – Shutdown State

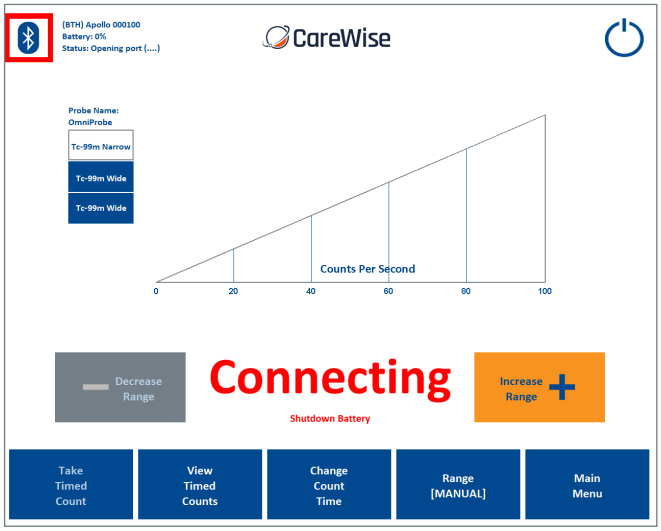


Figure 38 – Shutdown State.

Over-Range Error – [Figure 39] If If the measured count rate exceeds the measurement capacity of the probe (e.g. by moving the probe in the vicinity of a very high level of radioactivity), the system will enter an 'over-range' state, leading to an audible warning and an infinity symbol being displayed in place of the measured count rate value. Moving the probe away from the source of radioactivity will reinstate the default 'counting' state of the system.

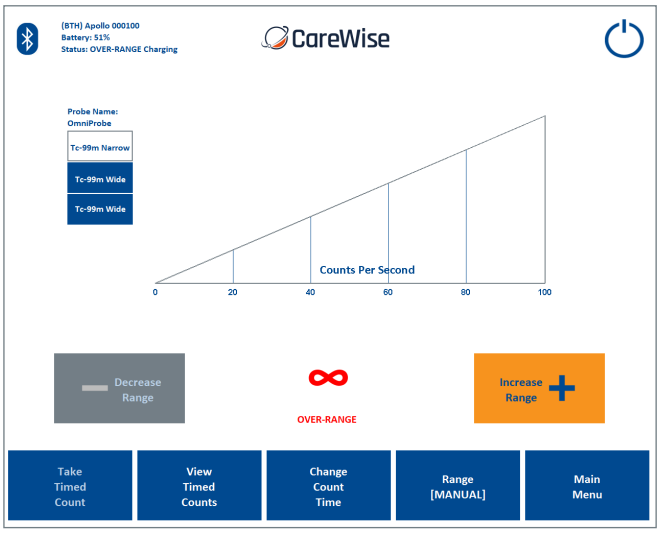


Figure 39 – Over-Range Error.

Not Enough Radiation Detected Error – [Figure 40] This error will appear if the probe does not detect enough radiation to complete the System Test [Section 2.4-7]. Ensure that the probe is fully inside the check source holder and that the source disc is less than two years old. Reattempt System Test.

If this error continues to appear when performing a System Test, the probe may be damaged. Contact Care Wise on +1-813-626-6848 (US & Canada) +44 (0)1273 497600 (Europe & Worldwide) or e-mail support@carewise.com for assistance.

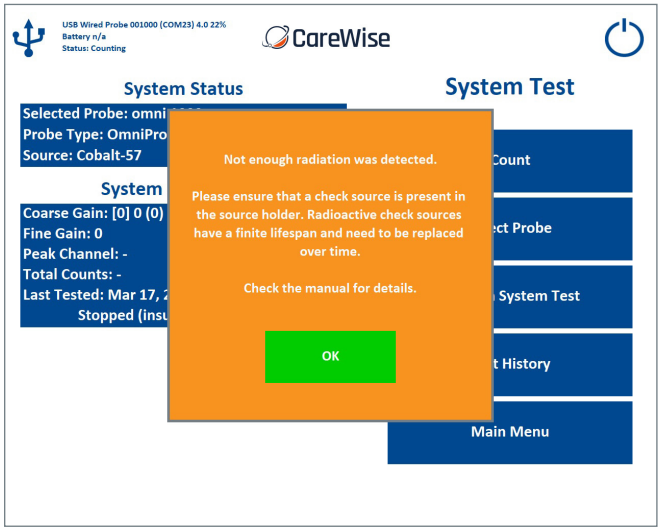


Figure 40 – Not Enough Radiation Detected Error.

Appendix D

EMC Precautions

Special precautions regarding EMC (Electromagnetic Compatibility) and the Care Wise C-Trak® Apollo System.

The C-Trak® Apollo System conforms to IEC 60601-1-2 standards for electromagnetic compatibility. However, the Apollo System requires special precautions regarding EMC and needs to be installed and put in service according to the EMC information provided in this User Guide. The customer/user of the C-Trak® CW4000 should assure that it is used in such an environment.

The following may result in increased emissions or decreased immunity of the Care Wise CW4000 Apollo System:

- The use of accessories, cables or other components other than those specified, provided or sold by Care Wise (see Product/Parts List in Appendix F).
- Unauthorized replacement parts or additional components internal to the Apollo System.
- The C-Trak® CW4000 is intended for use in an electromagnetic environment in which radiated RF (Radio Frequency) disturbances are controlled.
- Interference may occur in the vicinity of equipment marked with the symbol  .
- The use of portable or mobile RF communications equipment within close proximity to the Apollo System or other nearby Medical Electrical Equipment.

  Recommended separation distance:

  - d=1.2√P (150 kHz to 80 MHz)
  - d=1.2√P (80 MHz to 800 MHz)
  - d=2.3√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).
- The use either adjacent to, or stacked with other equipment, unless previously verified that such use does not affect performance.

Electromagnetic environment guidance:

- The C-Trak® CW4000 uses RF (Radio Frequency) 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.
- The C-Trak® CW4000 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.
- Use on floors that are wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
- Main power should be that of a typical commercial or hospital environment.
- Power frequency magnetic fields should be at levels of a typical location in a typical commercial or hospital environment.

Appendix E

Return Authorization Form

Southern Scientific

RMA Number:
(For internal use only)

After completing, please save the form and return to: info@southernscientific.co.uk

Bill to:	Ship to: ☐ *Same as Bill to Information*
Primary Contact:	**Primary Contact:** .....
Company Name:	**Company Name:** .....
Address:	**Address:** .....
Line 2:	**Line 2:** .....
City:	**City:** .....
Zip/Postcode:	**Zip/Postcode:** .....
Telephone:	**Telephone:** .....
Fax:	**Fax:** .....
Email:	**Email:** .....

QTY:	Model No:	Serial No:	Description of Problem (In Detail):

☐ **Warranty Repair** _____ ☐ **Calibration** ☐ **Repair**
Enter Original Order No.

☐ **Billable** _____
Enter Purchase Order No.

☐ **Service Contract** _____
Enter Contract No.

PLEASE NOTE: Declaration of Decontamination of Instruments and Components

This instrument will only be accepted for repair or service if adequate cleaning has been carried out. If on arrival at Southern Scientific Ltd the instrument is found to be contaminated, it will be returned, and any associated costs will be charged to the customer.

Herewith me (I) assure that the instrument has been decontaminated and is free from Hazardous Biological, Chemical, and Radioactive Material:

Name: _____ **Signed:** _____ **Date:** _____

Southern Scientific Limited, Scientific House, Henfield Business Park, Shoreham Rd, Henfield, BN5 9SL, UK
www.southernscientific.co.uk | +44 (0) 1273497600 | info@southernscientific.co.uk

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Appendix F

Care Wise Product List

C-Trak® Apollo Systems and Components	Product Code
1. C-Trak® Apollo standard systems	
C-Trak® Analyser Apollo Stand Alone	CW5-APO1-06
2. OmniProbes®	
C-Trak® OmniProbe® Standard device with snap on Technetium Collimator (Angled)	CW5-OMNI1-01
Standard OmniProbe® with snap on Technetium Collimator (Angled) with Medcoat	CW5-OMNI1-10
Standard OmniProbe® with snap on Technetium Collimator (Straight)	CW5-OMNI1-02
OmniProbe® EL device straight	CW5-OMNI1-04
OmniProbe® EL device 20°	CW5-OMNI1-05
OmniProbe® EL device 90°	CW5-OMNI1-06
OmniProbe® PET device	CW5-OMNI1-08
3. Accessories	
a. C-Trak® Apollo Wireless Handset Kit	CW5-APO1-04
b. C-Trak® OmniProbe® collimators	
Standard	CW5-CTXX-01
Lechner (3 mm opening)	CW5-CTXX-02
c. Apollo Printer	CW5-CTXX-03
d. Apollo Power Cable	CW5-CTXX-04
3 m USB cable for C-Trak® Apollo Wireless Handset	CW5-CTXX-33
e. C-Trak® Base Unit Power Supply (Brick)	CW5-CTXX-05
f. Apollo Quick-Release Bracket	CW5-CTXX-06
g. C-Trak® OmniProbe® Probe Cable	CW5-CTXX-07
h. Check Source Cobalt 57 - 5µCi	CW5-CTXX-08
Cobalt 57 - 10µCi	CW5-CTXX-09
Sodium (Na) 22 - 5µCi	CW5-CTXX-10
i. Analyser and Probe Carrying Case Apollo System	CW5-CTXX-32
j. C-Trak® OmniProbe® EL device Carrying Case	CW5-CTXX-14
k. C-Trak® OmniProbe® standard device Carrying Case	CW5-CTXX-15
l. Check Source Holder C-Trak® OmniProbe® Standard	CW5-CTXX-16
C-Trak® OmniProbe® EL devices	CW5-CTXX-17
C-Trak® OmniProbe® PET	CW5-CTXX-18
m. C-Trak® Cart	CW5-CTXX-23
C-Trak® Cart Cover	CW5-CTXX-31
n. Apollo Wireless Handset	CW5-APO1-05
o. USB Foot Pedal	CW5-CTXX-30
p. Apollo Handset Docking Station	CW5-CTXX-28
q. Apollo USB Wall Charger	CW5-CTXX-29
r. Cleaning Brushes for Collimator (Pack of 5)	CW5-CTXX-24

Appendix F (continued)

4. Service Contracts

Care Wise understand the need for outstanding services to minimise instrument downtime and maximise reliability. The most cost effective way to do this is through our service contracts, which include:

Annual Preventative Maintenance (return to base) – Annual preventative maintenance checks on your instrument to ensure system reliability.

50% discount on parts and labour for repairs due to accidental damage.

Protection against mechanical failures (repair at no cost) – Should your system suffer mechanical failure Care Wise will provide a full repair at no additional cost.

Loan units at no charge should your components ever require repair (subject to availability) – Care Wise will send you a loan instrument whilst maintenance work is being carried out on yours to ensure there is no instrument downtime.

A new calibration check source after 18 months.

Appendix G

Radioactive Material Exempt Quantities

(Per U.S. NRC & State Regulations)

This radioactive material conforms to the conditions and limitations specified for radioactive material in:

- 49CFR173.421
- 10CFR30
- 10CFR30.71, Schedule B Exempt Quantities
- BS 5288/C11111

The radioactive material contained in the package is an exempt quantity from USNRC and/or Agreement State licensing requirements.

The radiation exposure rate at any point on the external surface of this package does not exceed 0.5 milli rem/hour.

No other hazard labeling and shippers declaration are required or authorised.

Radioactive Material —— Not for Human Use —— Introduction Into Foods, Beverages, Cosmetics, Drugs, or Medicinals, or Into Products Manufactured for Commercial Distribution is Prohibited —— Exempt Quantities Should Not be Combined.

The quantity of radioactive material contained in these products is extremely small and present no known radiation hazard.

However, it is always good practice to minimise exposure by following the basic principles of time, distance and shielding. Solid, sealed exempt quantity sources require no special handling but when working with liquid sources, gloves and laboratory coats are recommended.

Eating, drinking and smoking should be prohibited in areas where radioactive material is used or stored.

Use of radioactive material should be supervised by a responsible person and in authorised areas. Exempt quantity products should be used only as intended and in accordance with instructions provided. All radioactive material should be securely stored when not in use.

These exempt quantity products may be disposed of in regular waste providing all radiation symbols have been removed or defaced. When disposing of liquid exempt quantities, it is recommended that they be flushed into the public sewer system diluted with large volumes of water.

For UK road transport under IRR 17 and the Carriage of Dangerous Goods (2009) Regulations, the check sources are classed as Exempt; the consignment activity will always be below the exemption limit of 1 MBq.

Manufactured and Distributed by:
SPECTRUM TECHNIQUES
106 Union Valley Road, Oak Ridge, Tennessee 37830, USA,
Tel: 865-482-9937, Fax: 865-483-0473
Web: www.spectrumtechniques.com

Appendix H

Intended Use

The C-Trak® Apollo system (CW4000) is the new iteration of the existing Galaxy CW4000 device; an active, invasive medical device comprised of a pre-compliant Panel PC incorporating an analyser MCA, power supply, Wireless accessory, gamma probe (OmniProbe), and probe cable (either USB where specified or coaxial signal cable, depending on the chosen use mode).

The device and wireless accessory have a defined lifetime of seven years. There are no safety implications of using the device or any accessory after this period as long as the device is in good condition and the performance checks stated in the manual are performed as required prior to use.

The gamma probe (OmniProbe) works using scintillation technology which converts radiation counts into an electronic signal which is then processed by proprietary Apollo software. The software provides feedback to the user about how much radiation is being detected from a source; feedback is numerical, graphical, and audible.

The basic intent of the Apollo system is to provide the user with feedback about the location of sources of radiation in an intraoperative environment. This information is used by surgeons to indirectly locate various tissues of interest, e.g. tumours or lymph nodes that might harbour metastatic disease.

The user is either a surgeon trained in the diagnosis, search for, and removal of various forms of cancerous tissues or tissues of clinical interest, or a nuclear medicine physician experienced with the use of radiolabelled agents used to localise tissues of clinical interest. The surgeon is supported by trained operating room nurses, who assist the surgeon in the use of the system, under the surgeon's supervision. The patient has no direct influence over the use of the device and the system itself does not perform any diagnostic function.

In normal use, the operator of the CW4000 views the product from the front, facing the computer screen usually at a distance no greater than nine (9) feet. The ID/Serial Number Label is on the rear of the product (computer) and is intended to be viewed in a normal, room lighting environment (500 lx or greater) by a person with a visual acuity (corrected, if necessary) of 20/20 at a distance of approximately 12-18 inches (a normal reading distance). Aside from the serial number, the information included on this label is also available in the printed User's Guide (included with each product) and the on-screen User's Guide.

Product operation follows the basic guidelines as outlined in the NEMA NU 3, Performance Measurements and Quality Control Guidelines for Non-Imaging Intraoperative Gamma Probes.

The Apollo system and accessories are non-sterile devices that are to always be used inside a sterile sheath or similar appropriate sterile barrier system. There are provisions for reprocessing and sterilising the device described in Section 5.

The intended application for this system is to locate tissues of clinical interest in Sentinel Lymph Node Biopsies (SLNB procedures) for various cancer types, parathyroid procedures and, tumour localisation.

There are no limitations to the intended population the device may be used on with regards to age or patients with pre-existing conditions. The only factor that should be considered is the size and selection of probe that best suits the site of the intended procedure (i.e. use of a slimmer collimator where required).

The Apollo system may also be used for the localisation of I-125 seeds.

The system is NOT to be used on the following:

- Central Nervous System (CNS): the Brain, Meninges and Spinal Cord.
- Central Circulatory System, meaning the following blood vessels: *arteriae pulmonales, aorta ascendens, arcus aortae, aorta descendens to the bifurcatio aortae, arteriae coronariae, arteria carotis communis, arteria carotis externa, arteria carotis interna, arteriae cerebrales, truncus brachiocephalicus, venae cordis, venae pulmonales, vena cava superior and vena cava inferior.*

Appendix I

Disposal Information

Upon the system's end of life, the following disposal routes must be adhered to:

Monitor, Power supply and Cable

Disposal route following WEEE (EU) or applicable E-Waste (US) regulations after necessary cleaning/disinfection.

Monitor Stand

Disposal route following local recycling guidance for metals after necessary cleaning/disinfection.

Co-57 Check Source

The exempt quantity check source may be disposed of via a regular waste route provided that all radiation hazard symbols and text have been removed or obscured permanently.

Appendix J

Care Wise Contact Information

Any serious incidents related to the use of this device should be reported to the manufacturer, distributor and/or importer, as well as to the relevant regulatory authority(ies).

Manufacturer – Europe & Worldwide:

Southern Scientific, Ltd.

Scientific House, The Henfield Business Park
Shoreham Road, Henfield, West Sussex
BN5 9SL, United Kingdom

E-mail: sales@carewise.com, support@carewise.com
Tel: +44 (0)1273 497600, Fax: +44 (0)1273 497626

Web: www.southernscientific.co.uk

Distributor – USA & Canada:

Care Wise c/o LabLogic Systems Inc.

1911 N US HWY 301, Suite 140
Tampa, FL 33619, USA

E-mail: sales@carewise.com, support@carewise.com
Tel: +1-813-626-6848, Fax: +1-813-620-3708

Web: www.carewise.com

Authorised Representative – Europe:

Emergo Europe

Prinsessegracht 20
2514 AP The Hague
The Netherlands

Important Information

Probe Handling

Treat the probe as you would any expensive, delicate instrument. Inside the probe are crystals and a glass photomultiplier tube. If the probe is dropped or hit against something hard, it can break.

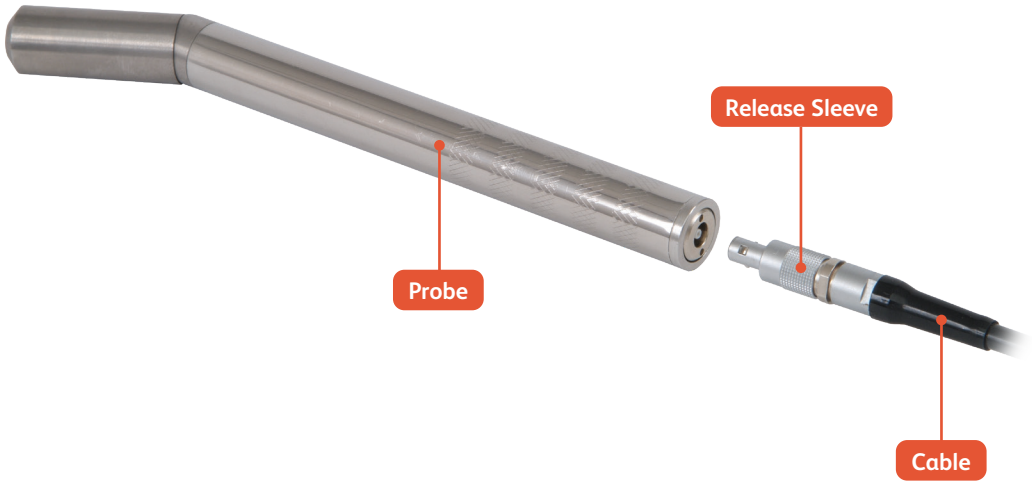
PLEASE HANDLE CAREFULLY

Figure 41 – Detaching the C-Trak® Cable.

(1) Grasp cable connector by release sleeve.

(2) Gently pull release sleeve away from probe as shown below. Cable will release.

Figure 42 – Overview of Probe and Cable.



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