

Standard Operating Procedure <b>ECG Machines</b>	
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## 1.0 POLICY

This standard operating procedure (SOP) describes the correct procedures when using the GE Healthcare MAC™ 2000 ECG (electrocardiogram) machines for clinical research, including clinical trials, in the W.J. Henderson Centre for Patient-Oriented Research (WJHCPOR). The ECG Machines are portable devices intended to be used by qualified and trained users of the WJHCPOR using surface electrodes to acquire, analyze, display, and record information as 6-lead or 12-lead ECG measurements for pediatric (0-15 years) and adult research participants.

## 2.0 PURPOSE

All users of the WJHCPOR should familiarize themselves with this SOP to ensure correct procedures when taking 6-lead or 12-lead ECG measurements using the ECG machines.

## 3.0 RESPONSIBILITY

Users are responsible for:

- Attending orientation and training on the proper use of the ECG machines.
- Following the procedures listed in this SOP. **NOTE:** If at any time users are unsure how to operate the ECG machines safely, please refer to the instructional manual (see Appendix A), quick reference guide (see Appendix B) and/or ask the designated KGHRI staff member for assistance.
- Reporting any damage to the ECG machines (or accessories) to the designated KGHRI staff member immediately so equipment repairs can be made.
- Cleaning the ECG machines after each use and between research participants.

KGHRI is responsible for:

- Ensuring all ECG machines are in good repair and labelled with appropriate contact information for maintenance and repair.
- Training new users in safe usage and maintenance of the ECG machines, documenting the training of all users, and supervising use when necessary.
- Ensuring instructional manuals (see Appendix A), quick reference guide (see Appendix B), and data sheet (see Appendix C) are readily available to all users, if required.
- Ensuring that all the regular and periodic maintenance required for the ECG machines is carried out and recorded in the Maintenance Log. The designated KGHRI staff member will contact Kingston Health Sciences Centre (KHSC) Clinical Engineering Department when regular maintenance inspection and repairs are required.
- Ensuring the records of repair are kept and available for inspection.
- Providing appropriate cleaning supplies to users of the WJHCPOR.

## 4.0 PROCEDURE

### Turning on/off the ECG Machines

- Locate the power button on the top left hand corner (as shown in the images below) on the keypad of the ECG machine. Push and hold the power button to turn on the ECG machine. The system welcome screen will be visible on the display when the ECG machine is on and ready for use. The ECG machine will automatically conduct a self-test as soon as the ECG machine turns on. If there are any errors, a message will be noted.





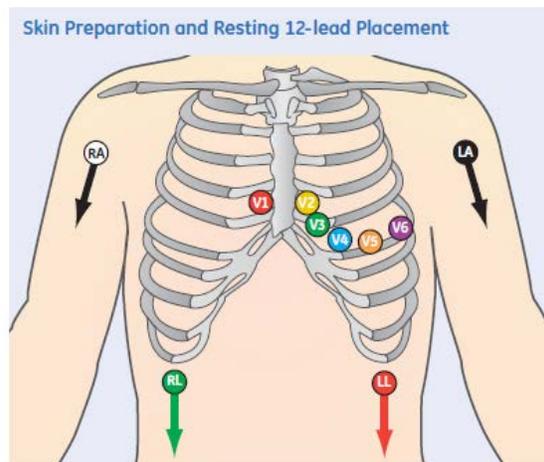
- When the ECG machine is not plugged into an electrical wall power outlet, the Battery LED light (located on top left hand corner as shown in the images above) will not be seen when the ECG machine is on. If the ECG machine is plugged into an electrical wall power outlet the Battery LED light will show a steady amber light indicating that the battery is charging. The Battery LED light will be flashing amber when the battery is low. If the Battery LED light is flashing amber plug the ECG machine into an electrical wall power outlet to charge the internal battery.
- The ECG machine does not need to be plugged into an electrical wall power outlet to be operating as long as the internal battery is charged. When the ECG machine is plugged into an electrical wall power outlet, the Power LED light (located on the top left hand corner as shown in the images above) will be seen as green indicating that the unit is receiving power.
- The ECG machine does not have a touch screen display option. You need to use the Function Keys, Keypad, and Curser Control Keys/Trimpad (as shown in the images above) to change screen options and to enter data. The ECG display monitor screen and keyboard are fixed and do not move or bend. **DO NOT** touch the display monitor screen or attempt to bend/move the display monitor screen or keypad as it will damage the ECG machine.
- To turn the ECG machine off, push and hold the power button. The ECG machine will beep and turn off.

### Preparing the Participant's Skin for Electrodes

- Careful skin preparation is key for obtaining a strong ECG signal. Ensure that each electrode placement site is dry, clean and free from excessive hair.
- Use a razor to remove any excessive hair.

- A skin preparation cream can be used to help decrease each site area, if needed (optional step). Wipe each site area with an alcohol wipe to clean the surface. Dry off any excess moisture with a gauze pad.
- Once the skin surface is dry, apply electrodes to the prepared sites, as per the table and image below for 12-Lead electrode placement.

AHA Label	Electrode Placement
V1	Fourth intercostal space next to the sternum on the right side.
V2	Fourth intercostal space next to the sternum on the left side.
V3	Midway between locations V2 and V4.
V4	At the mid-clavicular line in the fifth intercostal space.
V5	At the anterior axillary line on the same horizontal level as V4.
V6	At the mid-axillary line on the same horizontal level as V4 and V5.
RA and LA	Place on the corresponding right and left wrist. An alternate placement to reduce muscle artifact is on the right and left deltoid respectively.
RL and LL	Place on the corresponding right and left ankle. An alternate placement to reduce muscle artifact is on the upper leg as close to the torso as possible.



### Connecting the Participant Cable

- Ensure your electrodes are properly placed on your research participant, as shown in the image above.
- Trace each individual lead wire from its acquisition cable label to the coloured connector and then to the proper electrode to ensure that it is matched to the correct label location.
- Connect the end of the correct lead wire to the electrode. Each lead wire has an adaptor at the end that actually connects to the electrode.

## Using and Disposing of Electrodes

- Users can use two options for the electrodes when operating the ECG machine. Both options are available for users in the WJHCPOR:
  - Preferred Option: Use non-polarizing silver/silver-chloride electrodes (as shown in image below) with the ECG machines (see “Using the ECG Machine during Defibrillation” section below). When using these electrodes please ensure all opened electrode packs are stored in the sealed plastic bag provided in the trolley cart’s basket. Clip the adaptor on the lead wire to the electrode (as shown in image below).



SilverMactrode™ Plus Electrodes



Clipping Electrodes with Mactrode™ Clips

- Alternate Option: Use foam electrodes (as shown in image below) with the ECG machines. Place the metal clip on the electrode into the hole located on the back of the adaptor on the lead wire and slide the metal clip to lock the electrode into place (as shown in image below). **Note**: these types of electrodes are polarizing (see “Using the ECG Machine during Defibrillation” section below).



Medi-Trace™ 530 Foam Electrodes



Clipping Electrodes with SilverTrace™ Clips

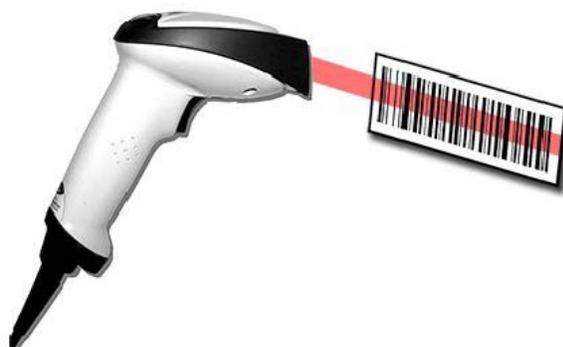
- Electrodes are single-use only. Dispose in regular waste containers after use. If the electrodes are saturated with blood/tissue/bodily fluid, they must be placed instead in the yellow coloured biohazardous waste bin/container.

## Entering Participant Information using Function Keys and Keyboard

- Open the “Enter Patient Data” window by pushing the Function Key that lists “Patient Data”. The ECG machines have been pre-programmed so that the default power up mode has been set to “Resting ECG”. Users should see “Resting ECG” on the display monitor screen at the top left hand corner. If you notice this option is not automatic, press the Function Key that lists “More”, press “Main Menu”, press “Resting ECG”, and press “Patient Data” to open the window.
- Enter your participant information. Remember to use a unique participant identification number assigned to your participant as part of your clinical research or clinical trial instead of entering their first and last name. The ECG machines are used by many users on the floor.
- Use the Function Keys that list “Page Up” and “Page Down” or the “Curser Control Keys/Trimpad” on the keypad to move through the participant information windows. Use the keypad to enter participant information.
- When all of the participant information has been entered, press “Save”, to save the data. If you want to cancel the participant information entered, press “Cancel”.

## Entering Participant Information using Barcode Reader

- Using a barcode reader can simplify the entry of the participant information. When you scan a participant’s barcode, it retrieves the participant’s information encoded in the barcode.
- KGHRI only provides the bar code readers as an accessory for the ECG machines. Users **MUST** provide their own barcodes, if they want to use this feature.
- Scan the participant’s barcode when the following prompt is displayed on the display monitor screen: “Scan the Patient Barcode”, as shown in the image below. The following message is displayed on the screen: “Please wait”.

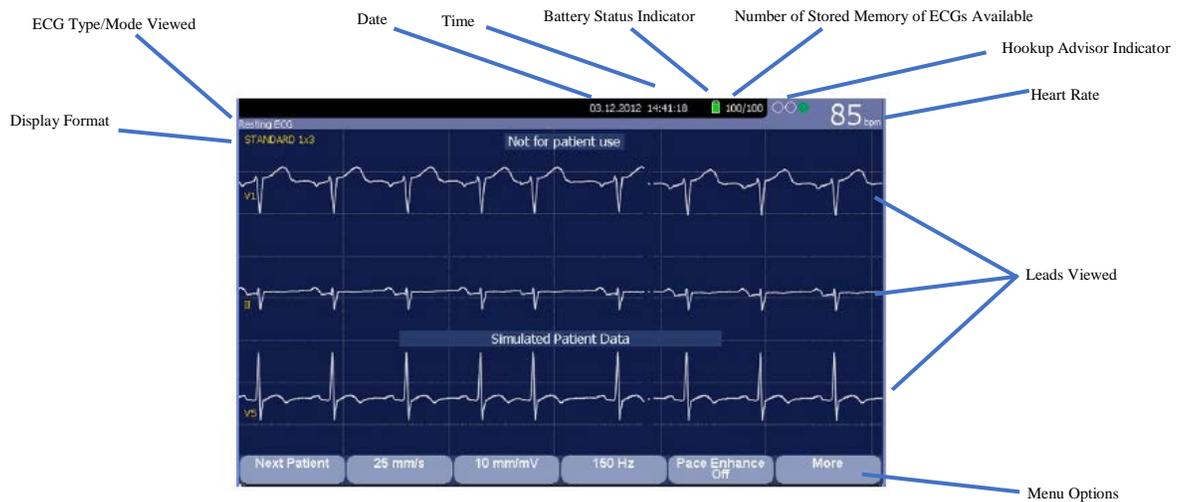


- The barcode reader will beep. The “Enter Patient Data” window opens with the information from the participant’s barcode entered into the appropriate fields.

- Confirm that the information entered is accurate. Enter or modify participant information as necessary.
- After verifying that the participant information is correct, press “Save”, to save the participant information. If you want to cancel the participant information entered, press “Cancel”.

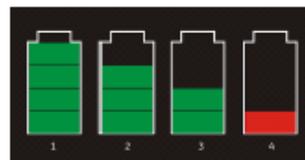
### Recording a Resting ECG

- The Resting ECG mode is the default power up mode. When the ECG machine is turned on, the “Resting ECG” is displayed in the top left corner on the display screen window (as shown in the image below). You can modify the default ECG Type in the “Basic Setup”. **NOTE:** Additional options (“Arrhythmia” and “Stress Test”) are not available for these ECG machines.
- The date, time, battery status indicator (charge left in the internal battery), hookup advisor indicator (as shown in the image table below), and participant’s heart rate (bpm) are displayed in the top right corner on the display screen window. The menu options (Function Keys) are located on the bottom of the display screen window and include the ability to adjust the speed of the waveform, magnitude of the ECG signal, frequency, leads to include in printout, and turn on/off pacemaker mode. The leads are viewed in the middle of the display screen window. Change the leads viewed by pressing “Leads”.



#### Hookup Advisor Indicators

Indicator	Description
Red	Indicates a leadfail condition or extreme baseline shifts. The red indicator is always the left-most circle of the indicator and flashes when lit.
Yellow	Indicates muscle artifact, power line interference, baseline wander, or electrode noise. The yellow indicator is always the middle circle of the indicator. <b>NOTE:</b> In RR Analysis mode, the yellow indicator is not active. RR Analysis supports only the red and green indicators of Hookup Advisor.
Green	Indicates acceptable signal quality. The green indicator is always the right-most circle of the indicator.



#### Battery Status

Item	Description
1	The battery is fully charged and above 75%.
2	The battery charge is above 50%.
3	The battery charge is above 25%.
4	The battery charge is below 25%. This status is also used when the battery charge is unknown.

- Use the Function Keys below the menu options to adjust the mm/sec (speed), mm/mV (gain), and Hz (filter) until the waveforms are configured as desired.
- If a participant has a pacemaker, use the Function Key to turn on “Pace Enhance” mode. If a participant does not have a pacemaker, use the Function Key to turn off “Pace Enhance” mode.
- Select “More” then “Printer Leads” to scroll through the leads or change the lead format. The 12 leads available for viewing are I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, and V6.
- When the waveforms are configured, press “ECG” to begin the acquisition. A progress bar will be displayed indicating the percentage of data acquired. When the acquisition is complete, one of two options occurs, depending on the setting of the “Preview Before Analysis” option on the “Resting ECG Setup” window:
  - If the “Preview Before Analysis” option is enabled, a preview of the 10-second ECG is displayed. You will have the option to discard the reading (press “Cancel”) and restart the recording again or print a copy of the ECG. You also have the option to save, transmit, or reanalyze the data.
    - Use the menu options to change participants, to print a copy of the ECG or to save, transmit, or reanalyze the data.
  - If the “Preview Before Analysis” option is not enabled, the ECG data is analyzed and printed after it is acquired.
    - Use the menu options to change participants, to print another copy of the ECG or to save, transmit, or reanalyze the data.
    - Select “Copy” or “Print” to print an additional copy.
    - Select “Save” to store the current ECG report. This option is available when the internal storage option is enabled in the “Basic Setup”.
    - Select “Transmit” to send the ECG report to the location defined on the “Communication Setup” window. This option applies only if a valid LAN or Modem communication option is enabled.
    - Select “Export to SD Card” to export the ECG report to the SD card.
- The “Resting ECG” type/mode allows you to generate rhythm reports. These are printed reports only. You cannot store them to internal memory or transmit them. Press “Rhythm” to begin recording a continuous rhythm ECG strip. Press “Stop” to stop the printing of the continuous rhythm ECG strip.
- The ECG machines allow for an internal storage of up to 200 ECG before saved data is replaced with new data.

- **NOTE:** When transmitting ECG data to Sponsors/CROs or academic institutions through a valid LAN or Modem communication, Sponsors/CROs or academic institutions will need to know the make and model of the ECG machines (GE Healthcare MAC™ 2000 ) in order to ensure they have downloaded and set-up the correct software to be able to receive the ECG data/records.
- Users **MUST** delete their participants' data from the ECG machines after each use once all ECG measurements are printed, saved, and/or transmitted.
  - To delete all records from the ECG machines' internal storage, use the Function Keys and press "Main Menu", then press 'File Manager". Once the "File Manager" window opens, do one of the following:
    - To delete select records, press "Select" and use the "Curser Control Keys/Trimpad" to select the record(s) you want to delete; or
    - To delete all of the records in storage, press "Select All".
  - Press "Delete". A window opens and prompts you to confirm that you want to delete the selected record(s).
    - To cancel the deletion, press "No".
    - To delete the record(s), press "Yes".

### **Editing Stored ECG Records**

- Using the Function Keys, press "More", press "Main Menu" and press "File Manager".
- Using the Function Keys, press "Select" to highlight the individual record that you want to edit and then press the centre of the Curser Control Keys/Trimpad. This step will highlight the individual record. You may only select one record to edit at a time.
- Using the Function Keys, press "Edit" to edit the selected record.
- Use the Curser Control Keys/Trimpad to select the participant information to be edited. Edit the participant information as required. Select "Page Down" and "Page Up" to access the other windows.
- Using the Function Keys, press "Save" to save the edited record.

## Printing ECG Records

- Using the Function Keys, press “More”, press “Main Menu” and press “File Manager”.
- Using the Function Keys, press “Select” to highlight the individual record that you want to print and then press the centre of the Curser Control Keys/Trimpad. This step will highlight the individual record. If you want to print all of the records, press “Select All” and all the records will automatically be highlighted.
- Using the Function Keys, press “Print” to print the selected record(s) to the thermal paper (8.5” x 11”, white patient data area, red grid 155 mm wide, z-fold, hole queue) via the internal printer built into the ECG machines.

## Transmitting ECG Records

- Using the Function Keys, press “More”, press “Main Menu” and press “File Manager”.
- If you want to print a list of stored records, using the Function Keys press “Print Directory”.
- To transmit stored records, use the Function Keys and press “Select All” (to select all stored records) or “Select” (to choose the stored record(s) to transmit; use the Curser Control Keys/Trimpad to highlight the record(s)).
- Using the Function Keys, press “Transmit” to transmit the selected record(s). One of two things will happen depending on the number of locations defined in the “Communications Set-up”:
  - If only one location is defined, the files are transmitted to the default location.
  - If multiple locations are defined, a window listing the locations opens. Select the correct location and press “OK”.

## Exporting ECG Records

- Stored records can be exported from internal storage to a secure digital (SD) card.
 

**NOTE:** GE Healthcare recommends using a secure digital high capacity (SDHC) card with a capacity of 4 GB, either supplied by GE Healthcare or manufactured by SanDisk.
- To transmit stored records to a SD or SDHC card, use the Function Keys and press “Select All” (to select all stored records) or “Select” (to choose the stored record(s) to transmit; use the Curser Control Keys/Trimpad to highlight the record(s)).

- Insert the SD or SDHC card into the MAC 2000 SD Card Slot on the back of the ECG machine as shown in the image below. Make sure the SD or SDHC card has sufficient free space for the selected record(s) and that it is not write protected. If there is not enough sufficient space on the SD or SDHC card a message will appear indicating that.



- Using the Function Keys, press “More” and then press “Export”. The Function Keys will change to allow you to select the format in which you want to export the record(s).
- To export the data in XML, press “Hilltop XML”. One of two things will happen:
  - If a shared directory was defined, a window opens for you to select the destination.
    - To export to the shared directory, use the Function Keys and press “Shared Directory” in the window.
    - Use the Function Keys and press “OK”. The selected records are exported to the shared directory.
    - A window opens to inform you of the export’s progress. The window closes when the export is complete.
    - **NOTE:** When exporting to a shared directory, the ECG machines logs onto the directory with the user name and password defined in the “Communications Setup” window. If either of those values is incorrect, you will receive an error message. Correct the user name and password on the “Communications Setup” window and repeat the export process.
  - If a shared directory was not defined, the selected records are exported to the SD or SDHC card.
    - To export to the SD or SDHC card, use the Function Keys and press “SD Card” in the window.

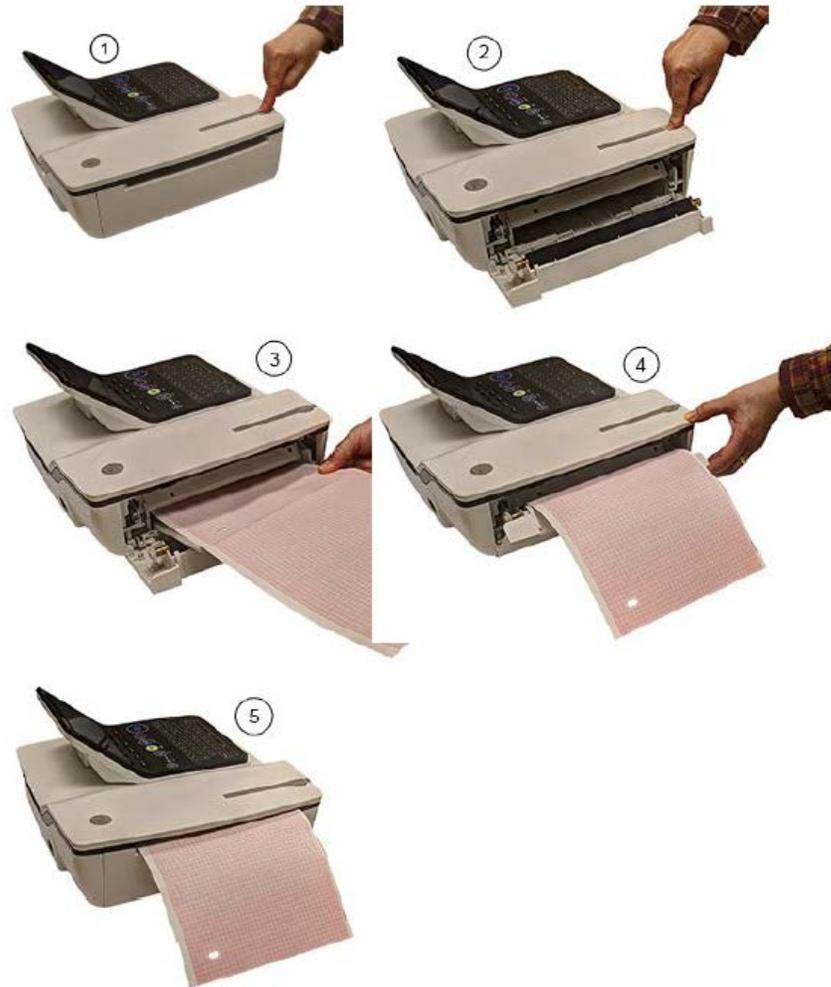
- Use the Function Keys and press “OK”. The selected records are exported to the SD or SDHC card.
  - A window opens to inform you of the export’s progress. The window closes when the export is complete.
- To export the data in PDF, using the Function Key and press “PDF”. One of two options are available:
  - To export to the SD or SDHC card, use the Function Keys and press “SD Card” in the window. Use the Function Keys and press “OK”. The selected records are exported to the SD or SDHC card.
  - To export to the shared directory, use the Function Keys and press “Shared Directory” in the window. Use the Function Keys and press “OK”. The selected records are exported to the shared directory.
  - For both options above, a window opens to inform you of the export’s progress. The window closes when the export is complete.

### **Using the ECG Machine during Defibrillation**

- The ECG machine is protected against the effects of cardiac defibrillator discharge. It is not necessary to remove the ECG electrodes prior to defibrillation, as long as non-polarizing electrodes such as silver/silver-chloride types are used.
- If using polarizing electrodes (i.e. foam electrodes), it is recommended to disconnect the lead wires from the research participant before delivering the shock as a defibrillator discharge current may cause the electrodes to retain a residual charge causing polarization which blocks acquisition of the ECG signal. The actual electrodes can remain on the research participant and the lead wires can be re-attached after defibrillation occurs.

### **Refilling Thermal Paper**

- Press the push button on the top of the ECG machine to open the printer door. See Steps 1 & 2 as shown in the image below.
- Extend the top sheet of the pack of thermal paper and insert the pack of the thermal paper into the paper compartment. Align the top sheet of the thermal paper to the line located on the near side of the printer door. See Step 3 as shown in the image below.
- Close the printer door until it clicks into place. See Steps 4 & 5 as shown in the image below.



### Cleaning ECG Machine Accessories

- After each research participant use, users **MUST** wipe down the ECG machine (unit, display monitor screen, bar code reader, lead wires, and adaptors) with Oxivir®/Accel® INTERVention wipes, similarly used for all other equipment, furniture, and surfaces located within the WJHCPOR.
- **DO NOT** use any other cleaning products as it could damage the ECG machines. Ensure the ECG machines are off before cleaning.

- Approved cleaning agents for the GE Healthcare MAC™ 2000 ECG Machine:
  - For the Unit and Display Monitor Screen:
    - Accel® INTERVention
    - Oxivir® Five 16
    - Oxivir® TB
    - Virex™ II 256
    - Mild dishwashing detergent
    - Clean, soft cloth
    - Water
  - For the Lead Wires, Bar Code Reader, and Adaptors:
    - Accel® INTERVention
    - Oxivir® Five 16
    - Oxivir® TB
    - Virex™ II 256
    - Virex™ TB
    - Mild dishwashing detergent
    - Clean, soft cloth
    - Water

**NOTES:**

- The ECG machines are compatible with cleaning agents that contain chemicals listed below, either individually or as a combination with respective concentration:
  - 50% propyl alcohol (50% propan-1-ol)
  - 25% iso propyl alcohol (25% propan-2-ol)
  - 25% ethanol
- When using Oxivir® Five 16 it is recommended on the lead wires and adaptors to carry out a potable water rinse periodically to alleviate any detergent residue left behind.
- **DO NOT** use the following cleaning agents on the GE Healthcare MAC™ 2000 ECG Machine (unit, display monitor screen, bar code reader, lead wires and adaptors) as it will damage equipment surfaces:
  - Organic and ammonia-based solvents
  - Abrasive cleaning agents
  - Alcohol
  - Virex (only Virex™ II 256 and Virex™ TB allowed as listed above)
  - Sani-Master

## 5.0 SOP HISTORY

<b>SOP Number</b>	<b>Date Issued</b>	<b>Summary of Revisions</b>
SOP-EM-01	01-MAY-2019	Original version.