WHALETEQ

Common Mode Rejection Ratio Tester
(CMRR 3.0+)

User Manual

(Revision 2022--2022.05.06)
PC Software Version V1.0.5.11

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1   Introduction

WhaleTeq Co., Ltd keeps focusing on single channel and multichannel ECG test systems in ECG standards. However, those systems do not cover *common mode rejection ratio* due to the nature of test (double shielding construction, noise free environment).

To meet this need, WhaleTeq had developed CMRR 2.0 test system and CMRR 2.0 requires an external function generator and multimeter to set up the test environment. Considering the additional equipment CMRR 2.0 requires, this would cause test to become complicated. Therefore, WhaleTeq Co., Ltd developed CMRR 3.0+ with built-in sine wave signal generator and Vc voltage measuring circuit so that user can conduct CMRR test without complicated steps.

CMRR 3.0+ uses double shielding construction according to various IEC standards and includes the following features

- Built-in sine wave signal generator to provide signals with various voltages and frequencies required by variable standards. CMRR 3.0+ provides 20 Vrms, 2.828 Vrms, 0.5 Vrms and 2 Vrms (required by IEC 60601-2-26 for EEG test). Furthermore, CMRR 3.0+ also provides 70.7 Vrms signal to expand the test scope to 120dB under output measuring at 1mm unit. Also output signal frequencies covers 50 Hz, 60 Hz, 100 Hz, and 120Hz.

- Use coarse and fine knobs to adjust the variable capacitance value Ct. The sum of Ct and Cx (stray capacitance) shall be 100pF.

- Built-in voltage measuring circuit for Vs and Vc voltages. Vs value indicates the signal voltage generated by built-in sine wave generator and Vc value is the voltage behind 100 pF capacitive voltage divider. User can easily confirm whether Vc value is half of Vs value while adjusting capacitor value Ct.

- Offer a precise and stable ± 300mV DC power supply.

- Provide imbalance impendence and DC offset options. Use MCU to control relay to switch on and off within the isolated circuit.

- Provide output terminals of Vs, Vc, Monitor and GND for monitoring applied voltages in the calibration process. For Monitor output terminal, it's designed to confirm voltage value Vc. Due to the high impedance brought by 100 pF at 50/60/100/120hz, this causes typical multimeters being not able to measure precisely. Besides, it requires non-load output voltage at 10 Vrms in certain IEC standards. Therefore, WhaleTeq CMRR 3.0+ uses 10:1 (100MΩ：10MΩ）voltage divider and designated circuit design as the best compromise solution for accuracy, circuit load, noise and input impedance of typical multimeters. Therefore, the Monitor terminal voltage shall be Vc/11 Vrms.

- CMRR 3.0+ is equipped with a touch screen which enables to adjust and display all required test parameters on the screen.

- Support variable standards: IEC60601-2-25/27/47/26, YY0782/0885/1079/1139, AAMI/ANSI EC11/13.

- Via USB interface connection, CMRR 3.0+ can be controlled by PC software or SDK (Software Development Kit).

- Assistant software simplifies medical standards with test procedures, test options and pass criteria. User can easily select and click to conduct the required tests.

2 Electrical Diagram

Figure 2-1 indicates the electrical diagram of CMRR 3.0+. Ct is the adjustable variable capacitance and Cx is the stray capacitance between inner shield and outer shield.

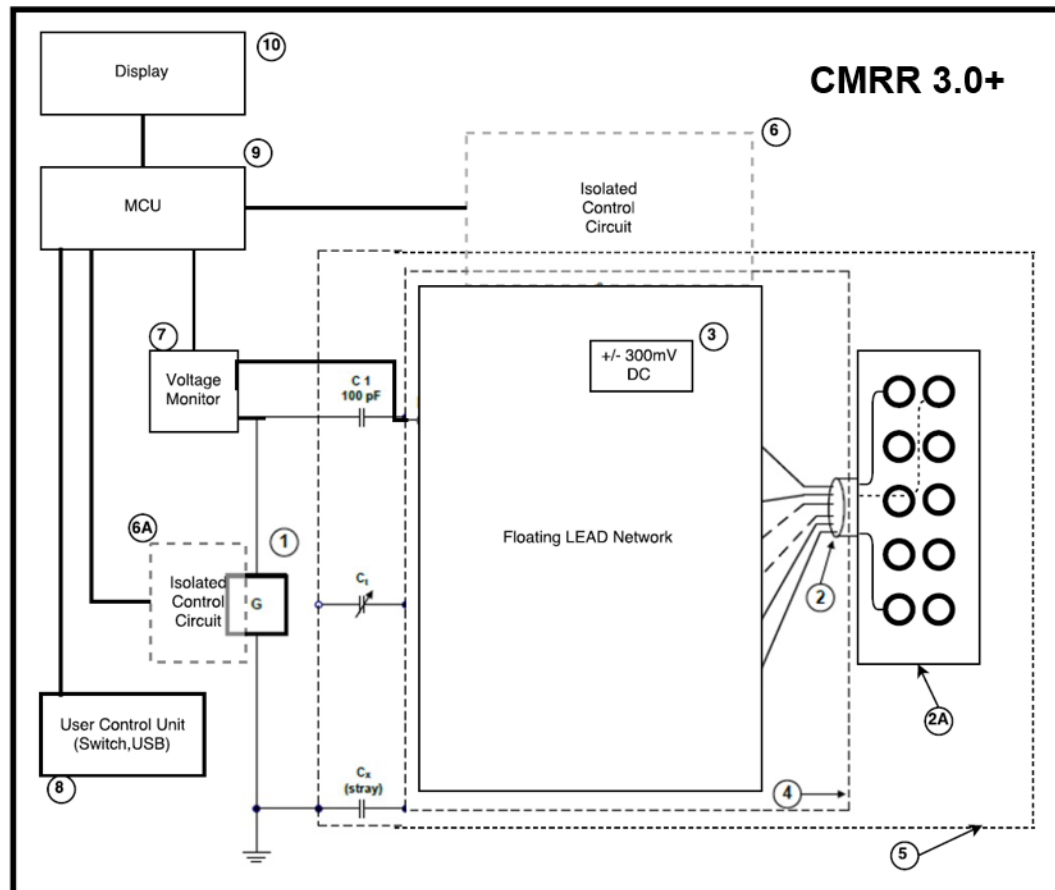**Figure 2-1, CMRR 3.0+ Electrical Diagram**

Item:
1   Signal generator
2   Internal connection wires
2A   Electrode terminals
3   ±300 mV DC Power Source
4   Inner Shield
5   Outer Shield
6   Isolated control circuit (electrode)
6A   isolated control circuit (signal generator)
7   Voltage monitor (Vs, Vc)
8   User control unit (Switch, USB)
9   MCU
10   LCD display module

*6 and 6A are the isolated circuits for isolating noises existed in power source and signal.

3 Set Up a Noise Free Test Environment

3.1 Reduce environmental noise and connect outer shielding to the ground plane.

It's a must to reduce noise when testing ECG. Please refer to the below figure and description for reducing environmental noise.

(1)   Place a metal sheet or a metal bench under ECG DUT and CMRR 3.0+
(2)   Connect GND terminal (outer shielding point) of CMRR 3.0+ to the metal sheet or the metal bench.
(3)   Connect the metal frame of ECG DUT to the metal sheet or the metal bench.
(4)   Tester shall keep distance from the test system, to prevent from body capacitance effect. Else, tester shall touch the metal sheet or the metal bench to connect to the common ground plane.

Please refer to figure 3-1：

Figure 3-1. Reference Wiring Diagram

Once set up the test environment per figure 3-1, turn on ECG DUT and adjust the sensitivity level to 10 mm/mV. After that, turn off line frequency notch filter of ECG DUT and adjust Supply Voltage of CMRR 3.0+ to "off". Make sure ECG noise level is below 1mm (0.1 mVpp).

3.2 Shielding Case of ECG Holter

If the noise is still high when testing ECG Holter in accordance with section 3.1, refer to figure 3-2 showing the connection method as per stated in IEC60601-2-47 and YY0885. Wrap the electrode cables and ECG DUT with foil separately and connect the foil-wrapped electrode cables to "CM point" of CMRR 3.0+. The CM point connects to the driven-shield layer (inner shield) of CMRR 3.0+. The foil-wrapped ECG requires to connect to ground shield layer (outer shield) and then connect to the metal sheet or metal bench under CMRR 3.0+ and ECG DUT. The last step is to place foil-wrapped electrode cables and foil-wrapped ECG DUT into the shielding case. Please notice the foil wrapped electrode cables shall not get touch with shielding case.
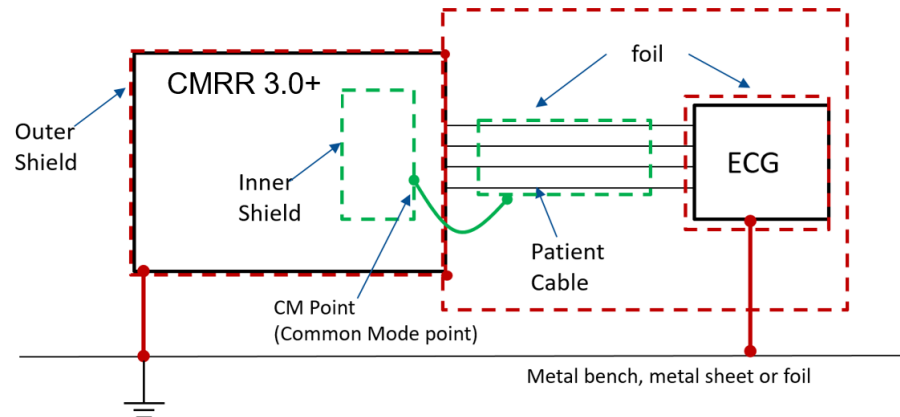
Figure 3-2, Wiring diagram of ECG DUT, CMRR 3.0+ and shielding case
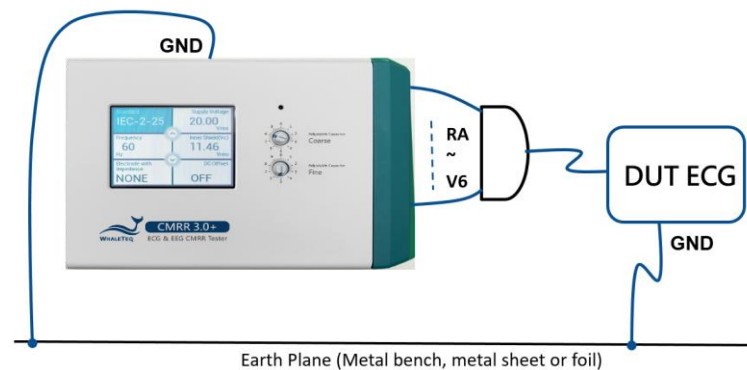
Once set up the test environment per figure 3-2, turn on ECG DUT and adjust the sensitivity level to 10 mm/mV. After that, turn off line frequency notch filter of ECG DUT and adjust Supply Voltage of CMRR 3.0+ to "off". Make sure ECG noise level is below 1mm (0.1 mVpp).

3.3 Shielding Case Assembling Instructions for Testing Holter Monitor
(1) Fasten the two side metal holders into the tapped holes of CMRR 3.0+
(2) Connect patient cables to ECG DUT and place both DUT and patient cables in the shielding case.
(3) Wrapped patient cables and ECG DUT with the foil paper. Connect the foil paper portion of patient cables to CM Point of CMRR 3.0+ and connect the foil paper portion of ECG DUT to the reference outer shielding which refer to any screw holes of the shielding case.
(4) Fasten the upper cover of shielding case.
(5) Connect patient cables to the terminals of CMRR 3.0+ and fasten the side metal holders of shielding case with CMRR 3.0+ per shown in Figure.3-3.

Figure. 3-3, CMRR 3.0+ with Shielding Case

3.4 Shielding Covers for the Electrode Cables
(1) Please fasten the bottom shielding cover to the right-side panel of CMRR 3.0+ for reducing main frequency interference. (see Figure.3-4)

Figure. 3-4, CMRR 3.0+ with bottom shielding cover

(2) As the bottom shielding cover is connected to Vc, Vc would be unstable due to the outer noise. When Vs is 2.828V (Vc=1.414V), Vc has the possibility to exceed 1% tolerance. At the time, please fasten the top shielding cover with CMRR 3.0+, to control Vc voltage within 1% tolerance. (See Figure. 3-5)

Fig. 3-5, CMRR 3.0+ with top shielding cover

4 Principle of the CMRR test

4.1 Common mode rejection ratio explained

A perfect device measuring a differential voltage should not respond to the level of common mode voltage which appears at both inputs. For example, a multimeter where the plus terminal is +100.017V and the minus terminal is +100.001V should theoretically indicate measured voltage of 16mV.

In practice, due to slight differences in resistances used in differential amplifiers, some of the common mode voltage will come through as an error. The common mode rejection ratio or CMRR indicates the ability of the equipment to reject these common mode voltages.

A scale of dB is normally used as the ratio can range from as low as 100 up to 100,000 (40dB to 100dB). A CMRR of 60dB indicates a ratio of 1000, and means that common mode voltages will be reduce by a factor of 1000. In the example given, equipment with a CMRR of 60dB would have the common voltage (+100V) reduced to 100mV, still a significant error relative to the differential voltage of 16mV. In practice, the common mode voltage is usually not more than 10 times the differential voltage, so a CMRR of 60dB

would only result in a 0.1% error.

The most common source of common mode noise is mains voltages, i.e. 50/60Hz. Thus, CMRR in meters is usually specified at these frequencies. But it is important to note that CMRR varies with frequency.

Common mode rejection also varies with the impedance of the source, or more specifically the impedance imbalance, as the imbalance also upsets the measurement circuit. CMRR for multimeters is typically specified with a 1kΩ imbalance.

4.2   Common mode rejection in ECG equipment

ECG equipment can be subjected to a fairly high common mode voltage from mains noise (50/60Hz), and can have a much higher impedance imbalance. The test in the standard simulates 10Vrms, with an imbalance of 51kΩ//47nF, and allows an indication equivalent to 0.35mVrms (1mVpp). This requires ECG equipment to have a relatively large CMRR of 89dB[1]. In practice, ECG equipment handles this large CMRR in five ways:

- Intentional capacitance between the patient circuit and earth, small enough not to cause leakage current problems, but large enough to load the source, and reduce the voltage by 50% or more. This is the reason for the 100pF in the test circuit.

- "Right leg drive": this is similar to noise reducing headphones, where the "noise" is sensed on measurement leads (e.g. RA, LA, LL), inverted and then returned via the RL/N lead electrode. Also referred to a noise cancellation.

- Patient isolation barrier, which reduces the impact of the common mode voltage.

- High CMRR input op amps, to handle the residual common mode voltage

- Finally, filtering can be used to remove residual common mode mains noise

While filtering is often used in practice, it is reasonable to confirm that the hardware features can provide sufficient CMRR without filtering. This ensures that distortion of the signal will not occur. For this reason, mains notch filtering (ac filter) must be turned off for the test even if it requires special software to do so. This is one point where the IEC standard differs from US and other standards.

4.3   Test equipment

Refer to the standard for the test circuit.

From a testing point of view the series 100pF introduces significant complications, as it represents a very high impedance of about 30MΩ at 50/60Hz. This means that attempts to measure the applied voltage (10Vrms) with a normal multimeter will fail, because the meter has around 10MΩ input impedance. It is possible to use 1000:1 HV probe with an oscilloscope (100MΩ/3pF), but noise and other errors can be large. Even 100MΩ/3pF will load the circuit, so the voltage will change (increase) by about 5% after the HV probe is removed, which should be accounted for if such probes are used.

WhaleTeq CMRR 3.0+ equipment resolved the difficulty in measuring Vc by using 100MΩ/10MΩ 11:1

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[1] This value can be calculated from $20 \log_{10} (10V / 0.35mV)$

voltage divider and voltage measuring circuit to measure the common mode voltage Vc after 100pF automatically.

The 100pF also creates a problem with the position of the patient cable. If the cable is allowed to sit on an earthed plane, the stray capacitance can be enough to provide additional loading and reduce the actual common mode voltage. This stray capacitance is highly variable and thus can impact the test. For conservative tests, the cable should be supported off the earth plane, but remain above the earth plane in order to minimize noise.

For IEC 60601-2-25: 2011, IEC 60601-2-27 and IEC 60601-2-51, the test requires a 20Vrms source. This can be sourced from the mains supply but for those wishing to test at various frequencies and have good control over the applied voltage, use of a function generator is more convenient. A function generator is usually limited to 7.1Vrms (20Vpp). To resolve this problem, a sine wave signal generator is built in CMRR 3.0+. It offers test voltages and frequencies required by various standards, including 20 Vrms, 2.828 Vrms, 0.5 Vrms and 2 Vrms required by EEG (IEC60601-2-26) test. After resolving the drawbacks of external signal generator and insufficient supply voltage, the test setup becomes easy and time-saving.

Common mode rejection is also dependent on impedance imbalance. For this reason, the test also introduces an imbalance of 51kΩ//47nF in one lead only. Experience from tests indicates that without this imbalance, there is usually no visible indication on the ECG, but with the imbalance readings typically range between 3-7mm (0.3 ~ 0.7mVpp). This suggests that the value of imbalance impedance is critical for the tests. Although the diagram in the standard shows all switches open, for the purpose of the test, all switches should be closed except the lead being tested and some tests are in the opposite settings instead. CMRR 3.0+ uses MCU to control the relay switch, which makes it easy to set up various balance and imbalance impedance.

IEC 60601-2-25/27/47 requires a DC offset of ±300mV. CMRR 3.0+ uses MCU to control +/- 300mV DC offset and it is easy to set +/- 300mV DC offset with different imbalanced impedance electrodes. The CMRR 3.0+ DC offset is supplied by an internal battery. The lifetime of this battery is estimated to be at more than 40 hours under continuous use. Therefore, its time in service should be long for tests that only last a few seconds each time. In case there is a need to replace the battery, simply open the battery cover at the bottom of CMRR 3.0+.

5   Panel Function

5.1   Upper Panel

The upper panel of CMRR 3.0+ is shown in figure 5-1. Please see below introductions for the functions of LCD touch screen and knobs:

Figure 5-1, the upper panel of CMRR 3.0+

The whole CMRR 3.0+ operation can be done with the knobs on the upper panel. All of the parameters can be shown on the LCD touch screen.

5.1.1   LCD Touch Screen

The LCD touch screen displays all the options and test parameters.

The main page of LCD touch screen is used for select functions of "Standard", "Voltage", "Frequency", "Impedance" and "DC Offset" by touching the area.

Once selected, the area shall be with light blue background display. User can click the up arrow button or the down arrow button to switch between different options. For example, you can click the arrow bottom to quickly switch [Off], [20], [2.828], [0.5] and [2.0] Vrms for Supply Voltage under [Manual] standard.

Otherwise, user can double click the function to have all the options shown in a separated page.

5.1.2   [Coarse] Knob

Located at the right side of the LCD display, it is used to tune adjustable capacitance Ct to make its sum with stray capacitance Cx into 100pF. The coarse scale ranges by tens of pF, and the fine scale ranges by pFs.

5.1.3   [Fine] Knob

Located at the right side of the LCD display, it is used to tune adjustable capacitance Ct to make its sum with stray capacitance Cx into 100pF. The fine scale ranges by pFs.

5.1.4   70.71 Vrms Switch

A hole located above [Coarse] knob. Pressing the switch in the hole with a small-size screwdriver for 6 seconds launches the hidden 70.71 Vrms voltage setting function. When outputting 70.71 Vrms signal, user can press the hidden switch again or directly turn off the power switch, to stop the high voltage output.

Under the manual mode, the [70.71 Vrms] option can be selected to test a higher CMRR value.

5.2   Front Panel

The front panel of CMRR 3.0+ is shown in figure 5-2. Please see instruction to each terminal as below:

Figure 5-2, the front panel of CMRR 3.0+

Connectors on the front panel are mainly used for power supply, USB connection and calibration.

5.2.1   Tapped Hole

The front and back panels each has two tapped holes for fastening the shielding cover or the shielding case which is a CMRR 3.0+ optional accessory.

5.2.2   USB Connector

Once connected to a PC, CMRR 3.0+ can be commanded by CMRR 3.0+ PC software or CMRR 3.0+ SDK (Software Development Kit).

5.2.3   [DC 12V] Terminal

It connects the DC 12V power supply bundled with CMRR 3.0+ to provide the power required by operation.

5.2.4 Power Switch

It turns on or off the mains supply of DC 12V power supply.

5.2.5 [Vc] Terminal

It connects the common mode point inside CMRR 3.0+ to Vc terminal directly. This is intended for use in equipment calibration.

5.2.6 [Vs] Terminal

The voltage output of CMRR 3.0+ built-in sine wave signal generator. This is intended for use in equipment calibration.

5.2.7 [Monitor] Terminal

The output terminal of inner common mode point after it passes through 11:1 voltage divider. It measures the voltage of Vc decayed by a factor of 11 directly. This is intended for use in equipment calibration.

5.2.8 Grounding Terminal

Outer shield grounding that connects the metal sheet in figure 3-1 in tests to reduce noises.

5.3 Right Panel

The right panel of CMRR 3.0+ is shown in figure 5-3. It is mainly used to connect each electrodes of ECG.

Figure 5-3, the right panel of CMRR 3.0+

5.3.1   [CM Point] Terminal

Same as [Vc] terminal, it connects the inner common mode point (also referred to driven-shield layer or inner shield) of CMRR 3.0+ to this terminal. When the patient cable (electrode line) is wrapped in foil as an outer shield, the outer shield should connect to this common mode point.

5.3.2   RA/LA/LL/RL/V1~V6 Electrode Terminals

Each electrode terminal connects to the corresponding electrodes on the ECG under test respectively.

6   Operation

6.1   Stand-alone Operation

Before operating CMRR 3.0+, the bundled DC 12V power supply has to be connected to the [DC 12V] connector on the front panel with the switch at the right side to be turned to [On].

All of the operations of CMRR 3.0+ can be done with the touch screen and knobs on the upper panel. All the parameters can be displayed on the LCD touch screen.

6.1.1   Touch Screen for Setting Different Parameters
The touch screen can be used for selecting different functions such as Standard/Supply Voltage/Frequency/Inner Shield(Vc)/Electrode with Impedance/DC offset. In the main page, user can use the up arrow button or down arrow button to switch different options. Else, user can double click the function area to have all the options shown in a separated page.

6.1.1.1   Standard

Click on [Standard], totally 12 options can be selected as [Manual], [IEC60601-2-25], [IEC60601-2-27], [IEC60601-2-47], [YY1079], [YY1139], [YY0782], [YY0885], [EC11], [EC13], [IEC60601-2-26], [Noise]. Once the option for [Standard] is selected, the relevant setting options will be limited in accordance with the requirements of each standard. For example, when [IEC-2-25] is chosen, [Supply Voltage] is limited to [20 Vrms] and the frequency can only be 50 Hz or 60 Hz.
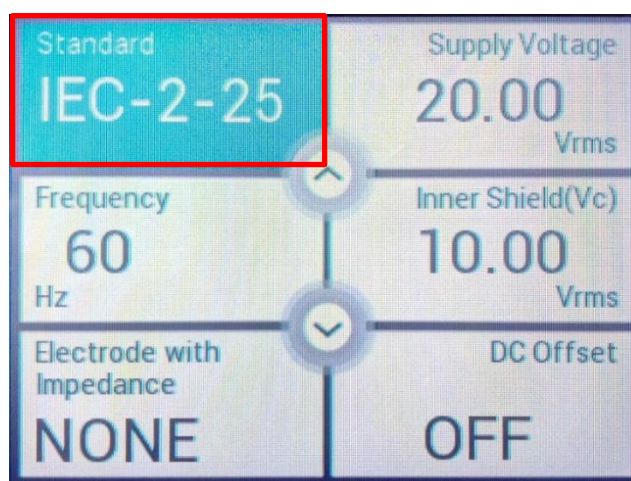

Figure 6-1, Options in "Standard"

6.1.1.2 [Supply Voltage] and [Frequency]

Select [Manual] in [Standard] option, and then select [Voltage]. Now the [Voltage] can choose [Off], [20], [2.828], [0.5] and [2.0] Vrms (200/56.6/8/1.422/5.66 Vpp) for Supply Voltage Vs (the output voltage of built-in sine wave signal generator) and 50/60/100/120 Hz for frequency.

After pressing the hole above [Coarse] knob for 6 seconds and launching the hidden voltage of 70.71 Vrms (200 Vp-p), a [70.71 Vrms] option becomes available for voltage Vs. Now it is possible to test a CMRR value that exceeds the requirement of standards. Although this voltage exceeds all of the standard requirements, it extends the range of CMRR test to 120dB (if the ECG output is measured at 0.1mV, then 20log(100 Vp-p/0.1 mV)=120 dB).
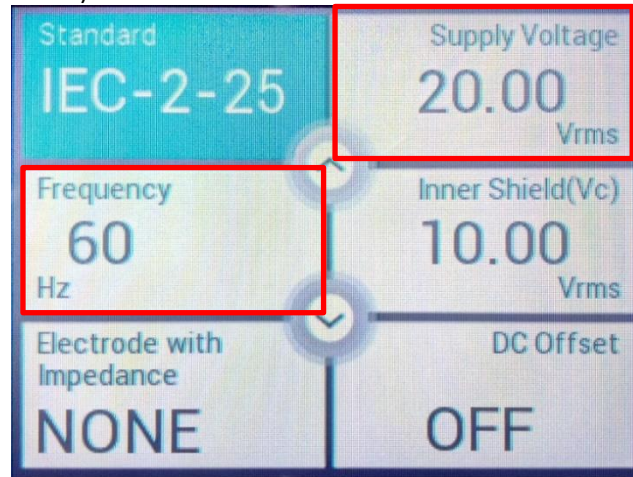

Figure 6-2, Options in [Supply Voltage] and [Frequency]

6.1.1.3 Inner Shield Vc

Once [Supply Voltage] (Vs) is selected, the [Coarse] / [Fine] knobs can be tuned to Inner shield Vc =Vs/2. This action automatically measures and monitors the voltage that passes variable capacitance Ct with built-in Vc voltage test circuit. By tuning [Coarse] / [Fine] knobs, the inner Ct is tuned until Ct+Cx (stray capacitance) =100 pF, where Vc will be half of the output of line frequency signal generator. For example, when Vs= 20 Vrms, Vc=10 Vrms.
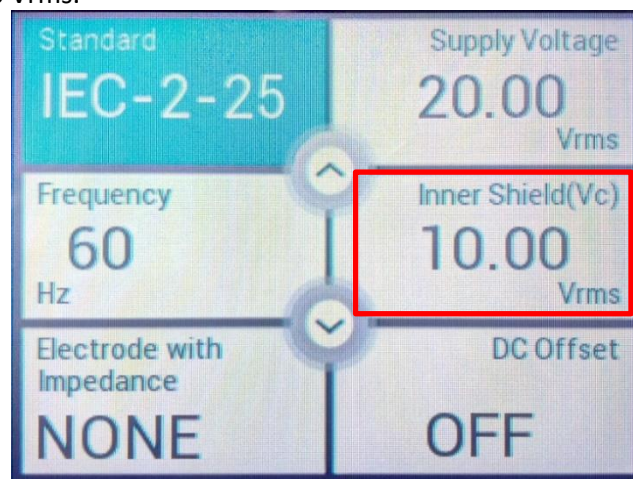

Figure 6-3, voltage display of "Inner Shield Vc"

6.1.1.4 Electrode with Impedance

Select [Electrode with Impedance] and click the arrow button (or double click to have all the options to show in the separated page) to choose whether to add 51KΩ/47nF parallel circuit to the test electrode (Electrode with/without Impedance). Adding 51KΩ/47nF to all or none of the electrodes is referred to balanced test. Adding 51KΩ/47nF to one of the electrodes, or all the electrodes except one, with the others in the opposite, is referred to imbalanced test. Available settings for CMRR 3.0+ are as follows:

- Electrode with Impedance: None, none of the electrodes is added 51KΩ//47nF parallel circuit, balanced test
- Electrode with Impedance: RA (LA/LL/V1~V6), only RA (LA/LL/V1~V6) is added 51KΩ//47nF and the other electrodes are not, imbalanced test
- Electrode with Impedance: All, all of the electrodes are added 51KΩ//47nF parallel circuit, balanced test
- Electrode without Impedance: RA (LA/LL/V1~V6), all of the electrodes are added 51KΩ/47nF except RA (LA/LL/V1~V6), imbalanced test
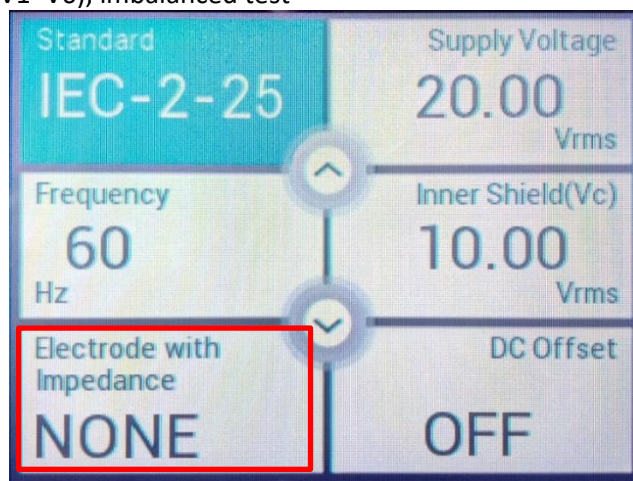

Figure 6-4, options in "Electrode with Impedance"

6.1.1.5 DC Offset

Select [DC Offset] and use the arrow button to choose whether to add ±300 mV DC offset or not. ±300 mV DC offset has to be tested on the electrode with imbalanced test. For example, choosing [RA] for [Electrode with/without Impedance] allows [±300 RA] to be chosen for [DC Offset]. There are 9 electrodes available for ±300 mV DC offset in total: RA, LA, LL, V1, V2, V3, V4, V5, V6.

As per the circuit diagrams in related standards, ±300 mV can be added only to [RA] for imbalance and DC offset testing.
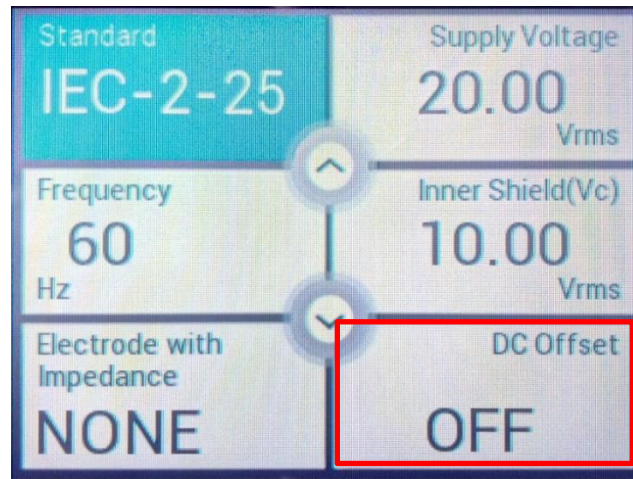
Figure 6-5, options in "DC Offset"

CMRR 3.0+ uses a built-in battery supplying the electricity required by DC offset option. Before turning off the power, user must check and confirm DC offset is switched to "OFF". If not, it would keep consuming battery power in the power-off status.

6.1.2   Test Exemplification

6.1.2.1   IEC60601-2-25: 2011

IEC 60601-2-25 is the testing standard for 12 leads diagnostic ECG. User can use CMRR 3.0+ and follow the below testing procedures based on IEC 60601-2-25 to conduct the test.

1. Set up a noise-free test environment as per figure 3-1.
2. Disconnect patient cables
3. Select "Standard" to "IEC-2-25"
4. Select "Supply Voltage" to "20 Vrms" and "Frequency" to "60 Hz"
5. Adjust Coarse and Fine knobs until Inner shield (Vc) is ~10 Vrms
6. Connect patient cable
7. Select "Electrode with Impedance" to "None"
8. Select "DC Offset" to "Off"
9. Measure ECG DUT all leads output for at least 15 seconds
10. Select "Electrode with Impedance" to "RA"
11. Measure ECG DUT all leads output for at least 15 seconds
12. Select "DC Offset" to "+300 RA"
13. Measure ECG DUT all leads output for at least 15 seconds
14. Select "DC Offset" to "-300 RA"
15. Measure DUT ECG all leads output for at least 15 seconds
16. Select "DC Offset" to "Off"
17. Select "Electrode with impedance" to "LA", then to "LL/V1~V6"
18. Measure DUT ECG all leads output for at least 15 seconds
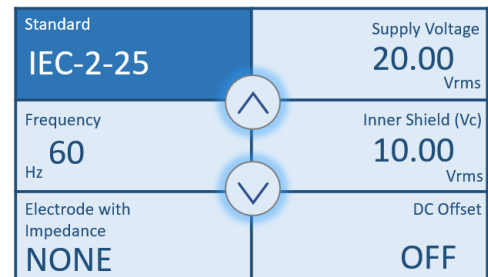
6.1.2.2   IEC60601-2-47: 2012

IEC 60601-2-47 is the testing standard for Holter monitor. User can use CMRR 3.0+ and follow the below testing procedures based on IEC 60601-2-47 to conduct the test.

1. Set up a noise-free test environment as per figure 3-1.
2. Disconnect patient cables
3. Setting CMRR 3.0+ "Standard" to IEC-2-47
4. Select "Supply Voltage" to "2.828 Vrms" and "Frequency" to "60 Hz"
5. Adjust Coarse and Fine knobs until Inner shield (Vc) is ~1.414 Vrms
6. Connect patient cables
7. Select "Electrode with Impedance" to "All" and "DC Offset" to "Off"
8. Measure and record the worst interference signal on ECG DUT
9. Select "DC Offset" to "+300 RA"
10. Measure and record the worst interference signal on ECG DUT
11. Select "DC Offset" to "-300 RA"
12. Measure and record the worst interference signal on ECG DUT
13. Select "DC Offset" to "+300 LA"
14. Measure and record the worst interference signal on ECG DUT
15. Select "DC Offset" to "-300 LA"
16. Measure and record the worst interference signal on ECG DUT
17. Select "DC Offset" "+300 LL/V1" (If LL/V1 electrodes exist)
18. Measure and record the worst interference signal on ECG DUT
19. Select "DC Offset" "-300 LL/V1" (If LL/V1 electrodes exist)
20. Measure and record the worst interference signal on ECG DUT
21. Select "DC Offset" to "Off"
22. Select "Electrode with impedance" to "None"
23. Measure and record the worst interference signal on ECG DUT
24. Select "Electrode with impedance" to "RA"
25. Measure and record the worst interference signal on ECG DUT
26. Select "Electrode with impedance" to "LA"
27. Measure and record the worst interference signal on ECG DUT
28. Select "Electrode with impedance" to "LL/V1" (If LL/V1 electrodes exist)
29. Measure and record the worst interference signal on ECG DUT
30. Select "Frequency" to "120 Hz" and "Supply Voltage" to "0.5 Vrms".
31. Repeat step. 7 ~ 29

6.1.2.3   IEC60601-2-26: 2012

IEC60601-2-26 is the medical standard for EEG. Based on the requirement of IEC60601-2-26, the output amplitude of all channels shall not exceed 100 µVp-v (10 mm p-v at 0.1 mm/µV gain), WhaleTeq suggests use RA/LA/LL/V1/V2/V3/V4/V5/V6 terminals to proceed balance and imbalance tests with DC offset options. This is to ensure the absolute balance of CMRR 3.0+ output signals and increase the precision of CMRR test.

The following test procedures are all followed the requirements stated in IEC60601-2-26 and can be taken as test examples of CMRR 3.0+. Due to the different naming rules between EEG and ECG standards, hereby we use Ch1, Ch2...etc, to prevent from further confusions.

1. Set up a noise-free test environment as per figure 3-1.
2. Disconnect electrode cables
3. Setting CMRR 3.0+ "Standard" to IEC-2-26
4. Select "Supply Voltage" to 2.0 Vrms and "Frequency" to "50 Hz" or "60 Hz"
5. Adjust Coarse and Fine knobs until Inner shield (Vc) is ~1.000 Vrms
6. Connect Ch1 to RA, Ch2 to LA, Ch3 to LL, Ch4 to V1, Ch5 to V2, Ch6 to V3, Ch7 to V4, Ch8 to V5 and short Ch9 with Chn and connect to V6.
7. Select "Electrode with Impedance" to "RA"
8. Select "DC Offset" to "Off"
9. Measure EEG Ch1 output for at least 60 seconds
10. Select "DC Offset" to "+300 RA"
11. Measure EEG Ch1 output for at least 60 seconds
12. Select "DC Offset" to "-300 RA"
13. Measure EEG Ch1 output for at least 60 seconds
14. Select "DC Offset" to "Off"
15. Select "Electrode with impedance" to "LA", "LL" ,"V1", "V2", "V3", "V4", "V5" and "V6" in sequences
16. Measure EEG Ch2~Ch9 output for at least 60 seconds.
17. Switch Ch10~Ch18 with Ch1~Ch9 and repeat step 7~16 to measure Ch10~Ch18
18. Repeat the switch procedures until Chn is measured
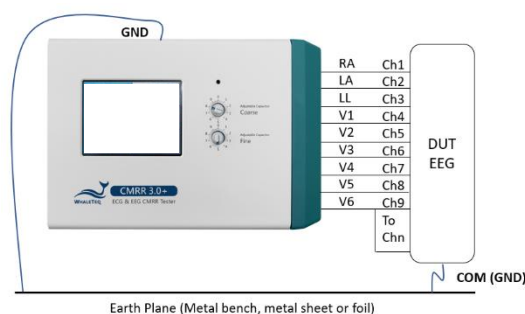
6.2   PC Software Operation

CMRR 3.0+ can be connected to PC via USB cable. Once connect to PC, CMRR 3.0+ can be controlled and commanded through PC software. User can also develop software by using CMRR 3.0+ SDK (Software Development Kit) to fulfill automated test requirements.

CMRR 3.0+ Assistant Software is the powerful add-on software provided by WhaleTeq, which enables PC to control CMRR 3.0+ parameter setting and simplify standards into selectable options, including test sequences required by each standard.
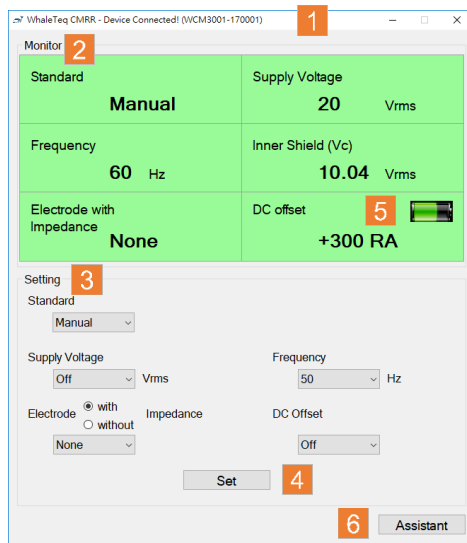
6.2.1   CMRR 3.0+ PC Software

CMRR 3.0+ PC software can control all the test parameters except adjusting Vc value via coarse knob and fine knob.

Once CMRR 3.0+ is connected to PC through USB interface, CMRR 3.0+ software will show the serial number in the title bar as shown in figure 6-6. The connection is successful if the serial number shows, otherwise the message "Device Not Found" will appear.

The parameters can be set once the connection is successful. The setting method is the same as stand-alone operation. After setting, click [Set] button to send the set parameters to CMRR 3.0+ in order to change its parameter values.

Since the 300 mV DC is supplied by battery, remained battery capacity will be displayed in the [DC Offset] field.

Please note that under the CMRR 3.0+ PC software mode, CMRR 3.0+ Touch LCD screen shall display "PC LINK.." and user shall be able to adjust the test parameters in CMRR 3.0+ PC software.

1. CMRR 3.0+ connection status
2. CMRR 3.0+ test parameter display
3. CMRR 3.0+ test parameter adjustment
4. Send setting parameters to CMRR 3.0+
5. Battery capacity of DC offset 300 mV
6. Launch CMRR 3.0+ Assistant software

Figure 6-6, CMRR 3.0+ PC software UI

6.2.2   CMRR 3.0+ Assistant Software

Refer to figure 6-7 for software interface of CMRR 3.0+ Assistant Software. This is mainly used to support test sequences required by various standards. As test sequences vary in each standard, CMRR 3.0+ Assistant Software can effectively simplify the complication of switching different test parameters.

The tab on top of the window indicates the supported standards, including IEC 2-25/27, IEC 2-47, YY0782, YY0885, YY1079/1139, EC11/13, IEC2-26, etc. Once select a standard, follow the software guide to go through the setting of test parameters. Also, the test can be conducted manually or automatically.

Here we take IEC 2-25/27 as an example to explain the test sequence. These two standards are put in one option because their test steps are completely the same. Other standards with same steps are YY1079/1139 and EC 11/13.

6.2.2.1   Step 1. Preparation

First, after clicking [IEC 2-25/27], the test step automatically starts at "Step 1. Preparation". It also explains required settings, as shown in the three green-shaded descriptions in figure 6-7:

1. No ECG patient cable is attached
2. The line frequency notch filter (if provided) of ECG is turned off
3. Set the ECG GAIN to 10 mm/mV and the sweep speed to 25 mm/s

Make sure ECG follows these three settings, and click [Next] to continue to next step.
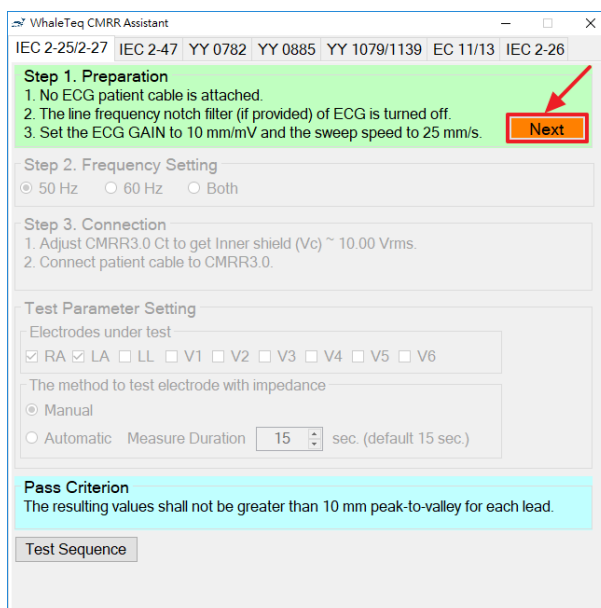
Figure 6-7, standards assistance window of CMRR 3.0+ Assistant

Before clicking [Next], if not familiar with the test sequence, user can click [Test Sequence] first to make the test sequence shown simultaneously, as shown in figure 6-8. The blue-shaded description texts in [Test Sequence] change as the test steps proceed. This makes the user to have a better understanding of the test sequences.
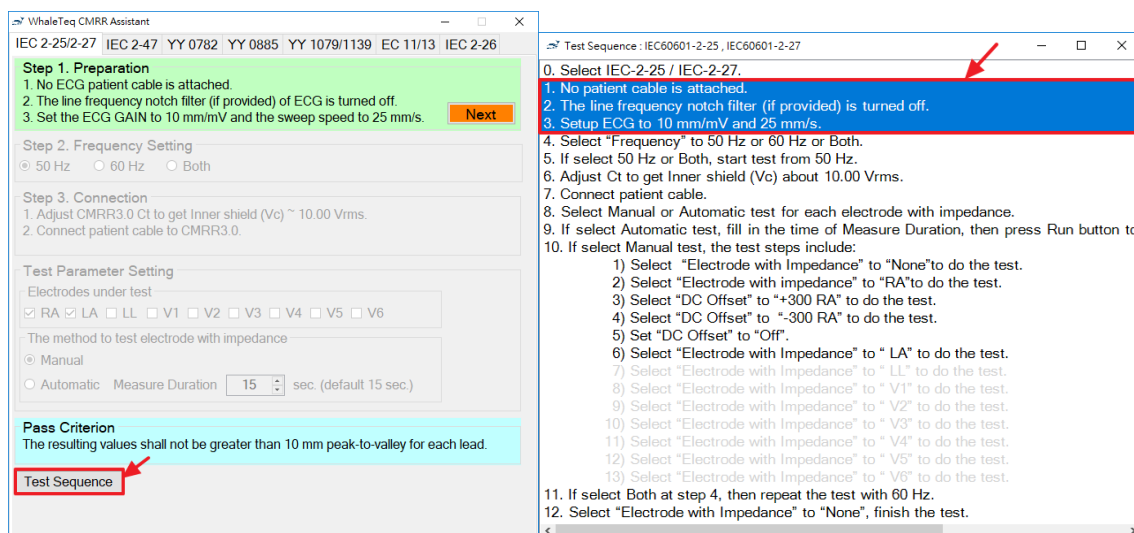
Figure 6-8, Software interface and test sequence description of CMRR 3.0+ Assistant

6.2.2.2   Step 2. Frequency Setting

Set the line frequency to either 50Hz or 60Hz, or both. When both frequencies are selected, the setting of 50Hz will be performed first, and the same setting would be performed automatically with frequency replaced with 60Hz.

6.2.2.3   Step 3. Connection

Connect to patient cable. This includes two settings:

1. Tune Ct until Vc= 10 mV (tune [Coarse]/[Fine] knob)
2. Connect patient cable to CMRR 3.0+ (after tuning Vc)

As the stray capacitance of patient cable affects the 100 pF capacitance value in CMRR 3.0+, Vc should be tuned after detaching patient cable.

6.2.2.4   Test Parameter Setting

Set the test electrodes first (not all the ECG models are having 12 leads). In figure 6-9, all the electrodes are selected to meet the requirements of IEC60601-2-25 and IEC60601-2-27. Then choose [Manual] of [Automatic] test. If manual test is chosen and [Test Sequence] is opened, the right window in figure 6-9 will appear after clicking [Run] button. According to test sequence of -2-25 standard, [Electrode with Impedance] will automatically choose [None] for balanced test. The test time will be automatically counted in second and shown at the upper right corner, with total test time shown below it. After recording the test result, please click [Next]. The setting will be automatically switched to [Electrode with Impedance RA] and the time at the upper right corner will be returned to zero and counted in second again.
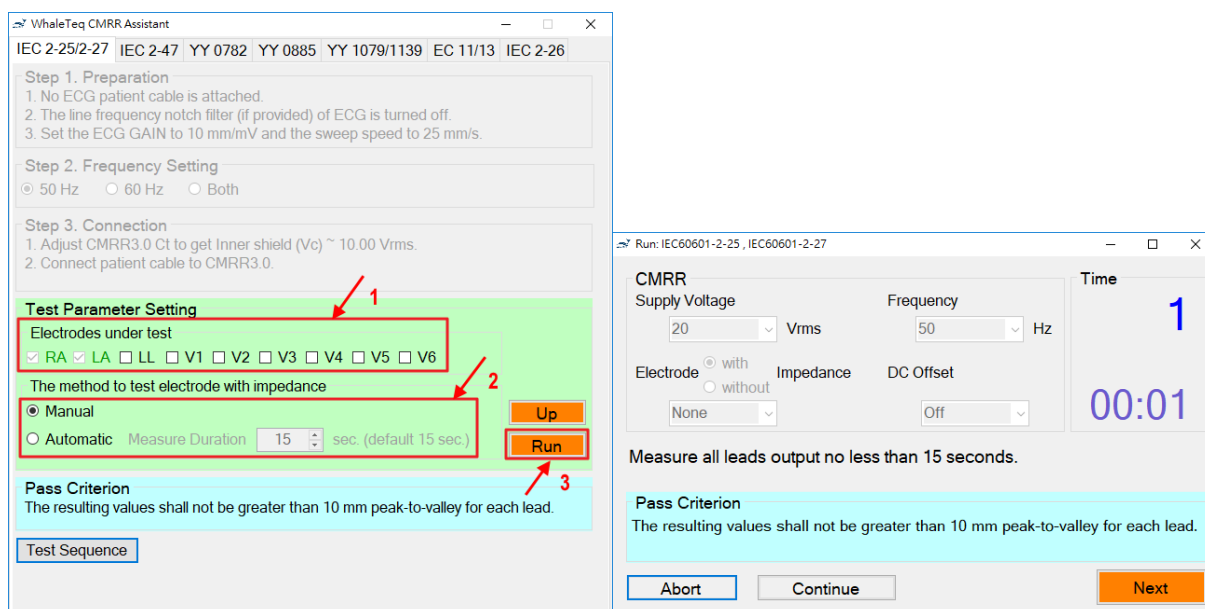
Figure 6-9, Software interface and run test windows of CMRR 3.0+ Assistant

The display of [Test Sequence] is shown as the highlighted 1) step in figure 6-10, which indicates a balanced test when setting [Electrode with Impedance: None]. As [Next] button being selected, [Test Sequence] automatically highlights 1)~13) step by step. This explains the complete steps in -2-25/27 test (refer to 6.1.2.1 showing detailed steps for IEC60601-2-25: 2011 as the example).
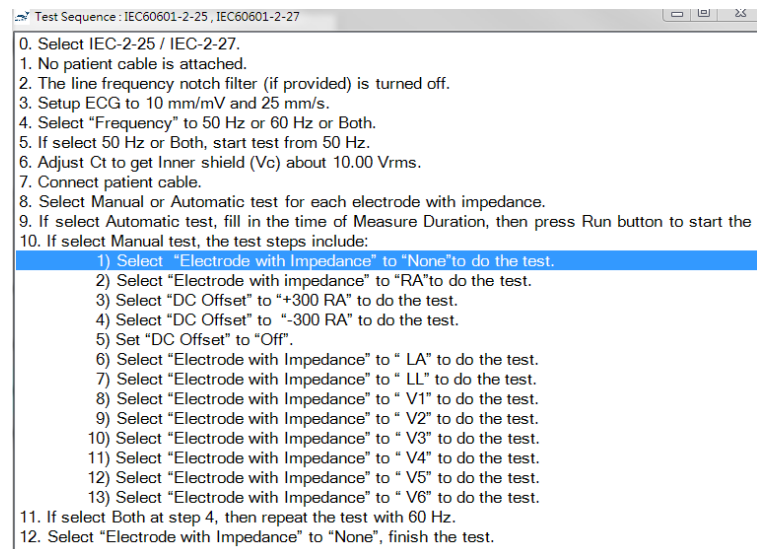
Figure 6-10, IEC 2-25/27 test sequence window

7   Software Development Kit (SDK)

WhaleTeq provides CMRR 3.0+ software development kit. All operating parameters and options have corresponding commands in the software development kit. The software development kit contains DLL (Dynamic-link library), which will provide highly efficient program binding and version upgrade, supports C/C++ header and C# interface, and can also be integrated with third-party tools and script languages.

8   Calibration and Validation

Both WHALETEQ CMRR 3.0+ and software have been system verified, and reports can be provided according to your needs.

Whaleteq original calibration service is equipped with calibration equipment specially designed for physiological simulator to ensure the accuracy of calibration, and can calibrate the offset value of the device within the original specification of Whaleteq. Under normal use, the device is recommended to be calibrated once a year. Please refer to the contact information and contact Whaleteq for the original calibration service.
Note: If Whaleteq detects that the components of the device are damaged and makes it impossible to adjust, it shall be sent back for maintenance.

9   Trouble shooting

Problem	Resolution
USB module (test unit) not recognized (USB driver is installed correctly)	Recognition of USB devices needs to be done in order: 1) Close WhaleTeq software if open 2) Disconnect the USB module for ~2s 3) Reconnect the USB module 4) Wait for the recognition sound 5) Start WhaleTeq software
USB module stops responding	Move the main function mode to "Off" and then return to the function being used. If this does not work, close WhaleTeq software, disconnect the USB

	module, reconnect the USB module and re-start the USB module.

10   Caution

10.1   Baseline noise test

When the CMMR 3.0+ is connected to the power supply, it is impossible to eliminate high frequency noise from switching power supplies. Such high frequency noise is unlikely to affect the test. However, in case of doubt, the operator can select the "NOISE" setting, turn the unit off and remove the power supply. The internal relays in the isolated circuit are a special latch type and will hold the NOISE setting even with the power removed. This allows the test to be performed without any concern from noise arising from internal or external switching power supplies.

10.2   Battery power consumption for DC offset function

CMRR 3.0+ uses a built-in battery supplying the power required by DC offset option. Before turning off the power, user must check and confirm DC offset is switched to "OFF". If not, it would keep consuming battery power in the power-off status.

10.3   Vs voltage drop with the multimeter of 1MΩ input impedance

"Vs" output of CMRR 3.0+ would have a 0.4% voltage drop when a multimeter with 1MΩ input impedance is used to monitor "Vs" output.

WhaleTeq recommends to use a 10MΩ input multimeter (ex. Fluke 87V) to minimize the voltage drop range.

Vs voltage drop with the multimeter of 1MΩ input impedance

10.4   QC Pass Label

Warranty void if QC PASS label is removed or tampered with.

10.5   Instrument description

The professional testing instrument, not a medical device, is for testing only, and will not involve human or clinical use.

11   CMRR 3.0+ Specifications

Item	Option	Spec
Supply voltage	0.5 / 2.828 / 20 / 2 / (70.71) (Vrms)	±1% [1]
CM point voltage	1.414 / 10/ 1/ (35.355) (Vrms)	±1% (0.25Vrms ±2%)

Frequency	50 / 60 / 100 /120 (Hz)	±1%
Electrode with Impedance	Change electrode via the touch screen of CMRR 3.0+	None/RA/LA/LL/V1~V6 /ALL
Electrode without Impedance	Change electrode via the touch screen of CMRR 3.0+	RA/LA/LL/V1~V6
Imbalance impedance, R	51kΩ	51kΩ ±1%
Imbalance impedance, C	47nF	47nF ± 5%
DC offset	Internal battery powered, can be added on RA/LA/LL/V1/V2/V3/V4/V5/V6	300mV ± 1% Up to 40hrs with intermittent use
100 pF capacitor	Use 11:1 (110MΩ:10MΩ) voltage divider to measure indirectly	100pF ± 5%
Environment	Intended for normal laboratory environment. The selection of critical components is known to be stable in the range shown. The 110MΩ divider may be affected by high humidity in excess of 85%.	15-30°C 10-75% RH

[1] Require to measure with the multimeter of higher accuracy.

12   Ordering Information

12.1   Package Contents
- CMRR 3.0+ x 1
- CMRR 3.0+ Software CD x1
- Top Shielding Cover x 1
- Bottom Shielding Cover x 1
- Compound terminal x 11
- USB Cable x 1
- Grounding Cable x 1
- 12V Power Supply Adapter, excluding power cord

12.2   Optional Software and Accessories
- CMRR Assistant Software: IEC60601-2-25/27/47
- CMRR Assistant Software: IEC60601-2-26,
- CMRR Assistant Software: YY0782/0885/1079/1139, AAMI/ANSI EC11/13
- External Shielding Case

13   Version Information

Version	Modify content	Issue date
20201231	Add Chap 7 Software Development Kit（SDK） Chap 8 Calibration and Validation Chap 9 Trouble shooting Chap 13 Version information	20201231
20210608	Add Chap 10 Cautions	20210608
20220506	Update	20220506

	1. Chap 4 Principle of the CMRR test 4.1 Common mode rejection ratio explained 2. Chap 8 Calibration and Validation	

14   Contact Information

WHALETEQ Co., LTD
service@whaleteq.com	(O)+886 2 2517 6255
8F., No. 125, Songjiang Rd., Zhongshan Dist., Taipei City 104474, Taiwan