WHALETEQ

Single Channel ECG Test System (SECG 4.0)

User Manual

Version: 2022-10-13

Disclaimer

WhaleTeq Co. LTD. provides this document and the programs "as is" without warranty of any kind, either expressed or implied, including, but not limited to, the implied warranties of merchantability or fitness for a particular purpose.

This document could contain technical inaccuracies or typographical errors. Changes are periodically made to the information herein; these changes will be incorporated in future revisions of this document. WhaleTeq Co. LTD. is under no obligation to notify any person of the changes.

The following trademarks are used in this document:

is a registered trademark of WhaleTeq Co. LTD

All other trademarks or trade names are property of their respective holders.

Contents

List of Table

List of Figure

1 Introduction

1.1 Basic concept

The WhaleTeq Single-channel ECG Test System 4.0 (SECG 4.0) provides a single waveform to one or more lead electrodes of diagnostic, ambulatory, or monitoring ECGs, for testing IEC/YY/JJG standards. The following diagram shows the single-channel concept:

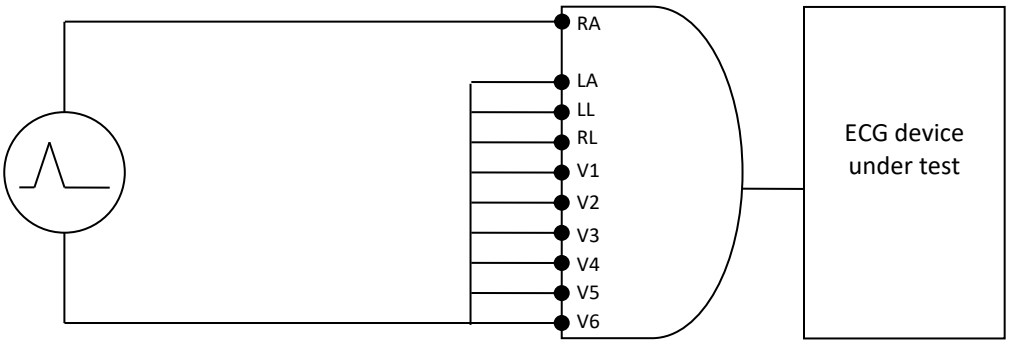


Figure 1: Single-channel Concept

Via a SECG 4.0, the system produces arbitrary waveforms (streamed from the PC with digital to analogue conversion) at up to ±5V, which is then applied to a precision 1000:1 divider to produce the voltages at up to ±5mV level (10mVpp). The SECG 4.0 contains resistor/capacitor networks, DC offset, pacing circuit, and relay switching to provide the full range of single-channel performance tests in IEC/YY/JJG standards as described in Section 1.2.

The basic range of tests in the standards include, for example:

- Sensitivity (accuracy of the mV/mm indication)
- Frequency response (sine wave, and impulse tests)
- Input impedance
- Noise
- Multichannel cross talk
- Accuracy of heart rate indication
- Pacemaker rejection
- Tall T-wave rejection

For a full list of tests, refer to the standard together with Section 1.2.

The system does not provide:

- CMRR tests (this requires a special noise free box, please refer to CMRR 3.0 on WhaleTeq website)
- Multichannel waveforms, such as the CSE, AHA, MIT databases (this requires a multichannel system, please refer to MECG 2.0 on WhaleTeq website)

1.2 Standards/Application

The following table shows the standards for which this system has been designed for including any limitations:

Table 1: Standard/Application

Standard	Clause(s)	Limitations / Notes
IEC 60601-2-25:2011 (Diagnostic)	201.12.4: All performance tests Except： ◆ CMRR test and baseline noise ➔ use WhaleTeq CMRR 3.0 ◆ Test referring to the CTS atlas (CAL/ANE waveforms)*, CSE database ➔ use WhaleTeq MECG 2.0 *Note: for most tests CAL/ANE waveforms are alternates. For two tests may be required (201.12.4.102.3, test of lead networks; and	For 201.12.4.101 (large DC offset test), the SECG is limited to ±1VDC. However, this is almost certainly enough to exceed the point of saturation. For the test circuit in figure 201.110, switch position A is not provided. This is considered an error in the standard due to the loading effect of R2. Instead the DC offset is provided in series with output as per Figure 201.106. (See section 3.2 for notes on switching between P1, P2 and P6.)

Standard	Clause(s)	Limitations / Notes
	201.12.4.105.3 test of ringing from mains notch filter)	
IEC 60601-2-27:2011 (Patient monitoring)	201.7.9.2.9.101 b), 4) and 6) (special test waveforms for Figure 201.101) 201.12.1.101, all performance tests except baseline noise and CMRR (use WhaleTeq CMRR3.0 for these tests)	No known limitations
IEC 60601-2-47:2012 (Ambulatory)	201.12.4, all tests except CMRR (use WhaleTeq CMRR 3.0 for these tests) For all 201.12.1.101 database tests, use WhaleTeq MECG 2.0 for these tests.	No known limitations
ANSI/AAMI EC 13 2002/(R)2007/C2008	All performance tests except CMRR and as noted left.	See below for Clauses 5.1.4 n) and 5.2.9.1 f), g) [1]

General limitation: this equipment is designed for use with isolated ECG circuits, as are generally provided for medical ECG. If applied to a non-isolated circuit, the noise may be excessive.

[1] 5.1.4 n) Fast QRS: The sampling rate is limited to 0.2ms, some distortion of the pulse is possible below 6ms.
5. 2.9.1 f), g): Functionality is not included at this time; note the test is not applicable to most ECG systems

1.3 Block diagram/SECG 4.0 Module overview

The following is a simplified block diagram of the system inside the SECG 4.0 module:

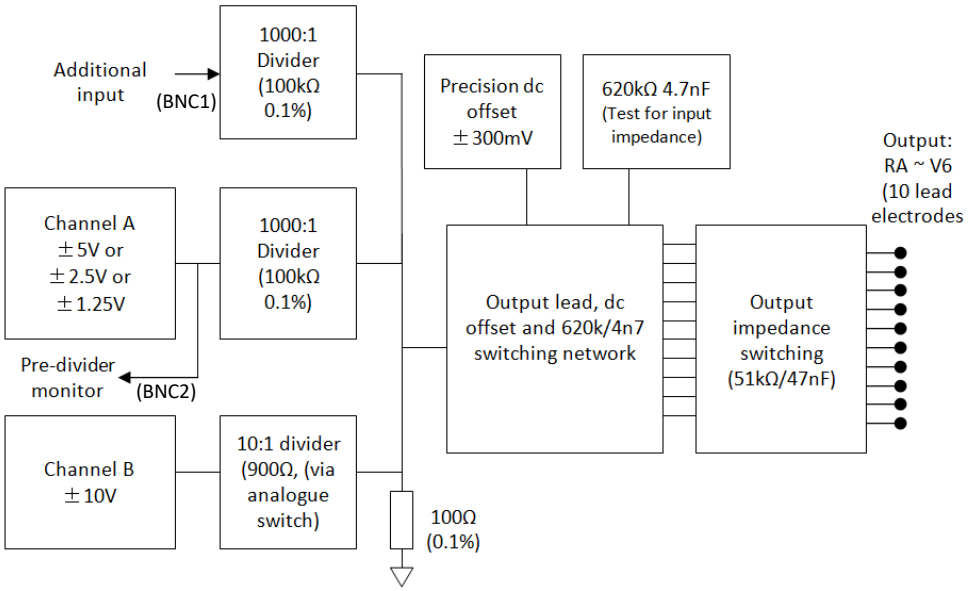


Figure 2: Simplified Block Diagram

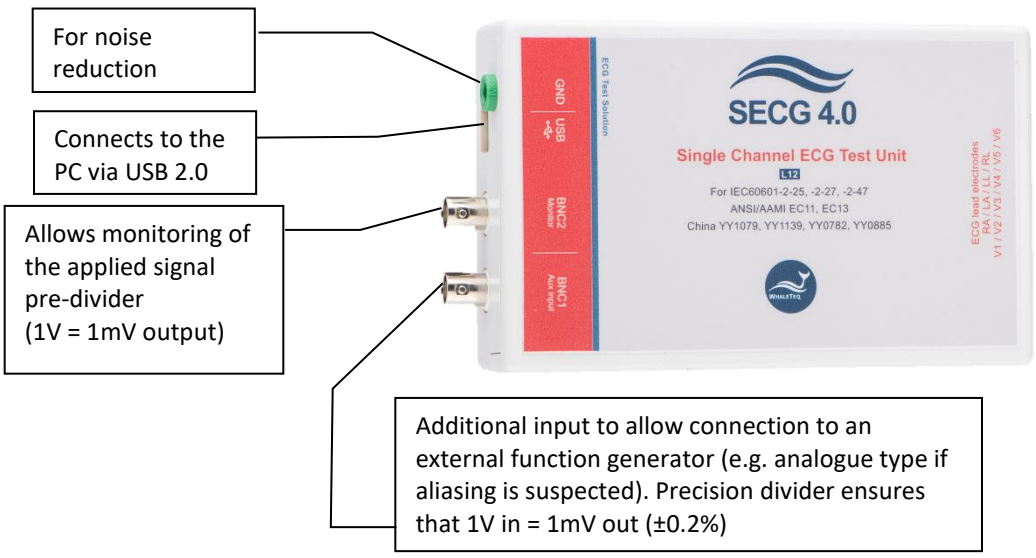


Figure 3: SECG 4.0 Module

1.4 Main specifications

In general, the system has been designed to the standards above, taking into account Clause 201.5.4 in IEC 60601-2-25 and IEC 60601-2-27. Below includes these parameters and also other system parameters necessary for testing. For reference, the system capability is provided.

Table 2: Main Specification

Parameter	Specification	System capability / notes
Main output voltage accuracy	±1% for amplitudes of 0.5mVpp or higher	±0.3%
Main output voltage resolution (DAC resolution)	2.5µV	In version 4.0, a single output range is used
Frequency / pulse repetition rate accuracy	±1%	±0.1%
Pulse duration / timing accuracy (excluding pacing)	±1ms	±0.2ms
Pacing pulse width accuracy	±5µs	±1µs
Pacing pulse amplitude accuracy, range	±2mV pulse: ±1% >2mV pulse: ±10% Range: ±2mV to ±700mV	±2mV pulse: ±0.3% 100mV pulse: ±1% or ±5mV
Pacing pulse characteristics	Rise/fall time 5µs Overshoot <1% Settling time <1%	
Pacing pulse overshoot (intentional)	Method A according to IEC 60601-2-27	
Resistor tolerance	±1%	±0.5%
Capacitor tolerance	±5%	±5%
Precision 1000:1 divider (100KΩ:100Ω)	±0.2%	±0.1%
Sample rate	5kHz ± 0.1%	5kHz ± 0.05% (50ppm)

Parameter	Specification	System capability / notes
DC offset (fixed, noise free, sourced from internal super capacitor)	300mV ± 1%	300mV ±0.1%
DC offset (variable, may include up to 50µVpp noise)	Setting ±1% or ±3mV	Setting ±1% or ±3mV
Power supply	USB +DC supply (no separate power supply required) 0.5A (high power mode)	Typical load<0.25A, up to 0.45A is possible if all relays are turned on
Environment	15 ~ 30°C (by design, not tested) 30 ~ 80% RH (design not tested)	Selection of components is such that no effect from the environment is expected.
Safety, EMC standards	No applicable safety standards (maximum internal voltages 12V DC) For EMC no testing performed. CE marking based on careful selection of parts, including USB protection IC, as well as special filters to reduce noise from microprocessor (8MHz) and DC/DC converter (200kHz).	

*Additional specifications may be provided on request.

2 Set up

2.1 Software installation

2.1.1 System requirements

The Single-channel ECG system uses a normal PC to interface and control the USB module.

PC requirements:

- Windows PC (Windows 7 or later, suggest to use the genuine version)
- Microsoft .NET 4.0 or higher
- Administrator access (essential for installing software, driver, and Microsoft .Net Framework)
- 1.5 GHz CPU or higher
- 1GB RAM or higher[2]
- USB port

2.1.2 SECG 4.0 Software Installation

Please follow the below steps to download and execute SECG Software.

1. Download SECG software from WhaleTeq website.
2. Browse to the download location.
3. Unzip the file to your destination folder.
4. Open the destination folder and make sure all files are unzipped in the same folder.
5. Double click on the *SingleChannelECG.exe* to execute the SECG4.0 program.

[2] Relative to normal PC processing, there is no special use of PC speed. However, there has been noted a slow increase in system RAM usage over long periods of time up to 30-40MB (related to MS Windows "garbage collection"). PCs with only 512MB or less installed and are running several other programs (in particular, Internet Explorer), may exceed the available RAM, requiring access to the hard drive and dramatically impacting speed. In this case, streaming interruptions and other problems may occur.

If SECG software can't be executed properly or this is the firsttime using WhaleTeq product, please refer to below two sections to confirm that USB driver and Microsoft .Net Framework 4.0 are all installed.

2.1.3 USB Driver Installation

If Windows device manager can't recognize WhaleTeq product, please follow the below instructions to Install Microchip® USB driver.

Microsoft Windows 10

As Windows 10 has built-in Microchip® USB Driver, there're no needs to install any drivers. It just takes a while for Windows Device manager to recognize and install the driver.

Microsoft Windows 8 and Windows 8.1

1. Windows 8 and Windows 8.1 can't recognize SEEG unit, please download "mchpcdc.inf" from WhaleTeq website. This driver is provided by Microchip® for using with PIC microprocessors having built-in USB function.
2. As mchpcdc.inf provided by Microchip® does not contain digital signature, please disable driver signature enforcement in Windows 8 and Windows 8.1. Please click here to watch the tutorial video.
3. When the USB module is connected for the first time, select manual installation, and point to the folder containing the above file. Then continue to follow the instructions to finish the installation. There may be a warning that the driver is not recognized by Windows®, and this can be ignored. Please click here to watch the tutorial video.

Microsoft Windows 7

1. Windows 7 can't recognize SEEG unit, please download "mchpcdc.inf" from WhaleTeq website. This driver is

provided by Microchip® for using with PIC microprocessors having built-in USB function.

2. When the USB module is connected for the first time, select manual installation, and point to the folder containing the above file. Then continue to follow the instructions to finish the installation. There may be a warning that the driver is not recognized by Windows®, and this can be ignored. Please click here to watch the tutorial video.

2.1.4 Microsoft .Net Framework 4.0 Installation

WhaleTeq software is developed by Microsoft .Net Framework 4.0. If SEEG software fails to launch properly, please check whether Microsoft .Net Framework 4.0 or higher versions was installed in the operation system.

If your PC does not install Microsoft .Net Framework 4.0 or higher versions, please download from Microsoft website. Please click here to watch the tutorial video (from 2:03).

2.2 Connecting to the ECG

For connecting the ECG device to the USB module, use the “ECG breakout box” provided. The ECG breakout box includes:

(1) RA~V6 terminals: Total 10 terminals, corresponding to the 10 electrodes of 12-lead ECG (or fewer lead channel ECG)
(2) GND terminal: The terminal connected to the ground.
(3) CMRR Imbalance with DC: The terminal is only used with CMRR 2.0 for CMRR testing purposes.

Alternately the ECG device under test can be directly connected to the USB module using a male D15 connector. The pinouts are:

1-RA	4 – RL	7 – V4	10 - V1
2-LA	5 –V6	8 – V3	11- NC
3-LL	6 – V5	9 – V2	12- GND

2.3 Environment, noise reduction

A noise-free environment is necessary for testing ECG equipment. This can be achieved relatively easily by
(a) using a metal bench or metal sheet underneath the ECG device under test and the WhaleTeq SECG test unit, and
(b) connecting SECG GND terminal to the sheet and also the frame ground (or EP terminal) of the ECG device under test:

Figure 4: Noise Reduction Environment Setup

With this setup, turn the ECG device under test to maximum sensitivity, turn off the AC filters (if possible) and confirm that the level of noise is acceptable for tests. For most tests, this setup is satisfactory without any special efforts. However, for the input impedance test with the 620kΩ is in series the imbalance in impedance can cause high noise. For this test, the AC filter may be turned on. If the noise is still excessive, move to an electrically quiet environment or increase the size of the metal sheet underneath and around the setup.

2.4 Firmware Update

Firmware Update only can be supported with specific hardware and firmware, so if your SECG 4.0 doesn't support the feature, please contact Whaleteq for upgrade at service@whaleteq.com.

Question:

How to check your SECG 4.0 has supported Firmware Update?

Answer:

Connect the SECG 4.0 device to PC. Go to "About", and check whether the **"F/W Version"** and **"H/W Version"** buttons are hidden. (Please see **Step 1** in the below section for where to find "About".)

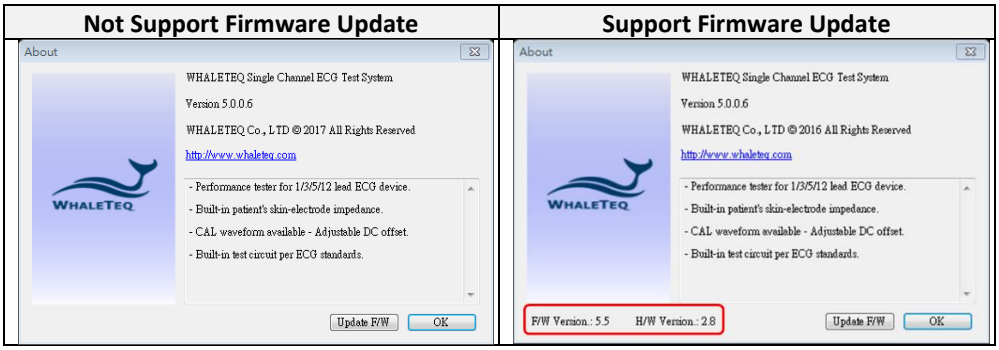


Figure 5: Firmware Update Confirmation

Note:

There are risks of losing data if improper options are performed during the firmware update period.

2.4.1 Firmware Update Instruction

If your SECG 4.0 supports "Firmware Update" feature. Below is the step-by-step instruction for how to update firmware:

Step 1.

Connect the SECG 4.0 device to PC, then open SECG application with version **5.0.0.6 or higher**. Move the cursor to System Menu Bar, right click your mouse. Then there will show up a menu, select "**About**".

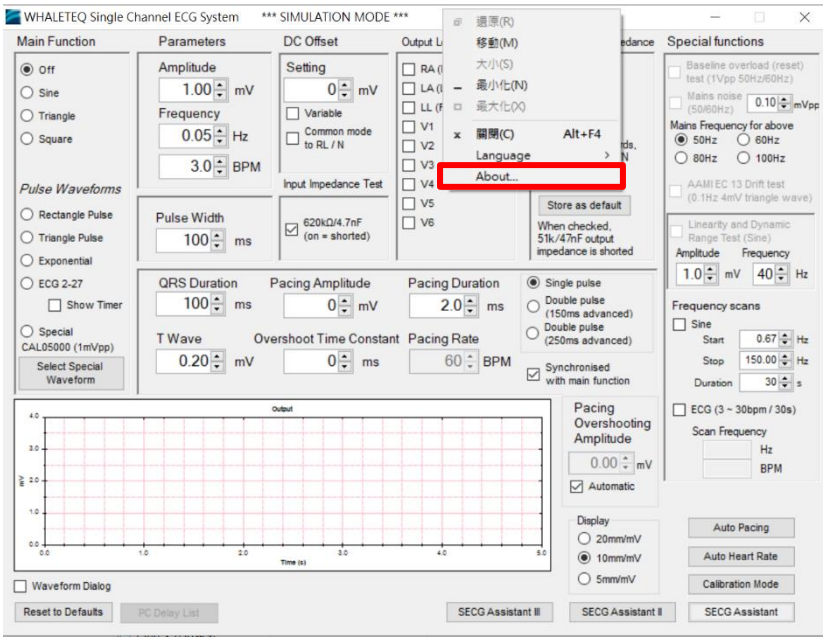


Figure 6: Function Table

Step 2.

"**About**" button is popped up. Press "**Update F/W**" button.

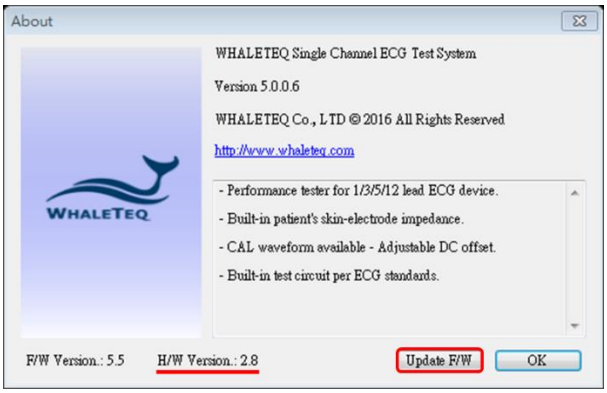


Figure 7: Update F/W Button.

Step 3.

Go to WhaleTeq website, refer to the below table to download compatible Firmware file.

Table 3: H/W F/W Version

Hardware Version	Firmware Version
2.7	4.4 or above
2.8 or above	5.5 or above

Step 4.

Back to SECG AP, select the downloaded firmware file.

Step 5.

The AP will show an information dialog. After pressing “OK”, the operation cannot be cancelled.

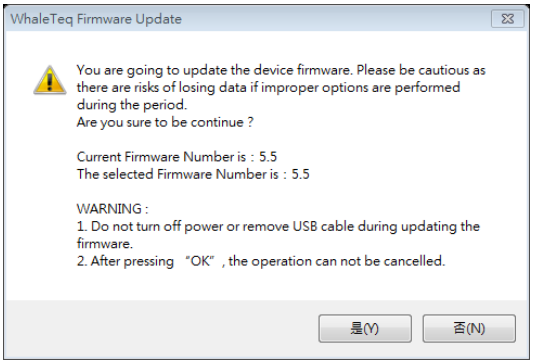


Figure 8: Information Dialog

Step 6.

Wait for firmware update complete.

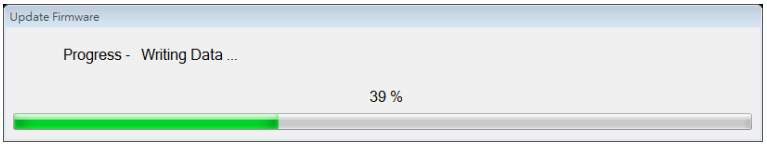


Figure 9: Firmware Updating

Step 7.

Please restart the SECG system to complete the firmware update process.

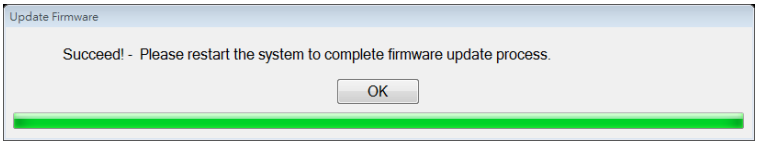


Figure 10: Firmware Update Completion

2.5 Main Screen

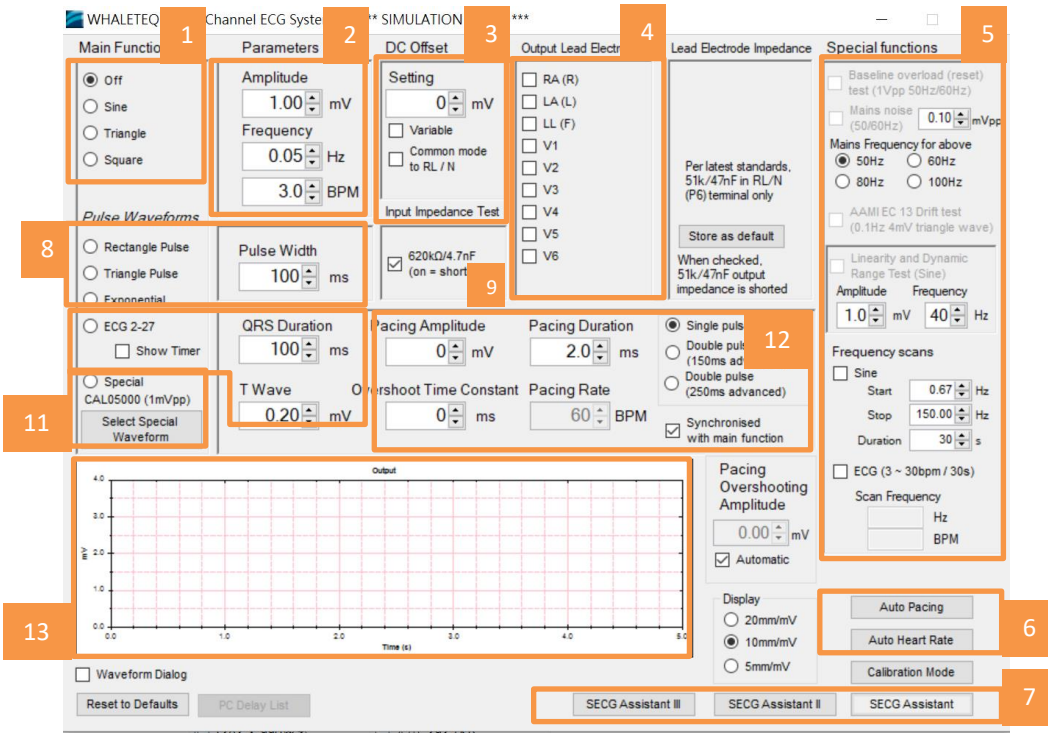


Figure 11: Main Screen

01 – Main Function：Select the main function (waveform) type, such as sine, triangle, etc.

02 – Main Parameters：General parameters for main waveform and pulse waveforms.

03 – DC Offset：DC offset settings.

04 – Output Lead Electrode：Select the lead electrode which the output is switched to.

05 – Special Functions：The functions for special test, such as frequency scan.

06 – Automated Functions：Provide automated test with different arrange combinations.

07 – SECG Assistant：Step-by-step guidance for standard performance tests. “SECG Assistant” is for IEC, “SECG Assistant II” is for YY and JJG (China standard), and “SECG Assistant III” is for GB.

08 – Pulse Waveforms：Select the pulse waveform type. “Pulse Width” is a related parameter.

09 – Input Impedance Test：Select if 620kΩ/4.7nF is in circuit (for input impedance test).

10 – ECG 2-27：A special waveform related to the ECG waveform (IEC 60601-2-27). QRS Duration and T Wave are the parameters for this waveform.

11 – Special Waveform：Provide CAL and AAMI waveforms. “Load ECG” function, the function allows customer to play their own waveform, is also provided here.

12 – Pacemaker Parameters：Parameters related to pacemaker pulses.

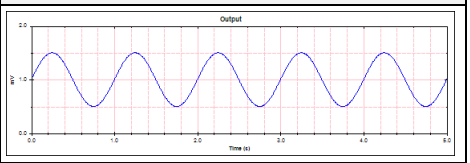
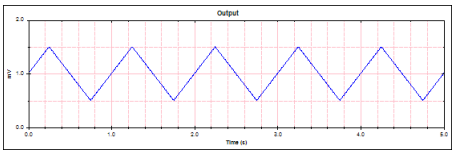
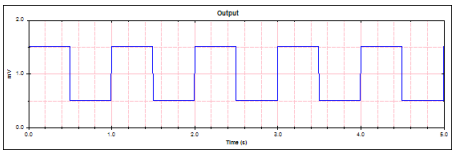
13 – Output Waveform：Provide a semi-real time graphical display of the current signal.

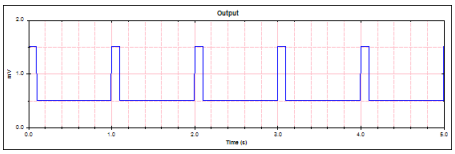
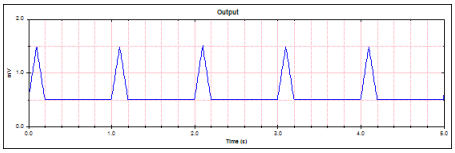
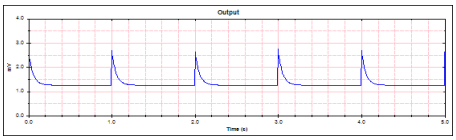
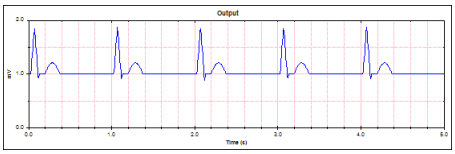
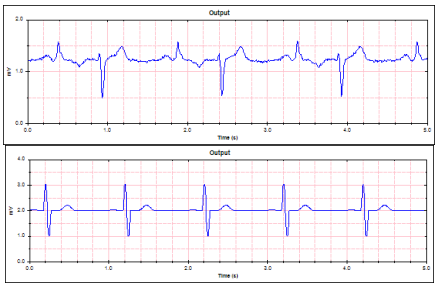
2.6 Description of Functional groups

2.6.1 Main function (main waveform)

This group allows the operator to select the main waveform to be used in the test, from the following:

Table 4: Main waveform

Waveform type	Description	Sample waveform
Sine	Basic sine wave, according to the amplitude (mVpp) and frequency (Hz or BPM)	
Triangle	Basic triangle wave, according to the amplitude (in mVpp) and frequency (Hz or BPM)	
Square	Basic square wave, according to the amplitude (mVpp) and frequency (Hz or BPM)	

Waveform type	Description	Sample waveform
Rectangle pulse	A rectangular pulse, according to the amplitude setting, pulse width (ms) and pulse repetition rate (frequency, Hz or BPM)	
Triangle pulse	A triangle pulse, according to the amplitude setting, base pulse width (ms) and pulse repetition rate (frequency, Hz or BPM)	
Exponential	Exponential waveform, used to Hysteresis test, according to the amplitude (mVpp) and frequency (Hz or BPM)	
ECG	Waveform according to IEC 60601-2-27, Figure 201.110 and 201.113, with adjustable parameters for amplitude (mVpp), frequency (Hz or BPM), QRS duration and T wave amplitude	
Special	A range of stored waveforms including ANSI/AAMI waveforms, some selected CAL waveforms, and loaded waveform. For these waveforms, the amplitude and frequency settings have no effect.	

2.6.2 Main Parameters

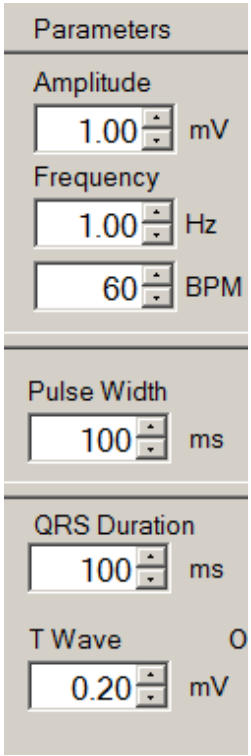


Figure 12: Main Parameters

Amplitude:
Adjust the waveform amplitude from 0 to 10mV at a 0.01mV resolution. For all waveforms, the amplitude represents the peak-to-peak value. For example, for a 1mV sine wave, the actual waveform varies between +0.5mV and -0.5mV. This correlates with testing requirements in standards.

Frequency:
The frequency can be set in either Hz or beats per minute (BPM). Changing one will automatically change the other to match. For pulse waveforms (rectangle, triangle, ECG), the frequency can also be referred to as the pulse repetition rate, or heart rate. For some pulse settings, the frequency is limited to prevent overlapping pulses.

Pulse Width:
Apply to rectangle, triangle, and exponential pulse waveforms only. For the rectangle, the pulse width is defined as the time between crossing the 50% point in rising and falling edges of the pulse[3]. For triangle pulses, the setting matches the base of the triangle pulse. For exponential pulse, the set pulse width is time constant. Pulse width can be set down to 2ms[4].

QRS Duration:
Allow the setting of the QRS component of the ECG wave in IEC 60601-2-27, in the range of 10 to 120ms, matching the requirements of the standard[5].

[3] To minimise ringing due to ECG notch filters, rectangle pulses have a rise time of 1ms. This means that a 20ms rectangle pulse will actually have a 21ms base and a 19ms at the top of the pulse. This definition ensures that the pulse integral matches the setting, e.g. a 3mV 100ms pulse will have an integral of 300µVs.

[4] Note the sampling rate is limited to 0.2ms. Therefore a 2ms pulse will have limited time resolution.

[5] This range has increased to include 10ms to allow for the new heart rate test in IEC 60601-2-27:2011 (a QRS of 10ms should not provide any heart rate).

T Wave:
Allow setting of the amplitude of the T-Wave in ECG waveforms, to verify tall T-wave rejection ability of patient monitors according to IEC 60601-2-27. The maximum amplitude is 2.5mV. For the heart rate accuracy test in IEC 60601-2-27, a T-wave component is not required. In this case, set the T-wave to zero.

2.6.3 DC Offset Setting

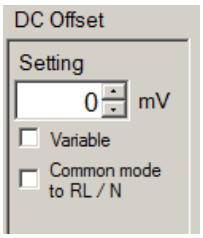


Figure 13: DC Offset Setting

This function allows the operator to switch in a DC offset. In the default condition (not variable), only +300mV, 0 or -300mV can be set. In this mode, the DC offset is sourced from an internal "supercapacitor" which at least 3 minutes of accurate and stable 300mV DC offset to be placed in series with the main waveform, without impacting the quality of that main waveform. The capacitor is charged while not in use (i.e., when the setting is zero).

In the variable mode, the DC offset is provided by a second channel. This mode is intended only for an investigation into the point in which "LEADS OFF" or similar alarms are provided. It is limited to 1000mV.

The "Common mode to RL/N" places the 300mV offset in series with the RL/N as per IEC 60601-2-25, switch position C in Figure 201.110.

2.6.4 Input Impedance Test

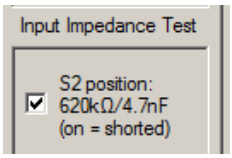


Figure 14: Input Impedance Test

This check box allows the user to switch in an impedance of 620kΩ//4.7nF in series with the main function, for testing the input impedance of the ECG device under test. When the check box is ticked, the impedance is shorted. The ±300mV DC offset can be used in conjunction with this test.

2.6.5 Output Lead Electrode

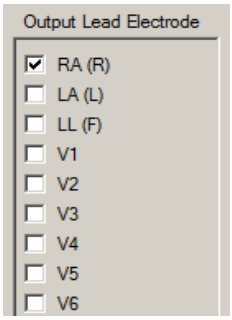


Figure 15: Output Lead Electrode

This section allows the user to select which lead electrode the output is connected to (e.g., terminal P1 in the IEC 60601-2-25, Figure 201.106). Unselected electrodes are connected to the system ground (terminal P2 in Figure 201.106).

More than one lead electrode may be selected. For example, if it is desired to have Lead I and Lead II have a positive indication, LA and LL can be selected.

2.6.6 Pacing parameters

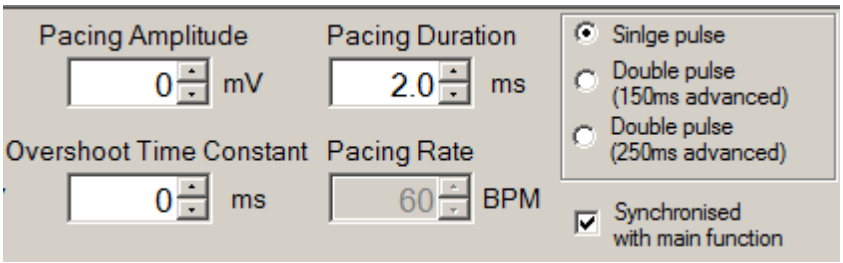


Figure 16: Pacing Parameter

In general, a pacemaker pulse can be added to any main function (sine/triangle/ECG etc.), with the following parameters:

Table 5: Pacing Parameter

Parameter	Description
Pacing amplitude	This can be set in steps of 2 ranging from -700 to +700mV. When set to zero the pacing function is turned off regardless of other pacemaker settings. When set at +2 or -2mV the pacing pulse comes from the main 1000:1 divider, which is accurate to better than ±1%. For settings above 2mV, the output comes from Ch2, which has a design accuracy of ±1% or ±5mV.

Parameter	Description
Pacing Duration	Can be set between 0.1 and 2.0ms, covering the range required by all standards.
Overshoot time constant	Settings from 2ms to 100ms, creates an overshoot according to Method A of IEC 60601-2-27 (0.25 of the pacing amplitude or 2mV, whichever is smaller).
Pacing rate/ synchronized with main function	If the “Synchronized with main function” checkbox is ticked, the pacing pulse will be synchronized with the main function, such as the ECG waveform in IEC 60601-2-27. If this box is not ticked, the user can set the pacing rate independent of the main function (e.g., 80 BPM as required by IEC 60601-2-27, 100 BPM according to IEC 60601-2-51).
Single/Double pulses, 150ms and 250ms advanced	This group selects whether single or double pulses are required according to IEC 60601-2-27. If double pulses are required, they can be 150 or 250ms advanced.

2.6.7 Output graphic display

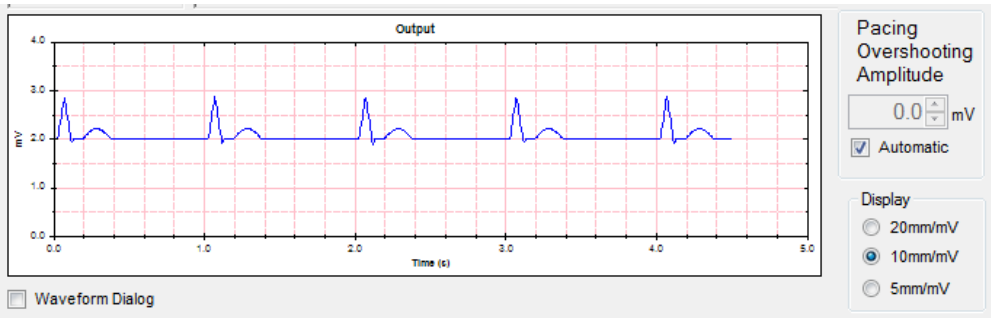


Figure 17: Output Graphic Display

The output display provides an image similar to that provided by ECGs. The sensitivity of the display range may be set at 4mm/mV, 10mm/mV, or 20mm/mV to cover the full range of waveforms offered by the system. The time rate is fixed.

The output display uses the same data as used in the DAC output and serves as a cross-check of the selected waveform, and also allows the user to view the original waveform as filters in the ECG device under test can substantially alter the waveform. Pacing pulses are shown in purple.

For Version 4.0, the output range is fixed at ±5mV.

2.6.8 Special functions

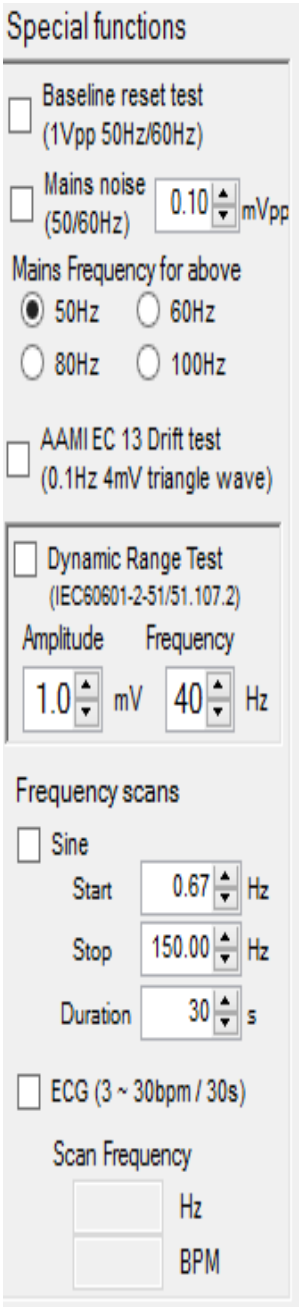


Figure 18: Special Function

Baseline reset test (sine wave only):
When checked the parameters are ignored and a large signal of 1Vpp (0.354Vrms) is applied. It is intended to test the ECG's response to overload, in a particular automated resetting of baseline (due to high pass filtering). When unchecked, the system reverts to the previous settings (e.g., 1mVpp 10Hz signal). Mains frequency of the test can be selected from 50Hz or 60Hz.

Mains noise (ECG 2-27 waveform only):
When checked adds a small sine wave at mains frequency of 50Hz or 60Hz. Range is from 0.05 ~ 0.2mVpp (additional range added for EC 13). Settings of 80Hz and 100Hz are used for calibration of capacitors only, not intended for testing ECGs.

AAMI EC 13 Drift test (ECG 2-27 waveform only):
When checked adds 4mVpp 0.1Hz triangle waveform to the ECG signal (for testing baseline drift).

Dynamic Range Test (square wave only):
When checked adds a 1mVpp waveform at the frequency indicated (20, 30, or 40Hz), intended for combination with an adjustable square wave for testing Clause 51.107.2 in IEC 60601-2-51.

Frequency scans:
Sine: may be used with IEC 60601-2-51 tests or to test systems with extended frequency response. This system uses a fixed sampling rate of 5kHzwhich has been found to reduce problems of beating from other digital sources. If beating still occurs, a separate analog input at BNC1 is provided to allow testing with analogue-type function generators.

ECG:
can be used for testing IEC 60601-2-27 heart rate below 30 BPM as indicated in the standard (0~30 BPM over 30s). As a frequency of “0” is infinitely long, the scan starts at 3 BPM.

2.6.9 Other Function (Auto Pacing, Auto Heart Rate, Cal. Mode)

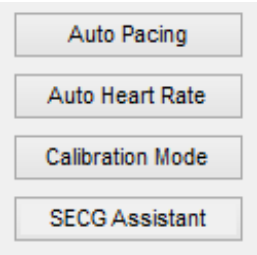


Figure 19: Other Function

Auto Pacing: This opens a new window for automatically cycling though all the combinations required for pacemaker testing in IEC 60601-2-27 (Clause 50.102.13).

Auto Heat Rate: This opens a new window for automatically cycling though all the combinations required for heart rate testing in IEC 60601-2-27 (Clause 50.102.15).

Calibration mode: Opens a new window (see Section 4)

Recommended use for Auto Pacing:
This option is intended to be used in conjunction with a trend mode in a patient monitor. If the patient monitor can reject pacing pulses, the heart rate should not be affected. Therefore, the test should be set up with a mode that has a constant heart rate.

For the tests in IEC 60601-2-27, the tests can be grouped into synchronized (heart rate and pacing is 60 BPM), and asynchronous (heart rate 30 BPM, pacing 80 BPM).

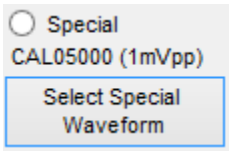
In addition, the ±2mV pacing pulse uses a separate range. Changing to this range can cause switching transients that can affect the heart rate. Therefore, separately out testing for ±2mV is recommended.

Based on experience, it is recommended to have a change interval of at least 30s. With the selected time, users should verify by simulation that the trend mode will clearly show up problems (e.g., deliberately set a wrong heart rate for 10s, and verify this is detectable).

Note that most patient monitors will have problems with the overshoot function. Users should experiment first to find the overshoot that the patient monitor can handle, or test this separately (limit the overshoot time to 0ms only).

Recommended use for Auto Heart Rate
As above, tests for the Auto Heart Rate are intended for use with trend monitoring on a patient monitor, and should be grouped according to heart rates.

2.6.10 Load ECG File



This function is implemented on the “Special Waveforms” form. In that form, a new button is created and a text box. The button name in code is “Load ECG”

Figure 20: Load ECG File

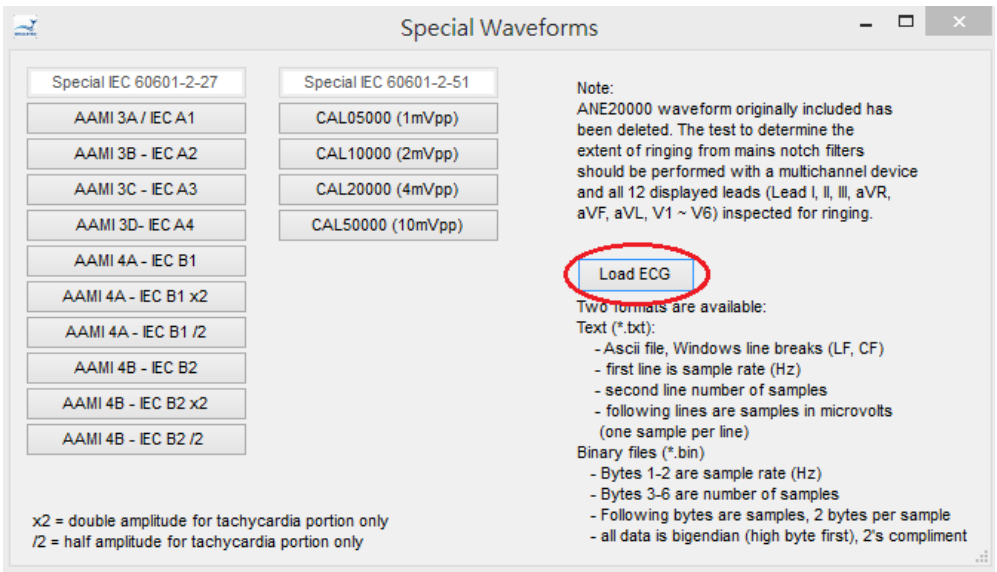


Figure 21: Load ECG File Button

The “Load ECG” function supports two formats – Text and Binary files

Text (*.txt)
- Ascii file, Windows line breaks (LF, CF)
- first line is sample rate (Hz)
- second line number of samples

- following lines are samples in microvolts
  (one sample per line)

Binary files (*.bin)
- Bytes 1-2 are sample rate (Hz)
- Bytes 3-6 are number of samples
- Following bytes are samples, 2 bytes per sample
- all data is bigendian (high byte first), 2's compliment

The maximum size of loaded file is 100 million samples.

2.7 Software Options – SECG Assistant

SECG Assistant software option is a companion software add-on to enhance the function of SECG 4.0. It supports IEC60601-2-25/27/47, YY1079/1139/0782/0885/9706.247, JJG 760/1041/1042, and GB9706.225/9706.227. What's more, it also supports IEC60601-2-26. SECG Assistant software allows the user to save a lot of testing time.

2.7.1 Activate the SECG Assistant Software

Once you have installed the SECG4.0, you may also activate your purchased SECG Assistant Software. **Please connect SECG to your computer**, then follow the two steps below to activate your SECG Assistant Software.

* Please note the activation of SECG-Assistant Software will be paired with only one computer or SECG 4.0 device. Make sure you choose the designated computer or SECG 4.0 device prior to the activation.

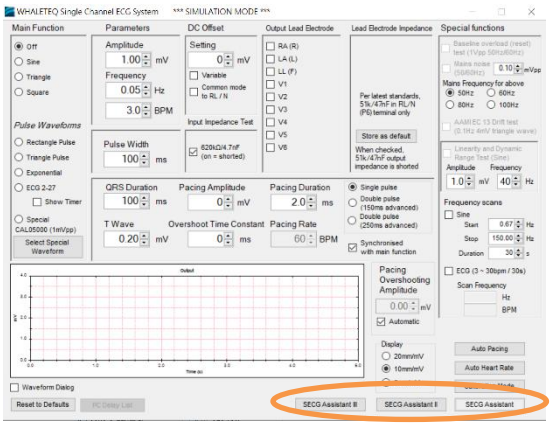


Figure 22: Activate the SECG Assistant Software Button

First click on the "SECG Assistant" button to launch SECG Assistant Software. When you launch your SECG Assistant Software for the first time, you will be prompted to enter your Active Key.

Step 1:

Copy the Hardware ID / SECG Device ID and send it to service@whaleteq.com to request for an Active Key.

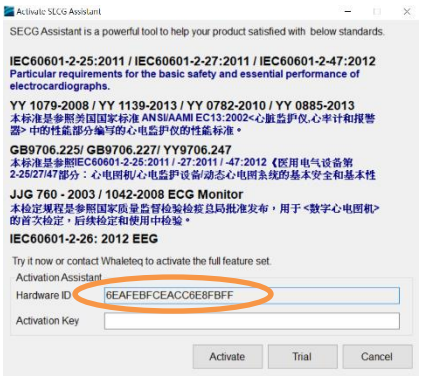


Figure 23: Hardware ID

Step 2:

A unique Active Key will be sent to the user via email. Enter the Active Key and click the Active button.

Your SECG Assistant is now activated.

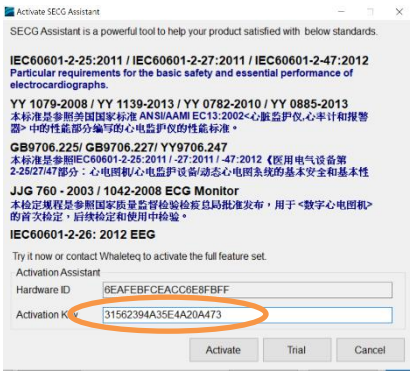


Figure 24: Activate Key

3 Testing to IEC and AAMI standards

3.1 Relation between IEC Figures and WhaleTeq SECG

As of 2012, all IEC standards have harmonized the test circuits. There remains some variation in the switch and parts numbering, however the circuit layout and parts are effectively identical.

To be flexible, the WhaleTeq equipment does not use the switch nomenclature in the standards. Rather, the user should simply follow the effective settings. For example, IEC 60601-2-27 may say “Close switches S, S2 and S4 …” which means “connect the function generator, short out both input impedance and DC offset functions”. With the concept of the test in mind, and some experience with using the WhaleTeq system, this translation becomes second nature.

The following table provides a cross references between switches and terminals referred to in the three IEC ECG related standards, the intended function, and settings in WhaleTeq’s Single Channel ECG.

Table 6: Cross-References Between Switches and Terminals

-2-25 / Figure106	-2-27 / Figure105	-2-47 / Figure101	**Function**	**WhaleTeq SECG Settings**
S2	S	S2	Connects the function generator to the ECG.	Automatically connected when function is selected.
S5	S1	None	Shorts out the 100kΩ (allows large signals)	The SECG automatically selects Ch1 for small signals and Ch2 for large signals[6].
S1	S2	S1	Shorts the 620kΩ used for the input	Input impedance, S2 checkbox (default condition is shorted)

[6] If no large signal is required, Ch2 is switched out by relay, to avoid noise from Ch2. Ch1 is always connected.

-2-25 / Figure106	-2-27 / Figure105	-2-47 / Figure101	**Function**	**WhaleTeq SECG Settings**
			impedance test.	
S3	S4	S3	Shorts out the DC offset circuit	Automatically selected if DC offset is set to zero
S4	S3	S4	Sets the polarity of the DC offset	Automatically selected if DC offset is set to +/-300mV
P1	P1	P1	Output signal	Any selected output lead electrode is connected to P1
P2/P3	P2/P3	P2/P3	Circuit ground	Any unselected output lead electrode is connected to P2
P6	P6	P6	Neutral electrode (RL/N), with series 51k/47nF	Terminal RL/N in the breakout box (pin 4) is permanently connected to GND/P3 via 51k/47nF

3.2 Terminals P1, P2 and P6

According to the test circuits in all three standards, terminals P1, P2 and P6 are defined. However, in some of the tests it is unclear if unused electrodes should be connected to terminal P2 or P6. IEC 60601-2-25, Clause 201.12.4.103 (Input impedance) provides an example case. At first the test states that:

> Compliance is checked using the test circuit of Figure 201.106

In that figure, it clearly states that terminals P1 and P2 are for LEAD WIRES, while P6 is intended only for the NEUTRAL ELECTRODE, or RL/N.

However the test then goes on to say:

> Connect the sine wave signal generator to any tested LEAD (P1 and P2) with all other LEAD WIRES connected to the N (RL) LEAD WIRE (P6)

The interpretation here is complicated as a “LEAD” refers to the displayed ECG waveform, not specific electrodes. Using Table 201.106, we can infer that for example, “LEAD V1” involves V1, RA, LA, LL, but not V2 – V6. The interpretation could be then that V1 should be connected to P1, with RA, LA and LL to P2, and V2-V6 are connected to terminal P6 along with RL/N. A more reasonable interpretation would be to follow the diagram and test each LEAD wire in turn (first RA, then LA, LL, V1 etc) with all unused LEAD wires connected to P2.

4 Software Development Kit

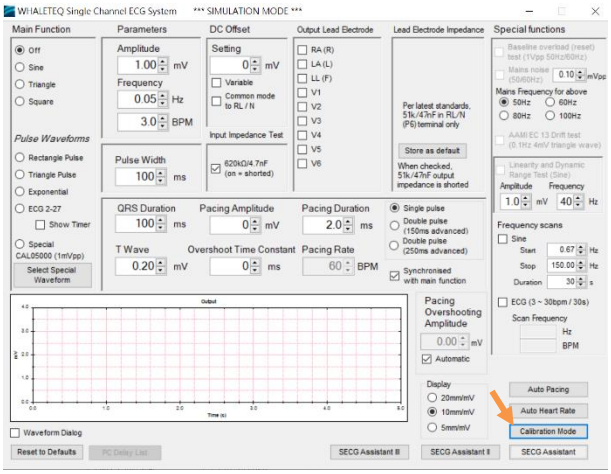
WhaleTeq provides SECG 4.0 software development kit. All operating parameters and options have corresponding commands in the software development kit. The software development kit contains DLL (Dynamic-link library), which will provide highly efficient program binding and version upgrade, supports C/C++ header and C# interface, and can also be integrated with third-party tools and script languages.

5 Calibration, software validation

The WhaleTeq SECG 4.0 has undergone a detailed system validation including software. A report for this can be provided on request.

Prior to shipping, each unit is tested for component values and output voltages, using a calibrated precision multi-meter. As WhaleTeq cannot provide ISO 17025 accredited calibration, laboratories which are required to follow ISO 17025 should perform calibration either periodically or on a before use basis, following normal procedures and practice. The extent of calibration may be limited depending on the needs of the laboratory.

As the calibration procedure is complicated, a software assisted calibration mode is provided. The software sets up the SECG as required for the particular tests, and instructs the user on what measurement to make (e.g. measure resistance between RA and RL).



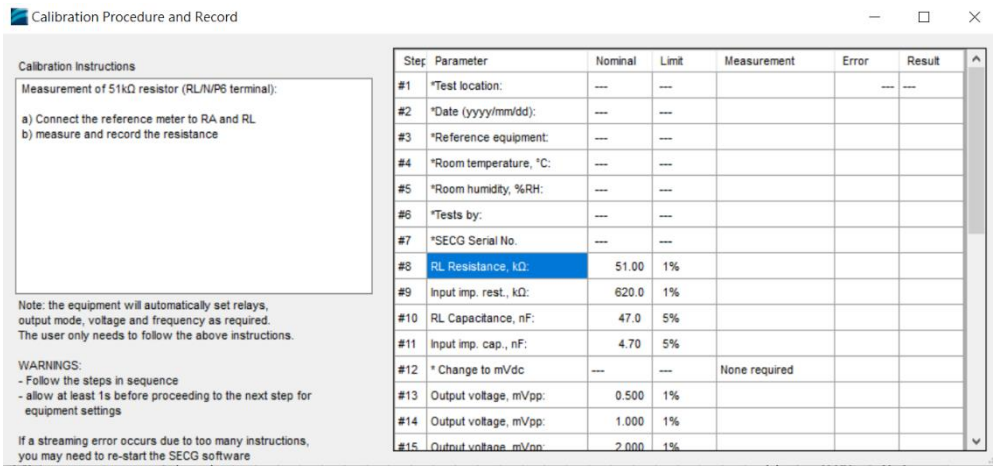


Figure 25: Software Assisted Calibration Mode

The user then enters the results into the form provided, and the software checks if the results are within allowable limits. When complete, the results of calibration are automatically copied to the notepad and stored in a text file at:

c:\WhaleTeq\SECG_Cal_yyyymmdd.txt

where “yyyymmdd” is the date based on the PC’s system. If a fixed width font such as “Courier New” is used, the data appears aligned.

The following manual procedure is retained here for reference and explanation. The calibration mode does not include pacemaker rise time, which is included in the manual procedure here.

Calibration procedure:

Table 7: Calibration procedure

Parameter	Nominal value, tolerance	Method
RL/N resistance	51kΩ ± 1%	The 51kΩ can be measured between any lead electrodes and RL/N terminals. Note: the resistors used are usually accurate to 0.1%, but the measured value will be closer to 51.22kΩdue to the inclusion of a 220Ω resistor used for DC offset. This remains in tolerance.

Parameter	Nominal value, tolerance	Method
Lead impedance capacitors	47nF ±5%	The 47nF can be measured between RA and RL/N using a calibrated capacitance meter, at 1kHz.
Input impedance resistor	620kΩ±1%	This can be measured as follows: • Set Main function to "Off" • Set output to RA • Open switch S2 (input impedance test) • Measure the resistance between RA and LL
Input impedance capacitance	4.7nF±5%	Measure as for the 620kΩ above, using a capacitance meter at 1kHz. Note: there is about 100pF stray capacitance in the circuit which is included in the measurement. However, even with this the measured result is within the limit.
Precision divider ratio (100kΩ:100Ω)	1000:1 ±0.2%	Resistance values are specified as 100kΩ and 100Ω ± 0.1%, but these cannot be verified once in circuit. An alternate method is used to verify the accurate ratio: • Set up a 10mVpp 0.1Hz square wave to output RA • Using the Fluke 8845A or equivalent precision meter, measure and record the peak to peak voltage at BNC2 by zeroing during the negative cycle, and measuring at the positive cycle (nominally 10Vpp). • Repeat this measurement at the output between RA and LL (nominally 10mV) • Calculate the ratio and confirm it is 1000:1 ±0.2%

Parameter	Nominal value, tolerance	Method
Output voltage	Setting ±1%	Method: • Set up 0.5mVpp 0.1Hz square wave, output to RA • Measure the peak to peak output between RA and LL, using the Fluke 8845A or equivalent, record this as output mVpp • Repeat for 1, 2, 5, and 10mVpp • Confirm all values are within 1% or 5µV of the set value Note: the Fluke 8845A has suitable accuracy at 10mVpp but has borderline accuracy at 1mVpp and lower. An alternate method is to measure the output at BNC2 and then use the divider ratio above.
DC offset (fixed ±300mV)	300mV ±1%	Method: • Set the equipment to “Off” • Select +300mV • Measure the voltage between RA and LL Note: the DC offset is sourced from an internal super capacitor which will discharge after ~10min. Tests in the standard are typically <<2 minutes.
DC variable	Setting ±5mV or 1%	Use the following procedure: • Set the equipment to “Off” • Select the “Variable” checkbox • Set to +200mV DC offset • Confirm the value is 200±5mV • Repeat for +600, +1000, -200, -600 and -1000mV
Output frequency	Setting ±1%	Method: • Set up 1mVpp 40Hz sine wave

Parameter	Nominal value, tolerance	Method
		• Measure the frequency at BNC2 using any appropriate meter Note: this verifies the system clock is accurate. Verification of other frequencies or timing is not as this is covered by software validation, although users are free to measure other frequencies and timing. The use of 40Hz is recommended to avoid beating with mains frequency.
Pacemaker pulse characteristics	Voltage ±10%, pulse width ±1%, rise time <10µs, overshoot <5%, settling time <5µs	The pacemaker pulse can be observed directly at the terminals RA and LL (with the output to RA terminal). Use a setting of +700mV 2ms, so the pulse can clearly be seen above any oscilloscope noise. Measure the amplitude, rise and fall time and overshoot.

5.1 Self-Calibration

Self-calibration assists the user calibrates SECG 4.0 before testing.

1. Set up the parameters of the SECG 4.0 AP to “Square, 5 mV, 0.1 Hz” and output to the RA lead electrode as the figure shown below:

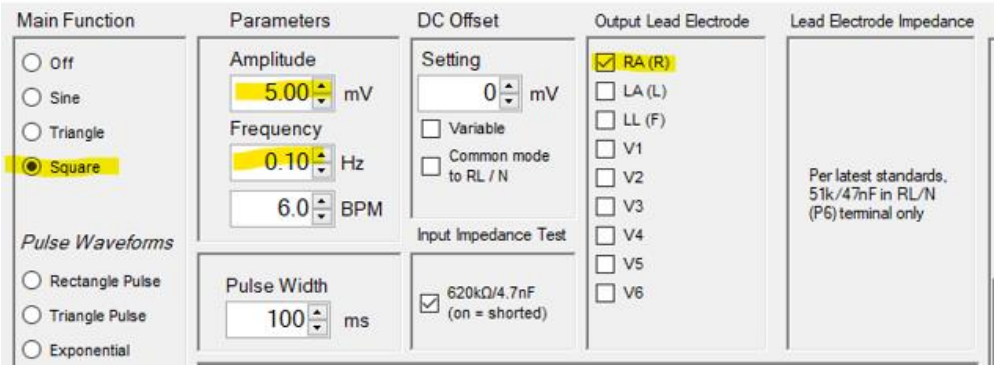


Figure 26: SECG 4.0 Interface

2. Connect the multimeter (Please use the models which are 6 1/2 (6 1/2 digits) or more) to RA and LA of SECG 4.0, and measure the DC mV. The value should be in 1% of 5 mV because the output amplitude of SECG 4.0 gives alternating 5s (0.1 Hz square wave) phases at -2.5mV and +2.5mV, which the multimeter is zeroed (delta function) at one phase (e.g., -2.5mV), with reading taken from the other phase (e.g., +2.5mV) to obtain the 5mV peak-peak value.

Figure 27: Self-Calibration Setup

3. SECG 4.0 DC offset check is shown as the red square in the figure below. SECG 4.0 connects DC in series with electrode wire (in the case, RA).

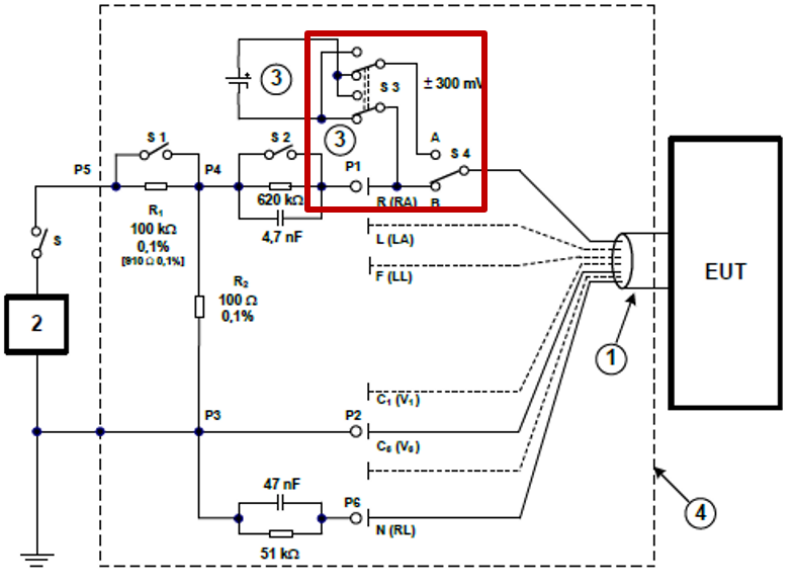


Figure 28: SECG 4.0 ±300 mV DC offset

4. The user can verify the DC voltage by setting up the parameters of SECG 4.0 AP to “Square, 0 mV, 0.1 Hz, DC Offset Setting to 300 Mv and select RA ”.

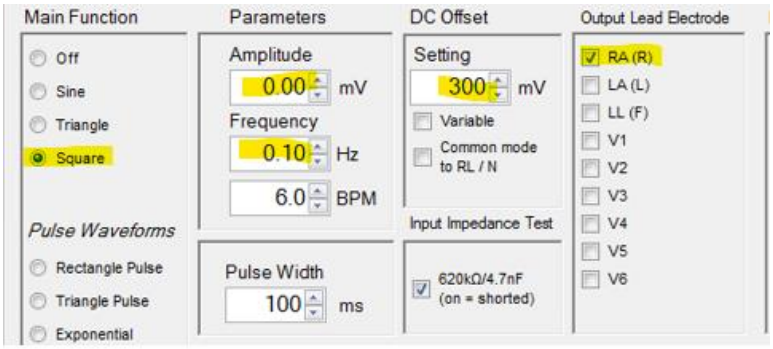


Figure 29: DC Voltage Verification (300mV)

5. Connect the multimeter to RA and LA of SECG 4.0 and measure the DC voltage. The value should be in 1% of 300 mV. The setup is shown in the below figure.

Figure 30: Self-Calibration Setup

6. If the user wants to check the DC voltage other than 300 mV, set the DC voltage from -1000 mV to +1000 mV with 5% accuracy. Please look at the figure below for details. (This extra DC voltage can support some other than 300 mV testing, like IEC60601-2-25, 201.12.4.101 “Indication of inoperable ECG”, this test item may need DC voltage more than 300 mV)

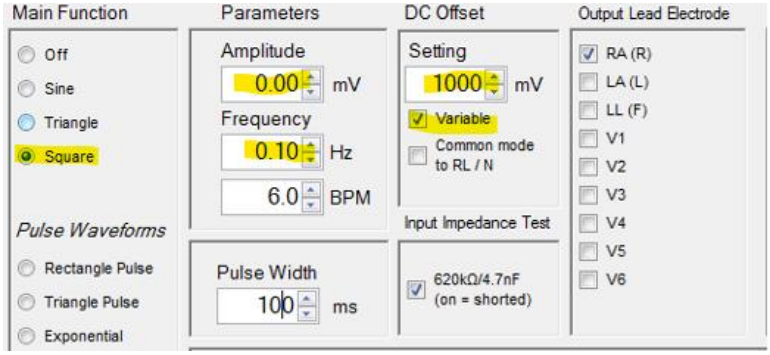


Figure 31: DC Voltage Verification (>300mV)

7. Use the same way as above to check the DC voltage with the multimeter.

The above steps assist the user to make sure SECG 4.0 is outputting correct signals before the test.

Reminder: Self-calibration is to facilitate the user to quickly confirm the signal quality before testing, not to replace the original calibration service

recommended every year.

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.

6 Trouble shooting

Table 8: 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.

7 Cautions

1. Before using products, use a grounded wrist strap or touch a grounded safely object or a metal object, such as the power supply case, to avoid damaging them due to static electricity.
2. WhaleTeq does not recommend to connect test equipment with DUT to conduct Electrostatic Discharge (ESD) test. This may cause

unexpected damages to test equipment. Please contact WhaleTeq for alternatives before ESD test.

3. For operating “Firmware Update” feature, there are risks of losing data if improper options are performed during the Firmware Update period.
4. Warranty void if QC PASS label is removed or tampered with.
5. The professional testing instrument, not a medical device, is for testing only, and will not involve human or clinical use.

8 Purchasing Information

8.1 Standard accessories

- ✓ SECG 4.0 host x 1
- ✓ 12-lead breakout box x 1
- ✓ Wire tie x 12
- ✓ USB cable x 1
- ✓ Grounding wire x 1

8.2 Purchase software and accessories

- ✓ SECG Standard assistant software: IEC 60601-2-25:2011
- ✓ SECG Standard assistant software: IEC 60601-2-27:2011
- ✓ SECG Standard assistant software: IEC 60601-2-47:2012
- ✓ SECG Standard assistant software: GB9706.225-2021
- ✓ SECG Standard assistant software: GB9706.227-2021
- ✓ SECG Standard assistant software: YY9706.247-2021
- ✓ SECG Standard assistant software: YY1079-2008
- ✓ SECG Standard assistant software: YY1139-2013
- ✓ SECG Standard assistant software: YY0782-2010
- ✓ SECG Standard assistant software: YY0885-2013
- ✓ SECG Standard assistant software: JJG760-2003
- ✓ SECG Standard assistant software: JJG1041-2008
- ✓ SECG Standard assistant software: JJG1042-2008
- ✓ USB Power isolator: WUI100

9 Version information

Table 9: Version Information

Version	Modify content	Issue date
20201231	Add Chap 4 Software Development Kit（SDK） Chap 8 Purchasing information Chap 9 Version information	20201231
20210629	Add Chap 7 Cautions	20210629
20211126	Add Chap 5.1 Self-calibration	20211203
20221013	Update Chap 2.5 Main Screen Chap 2.7 Software Options — SECG Assistant Chap 8.2 Purchase software and accessories	20221014

10 Contact WhaleTeq

WHALETEQ Co., LTD

service@whaleteq.com | (O)+886 2 2517 6255

8F., No. 125, Songjiang Rd., Zhongshan Dist., Taipei City 104474, Taiwan