WHALETEQ

Single Channel EEG Test System (SEEG 100E)

User Manual

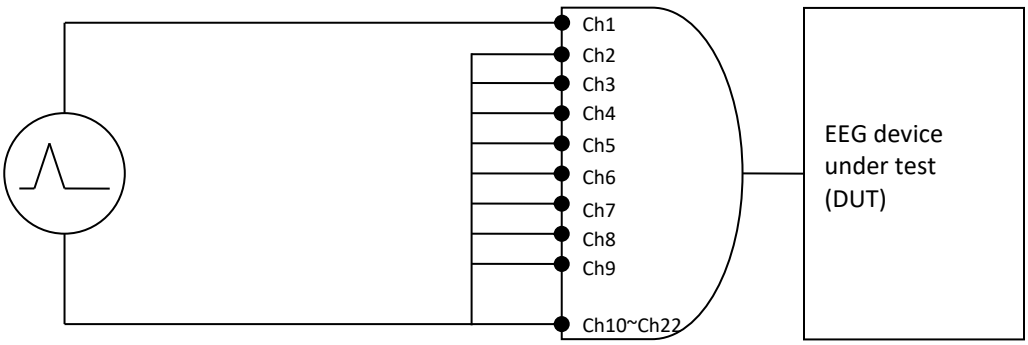
Revision 2019-08-23
PC Software Version 1.0.5.10

Contents

1 Introduction

1.1 Basic concept

WhaleTeq Single Channel EEG Test System provides a single waveform to one or more lead electrodes of EEGs, for testing to IEC particular standards. The following diagram shows the single channel concept:



(Figure 1) Single channel concept

Via a SEEG 100E, the system produces arbitrary waveforms (streamed from the PC with digital to analogue conversion) at up to ±1V, which is then applied to a precision 500:1 divider to produce the voltages at up to ±1mV level (2mVpp). The SEEG 100E contains resistor/capacitor networks, dc offset, and relay switching to provide the full range of single channel performance tests in IEC standard.

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

- Sensitivity (accuracy of the µV/mm indication)
- Frequency response (sine wave, and impulse tests)
- Input impedance
- Noise

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

The limitations of the system are as below:

- Exclude input noise and CMRR tests (this requires a special noise free test unit, available from WhaleTeq)
- There are 22 terminals (Ch1~Ch22) in EEG breakout box. However, there are only 9 terminals (Ch1~Ch9) could output waveforms, and the rest 13 terminals (Ch10~Ch22) are connected to ground. Please refer to section 2.2 for details.

1.2 Standards/Application

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

Standard	Clause(s)	Limitations/Notes
IEC 80601-2-26:2012	201.12.1	201.12.1 all performance tests except 201.12.1.104 input noise and 201.12.1.106 CMRR tests

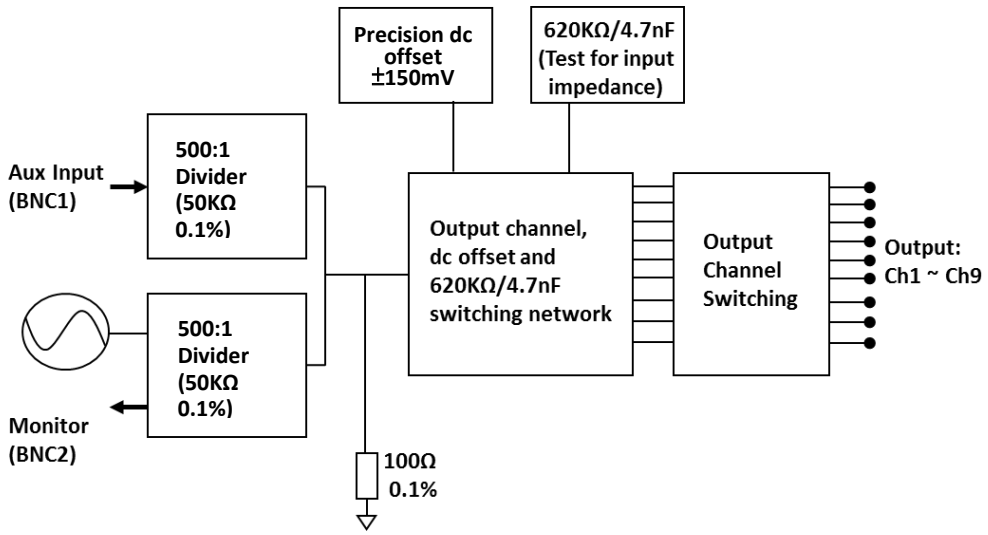
General limitation:

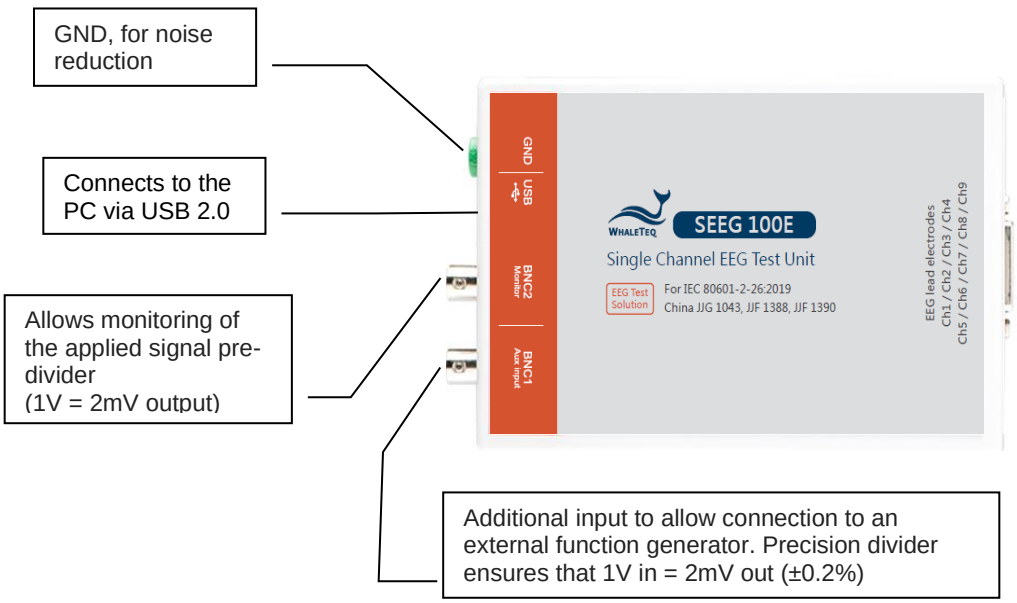
(1) This equipment is designed for use with isolated EEG circuits, as are generally provided for medical EEG. If applied to a non-isolated circuit, the noise may be excessive.

(2) In EEG breakout box, there are 22 terminals. But there are only 9 terminals could output waveforms, the rest 13 terminals are connected to ground.

1.3 Block diagram/SEEG 100E Module overview

The following is a simplified block diagram of the system inside the SEEG 100E module:





1.4 Main specifications

In general, the system has been designed in accordance with IEC 80601-2-26:2019 standard. Test parameters and specifications required for testing are listed as following:

Parameter	Specification
Main output voltage accuracy	±1% for amplitudes of 0.2mVpp or higher
Main output voltage resolution (DAC resolution)	0.5µV
Frequency / pulse repetition rate accuracy	±1%
Pulse duration / timing accuracy	±1ms
Resistor tolerance	±1%
Capacitor tolerance	±5%
Precision 500:1 divider (50KΩ:100Ω)	±0.2%
Sample rate	5kHz ± 0.1%
DC offset (fixed, noise free, from internal super capacitor)	150mV ± 1%
DC offset (variable, may include up to 50µVpp noise)	Setting ±1% or ±3mV
Power supply	USB +5Vdc supply (no separate power supply required) 0.5A (high power mode)
Environment	15 ~ 30°C (by design, not tested) 30 ~ 80% RH(design not tested)
Safety, EMC standards	No applicable safety standards (maximum internal voltages 12Vdc) 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).

1.5 Cautions

- Before using products, use a grounded wrist strap or touch a grounded object or a metal object, such as the power supply case, to avoid damaging them due to static electricity.
- 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.

2 PC Software Mode

2.1 Installation and Environment

2.1.1 System requirements

The Single Channel EEG system uses a normal PC to interface and control the USB module.

PC requirements:

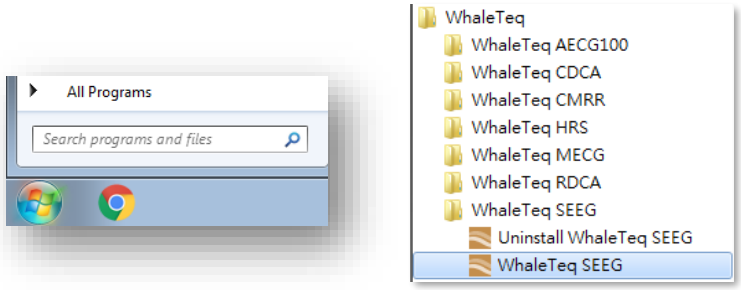
- Windows PC (Windows 7 or later, suggest to use the genuine version)
- Microsoft .NET 4.0 or higher
- Administrator access (essential for installing software, driver, and Microsoft .Net Framework)
- 1.5 GHz CPU or higher
- 1GB RAM or higher[1]
- USB port

2.1.2 SEEG Software Installation

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

- Download SEEG software from WhaleTeq website.
- Browse to the download location
- Unzip the file to your destination folder
- Click the installation file in the destination folder to initiate the installation process.
- When the installation is completed, SEEG software would be executed automatically. User can also execute SEEG software via selecting “All Programs” → “WhaleTeq” → “WhaleTeq SEEG” in Windows startup program manager.

[1] 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 SEEG software can't be executed properly or this is the first time using WhaleTeq product, please refer to section 2.1.3 and 2.1.4 to confirm that USB driver and Microsoft .Net Framework 4.0 are all installed.

2.1.3 First Time Using WhaleTeq Product - 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

- 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.
- 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.
- 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

- 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.

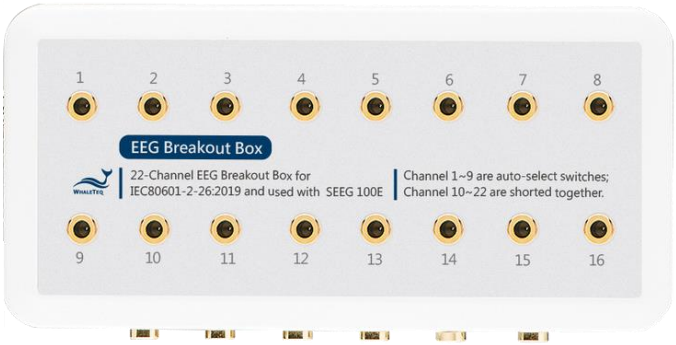
- When the USB module is connected for the first time, select manual installation, and point to the folder containing the above file. Then continue to follow the instructions to finish the installation. There may be a warning that the driver is not recognized by Windows®, and this can be ignored. Please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

2.1.4 First Time Using WhaleTeq Product – 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 EEG

For connecting the EEG device to the SEEG 100E and use the provided 22 channels “EEG breakout box”. There are only 9 terminals (Ch1~Ch9) could output waveforms, and the rest 13 terminals (Ch10~Ch22) are connected to ground. Below is the photo of EEG breakout box.



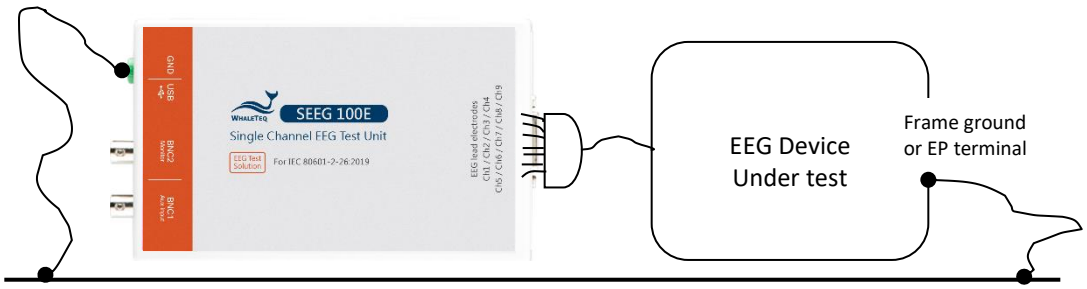
Alternately the EEG device under test can be directly connected to the SEEG 100E module using a male D15 connector. The pin outs are:

1-Ch1	4 –GND	7 –Ch6	10 –Ch9
2-Ch2	5 –Ch4	8 –Ch7	
3-Ch3	6 –Ch5	9 –Ch8	

Note: Ch10 ~ Ch22 connect to pin 4 (GND).

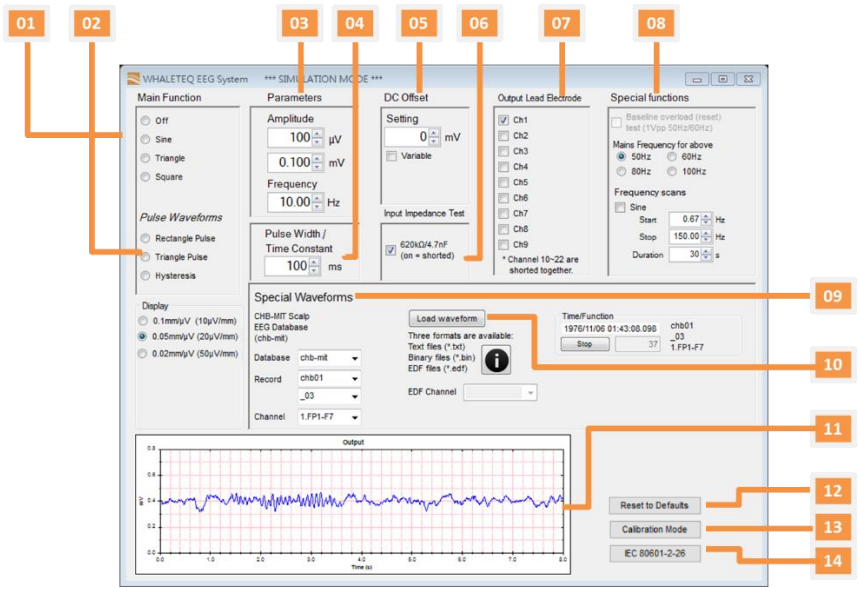
2.3 Environment, noise reduction

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



With this set up, turn the EEG 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 set up 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 set up.

2.4 Main screen

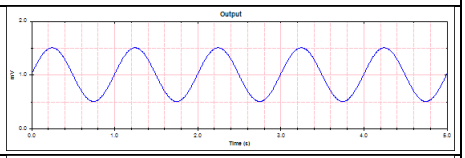
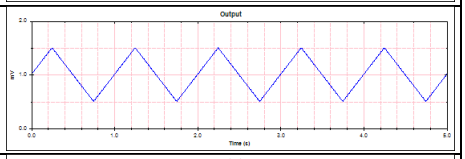
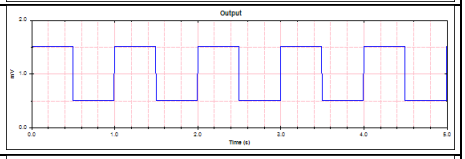
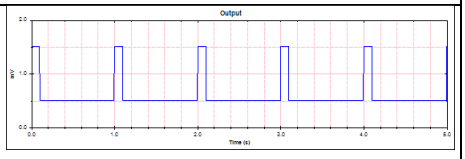
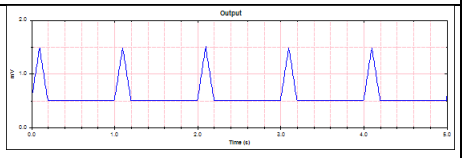
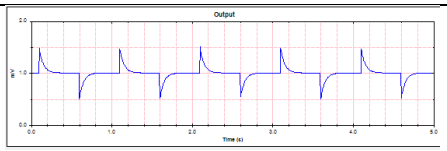
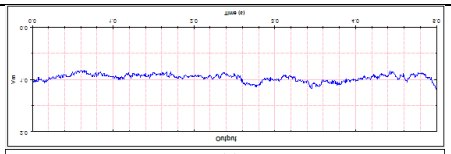
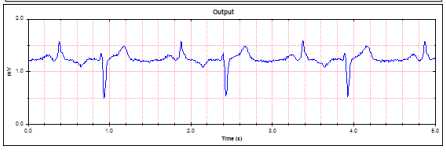


01- Select the main function (waveform) type, such as sine, triangle and square wave.
02- Select the pulse function (waveform) type, such as rectangle pulse, triangle pulse and Hysteresis.
03- Parameter setting
04- Select the pulse width for rectangle and triangle pulse only, time constant for hysteresis only.
05- DC offset setting.
06- Select if 620kΩ/4.7nF is in circuit (for input impedance test).
07- Select the lead electrode which the output is switched to (Ch1~Ch9).
08- Special functions
09- Select PhysioNet EDF format waveform and download directly from Internet
10- Load text and binary format waveforms from local.
11- Provide a semi-real time graphical display of the current signal
12- Reset to default
13- Calibration mode
14- IEC-80601-2-26 helper

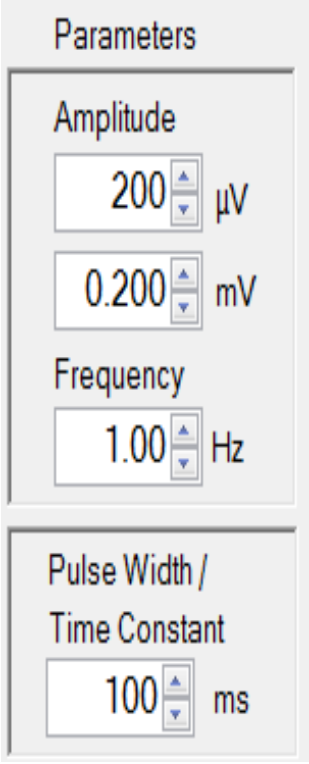
2.5 Description of Functional groups

2.5.1 Main function (main waveform)

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

Waveform type	Description	Sample waveform
Sine	Basic sine wave, according to the amplitude (mVpp) and frequency (Hz).	
Triangle	Basic triangle wave, according to the amplitude (in mVpp) and frequency (Hz).	
Square	Basic square wave, according to the amplitude (in mVpp) and frequency (Hz).	
Rectangle pulse	A rectangular pulse, according to the amplitude setting, pulse width and pulse repetition rate (frequency, Hz).	
Triangle pulse	A triangle pulse, according to the amplitude setting, base (pulse) width and pulse repetition rate (frequency, Hz).	
Hysteresis	Exponential waveform, used for hysteresis test (set amplitude to ±0.5mV, time constant 50ms, adjustable).	
EDF File Manager, Load Waveforms	A range of stored waveforms including: (1) load waveform and (2) load PhysioNet database through internet, then play. For these waveforms, the amplitude and frequency settings have no effect.	 

2.5.2 Main parameters

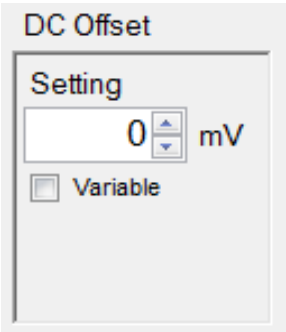


Amplitude:
Can be set in either mV or µV, changing one will automatically change the other to match. The waveform amplitude from -2 mV to +2 mV at a 0.001mV (1 µV) resolution. For all waveforms the amplitude represents the peak to peak value. For example, for a 1mV sine wave the actual waveform varies between +0.5mV and -0.5mV. This correlates with testing requirements in standards.

Frequency:
Set in either Hz. Continuous waveform (Sine, Triangle and Square), can up to 500 Hz, for pulse waveforms (rectangle, triangle), the frequency can also be referred to as the pulse repetition rate. For some pulse settings the frequency is limited to prevent overlapping pulses (limit to 5 Hz).

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

2.5.3 DC offset setting



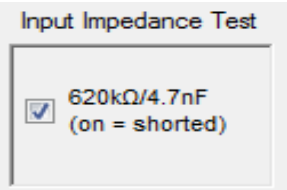
This function allows the operator to switch in a dc offset. In the default condition (not variable), only +150mV, 0 or -150mV can be set. In this mode, the dc offset is sourced from an internal "super capacitor" which at least 3 minutes of accurate and stable 150mVdc offset to be placed in series with 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. It is limited to 1000mV.

[2] To minimise ringing due to EEG 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.

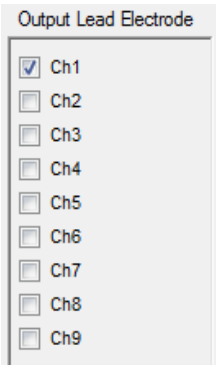
[3] Note the sampling rate is limited to 0.2ms. Therefore, a 2ms pulse will have limited time resolution.

2.5.4 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 EEG device under test. When the check box is ticked, the impedance is shorted. The ±150mVdc offset can be used in conjunction with this test.

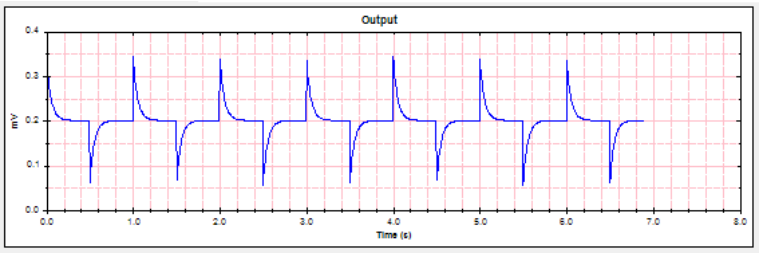
2.5.5 Output lead electrode



This section allows the user to select which lead electrode the output is connected to (i.e. terminal P1 in the IEC 80601-2-26:2019, Figure 201.104). Unselected electrodes are connected to the system ground (terminal P2 in Figure 201.104).

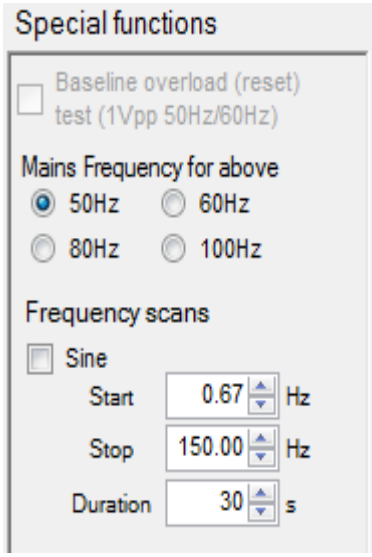
More than one lead electrode may be selected.

2.5.6 Output graphic display



The output display provides an image similar to that provided by EEGs. The sensitivity of the display range may be set at 0.1mm/µV, 0.05mm/µV or 0.02mm/µV 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.

2.5.7 Special functions



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 EEG's response to overload, in 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.

Frequency scans:
Sine: may be used 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 analogue input at BNC1 is provided to allow testing with analogue type function generators.

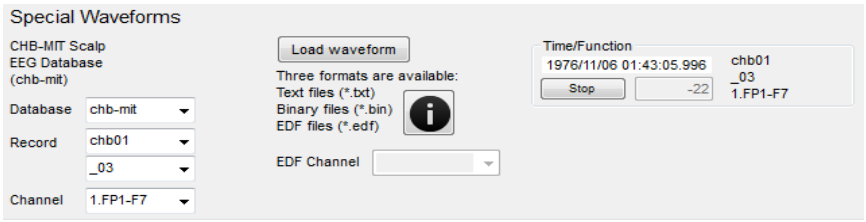
2.5.8 Special waveforms and load waveform

There are two features on the bottom right frame: "Special Waveforms" and "Load waveform". For these two features, the amplitude and frequency settings have no effect.

Special Waveforms:
WhaleTeq SEEG can play PhysioNet waveforms with 1 electrode at each time. This feature will download waveforms from PhysioNet directly. Please check your internet status before use this feature.

The SEEG built-in databases are as below：

- *EEG Motor Movement/Imagery Database (eegmmidb)*：
  Each volunteer performed different motor/imagery tasks while 64-channel EEG were recorded. Here for more details.
- *CHB-MIT Scalp EEG Database (chbmit)*：
  This database, collected at the Children's Hospital Boston, consists of EEG recordings from pediatric subjects with intractable seizures. Each seizure is annotated. Here for more details.



Load waveform:

The "Load waveform" function supports three formats – Text, Binary and EDF 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)

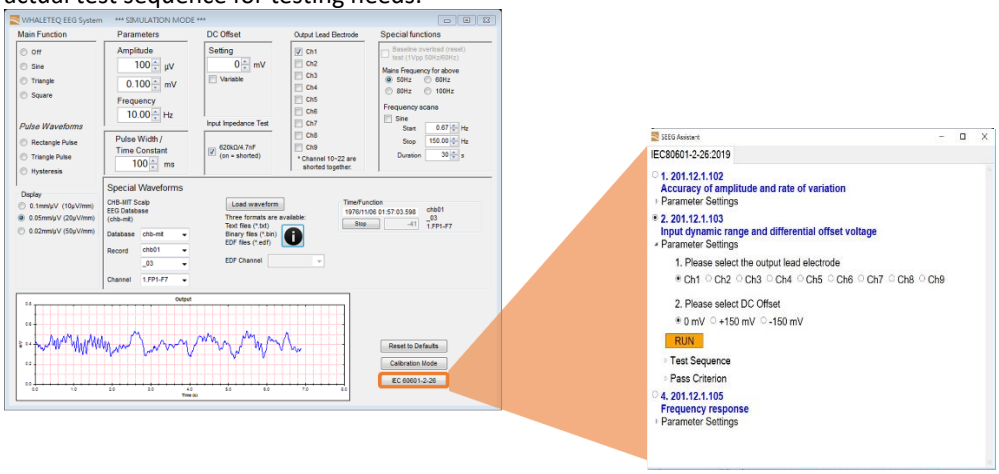
- Bytes 1-2 are sample rate (Hz)
- Bytes 3-6 are number of samples
- Following bytes are samples, 2 bytes per sample
- all data is big-endian (high byte first), 2's compliment

EDF files (*.edf)

This is a commonly used but complicated format. Here for the format details.

2.6 IEC 80601-2-26 Helper

It is a companion software add-on to enhance the function of SEEG 100E. It supports the latest EEG standards IEC80601-2-26:2019 with detailed preset parameter settings and actual test sequence for testing needs.



2.7 Calibration, software validation

WHALETEQ SEEG 100E 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 SEEG as required for the particular tests, and instructs the user on what measurement to make (e.g. measure resistance between ch1 and ch2).

#1	*Test location:	---	---	WhaleTeq, Taipei, Taiwan		
#2	*Date (yyyy/mm/dd):	---	---	2015/10/27		
#3	*Reference equipment:	---	---			
#4	*Room temperature, ˚C:	---	---	25		
#5	*Room humidity, %RH:	---	---	50		
#6	*Tests by:	---	---	Joseph Liu		
#7	*SECG Serial No.	---	---	WEE1501111		
#8	Input imp. rest., kΩ:	620.0	1%	621	0.2%	Pass
#9	Input imp. cap., nF:	4.70	5%	4.6	-2.1%	Pass
#10	* Change to mVdc	---	---	None required		---
#11	Output voltage, mVpp:	0.200	1%	0.201	0.5%	Pass
#12	Output voltage, mVpp:	0.400	1%	0.401	0.2%	Pass
#13	Output voltage, mVpp:	0.500	1%	0.501	0.2%	Pass
#14	Output voltage, mVpp:	0.800	1%	0.801	0.1%	Pass
#15	Output voltage, mVpp:	1.000	1%	1.001	0.1%	Pass
#16	Output voltage, mVpp:	1.200	1%	1.201	0.1%	Pass
#17	Output voltage, mVpp:	1.500	1%	1.501	0.1%	Pass
#18	Output voltage, mVpp:	2.000	1%	2.000	0.0%	Pass
#19	Fixed DC offset, mV:	300.0	1%	300.0	0.0%	Pass
#20	Variable DC offset, mV:	+200	5%	200	0.0%	Pass
#21	Variable DC offset, mV:	+600	5%	600	0.0%	Pass
#22	Variable DC offset, mV:	+1000	5%	1000	0.0%	Pass
#23	Variable DC offset, mV:	-200	5%	-200	0.0%	Pass
#24	Variable DC offset, mV:	-600	5%	-605	0.8%	Pass
#25	Variable DC offset, mV:	-1000	5%	-1000	0.0%	Pass
#26	*Pre-divider out, Vdc	2.000	---	1.999	---	---
#27	Divider ratio:	1000	0.2%	1000.5	0.0%	Pass
#28	Frequency, Hz:	10.00	1%	10.00	0.0%	Pass
#29	Frequency, Hz:	40.00	1%	40.02	0.1%	Pass
#30	Overall Result:	20	---	20	---	Pass

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\SEEG_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.

2.7.1 Calibration procedure

Parameter	Nominal value, tolerance	Method
Input impedance resistor	620kΩ±1%	This can be measured as follows: • Set Main function to "Off" • Set output to ch1 • Uncheck "620KΩ/4.7nF" Measure the resistance between ch1 and ch2
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 (50kΩ:100Ω)	500:1 ±0.1%	Resistance values are specified as 50kΩ 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 2mVpp 0.1Hz square wave to output ch1 • 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 1Vpp). • Repeat this measurement at the output between ch1 and ch2 (nominally 2mV) Calculate the ratio and confirm it is 500:1 ±0.2%
Output voltage	Setting ±1%	Method: • Set up 0.2mVpp 0.1Hz square wave, output to ch1 • Measure the peak to peak output between ch1 and ch2, using the Fluke 8845A or equivalent, record this as output mVpp • Repeat for 0.4, 0.5, 0.8, 1, 1.5 and 2mVpp

		• 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 ±150mV)	150mV ±1%	Method: ● Set the equipment to "Off" ● Select +150mV ● Measure the voltage between Ch1 and Ch2 Note: the DC offset is sourced from an internal super capacitor which will discharge after ~10min. Tests in the standard are typically less than 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 10/40Hz sine wave • Measure the frequency at BNC2 using any appropriate meter ● Note: this verifies whether 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.

3 Trouble shooting

Problem	Resolution
SEEG 100E 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
SEEG 100E 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 SEEG 100E module, reconnect the SEEG 100E module and re-start the SEEG 100E module.

4 Contact details

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