WHALETEQ

Multichannel ECG Test System (MECG 2.0)

User Manual

Revision 2022-05-22
PC Software Version 2.0.10.6

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

The WhaleTeq Multichannel ECG Test System provides a full 12 lead waveforms for testing diagnostic, ambulatory or monitoring ECG, for testing to IEC particular standards.

Version 1.0 was designed according to the circuit in IEC 60601-2-51, modified by using precision, low offset op-amps (<0.5µV) and 0.1% resistors in the output divider circuits and networks to provide greater accuracy. For Version 2.0, released in November 2012, the IEC 60601-2-51 circuit was further modified with DAC compensation[1] and electronic Wilson Terminal offset[2] to further improve the accuracy of the system in the very low voltage area, for example, to ensure an accurate ST segment in V1 ~ V6 around 200µV. Both versions are identical from the user interface.

The standard range is ±5mV to cover the waveforms in IEC 60601-2-25:2011. Systems with wider ranges can be provided on request.

The system makes use of continuous streaming of digital data over a USB connection, with test unit providing a stable real-time output with crystal oscillator accuracy and internal checks to ensure that no data is lost.

All waveforms are looped to the beginning when the end of the file is reached.

The system has embedded[3] the CAL, ANE and biological ECG waveforms from the CTS database referred to in IEC60601-2-25:2011 (formerly IEC 60601-2-51).

A custom design module has been developed to work with a large number of waveforms from Physio net website (Format 16 and Format 212), including directly linking with the website and downloading the necessary files.

It is expected that users will have specific applications and waveforms for testing the equipment. Contact WhaleTeq (service@whaleteq.com) for a custom designed PC software to interface between the waveforms required and the USB module.

[1] Applied to the ±2.5mV range, to cover all CAL, ANE waveforms except CAL30000 and CAL50000.

[2] In the recommended circuit of IEC 60601-2-51, the Wilson Terminal offset is provided in hardware. This configuration was found to add errors in V1 to V6 of up to 20µV.

[3] The term “embedded” here means the raw digital data is embedded in the software and cannot be accessed directly. Raw digital data cannot be released due as it is propriety data.

1.1 System Description

The system consists of the host PC (PC), the "Multichannel ECG Test Unit" (Test Unit) and the ECG device under test (DUT).

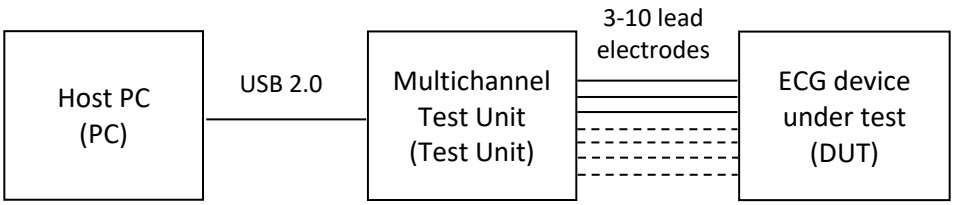


Figure 1: System Description

The PC software currently allows the user to select the waveform from one of three sources:

CTS database (as per IEC 60601-2-25:2011)
This includes the ANE, CAL and biological waveforms as detailed in the standard. Once selected there is no need to adjust anything.

Fixed waveforms (sine, triangle, pulse)
This allows the adjustment of amplitude and frequency by the user according to settings on the screen. These waveforms are intended for reference only, but could be used for some "single channel" performance tests.

Biological waveforms from the "Physio net" website
This allows the loading of files based on Format 16 or 212 format (other formats may be considered on request).

Once the waveform is selected and the user presses the "Play" button, the waveforms are streamed to the test unit. The test unit converts these to 8 analog channels of data[4] at signal levels 500 times higher than the final output (e.g. for 1mVpp output, the intermediate output is 500mVpp). These 8 signals are then placed through a precision dividers and network as described in Annex II of IEC 60601-2-51, to produce the low-level signals necessary for 10 lead electrodes (12 lead ECG).

[4] In a normal "12 lead" ECG, four of the waveforms (Lead III, aVR, aVL and aVF) can all be derived from the other leads (Lead I, Lead II, V1 ~ V6). Therefore the so called "12 lead ECG" can be produced from 8 channels. See also IEC 60601-2-51 Annex II circuit.

1.2 Application Revision Update

Associated with software release 1.6.0.0, the following features were included:

- The reverse Wilson Terminal offset is now implemented in software rather than hardware, to reduce errors associated with the hardware circuit
- DAC compensation is applied for equipment with serial Nos 2012-008 and higher
- The 1.25mv range is disabled (2.5mV with DAC compensation now achieves the required accuracy).

The software detects which serial number is attached and applies for the appropriate compensation. Equipment with serial numbers earlier than 2012-008 will continue to operate with the software as before.

As MECG 2.0 is equipped with a 12-bit DAC, it is must to use the DAC compensation file. For users purchasing MECG 2.0 in 2020 (serial number as ME2001-XXXXXX), if the testing requires, please refer to 3.5.2 ‘’How to Update DAC Compensation File’’ to update the DAC compensation file.

2 Hardware Specifications

Table 1: Specifications

Item	Details / Reference	Value
Output channels	The 8 output channels are provided through a network as specified in IEC 60601-2-51 to provide signals to 10 lead electrodes; in the device under test, this will be displayed as 12 leads.	8 outputs 10 lead electrodes 12 leads
Voltage accuracy[5]	IEC 60601-2-51 specifies a limit of ±1%, but does not provide a lower limit (all systems must have a lower limit).	For MECG 2.0, ±1% for values greater or equal to

[5] The accuracy specification is for a single point. Since the tests in IEC 60601-2-25:2011 are effectively for 2 points, the applied error can be theoretically twice the declared values. However, the probability of this is very small, and most cases 2 points will be within the required above specification.

	An inferred specification of 1% ±5µV is derived from the device under test specification in IEC 60601-2-51 of 5% ±25µV.	500µV and ±5µV for values under 500µV. For MECG 2.0 (2020), ±1% for values greater or equal to 100µV and ±5µV for values under 100µV.
Output voltage resolution	MECG 2.0 uses 12-bit DAC and MECG 2.0 (2020) uses 16-bit DAC.	2.4µV for MECG 2.0 and 0.15µV for MECG 2.0 (2020)
Output voltage	The output voltage on most of the database/ECG is +5mV~-5mV.	±5mV
Output noise level 0-150Hz	Output noise should not influence the test. A value a 5µV is suitable for this requirement. Can be verified by monitoring the signal in the device under test using a “diagnostic” filter setting.	<5µV
Time accuracy	IEC 60601-2-51 does not provide any limits. An inferred limit from the device under test. An inferred limit of ±1% is used (see). The system’s design accuracy exceeds 0.1% as a 100ppm crystal reference is used.	±1%
Sampling rate	A maximum sampling rate of 1kHz matches the sampling rates of ECG files.	1kHz (8 channels)
Power supply	Powered from the USB supply (5V 0.2A)	N/A
Environment	Intended for normal laboratory environment. The selection of critical components such as reference voltages, DAC, precision resistors are known to be stable in the range shown.	15-30°C 10-95% RH

3 Start to Use MECG 2.0

3.1 Software Installation

3.1.1 System Requirements

The Multichannel ECG system uses a normal PC to interface and controls the USB module. The PC should meet the following requirements[6]:

- Windows PC (XP or later, suggest to use the genuine version)
- Microsoft .NET 4.0 or higher
- Administrator access (essential for installing software/driver)
- 512MB RAM or higher
- USB port

3.1.2 MECG 2.0 Software

The software can be obtained from the enclosed CD or download from the WhaleTeq website.

- Download software from the WhaleTeq website.
- Unzip the file and double click the installation file
- When the installation process is completed, click the MECG 2.0 icon on the desktop to execute or select MECG 2.0 software in the start menu

3.1.3 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 8 and Windows 8.1

- Windows 8 and Windows 8.1 can't recognize MECG 2.0, please download "mchpcdc.inf" from WhaleTeq website. This driver is provided by Microchip® for using with PIC microprocessors having built-in USB function.

[6] 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. See Trouble shooting section for more details.

- As mchpcdc.inf provided by Microchip® does not contain digital signature, please disable driver signature enforcement in Windows 8 and Windows 8.1.
- 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.

Microsoft Windows 7

- Windows 7 can't recognize MECG 2.0, 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.

3.1.4 First Time using WhaleTeq Product – Microsoft .Net Framework 4.0 Installation

WhaleTeq software is developed by Microsoft .Net Framework 4.0. If MECG 2.0 PC software fails to execute properly, please check whether Microsoft .Net Framework 4.0 or higher versions was installed in the operation system.

If your PC hasn't installed Microsoft .Net Framework 4.0 or higher versions, please download from Microsoft website.

3.2 Set up

Connect the USB module (test unit) to any USB socket of the PC. Note: if the socket is changed, it may take the PC a short amount of time to recognize and connect to the system.
Run the WhaleTeq Multichannel ECG software. If the USB module is not recognized, a message will be displayed. In this case, repeat the process, ensuring sufficient time for the PC to recognize the USB module prior to starting the WhaleTeq software.

For connecting the ECG device under to the USB module, use the “ECG breakout box” provided. 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 - V3 (V4)	10 - V6 (V1)
2 - LA	5 - V1 (V6)	8 - V4 (V3)	
3 - LL	6 - V2 (V5)	9 - V5 (V2)	

Note:
For systems after September 2011, V1 ~ V6 are reversed as shown in the brackets.

3.3 Environment, Noise reduction

A noise free environment is necessary for testing ECG equipment. This can be achieved relatively easily by using a metal bench or metal sheet underneath the ECG device under test, the WhaleTeq MECG test unit, and also connecting together the ground as shown:

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 set up is satisfactory without any special efforts.

Figure 2: Set up a noise-free test environment

3.4 Live Update Application/ Firmware

MECG will auto-check if your application/firmware is the latest version. If a new version application/firmware is found, you will be prompted to update to the version.

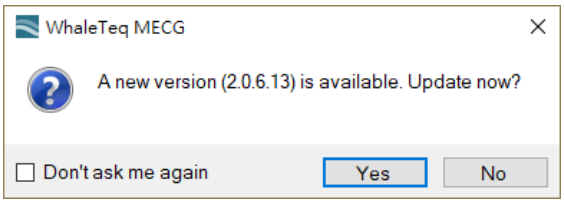


Figure 3: Update Application/ Firmware

3.5 Manually Update Firmware/DAC Compensation File

Firmware Update can only be supported with specific hardware and firmware. If your device doesn't support this function, please contact WhaleTeq service@whaleteq.com for more information.

Question:

How to check whether your MECG 2.0 supports firmware update or not?

Answer:

Connect the MECG 2.0 to a PC and go to the ''About'' dialog to check if ''F/W Version'' and ''H/W Version'' show. Please see ''3.5.1 How to Update Firmware'' step 1 to learn where the ''About'' dialog is.

Not Support Firmware Update	Support Firmware Update
	

Figure 4: Firmware Update Window

Caution:
There are risks of losing data if improper options are performed during the Firmware Update period.

3.5.1 How to Update Firmware

If the device supports “Firmware Update” feature, here are the steps to update the device firmware:

Step 1.
Click on the icon in the windows title bar to show the system menu, and click the system menu -> “About…” to show the About dialog.

Figure 5: ”About” Button

Step 2.
Click the “Update F/W” button and select the firmware image file

Figure 6: “Update F/W” Window

Step 3.
The application will show an information dialog. After pressing “OK”, the updating operation cannot be terminated.

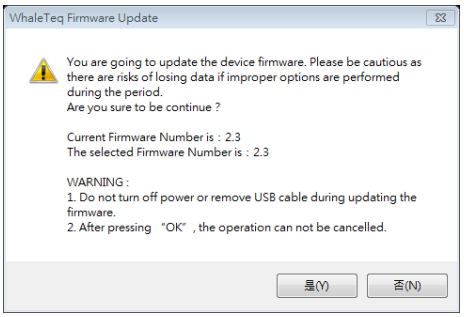


Figure 7: ''Confirm update'' Window

Step 4.

Wait for Firmware Update completed.

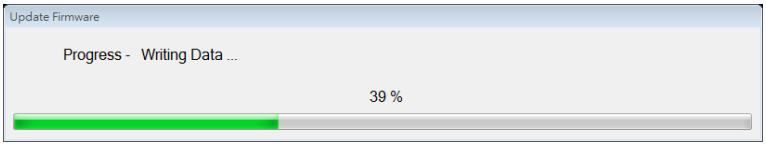


Figure 8: Firmware Updating

Step 5.

Please restart the system to complete firmware update process.

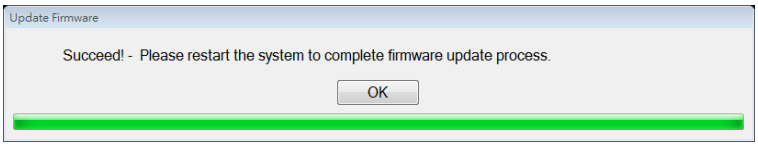


Figure 9: Firmware Update Completed

3.5.2 How to Update DAC Compensation File

The DAC compensation data is stored in a file which is sent in the shipping notice email. This avoids the need to re-publish the MECG PC software with each serial number.

The file is named “MECG_DACyynnnnn.txt” with yy as the year and nnnn as the sequential serial number, as shown on the label at the button of the MECG equipment. The file is approximately 220kB (compensation data for 8 channels with 4096 codes for each).

For users with serial numbers dated before WME2101-XXXXXX (the MECG 2.0 purchased before 2021), if the testing requires, please update the DAC compensation file.

To update the file, please follow the steps below:

1. Copy the file to the “C:\Whaleteq\” folder.

2. When the MECG software is running, it reads the serial number of the MECG equipment connected, and looks for the corresponding DAC compensation file. If the file is found, the following text will appear in the title:
“WHALETEQ Multichannel ECG Simulator V2.0.2.3 (with DAC Compensation)”

If the file is not detected, the software will keep running, but the text will be:
“ WHALETEQ Multichannel ECG Simulator V2.0.2.3 (Without DAC Compensation)”

DAC compensation is most likely to be of interest only for testing against the CTS database in IEC 60601-25:2011, and its applicability also depends on the measurements made by the ECG under test. DAC compensation is typically less than 10µV for any individual point. This could affect, for example, the accuracy of measurements made in the ST segment.

For users applying tests with waveforms based on real biological recordings, the recording itself contains noise well in excess of 10µV, so that DAC compensation is irrelevant.

DAC compensation data will be kept by WhaleTeq, so that any time if the data is lost (e.g.: transferring to a new PC), a copy can be requested.

4 Software Development Kit（SDK）

WhaleTeq provides Windows SDK (Software Development Kit) for MECG2.0. All test parameters correspond to specific SDK commands and DLL (Dynamic-link library) shared library can be used for efficient program binding and version upgrade. Support C/C++ header, C# interface, third party tools and script language integration such as Python.

5 Calibration and Validation

As per ISO/IEC 17025, the system should be calibrated either before use or on a periodic basis. For the system critical aspects are voltage and time accuracy.

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.

5.1 Self-Calibration

Self-calibration assists the user calibrates MECG 2.0 before testing.

- Output Voltage Confirmation

  Accuracy requirement specification
  IEC 60601-2-25:2011, Clause 201.5.4 cc) requires that voltages applied are accurate within ±1%. Since no minimum limit is stated (and it is impossible to apply ±1% for very small voltages), WhaleTeq has applied a rule of 20% of the EUT limit. This is effectively ±5µV for up to 500µV, ±8µV from 500 to 800µV and ±1% for values above 800µV. All values are taken with respect to the baseline.

  Overview/ Explanation
  Please contact WhaleTeq for obtaining the PC software with “calibration mode”, which produces a slow 0.1Hz square wave with an amplitude as set on the display. For example, with 0.2mV setting, the output will slowly cycle between 0.000mV and 0.200mV, changing every 5s.
  User shall confirm that the value is the same as set on the screen using a precision multimeter of accuracy equivalent to the Fluke 8845A[7]. To eliminate the effect of small dc offsets (which are not relevant to ECG equipment), the meter should be zeroed during the time in which a nominal 0.000mV is output (time in which the value is close to 0.000mV).

  Each of the 8 outputs must be tested individually (LA, LL, V1 ~ V6), using RL as the reference. For V1~V6, the output will be 5/3 (1.6666…) higher than the setting, due to Wilson Terminal offset. For example, a setting of 5mVpp will result in an output of 8.333mV.

  During shipping, the full values of 0.5, 1, 2, 3 and 5mV with both negative and positive values a checked (a total of 5 x 2 x 8 = 80 points). For regular calibration, the user may limit the check to +2mV and +5mV (total 2 x 8 = 16

[7] The Fluke 8845A has an accuracy specification equivalent to ±3.5µV on the 100mV range which is suitable for this calibration.

points), as the intermediate values are unlikely to change, and the values at 2, 5mV are within 0.1% of the shipping test.

Equipment required

Precision 6 ½ digit multimeter (DMM), such as a Fluke 8845A, 100mV range (or lower if provided).

Method

1. Through MECG software, set “Square, 0.1 Hz, 5 mV” and click “Load”, then click “Play” as the figure below:

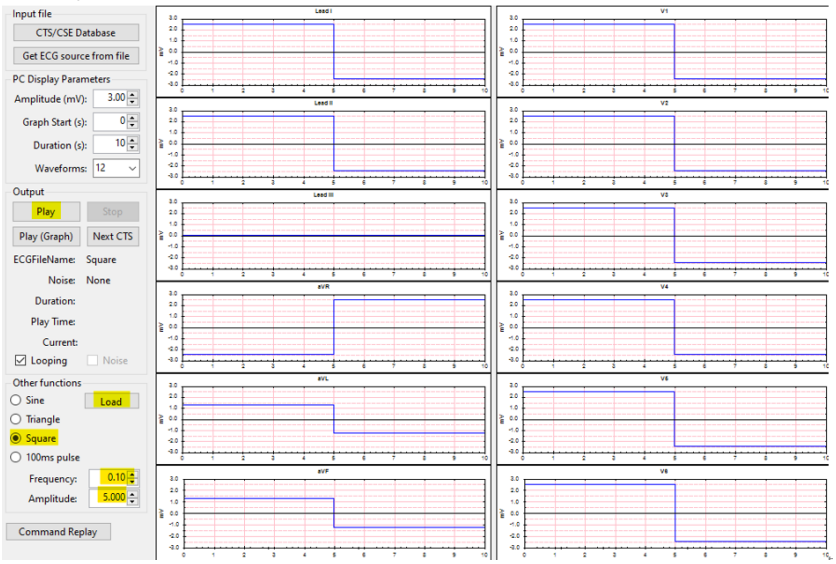


Figure 10: Self-calibration settings

2. Connect a multimeter to the RA and LA jacks of the MECG 2.0 to measure the DC mV. It should be in ±1% of 5 mV as the figure below. The MECG 2.0 output amplitude gives alternating 5s (0.1 Hz square wave) phases at -2.5mV and +2.5mV, so set the multimeter to zero (delta function) at one phase (e.g.: -2.5mV), with reading taken from the other phase (e.g.: +2.5mV) to obtain the 5 mV peak-peak value.

Figure 11: Connection to a multimeter

3. Connect the multimeter to the RA and V1 jacks of the MECG 2.0 to measure the DC mV. It should be in ±1% of 8.33 mV [V1 = V1 + (RA+LA+LL)/3 = 5 + (0+5+5)/3 = 8.33 mV] as the figure below. Then set the multimeter to zero (delta function) at one phase (e.g.: -4.17mV), with reading taken from the other phase (e.g.: +4.16mV) to obtain the 8.33 mV peak-peak value.

Figure 12: Measure the DC mV

4. Repeat step 3 to connect the multimeter to the RA and V2, and then the V3 to V6 of the MECG 2.0 to measure the DC mV. All the V2 to V6 should be in ±1% of 8.33 mV.

- Frequency/Time Confirmation

Accuracy requirement specification

Time accuracy is not specified in IEC 60601-2-25:2011. Based on the requirements for the device under test, a time accuracy of ±1ms over a 100ms period (equivalent to ±1%) should be sufficient.

General description of method

Connect a meter to terminals V1 and RL, using a meter which can detect frequency from signals around 10mVrms.

To verify the frequency, the sine or square function can be utilized. The selected frequency should be higher to allow accurate measurement. A frequency of 40Hz is suitable for this purpose. The digital nature of the system is that only one point needs to be confirmed.

Equipment required

Any suitable meter that can measure frequency with an uncertainty of ±0.2% at 40Hz.

Method

1. Select “Sine” from the “Other functions” section
2. Set the amplitude 10mVpp
3. Set the frequency to 40Hz
4. Press the “Load” button
5. Press the “Start” button
6. Connect the frequency meter to LEAD I monitor (if provided) or V1
7. Measure the frequency and confirm it is within ±1% of the setting

6 Standalone Behavior

To support subclause 202.6.2.1.10 and 202.6.2.6 in IEC60601-2-25. MECG (with firmware version 2.3 or above) is kept outputting the CAL20110 signal after power-on, and stopped outputting the signal after connecting to MECG application

7 Software Operation

7.1 Main screen

Figure 13: Main screen

01- CTS/CSE Database: Load a built-in waveform from the CTS or CSE

02- Get Source from file: Load an ECG waveform from Physionet or local PC

03- Display Parameters: Set the parameters about screen display

04- Output Waveform: Start and stop the waveform output

05- Other Waveforms: Select other waveforms such as Sine, triangle (press “Load” to load them into memory and screen)

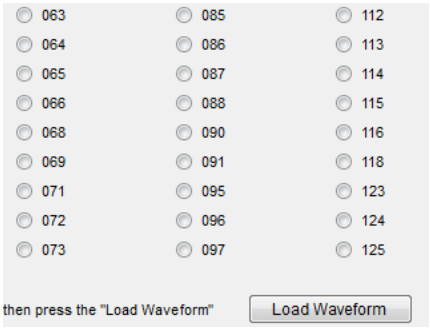
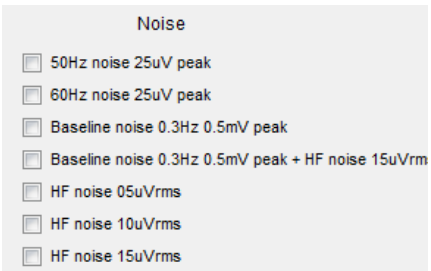
06- Command Replay: Use “Command” to auto display waveform

07- Graph View: Graphs of the output waveforms (for reference only)

7.2 CTS/CSE Database

Press the “CTS/CSE Database” button, a new screen will open allowing the user to select from the 19 CTS and 100 CTE database waveforms, as explained below:

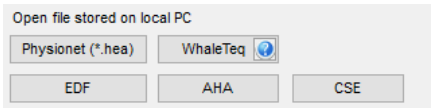
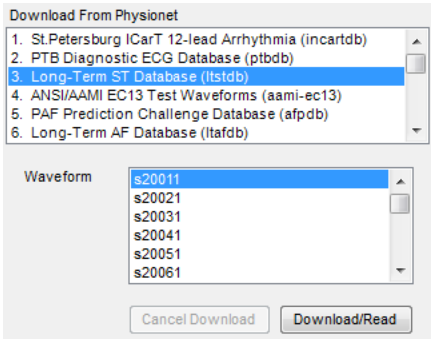
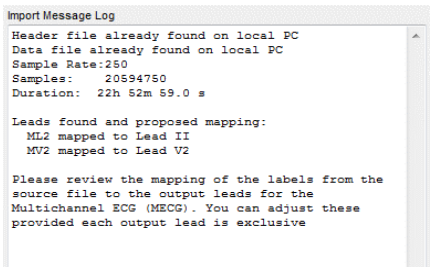
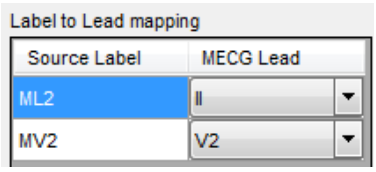
Table 2: CTS/CSE Database

	After selecting the desired waveform, press the “Load Waveform” button to load it into the PC memory.
	If noise waveforms are needed (see IEC 60601-2-51), these can be optionally selected (by checkbox). Noise waveforms are added only to the outputs associated with Lead I and Lead II, but through the network should appear on RA, V1 ~ V6. Noise waveforms do not appear on the display as they are added run-time.

7.3 Load ECG Source from File

This function is set up to work with popular waveforms from the PhysioNet website and other databases. As the software can work directly with the website, the user does not need any knowledge about the PhysioNet site, file formats and the like. However, note that there are many formats and options available. The current MECG works with Format 16 and Format 212 with common options.

Table 3: Load ECG Source from File

	Use these buttons if the ECG files are already on your PC. For PhysioNet files, select the *.hea file of interest. The *.dat file should be in the same directory.
	Use this section to automatically download from the internet. The downloaded file(s) will be stored in “C:\Physionet”. If the file has already been downloaded before, the software will use the PC version.
	The import message log provides feedback on what the software is doing with the file. As many PhysioNet files exceed ±5mV (due to noise, drift or large physiological signals) and lead mapping is not always clear, the user should check these messages.
	As there are many labels used for waveforms in the PhysioNet website, the MECG software will make a “best guess” which output lead the waveform should be mapped to. However, the user can adjust these provided that selected leads are exclusive.

7.3.1 WhaleTeq Format

The WhaleTeq text format is defined as follows:

Line Number	Description
1	Sample Rate in Hertz unit
2	Number of samples (N) for all channel
3	"start"
4	"Lead I"
5	Lead I sample 1
6	Lead I sample 2
...	...
N+3	Lead I sample (N-1)
N+4	Lead I sample N
N+5	"Lead II"
N+6	Lead II sample 1
N+7	Lead II sample 2
...	...
2N+4	Lead II sample (N-1)
2N+5	Lead II sample N

2N+6	"V1"
2N+7	V1 sample 1
2N+8	V1 sample 2
...	...
3N+5	V1 sample (N-1)
3N+6	V1 sample N
3N+7	"V2"
3N+8	V2 sample 1
3N+9	V2 sample 2
...	...
4N+6	V2 sample (N-1)
4N+7	V2 sample N
4N+8	"V3"
4N+9	V3 sample 1
4N+10	V3 sample 2
...	...
5N+7	V3 sample (N-1)
5N+8	V3 sample N

5N+9	"V4"
5N+10	V4 sample 1
5N+11	V4 sample 2
...	...
6N+8	V4 sample (N-1)
6N+9	V4 sample N
6N+10	"V5"
6N+11	V5 sample 1
6N+12	V5 sample 2
...	...
7N+9	V5 sample (N-1)
7N+10	V5 sample N
7N+11	"V6"
7N+12	V6 sample 1
7N+13	V6 sample 2
...	...
8N+10	V6 sample (N-1)
8N+11	V6 sample N

Figure 14: WhaleTeq Format

WhaleTeq format support sample rate from 100Hz ~ 1000 Hz.

Do not change the keywords, including “start”, “Lead I”, “Lead II”, and “V1” to “V6”, or the data file cannot be correctly loaded.

7.3.2 EDF Format

The MECG 2.0 software supports loading and playing EDF file format. To enable this function, you must purchase an additional authorization code. After this function is enabled, click ‘’EDF’’ to load and play the EDF file, and the PhysioNet Non-Invasive Fetal ECG Database (nifecgdb) can be downloaded and played directly in the MECG 2.0 software.

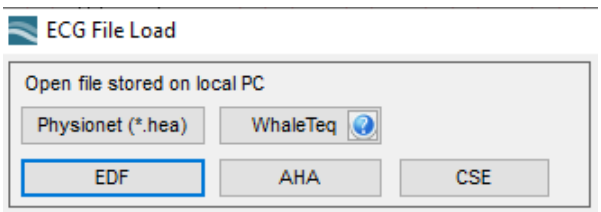


Figure 15: ’’ECG File Load’’ Window

Connect the MECG 2.0 to a PC and click ‘’EDF’’, then the ‘’License Activation’’ pop-up window shows.

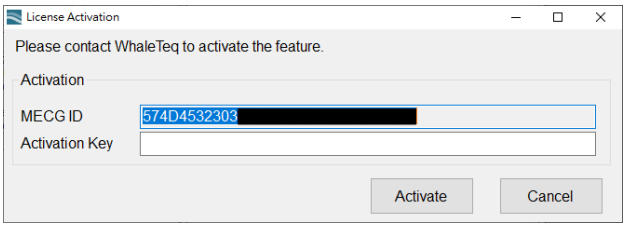


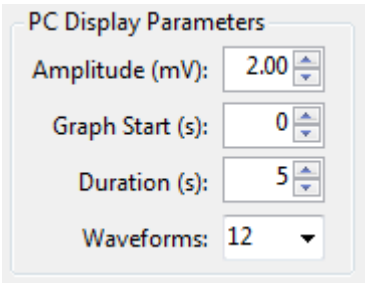
Figure 16: ‘’License Activation’’ Window

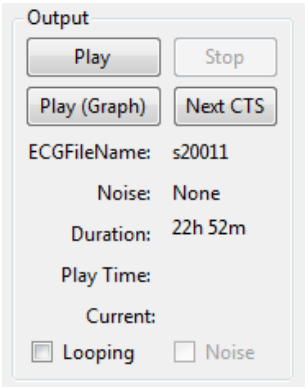
To purchase this authorization code, please contact WhaleTeq and provide your MECG ID.

7.4 Display Parameters / Output Waveforms

The output and display can be controlled as follows:

Figure 17: Display Parameters / Output Waveforms

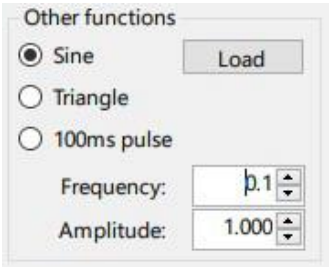
	These settings adjust only the display of the waveforms on the PC, and do not have any impact on the output. Selection of waveforms is limited to: 12 – all 12 leads 6 – Leads I, II, III, aVR, aVL, aVF 3 – Leads I, II, III 1 – Lead I only Note: Leads III, aVR, aVL, aVF are derived from Lead I, II and in general do not use the data if supplied.

	Waveforms can be started or stopped at anytime. • The output can be started from a mid-point in the file with “Play (Graph)” button, but adjusting the starting point “Graph Start (s)” of the graphs prior to pressing play. • “Next CTS” button, allowing quick access to the next waveform in the CTS database • A “Looping” checkbox, allowing the user to repeatedly play the same waveform. • “Noise” checkbox, allowing the user to quickly see the impact of the noise on the ECG under test

7.5 Other Waveforms

Basic waveforms are selectable as below:

Figure 18: Other Waveforms

	The following other functions can be selected: - Sine wave, adjustable amplitude and frequency - Triangle wave, adjustable amplitude and frequency - 100ms pulse, adjustable amplitude and frequency The user needs to press the “load” button to put these waveforms in memory. For these settings, the sampling rate is fixed at 1kHz. Due to the relatively low sample rate, this output is not suitable for frequency response analysis and should be used for reference only.

	Note : The frequency range is 0.1~100 Hz, the frequency resolution is 0.1Hz/step.

7.6 Command Replay

To increase test efficiency, MECG provides “Command Replay” feature. Edit your test sequences with command script, and automatically output the setting waveforms.

The command script could be automatically generated while the user operates MECG. This means user could operate the test procedure for the one time, then edit, save and replay the script.

Supported Command Scripts:

Table 4: Supported Command Scripts

Command	Parameter		Description	Example
CTS_CSE_Load	*CTS/CSE ID*	Record code for the waveform	Load CTS or CSE waveform with optional noise pattern.	`CTS_CSE_Load PCTH033.CYC 50HZ.N10`
	Noise	Noise pattern		
LoadLocal_Physionet	*Waveform file path*	Waveform file (*.hea) path on your local PC	Load the Physionet waveform (*.hea) file on local PC.	`LoadLocal_Physionet D:\Whaleteq\WhaleteqMECG\100.hea`
AcceptLeads	*LeadList*	The lead list for mapping, number of the list should match loaded waveform.	Map the leads of the loaded Physionet waveform.	`AccepetLeads I II None None None None V1 V2 V3 V4 V5 V6`
LoadLocal_AHA	*Waveform file path*	Waveform file (*.ecg) path on your local PC	Load the AHA waveform (*.ecg) file on local PC.	`LoadLocal_AHA D:\whaleteq\WhaleteqMECG\1001.ecg`
LoadLocal_AHA_TXT	*Waveform file path*	Waveform file (*.txt) path on your local PC	Load the AHA text format waveform (*.txt) on local PC.	`LoadLocal_AHA_TXT D:\WhaleteqMECG\1001.txt`
LoadLocal_CSE	*Waveform file path*	Waveform file (*.DCD) path on your local PC	Load the CSE waveform (*.DCD) file on local PC.	`LoadLocal_CSE D:\WhaleteqMECG\MA1_001.DCD`

LoadWhaleteq_TXT	*Waveform file path*	Waveform file (*.txt) path on your local PC	Load the WhaleTeq format waveform (*.txt) file on local PC.	`LoadWhaleteq_TXT D:\WhaleteqMECG\MECG_227ECG_.txt`
StartPlay	*N/A*		Start outputting the loaded ECG signal data through the MECG device.	`StartPlay`
StopPlay	*N/A*		Stop the current signal outputting.	`StopPlay`
Continue	*Seconds*	Number of seconds before continuing next command.	Pause the command replay for specified seconds then continue.	`Continue 200`
Process	*Executable PathArg*	The executable file path and arguments (optional).	Invoke an executable to run. Command replay would continue next command immediately.	`Process NotePad.exe result.txt`
ProcessWait	*Executable PathArg*	The executable file path and arguments (optional).	Invoke an executable to run. Command replay would pause until the running process finished.	`ProcessWait NotePad.exe result.txt`

Below is a demo for command script:

Table 5: Demo for Command Script

Demo	Explain
CTS_CSE_Load PCTH009.CYC	Load CSE009 waveform
StartPlay	Start to output the waveform
Continue 144	Continue the behavior for 144 seconds
LoadLocal_Physionet C:\Physionet\01.hea	Load Physionet “01” waveform from local PC
AcceptLeads II I	Lead mapping to Lead II, Lead I
StartPlay	Start to output the waveform
Continue 14	Continue the behavior for 144 seconds
StopPlay	Stop to output the waveform

7.7 Graph View

By default, the 12-lead ECG waveforms are all displayed in the main window. To get more details of the waveforms, you can double-click one of the waveform graphs to show the ECG Signal dialog.

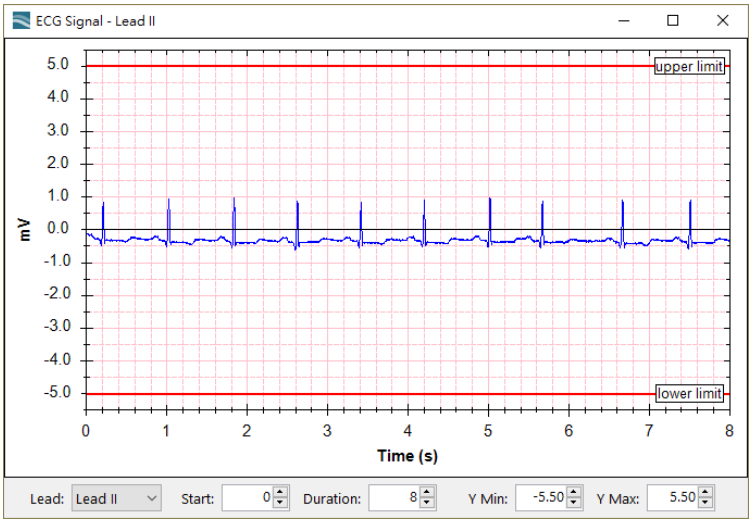


Figure 19: View ECG waveforms

8 Trouble Shooting

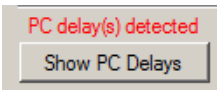
Table 6: Trouble Shooting

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 streaming is interrupted (occasional)	**USB Module with firmware before Aug 2011** The system automatically detects streaming delays, attempts to move the system to "Off" mode and provides the user with a warning. To resume operation, restart the function that was being previously used. In some cases, it may be necessary to restart software / USB module. **USB Module with firmware from Aug 2011** The system automatically detects streaming delays, but continues to stream data and simply

	records the time and length of delay. See section 5.6 above.
USB streaming is interrupted (frequent)	This indicates the PC is involved in tasks that take longer than 300ms to complete, which may include starting screen savers, background virus checks and the like, or due to lack of RAM. For long-run test, the PC should run only the MECG software, and all background tasks should be disabled. Alternately use a PC with at least 1GB of memory.
USB module stops responding	Move the Output mode to “Stop” and then return to “Play” 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.

8.1 Long-term tests (continuous) streaming

While modern PCs give the appearance of real time, the core structure does not guarantee interruption free streaming of serial data to a peripheral. Previous versions of the MECG have incorporated a feature to detect interruptions, stop streaming and inform the user.



Since August 2011, this feature has been modified so that the system simply records the time and duration of the streaming interruption. In many cases, the interruptions are rare and short (<20ms), and unlikely to influence the outcome of a test. When a streaming error occurs, “PC delay(s) detected” message is shown on the bottom left corner, and button “Show PC Delays” appears to allow the user to view the delays.

9 Caution

- 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.
- 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.
- For operating “Firmware Update” feature, there are risks of losing data if improper options are performed during the Firmware Update period.

- Warranty void if QC PASS label is removed or tampered with.
- The professional testing instrument, not a medical device, is for testing only, and will not involve human or clinical use.

10 Ordering Information

10.1 Standard accessories

- ✓ MECG2.0 Host x 1
- ✓ MECG2.0 Software CD x 1
- ✓ Breakout box x 1
- ✓ USB Wire x 1
- ✓ Wire buckle x 12
- ✓ Ground wire x 1

10.2 Optional Software and Accessories

- ✓ MECG EDF file decoder
- ✓ USB feed regulator isolator: WUI100

11 Version Information

Table 7: Version Information

Version	Modify content	Issue date
20201231	Add Chap 4 Software Development Kit（SDK） Chap 9 Caution Chap 10 Ordering Information Chap 11 Version information	20201231
20210628	Add Chap 9 Caution	20210628
20220522	Add 3.5.2 How to Update DAC Compensation File 5.1 Self-Calibration > Output Voltage Confirmation > Method	20220522

12 Contact WhaleTeq

WHALETEQ Co., LTD

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

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