WHALETEQ

Multichannel ECG Test System
(MECG 2.0)

User Manual

For use with Software version 1.6.x.x and 2.0.x.x

(Revision 2015-08-14)
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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 compensation¹ and electronic Wilson Terminal offset² 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 embedded³ 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 Physionet 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.
2 System description

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

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 “Physionet” web-site**
  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 analogue 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).

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\(^4\) 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.
2.1 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.

- 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 the appropriate compensation. Equipment with serial numbers earlier than 2012-008 will continue to operate with the software as before.

Additionally the following features were have been added to help the user with testing:

- A “Next CTS” button, allowing quick access to the next waveform in the CTS database.

- A “Noise On” checkbox has been added, allowing the user to quickly see the impact of the noise on the ECG under test.

These features are not yet added to the relevant sections of this manual.
3 Set up

3.1 Software installation

3.1.1 System requirements
The Multichannel ECG system uses a normal PC to interface and control the USB module. The PC should meet the following requirements:\footnote{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.}
- Windows PC (XP or later)
- Microsoft .NET 2.0 or higher
- Administrator access (if necessary for installation of software/driver)
- Free USB port

3.1.2 PC Software installation
Software can be installed directly from the WhaleTeq website.

There are three options provided:
- Direct installation from the internet (if compatible with network/system)
- Copy zip file to PC and run “setup.exe” file
- Copy zip file to PC, change “setup.abc” file to “setup.exe” and run (this option is provided for systems that may block “.exe” extensions)

The current software is based on .NET 2.0 which is intended for broad compatibility.

3.1.3 USB driver installation
The system uses a USB mode called “CDC” which emulates a serial COM port for which Microsoft Windows® already has the driver for this installed. However, it is necessary to link the test unit to this driver, which follows a process similar to installing a driver.

A copy of the linking file “mchpcdc.inf” can be downloaded from WhaleTeq website. When the USB module is first connected, select manual installation, and point to folder containing the above linking file. Continue to follow instruction. There may be a warning that the driver is not recognized by Windows® which can be ignored. This linking file is provided by Microchip® for use with PIC microprocessors having in built USB function.
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 test 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 pin outs are:

<table>
<thead>
<tr>
<th>Pin</th>
<th>Signal</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>RA</td>
</tr>
<tr>
<td>2</td>
<td>LA</td>
</tr>
<tr>
<td>3</td>
<td>LL</td>
</tr>
<tr>
<td>4</td>
<td>RL</td>
</tr>
<tr>
<td>5</td>
<td>V1 (V6)</td>
</tr>
<tr>
<td>6</td>
<td>V2 (V5)</td>
</tr>
<tr>
<td>7</td>
<td>V3 (V4)</td>
</tr>
<tr>
<td>8</td>
<td>V4 (V3)</td>
</tr>
<tr>
<td>9</td>
<td>V5 (V2)</td>
</tr>
<tr>
<td>10</td>
<td>V6 (V1)</td>
</tr>
</tbody>
</table>

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 SECG test unit, and also connecting together the ground as shown:

With this set up, 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.
4 Calibration

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.

4.1 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
The PC software is provided with a “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.

The user should confirm that the value is the same as set on the screen using a precision multimeter of accuracy equivalent to the Fluke 8845A. To eliminate the effect of small dc offsets (which are not relevant to ECG equipment), the meter should be zeroed during 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 0.2, 0.5, 1, 2, 3 and 5mV with both negative and positive values a checked (a total of 6 x 2 x 8 = 96 points). For regular calibration, the user may limit the check to +2mV and +5mV (total 2 x 8 = 16 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).

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6 The Fluke 8845A has an accuracy specification equivalent to ±3.5µV on the 100mV range which is suitable for this calibration.
Method
1. Select the calibration mode
2. Set the amplitude +2mV
3. Press the “Load” button
4. Press the “Play” button
5. Connect the DMM between LA and RL
6. Zero the DMM during the zero half of the cycle
7. Record the DMM value during the output half of the cycle
8. Repeat for LL, V1~V6
9. Repeat LA test at +5mV
10. Confirm all measurements are within 20% of the EUT limit in the standard

4.2 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
5 Operation

5.1 Main screen

Click to load a waveform from the CTS

Click to load an ECG waveform Physionet site

Display parameters

Start and stop the output

Select other functions such as Sine, triangle waveforms (press “Load” to load them into memory)

Graphs of the output waveforms (for reference only)
5.2 Selecting a CTS database waveform

Press the “Get from CTS” button, a new screen will open allowing the user to select from the 120 CTS database waveforms, as explained below:

After selecting the desired waveform, press the “Select” button to load it into the PC memory.

If noise waveforms are needed (see IEC 60601-2-51), these can be optionally selected (by check box). 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.
5.3 Selecting an ECG waveform from file

This function is set up to work with popular waveforms from the Physionet website. 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>
<thead>
<tr>
<th>Action</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Use this button if the Physionet files are already on your PC.</td>
<td>Select the *.hea file of interest. The *.dat file should be in the same directory.</td>
</tr>
<tr>
<td>Use this section to automatically download from the internet.</td>
<td>The downloaded file(s) will be stored in c:\Physionet.</td>
</tr>
<tr>
<td>If the file has already been downloaded before, the software will</td>
<td>use the PC version.</td>
</tr>
<tr>
<td>The import message log provides feedback on what the software is</td>
<td>not always clear, the user should check these messages.</td>
</tr>
<tr>
<td>As there are many labels used for waveforms in the Physionet website,</td>
<td>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.</td>
</tr>
</tbody>
</table>
Selecting Other Functions

Basic waveforms are selectable as below:

- Sine wave, adjustable amplitude and frequency
- Triangle wave, adjustable amplitude and frequency
- 100ms pulse, adjustable amplitude and frequency
- Calibration mode (see 4.1 above)

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.
5.4 Starting, stopping and display of waveforms

The output and display can be controlled as follows:

<table>
<thead>
<tr>
<th>Waveforms can be started or stopped at anytime.</th>
</tr>
</thead>
<tbody>
<tr>
<td>In addition, the output can be started from a mid point in the file, but adjusting the starting point of the graphs prior to pressing play.</td>
</tr>
<tr>
<td>For example if the “Graph Start” (see below) is adjusted to 300s, pressing the “Play (Graph) button will start from 300s (6 mins).</td>
</tr>
</tbody>
</table>

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

5.5 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.
## Specifications

<table>
<thead>
<tr>
<th>Item</th>
<th>Details / Reference</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Output channels</td>
<td>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.</td>
<td>8 outputs 10 lead electrodes 12 leads</td>
</tr>
<tr>
<td>Voltage accuracy(^7)</td>
<td>IEC 60601-2-51 specifies a limit of ±1%, but does not provide a lower limit (all systems must have a lower limit). An inferred specification of 1% ±5µV is derived from the device under test specification in IEC 60601-2-51 of 5% ±25µV.</td>
<td>±1% (&gt;800µV) ±5µV (&lt;500µV) ±8µV (&lt;800µV)</td>
</tr>
<tr>
<td>Output noise level 0-150Hz</td>
<td>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.</td>
<td>&lt;5µV</td>
</tr>
<tr>
<td>Time accuracy</td>
<td>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 4.2). The system’s design accuracy exceeds 0.1% as a 100ppm crystal reference is used.</td>
<td>±1%</td>
</tr>
<tr>
<td>Sampling rate</td>
<td>A maximum sampling rate of 1kHz matches the sampling rates of ECG files.</td>
<td>1kHz (8 channels)</td>
</tr>
<tr>
<td>Power supply</td>
<td>Powered from the USB supply (5V 0.2A)</td>
<td>N/A</td>
</tr>
<tr>
<td>Environment</td>
<td>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.</td>
<td>15-30° C 10-95% RH</td>
</tr>
</tbody>
</table>

\(^7\) 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.
### 7 Trouble shooting

<table>
<thead>
<tr>
<th>Problem</th>
<th>Resolution</th>
</tr>
</thead>
<tbody>
<tr>
<td>USB module (test unit) not recognized (USB driver is installed correctly)</td>
<td>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</td>
</tr>
</tbody>
</table>
| 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 duration tests, 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 Contact details

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