medlab
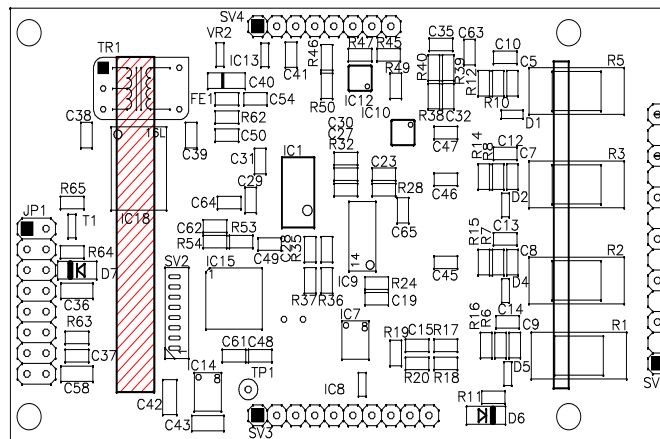
Three Lead
ECG OEM board
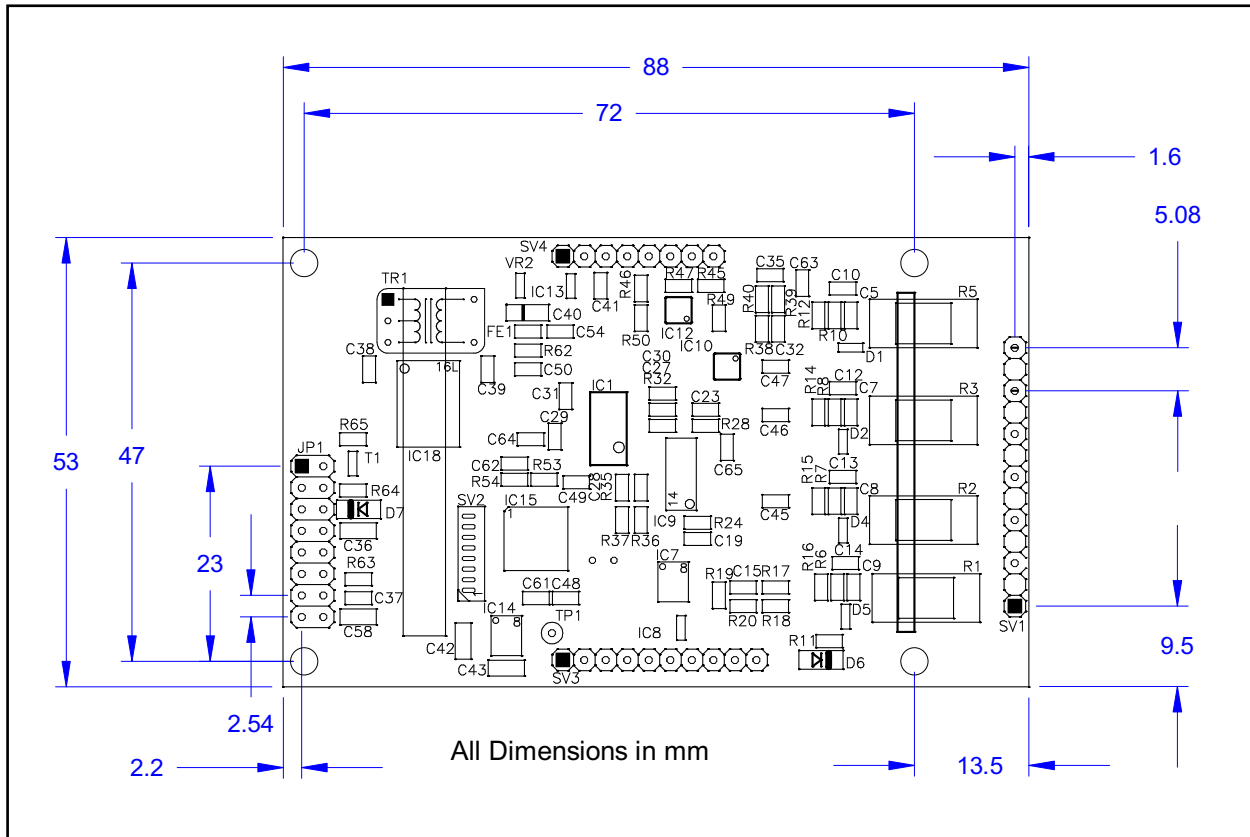
EG01010

Technical Manual

Version 1.06

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Mechanical Dimensions of the Module

Mechanical drawing, top view of the module (1:1)

Overview

The scope of this document is the description and specification of Medlab's three lead ECG board EG01010. It should help anybody who is familiar with both programming and basic electronics to select the proper hardware and software version for his application as well as to help him integrate the board into his own electronic system.

The EG01010 measures one of three channels of ECG using a three lead cable. Through the use of the second transmission protocol and an additional respiration board it is also possible to measure the respiration rate.

The ECG board has two connectors, as seen on the drawing on next page. The ECG module is connected to the host system via the host and power connector. It provides the power supply for the board and the communication with the host system. The EG01010 has full patient isolation on board, that means that the input voltage of 5V has no galvanic contact to patient. The isolation gap can be easily seen on the board and this area is only bridged by a transformer and the opto couplers. The patient cable is connected to the ECG module by the patient cable connector. The ECG-board is defibrilation protected. It is important that the board is directly connected to the ECG-cable connector and cable. This is to ensure the patient isolation and the correct measurements of the board.

With a three lead cable, the module can output the following channels: I or II or III. Only one curve at a time can be measured, e.g. Einthoven I or II or III. By using an optional respiration board in conjunction with the second transmission protocol it is also possible to measure the respiration rate of the patient. This is achieved by measuring the impedance change between the electrodes.

The isolated ground of the module is switched to the unused electrode in the respective setting, e.g. isolated ground is on the left leg electrode if the module is set to channel I, left hand electrode if module is set to channel II and right hand electrode if channel III is selected.

There are two transmission protocols for communication with the main unit available. The used protocol is depending on the installed software version. The baud rate used for the data transmission is also depending on the used protocol.

Description of the Module and Connectors
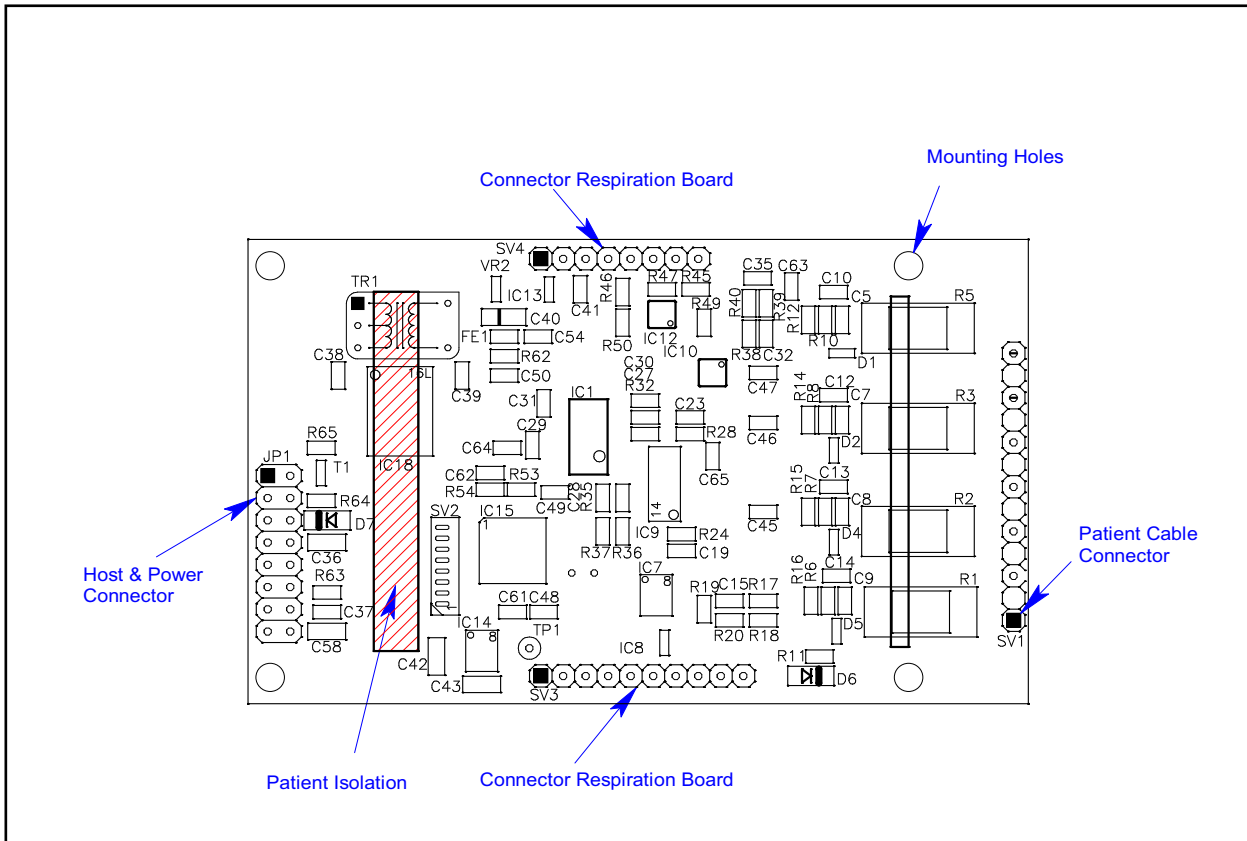
Description of connectors and areas of the module (1:1)

Physical Units of Transmitted Data

Scaling of ECGs is normally done in the unit "cm/mV" for the Y-axis and in "mm/sec" for the X-axis.
The respiration rate is transmitted in „rpm" (respirations per minute).
The pulse rate is transmitted in „bpm" (beats per minute).
The transmission speed for the wave is indicated in Hz (sec^{-1}).
The ECG amplitudes are normally indicated in „cm/mV". Since this is depending directly on the resolution of the screen the user is working with, the transmitted samples are not directly scaled in this unit, but fall into the range of 0-0xF7 (8 Bit samples, 0xF8 to 0xFF reserved for commands). It is within the responsibility of the user to scale the transmitted samples in a way that the waves displayed onto his screen fit to the usual scales used in medicine, 0.5, 1, 2 and 4 cm/mV. The amplification of the module in the different amplification stages is:

Stage 1	Stage 2	Stage 3
1mv = 32	1mV = 64	1mV = 128

Normal values for the trace speed are 12.5 mm/sec, 25 mm/sec and 50 mm/sec.

Technical Data (Specifications)

Mechanical data: 88 mm x 53 mm
                              see page 4 for board drawing
                              4 layer PCB, thickness 1.5 mm

Maximum height: 12 mm
With respiration option: 25 mm

Attachment: four M2.5 screws in the corners of the PCB

Weight: 32 g

Operating voltage: 5 Volt, ± 10 %, 45 mA

Power consumption: 225 mW while measuring

Input: Defibrillation protected
Patient Isolation: CF, 4000 Volts RMS

Amplification: Three levels, user selectable
Data transmission: Three frequencies, user selectable
Filtering: Integrated 50 Hz or 60 Hz notch filter

Amplifier frequency range: 0.05 to 70 Hz

Pulse detection: 30 .. 247 bpm ± 1%, ± 1 Digit, 8 beat average
Respiration detection: 5 .. 99 rpm ±3%, ± 1 Digit, 8 samples average (option)

Output: Asynchronous serial output with CMOS levels (0 ... 5 V)
                              Hardware pulse trigger output, CMOS levels (0 ... 5 V)
                              Both outputs fully isolated from patient

Protocol: Standard bidirectional serial protocol, see description
                              on following pages

Connector: Connectors compatible to Medlab EG05000 five channel OEM board
                              Optional connectors for Medlab 00731 respiration board
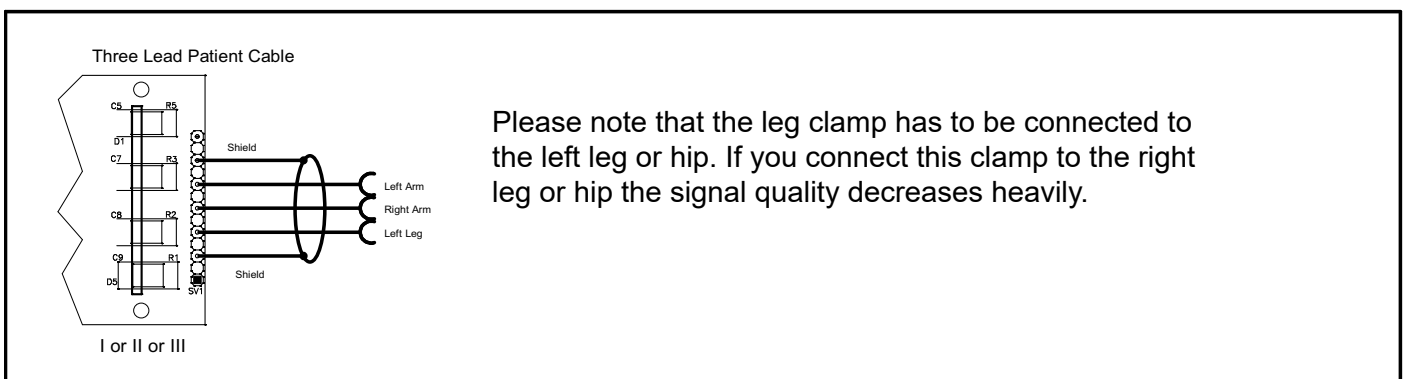
Connectors

(see attached drawing for location)

Header for host connection

JP1:
	1	Ground
	2	Ground
	3	Txd (RS232 level +/- 5Volt)
	4	Txd (TTL level)
	5	Rxd (RS232 level +/- 5Volt)
	6	Rxd (TTL level)
	7	Not connected
	8	Not connected
	9	Not connected
	10	Not connected
	11	Pulse Trigger output
	12	Pulse Trigger output
	13	Shutdown (V_{CC} level on this pin powers down module)
	14	Shutdown (V_{CC} level on this pin powers down module)
	15	V_{CC} input
	16	V_{CC} input

Note: The pulse trigger is a high active, rectangular signal with a pulse width of 33 ms. Delay to the R wave can be adjusted by a command.

Header for patient cable connection

SV1:
	1	Unused
	2	SHIELD
	3	LL-IN
	4	RA-IN
	5	LA-IN
	6	SHIELD
	7	Unused

Three Lead Patient Cable

Please note that the leg clamp has to be connected to the left leg or hip. If you connect this clamp to the right leg or hip the signal quality decreases heavily.

ECG cable connection

Remark:

For respiration measurement (optional respiration board needed), electrodes should be attached to chest and hip, not arm and leg.

Technical Description for TRF EN 60601-2-27

When preparing a test report form (TRF) for proof of compliance of the user's medical product to EN 60601-2-27, the following remarks / technical data will be helpful or needed:

Input Impedance:	> 10 MOhm
Common mode rejection ratio:	> 90 dB at 50 Hz or 60 Hz
Input Dynamic Range:	±5 mV AC, ±300 mV DC
Defibrillator Discharge Recovery:	<10 sec per IEC 601-2-27
	<10 sec per AAMI EC13-1992
Leads-off sensing current:	Applied currents less than 150 nA

The following information references particular sections of EN 601-2-27

Respiration (optional), section 201.7.9.2.9.101 b) 1)
Applied currents less than 80 µA @ 80 kHz square

Tall T-wave rejection, section 201.9.2.9.101 b) 2)
T-wave of 1.1 mV amplitude will not affect heart rate determination.

Heart rate averaging, section 201.7.9.2.9.101 b) 3)
TBD

Response to irregular rhythm, section 201.7.9.2.9.101 b) 4)
A1) Ventricular bigeminy: the EG01010 counts both large and small QRS complexes to display a rate of 80 bpm.

A2) Slow alternating ventricular bigeminy: the EG01010 counts both large and small QRS complexes to display a rate of 60 bpm.

A3) Rapid alternating ventricular bigeminy: the EG01010 counts all QRS complexes to display a rate of 120 bpm.

A4) Bi-directional systoles: the EG01010 counts all QRS complexes to display a rate of 90 bpm.

Heart rate meter response time, section 201.7.9.2.9.101 b) 5)
a) Change from 80 to 120 BPM: 4 sec

b) Change from 80 to 40 BPM: 7 sec

Time to alarm for tachycardia, section 201.7.9.2.9.101 b) 6)

Waveform B1:	Amplitude	Time to alarm
	0,5 mV	1 sec
	1 mV	1 sec
	2 mV	1 sec
Waveform B2	Amplitude	Time to alarm
	1 mV	1 sec
	2 mV	1 sec
	4 mV	1 sec

Pacemaker pulse display capability, section 201.12.1.101.12
The EG01010 is capable of displaying the ECG signal in the presence of pacemaker pulses with amplitudes of ± 2 mV to ± 700 mV and durations of 0.1 ms to 2.0 ms. An indication for the pacemaker pulse is provided.

Pacemaker pulse rejection, section 201.12.1.101.13

Without over/undershoot:

a) For single (ventricular-only) pacemaker pulses alone, with 0.1 and 2.0 ms pulse-widths and ± 2 mV and ± 700 mV pulse-amplitudes, the EG01010 correctly displays heart rate as zero bpm (Asystole).

b) For single (ventricular-only) pacemaker pulses with normally paced QRS-T, with 0.1 and 2.0 ms pulse-widths and ± 2 mV and ± 700 mV pulse-amplitudes, the EG01010 correctly displays heart rate of the QRS-T rhythm (60 bpm for the specified test waveform).

c) For single (ventricular-only) pacemaker pulses with ineffectively paced QRS pattern, with 0.1 and 2.0 ms pulse-widths and ± 2 mV and ± 700 mV pulse-amplitudes, the EG01010 correctly displays heart rate of the underlying QRS-T rhythm (30 bpm).

d) For atrial/ventricular pacemaker pulses alone, with 0.1 and 2.0 ms pulse-widths and ± 2 mV and ± 700 mV pulse-amplitudes, the EG01010 correctly displays heart rate of zero bpm (Asystole).

e) For atrial/ventricular pacemaker pulses with normally paced QRS-T, with 0.1 and 2.0 ms pulse-widths and ± 2 mV and ± 700 mV pulse-amplitudes, the EG01010 correctly displays heart rate of the QRS-T rhythm (60 bpm).

f) For atrial/ventricular pacemaker pulses with ineffectively paced QRS pattern, with 0.1 and 2.0 ms pulse-widths and ± 2 mV and ± 700 mV pulse-amplitudes, the EG01010 correctly displays heart rate of the underlying QRS-T rhythm (30 bpm).

With over/undershoot:

a) For single (ventricular-only) pacemaker pulses alone, with 0.1 and 2.0 ms pulse-widths and ± 2 mV and ± 700 mV pulse-amplitudes, the EG01010 correctly displays heart rate of zero bpm (Asystole).

b) For single (ventricular-only) pacemaker pulses with normally paced QRS-T, with 0.1 and 2.0 ms pulse-widths and ± 2 mV and ± 700 mV pulse-amplitudes, the EG01010 correctly displays heart rate of the QRS-T rhythm (60 bpm).

c) For single (ventricular-only) pacemaker pulses with ineffectively paced QRS pattern, with 0.1 and 2.0 ms pulse-widths and ± 2 mV and ± 700 mV pulse-amplitudes, the EG01010 correctly displays heart rate of the underlying QRS-T rhythm (30 bpm).

d) For atrial/ventricular pacemaker pulses alone, with 0.1 and 2.0 ms pulse-widths and ± 2 mV and ± 700 mV pulse-amplitudes, the EG01010 correctly displays heart rate of zero bpm (Asystole).

Software Protocol Description

The normal connection to the board is done via serial, asynchronous communication. Both CMOS and RS232 (+/- 5Volt level) voltage levels are available. The device uses one of two protocols. The protocol is selected by the installed software version.

Protocol 1:
The first protocol is the original protocol which ensures backwards compatibility of the board in existing devices. This protocol is token oriented. Special marker bytes that are not present in the normal data stream mark the meaning of the following byte.

Protocol 2:
The second protocol is designed follwing the protocol of the EG05000. This protocol is able to communicate the respiration data together with the selected ECG signal, if a respiration board is fittet to the ECG module.

For details please see the protocol descriptions on the following pages.

The RS232 voltage levels are helpful during evaluation of the board, which can be done using a PC and a special software. The connection in the customer's final system could be done through 0V/5V levels, which saves parts on the customer's side of the data stream.

Connector JP1 is compatible with the interface connector on Medlab's EG05000 five channel ECG OEM board. Therefore, test cables that have been built for this board can also be used for the EG01010 board.

Serial Transmission Protocol 1

All data is transmitted at 9600 baud, 8 bits, 1 stop bit, no parity. Each time a pulse is detected by the board's internal algorithm, a block with a new, averaged pulse rate is transmitted. The pulse detector is of high quality, and the point in time where the pulse marker (0xFA) is transmitted can be used for triggering applications that require to synchronize other devices to a patient's R-wave.

The ECG wave sample points are transmitted continuously with 50, 100 or 300 bytes per second, according to the user's last command. The curve sample points lie between 0 and 246, with the neutral line of the ECG being at 128.

Values that are higher than 246 (0xF6) are used for marking the following byte as a new data values according to the following definition:

Marker byte	Meaning of following byte(s)	Commands accepted by the module	
0xF8	wave sample points follow	"N"	normal operation mode
		"M"	switch to simulation mode
		"S" "0"	send ECG trace with 300 Hz
0xF9	Respiration rate follows (optional respiration board needs to be present)	"S" "1"	send ECG trace with 100 Hz
		"S" "2"	send ECG trace with 50 Hz
		"A" "0"	amplification stage 0
		"A" "1"	amplification stage 1
0xFA	Pulse value follows	"A" "2"	amplification stage 2
		"G" "0"	channel III
0xFB	Info byte follows	"G" "1"	channel II
		"G" "2"	channel I
0x11	The only info byte defined is 0x11, "LEAD OFF" Others may be added in the future	"D" "0"	show ECG curve
		"D" "1"	show respiration curve
		"5"	turn on 50 Hz notch filter
		"6"	turn on 60 Hz notch filter
		"C"	calibrate, send 1mV pulse
		"T" "0"	Pulse trigger 15 ms after R
		"T" "1"	Pulse trigger 50 ms after R
		"T" "2"	Pulse trigger 100 ms after R
		"T" "9"	Pulse trigger middle between R
		"P" "0"	Pacemaker detection off
		"P" "1"	Pacemaker detection on

Example transmitted data stream :

Wave Marker	Wave Samples	Pulse 120	Wave Marker	Wave Samples
0xF8	0x20 0x23 0x25	0xFA 0x78	0xF8	0x25 0x25 0x26

Time
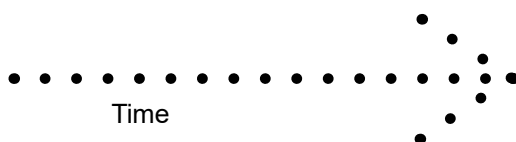
<u>Commands accepted by the Module</u>

All commands have a one or two byte structure. They are also sent to the module with 9600 baud. The commands are sent in ASCII format.

Basic Bandwidth of ECG amplifier (Diagnostic or Monitoring mode):

„F"   Parameter: "0" or "1"

„0"   bandwidth of the amplifier DC-80 Hz   Diagnostic mode (bear in mind mains filter setting)

„1"   bandwidth of the amplifier 0.67-40 Hz Monitoring mode (reset value)

„S"   extra strong filter, lower edge frequency 2 Hz

Transmission frequency of the waveform packet:

„S"   Parameter: "0", "1", "2" (0x53 0x31 for example for „S1")

„0"   send waveform packets 300 times per second

„1"   send waveform packets 100 times per second   (reset value)

„2"   send waveform packets 50 times per second

Amplification of the waveforms

„A"   Parameter: "0", "1", "2" or "3" (0x41 0x31 for example for „A1")

„0"   Amplification stage 1   (lowest amplification, should be scaled to 0.5 cm/mV)

„1"   Amplification stage 2

„2"   Amplification stage 3   (highest amplification, should be scaled to 2 cm/mV)

Each amplification stage has **double the sensitivity** of the previous stage

Channel selection (1 wave channel can be selected)

„G"   Parameter: "0", "1" or "2"   (for Einthoven III, II or I selection)

Filtering of the waveforms for 50 and 60 Hz line frequency:

„5"   50Hz Filter on

„6"   60 Hz Filter on

Selecting the transmitted waveform:

„D"   Parameter: „0" or „1" (0x44 0x30 for example for „D0")

„0"   Show ECG trace   (reset value)

„1"   Show respiration waveform   (optional respiration board needed)

Calibration mode (1mV rectangle transmitted for 250 samples):

„C"   output 250 samples of 1 mV rectangular waves, then go back to normal mode

Simulated data outputs (useful for testing or exhibitions):

„M"   use simulated output waves and values

„N"   use real input for data transmission   (reset value)

Set delay of the pulse trigger signal (active high, 33 ms duration):

„T"   Parameter: „0" , „1" , „2" , or „9"

„0"   Delay of the pulse trigger signal 15 ms   (reset value)

„1"   Delay of the pulse trigger signal 50 ms

„2"   Delay of the pulse trigger signal 100 ms

„9"   The signal triggers in the middle between R waves

Pacemaker detection on or off:

„P"   Parameter: „0" , „1"

„0"   Pacemaker detection off

„1"   Pacemaker detection on   (reset value)

Test Program for Protocol 1
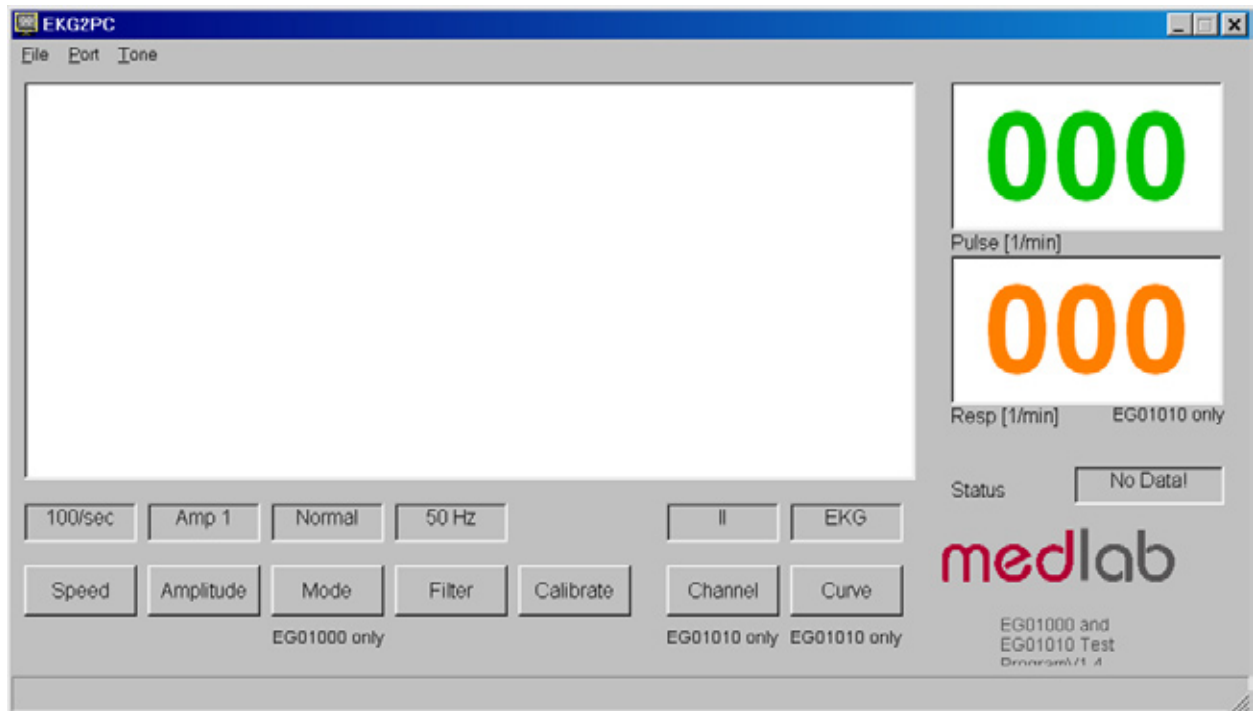
For easy integration of the module into medical systems, a test software has been made available. The EG01010 can be connected directly to a PC, the received data is shown on the screen.

To run the program, connect the EG01010 board to the serial port of a PC. If the PC has no serial port, please use a USB to RS232 adapter and install the driver of this adapter first and make sure to create a virtual serial port. Connect the power input to a 5 volts DC source. Then start the program on your PC and select the serial port number in the "Port" menu.

Commands can be sent to the board by pressing the command buttons in the application. Since the same software can be used for the one channel EG01000 and the three channel EG01010 board, some buttons have no function when used with the EG01010.

The software is available free of charge on: **www.medlab.eu**, on the page describing the EG01010. The software is available in a Visual Basic 6 and a Visual C# version.
The source code of the chosen test program is also included in the download package.

Serial Transmission Protocol 2

The board can transmit a single ECG waveform and optionally a respiration waveform synchronously, a pulse value, a respiration value (if the optional respiration board is fitted to the base ECG board) and several status bytes. Transmission is done in blocks. The integrity of the blocks is secured by:
1)   an even parity bit in each transmitted byte.
2)   a checksum for each block
Even parity in this case means that the sum of all bits in one byte, including the parity bit, is „0".

The module can receive commands over its serial interface. For example, the user can select transmission speed of the wave block, set the amplification of the ECG amplifiers and select which channels should be transmitted by the board. The transmitted channels that are available with a three lead cable are:
1)   I, Einthoven Lead or
2)   II, Einthoven Lead or
3)   III, Einthoven Lead
4)   Respiration curve (optional respiration board needed)

To reduce overhead for the waveform transmission, the wave block uses another checksum algorithm as the status and value blocks do.
The EG01010 works with a three lead cable.
The board contains a lead-off detection that gives information about a non-connected electrode.

Transmission is done in blocks. The basic interface parameters are:

115200 baud, 1 start bit, 8 data bits, an even parity bit and one stop bit.

The first block transmitted will be a status block.

The default settings after power up are:
100 wave blocks per second, II activated, 1cm/mV amplification, monitoring bandwidth, 50 Hz filter active.
The host can adjust this to his needs by sending commands to the module.
To keep the traffic on the serial line as low as possible, the following protocol has been implemented. The reasons for choosing this protocol where as following:
The wave blocks are to be transmitted quite often (up to 300 times per second) and sometimes they contain only one channel of information. For this single channel, one needs at least: a block header, a counter, a checksum and the wave sample value itself. To reduce overhead, the number of wave samples in package have been packed into one byte, together with the checksum. The checksum for the wave packet is therefore only 4 bits long, because the remaining four bits are needed for the wave counter. The status and the value blocks use 7 bit checksums. There is still enough security, because each byte has its own parity bit.

Transmitted blocks:

1. There are three types of regular data packets, **waveform blocks**, **value blocks** and **status blocks**. Beginning of a packet is indicated by the marker 0xF8 (wave), 0xF9 and 0xFA (values) and 0xFC (status). Every other transmitted byte has a value of less than 0xF8. This allows for easy synchronisation.

2. Waveform blocks are transmitted 50, 100, 150 or 300 times per second, as defined by the last „Speed" command. Initial value is 100 / sec.

3. Status blocks are transmitted once per second.

4. Value blocks are transmitted at each detected pulse (0xFA marker, can be used for a pulse „beep") and at each detected respiration (0xF9 marker).

5. The data protocol is self synchronizing, e.g. one cannot loose synchronisation when some bytes are lost during transmission. Only one package is lost in that case.

6. There is one special package: after receiving the command „I" („identify"), the board sends a string that contains the board's name, hardware version info („H0"), and software version info („S01"). This string is in ASCII format, and is zero terminated. The identification block starts with marker 0xFD, to ease decoding.

   Example for answer to identify command:

   <0xFD>"EG01010H0S61"<0x00>

   On the next page, the structure of the blocks are described.

	Bit 7	**Bit 6**	**Bit 5**	**Bit 4**	**Bit 3**	**Bit 2**	**Bit 1**	**Bit 0**
Byte 1 **Sync**	1	1	1	1	1	0	0	0
Byte 2 **Ctr/Chk**	Bit 3 Ctr	Bit 2 Ctr	Bit 1 Ctr	Bit 0 Ctr	Bit 3 Chksum	Bit 2 Chksum	Bit 1 Chksum	Bit 0 Chksum
Byte 3 **Wave 1**	Bit 7 Wave 1	Bit 6 Wave 1	Bit 5 Wave 1	Bit 4 Wave 1	Bit 3 Wave 1	Bit 2 Wave 1	Bit 1 Wave 1	Bit 0 Wave 1
Byte 4 **Wave 2**	Bit 7 Wave 2	Bit 6 Wave 2	Bit 5 Wave 2	Bit 4 Wave 2	Bit 3 Wave 2	Bit 2 Wave 2	Bit 1 Wave 2	Bit 0 Wave 2
....								

2+Ctr bytes are transmitted in this block. Ctr is the number of wave samples in the block.

The checksum is the sum of all bytes in the block, with byte 2, the chksum itself, ignored for the sum. It includes the sync character (byte 1). Since only 4 bits can be used, the result is "anded" with 0x0F.

The wave samples are limited to a number of 0xF7, so no mix-up with sync bytes can occur.

The channels are not mapped to a byte position in the block, since the user can freely enable/disable the channels independently of each other.

The transmission sequence is always: I or II or III, Respiration

Example 1: the host requests „I" and transmits „(0x43, 0x01)". Wave 1 of the answer will be „I", the block being 3 bytes long.

Example 2: the host requests „III" and „respiration" and transmits „(0x43, 0x84)".

Wave 1 will be „III", wave 2 will be the respiration waveform, the answer block being 4 bytes long.

A value block contains three bytes:

	Bit 7	**Bit 6**	**Bit 5**	**Bit 4**	**Bit 3**	**Bit 2**	**Bit 1**	**Bit 0**
Byte 1 **Sync**	1	1	1	1	1	0	Bit 1 Type	Bit 0 Type
Byte 2 **Chksum**	0	Bit 6 Chksum	Bit 5 Chksum	Bit 4 Chksum	Bit 3 Chksum	Bit 2 Chksum	Bit 1 Chksum	Bit 0 Chksum
Byte 3 **Value**	Bit 7 Value	Bit 6 Value	Bit 5 Value	Bit 4 Value	Bit 3 Value	Bit 2 Value	Bit 1 Value	Bit 0 Value

3 bytes are transmitted in this block.

Type == 00 → not used

Type == 10 → respiration value

Type == 01 → pulse value

Type == 11 → not used, but reserved for future extensions

The checksum is the sum of all bytes in the block, with byte 2, the chksum itself, ignored for the sum. It includes the sync character (byte 1). Since only 7 bits are used, the result is "anded" with 0x7F.

The values are limited to a number of 0xF7, so no mix-up with sync bytes can occur.

A Status block contains six bytes:

	Bit 7	Bit 6	Bit 5	Bit 4	Bit 3	Bit 2	Bit 1	Bit 0
Byte 1 **Sync**	1	1	1	1	1	1	0	0
Byte 2 **Chksum**	0	Bit 6 Chksum	Bit 5 Chksum	Bit 4 Chksum	Bit 3 Chksum	Bit 2 Chksum	Bit 1 Chksum	Bit 0 Chksum
Byte 3 **Electrode**	0	Respwav	MI	X	X	X	X	X
Byte 4 **Channels**	0	X	X	X	X	III	II	I
Byte 5 **EKGStat**	0	Bit 1 Filter 2	Bit 0 Filter 2	EMG Filter1	Bit 1 Amp	Bit 0 Amp	Bit 1 Speed	Bit 0 Speed
Byte 6 **Status**	0	N	X	X	Bit 3 S3	Bit 2 S2	Bit 1 S1	Bit 0 S0

5 bytes are transmitted in this block. „X" means the bit is unused and undefined.

The checksum is the sum of all bytes in the block, with byte 2, the chksum itself, ignored for the sum. It includes the sync character (byte 1). Since only 7 bits are used, the result is "anded" with 0x7F.

Electrodes, Byte 3:   a „1" in the respective bit position 0 .. 4 means this electrode is connected

        Respwav: „1"   respiratory waveform sample is transmitted

                  „0"   respiratory waveform sample is not transmitted

        MI (main interf.)   „1"   large 50/60 Hz interference detected

                  „0"   large 50/60 Hz interference is not detected

Channels, Byte 4:   a „1" in the respective bit position 0 .. 6 means this wave is transmitted

EKG Status, Byte 5:   Speed: „00"   50 wave blocks per second

                  „01"   100 wave blocks per second

                  „10"   150 wave blocks per second

                  „11"   300 wave blocks per second

Amp:	„00"	Amplification stage 1 (lowest)	
	„01"	Amplification stage 2	
	„10"	Amplification stage 3	
	„11"	Amplification stage 4 (highest)	
Filter1:	„0"	EMG filter off	
	„1"	EMG filter on	
Filter2:	„00"	50/60 Hz filter off	
	„01"	50 Hz filter on	
	„10"	60 Hz filter on	

Status, Byte 6:	N	0	Adult mode
		1	Neonatal mode
	S0..3	0000	Normal operation
	S0..3	0001	Normal operation, pacemaker detected
	S0..3	0100	Initializing
	S0..3	0101	Searching for electrodes
	S0..3	1000	Simulated output
	S0..3	1010	Selftest error
	Rest:		Not used, but reserved

„Selftest error" (10) errors are fatal. The module will never go into measuring state.

Status message 8 will be transmitted as long as simulated data is transmitted.

Commands from Host to Module

All commands have a one or two byte structure. They are also sent to the module with 115200 baud. The commands are sent in ASCII format.

Basic Bandwidth of ECG amplifier (Diagnostic or Monitoring mode):

„F"   Parameter: "0" or "1"

„0"   bandwidth of the amplifier DC-80 Hz   Diagnostic mode (bear in mind mains filter setting)

„1"   bandwidth of the amplifier 0.67-40 Hz   Monitoring mode (reset value)

„S"   extra strong filter, lower edge frequency 2 Hz

Transmission frequency of the waveform packet:

„S"   Parameter: "0", "1", "2" or "7"   (0x53 0x31 for example for „S1")

„0"   send waveform packets 50 times per second

„1"   send waveform packets 100 times per second   (reset value)

„2"   send waveform packets 150 times per second

„7"   send waveform packets 300 times per second

Amplification of the waveforms

„A"   Parameter: "0", „1", "2" or "3"   (0x41 0x31 for example for „A1")

„0"   Amplification stage 1   (lowest amplification, should be scaled to 0.5 cm/mV,
                                                                   reset value)

„1"   Amplification stage 2

„2"   Amplification stage 3

„3"   Amplification stage 4   (highest amplification, should be scaled to 4 cm/mV)

Each amplification stage has **double the sensitivity** of the previous stage

Channel selection (lead I, II or III and respiration can be selected)

„C"   Parameter: 1 byte, explained in the following list:

(0x01)   send Lead   I

(0x02)   send Lead II   (reset value)

(0x04)   send Lead III

(0x81)   send Lead   I and respiration

(0x82)   send Lead II and respiration

(0x84)   send Lead III and respiration

(others) invalid

Example: to receive II and respiration, send 0x43 (character C), 0x82

Filtering of the waveforms for 50 and 60 Hz line frequency:

„5"   Parameter: "0", "1" or "2"   (0x35 0x30 for example for „50")

„0"   50Hz and 60Hz Filter off

„1"   50Hz Filter on   (reset value)

„2"   60 Hz Filter on

Filtering of the waveforms for EMG interference (~15-30Hz):

„E"   Parameter: „0" or „1"   (0x45 0x30 for example for „E0")

„0"   EMG Filter off   (reset value)

„1"   EMG Filter on

Set board to adult mode or neonate/pediatric mode: [1]

"N"   Parameter: "0" or "1"   (0x4E 0x30 for example for "N0")

"0"   board is in adult mode   (reset value)

"1"   board is in pediatric/neonate mode

Disabling the QRS detector in presence of large main interference:

„B"   Parameter: „0" or „1"   (0x42 0x30 for example for „B0")

„0"   QRS detector enabled   (reset value)

„1"   QRS detector disabled in presence of large main interference

Calibraton mode (1mV rectangle transmitted for 250 samples):

„K"   output 250 samples of 1mV rectangular waves, then go back to normal mode

Update electrode configuration. Recognizes newly connected electrodes

„q0"   Newly connected electrodes are recognized after this command has been sent to the module. Also any
         other command except "K" and "I" starts a new search for connected electrodes.

Simulated data outputs (useful for testing or exhibitions):

„M"   Parameter: „0", or „1"

„0"   use real input for data transmission   (reset value)

„1"   use simulated output waves and values

Pacemaker detection on or off:

„P"   Parameter: "0", "1", "2" or "3"

„0"   do not detect pacemaker pulses, pacemaker detector bypassed, pacemaker pulses possibly
         counted as heart beats

„1"   detect pacemaker pulses, mark them in all waveforms, except respiration and suppress counting
         them as heart beats   (reset value)

„2"   detect pacemaker pulses, mark them in none of the waveforms, and suppress counting them as
         heart beats

„3"   detect pacemaker pulses, do not mark them in the ecg waveforms, but mark them in respiration
         waveform, and suppress counting them as heart beats

Set delay of the pulse trigger signal (active high, 33ms duration):

„T"   Parameter: „0" , „1" , „2" , or „9"

„0"   Delay of the pulse trigger signal 15ms   (reset value)

„1"   Delay of the pulse trigger signal 50ms

„2"   Delay of the pulse trigger signal 100ms

„9"   The signal triggers in the middle between R waves

Identification of the module:

„I"   Identify. A zero terminated ASCII string is transmitted showing module information. The identification block
         start with marker 0xFD.

[1] the new edition of 60601-2-27 requires different detection ranges for adults and neonates. See page 8 "QRS detection", for
details. The EG01010 complies with all requirements of the new (and the old) standard. The board powers up in adult mode, the
firmware is therefore compatible to the older versions that did not have a neonatal mode.

Test Program for Protocol 2
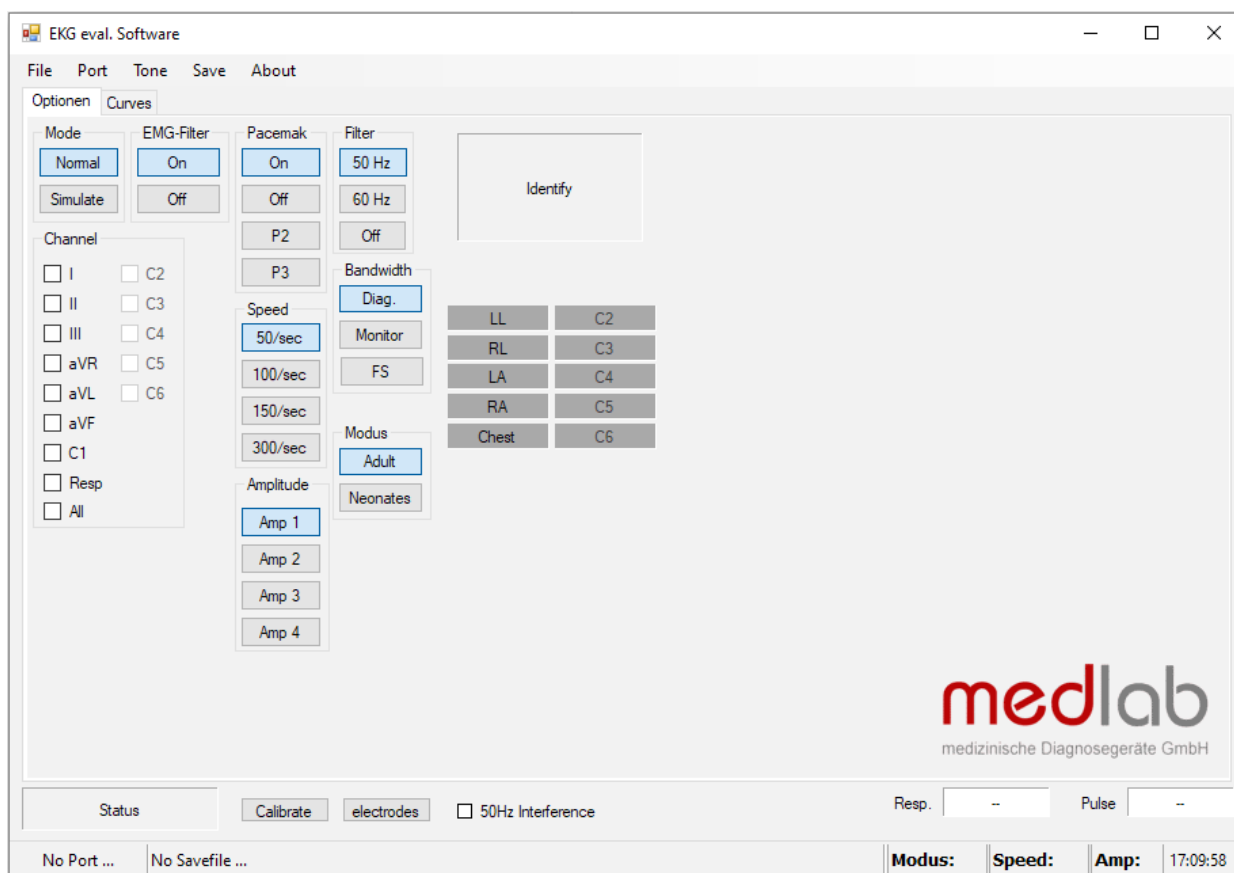
For the second protocol the test program of the EG05000 is to be used.

To run the program, connect the EG01010 board to the serial port of a PC. If the PC has no serial port, please use a USB to RS232 adapter and install the driver of this adapter first and ensure to create a virtual serial port. Connect the power input to a 5 volts DC source. Then start the program on your PC and select the serial port number in the "Port" menu.

Commands can be sent to the board by pressing the command buttons in the application. The channels can be selected on the panel channels.
Please keep in mind that the EG01010 is unlike the EG05000 a 3 channel ECG-board and isn't able to send the data of all channels plus the repirational data in one package. These limitations of the board and its protocol also affect the use of the test program as it isn't possible to use any other channels than I, II, III or respiration. It is also not possible to see more than one of these channels and the respiration graph at the same time.

The software is available free of charge on: **www.medlab.eu**, on the page describing the EG05000. The software is available in a Visual Basic 6 and a Visual C# version. The source code of the chosen test program is also included in the download package.

Regulatory Considerations

The device that has been described in this document is **not a final medical product**. That means that it cannot be used as a standalone unit for patient use.
Therefore, the EG01010 has not been - and also cannot be - CE-marked. The customer has to undertake the procedure of CE-marking the final product that contains the module. However, several products on the market have successfully passed this certification using this OEM module.
The module complies with the following standards, as far as applicable:

IEC60601-1
EN 60601-1:2006+Cor.:2010+A1:2013
EN 60601-1-2:2015
EN 60601-2-27:2014
ANSI/AAMI EC13:2002
ANSI/AAMI EC57:1998
ANSI/AAMI EC57:2012

During testing and certification of a product, also the user manual of the final product needs to be certified. The user manual has to contain certain technical data and warnings to the end users. We can support customers by supplying material for the manual that has been used during the certification process of Medlab's devices.

History

Rev. 1.00:   Initial version
Rev. 1.01:   Corrected typing errors; changed manufacturer address
Rev. 1.02:   Corrected some values on p. 12
Rev. 1.03:   Corrected box on p. 7
Rev. 1.04:   Edited for EN 60601-2-27:2014
Rev. 1.05:   Second software protocol added, reference to optional respiration board added in chapter overview,
                     chapter test program reworked
Rev. 1.06:   Rework to distinguish the two software protocols better and general rework

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