medlab

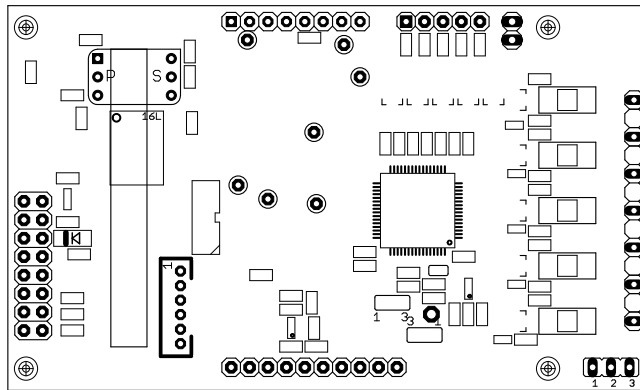# Twelve Lead
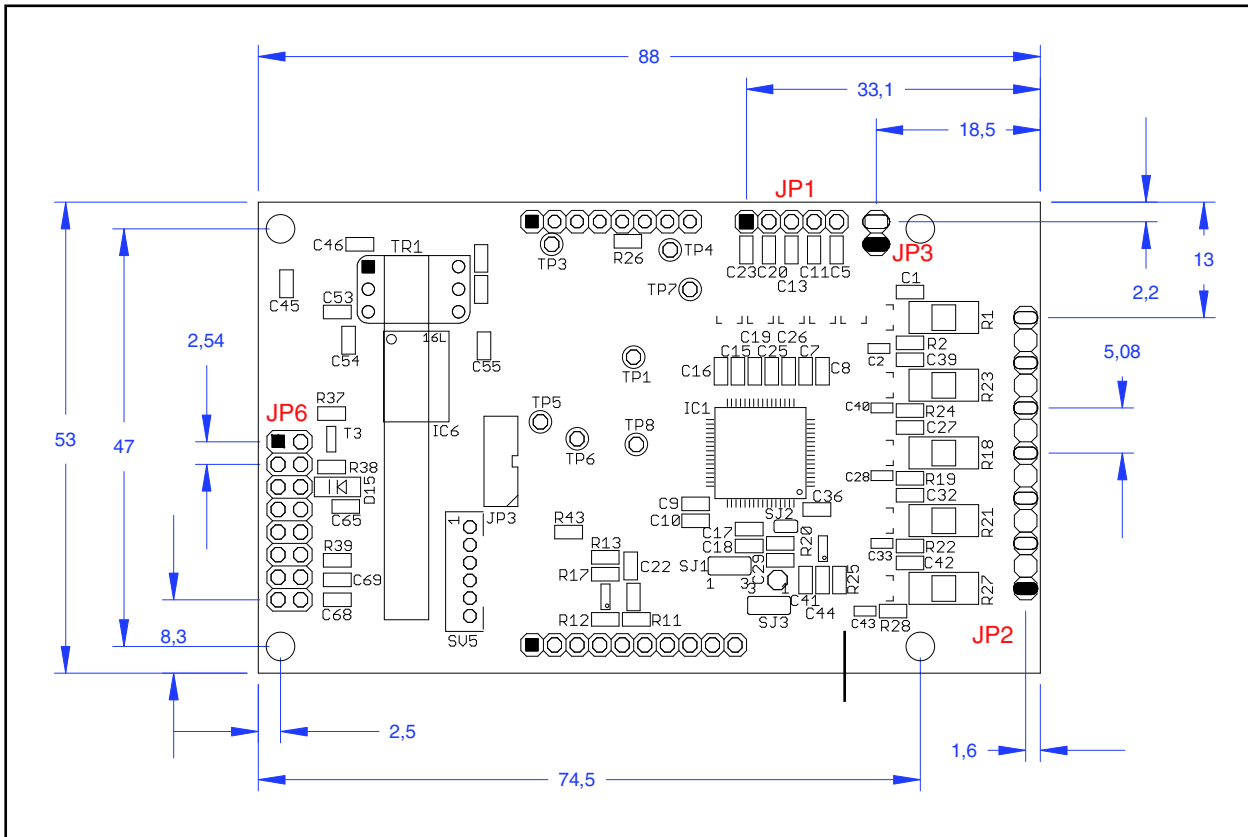# ECG OEM board

EG12000

Technical Manual

Version 1.06

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Mechanical Dimensions

Mechanical drawing, top view of the module (DXF data available upon request)

Overview

The EG12000 is a twelve channel ECG module. The module can work with a ten lead cable to show 12 channels, with a five lead cable showing 7 channels, with a four lead cable showing 6 channels and with a three lead cable to show one channel of ECG.

The board includes a full type CF patient isolation and is powered by a single 5 V DC supply, consuming less than 250 mW. The limb leads (see page 5 for definition) are defibrillation protected. For the remaining Wilson leads, the defibrillation protection has to be integrated into the ECG cable. It is possible to measure the respiration rate of the patient using the impedance change between the limb electrodes. For this, the optional respiration board has to be attached to the module.

When using a ten lead cable, the module can output the following channels synchronously: I, II, III, aVR, aVL, aVF, C1, C2, C3, C4, C5, C6.

When using a five lead cable, the module can output the following channels synchronously: I, II, III, aVR, aVL, aVF, Cx, "x" depending on electrode placement.

When using a four lead cable, the module can output the following channels synchronously: I, II, III, aVR, aVL, aVF.

When using a three lead cable, the module can output the following channels: I or II or III, depending on electrode placement.

Definition of Terms

Leads

The number of wires attached to the patient, to his arms, legs and chest. Normally, the term "lead" is also often used for channels, which is not fully correct. It is, for example, possible to measure 12 channels with 10 leads, but only one channel can be measured with three leads attached.

Channels

The different ECG curves that can be measured and displayed. Since the definition of some of the classical ECG channels is redundant when compared to others, more channels than leads can exist.

Limb Leads

The four cable leads that are attached to electrodes which are positioned on the patient's right arm, left arm, right leg and left leg. To improve signal quality, they can be placed to right and left shoulder and right and left hip instead, without changing the ECG trace shape.

Chest Leads

The six cable leads that are attached to the chest of the patient.

I, II, III

The classical "Einthoven" ECG channels.

aVR, aVL, aVF

The augmented Goldberger channels.

C1, C2, C3, C4, C5, C6

The Wilson channels, measured over the chest leads. Sometimes also referred to as V1..V6. Due to the definition of the chest leads, it is not possible to measure these channels without also having the limb leads attached to the patient.

Three lead ECG cable

A cable that is attached to the patient using three electrodes. One channel can be measured, either Einthoven I, II, or III, depending on electrode placement.

Four lead ECG cable

A cable that is attached to the patient's limbs using four electrodes. Six channels can be measured, but four of them contain redundant information. These channels are I, II, III, and the Goldberger channels.

Five lead ECG cable

A cable that is attached to the patient using five electrodes. Seven channels can be measured, but four of them contain redundant information. The additional channel when comparing with the four lead cable is typically placed into one of the Wilson electrode positions. It is possible to record I, II, III, aVR, aVL, aVF, and one C channel.

Ten lead ECG cable

By using a ten lead cable (sometimes also referred to as a 12 lead cable, although 12 channels is meant), one can measure the 6 channels that a four lead cable delivers, plus the Wilson channels C1 .. C6. Four electrodes are placed on the limbs of the patient, six electrodes on the chest.

Electrodes

Best results are obtained if the ECG is connected to the patient using disposable, self sticking, pre-geled electrodes. Many different brands are available on the market. If the aluminium bag they are in has been opened, these electrodes tend to dry out and become unusable within two to three weeks.

Colour Coding

The clamps of the ECG cable that are attached to the electrodes are colour coded, to ease connection for medical personnel. There are two definitions for these colours:

AHA colours, used in the USA and Canada, and IEC colours, used in all other countries.

Electrode	Abbreviation	IEC Colour	AHA Colour
Right Arm	RA	Red	White
Left Arm	LA	Yellow	Black
Right Leg	RL	Black	Green
Left Leg	LL	Green	Red
Chest 1	C1 (V1)	White-Red	Brown-Red
Chest 2	C2 (V2)	White-Yellow	Brown-Yellow
Chest 3	C3 (V3)	White-Green	Brown-Green
Chest 4	C4 (V4)	White-Brown	Brown-Blue
Chest 5	C5 (V5)	White-Black	Brown-Orange
Chest 6	C6 (V6)	White-Violet	Brown-Purple

Host

The system where the ECG board is connected to, containing a microcontroller or an embedded PC, receiving data from the ECG board and sending commands to the board.
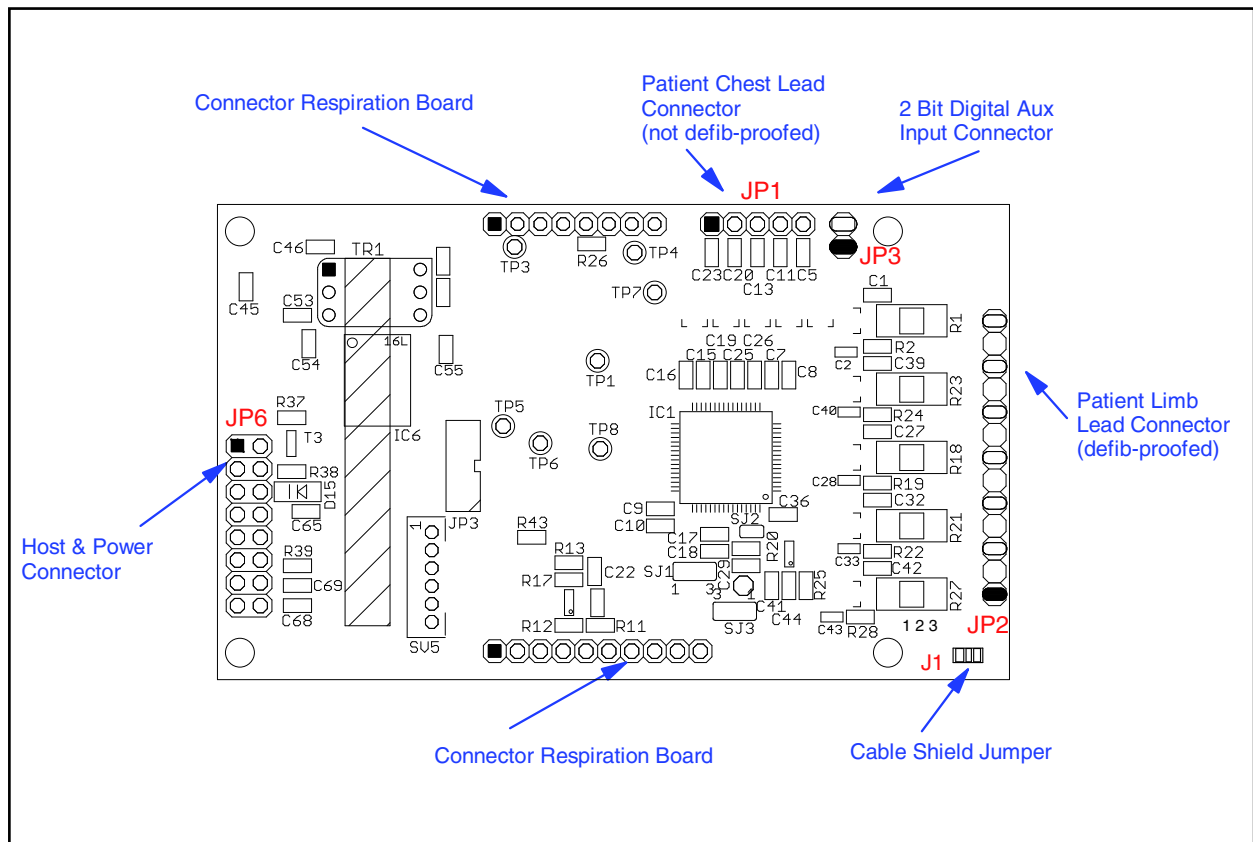
Protocol

Format of the data blocks that are sent from the EG12000 to the host.

Commands

One- or two byte blocks that transfer commands of the host to the EG12000.

Module Connectors

Description of connectors and areas of the module

Physical Units of Transmitted Data

Scaling of ECGs is done in the unit "cm/mV" for the Y-axis and in "mm/sec" for the X-axis. This is a holdover from the times when ECGs had been recorded on paper strips.

Respiration rate is transmitted in respirations per minute, „rpm".

Pulse rate is transmitted in beats per minute, „bpm".

Transmission speed for the wave is indicated in Hz (sec^{-1}).

ECG amplitudes are normally indicated in „cm/mV". Since this is directly depending on the resolution of the screen the user is working on, the transmitted samples are not scaled, 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	Stage 4
1mV = 32	1mV = 64	1mV = 128	1mV = 256

Typical 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 (DXF data available upon request) 4 layer PCB, thickness 1.6 mm
Maximum height: With respiration option:	12 mm 25 mm
Attachment:	four M2.5 screws in the corners of the PCB
Weight:	32 g
Operating voltage:	5 Volt, +/- 5 %, 50 mA
Power consumption:	250 mW while measuring
Input: Isolation: Leakage current:	Defibrillation protected 4000 Volts RMS Better than type CF requirements (10 µA)
Amplification: Data transmission: Filtering:	Four levels, user selectable Four frequencies, user selectable 50 Hz or 60 Hz notch filter included
Amplifier frequency range:	0.05 to 70 Hz. Adjustable lower edge frequency, 0.05 or 0.66 Hz
Pulse detection: Respiration detection:	30 .. 247 bpm +/- 1%, +- 1 Digit, 12 beat average 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, 115200 Baud
Connector: Defib Protection:	Connectors compatible to Medlab EG05000 five channel ECG OEM board Limb leads and C1 lead defibrillation protected Chest leads C2..C6 not defibrillation protected
Shielding:	ECG cable shielded with isolated ground, or with shield dri- ver, jumper selectable.

Connectors
Header for host connection:

JP6:
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
14	Shutdown - VCC level on this pin powers down module
15	VCC input
16	VCC input

Header for patient cable connection

JP1:   Chest leads (not defibrillation protected)
1	C6-IN	C6 input
2	C5-IN	C5 input
3	C4-IN	C4 input
4	C3-IN	C3 input
5	C2-IN	C2 input

JP2:   Limb leads & C1 (defibrillation protected)
1	C1-IN	C1 input
2	ISOGND	Isolated ground
3	LL-IN	Left leg input
4	RA-IN	Right arm input
5	LA-IN	Left arm input
6	SHIELD	ECG cable shield (Isolated ground or driven shield)
7	RL-IN	Right leg input

The shielding of the ECG cable can be connected to the isolated ground or to a shield driver, by setting J1 accordingly: ECG cable shield connected to Iso Ground - 1-2 shorted,
ECG cable shield connected to Shield Driver - 2-3 shorted
(For full EG05000 compatibility, set the jumper to iso ground)

JP3:   Digital Aux Inputs (can be used for cable type coding, no defibrillation protect.)
1	K1 Bit	Digital input K1, internal pull up
2	K2 Bit	Digital input K2, internal pull up
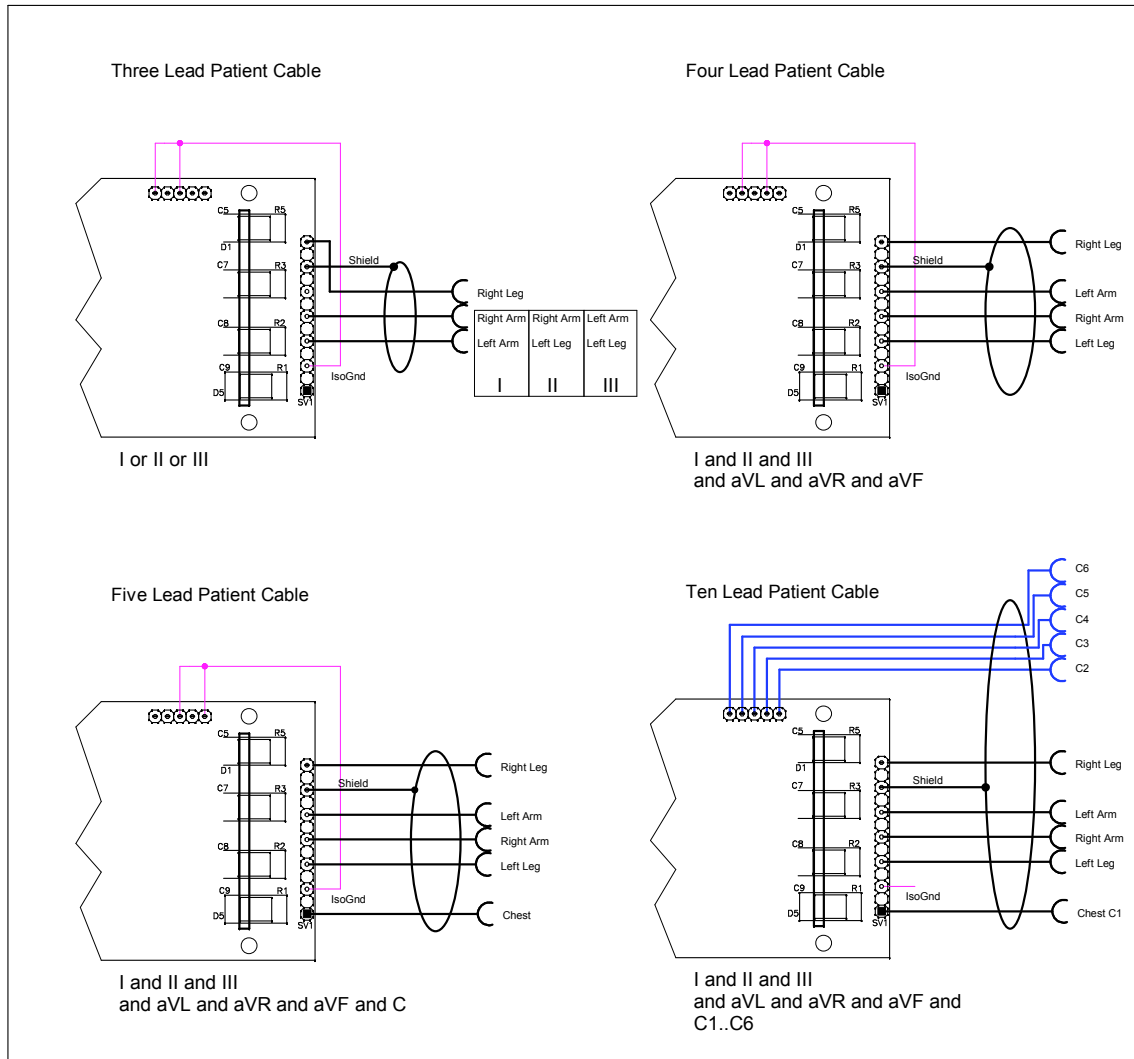
ECG cable connection. Blue leads not protected against defibrillation, use cable with integrated protection on these leads. Magenta shows the internal connector coding for auto detection of this type of cable.

ECG Cable Coding

In many applications, the end user shall be able to connect either a three, four, five or ten channel cable to the same connector of the final medical device. In order not to show false "lead-off" messages, the host needs to know which cable is currently connected.

There are two possibilities:

The user can connect two of the unused **Cx** pins in the three, four or five lead cable to isolated ground in the respective ECG connector, and the board will recognize this coding as eplained in the above drawing. No extra pins in the connector are needed for this type of coding.

Alternatively, the system can use two spare digital inputs, K1 and K2, to code the connected cable: In the connector of the ECG cable, there can be bridges that are connecting K1 and K2 to isolated ground or leave them open. The two bits K1 and K2 are transmitted unchanged in the protocol of the module. The user is free to assign the different coding to the respective cable. The connector needs two extra pins.

By using one or the other method, four cables can be coded, and therefore, three, four, five and ten lead cables can be distinguished from each other.

Technical Description for TRF EN 60601-2-27

When preparing a test report form (TRF) for proof of compliance of a medical product to EN 60601-2-27:2014 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 60601-2-27

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

Tall T-wave rejection, section 201.7.9.2.9.101 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)
The pulse rate is averaged over the last 12 detected pulses.

QRS Detection, section 201.12.1.101.15 (various sections)
If the EG12000 is set to adult mode, the heart rate meter will not respond to ECG signals having a QRS amplitude of 0,15mV or less, or R-waves of a duration of 10 ms or less, with an amplitude of 1 mV.
The detection range of QRS amplitudes is 0,5 mV to 5 mV, for durations of the QRS complex ranging from 70 ms to 120 ms, up to a signal rate of 300 BPM.
If the EG12000 is set to neonate mode, the detection range of QRS amplitude is 0,5 mV to 5 mV, for durations of the QRS wave ranging from 40 ms to 120 ms, up to a signal rate of 350 BPM.

Response to irregular rhythm, section 201.7.9.2.9.101 b) 4)
A1) Ventricular bigeminy: the EG12000 counts both large and small QRS complexes to display a rate of 80 bpm.
A2) Slow alternating ventricular bigeminy: the EG12000 counts both large and small QRS complexes to display a rate of 60 bpm.
A3) Rapid alternating ventricular bigeminy: the EG12000 counts all QRS complexes to display a rate of 120 bpm.
A4) Bi-directional systoles: the EG12000 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: 5 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 EG12000 is capable of displaying the ECG signal in the presence of pacemaker pulses with amplitudes of ±2 mV to ±700 mV and durations of 0.5 ms to 2.0 ms. An indication for the pacemaker pulse is provided.

Pacemaker pulse rejection, section 201.12.1.101.13

Without over and undershoot (rectangular pulse):
a) For single (ventricular-only) pacemaker pulses alone, with 0.1 and 2.0 ms pulse-widths and ±2 mV and ± 700 mV amplitudes, the EG12000 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 EG12000 correctly displays the 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 EG12000 correctly displays the 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 amplitude, the EG12000 correctly displays a 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 EG12000 correctly displays the 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 EG05000 correctly displays the heart rate of the underlying QRS-T rhythm (30 bpm).

With over and 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 EG12000 correctly displays a 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 EG12000 correctly displays the 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 EG12000 correctly displays the 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 amplitudes, the EG12000 correctly displays the 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 EG12000 correctly displays the 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 EG05000 correctly displays the heart rate of the underlying QRS-T rhythm (30 bpm).

Serial Transmission

The normal connection to the board is done via serial, asynchronous communication at 115200 baud, 8 data bits, an even parity bit and one stop bit. Both CMOS and RS232 (+/- 5 Volt level) voltage levels are available.

The protocol is block oriented. Each block has a checksum within the transmitted data.

The RS232 voltage levels are helpful during evaluation of the board, which can be done using an ordinary 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 JP6 is compatible with the interface connector on Medlab's EG05000 five channel ECG OEM board. Therefore, test cables that had been built for this board can be used also for the EG12000 board.

The EG12000 sends data and receives commands. Commands are one byte characters, some of them have an additional parameter, others just toggle an internal switch in the module.

The neutral line of the ECG always lies around 128, as the module transmits unsigned data.

The protocol is a superset of the EG05000 protocol: compared to this, there are two additional blocks, the chest lead wave block, and the chest lead status block. A few commands exist that are not present in the EG05000.

For details, please see the protocol description on the following pages.

Serial Protocol

The board transmits up to 12 (13 with respiration curve) graphical waveforms 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.

To reduce overhead for the waveform transmission, the wave block uses another checksum algorithm as the status and value blocks do.

The EG12000 works with a three lead-, a four lead, a five lead or a ten lead cable. Only parts of the maximum number of channels can be measured if not all the electrodes are connected (see page 10).

The board contains a lead-off detection that gives information about each single non-connected electrode.

It is not possible for the module to detect automatically which cable is connected, since the situation is the same whether, for example, a three lead cable, or a five lead cable with two non-attached electrodes is used.

It is recommended for the user to use a connection system with coded cables (shorted, unused pins in the connector for example) to make the host system aware of which cable currently is connected to the EG12000 and to ignore lead-off messages that do not exist for the respective cabling system. Inputs K1 and K2 can be used for this purpose. A simpler, but less comfortable solution is to have the end-user select which cable is connected in a menu in the host.

Channels that are requested by the host but cannot be measured because of no electrode contact or the respective lead missing in the cable are transmitted as "0x80", neutral line.

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

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

The first block transmitted will be a status block.

The usage of a high baud rate is necessary because in case all channels are selected, a large amount of data is transmitted per second.

The default settings after power up are:

100 wave blocks per second, I,II,III activated, 1cm /mV amplification, monitoring bandwidth (0.66 Hz lower edge frequency), 50 Hz filter active. The host can adjust this to his needs by sending commands to the module.

To keep traffic on the serial line as low as possible, the following protocol has been implemented. The reasons for choosing this protocol were as following:

Especially the wave blocks are to be transmitted quite often (up to 300 times per second) and contain only one channel of real information sometimes. For this single channel, one needs at least: a block header, a counter, a checksum and the wave sample. To reduce overhead, the number of waves has been packed into one byte together with the checksum. Thus, the checksum for the wave packet can only be 4 bits long, because four bits are needed for the wave counter. The status and the value blocks use 7 bit checksums. This is still a secure transmission, because each byte also has its own parity bit.

Transmitted blocks:

1. There are five types of regular data packets, **limb waveform blocks**, **chest waveform blocks, value blocks, status blocks and chest status blocks**. Beginning of a packet is indicated by the marker 0xF8 (limb waves), 0xF9 and 0xFA (values), 0xFC (status), 0xFE (chest waves) and 0xFF (chest status). Every other transmitted byte has a value of less than 0xF8. Therefore, synchronisation is easy.

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

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 lose the synchronisation if 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 an answer to identify command:

    <0xFD>"EG12000H0S01"<0x00>

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

Limb waveform blocks contain between 3 and 10 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	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
Byte 5 **Wave 3**	Bit 7 Wave 3	Bit 6 Wave 3	Bit 5 Wave 3	Bit 4 Wave 3	Bit 3 Wave 3	Bit 2 Wave 3	Bit 1 Wave 3	Bit 0 Wave 3
Byte 6 **Wave 4**	Bit 7 Wave 4	Bit 6 Wave 4	Bit 5 Wave 4	Bit 4 Wave 4	Bit 3 Wave 4	Bit 2 Wave 4	Bit 1 Wave 4	Bit 0 Wave 4
....								

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, including the sync character, modulo 16.

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

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

The transmission sequence is always: I, II, III, aVR, aVL, aVF, C1, Respiration

Example 1: the host requests „I",„aVF", and „C1" to be transmitted. Wave 1 will be „I", Wave 2 will be „aVF", and Wave 3 will be „C1" , the block being 5 bytes long.

Example 2: the host requests „C1" and respiration waveform to be transmitted. Wave 1 will be „C1", Wave 2 will be respiration waveform, the block being 4 bytes long.

Chest waveform blocks contain between 3 and 7 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	1	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
Byte 5 **Wave 3**	Bit 7 Wave 3	Bit 6 Wave 3	Bit 5 Wave 3	Bit 4 Wave 3	Bit 3 Wave 3	Bit 2 Wave 3	Bit 1 Wave 3	Bit 0 Wave 3
Byte 6 **Wave 4**	Bit 7 Wave 4	Bit 6 Wave 4	Bit 5 Wave 4	Bit 4 Wave 4	Bit 3 Wave 4	Bit 2 Wave 4	Bit 1 Wave 4	Bit 0 Wave 4
....								

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, including the sync character, modulo 16.

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

The channels are not mapped one to one to the byte position in the block, since the user can freely enable/disable all channels independently.

The transmission sequence is always: C2, C3, C4, C5, C6

Example 1: the host requests „C3",„C4" and „C5" to be transmitted. Wave 1 will be „C3", Wave 2 will be „C4" and Wave 3 will be „C5", the block being 5 bytes long.

Value blocks contain 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, including the sync character, modulo 128.

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

Status blocks contain five 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	Bit5 Chksum	Bit 4 Chksum	Bit 3 Chksum	Bit 2 Chksum	Bit 1 Chksum	Bit 0 Chksum
Byte 3 **Electrode**	0	Resp-wav	X	Chest	RA	LA	RL	LL
Byte 4 **Channels**	0	C1	aVF	aVL	aVR	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	K2	K1	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, including the sync character, modulo 128.

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
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
	K1		State of the digital input K1
	K2		State of the digital input K2
	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 will be transmitted as long as simulated data is transmitted.

Chest status blocks contain four 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	1	1
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	X	X	C6	C5	C4	C3	C2
Byte 4 **Channels**	0	X	X	C6	C5	C4	C3	C2

Electrode, Byte 3:	„1" in the respective bit position 0 .. 4 means this electrode is connected
Channels, Byte 4:	„1" in the respective bit position 0 .. 4 means this waveform is transmitted

Commands

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   (+mains filter setting!)

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

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)

„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 (see page 7)

Channel selection limb leads and respiration curve (1-8 wave channels can be selected):

„C"   Parameter: 1 byte. Each bit in the parameter byte set to „1" stands for a transmitted wave, a „0" means that the wave will not be transmitted.

10000000   respiration

01000000   C1

00100000   aVF

00010000   aVL

00001000   aVR

00000100   III

00000010   II

00000001   I

Example: to receive I, aVR and respiration, send: 0x43 (character ‚C'), 0x89

Channel selection chest leads (1-5 wave channels can be selected):

„D"   Parameter: 1 byte. Each bit in the parameter byte set to „1" stands for a transmitted wave, a „0" means that the wave will not be transmitted.

00010000   C6

00001000   C5

00000100   C4

00000010   C3

00000001   C2

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

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

„0"   50 Hz and 60 Hz Filter off

„1"   50 Hz Filter on

„2"   60 Hz Filter on

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

„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

Calibration 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", or „1"

„0"   do not detect pacemaker pulses

„1"   detect pacemaker pulses   (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

Identification of the module:

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

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[1] the new edition of 60601-2-27 requires different detection ranges for adults and neonates. See page 11, "QRS detection", for details. The EG12000 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

A Microsoft Windows program (Monitor.exe) is available upon request. The program does not need any installation, just copy it to a directory of your choice and run it.

The software allows the selection of transmitted channels, sample rate and amplification as well as selecting filters.

It graphically displays the selected channels.

Regulatory Considerations

The device that has been described in this document is <u>not a final medical product.</u> That means that it cannot be used as a standalone unit to use it on patients.
Therefore, the EG12000 has not been - and also cannot be - CE-marked. The customer has to undertake the procedure of CE-marking with the final product that contains the module. However, several products on the market have successfully passed this certification.
The module complies with the following standards, as far as applicable:

EN 60601-1:2006
EN 60601-1:2006+Cor.:2010+A1:2013
EN 60601-1-2:2007
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. Please also see pages 11 and 12 for data that might be needed to fill in a test report form (TRF).

History:

Rev. 1.00:	Initial Revision
Rev. 1.01:	Minor graphical changes
Rev. 1.02:	JP2 Pin 1 position changed
Rev. 1.03:	Shield driver description added
Rev. 1.04:	Changed manufacturer address, corrected typos
Rev. 1.05:	Added neonatal mode
Rev. 1.06:	Edited for EN 60601-2-27:2014

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