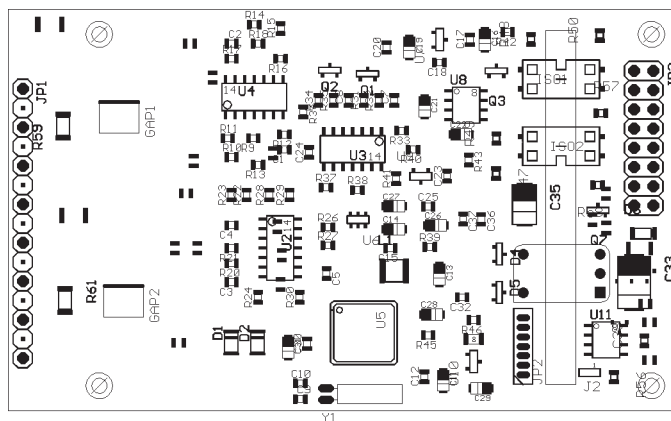


medlab

Two Channel Invasive Blood Pressure OEM board

EG 02000

Technical Manual



Contents:

Mechanical dimensions, overview	3
Specifications	5
Connector assignment	6
Serial transmission	7
Software protocol	8
Physical units	11
Transducer manufacturers	13
Regulatory considerations	14

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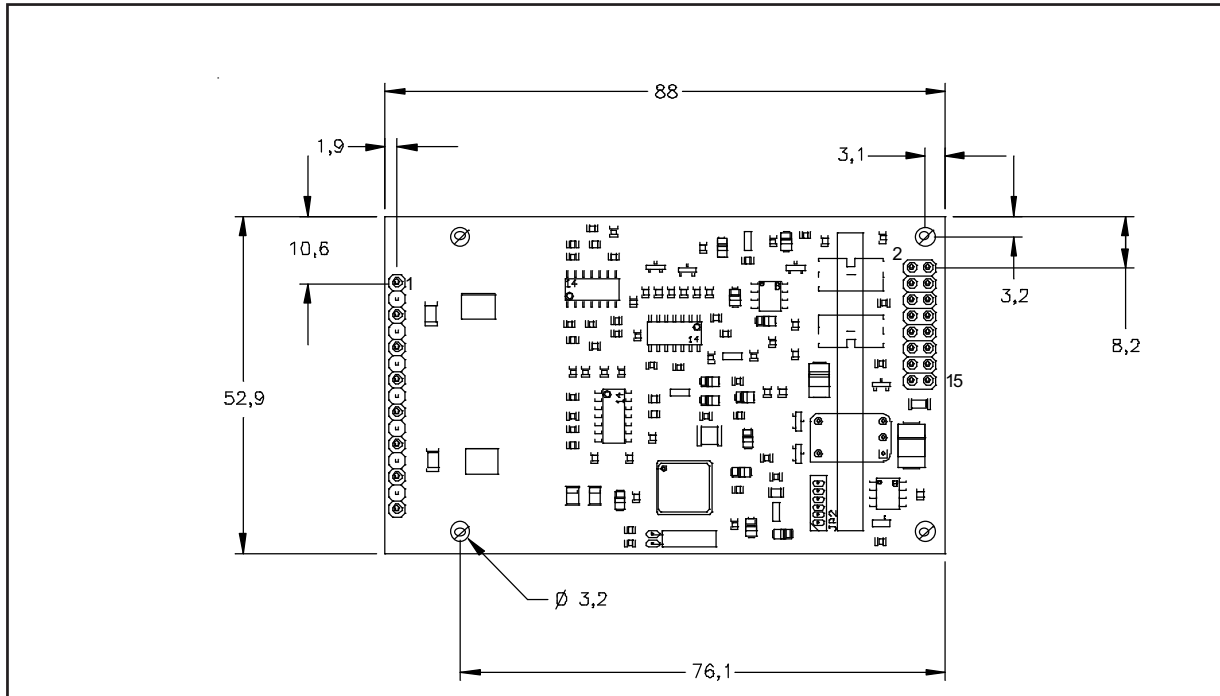
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Mechanical Dimensions



Top view of the PCB (not to scale, all dimensions in mm)

Overview

The scope of this document is the description and specification of the EG02000, a two channel invasive blood pressure module.

It will help anybody who is familiar with programming and medical electronics to integrate the module into his own medical system.

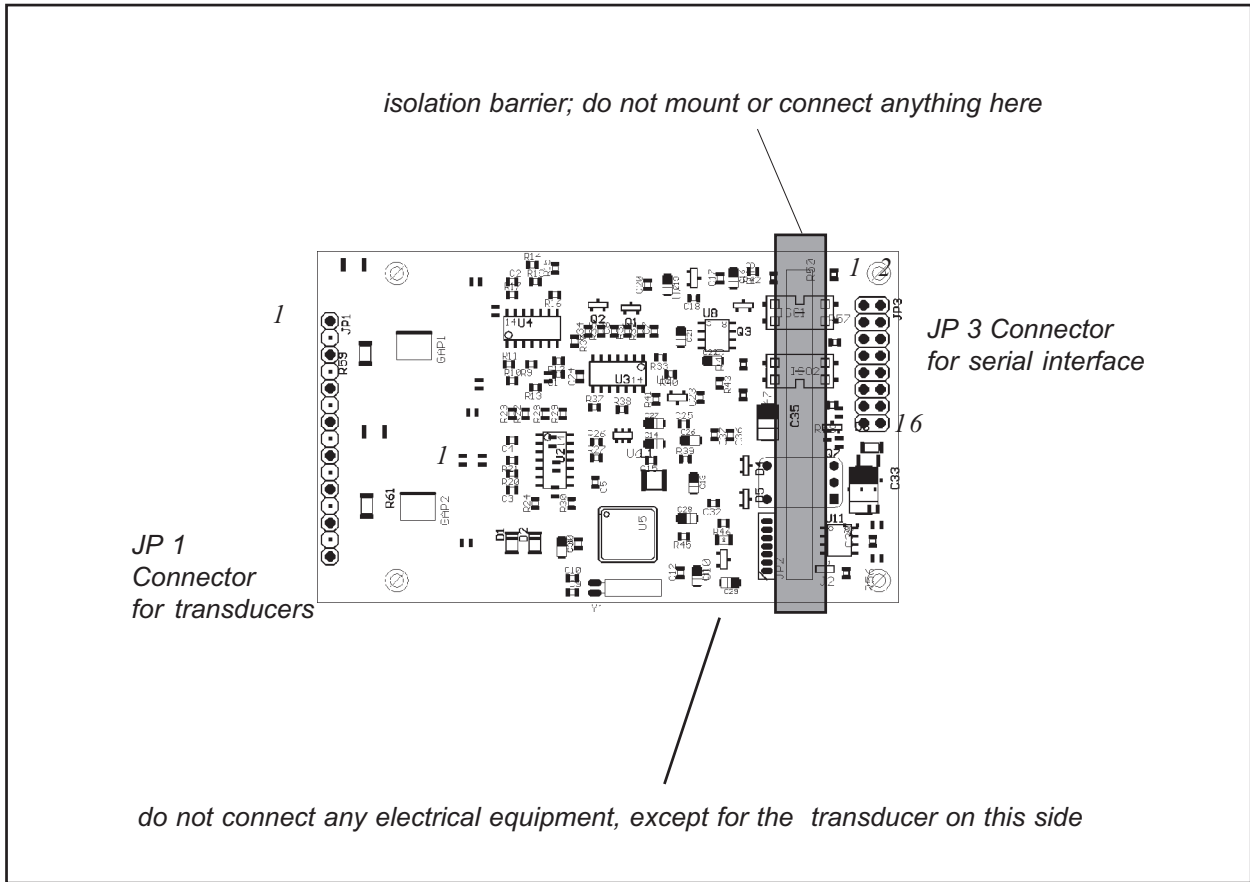
The EG02000 is connected to up to two standard pressure transducers that are produced by several manufacturers. The module works with all sensors that offer a sensitivity of $5\mu\text{V/V/mmHg}$.

It allows independent adjustment of the zero level of each channel after the patient has been connected to the system or has been moved.

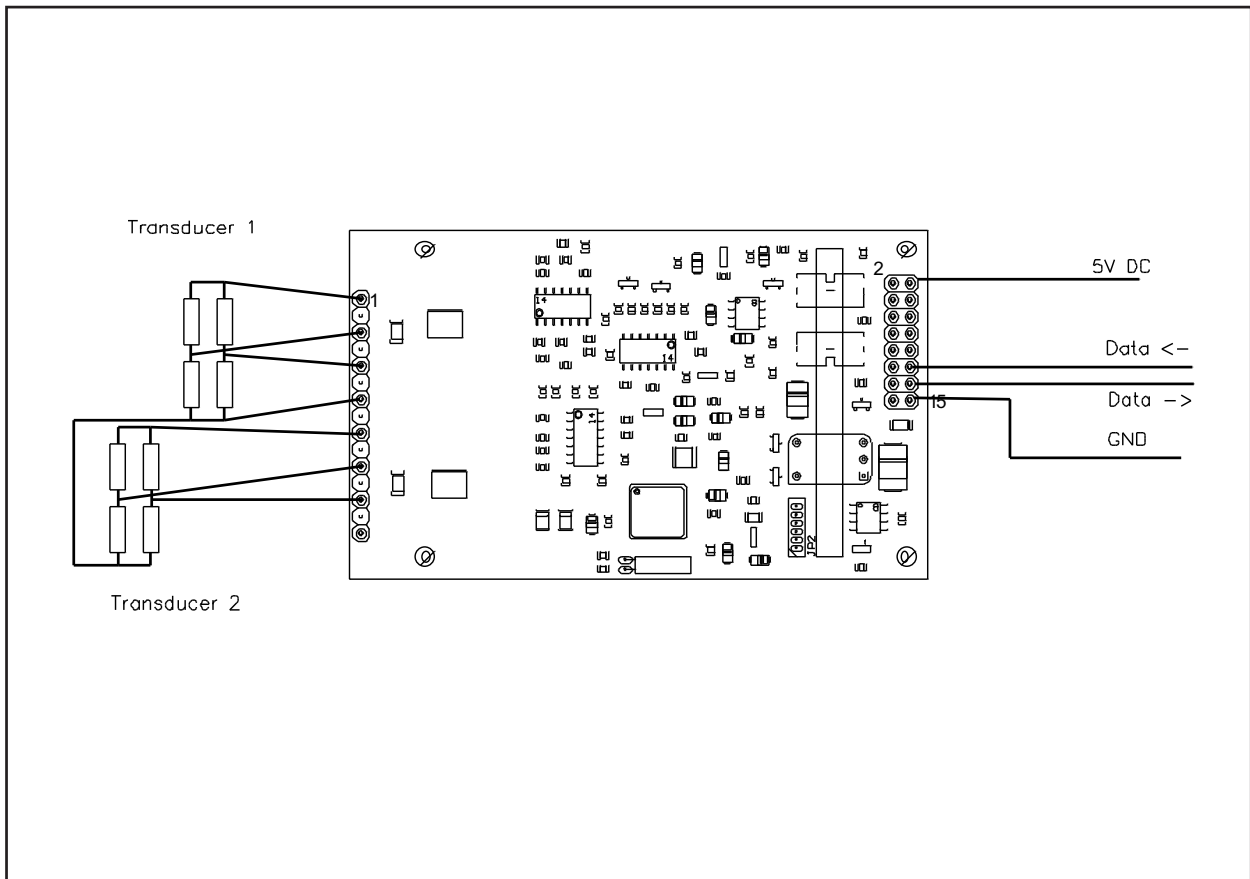
The other, isolated side of the module connects to a standard, asynchronous, bi-directional serial interface.

The EG02000 transmits pressure waveforms, pressure values and detected pulse rates as well as status info for each channel.

The patient side is fully isolated on the module, including power generation for the isolated side and data transmission over opto-couplers.



Connector locations and electrical isolation



Connection of the board to a PC and to the transducers for evaluation

Technical Data

Mechanical data:	see attached sheet with board drawing. 2 layer PCB, thickness 1.5 mm, 88 x 53mm
Attachment:	four M2.5 screws in the corners of the PCB
Weight:	20 g
Operating voltage:	5 Volt, +/- 10% , 70mA without transducers
Power consumption:	< 350mW while measuring + transducer power
Input: Isolation:	defibrillation protected 4000 Vrms standard
Channels:	two
Frequency response:	0 - 28 Hz (-3dB)
Calibration: Curve transmission: Filtering:	factory calibrated three frequencies, user selectable, 50/100/150 Hertz integrated 50 Hz or 60 Hz notch filter
Pulse detection:	30 .. 250 bpm +/- 1%, +/- 1 Digit, 8 beat averaging
Pressure range: Zero Range: Pressure accuracy:	-99mmHg - 310mmHg + - 70mmHg +/- 1%, +/- 1 digit over the full range
Protocol:	standard bidirectional serial protocol, see description on following pages
Transducer: Bridge resistance:	5µV/V/mmHg, disposable or re-usable Minimum 180 Ohm

Connectors

(see drawing on page 4 for location)

Header for host connection:

JP3:	1	VCC
	2	VCC
	3	Not connected
	4	Not connected
	5	Not connected
	6	Not connected
	7	Not connected
	8	Not connected
	9	Not connected
	10	Not connected
	11	Data in, -/+ 5Volt level
	12	Data in, TTL level
	13	Data out, -/+ 5 Volt level
	14	Data out, TTL level
	15	Gnd
	16	Gnd

Header for patient cable connection

JP 1:	1	Reference channel 1
	2	not used
	3	Negative input 1
	4	not used
	5	Positive input 1
	6	not used
	7	patient ground
	8	not used
	9	Reference channel 2
	10	not used
	11	Negative input 2
	12	not used
	13	Postive input 2
	14	not used
	15	Cal (Factory use only)

Serial Transmission

The normal connection to the board is done via serial, asynchronous communication with 9600 baud, 8 data bits, one stop bit, no parity. Both TTL and RS232 (+/- 5 Volt level) voltage levels are available.

The real RS232 is 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 TTL levels, which saves parts on the customer's side of the data stream. The connector JP 3 is compatible with the interface connector on Medlab's EG00301 Spo2 OEM board. Therefore, test cables that had been built for the pulse oximeter board can be used also for the IBP board.

The EG2000 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 EG2000 module.

Serial Transmission Protocol

The board transmits two pressure waves and values that range from -99 to +300mmHg. For each channel, systolic (SYS), mean arterial pressure (MAP) and diastolic pressure (DIA) is calculated. On both channel, also a pulse rate is calculated. It is assumed that the pulse rate is equal for both channels, so only one of them is transmitted. The module selects the channel that has a higher amplitude for transmission of the pulse rate.

Additionally to the waveforms, systolic, diastolic and mean pressure are transmitted together with some status information and a pulse rate value.

The data is transmitted with 9600 baud, 1 start bit, 8 data bits, no parity, one stop bit.

To keep traffic on the serial line as low as possible, the following protocol has been implemented:

Since it is not economical to transmit 16 bit values for the pressures, there is no obvious method for transmission of negative numbers, since 9 bit values are transmitted for the pressure values. On the other hand, pressure values of -99 to 300 mmHg have to be transmitted. Therefore, all numbers are incremented by 100 mmHg before transmission. **The receiver side is responsible for subtracting the value of 100 (decimal) before any display or storage of the received numbers takes place.** This is the easiest and safest way to transfer negative values in environments ranging from 8-Bit microcontrollers to 64-Bit PC environments.

Transmitted packets

There are three types of regular data packets, **waveform packets**, **status packets** and **value packets**. Beginning of a packet is indicated by a „1“ in the highest bit of the first byte of the packet. Every other byte has a „0“ in bit 7.

Waveform packets are transmitted 50, 100 or 200 times per second, as defined by the last „Speed“ command. Initial value is 100 packets / sec.

The higher bits of the values (bit 8 and 9) are stripped from the values and transmitted in separate bytes to free bit 7 for synchronisation purposes.

Information packets are transmitted once per second.

Status packets are transmitted at least once every 5 seconds, or when they are needed, for example if a sensor is removed.

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

There is one special package: after receiving the command „I“ („identify“), the board sends a string that contains manufacturer info, version info, serial number and calibration date of each module. This string is in ASCII format and is zero terminated. For ease of decoding this message, the first byte of this string is 0xE0.

Example for answer to identify command:

Medlab GmbH	(Manufacturer)
IBP OEM V1.0	(Version)
Cal.: 11.01.04	(Calibration Date)
SN: 0100	(Serial Number)

A waveform packet contains three bytes:

	Bit 7	Bit 6	Bit 5	Bit 4	Bit 3	Bit 2	Bit 1	Bit 0
Byte 1 Sync	1	1	0	0	Bit 8 Wave 1	Bit 7 Wave 1	Bit 8 Wave 2	Bit 7 Wave 2
Byte 2 Wave 1	0	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 3 Wave 2	0	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

A status packet contains three bytes:

	Bit 7	Bit 6	Bit 5	Bit 4	Bit 3	Bit 2	Bit 1	Bit 0
Byte 1 Sync	1	1	0	1	X	X	Pulse Marker 2	Pulse Marker 1
Byte 2 Status 1	0	X	X	X	Bit 3 Sta- tus 1	Bit 2 Sta- tus 1	Bit 1 Sta- tus 1	Bit 0 Sta- tus 1
Byte 3 Status 2	0	X	X	X	Bit 3 Sta- tus 2	Bit 2 Sta- tus 2	Bit 1 Sta- tus 2	Bit 0 Sta- tus 2

An information packet contains nine bytes:

	Bit 7	Bit 6	Bit 5	Bit 4	Bit 3	Bit 2	Bit 1	Bit 0
Byte 1 Sync	1	0	Bit 8 SYS 1	Bit 7 SYS 1	Bit 8 MAP 1	Bit 7 MAP 1	Bit 8 DIA 1	Bit 7 DIA 1
Byte 2 SYS 1	0	Bit 6 SYS 1	Bit 5 SYS 1	Bit 4 SYS 1	Bit 3 SYS 1	Bit 2 SYS 1	Bit 1 SYS 1	Bit 0 SYS 1
Byte 3 MAP 1	0	Bit 6 MAP 1	Bit 5 MAP 1	Bit 4 MAP 1	Bit 3 MAP 1	Bit 2 MAP 1	Bit 1 MAP 1	Bit 0 MAP 1
Byte 4 DIA 1	0	Bit 6 DIA 1	Bit 5 DIA 1	Bit 4 DIA 1	Bit 3 DIA 1	Bit 2 DIA 1	Bit 1 DIA 1	Bit 0 DIA 1
Byte 5 Hbit 2	0	Bit 7 Pulse	Bit 8 SYS 2	Bit 7 SYS 2	Bit 8 MAP 2	Bit 7 MAP 2	Bit 8 DIA 2	Bit 7 DIA 2
Byte 6 SYS 2	0	Bit 6 SYS 2	Bit 5 SYS 2	Bit 4 SYS 2	Bit 3 SYS 2	Bit 2 SYS 2	Bit 1 SYS 2	Bit 0 SYS 2
Byte 7 MAP 2	0	Bit 6 MAP 2	Bit 5 MAP 2	Bit 4 MAP 2	Bit 3 MAP 2	Bit 2 MAP 2	Bit 1 MAP 2	Bit 0 MAP 2
Byte 8 DIA 2	0	Bit 6 DIA 2	Bit 5 DIA 2	Bit 4 DIA 2	Bit 3 DIA 2	Bit 2 DIA 2	Bit 1 DIA 2	Bit 0 DIA 2
Byte 9 Pulse	0	Bit 6 Pulse	Bit 5 Pulse	Bit 4 Pulse	Bit 3 Pulse	Bit 2 Pulse	Bit 1 Pulse	Bit 0 Pulse

Waveform Packet:

Sync Synchronisation bit and high bits (bit 8 and bit 7) of wave 1 and wave 2

Wave 1 Bits 0..6 of wave 1

Wave 2 Bits 0..6 of wave 2

Status Packet:

Sync Synchronisation bit and „pulse detected“ bits for channel 1 and 2
can be used to „beep“ on systole detection

Status 1 Status according to the table on the next page for channel 1

Status 2 Status according to the table on the next page for channel 2

Info Packet:

Sync Synchronisation bit and high bits (bit 8 and bit 7) of sys 1, map 1 and dia 1

Sys1 Bits 0..6 of Systolic pressure value of channel 1

Map1 Bits 0..6 of Mean arterial pressure value of channel 1

Dia1 Bits 0..6 of Diastolic pressure value of channel 1

Hbit2 High bits (bit 8 and bit 7) of Sys2, Map2 and Dia2, high bit (bit 7) of pulse rate

Sys2 Bits 0..6 of Systolic pressure value of channel 2

Map2 Bits 0..6 of Mean arterial pressure value of channel 2

Dia2 Bits 0..6 of Diastolic pressure value of channel 2

Pulse Bits 0..6 of Pulse rate

Status Bits

0	0000	Normal operation
1	0001	No waveform found
2	0010	Zeroing in process
3	0011	Value out of range
4	0100	Zeroing failed
5	0101	Initializing
6	0110	Zeroing ok
7	0111	No sensor connected
8	1000	Sensor connected
9	1001	Simulated output
10	1010	Not calibrated
11	1011	Selftest error
12-15	1100 - 1111	Not used, but reserved

„Selftest error“ (11) and „Not calibrated“ (10) errors are fatal. The module will never go into measuring state.

Status messages 2,3,4,5,8 are messages that are transmitted during 10 seconds only, then they will go away until triggered again by the module.

Status messages 7 and 9 will be transmitted as long as simulated data is transmitted and/or as long as no sensor is connected to the respective channel.

Commands from Host to Module

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

Transmission frequency of the waveform packet:

- „S“ Parameter: „0“, „1“, or „2“ (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

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

- „5“ filter waveform with a 50Hz notch filter
- „6“ filter waveform with a 60Hz notch filter

User Zeroing the pressure channels:

- „Z“ Parameter: „1“, „2“ or „3“
- „1“ Zeroing of only channel 1, channel 2 remains unchanged
- „2“ Zeroing of only channel 2, channel 1 remains unchanged
- „3“ Zeroing of channel 1 and channel 2

Simulated data outputs (useful for testing or exhibitions):

- „O“ (like "Original") use real input for data transmission (reset value)
- „M“ use simulated output waves and pressure values

Identification of the module:

- „I“ Identify. An ASCII string is transmitted showing module information. For easier decoding, the first character transmitted in this block is 0xE0. This is a sync byte only and should be detected, but does not need to be decoded.

Physical units of transmitted data

All transmitted pressures are in mmHg. A value of 100 has to be subtracted from all pressures, including transmitted waveforms, systolic, mean and diastolic values. This can generate negative pressures, which is correct, since the measurement range lies between -99 mmHg and + 300mmHg. Negative pressures are existing because the measured pressures are relative values, normalized (zeroed) to the pressure at the heart level of the patient.

All transmitted pulse rates are in 1/min, e.g. bpm (beats per minute).

Transducer Manufacturers

Compatible transducers with a sensitivity of $5\mu\text{V/V/mmHg}$ are for example manufactured by:

Medex	www.medexmed.com
Sensoror	www.sensoror.no
Utah Medical	www.utahmed.com

Regulatory considerations

The device that has been described in this document is not a final medical product. That means that it can not be used as a standalone unit to do measurements on a patient. Therefore, the OEM IBP has not to be CE-marked. The customer has to undertake the procedure of CE-marking with the final product that he builds up with the PCB. The EMC-regulatories are not violated by the module because of his extreme low power requirements and his proper filtering and decoupling of power supply.

Second, the device is not FDA approved, which is also not possible for a module. Only final products that will be sold in the USA have to and can undertake the process of 510K approval.

Document Revisions:

V1.0	Initial release
V1.1	Changed "Zero all" command from "Z0" to "Z3"
V1.2	Corrected pin numbering of JP3, corrected minor typing errors, added mechanical drawings
V1.3	Corrected command for simulated output (page 12)
V1.4	Corrected parameters for simulated output (page12)
V1.5	Corrected status messages, "NO WAVE" was missing (page 11)
V1.6	Added description of Info message sync byte 0xE0 Corrected negative/positive input description on page 6
V1.7	Changed company address information