![SONOTEC logo]

Technical Data Sheet

BLD03/50M

Blood Leak Detector

Original

Revision: 1.2L │ 2022-06-07

General

Description

The Blood Leak Detector BLD03/50M is a non-invasive, optical sensor designed to detect smallest amounts of blood in a clear fluid through an optical transparent and flexible tubing.

The sensor consists of a sensor head with connection line and an external electronic board (PCB) with integrated firmware.

The BLD03/50M meets highest demands on patient safety and reliability: The firmware has been designed according to the requirements of the international standard IEC 62304:2006 + AMD1:2015, safety class C.

The sensor is developed as a built-in component integrated into a medical device.

Scope of delivery

	Article number
Set BLD03/50M, class C Including:	700 01 0409
Sensor head BLD03/50	200 05 0008
PCB BLD03M, programmed, class C	200 01 0339

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Sensor Head BLD03/50

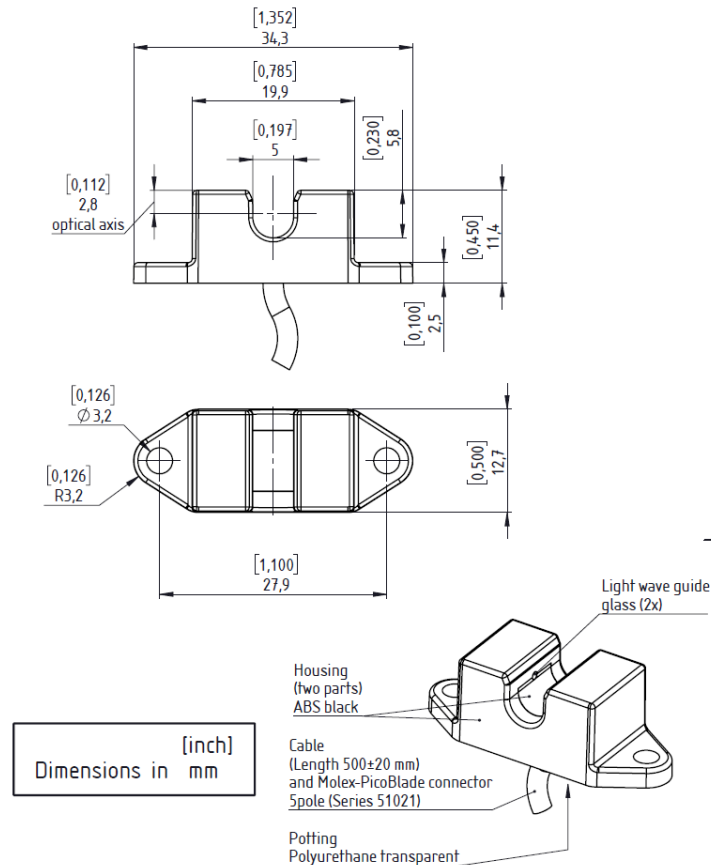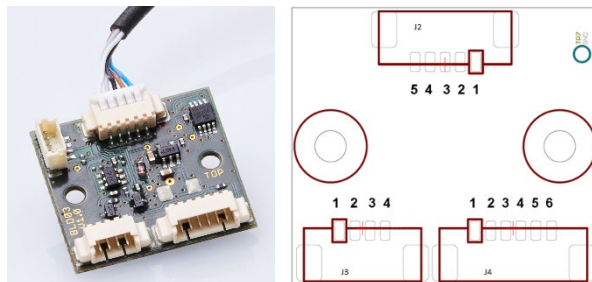| Technical data	
Measuring method	Optical transmission measurement, LED
Specification	Sensor head BLD03/50 - channel width 5.0 mm
Article number	200 05 0008
Materials	Housing: ABS and glass Potting: PUR (transparent)
Measuring channel	Width: 5.0 mm; Height: 5.8 mm
Mounting	Two mounting holes (Ø = 3.25 mm) ⓘ The sensor must be installed on a plane surface.
Operating temperature	+5 °C ... +50 °C
Storage temperature	–20 °C ... +80 °C
Working humidity	20 % ... 75 % relative humidity (not condensing)
Storage humidity	10 % ... 90 % relative humidity (not condensing)
Protection	IP67 (Sensor head without connector)
Requirements for tube ⓘ Please provide us with a sample of the tube (approx. 30 cm), so that we can test the usability of your tube.	Tube is inserted into sensor without any coupling fluid. Tube must always be inserted completely into sensor channel. ⚠ **WARNING** Make sure that the tube remains in position and will not slide out of the sensor channel while operation.
Outer diameter	5.5 ... 7.0 mm
Wall thickness	≤ 1.25 mm
Material	Plastics, e.g. PVC, PE, silicone, PUR, other materials on request

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Technical data

Special features	Tube must be optically transparent within the spectral range of about 415 nm
Elasticity	Tube must be able to adjust flexibly
Liquid requirements	Optically transparent liquids
Cable	Sensocord®-M-UL, 5 × AWG 28, unshielded, black Length: 500 mm ± 20 mm
Connector	Molex PicoBlade 51021-0500, Single Row, 5 circuits, 1.25 mm
Directives/Standards	The sensors were developed to be tested with respect to the following standards: • Safety requirements: IEC 60601-2-16:2018 • EMC: IEC 60601-1-2:2014 (4th edition) + AMD1:2020
Scope of delivery	Sensor Head BLD03/50 (connection cable included) Technical data sheet
Labelling	Each sensor head is labelled with its part number and unique serial number

Technical drawing

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Printed Circuit Board BLD03M

Technical Data	
Measuring method	Optical transmission measurement
Specification	Printed Circuit Board BLD03M V1.1, FW V04.05
Article number	200 01 0339
Blood threshold	Light attenuation of 8 % compared to the calibrated light intensity
Blood sensitivity	Reliable detection of a blood leakage ≥ 0.35 ml/min at a dialysis fluid flow rate of 800 ml/min, haematocrit level of 32 %. ⓘ The indication above is a worst case scenario. Depending on tube properties, application and process characteristics the sensor may detect also smaller amounts of blood.
Measurement accuracy	± 1 %
Response time for blood alarm	Time that passes before a blood alert is actually issued in case of a blood contamination. 280 ms ± 10 ms
Response time for plausibility test	Time that passes before a plausibility alert is actually issued in case a non-plausible signal. 550 ms ± 20 ms
Operating voltage	+3.1 (-1.5 %) ... +5.5 (+2 %) VDC with a ripple lower than 25 mVpp ⓘ No overvoltage protection and no reverse polarity protection implemented. Appropriate protective measures must be taken on the medical device side.
Current consumption	≤ 40 mA without additional load ⓘ The power supply must be limited to maximum current of 200 mA by means of suitable equipment in the machine (fuse / regulator / etc.).
Max. output current	± 50 mA ⓘ Stresses beyond the maximum rating may cause permanent damage to the device.

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| Technical Data	
Safety aspects	Self-test – A self-test routine can be triggered via digital input.
Operating temperature	+5 °C … +50 °C
Storage temperature	-20 °C … +80 °C
Working humidity	20 % … 75% relative humidity (not condensing)
Storage humidity	10 % … 90 % relative humidity (not condensing)
Directives/Standards	The sensors were developed to be tested with respect to the following standards: • Safety requirements: IEC 60601-2-16:2018 • EMC: IEC 60601-1-2:2014 (4th edition) + AMD1:2020 • Software is developed acc. to IEC 62304:2006 + AMD1:2015 The embedded software is classified as "C"
Scope of delivery	PCB BLD03M V1.1, FW V04.05 Technical Data Sheet Operating Manual
Labelling	Each Printed Circuit Board is labelled with its product number and its unique serial number

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Electrical Connection

ATTENTION

The board needs to be protected against unintended contact with other conductive parts.

J2 – Connection to Sensor Head

Connector	Board connector header; 5-pin; 1.25 mm Molex: 53261-0571	

Assignment	Pin	Connection	
	1	GND	
	2	VDD	
	3	SDA of I²C	
	4	SCL of I²C	
	5	LED+	
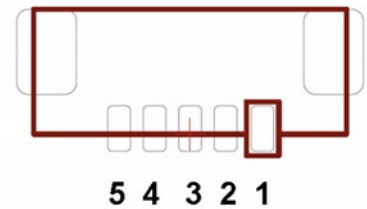
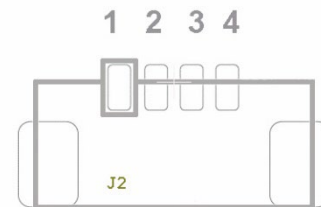**J3 – Serial Interface**

Intended for use with another software version.

| Connector	Board connector header; 4-pin; 1.25 mm Molex: 53261-0471	

Assignment	Pin	Connection	
	1	Operating voltage	
	2	GND	
	3	Not used	
	4	Not used	

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J4 – Logical Interface

Connector	Board connector header; 6-pin; 1.25 mm Molex: 53261-0671		
Assignment	**Pin**	**Function**	
	1	Operating voltage 3.1 ... 5.5 VDC	
	2	GND	
	3	Output "Blood Alarm"	
	4	Input "External Self-Test" (high active)	
	5	Output "Plausibility"	
	6	Input "Calibration" (high active)	

1 2 3 4 5 6

J1
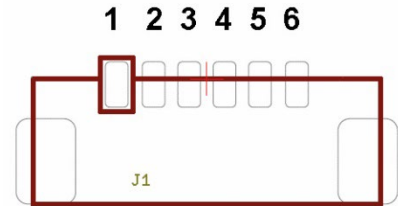
| Logical specification	Output	Signal level	Condition
Signal at output	Blood S05-006	High	Blood
		Low	No blood (clear liquid)
	Plausibility S05-005	High	No plausibility error nor device error
		Low	Plausibility error or device error

ⓘ The logical output signal of "Plausibility" has the highest priority, thus signals on the logical output "Blood" are only valid if the logical output "Plausibility" is set to high.

Logical specification	Input	Signal level	Condition
Signal at input	Self-Test S05-007	High	Start self-test
		Low	-
	Calibration S05-008	High	Start calibration
		Low	-

ⓘ The logical input signal of "Calibration" has the highest priority, thus a self-test will be started only if the logical input "Self-Test" is high **and** the logical input "Calibration" is low.

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Logical level	Parameter	Condition	Operating voltage V_{CC}	Min	Typ	Max	Unit
Signal at output	Output V_{OH} High Voltage	I_{OH} = -100 µA	3.1 ... 5.5 V	V_{CC}-0.1	---	---	V
		I_{OH} = -16 mA	3.1 V	2.4	---	---	V
		I_{OH} = -24 mA	3.1 V	2.3	---	---	V
		I_{OH} = -32 mA	4.5 V	3.8	---	---	V
	Output V_{OL} Low Voltage	I_{OL} = 100 µA	3.1...5.5 V	---	---	0.1	V
		I_{OL} = 16 mA	3.1 V	---	---	0.4	V
		I_{OL} = 24 mA	3.1 V	---	---	0.55	V
		I_{OL} = 32 mA	4.5 V	---	---	0.55	V
Signal at input	Input V_{IH} High Voltage		3.1 ... 5.5 V	2.0	---	---	V
	Input V_{IL} Low Voltage		3.1 ... 5.5 V	---	---	0.8	V

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Technical drawing
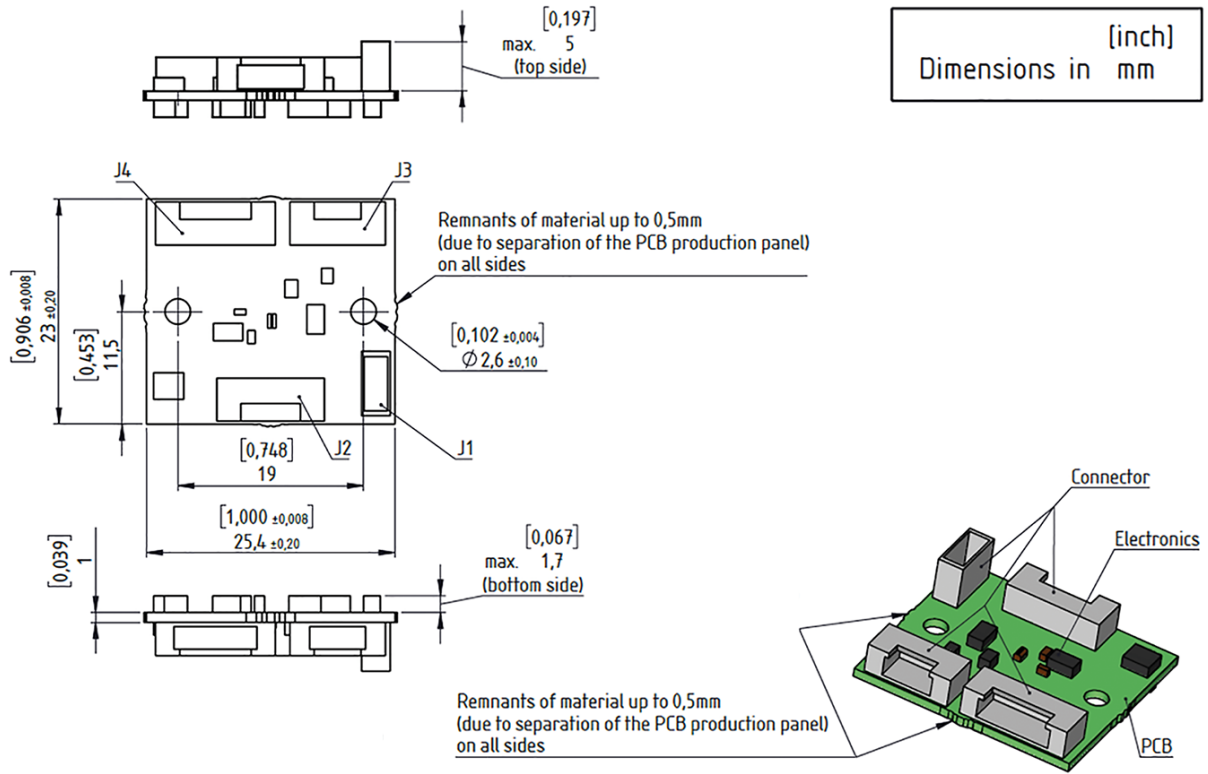
Drawings are not to scale. Dimensions in mm, unless otherwise specified. Information is subject to change without notice. SONOTEC is a registered trademark.

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