



## Technical Data Sheet

### **BLD03/50I**

Blood Leak Detector

Original

Revision: 1.2 | 2022-06-07

## General

### Description

The Blood Leak Detector BLD03/50I 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 BLD03/50I consists of a sensor head with connection line and an external electronic board (PCB) with integrated firmware.

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

### Scope of delivery

	Article number
<b>Set BLD03/50I, class A</b> Including:	700 01 0408
<b>Sensor head BLD03/50</b>	200 05 0008
<b>PCB BLD03I, programmed, class A</b>	200 01 0338

## Sensor Head BLD03/50

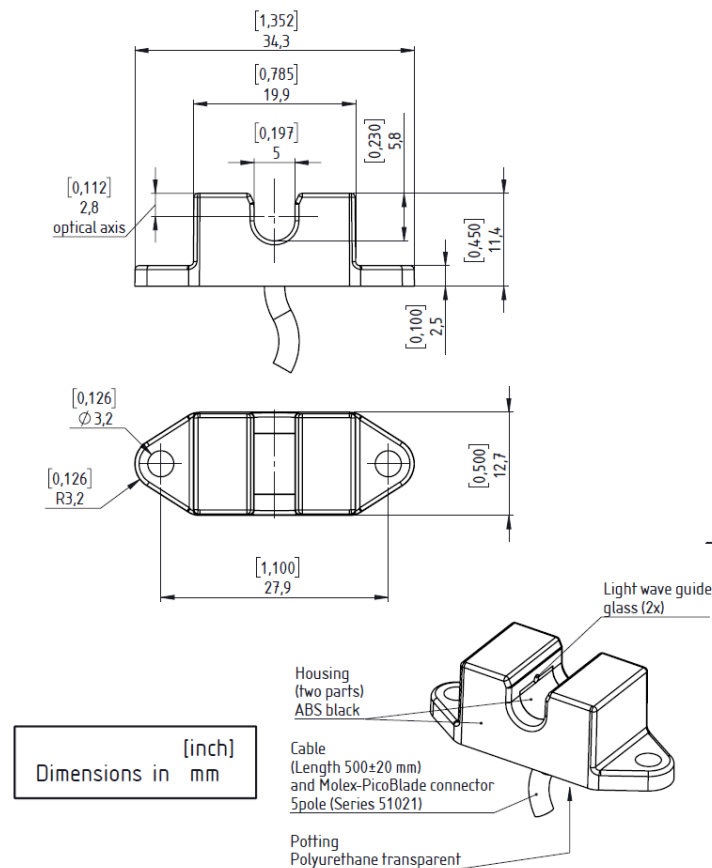


Technical data	
<b>Measuring method</b>	Optical transmission measurement, LED
<b>Specification</b>	Sensor head BLD03/50 - channel width 5.0 mm
<b>Order number</b>	200 05 0008
<b>Materials</b>	Housing: ABS and glass Potting: PUR (transparent)
<b>Measuring channel</b>	Width: 5.0 mm; Height: 5.8 mm
<b>Mounting</b>	Two mounting holes ( $\varnothing = 3.25$ mm) <div style="border: 1px solid black; padding: 2px;"><b>ⓘ</b> The sensor must be installed on a plane surface.</div>
<b>Operating temperature</b>	+5 °C ... +50 °C
<b>Storage temperature</b>	-20 °C ... +80 °C
<b>Working humidity</b>	20 % ... 75 % relative humidity (not condensing)
<b>Storage humidity</b>	10 % ... 90 % relative humidity (not condensing)
<b>Protection</b>	IP67 (Sensor head without connector)
<b>Requirements for tube</b>	Tube is inserted into sensor without any coupling fluid. Tube must always be inserted completely into sensor channel. <div style="border: 1px solid black; padding: 2px;"><b>ⓘ</b> Please provide us with a sample of the tube (approx. 30 cm), so that we can test the usability of your tube.</div> <div style="border: 1px solid black; padding: 2px;"><b>⚠ WARNING</b> Make sure that the tube remains in position and will not slide out of the sensor channel while operation.</div>
<b>Outer diameter</b>	5.5 ... 7.0 mm
<b>Wall thickness</b>	$\leq 1.25$ mm
<b>Material</b>	Plastics, e.g. PVC, PE, silicone, PUR, other materials on request

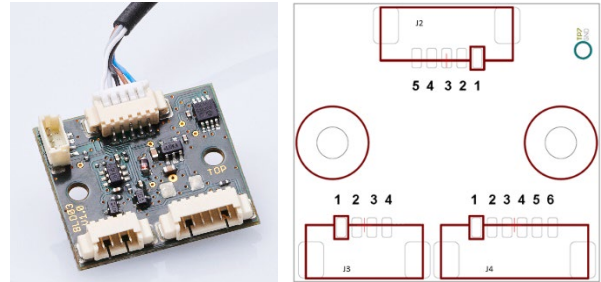
## Technical data

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: <ul style="list-style-type: none"> <li>• Safety requirements: IEC 60601-2-16:2018</li> <li>• EMC: IEC 60601-1-2:2014 (4<sup>th</sup> edition) + AMD1:2020</li> </ul>
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



## Printed Circuit Board BLD03I



Technical data	
<b>Measuring method</b>	Optical transmission measurement
<b>Specification</b>	Printed Circuit Board BLD03I V1.1, FW V04.05
<b>Order number</b>	200 01 0338
<b>Blood threshold (adjustable)</b>	Light attenuation of 8 % compared to the calibrated light intensity (default setting) <div style="border: 1px solid black; padding: 5px; margin-top: 5px;">                         ⓘ Adjusting the blood threshold will have direct impact on blood sensitivity.                     </div>
<b>Blood sensitivity</b>	At blood threshold of 8 % (default setting): Reliable detection of a blood leakage $\geq 0.35$ ml/min at a dialysis fluid flow rate of 800 ml/min, haematocrit level of 32 %. <div style="border: 1px solid black; padding: 5px; margin-top: 5px;">                         ⓘ Blood sensitivity is depending on tube properties, application, process characteristics and blood threshold.                     </div>
<b>Measurement accuracy</b>	$\pm 1 \%$
<b>Response time for blood alarm (adjustable)</b>	Time that passes before a blood alert is actually issued in case of a blood contamination. 280 ms $\pm$ 10 ms (default setting)
<b>Response time for plausibility test</b>	Time that passes before a plausibility alert is actually issued in case of a non-plausible signal. 550 ms $\pm$ 20 ms
<b>Operating voltage</b>	+3.1 (-1.5 %) ... +5.5 (+2 %) VDC with a ripple lower than 25 mVpp <div style="border: 1px solid black; padding: 5px; margin-top: 5px;">                         ⓘ No overvoltage protection and no reverse polarity protection implemented. Appropriate protective measures must be taken on the medical device side.                     </div>
<b>Current consumption</b>	$\leq 40$ mA without additional load <div style="border: 1px solid black; padding: 5px; margin-top: 5px;">                         ⓘ The power supply must be limited to maximum current of 200 mA by means of suitable equipment in the machine (fuse / regulator / etc.).                     </div>

## Technical data

**Max. output current** ± 50 mA

ⓘ Stresses beyond the maximum rating may cause permanent damage to the device.

**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 "A"

**Scope of delivery** PCB BLD03I V1.1, FW V04.05  
Technical Data Sheet  
Operating Manual  
Serial interface Description

**Labelling** Each Printed Circuit Board is labelled with its product number and its unique serial number

## Electrical Connection

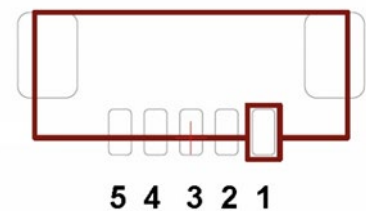
### ATTENTION

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

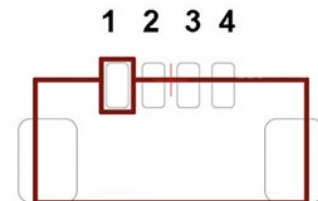
Assignment	Pin	Connection
	1	GND
	2	VDD
	3	SDA of I <sup>2</sup> C
	4	SCL of I <sup>2</sup> C
	5	LED+



#### J3 – Serial Interface

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

Assignment	Pin	Connection
	1	Supply voltage 3.1 ... 5.5 VDC
	2	GND
	3	Tx
	4	Rx

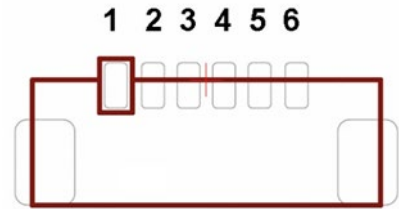


Serial interface	Parameter	Value
	Bits per second	115200
	Data bits	8
	Parity	none
	Stop bits	1
	Flow control	none

#### J4 – Logical Interface

**Connector** Board connector header; 6-pin; 1.25 mm Molex: 53261-0671

Assignment	Pin	Function
	1	Supply voltage 3.1 ... 5.5 VDC
	2	GND
	3	Output "Blood"
	4	Input "Self-Test" (high active)
	5	Output "Plausibility"
	6	Input "Calibration" (high active)





Logical specification	Output	Signal level	Condition
Signal at output	Blood	High	Blood
		Low	No blood (clear liquid)
	Plausibility	High	No plausibility error nor device error
		Low	Plausibility error or device error

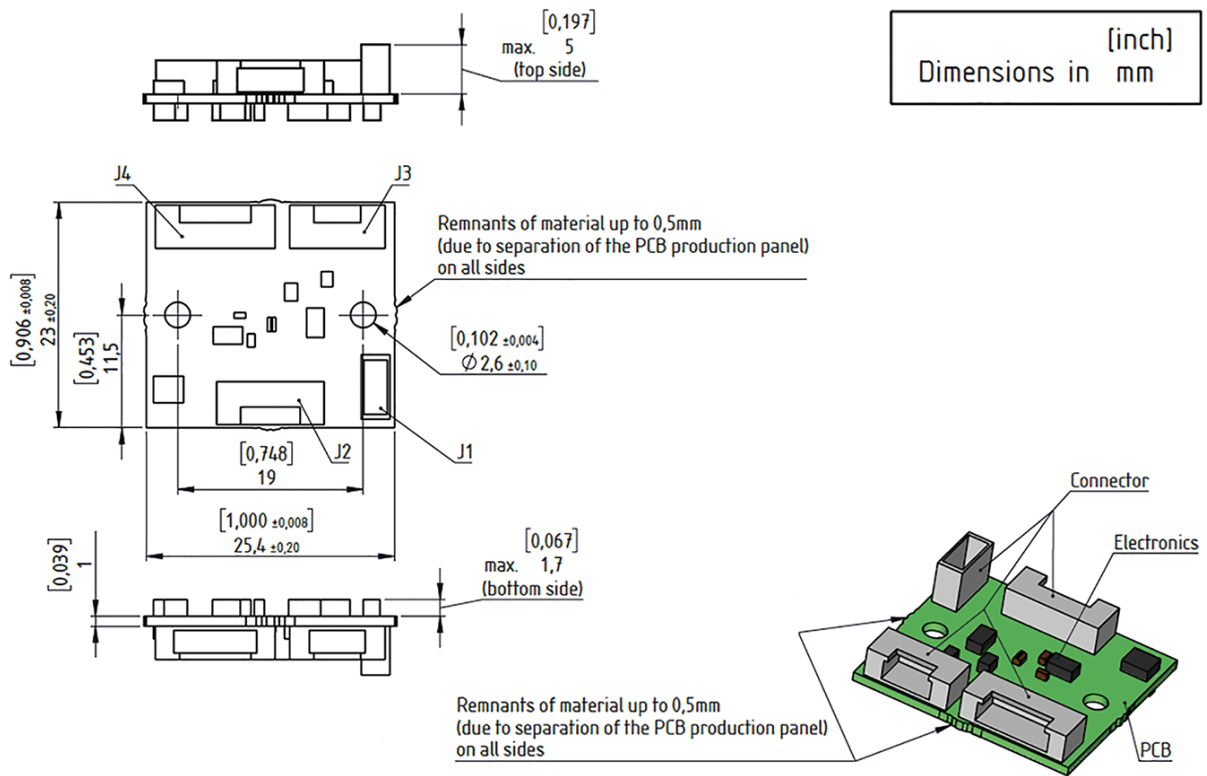
ⓘ The logical output signal of “Plausibility” has the highest priority, thus signals on the logical output “Blood” are only valid if the logical output “Plausibility” is set to high.

Logical specification	Input	Signal level	Condition
Signal at input	Self-Test	High	Start self-test
		Low	-
	Calibration	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.

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

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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