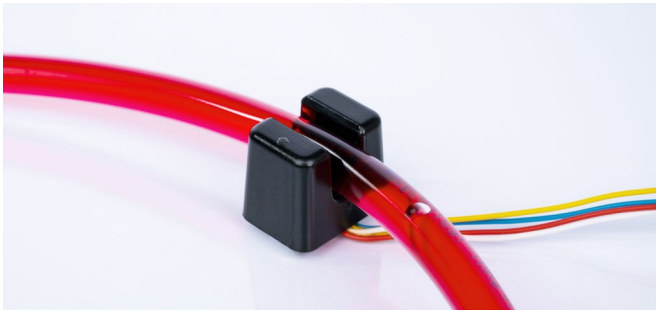
Technical Data Sheet

SONOCHECK ABD07.xx-1

for Medical Applications

Ultrasonic air bubble sensor for non-invasive measurement



The air bubble sensor **SONOCHECK® ABD07/xx-1** is used to detect air or gas bubbles in flexible plastic tubes and is intended to prevent air infusions. The sensor has no contact with the liquid and is suitable for applications particularly in medical devices. Designed as a component for fixed installation in machines and equipment it can be mechanically and electrically integrated. The sensor sensitivity can be adapted to the requirements of individual operating conditions on request.

Technical data

SONOCHECK® type ABD07/xx-1 **Air Bubble Detector**		
Measuring method	Ultrasound	
Version/ designs	The sensor version depends on the tube specification.	
Bubble sensitivity	Depends on sensor version, sensor settings and tube specification Please contact our service for more information.	
Dynamic operating point	The sensor has a dynamic operating point to compensate for changing acoustic conditions. This ensures reliable bubble detection over a wide operating range.	
Requirements for the tube	**Parameter**	**Property**
	Outer diameter	3.2 to 9.6 mm, according to specification of the sensor
	Wall thickness	Optimum: 10 to 20 % of outer diameter
	Material	Plastic, e.g. PVC, PE, silicone, PUR Other materials on request or only after tests.
	Special Features	Tube must be smooth on outside, no fabric tube
	Elasticity	Tube must be able to adjust flexibly
	ⓘ **NOTE!** If possible, please provide us with a tube sample. In this way an optimal channel width and suitable settings can be selected.	
	⚠ **WARNING!** The tube must be inserted completely and dry. It must be ensured that the tube remains in position and does not slip out of the sensor channel.	

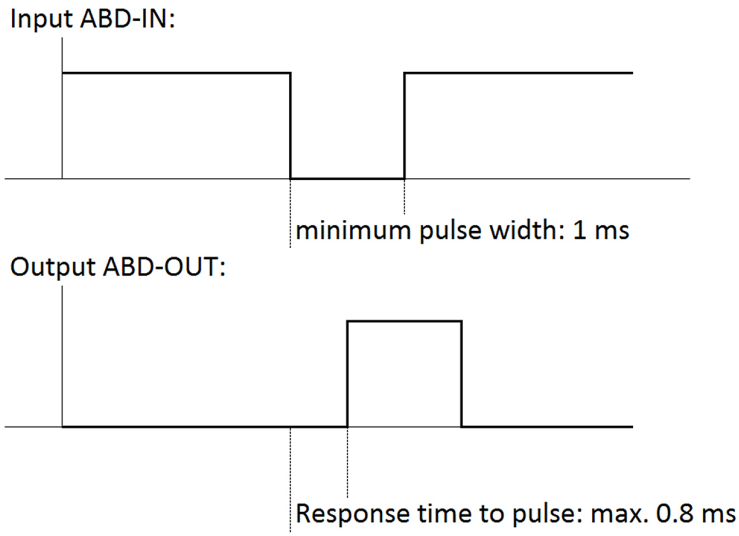
Requirements for the liquid	Water, blood, solutions or other low-viscosity liquids containing no or few solids
Measuring cycle	⚠ 200 µs
Response time	< 2 ms liquid to bubble/ air
Adjustment time of dynamic operating point	< 2 ms bubble to liquid without bubbles (see bubble sensitivity) 🛈 **NOTE!** This requires a sensor, which previously signaled liquid for a filled tube. Due to the dynamic operating point of the sensor, the setting time from bubble to liquid can be extended if a static bubble was previously in the measuring channel for a longer time (e.g. bubble with dwell time of 2 to 30 seconds). For longer residence time of air or bubble in the measurement channel please see next adjustment time. < 100 ms empty/ no tube to tube filled with clear FLUID 🛈 **NOTE!** This requires a previously successful start procedure.
Holding time	On request: Delays or holding times for bubble events
Start Procedure Init Interval Initial Test	After power on or at restart the init interval is started. Inside this period the sensors act to serial commands via Input ABD-IN. After the init interval, the initial test will be performed. This includes test routines and the output level is changed several times. Both, init interval and initial test, takes approx. 1.6 to 1.8 s, at least 1.5 s.
Operating voltage	+5 ± 0.2 VDC ⚠ **WARNING!** The machine must have an appropriate limitation of voltage. Max. rating of voltage is 5.5 V.
Current consumption	≤ 30 mA ⚠ **WARNING!** Power supply must be limited to max. current of 200 mA by means of suitable equipment in machine (fuse/ regulator/etc.)
Connecting cable	4 x single wires (0.14 mm²); firmly connected to the sensor; length: 50 ± 2 cm

Inputs and outputs

Color	Signal/ Type	Specification
Red	Operating voltage *Ratings* *VCC = +5 ± 0.2 VDC*	Operating voltage, provided by machine
Blue	Ground (GND)	
Yellow	ABD-IN/ Input, 5 V logic, TTL *internal pull up 10kΩ to +5V* *Ratings:* *V_{OL} = -0.2 to 0.8 V* *V_{OH} = 3.0 to 5.5 V*	Digital input (Bubble Test, L-active) *Alternative configurable as* • *Serial input of UART* • *Digital input (Bubble Test H-active, reset L-active)* • *Frequency output (open collector, Ratings: IOL =max -5mA)*
White	ABD-OUT/ Output, 5 V logic, TTL, push-pull *Ratings: $I_{OH/OL}$ = max. ±5 mA*	**Signals at outputs** / **Condition** / Digital output / LED Liquid / L / green Air/ Bubble / H / red Internal error (self-test) / H / red *Alternative configurable as* • *Switching output with adjusted levels* • *Serial output of UART* • *Pulse-width-modulation (PWM, width of pulse depends on bubble size).*

🛈 **NOTE!** The visualization of the sensor status by means of LED is for information only and is not considered as an optical alarm message.

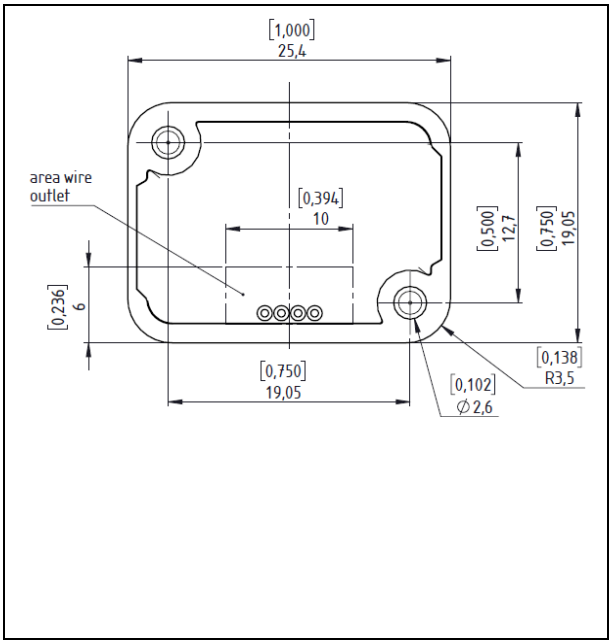
⚠ **WARNING!** The sensor output is not short circuit proof, any overvoltage or overcurrent exceeding the maximum rating will permanently damage the sensor. There is no protection against reverse polarity.

ABD-IN, Bubble test input (default configuration)	The bubble test input triggers the sensor to simulate bubbles. The signal is low active. The minimum pulse width is 1 ms. During this period the transmitted ultrasonic pulses are decreased. This reduced signal is processed by the sensor in the same way as a real bubble would be processed. That means, the sensor does not differentiate between a real bubble and the test, the output ABD-OUT including the LED is set to 'Air/Bubble'.  Timing diagram of bubble test for digital output. ⓘ **NOTE!** In serial mode (see alternative configuration) the bubble test is also available, but the timing is slightly different. Please contact our service for more information.
	⚠ **WARNING!** At high flow rates (flow speed > 0.5 m/s) the sensor might miss real bubbles during the period of the bubble test.
Maintenance	Maintenance-free
Environmental conditions	Operating temperature: +5 °C to +60 °C Storage temperature: -20 °C to +60 °C Operating humidity: 20 % to 75 % relative humidity (not condensing) Storage humidity: 10 % to 95 % relative humidity (not condensing)
Mounting	Via 2 recessed holes on rear side of sensor (see technical drawings); self-tapping screws for plastics, Ø 3 mm, screw-in depth: min. 4 mm, max. 6 mm
	Plane mounting with complete surface required; Maximum torque: 0.6 Nm
Protection	IP67* only from front side in mounted state * *related to IEC 60529*
Materials	Housing: molded ABS Backside potting: Epoxy Cable: PVC

Cleaning	The sensor is not intended to be sterile. It is envisaged to routinely clean the sensor with commercially available cleaning and disinfectant solutions. It can be cleaned and disinfected by wiping or spraying from the front side. 🛈 **NOTE!** The chemical resistance must be tested by customer for the expected conditions of use.
	⚠ **WARNING!** It is forbidden to sterilize the sensor, with e.g. steam, ethylene oxide-, gamma- or beta-sterilization. Cleaning is prohibited with white spirit or acetone. It is not allowed to clean the sensor by immersion in solvents or other liquids
General safety (if used in medical devices)	There is no “Fail-Safe-Architecture” implemented. However, some self-test routines are implemented and the sensor can be tested externally. To ensure that the sensor is working properly, the machine controlling the sensor shall periodically trigger the bubble test and check that the sensor output is set to "Air/Bubble". Additionally, the sensor must be restarted at least once in 24 h to prevent unrecognized faults. 🛈 **NOTE!** By using the serial output (see alternative configuration) with secured data frame, a higher level of safety can be achieved. Please contact our service for further information about alternative configurations of the sensor.
	⚠ **WARNING!** All settings (e.g. bubble sensitivity, bubble test) must be carefully adjusted and checked according to the medical application (e.g. tubing). Final functional tests are in responsibility of customer. Please contact our service to find optimal settings for your application.
Electrical safety	For MOPP (Means Of Patient Protection) acc. IEC 60601-1: The protection from SECONDARY CIRCUITS requires an installation of a SELV (Safety Extra-Low Voltage) converter prior to connecting the sensor to the medical device. This ensures that no higher voltage than 60 V can occur at the sensor under any circumstances. Internal insulation of inner electronic to the outside with > 1000 VAC (*). It applies 2 × MOPP, secondary circuit, according IEC 60601-1, Table 6 The classification as Applied Part “CF” in combination with the medical device and tubing is possible, depending on application. (*) Applies only to the front side of the mounted sensor (back side excluded.)
Notes to installation	The sensor is delivered without connector. The cable ends are open and only protected against ESD inside the packaging. Therefore, during installation of the sensor a prevention against ESD is necessary.
Flammability classification	The sensor has a power consumption of < 300 mW. Devices with power consumption less than 15 W do not need flammability classification acc. to UL94.
Directives/ standards	The sensors were developed to be tested with respect to the following standards: • Safety Requirements: IEC 60601-1:2005 (3rd edition) • EMC: EN 60601-1-2:2007 (3rd edition) • Acoustic Output (Ultrasonic): IEC 61157:2007 • Software is developed acc. to IEC 62304:2006 + AMD1:2015 The software is classified as “C”.

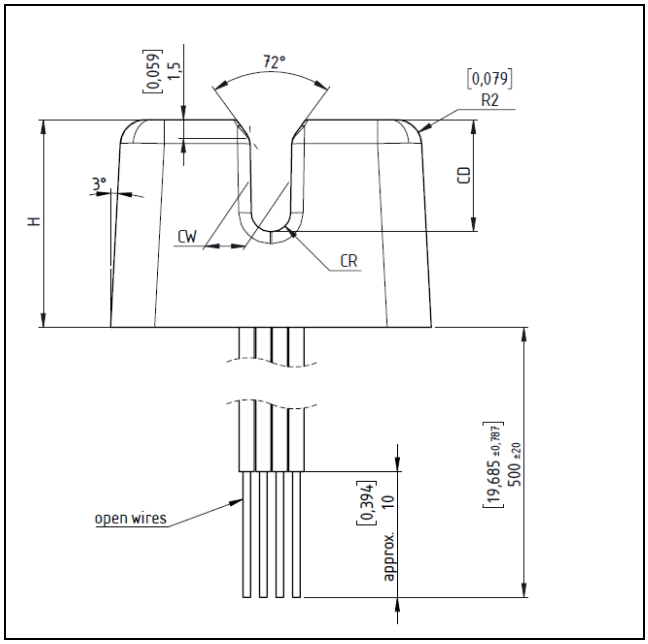
Labelling	Each sensor is labelled with its product number and its unique serial number. The label is located on the connection line.
Scope of delivery	• SONOCHECK air bubble detector, type ABD07/xx-1 • Technical data sheet
Accessories/ options	ABD Monitor for configuration and diagnostics, consisting of: • USB data converter (Type 007) • USB cable, type A-B, length 1.5 m • ABD Monitor software

Technical drawings



Sensor dimensions in mm [inch]

(The drawings are not to scale)



Channel dimensions and sensor height

Information for ordering

Specification	ABD07/25-1		ABD07/30-1		ABD07/50-1		ABD07/80-1	
	[mm]	[inch]	[mm]	[inch]	[mm]	[inch]	[mm]	[inch]
Outer diameter of tube	3.2	1/8	4.0	0.157	6.4	1/4	9.6	3/8
CW: Channel width	2.5	0.1	3.2	0.125	5.1	0.2	7.9	0.31
CD: Channel depth	8.1	0.319	8.8	0.346	10.2	0.4	13.1	0.516
CR: Channel radius	R1	0,039	R1,5	0,059	R2	0,79	R3	0,118
H: Sensor height	15.75	0.62	16.5	0.65	17.8	0.7	21	0.827
Order number	200 02 0087		200 02 0088		200 02 0089		200 02 0090	

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