SONOTEC

Air Bubble Detector

Type

SONOCHECK® ABD05/xx

Operating Manual

Revision: 2.1; Date: 2020-07-22

Contents

1 Notes on operating manual

1.1 General

Thank you for choosing the SONOCHECK® ABD05.

This manual forms part of the SONOCHECK® ABD05 and must be read carefully, before working with the sensor. It contains all the information needed to ensure proper and efficient use, along with all the instructions to ensure safe operation of the SONOCHECK® ABD05.

1.2 Symbols used

Hazards or special information is indicated in the following ways:

⚠ DANGER	Warns of **imminent threat of danger** with very high risk. If not avoided, it will result in death or serious injury.
⚠ WARNING	Warns of **possibly imminent danger** with moderate risk. If not avoided, it could result in death or serious injury.
⚠ CAUTION	Warns of **danger** with low risk. If not avoided, it may result in minor or moderate injury.
ATTENTION	Warns of danger. If not avoided, it may result in material damage.

NOTE!
This paragraph provides information or draws attention to special features.

2 Safety regulations

2.1 User qualifications

⚠ WARNING **Risk of death or severe injury.**

The SONOCHECK® ABD05 must only be installed and operated by users who have read and understood the entire content of operating manual. **Ensure to read all safety regulations below and the special regularities for the use in medical devices (see chapter 6).**

2.2 General safety information

The SONOCHECK® ABD05 is a state of the art product that complies with all applicable safety regulations. The sensor is factory tested and is delivered in a safe condition for operation. **For the use in medical devices (MDEV) see the special regularities in chapter 6.** The following general safety instructions apply:

⚠ DANGER **Severe measurement error with high risk for patient safety possible.** Liquid in the measuring channel may conduct ultrasound. In this case the detection of bubbles, empty tube or missing tube may fail.

During operation must never be any liquid medium in the sensor channel. Ensure, that sensor and the measuring channel are always dry and clean and that the associated tubing stays intact during sensor operation.

⚠ WARNING **Risk of death or severe injury.** Incorrect installation and use of the SONOCHECK® ABD05 sensor and its components can present a hazard for the user and the patient, if it is integrated in a medical device.

- The integrator is responsible for the legal compliance of the SONOCHECK® ABD05 installation and its documentation.
- Observe all requirements and conditions specified in the ‘Technical Data Sheet’. It is forbidden to exceed or fall below the listed limits – even for a short period.
- The SONOCHECK® ABD05 must never been immersed. Sensor – especially sensor channel – must be kept dry and clean.
- The SONOCHECK® ABD05 must only be exposed to a minimal risk of mechanical damage. In other cases, the sensor must be protected against mechanical influences. Avoid any pulling or torsion movements on tube during operation.
- If there is malfunction or damage, or if there is a suspicion that the sensor is no longer functioning properly, take it out of operation immediately.
- The sensor must never be opened. It does not contain any user-serviceable parts.
- Any kind of sensor modification is prohibited.

3 Sensor description

3.1 Intended use

The air bubble detector (ABD) SONOCHECK® ABD05 is used to detect air and gas bubbles or foam in flexible plastic tubes filled with liquids like blood, blood plasma, water or saline solution. In medical devices the sensor is intended to prevent air infusions which could lead to an endangerment of patient. The sensor has no contact with the liquid and is suited for disposable tubes.

The SONOCHECK® ABD05 is designed as a component for fixed installation in machines and equipment e.g. machines for blood treatment, injectors or dialysis machines and is mechanically and electrically incorporated into the controller.

The sensor can be used in various environments such as blood component collection centers, catheter laboratory, OR, emergency room, intensive care unit, CT environment as well as for inter- and intra-hospital transportation. Furthermore, it is possible to use the sensors in ambulances or for emergency operations outside clinical environments.

Any misuse (e.g. as hose clamp or butterfly valve) as well as any use other than the designated - is prohibited and can result in death (depending on the application), serious injury or damage to property. The SONOTEC GmbH accepts no liability for damage, including to third parties, caused by improper handling of the sensor.

3.2 Construction

The sensor consists of the measuring cell and connected circuit boards with the evaluation electronics. The measuring cell is an integrative part of the housing. The channel width is adjusted to the type of the tube. The exact sensor design depends on the diameter, the hardness and, where required, the liquid medium. Two designs are available:

- Rectangular design
- Circular design

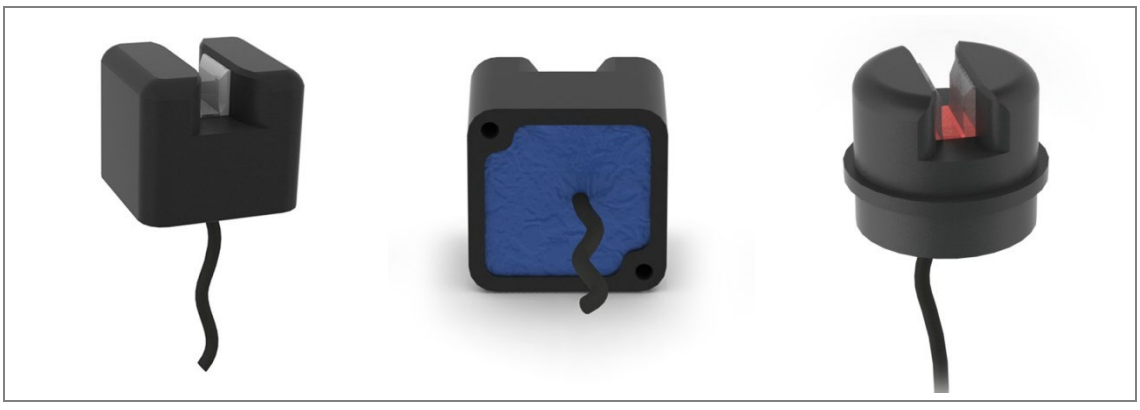


Figure 1: Version with rectangular design (view from side and below) and version with circular design (view from side)

For the specifications (different measuring channels) see the ‘Technical Data Sheet’.
In case of very small tubes or tubes with a very low wall thickness (less than 10 % of the outer diameter) a cover is necessary to press the tube firmly on the right position. A different sensor series is available for these applications. Contact our service as well for customized adaptations.

3.3 Measuring method and functioning

An ultrasound method based on short, high-frequency pulses is used for the measurement. When liquid is in the tube, the **ultrasonic signal passes through the tube** to the receiver.

The intensity of the ultrasound transmitted into the liquid is so low, that no biological effect can occur. This was tested and confirmed with different fluids, including human blood.

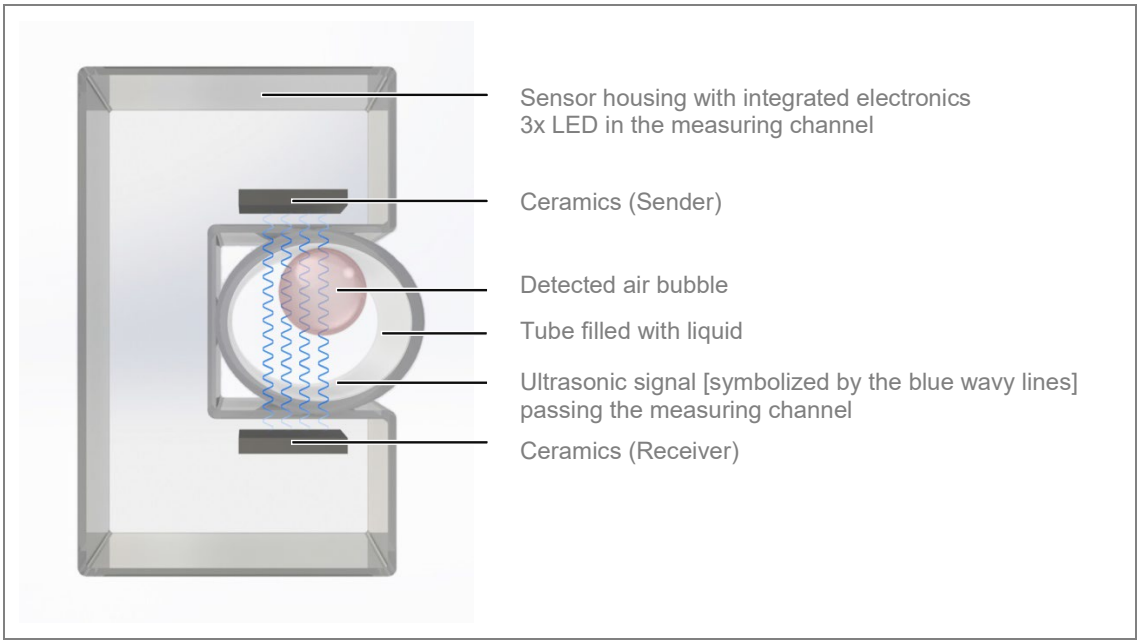


Figure 2: Sensor design and function [symbolic representation]

The maximum value of the received signal amplitude is recorded in a defined period.

Bubbles in the liquid stream result in a reduction of the signal as the ultrasound is significantly attenuated by air. So if there is a bubble in the measuring path, the proportion of ultrasound that reaches the receiver is considerably lower – how much depends on the bubble size as well.

The integrated electronics of the sensor evaluates the amplitude of the received signal and **sets the output accordingly**.

The **sensor includes 3 LEDs** in colors red, green, and blue at the bottom of channel to **indicate the state of measuring**. These LEDs are freely configurable. For default settings see chapter 4.2 Output specification: default settings and sensor status via LED.

3.4 Bubble sensitivity

The bubble sensitivity of the sensor depends on the diameter of the tubing, the mounting position of the sensor and on the correct coupling. Bubbles with a diameter larger than 30 % ... 50 % of the inner diameter of the tubing will be detected.

⚠**Observe chapter 7 Optimal mounting position,** installation **for correct installation.**

When the sensor is installed as recommended, bubbles with the following size can be detected:

Sensor type	Tubing			Bubble Detection: Ø and Volume		
SONOCHECK®	**Material**	**Outer Ø**	**Inner Ø**			
ABD05.50 / ABD05.51	PVC	4.0 mm	1.6 mm	mostly >	1.5 mm	2 µl
				reliably >	2.0 mm	4 µl
ABD05.52 / ABD05.53	PVC	6.8 mm	4.3 mm	mostly >	2.0 mm	4 µl
				reliably >	3.5 mm	20 µl
ABD05.54 / ABD05.55	PVC	2.8 mm	2.0 mm	mostly >	1.2 mm	1.0 µl
	Silicone	3.0 mm	1.0 mm	reliably >	1.5 mm	1.5 µl
ABD05.56	PVC	2.4 mm	0.8 mm	reliably >	1.0 mm	0.5 µl
ABD05.57	PVC	5.5 mm	3.5 mm	mostly >	2.0 mm	4 µl
				reliably >	2.9 mm	10 µl

Table 1: Bubble sensitivity depending on sensor type

3.5 Sensor software

The sensor software is structured into 2 modules. These modules are strictly separated and operate alternately. For more detailed description of modes contact our support.

Module	Safety class.	Operational mode	Function
Main	C	Start mode	After power on or on restart the ‘Init Interval’ is started. In this period the sensors acts to commands of serial interface (see notes to input ABD-IN). After ‘Init Interval’ the ‘Initial Test’ will be performed. Both, ‘Init Interval’ and ‘Initial Test’, take approx. 1.5 s. Afterwards ‘Normal Mode’ will be started.
		Normal mode	Measuring and detection of bubbles Cyclical Self-Test Output of result
Boot	A	Boot mode	Service Adjusting settings Updating of software

Table 2: Modules in Software

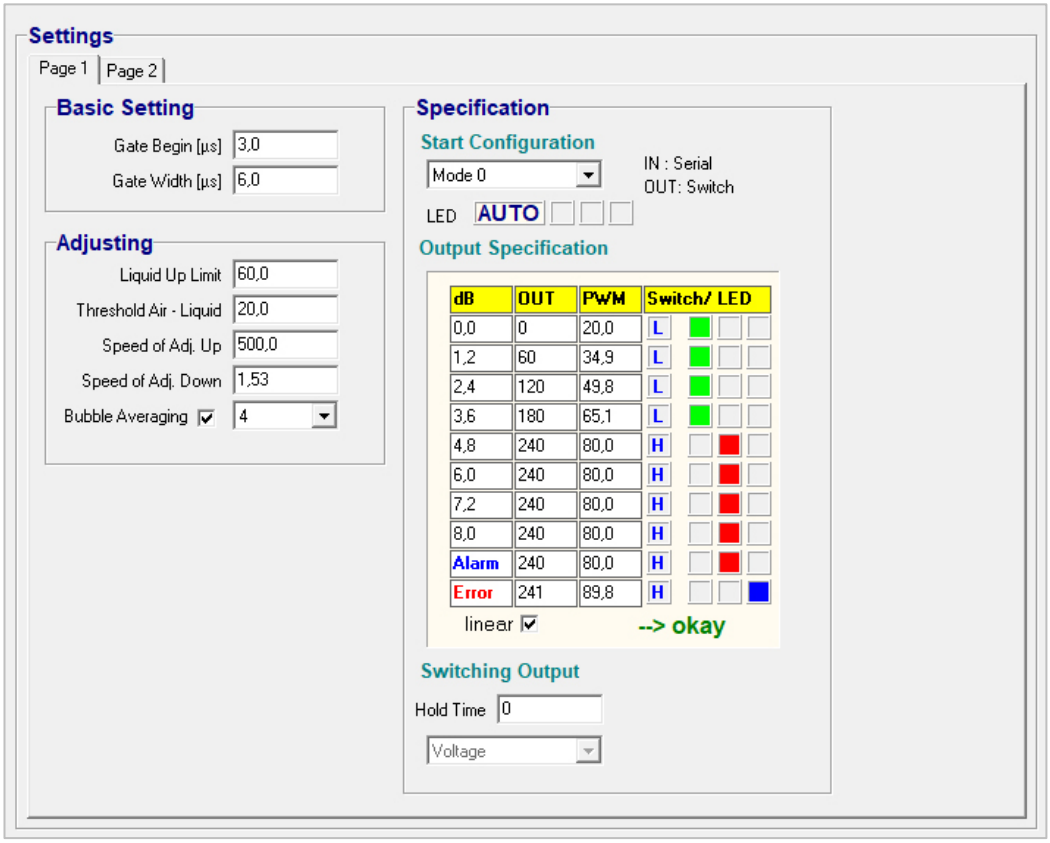
3.6 Settings and default parameters

Default settings are archived in files. The settings as shown in the figures on the following page (screenshots of ABD Monitor, optional accessories) are similar for the entire family ABD05.xx, V1.43.

Deviating from this are the parameters for adjusting the gate (ABD Monitor settings: tab ‘Page 1’) and the CRC (tab ‘Page 2’). Please find the default parameters in table.

Sensor	Gate begin	Gate width	CRC
ABD05.50 | ABD05.51 | ABD05.52 | ABD05.53	3.0 µs	6.0 µs	$4C37
ABD05.54 | ABD05.55 | ABD05.56		1.0 µs	$C735
ABD05.57 | ABD05.60 | ABD05.62		6.0 µs	$4C37

Table 3: Default Settings



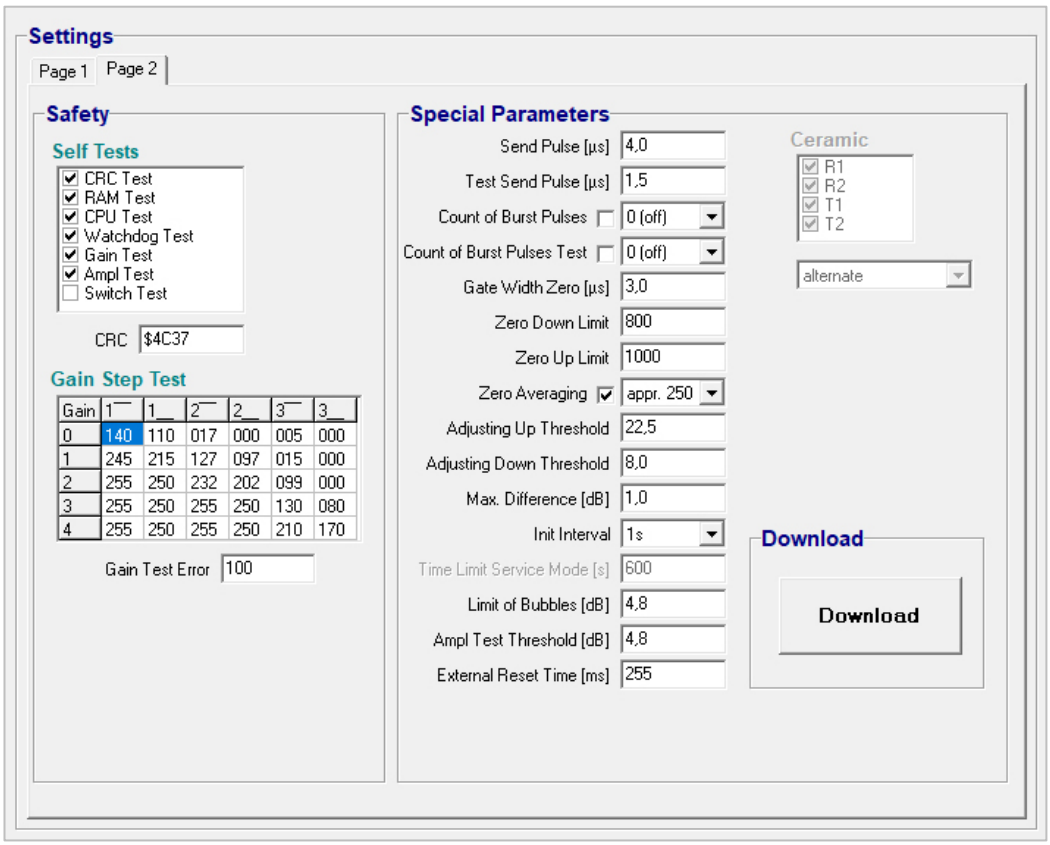


Figure 3 | 4: Settings for sensor SONOCHECK® ABD05.50 (ABD05.51 … ABD05.57 / ABD05.60 / ABD05.62 are similar)

3.7 Adaption of sensor parameters: ABD Monitor (optional accessories)

The software ABD Monitor (see screenshots last page) displays measured data in real time, stores the data of a predefined period and allows for a detailed analysis of the sensor performance. Parameter settings can be tested and assessed instantly. Integration of the sensor into MDEV, troubleshooting or fine tuning are supported as well. (see as well chapter 9 page 36). Contact our service.

3.8 Sensor identification

Identification of sensor can be read by serial commands in Interface Mode 3, resp. in Boot Mode. For detailed information see ‘Description of serial interface’.

Identification	Value [dec]	Meaning	Description
DeviceType	20	Air Bubble Detector	Kind of sensor
SensorType	05	ABD05.xx	Type of sensor family
SensorSubType	50 ... 57 / 60 / 62	ABD05.**50** … **57** / ABD05.**60 / 62**	Subtype of sensor in its family
HW	2	Type of board	Board ABD05_09/ _10
FW	143	V01.43	Version of Software (main version)
VersionCode	41	ABD05.xx / V1.43	Short code for sensor type including version of hardware and software
SN	0 ... 65535	e.g. 10001	Serial Number
Model	0	HW V1.0	Code for variant of sensor
Year	15 ...	e.g. 15 = 2015	Year of manufacturing
MCUType	330	C8051F330	Code for type of MCU on board
BootVersion	4	board ABD05_09/_10	Code for version of boot loader
BootType	01	boot loader written for MCU family 8051	Code for type of boot loader

Table 4: Modules in Software

4 Interfaces and outputs

The configuration of the sensor can be adjusted to customer requirements. For example, the output can be configured as switching output or as serial output.

Tools for the adjustment of the sensor configuration are available as optional accessories. For the sensor use in medical devices see as well the details in chapter ‘6 Information for the use in medical devices’.

4.1 Output ABD-OUT

The result of bubble detection is communicated to the machine depending on sensor parameter ‘interface mode’, either via:

- Switching output (default)
- Serial output: coded data about bubble size and alarms in frames, repetition rate = 1 ms
- Pulse width modulated signal (PWM): pulse width coded information about bubble size and alarms, period of signal = 1 ms

The output is tested using a read back line during ‘Initial Test’. After restart the entire test procedure of ‘Initial Test’ is performed. These tests include test of watchdog and output ABD-OUT. Sleep failures or other second failure will be recognized.

4.2 Output specification: default settings and sensor status via LED

The default configuration of the output ABD-OUT is switching output with the following specification:

Condition	Signal at output (H/L: TTL output)	LED
Air/bubble	H	Red
Liquid	L	Green
Internal error (self-test)	H	Blue

Table 5: Output specification (default)

The LEDs can be assigned to internal events, like bubble, fault or liquid individually. The LEDs can be remote controlled by the MDEV (in Mode 0/ 1/ 2/ 8 only). The LEDs are intended to support the user during treatment with sensor status information, but must not be considered as optical alarm messaging.

4.3 Input ABD-IN

The sensor provides an input ABD-IN. It is used as serial input to control the sensor (e.g. remote control of LED) and for service (e.g. entering ‘Boot Mode’). This input can be used as digital input to release a ‘Bubble Test’.

4.4 Serial Interface (UART)

The sensor provides UART, which is connected to ‘ABD-OUT’ as Tx and ‘ABD-IN’ as Rx.
In ‘Normal Mode’ the UART is enabled on disabled depending on configured Interface Mode.

If enabled, the UART is initialized to:

Baud rate 115,200 kBaud / 1 stop bit / no parity / no handshaking.

Independent of the ‘interface mode’ of the sensor, the UART is always enabled:

- For 1 second after power on or after restart (during ‘Init Interval’).
  Within this period the sensors acts to commands via serial interface. Such a way the ‘Boot Mode’ can always be entered, independent of interface configuration.
  It is necessary to provide service.

- In boot mode.

5 Interface Modes

The input/output configuration of the sensor depends on operating mode and interface configuration. Parameters can be changed with the help of the ABD Monitor software.

For detailed information to serial commands, see the corresponding document:
'**Specification of Serial Interface**'

5.1 Overview interface modes

The sensor supports the following interface modes (for detailed description see the following chapters):

Mode	Specification output	Specification input	Remarks
0	Switching output	Serial input for controlling or for generating bubble test	Default setting
1	Serial output, short protocol for measuring the bubble size		---
2	Serial output, long protocol for service and diagnosis		---
3	Serial output, dialog mode		Service only. Not suitable for applications with safety requirements
4	Switching output	Digital test signal to generate 'Bubble Test', L active	---
5		Digital test signal to generate 'Bubble Test', H active	---
6	Pulse Width Modulation	Digital test signal to generate 'Bubble Test', L active	---
7		Digital test signal to generate 'Bubble Test', H active	---
8		Serial input for controlling or for generating bubble test	---

Table 6: Supported Interface Modes of Sensor series SONOCHECK® ABD05.xx

5.2 Interface Mode 0 (default)

The output is configured as switching output, the input as serial input.

'Safe State' of the sensor	Output ABD-OUT = H.

Default settings of ABD_OUT (can be changed by parameters):

Event / Operating mode	Priority	Signal on ABD-OUT
Liquid	Low	L
Air / Bubble	Medium	H
Internal error (self-test)	High	H
Serious fault (watchdog)	Highest	H
Start procedure after power on or reset (approx. 1 s)	--	H **Note:** After 'Init Interval' the 'Initial Test' will be performed. This includes test routines for checking output ABD-OUT. Level of output will change several times.
Boot mode	--	UART Tx **Note:** Serial data are transmitted on demand. In inactive state = H

Table 7: Output in Interface Mode 0

The input is configured as serial input of UART. The sensor reads serial commands.

⚠ WARNING **Incorrect or insufficient communication between sensor and MDEV may have an impact on patient's safety.**

To reach a high level of safety it is essential, that the output is checked during operation with filled tubing. The serial command CmdBubbleTest must be sent cyclically within the FTT of MDEV.
(See notes in chapter 6.3 'Bubble Test'.)

5.3 Interface Mode 1 / 2

The Interface Modes 1 or 2 are used for bubble detection with transmitted information about bubble size. The input/output are connected to UART of sensor. In both modes the output is configured as serial output, the input is configured as serial input.

Interface Mode 1:
A sequence of 3 bytes is emitted every millisecond which provides information about bubble size in data byte 'ABD-Out'.

Interface Mode 2:
A sequence of 5 bytes is emitted every millisecond which provides information about bubble size and further measuring data in data byte 'ABD-Out'.

The start pattern and the CRC guarantee that the signal sequence is interpreted accurately. The superior control unit interprets any lack of serial signals as fault state.

'Safe State' of the sensor	The 'Safe State' is defined as one of the following states: • ABD-OUT = static H (high level) or static L (low level) • The transmitted serial data ABD-Out contains the code for *bubble / measuring fault*: 240 or *device fault*: 241.

The serial transmitted data can be configured. The default settings are:

Event / Operating mode	Priority	Signal on ABD-OUT
Liquid	Low	UART Tx / Data ABD-Out = 0 ... 239, represents the bubble size
Air / Bubble	Medium	UART Tx / Data ABD-Out = 240
Internal error (self-test)	High	UART Tx / Data ABD-Out = 241
Serious fault (watchdog)	Highest	Static High
Start procedure after power on (approx. 1 s)	--	H (high level) **Note:** After 'Init Interval' the 'Initial Test' will be performed. This includes test routines for checking output ABD-OUT. Level of output will change several times.
Boot mode	--	UART Tx **Note:** Serial data are transmitted on demand. In inactive state = H (high level)

Table 4: Output in Interface Mode 1 / 2

To check the sensor functionality, the serial command **`CmdBubbleTest`** can be used.

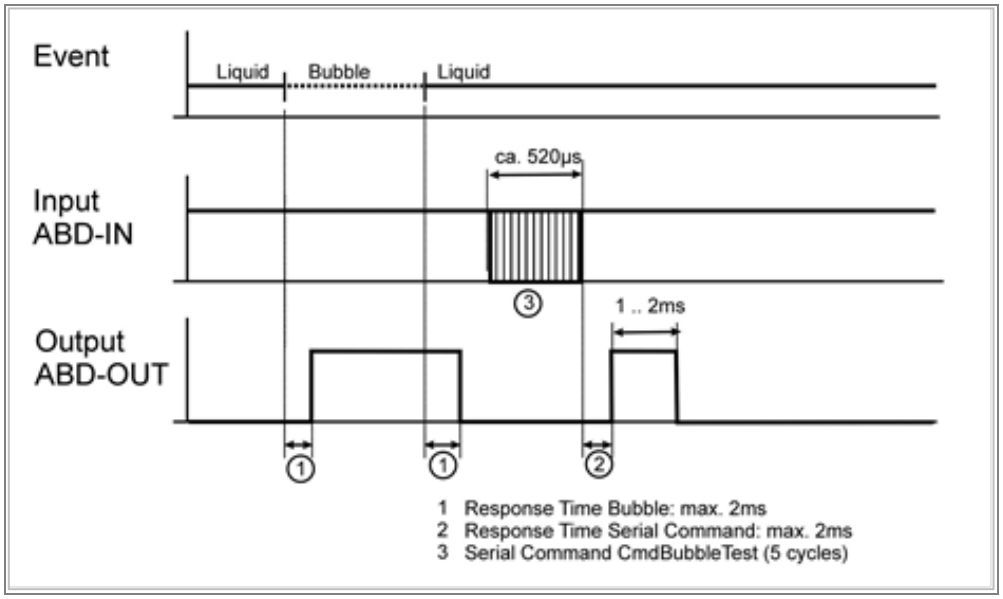


Figure 5: Signal on Output in Interface Mode 1

5.4 Interface Mode 3

The ‘Interface Mode 3’ is used for service only (e.g. to read sensor identification). This mode is not suitable for bubble detection in real time.

Input / output are connected to UART of sensor. The output is configured as serial output; the input is configured as serial input. The sensor is able to react to serial commands for controlling and responds only on demand, on request by the machine (dialog operating).

5.5 Interface Mode 4 / 5

The output is configured as switching output, the input is configured as test input

'Safe State'	Interface Mode 4: Output ABD-OUT = H (high level) Interface Mode 5: Output ABD-OUT = L (low level)

The assignment to events can be configured. Default settings are:

Event / Operating mode	**Priority**	**Signal on ABD-OUT**	
		Interface Mode 4	**Interface Mode 5**
Liquid	Low	L	H
Air / Bubble	Medium	H	L
Internal error (self-test)	High	H	L
Serious fault (watchdog)	Highest	H	H **Note:** If the 'Bubble Test' is applied, this state could be reliably recognized as fault by the MDEV.
Start Mode	--	H **Note:** Note: After 'Init Interval' the 'Initial Test' will be performed. This includes test routines for checking output ABD-OUT. Level of output will change several times.	
Boot mode	--	UART Tx **Note:** Serial data are transmitted on demand. In inactive state = H	

Table 8: Output in Interface Mode 4 / 5

⚠ WARNING **Incorrect or insufficient communication between sensor and MDEV may have an impact on patient's safety.**

To reach a high level of safety it is essential, that the output is checked during operation with filled tubing. The 'Bubble Test' must be performed cyclically within the FTT of MDEV (see chapter 6.3 'Bubble Test').

Operating Mode	Specification of Input ABD-IN
Normal Mode	The input is configured as test input to release a ‘Bubble Test’. Interface Mode 4: L-active pulse Interface Mode 5: H-active pulse For the duration of active pulse the sensor simulates a bubble alarm. The output will react accordingly. The MDEV can verify proper signaling. The min. pulse width is 300 µs.
Start Mode	The input is configured after power on or after restart during ‘Init Interval’ as serial input Rx of UART. The ‘Init Interval’ takes approx. 1 s. During this period the sensor reacts to all commands. Such a way the Boot Mode can be always entered, independent of configuration.
Boot Mode	UART Rx **Note:** Serial data are transmitted on demand. In inactive state = H

Table 9: Input in Interface Mode 4 / 5

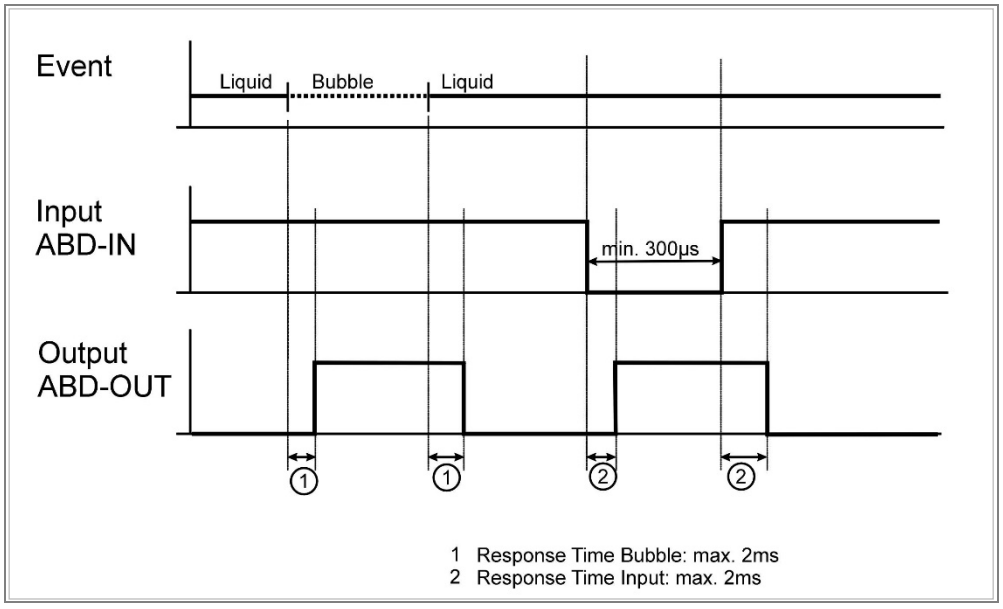


Figure 6: Signal on Output in Interface Mode 4

5.6 Interface Mode 6 / 7

The output is configured as PWM output, the input is configured as test input.

'Safe State' The 'Safe State' is defined as one of the following states:

- ABD-OUT = static H or static L
- The modulation of PWM output is set to the defined values (configurable): *for bubble* = 80 % or *fault* = 90 %.

The output signal can be configured. The default settings are:

Event / Operating mode	Priority	Signal on ABD-OUT
Liquid / small bubbles	Low	PWM signal: 20 … < 80 %, represents bubble size
Air / Bubble	Medium	80 %
Internal error (self-test)	High	90 %
Serious fault (watchdog)	Highest	Static H
Start Mode	--	H **Note:** After 'Init Interval' the 'Initial Test' will be performed. This includes test routines for checking output ABD-OUT. Level on output will change several times.
Boot mode	--	UART Tx **Note:** Serial data are transmitted on demand. In inactive state = H

Table 10: Input in Interface Mode 6 / 7

Operating Mode	Specification of Input ABD-IN
Normal Mode	The input is configured as test input to release a ‘Bubble Test’. Interface Mode 6: L-active pulse Interface Mode 7: H-active pulse For the duration of the active pulse the sensor simulates a bubble alarm. The output will react accordingly. The MDEV can verify proper signaling. The min. pulse width is 300 µs.
Start Mode	The input is configured after power on or after restart during ‘Init Interval’ as serial input Rx of UART. The ‘Init Interval’ takes approx. 1 s. During this period the sensor reacts to commands of serial interface. Such a way the Boot Mode can be always entered, independent of configuration.
Boot Mode	UART Rx **Note:** Serial data are transmitted on demand. In inactive state = High

Table 11: Input in Interface Mode 6 / 7

To reach a high level of safety it is essential, that during operation the output is checked with a filled tubing. This can be achieved by periodically performing the ‘Bubble Test’: the serial command CmdBubbleTest can be applied.

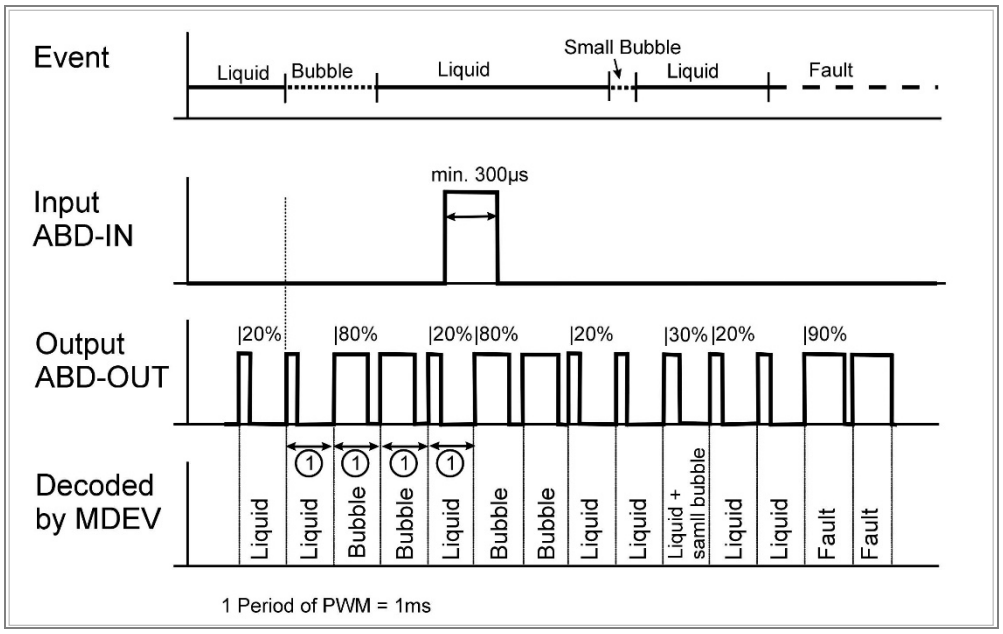


Figure 7: Signal on Output in Interface Mode 7

5.7 Interface Mode 8

The output is configured as PWM output, the input is configured as serial input

'Safe State'	The 'Safe State' is defined as one of the following states: • ABD-OUT = static H or static L • The modulation of PWM output is set to the defined values (configurable): *for bubble* = 80 % or *fault* = 90 %

The output signal can be configured. The default settings are:

Event / Operating mode	Priority	Signal on ABD-OUT
Liquid	Low	PWM signal: 20 … < 80 %, represents bubble size
Air / Bubble	Medium	80 %
Internal error (self-test)	High	90 %
Serious fault (watchdog)	Highest	Static H
Start Mode	--	High **Note:** After 'Init Interval' the 'Initial Test' will be performed. This includes test routines for checking output ABD-OUT. Level on output will change several times.
Boot Mode	--	UART Tx **Note:** Serial data are transmitted on demand. In inactive state = H

Table 12: Input in Interface Mode 8

The Input is configured as serial input of UART. The sensor is able to react to serial commands.

To reach a high level of safety it is essential, that during operation the output is checked with a filled tubing. This can be achieved by periodically performing the 'Bubble Test': the serial command CmdBubbleTest can be applied.

6 Information for the use in medical devices

For the use in medical devices (MDEV) special regularities apply. The following information and instructions partly refer to the previous chapters. Ensure, that you have read and understood the description of the interface and the interface modes.

The sensor offers different features to ensure a high level of patient safety:

- Fail-safe architecture, incl. self-test procedures and ‘Initial Test’.
- Secured data transmission via serial interface or PWM
- Switching output and periodical ‘Bubble Test’.

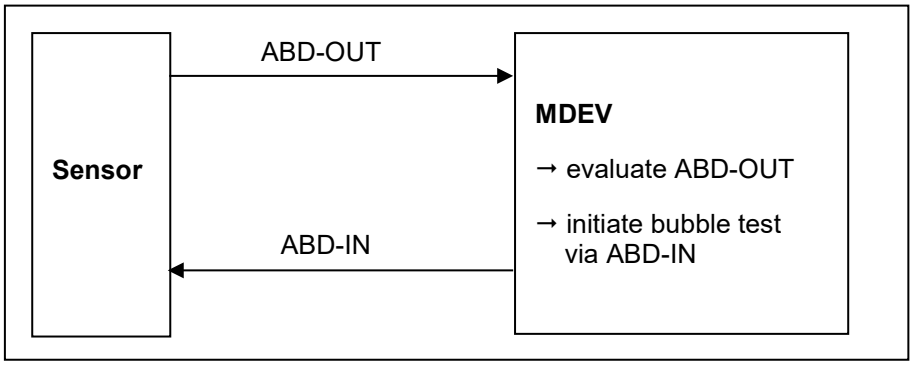
⚠ WARNING

The sensor has no direct access to controlling components, like e.g. pumps or valves.

It is the responsibility of the manufacturer of the MDEV to establish a safe and efficient interface between sensor and MDEV.

The sensor provides safety related information to the MDEV. It is the responsibility of the MDEV to read all safety related information the sensor provides and to react in an appropriate manner.

The SONOCHECK® ABD05 together with the MDEV and other components of the MDEV (like e.g. pumps or valves) form a system for the protection of the patient.



The sensor has no direct access to control components. All bubble detection results are transmitted to the machine via signal lines. An alarm handling must be implemented in the medical device.

The sensor provides different options to achieve a high degree of safety. Via software different input/output configurations for the interface between sensor and machine can be selected. The following chapters describe these different options.

6.1 'Fail-Safe Architecture'

The sensor is connected to the controlling and protective unit of the medical device (MDEV). It is classified under the Medical Device Directive 93/42/EEC as a class IIb product. The sensor design includes a 'Fail-Safe-Architecture'. Be aware, that a 'fail safe' sensor might fail, but this will always happen in a safe and secure way.

The sensor performs a 'Cyclical Self-Test' during operation. Furthermore, a black box test is implemented, the 'Initial Test'. This 'Initial Test' is executed after every restart or power-on.

⚠ WARNING Safety depends on the regular performance of tests. In case of permanent treatment the sensor has to be restarted in time interval of max. MFTT of MDEV = 24 h. Self-test cycle during measuring inside interval of max. = 0.3 s. The FTT of MDEV must be higher than 0.3 s.

The sensor supports different interfaces to the MDEV:

- Switching output and digital input ABD-IN ('Bubble Test'), to check the proper function of the output. The MDEV must periodically send a test signal. Thus the correct function of the switching output can be verified by the MDEV.
- A serial interface for a real-time transmission of data, including the bubble size and alarm state to the MDEV, and for controlling the sensor.
- Pulse-width-modulated output signal, with coded information about the bubble size.

6.2 'Initial Test' – enter boot mode

After Power-on or reset the sensor starts with the 'Init Interval'. It takes approx. 1 s. Within this period the sensors reacts to serial commands. In such a way the sensor can always be switched to the boot mode, independent of the interface configuration.

The 'Initial Test' follows the 'Init Interval'. This 'Initial Test' includes the test of the watchdog and of the output ABD-OUT. Sleeping failures or other second failures will be recognized by the sensor during this test.

6.3 'Bubble Test'

The test is implemented to check the correct functioning of output. The test has to be initiated by the MDEV. The procedure depends on the interface mode:

Mode 4 / 6: For the duration of active L (low signal) on input ABD-IN, the sensor simulates a bubble.

Mode 5 / 7: For the duration of active H (high signal) on input ABD-IN, the sensor simulates a bubble.

Mode 0 / 1 / 2 / 8: For the duration of a defined cycle count the sensor simulates a bubble. The count of cycles is transmitted as parameter in serial command. Each cycle takes 200 µs.

The output ABD-OUT will act appropriately and the behavior must be verified by the MDEV:

Mode 0/ 4: The switching output will be set to H (high) for the period of the assumed bubble

Mode 5: The switching output will be set to L (low) for the period of the assumed bubble

Mode 1/ 2: The transmitted serial data will indicate the assumed bubble

Mode 6/ 7/ 8: The PWM signal will be coded to indicate the assumed bubble

The bubble simulation is done by a reduction of the amplitude of the sent pulse (ca. -8dB). By the test is checked whether the sensor is functioning properly across all modules. This reduced signal is processed in the same way as a real bubble would be. That means, the sensor does not differentiate between a real bubble and the test.

NOTE!

To ensure, that the sensor is working properly, the MDEV must trigger the bubble test periodically, when the sensor is in the state 'Liquid' (sensor is working properly and no real bubbles in the sound path).

In all other states the test is effectless, since the sensor is already in 'Safe State' (static H).

6.4 Response time

The internal measuring cycle is 200 µs. Each reduction of the received acoustic signal will be evaluated. To avoid false alarms smoothing functions are implemented by parameter settings.

Switching Output

In each cycle of 200 µs the sensor evaluates the internal measuring signal. The switching output is set accordingly.

Smoothing	Influence on sensor response time
Recommended default settings	Response time to bubbles approx. 1 … max. 2 ms
Reduction by parameter settings	Down to min. 0.2 ms

Serial Output / PWM Output

The output interval via serial interface or PWM period is defined to 5 cycles (= 1 ms). Therefore the time from detecting bubble to a complete reception of signal by the superior controlling unit is given to 1 … max. 2 ms. Delay and dwell time on bubble occurrence can be configured on demand.

6.5 Indicating the measuring state with the LEDs

NOTE!
There is no optical or acoustical alarm. The sensor provides LEDs to signalize the state of bubble detection only for information. This LED must not be used as a part of an alarm messaging system.

The LEDs are freely configurable. They can be assigned to internal events, like bubble, fault or liquid, or they can be remote controlled by the MDEV in Interface Mode 0 / 1 / 2 and 8. The LEDs shall support the user during the treatment only for information, it must not be considered as an optical alarm.

The LED's can be set remotely by the medical device or automatically by the sensor itself.

6.6 Watchdog | Voltage monitor 3.3 V

The implemented watchdog has direct control of the ABD-OUT output signal. In case the 'Self-Test' detects a software or hardware failure, the watchdog sets the output to static H (high, 'Safe State'). If the output is configured as serial output or PWM output, the missing signals are clear detectable by the MDEV, as the continuously sent data or information on the respective output is missing.

Additionally the watchdog serves as voltage monitor for the operating voltage of 3.3 V, supplied to the microcontroller. In the case of overvoltage, the watchdog sets the output line ABD-OUT to static H (high, 'Safe State').

The full functionality of watchdog, including the voltage monitor is checked in the 'Initial Test' after power on or restart.

6.7 Safety / Directives

Item	Meaning
Architecture	Single channel architecture / Fail-safe
Software	Software developed acc. DIN EN 62304:2006, classified as “C” (Module Main).
Security	The sensor is developed according to standards and directives for medical devices: IEC 60601-1:2005.
‘Initial Test’ Self-test	The sensor performs an ‘Initial Test’ each time after power on or restart. The sensor has to be restarted by the medical device at least once a day, to ensure regular execution of the ‘Initial Test’. During normal operation, the self-test is performed at least one time in each 0.3 s time frame.
EMC	The sensor was designed to fulfill the requirements according to IEC 60601-1-2: 2007 (3rd edition). This was verified at SONOTEC® by realistic tests. The test must be performed by the manufacturer of the medical device in mounted state.
Electrical safety	Classified as applied part “CF” in combination with machine and tubing. Insulation between the outside of the housing and electrical components: > 1000 V AC.
Acoustical safety	The sensor fulfills the requirements according to EN 61157:2008, and is suitable for the use with human blood.
Restriction of hazardous Substances	The sensor fulfills the requirements according to the DIRECTIVE 2011/65/EU 8th of June 2011. The sensor is RoHS compliant, with permissible exemptions under EU-RoHS III 7cI and IV 15
Traceability	Traceability is ensured for all relevant parts of the sensor.

Table 13: Safety / directives SONOCHECK® ABD05

7 Optimal mounting position, installation and coupling

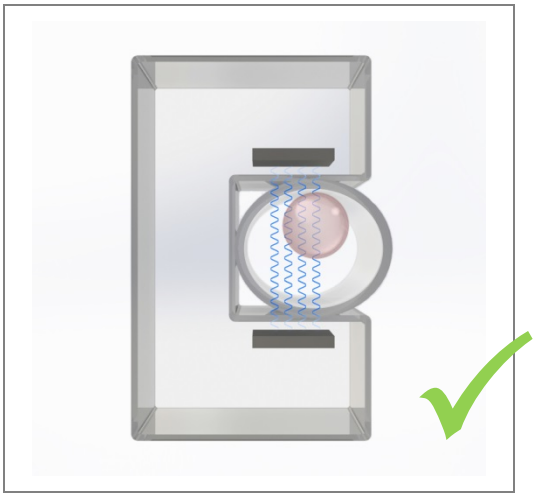
The SONOCHECK® ABD05 is designed as a component for the integration into machines and equipment, and must be mechanically and electrically incorporated into the controller of the device.

⚠ WARNING **No or low bubble sensitivity due to liquid in measuring channel poor coupling of ultrasound and incorrect installation possible.**

Failed bubble detection can pose a serious danger to patients.

Read the following chapters carefully and observe all requirements.

Recommended installation:



→ Tubing fits in the measuring channel: coupling surface is sufficiently large for the coupling of ultrasound, tube is not squeezed

→ Recommended sensor orientation: Bubbles move along the highest path in the tube within the sound path (see as well chapter 7.2 p. 30).

→ Tube and measuring channel are dry and clean.

⚠ Observe the safety regulations and the descriptions in the following chapters!

Figure 8: Good bubble sensitivity [symbolic representation: not in scale, blue wavy lines = ultrasonic path]

Please find the values for bubble sensitivity in case of correct coupling in chapter 3.4 Bubble sensitivity page 9.

For each application the sensor has to be adjusted to the applied tubing carefully. It is recommended to evaluate the bubble sensitivity for the application with the help of the ABD Monitor (optional accessories, contact our support).

7.1 Selecting the correct sensor version: measuring channel and tubing

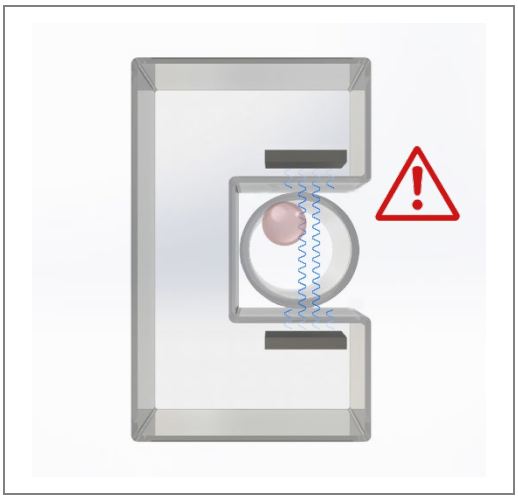
The reliable detection of bubbles and the bubble sensitivity depend among other conditions on the selection of the correct sensor version.

Only if the sensor channel matches the tube (depending on outer diameter and hardness), the coupling surface is large enough to couple sufficient ultrasound into the tube.

Tube installation to be avoided:

Low bubble sensitivity possible. → Bubbles might not pass the sound path (symbolized by the blue wavy lines) because of unfitting tube.

Amount of coupled ultrasound is too low:



Squeezed: parts of tube outside the channel:

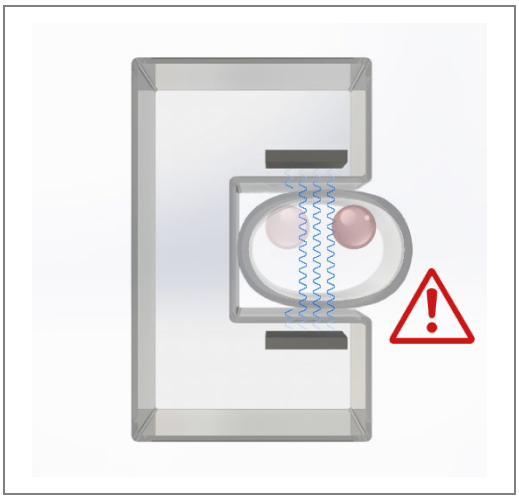


Figure 9 | 10: Tube too small / too large [symbolic representation: not in scale, blue wavy lines = ultrasonic path]

7.2 Defining correct installation position: sensor orientation and bubble sensitivity

Recommended sensor assembly:

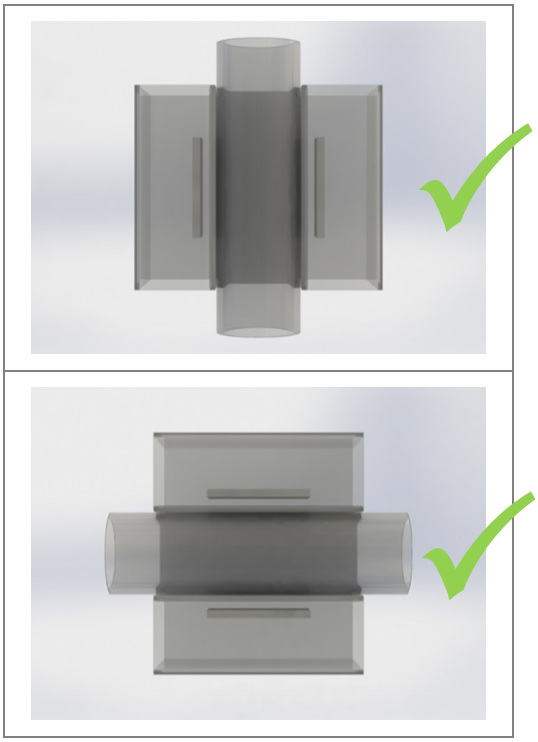


Figure 12 / 13: Good bubble sensitivity: vertical or horizontal position [side view]

Mounting position to be avoided:

Low bubble sensitivity possible.

→ Bubbles do not pass the sound path in the center of the measuring channel

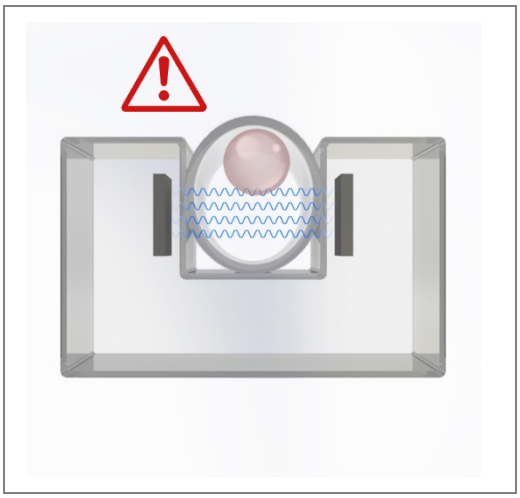
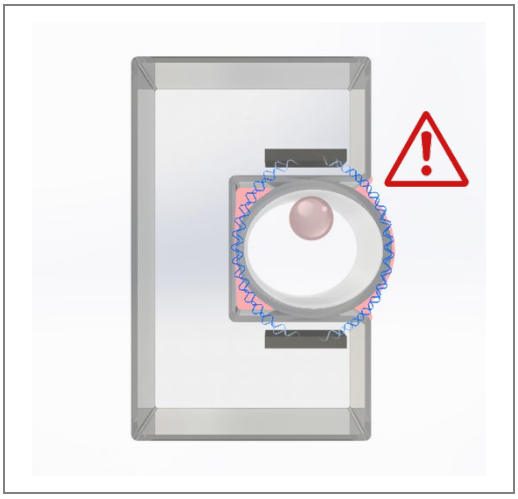


Figure 11: Poor bubble sensitivity due to sensor orientation [symbolic representation: not in scale, blue wavy lines = ultrasonic path]

7.3 Forbidden liquid in the sensor channel: correct coupling and bubble sensitivity

Coupling medium or liquids (cleaning agents) in sensor channel are strictly prohibited!



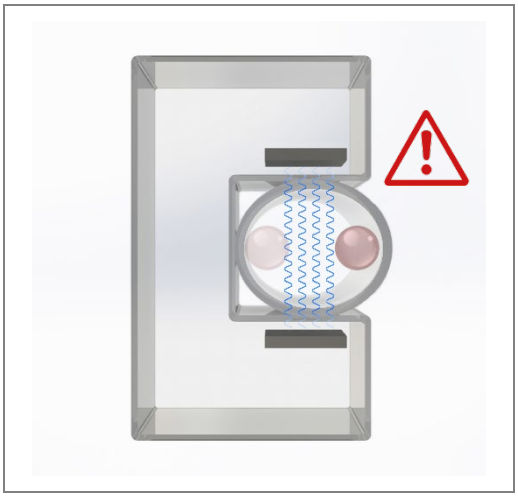
→ Ultrasound may be conducted past the tube to the receiver.

Sensor will not detect bubbles, empty tube or missing tube, because there is no signal reduction.

Figure 14: No coupling to tube because of liquid in sensor channel [symbolic representation, simplified: not in scale, blue wavy lines = ultrasonic path]

7.4 Bends in the tube: turbulences and bubble sensitivity

Recommendation for tube guidance



The tube guidance before and after the sensor might affect the path of bubbles.

→ Bends in the tube generate turbulences that change the bubble path. For reliable bubble detection avoid sharp bends of the tubing within 5 cm [approx. 2 inch] before and after the sensor.

Figure 15: No bubble detection because of turbulences caused by bends in the tube [symbolic representation: not in scale, blue wavy lines = ultrasonic path]

7.5 Mounting of the sensor

The sensor is mounted as follows:

Sensor version	Mounting
Rectangular	Recessed M4 threaded holes on the rear of the sensor (see drawing in 'Technical Data Sheet')
Circular	Appropriate clamping fixture (must be provided) to fasten the round sensor base

Table 14: Attachment of different sensor design types

NOTE!

During operation, the tubing must be securely held in the channel of the sensor. If this is not possible, an additional fixture must be installed.

7.6 Connecting the Sensor

⚠ WARNING **Risk of death or severe injury.**

Sensor damage can affect the safety of patients and operators..

There is no protection against reverse polarity implemented. In the case of reverse polarity the internal circuit is shortened and a high current occurs.

Protect the lines of power supply against overvoltage!

There is no fuse in the sensor. The power consumption must be limited in MDEV. The maximum current must be rated to 200 mA!

The connecting cable is fixed to the sensor (compare 'Technical Data Sheet').

Color	Connection
Red	Operating voltage +5 ± 0.2 VDC
Yellow	Control input (e.g. for reset / LED activation)
White	Output (5 V logic, TTL)
Blue	Ground (GND)
Shielding	Must be connected to ground (blue) at terminal

Table 15: Connecting the sensor

8 Operating the Sensor

All requirements in chapter ‘2 Safety regulations’ as well as the specifications in the ‘Technical Data Sheet’ must be adhered to.

⚠ WARNING

Risk of death or severe injury.
Operating errors can affect the safety of patients and operators.

The SONOCHECK® ABD05 must only be operated by trained staff. The manufacturer of MDEV is responsible to support operators with all necessary safety instructions as well as required information for a secure sensor handling, especially the instructions for tube insertion and error handling.

8.1 ‘Initial Test’ after power on or restart

After power on or restart the sensor is ready for measuring within approximately 1.5 seconds

NOTE!

The sensor starts with ‘Init Interval’, which takes approximately 1 second. Then the ‘Initial Test’ is performed, which takes max. 0.5 seconds. Afterwards the normal operation mode is started.

8.2 Inserting the tube

⚠ DANGER

Severe measurement error with high risk for patient safety possible.
Liquid in the measuring channel may conduct ultrasound. In this case the detection of bubbles, empty tube or missing tube may fail.

In the measuring channel must never be any liquid medium. Do never use any coupling medium.

ATTENTION

Incorrect tube insertion can damage the measuring channel as well as the tubing.

- It is only allowed to press the tubing by fingers. Never use sharp tools (e. g. screw drivers or scissors) to press the tubing into the channel.

Incorrect tube insertion can have an impact on sensor performance.

- Never stretch or bent the tube before placing it in the channel if not other recommended by SONOTEC®. This may alter the coupling stability and the sensor may produce incorrect or no results.

Observe the ‘Requirements for tube’ in the ‘Technical Data Sheet’.

If no tube is inserted or if the tube is empty, the LED in the channel lights up red.

1. Place the tube in the measuring channel. Press the tube slightly by hand until it meets the bottom of the channel.

↳ The sensor is ready for operation. When the tube is filled with liquid, the LED in the channel lights up green.

↳ If an air bubble is detected, the LED in the channel lights up red and sends defined signals to the connected device.

Foam in the liquid will be detected as air.

8.3 Monitoring sensor during operation

⚠ DANGER **Severe measurement error with high risk for patient safety possible.**
Liquid in the measuring channel may conduct ultrasound. In this case the detection of bubbles, empty tube or missing tube may fail.

In the measuring channel must never be any liquid medium. Ensure, that sensor and the measuring channel are always dry and clean and that the associated tubing stays intact during sensor operation.

⚠ WARNING **Risk of death or severe injury.**

Defect sensors can affect the safety of patients and operators.

In case of serious electrical device faults the sensor does not operate anymore. Disconnect the sensor immediately of power supply to prevent an overloading or overheating of internal corrupt components.

If there is visible damage (deformation or crack in housing and measuring channel, LED is not illuminated) or if malfunctions indicate, that the equipment is not operating, take the sensor out of operation immediately.

Replace the sensors. Defect sensors are no longer permitted for usage.

NOTE!

Continuous use and significant temperature fluctuations change the flexibility of the tubing, the propagation of the ultrasonic signal and therefore the acoustic conditions. The sensor automatically adjusts itself to these changes.

In case of permanent treatment the sensor has to be restarted in time interval of max. 24 h.

⇨ **Restart the sensor after 24 h of use to perform the implemented self-test routines.**

Avoid any pulling or torsion movements on tube during operation.

8.4 Cleaning and disinfection

⚠ DANGER **Severe measurement error with high risk for patient safety possible.**
Liquid in the measuring channel may conduct ultrasound. In this case the detection of bubbles, empty tube or missing tube may fail.

In the measuring channel must never be any liquid medium. Do never clean or disinfect, when the operating voltage is applied. Put the sensor back into operation only when measuring channel and tube are completely dry and clean.

⚠ WARNING **Risk of death or severe injury.**
Defect sensors can affect the safety of patients and operators.

Incorrect cleaning can damage the SONOCHECK® ABD05 (e.g. measuring channel, potting, wires).

Cleaning is prohibited:

- in a steam sterilizer, with hot steam in general or by ethylene oxide, gamma- or beta-sterilization
- with white spirit, acetone or acetone-based solutions
- by immersion in solvents or other liquids.

The sensor is not intended to be sterile.

It is intended to clean the sensor routinely with commercially available cleaning agents and disinfectants (wipe disinfection). Customary spray disinfectants can be used for disinfection, if necessary.

9 Maintenance, service, troubleshooting and repairs

The SONOCHECK® ABD05 is maintenance-free.

9.1 Service and troubleshooting

⚠ WARNING **Risk of death or severe injury.**
Defect sensors can affect the safety of patients and operators.
If there is visible damage or if malfunctions indicate, that the equipment is not operating, take the sensor out of operation immediately and disconnect the power supply.

The sensor has self-test routines and sets defined output signals if an error is detected. See chapter 6 page 24 for details.

The LED in the channel lights up blue, if an error occurs.

The error handling can be adapted to individual requirements.

In case of major problems, please contact our support:

Manufacturer – Headquarters Germany

SONOTEC GmbH
Nauendorfer Str. 2
06112 Halle (Saale), Germany

Tel.: +49 (0)345 / 133 17- 0
sonotec@sonotec.de
www.sonotec.eu

Americas

SONOTEC US Inc.
190 Blydenburgh Rd
Suite 8, 2nd Floor
Islandia, New York 11749, USA

Tel.: +1 631 / 415 4758
sales@sonotecusa.com
www.sonotecusa.com

Keep available:

- Sensor type | HW Version | serial number.
  (Please find the information on the type label; see as well chapter 3.8 Sensor identification)
- If you use ABD Monitor software and if available: exported measurement data
- Brief description of failure.

For service and diagnostics the sensors can be connected via USB Data Converter to a computer. Using computer software ABD Monitor you can observe the behavior of sensor and the reaction to bubbles. For debugging or archiving you can export data into Excel or Text files.

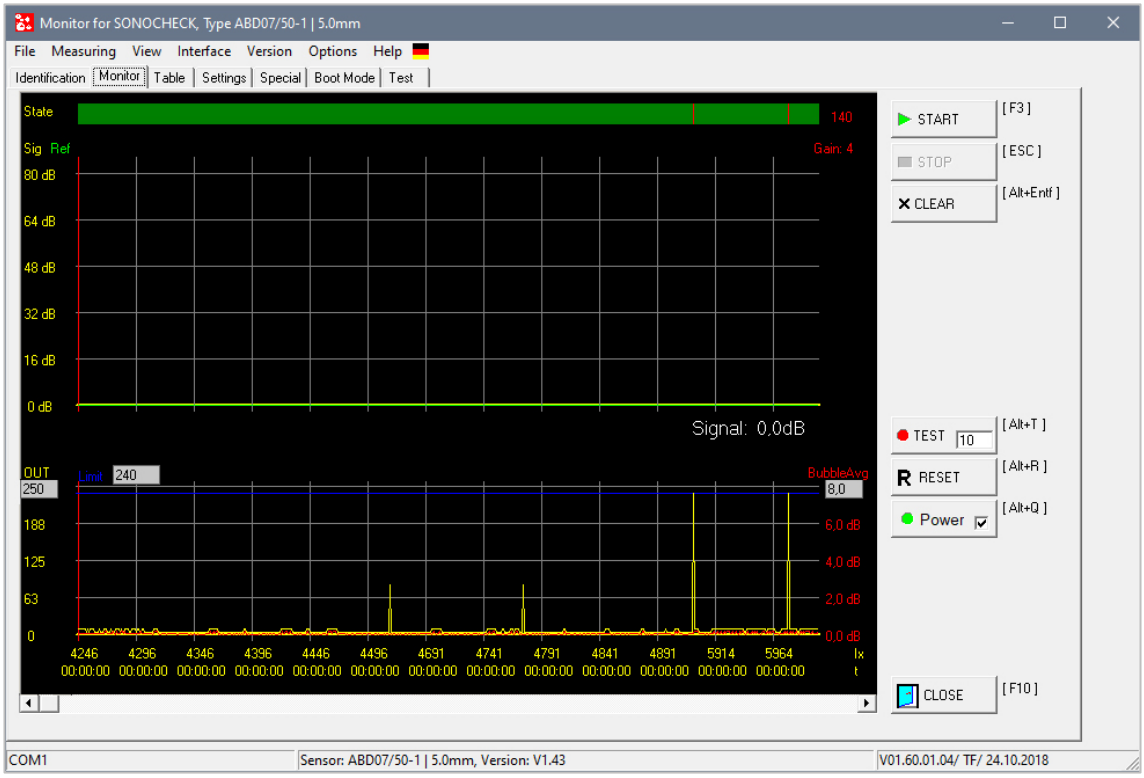


Figure 16: Screenshot of ABD Monitor - typical tracking of bubbles: Tiny bubble (no alarm) / small bubble (alarm is just released), for released alarm see the status bar

For details see ‘SONOCHECK® Notes to Settings’.

9.2 Repairs

⚠ WARNING **Death or severe injury possible!**

Incorrect repairs of the SONOCHECK® ABD05 sensor can damage the sensor and constitute a hazard for the safety of patients and operators.

The sensor must never be opened. The sensor does not contain any user-serviceable parts. Repairs must be carried out by the manufacturer. Any kind of sensor modification is prohibited.

10 Disposal

The sensor can be recycled as normal electronic scrap. The sensor does not include any dangerous substances.

Electrical and electronic equipment can pose serious health and environmental risks if it is not properly disposed of. For this reason it must not be disposed of in domestic waste according to WEEE directive 2012/19/EU (Waste Electrical and Electronic Equipment Directive) but separately at designated collection points or has to be sent back to the manufacturer.

The following symbol on the device refers to the legal obligation in Germany to arrange a separate disposal for electronic equipment. It has to be handled according to specific processes (e.g. concerning the batteries or circuit boards) to ensure a safe, environmentally-friendly recycling or the separate disposal of different device components.

The taking back of used equipment is regulated differently in the various countries and regions. Consult the local authorities and other competent public authorities to inform yourself about the taking back conditions of commercially used electrical equipment.

The sensor does not contain harmful substances that have to be labelled separately regarding the disposal as mercury (Hg), cadmium (Cd), lead (Pb) or hexavalent chromium (e.g. in galvanized parts or circuit boards).

11 Personal notes