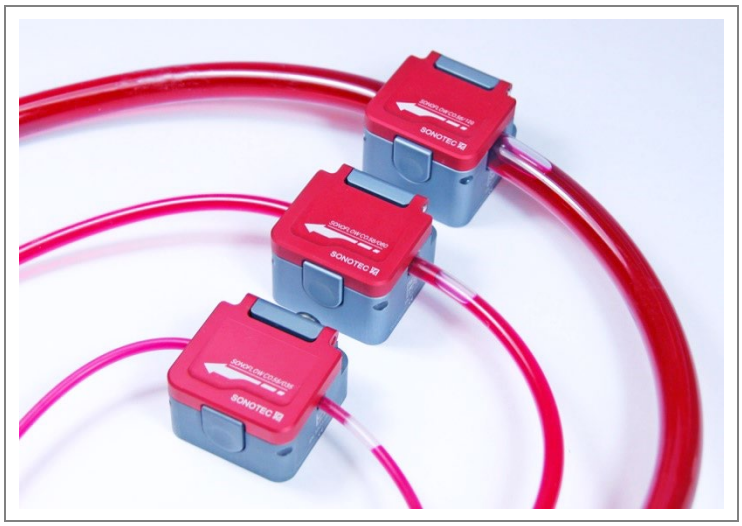


The sensor series SONOFLOW CO.56 – designed as clamp-on-sensors – measures the flow rate of liquids and detects bubbles in plastic tubes of different diameters or materials within a few milliseconds.

The flow-bubble sensors have no contact to the medium or product and are suitable for applications in fields with strict hygienic standards e.g. the medical industry. The ultrasonic sensors with complete built-in electronics can be easily integrated into machines or apparatuses.

In addition to our standard sensors, we also manufacture customer-specific solutions regarding housing materials, colors, mechanical dimensions, output specifications and parameter settings.

Overview sensors

Specification SONOFLOW	Order-No.	Max. Flow Range	Measuring channel (☐ CH = CW)	Dimensions (L × W × H)	Weight
CO.56/035	200 04 0009	3 000 ml/min	3.5 mm	44 × 44 × 28 mm	120 g
CO.56/044	200 04 0010	5 000 ml/min	4.4 mm	44 × 44 × 30 mm	125 g
CO.56/060	200 04 0011	6 000 ml/min	6.0 mm	44 × 44 × 32 mm	130 g
CO.56/080	200 04 0012	8 000 ml/min	8.0 mm	44 × 44 × 34 mm	135 g
CO.56/120	200 04 0013	12 000 ml/min	12.0 mm	44 × 44 × 36 mm	140 g
CO.56/140	200 04 0014	14 000 ml/min	14.0 mm	44 × 44 × 38 mm	145 g

Tubing properties

The selection of the right sensor depends on tubing dimensions as well as on tubing properties.
If possible, please provide us with a tubing sample (minimum length of 50 cm).

Specification SONOFLOW	Tubing OD	Tubing ID	Factory Calibration Tubing
CO.56/035	4.0 mm	3.0 mm	PVC, 3500304 [1]
CO.56/044	5.0 mm	3.0 mm	PVC, 702101031099 [2]
CO.56/060	7.0 mm	5.0 mm	PVC, 702101051099 [2]
CO.56/080	9.0 mm	6.0 mm	PVC, 702101061599 [2]
CO.56/120	14.0 mm	10.0 mm	PVC, 702101102050 [2]
CO.56/140	16.0 mm	12.0 mm	PVC, 702101122050 [2]

Manufacturer: 1 Deutsch & Neumann GmbH, 10585 Berlin (Germany) | 2 ESSKA.de GmbH, 20537 Hamburg (Germany)

Flow accuracy / repeatability

Specification SONOFLOW	**Flow measurement accuracy after 30 min sensor warm-up, no thermal gradients, trained staff for removing / insertion of tubing.** Flow measurement repeatability at constant conditions, after 30 min warm-up, no thermal gradients, lid remains closed, no removing / inserting of tubing, no movements of sensor or tubing.			
CO.56/035	< 300 ml/min:	**± 15 ml/min** ± 6 ml/min	≥ 300 ml/min:	**± 5 %** [3] ± 2 % [3]
CO.56/044	< 500 ml/min:	**± 25 ml/min** ± 10 ml/min	≥ 500 ml/min:	**± 5 %** [3] ± 2 % [3]
CO.56/060	< 600 ml/min:	**± 30 ml/min** ± 12 ml/min	≥ 600 ml/min:	**± 5 %** [3] ± 2 % [3]
CO.56/080	< 800 ml/min:	**± 40 ml/min** ± 16 ml/min	≥ 800 ml/min:	**± 5 %** [3] ± 2 % [3]
CO.56/120	<1 200 ml/min:	**± 60 ml/min** ± 24 ml/min	≥ 1 200 ml/min:	**± 5 %** [3] ± 2 % [3]
CO.56/140	< 1 400 ml/min:	**± 70 ml/min** ± 28 ml/min	≥ 1 400 ml/min:	**± 5 %** [3] ± 2 % [3]

3 of reading

Zero point stability: Flow measurement drifts less than 0.02 l/min in 24 h at zero flow.

Calibration and conditions of use

Calibration	Sensors are factory calibrated under the following conditions: ▪ PVC tubing as listed in table above (Tubing properties) ▪ Water at 23 °C ± 2 °C ▪ Warm up: at least 30 min (to compensate thermal effects) ▪ Zero calibration just before measurement procedure ▪ Normal pressure Calibration to customer tubing, fluid, flow range, temperature, etc. on request.
Media	Water, saline, human blood or other acoustically transparent liquids ⚠ **NOTE**: SONOTEC does not operate with human blood within the company premises. With respect to calibration, the difference between water and saline solution is negligible. For applications with blood (hemoglobin: Hb = 9 ± 2 g/dl) some special factors/settings can be modified after calibration (→ observe the instruction in the next chapter.) ⚠ **CAUTION:** If the sensor is applied to measure the flow of sensitive liquids, like human blood, the maximum flow velocity of fluid inside the tubing and inside the measuring channel shall be considered carefully. The blood cells could be harmed or damaged if transported at high velocities. It is the responsibility of the manufacturer of medical device to assess if there is a potential risk.
Conditions of use	⚠ **CAUTION:** The sensors need to be adjusted individually to special operating conditions ▪ in case of operation with tubing that is not listed in the table 'Tubing properties', since the accuracy of flow measurement and bubble detection can be affected and ▪ if the sensor is intended to measure with human blood at 37 °C and hemoglobin between 6 g/dl to 12 g/dl. Please contact us for details! ⚠ **NOTE:** Generally, the sensors are able to measure liquids in an extended operating temperature range of +1 to +50 °C and to measure blood within the ranges of Hb = 0 to 6 g/dl or Hb = 12 to 18.5 g/dl, but with limited accuracy only.

Accuracy depends on tubing, temperature, fluid properties and other conditions. Absolute accuracy is influenced by zero stability, resolution and zero offset effects. For details see next chapter.

Bubble detection and sensitivity

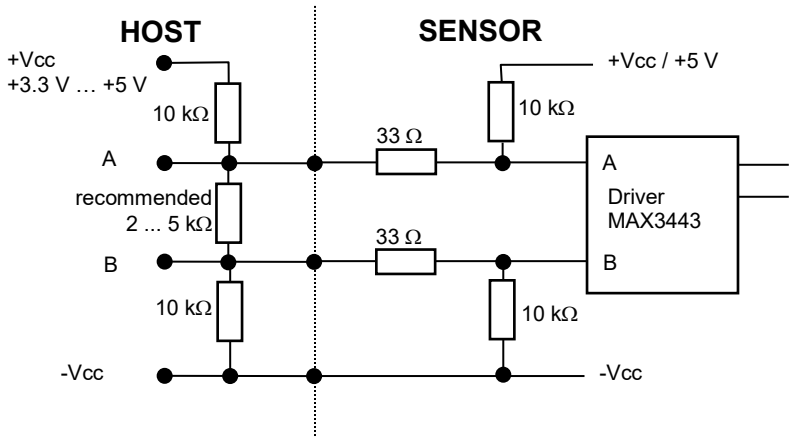
If bubbles with a size larger than the threshold are detected, the bubble alarm is set. The threshold depends on the sensor type. The sensitivity depends on the diameter of the tube and the mounting position.

Bubble sensitivity	Bubbles larger than the alarm threshold are detected. Larger amounts of foam in the liquid will be detected as air.	
	Specification SONOFLOW	**Threshold alarm**
	CO.56/035	2.0 mm [4]
	CO.56/044	2.0 mm [4]
	CO.56/060	3.5 mm
	CO.56/080	6.5 mm
	CO.56/120	9.0 mm
	CO.56/140	10.0 mm
Reaction time	Internal evaluation of bubbles within intervals of max. 1.6 ms	
Response time	< 10 ms; faster response time possible if needed	

4 Values valid in limited flow range of max. 900 ml/min, values for higher flow rate on request.

Technical data

SONOFLOW CO.56 **Flow-Bubble Sensor for liquids**	
Measuring method	Ultrasonic transit time difference measurement in transmission with two redundant measurement paths, dry coupling, no couplant required
Mounting	Fixed installation: 4 fixing holes M4, 8 mm deep
Tube insertion	▪ Tube must be put in manually without tools. Lid must be closed. ▪ No couplant (e.g. gel) permitted. ▪ Prevent excessive bending or tube compressing close to sensor (10 × inner tube diameter before and 5 × inner tube diameter behind the sensor)
Sensor materials	Measuring channel: PMMA black Housing: aluminum, anodized grey/red Hinge: stainless steel 1.4301 Potting compound (not accessible after mounting): PUR (blue)
Labelling (laser engraving)	▪ Arrow on lid indicating flow direction ▪ On side of housing (sensor type, hardware version, serial number, manufacturer with address)

Operating voltage	5 VDC +0.5/-0.1 VDC Internal suppressor diode to protect the sensor: Type: SMBJ5.0A | nom. 5 V | 600 W peak pulse power dissipation Inverse-polarity protection: In case of inverse polarity, the sensor is protected by the diode. A high short-circuit current flows.
Current consumption	< 150 mA ⚠ **ATTENTION**: Current must be limited externally to max. 250 mA (e.g. fuse) to minimize the risk of heating / fire as a consequence of a short-circuit.
RS-485 interface (SONOTEC protocol)	Half-duplex operation / 115.200 baud / no parity / 1 stop bit / no handshaking Dialog mode (on demand): Machine is intended to ask results cyclically, sensor does not have an own alarm equipment) Query cycle: 20 … 200 ms (typically) ⚠ **NOTE:** Description of the serial protocol for details upon request.  Recommended electrical connection of the RS-485 interface
RS-485 bus operation	Bus operation supported up to 12 subscribers, default address is #01 (can be changed with the help of SONOFLOW Monitor, permitted are addresses from #01 … #12)
Maintenance	Maintenance-free
Ambient temperature	+10 … +50 °C (see also chapter ‘Calibration and conditions of use’)
Media temperature	+10 … +50 °C, other temperatures available on request
Storage & transportation temperature	-20 ... + 70 °C
Humidity	10 … 95 % relative. humidity (not condensing)
Atmospheric pressure	620 hPa … 1060 hPa
Degree of protection	IP67

Scope of supply	▪ SONOFLOW CO.56/xxx flow-bubble sensor according to specification ▪ User documentation
Optional accessories	Calibration report
	SONOFLOW Monitor Software for setting parameters, recording measurements and update of sensor software consisting of ▪ USB Data Converter (type 012), for the connection to a computer ▪ USB cable, type A-B, length 2 m ▪ CD with Software SONOFLOW Monitor and driver for Windows

Directives and standards

Medical safety	Medical safety: IEC 60601-1 3rd edition
Electrical safety	For MEANS OF PATIENT PROTECTION (MOPP) according to IEC 60601-1: The protection from SECONDARY CIRCUITS requires an installation of a SELV (Safety Extra-Low Voltage) converter prior to connecting the sensor onto 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 metallic housing with > 1000 VAC. It applies 2 × MOPP, secondary circuit, according to IEC 60601-1, Table 6. The classification as Applied Part “CF” in combination with the medical device and tubing is possible, depending on the application.
Electromagnetic compatibility	EMC tests must be performed by manufacturer of medical device after built-in. Precondition for EMC is the safe, functional grounding of housing by means of screws or connection line. Pretests have been performed by SONOTEC acc. IEC 60601-1-2, 4th edition. ▪ IEC 61000-4-3 (electromagnetic immunity) 10 V/m | 80 MHz to 2.7 GHz | 80 % AM at 1 kHz ▪ IEC 61000-4-3 (electromagnetic immunity, wireless frequencies) Section 8.10 ▪ IEC 61000-4-8 (magnetic fields) 30 A/m | 50 Hz und 60 Hz ▪ IEC 55011 class B / CISPR 11 (electromagnetic emission), tests according to IEC 55016: 30 … 1000 MHz | 30 dBµV @ 10 m ▪ IEC 61000-4-2 (electrostatic discharges) ± 8 kV direct and indirect contact | ± 15 kV air ▪ IEC 61000-4-4/ IEC 61000-4-5/ IEC 61000-4-6: not applicable Rationale: Sensor doesn‘t provide a patient-coupled line and the cable length is below 3 m.
Further standards	▪ Software development: DIN EN 62304, class C ▪ RoHS: 011/65/EU, exception: III 7cl/ IV 15, RoHS (EU) 2015/863 ▪ Acoustic emission: IEC 61157, suitable for use on human blood

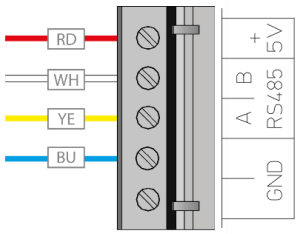
Use in medical devices and safety

The manufacturer of the medical device is responsible for the medical approval. SONOTEC as a component supplier supports the approval process and shares documents with a notified body (3rd party).

Medical safety	▪ PESS (Programmable Electrical Sub System) according to the IEC 60601. ▪ One-channel architecture / Fail Safe ▪ Cyclical self-tests of safe functionality of all essential components ▪ Output secured by watchdog: in case of major errors (for example software crashes), the output will be blocked ▪ After power on or software reset: initial test procedure (check of output circuit, watchdog functionality and locking of output)
Self-test	FTT: 0.7 s (cycle time of self-test), MFTT: 24 h (tests after power on or restart only; sensor must be restarted within the defined period)
Settings	Each sensor is factory calibrated. Each sensor has individual settings regarding zero adjustment and characteristics of flow and the sensor specific identification character (e.g. serial number of the sensor, type codes).
Use in medical applications	⚠ **CAUTION:** Sensors are normally delivered in a state that is **NOT FOR CLINICAL USE**, since the settings are not protected against any changes. Proper settings of the sensor are essential for medical safety. All settings must be adjusted and verified carefully according to the medical application. The settings must be protected against unintentional changes. Hence, the appropriate self-test routines must be enabled. Please contact us to ensure a delivery of sensors with specified, verified settings!
Special applications	⚠ **ATTENTION**: The sensors are not suitable to be applied in immediate proximity to operating surgical devices using high energized pulses e.g. electrosurgical knifes (radio frequency cautery). The sensors might be destroyed, the values of flow could be affected or the sensor could raise false bubble alarm due to the strong radiation along the tubing. Customized sensors with additional protection are available.

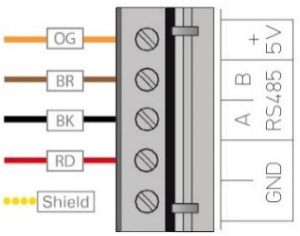
Type HW V1.0

Electrical connection			
Type	4 × wire, LiY / 0.14 mm²		
Length	1.0 m ± 0.1 m		
Connector	WECO terminal block		
Assignment	**Color**	**Connection**	**WECO Terminal**
	Red	+5 V	1
	White	RS-485 B	2
	Yellow	RS-485 A	3
	Blue	GND	4
			5
Grounding	⚠ **NOTE:** The metallic part of the housing of sensor must be connected to ground of machine by means of mounting or by shielded connection line! Metallic front of machine: Grounding by mounting screws. If the panel is not conductive, an additional grounding line has to be fixed on one of the four screws.		

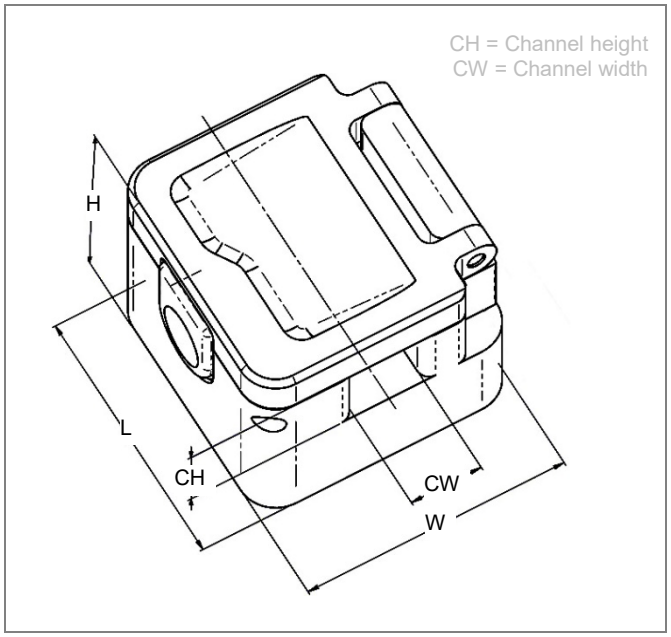


Type HW V1.1

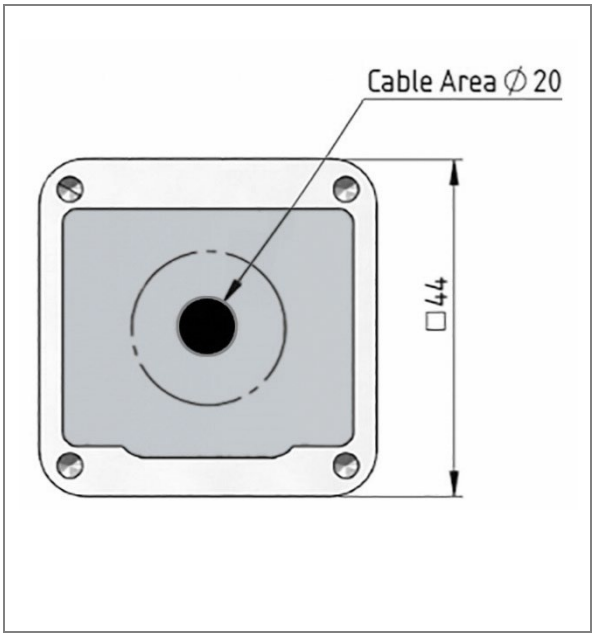
Electrical connection			
Type	UL-LifYDY / 5 × 0.08 mm² / shielded / Ø 3.5 ± 0.1 mm		
Length	2.5 m ± 10 cm		
Connector	WECO terminal block		
Assignment	**Color**	**Connection**	**WECO Terminal**
	Orange	VCC	1
	Brown	RS-485 B	2
	Black	RS-485 A	3
	Red	GND	4
	Shield / Yellow	Housing of sensor	5
Grounding	⚠ **NOTE:** The metallic part of the housing of sensor must be connected to ground of machine by means of mounting or by shielded connection line! Metallic front of machine: Grounding by mounting screws | Plastic front of machine: Grounding by connecting the shield of connection line to ground.		



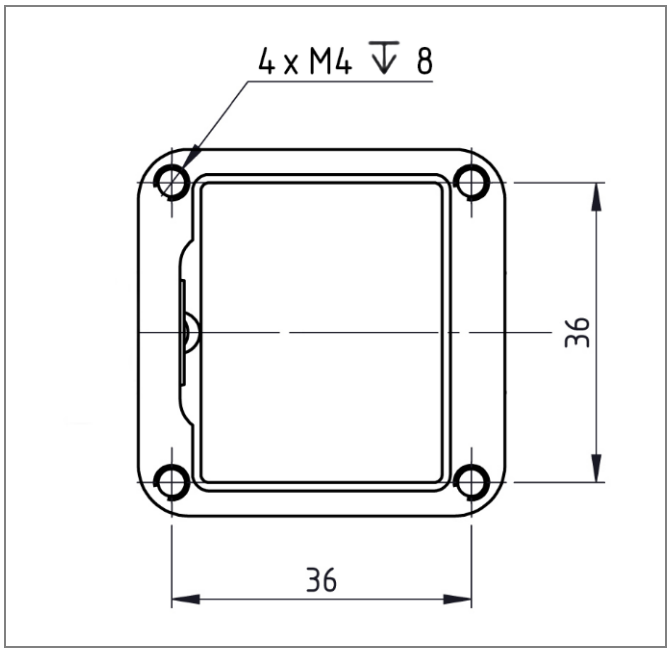
Technical drawings



Dimensions SONOFLOW CO.56



Rear side of sensor



Dimensions of drill holes for mounting

Drawings are not to scale. Dimensions in mm, unless otherwise specified. Information is subject to change without notice!

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Sensors of the **SONOFLOW CO.56 Pro V1.0** series are used to measure the flow rate of liquids and to detect air bubbles in tubes of various diameters.

The lightweight non-invasive sensors with small form factor are intended to be clamped on the tubing, free-hanging or built into a medical device. Specifically designed for implementation in medical devices such as cardiopulmonary bypass and dialysis machines the sensors fulfill high medical safety standards. Via an RS-485 interface the sensors are ready for bus operation of up to 12 devices.

Overview sensors

Specification SONOFLOW CO.56 Pro V1.0	Order-No.	Max. flow range	Channel width	Dimensions L × W × H	Max. weight
1/4″ × 1/16″	200 04 0037	4 000 ml/min	8.2 mm	46 × 35 × 32 mm	105 g
1/4″ × 3/32″	200 04 0038		10 mm	46 × 35 × 34 mm	100 g
3/8″ × 3/32″	200 04 0039	10 000 ml/min	12.3 mm	46 × 35 × 36 mm	110 g

Tubing properties

The selection of a suitable sensor depends on tubing dimensions as well as on tubing properties. A tubing sample (minimum length 1 m) for a first evaluation in the SONOTEC lab is reqired.

Material: PVC
Manufacturer: RAUMEDIC-ECC-Blood Line

Specification SONOFLOW CO.56 Pro V1.0	Tubing OD	Tubing ID	Wall thickness
1/4″ × 1/16″	3/8″	1/4″	1/16″
1/4″ × 3/32″	7/16″	1/4″	3/32″
3/8″ × 3/32″	9/16″	3/8″	3/32″

Other tube materials and diameters upon request. Contact our service.

Calibration and conditions of use

Calibration	Sensors are factory calibrated under the following conditions: ▪ PVC tubing as listed in table above (Tubing properties) ▪ Water at 23 °C ± 2 °C ▪ Warm up: at least 30 min (to compensate thermal effects) ▪ Zero calibration just before measurement procedure ▪ Normal pressure Calibration to customer tubing, fluid, flow range, temperature, etc. on request.
Media	Water, human blood or other acoustically transparent liquids ⚠ **NOTE**: SONOTEC does not operate with human blood within the company premises. With respect to calibration, the difference between water and saline solution is negligible. For applications with blood (hemoglobin: HB = 6 g/dl to 12 g/dl) some special sensor factors/settings can be modified after calibration (→ observe the instruction in the next chapter.)
Conditions of use	⚠ **CAUTION:** The sensors need to be adjusted individually to special operating conditions ▪ In case of operation with tubing not listed in the table 'Tubing properties', because the accuracy of flow measurement and bubble detection could be affected and ▪ If the sensor is intended to measure human blood at normally 37 °C and hemoglobin between 6 g/dl and 12 g/dl. Contact our service for more information!
	⚠ **NOTE:** Generally, the sensors are able to measure under the following conditions, however with limited accuracy only: ▪ Liquids in an extended operating temperature range of +1 to +50 °C ▪ Blood within the extended range of Hb = 0 to 18.5 g/dl

Accuracy depends on tubing properties, temperature, fluid properties and other conditions. Absolute accuracy is influenced by zero stability, resolution and zero offset effects. For details see next chapter.

Flow accuracy and repeatability

Specification SONOFLOW CO.56 Pro V1.0	Flow measurement accuracy after 30 min sensor warm-up, no thermal gradients, normal removing / inserting of tubing. Flow measurement repeatability at constant conditions, after 30 min warm-up, no thermal gradients, lid remains closed, no removing / inserting of tubing, no movements of sensor or tubing.			
1/4″ × 1/16″	< 400 ml/min:	**± 20 ml/min** ± 8 ml/min	≥ 400 ml/min:	**± 5 %*** ± 2 %*
1/4″ × 3/32″				
3/8″ × 3/32″	< 1 000 ml/min:	**± 50 ml/min** ± 20 ml/min	≥ 1 000 ml/min:	**± 5 %*** ± 2 %*

* of reading

Zero point stability: Flow measurement drifts less than 0.02 l/min in 24 h at zero flow.

Note: The above stated accuracy rates can only be achieved if the tolerance of the inner diameter of the used tubing is within ± 1.25 %.

Bubble detection and sensitivity

If air bubble sizes larger than the set threshold are detected a bubble alarm is generated. The set threshold depends on the sensor type. The bubble sensitivity depends on the actual application, e.g. tube properties, mounting position.

	Specification SONOFLOW CO.56 Pro V1.0	Bubble threshold for alarm (Diameter of sphere)
Bubble threshold for bubble alarm (adjustable, contact our service)	**1/4″ × 1/16″**	4 mm
	1/4″ × 3/32″	5 mm
	3/8″ × 3/32″	6 mm
Reaction time	Internal evaluation of bubbles within intervals of max. 1.6 ms	
Response time	< 10 ms; faster response time possible if needed	

Technical data

SONOFLOW CO.56 Pro V1.0 Flow-Bubble Sensor for liquids	
Measuring method	Ultrasonic transit time difference measurement in transmission with two redundant measurement paths, dry coupling, no couplant required
Mounting	Clamped on the tube, hanging freely or mounted into a medical device (cable outlet at the side of the sensor)
Tube insertion	▪ Tube must be put in manually without tools. Lid must be closed. ▪ No couplant (e.g. gel) permitted. ▪ To avoid any influences onto the measurement results due to possible turbulences prevent excessive bending or tube compressing close to sensor position (10 × inner tube diameter before, 5 × inner tube diameter behind the sensor)
Sensor materials	Measuring channel: PMMA black, Housing: aluminium, anodized black (optional: individual colors) Identification plate with label: stainless steel Bend relief and cable: plastics black
Labeling	Laser engraving: arrow on lid indicating flow direction; size of specified tube on lid inside; Identification plate: label on rear side (sensor type, hardware version, serial number, manufacturer including address)
Operating voltage	5 VDC +0.5/-0.1 VDC Internal suppressor diode to protect the sensor: Type: SMBJ5.0A | nom. 5 V | 600 W peak pulse power dissipation Inverse-polarity protection: In case of inverse polarity, the sensor is protected by the diode. A high short-circuit current flows.
Current consumption	< 150 mA Power supply of the sensor needs a current limiter, e.g. a fuse (minimize risk of a heating / fire as consequence of short-circuit) ⚠ **ATTENTION**: Current must be limited externally to max. 250 mA (e.g. fuse)

Electrical connection

Type: UL-LifYDY / 5 × 0.08 mm² / shielded / Ø 3.5 ±0.1 mm
Length: 2.5 m (± 10 cm), strain reliefs at each end, WECO terminal block for connection of SONOFLOW Monitor

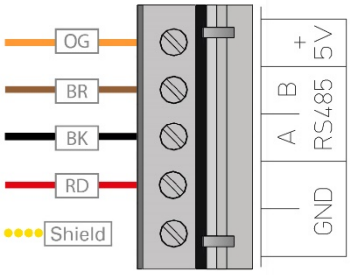
Grounding

⚠ **ATTENTION:**

The metallic housing of sensor must be grounded via the shield of connection line. Otherwise the measuring values of sensor could be affected by EMC and the sensor is not protected against ESD.

Assignment

Colour	Connection	WECO Terminal
Orange	VCC	1
Brown	RS-485 B	2
Black	RS-485 A	3
Red	GND	4
Shield / Yellow	Housing of sensor	5



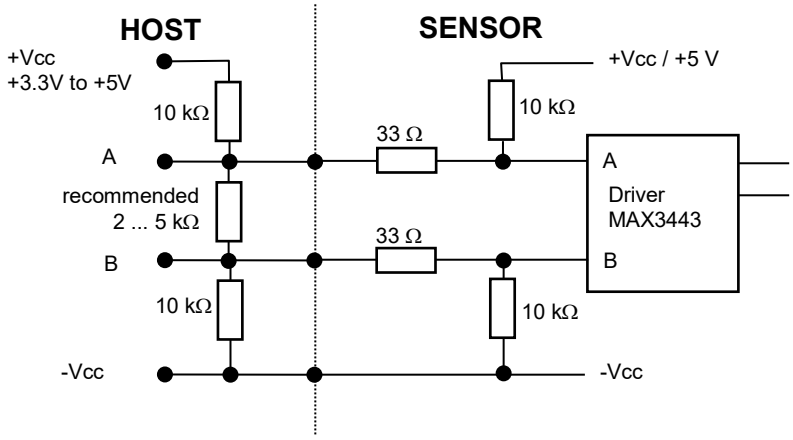
RS-485 interface

(SONOTEC protocol)

Half-duplex operation / 115.2 kbaud / 8 bit data / 1 stop bit / no parity bit / no handshaking

Dialog mode (on demand): machine is intended to ask results cyclically, sensor does not have an own alarm equipment)
Query cycle: 20 … 200 ms (typically)

NOTE: Description of serial protocol with details upon request.



RS-485 bus operation

Bus operation supported up to 12 subscribers, default address is #01 (can be changed with the help of SONOFLOW Monitor, permitted are addresses from #01 … #12)

Maintenance	Maintenance-free
Operating temperature	+10 … +50 °C (see also chapter ‘Calibration and conditions of use’)
Ambient / Media temperature	+15 ... +43 °C
Storage / Transportation temperature	-20 ... +60 °C
Humidity	10 … 95 % relative humidity (not condensing)
Atmospheric pressure	620 … 1060 hPa
Degree of protection	IP67, the sensor is completely potted
Scope of delivery	• SONOFLOW CO.56 Pro V1.0 • User documentation (‘Technical Data Sheet’)
Optional accessories	• Calibration report
	SONOFLOW Monitor Software for setting parameters, recording measurements and update of sensor software consisting of • USB Data Converter (type 012), for the connection to a computer • USB cable, type A-B, length 2 m • Link to Software SONOFLOW Monitor and driver for Windows • User documentation (‘Operating Manual’)

Directives and standards

Medical safety	Medical safety: IEC 60601-1 3rd edition
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 metallic housing 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.
Electromagnetic compatibility	EMC tests must be performed by manufacturer of the medical device in combination with the medical device. Precondition for EMC is the safe, functional earthing of housing by means of screws or connection line. Pretests have been performed by SONOTEC acc. IEC 60601-1-2, 4th edition. ▪ IEC 61000-4-3 (electromagnetic immunity) 10 V/m | 80 MHz to 2.7 GHz | 80 % AM at 1 kHz ▪ IEC 61000-4-3 (electromagnetic immunity, wireless frequencies) Section 8.10 ▪ IEC 61000-4-8 (magnetic fields) 30 A/m | 50 Hz und 60 Hz ▪ IEC 55011 class B / CISPR 11 (electromagnetic emission), tests according to IEC 55016: 30 … 1000 MHz | 30 dBµV @ 10 m ▪ IEC 61000-4-2 (electrostatic discharges) ± 8 kV direct and indirect contact | ± 15 kV air ▪ IEC 61000-4-4 / IEC 61000-4-5 / IEC 61000-4-6: not applicable Rationale: Sensor doesn‘t provide a patient-coupled line and the cable length is below 3 m.
Further standards	▪ Software development: DIN EN 62304, class C ▪ RoHS: 2011/65/EU, exception: III 7cl/ IV 15, RoHS (EU) 2015/863 ▪ Acoustic emission: IEC 61157, suitable for use on human blood

Use in medical devices and safety

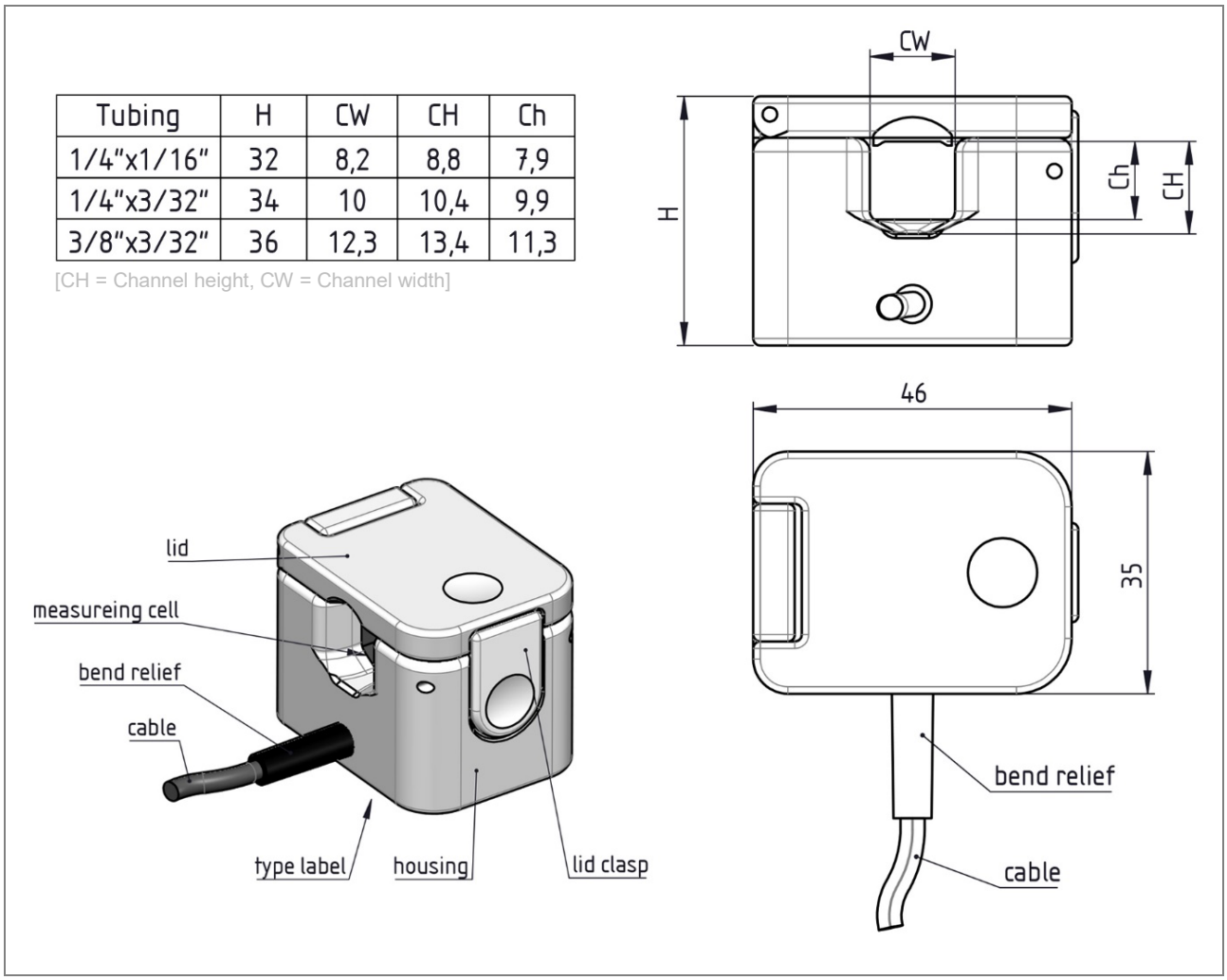
The manufacturer of the medical device is responsible for the medical approval. SONOTEC as supplier supports the approval process and shares documents with a notified body (3rd party) on request.

Medical safety	▪ PESS (Programmable Electrical Sub System) according to the IEC 60601. ▪ One-channel architecture / Fail Safe ▪ Cyclical self-tests of safe functionality of all essential components ▪ Output secured by watchdog: in case of major errors (for example software crashes), the output will be blocked ▪ After power on or software reset: initial test procedure (check of output circuit, watchdog functionality and locking of output)
Self-test	FTT: 0.7 s (cycle time of self-test), MFTT: 24 h (tests after power on or restart only; sensor must be restarted within the defined period)
Settings	Each sensor is calibrated by the manufacturer. Each sensor has individual settings regarding zero adjustment and characteristics of flow and the sensor specific identification character (e.g. serial number of the sensor, type codes).
Usage in medical applications	⚠ **CAUTION:** Sensors are normally delivered in a state that is **NOT FOR CLINICAL USE**, because the settings are not secured against any changes. Proper settings of sensor are essential for medical safety. All settings must be adjusted and verified carefully according to the medical application. The settings must be secured against unintentionally changes. Hence the appropriate self-test routines must be enabled. Please ask our staff to ensure a delivering of sensors with specified, verified settings!
Special applications	⚠ **ATTENTION**: The sensors are not suitable to be applied in immediate proximity to operating surgical devices using high energized pulses e.g. electrosurgical knifes (radio frequency cautery). The sensors might be destroyed, the values of flow could be affected or the sensor could raise false bubble alarm due to the strong radiation along the tubing. Customized sensors with additional protection are available.

Technical drawings

Tubing	H	CW	CH	Ch
1/4"x1/16"	32	8,2	8,8	7,9
1/4"x3/32"	34	10	10,4	9,9
3/8"x3/32"	36	12,3	13,4	11,3

[CH = Channel height, CW = Channel width]



Dimensions SONOFLOW CO.56 Pro V1.0

Drawings are not to scale. Dimensions in mm, unless otherwise specified. Information is subject to change without notice!

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SONOTEC

SONOFLOW® CO.56 Pro V2.0
Non-Invasive Clamp-On Flow-Bubble Sensors

The hybrid flow-bubble sensor SONOFLOW CO.56 Pro V2.0 combines accurate flow measurement and reliable air bubble detection in liquid filled medical tubing. The robust design with cyclical self-tests and fail-safe architecture prevents the sensor from any malfunction in order to ensure patient safety. The lightweight ultrasonic sensor can easily be clamped on the tubing or mounted onto medical devices. By meeting high medical standards SONOFLOW CO.56 Pro V2.0 is suitable for life safety-critical applications.

- Hybrid clamp-on sensor for combined flow measurement and air bubble detection
- Meets high medical standards ensuring patient safety and life support
- Safe operation in electromagnetically sensitive environments
- Free-hanging on medical tubing, e.g., extracorporeal life support systems (ECLS)
- Adaptor for fixed mounting onto medical devices
- Available for medical grade IV tubing sets

Key Features

- Highly accurate non-invasive flow measurement of liquids
- Reliable detection of air bubbles in liquid filled medical tubing
- Lightweight sensor with integrated electronics, no external transmitter required
- RS-485 interface for operating up to 12 sensors

Technical Safety Features

- Fail-safe architecture
- Cyclical self-tests ensuring functionality of all essential components
- Watchdog securing output in case of major errors
- Initial test procedure after power on or software reset

Regulatory Safety Standards

- **Medical Safety**
  IEC 60601-1 (3rd edition)
- **Electromagnetic Compatibility**
  IEC 60601-1-2 (4th edition)
- **Further Standards**
  Acoustic emission: IEC 61157
  RoHS compliance: 2011/65/EU

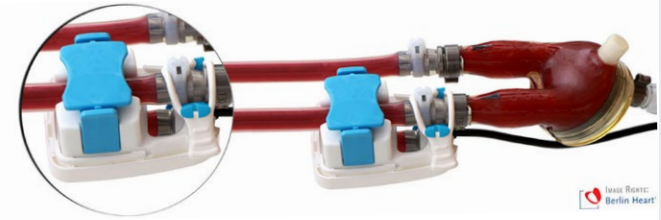
Technical Data

Measuring Method	Ultrasound for combined flow & bubble detection
Measuring Cycle	20 ms
Mounting	Clamped on the tubing (freely hanging) or mounted onto a medical device
Tubing (ID x WT)	1/4" × 1/16" | 1/4" × 3/32" | 3/8" × 3/32"

Interfaces	RS-485
Operating Voltage	5 VDC +0.5 / -0.1 VDC
Current Consumption	≤ 150 mA
Ambient / Media Temperature	15 ... +43 °C
Protection Class	IP67

Customization

- → High degree of customization
- → Customer-specific solutions regarding sensor design, parameter setting, interfaces, etc.
- → Calibration according to OEM requirements



Measurement Principles

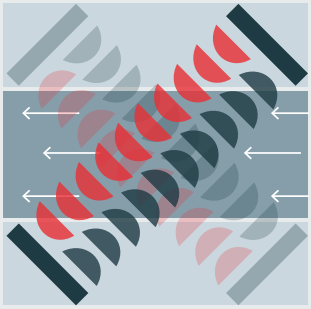
SONOFLOW CO.56 Pro V2.0 flow-bubble sensors combine the ultrasonic transit-time principle for flow measurement with intelligent ultrasonic transmission technology for bubble detection. Thus, the sensors are based on innovative safety concepts to guarantee maximum sensor reliability.

Flow Measurement | Ultrasonic Transit-Time

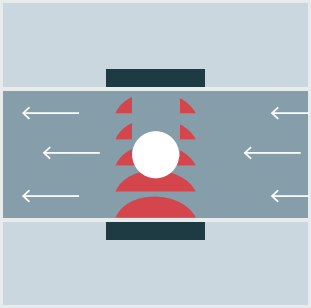
SONOFLOW sensors use ultrasound transit-time technology to accurately determine flow rates. The sensors measure the time of flight of the ultrasonic wave with and against the flow direction of the liquid. The time difference between both signals is a size for the velocity of the flowing liquid. The velocity together with the value of the cross-sectional area allow determining the specific flow volume. The volume results from the product of the flow velocity and the cross-sectional area of the tubing.

Bubble Detection | Ultrasonic Transmission Technology

The non-contact flow-bubble sensor incorporates intelligent ultrasonic transmission technology. The presence of air bubbles and obstructions is detected by means of dynamic amplitude monitoring. Depending on the sound impedance of the adjacent media, reflection and transmission take place at the interface. When an air bubble passes the sensor channel, the signal level of the transmitted sound wave drops. The higher the drop of the signal level, the larger the size of the air bubble.



Transit-time principle for clamp-on flow measurement



Amplitude monitoring for bubble detection

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Certified according to ISO 9001 and EN ISO 13485

Rev. 4

Sensors of the **SONOFLOW CO.56 Pro V2.0** series are used to measure the flow rate of liquids and to detect air bubbles in tubes of various diameters.

The lightweight non-invasive sensors with small form factor are intended to be clamped on the tubing, free-hanging or built into a medical device. Specifically designed for implementation in medical devices such as cardiopulmonary bypass, extracorporeal membrane oxygenation (ECMO), organ transport and dialysis machines the sensors fulfill high medical safety standards. Via an RS-485 interface the sensors are ready for bus operation of up to 12 devices.

Overview sensors

Specification SONOFLOW CO.56 Pro V2.0	Order-No.	Max. flow range	Channel width	Dimensions L × W × H	Max. weight
1/4″ × 1/16″	200 04 0047	4 000 ml/min	8.2 mm	46 × 35 × 32 mm	105 g
1/4″ × 3/32″	200 04 0046		10 mm	46 × 35 × 34 mm	100 g
3/8″ × 3/32″	200 04 0045	10 000 ml/min	12.3 mm	46 × 35 × 36 mm	110 g

Tubing properties

The selection of a suitable sensor depends on tubing dimensions as well as on tubing properties. A tubing sample (minimum length 1 m) for a first evaluation in the SONOTEC lab is required.

Material: PVC
Manufacturer: RAUMEDIC-ECC-Blood Line

Specification SONOFLOW CO.56 Pro V2.0	Tubing OD	Tubing ID	Wall thickness
1/4″ × 1/16″	3/8″	1/4″	1/16″
1/4″ × 3/32″	7/16″	1/4″	3/32″
3/8″ × 3/32″	9/16″	3/8″	3/32″

Other tube materials and diameters upon request. Contact our service.

Calibration and conditions of use

Calibration	Sensors are factory calibrated under the following conditions: ▪ PVC tubing as listed in table above (Tubing properties) ▪ Water at 23 °C ± 2 °C ▪ Warm up: at least 30 min (to compensate thermal effects) ▪ Zero calibration just before measurement procedure ▪ Normal pressure Calibration to customer tubing, fluid, flow range, temperature, etc. on request.
Media	Water, human blood or other acoustically transparent liquids ⚠ **NOTE**: SONOTEC does not operate with human blood within the company premises. With respect to calibration, the difference between water and saline solution is negligible. For applications with blood (hemoglobin: HB = 6 g/dl to 12 g/dl) some special sensor factors/settings can be modified after calibration (→ observe the instruction in the next chapter.)
Conditions of use	⚠ **CAUTION:** The sensors need to be adjusted individually to special operating conditions ▪ In case of operation with tubing not listed in the table 'Tubing properties', because the accuracy of flow measurement and bubble detection could be affected ▪ If the sensor is intended to measure human blood at normally 37 °C and hemoglobin between 6 g/dl and 12 g/dl. Contact our service for more information!
	⚠ **NOTE:** Generally, the sensors are able to measure under the following conditions, however with limited accuracy only: ▪ Liquids in an extended operating temperature range of +1 to +50 °C ▪ Blood within the extended range of Hb = 0 to 18.5 g/dl

Accuracy depends on tubing properties, temperature, fluid properties and other conditions. Absolute accuracy is influenced by zero stability, resolution and zero offset effects. For details see next chapter.

Flow accuracy and repeatability

Specification SONOFLOW CO.56 Pro V2.0	Flow measurement accuracy after 30 min sensor warm-up, no thermal gradients, normal removing / inserting of tubing. Flow measurement repeatability at constant conditions, after 30 min warm-up, no thermal gradients, lid remains closed, no removing / inserting of tubing, no movements of sensor or tubing.			
1/4″ × 1/16″	< 400 ml/min:	**± 20 ml/min** ± 8 ml/min	≥ 400 ml/min:	**± 5 %*** ± 2 %*
1/4″ × 3/32″				
3/8″ × 3/32″	< 1 000 ml/min:	**± 50 ml/min** ± 20 ml/min	≥ 1 000 ml/min:	**± 5 %*** ± 2 %*

* of reading

Zero point stability: Flow measurement drifts less than 0.02 l/min in 24 h at zero flow.

Note: The above stated accuracy rates can only be achieved if the tolerance of the inner diameter of the used tubing is within ± 1.25 %.

Bubble detection and sensitivity

If air bubbles sizes larger than the set threshold are detected a bubble alarm is generated. The set threshold depends on the sensor type. The bubble sensitivity depends on the actual application, e.g. tube properties, mounting position, etc.

	Specification SONOFLOW CO.56 Pro V2.0	Bubble threshold for alarm (Diameter of sphere)
Bubble threshold for bubble alarm (adjustable, contact our service)	**1/4″ × 1/16″**	4 mm
	1/4″ × 3/32″	5 mm
	3/8″ × 3/32″	6 mm
Reaction time	Internal evaluation of bubbles within intervals of max. 1.6 ms	
Response time	< 10 ms; faster response time possible if needed	

Technical data

SONOFLOW CO.56 Pro V2.0 Flow-Bubble Sensor for liquids	
Measuring method	Ultrasonic transit time difference measurement in transmission with two redundant measurement paths, dry coupling, no couplant required
Mounting	Clamped on the tube, hanging freely or mounted into a medical device (cable outlet at the side of the sensor)
Tube insertion	▪ Tube must be put in manually without tools. Lid must be closed. ▪ No couplant (e.g. gel) permitted. ▪ To avoid any influences onto the measurement results due to possible turbulences prevent excessive bending or tube compressing close to sensor position (10 × inner tube diameter before, 5 × inner tube diameter behind the sensor)
Sensor materials	Measuring channel: PMMA, metallized Housing: aluminum, anodized black (optional: individual colors) Identification plate with label: stainless steel Bend relief and cable: plastics black
Labeling	Laser engraving: arrow on lid indicating flow direction; size of specified tube on lid inside; Identification plate: label on rear side (sensor type, hardware version, serial number, manufacturer including address)
Operating voltage	5 VDC +0.5/-0.1 VDC Internal suppressor diode to protect the sensor: Type: SMBJ5.0A | nom. 5 V | 600 W peak pulse power dissipation Inverse-polarity protection: In case of inverse polarity, the sensor is protected by the diode. A high short-circuit current flows.
Current consumption	< 150 mA Power supply of the sensor needs a current limiter, e.g. a fuse (minimize risk of a heating / fire as consequence of short-circuit) ⚠ **ATTENTION**: Current must be limited externally to max. 250 mA (e.g. fuse)
Electrosurgical instruments (ESI)	The sensor is well protected against impact of radio frequency (RF) knife or other surgical instruments by means of metallized measuring channel. However, depending on the usage in surgery rooms it cannot be excluded completely, that flow measurement or bubble detection could be affected when a RF knife is used. Any tests with an electrosurgical instrument is the responsibility of the medical device manufacturer. The sensor performance strongly depends on the requirements derived from the actual application of the sensor in the machine. The sensor must be tied to ground potential safely during operation. ⚠ **ATTENTION:** Any direct contact between the electrodes of an electrosurgical instrument and the sensor housing must be avoided. The sensor might be destroyed by high energized pulses.

Electrical connection

Type: UL-LifYDY / 5 × 0.08 mm² / shielded / Ø 3.5 ±0.1 mm
Length: 2.5 m (± 10 cm), strain reliefs at each end, WECO terminal block for connection of SONOFLOW Monitor

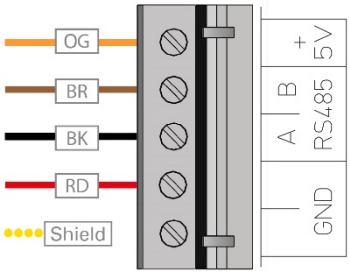
Grounding

⚠ **ATTENTION:**

The metallic housing of sensor must be grounded via the shield of connection line. Otherwise the measuring values of sensor could be affected by EMC and the sensor is not protected against ESD.

Assignment

Color	Connection	WECO Terminal
Orange	VCC	1
Brown	RS-485 B	2
Black	RS-485 A	3
Red	GND	4
Shield / Yellow	Housing of sensor	5



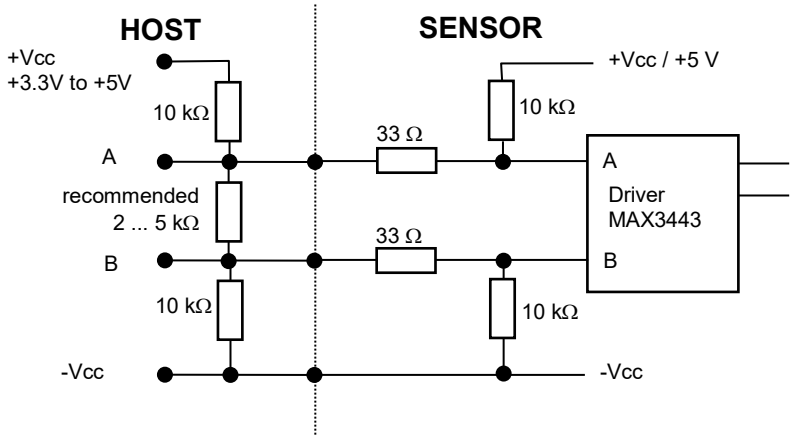
RS-485 interface

(SONOTEC protocol)

Half-duplex operation / 115.2 kBd / 8 bit data / 1 stop bit / no parity bit / no handshaking

Dialog mode (on demand): machine is intended to ask results cyclically, sensor does not have an own alarm equipment)
Query cycle: 20 … 200 ms (typically)

NOTE: Description of serial protocol with details upon request.



RS-485 bus operation

Bus operation supported up to 12 subscribers, default address is #01 (can be changed with the help of SONOFLOW Monitor, permitted are addresses from #01 … #12)

Maintenance	Maintenance-free
Operating temperature	+10 … +50 °C (see also chapter ‘Calibration and conditions of use’)
Ambient / Media temperature	+15 ... +43 °C
Storage / Transportation temperature	-20 ... +60 °C
Humidity	10 … 95 % relative humidity (not condensing)
Atmospheric pressure	620 … 1060 hPa
Degree of protection	IP67, the sensor is completely potted
Scope of delivery	• SONOFLOW CO.56 Pro V2.0 • User documentation (‘Technical Data Sheet’)
Optional accessories	• Calibration report
	SONOFLOW Monitor Software for setting parameters, recording measurements and update of sensor software consisting of • USB Data Converter (type 012), for the connection to a computer • USB cable, type A-B, length 2 m • Link to Software SONOFLOW Monitor and driver for Windows • User documentation (‘Operating Manual’)

Directives and standards

Medical safety	Medical safety: IEC 60601-1 3rd edition
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 metallic housing 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.
Electromagnetic compatibility	EMC tests must be performed by manufacturer of the medical device in combination with the medical device. Precondition for EMC is the safe, functional earthing of housing via the connection line. Pretests have been performed by SONOTEC acc. IEC 60601-1-2, 4th edition. ▪ IEC 61000-4-3 (electromagnetic immunity) 10 V/m | 80 MHz to 2.7 GHz | 80 % AM at 1 kHz ▪ IEC 61000-4-3 (electromagnetic immunity, wireless frequencies) Section 8.10 ▪ IEC 61000-4-8 (magnetic fields) 30 A/m | 50 Hz und 60 Hz ▪ IEC 55011 class B / CISPR 11 (electromagnetic emission), tests according to IEC 55016: 30 … 1000 MHz | 30 dBµV @ 10 m ▪ IEC 61000-4-2 (electrostatic discharges) ± 8 kV direct and indirect contact | ± 15 kV air ▪ IEC 61000-4-4 / IEC 61000-4-5 / IEC 61000-4-6: not applicable Rationale: Sensor doesn‘t provide a patient-coupled line and the cable length is below 3 m.
Further standards	▪ Software development: DIN EN 62304, class C ▪ RoHS: 2011/65/EU, exception: III 7cl/ IV 15, RoHS (EU) 2015/863 ▪ Acoustic emission: IEC 61157, suitable for use on human blood

Use in medical devices and safety

The manufacturer of the medical device is responsible for the medical approval. SONOTEC as supplier supports the approval process and shares documents with a notified body (3rd party) on request.

Medical safety	▪ PESS (Programmable Electrical Sub System) according to the IEC 60601. ▪ One-channel architecture / Fail Safe ▪ Cyclical self-tests of safe functionality of all essential components ▪ Output secured by watchdog: in case of major errors (for example software crashes), the output will be blocked ▪ After power on or software reset: initial test procedure (check of output circuit, watchdog functionality and locking of output)
Self-test	FTT: 0.7 s (cycle time of self-test), MFTT: 24 h (tests after power on or restart only; sensor must be restarted within the defined period)
Settings	Each sensor is calibrated by the manufacturer. Each sensor has individual settings regarding zero adjustment and characteristics of flow and the sensor specific identification character (e.g. serial number of the sensor, type codes).
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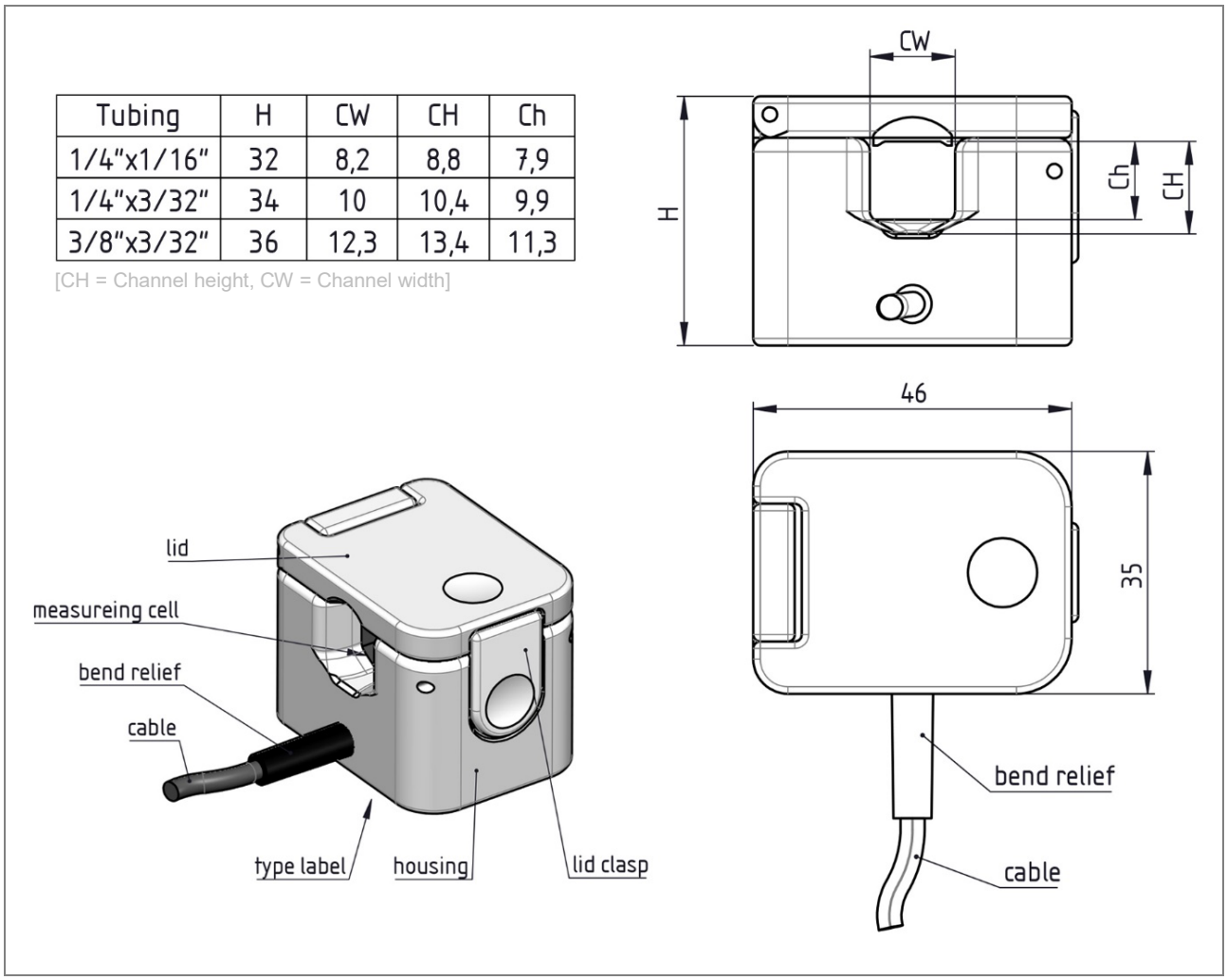

Dimensions SONOFLOW CO.56 Pro V2.0

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