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

Type 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	4 000 ml/min	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
1/2″ × 3/32″	200 04 0060	18 000 ml/min	15.5 mm	46 × 35 × 42 mm	140 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

Type 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″
1/2″ × 3/32″	11/16″	1/2″	3/32″

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

Calibration and conditions of use

Parameter	Specifications
Calibration	Sensors are factory calibrated under the following conditions: ▪ PVC tubing as listed in table above (Tubing properties) ▪ Water at 37 °C (blood adjusted) ▪ 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.) ⚠ **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 sensor is adjusted individually to special operating conditions. The sensor is intended to measure human blood at normally 37 °C and hemoglobin between 6 g/dl and 12 g/dl. **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, flow regime, temperature, fluid properties and other conditions, e.g. type of pumps. Absolute accuracy is influenced by zero stability, resolution and zero offset effects. For details see next chapter.

Flow accuracy and repeatability

Type 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″	< 400 ml/min:	**± 20 ml/min** ± 8 ml/min	≥ 400 ml/min:	**± 5 %*** ± 2 %*
3/8″ × 3/32″	< 1 000 ml/min:	**± 50 ml/min** ± 20 ml/min	≥ 1 000 ml/min:	**± 5 %*** ± 2 %*
1/2″ × 3/32″	< 1 800 ml/min:	**± 90 ml/min** ± 36 ml/min	< 1 800 ml/min:	**± 5 %*** ± 2 %*

of reading

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 %.

Ethylene oxide sterilization, electron beam sterilization or gamma sterilization of the tubing may impact its material properties, potentially affecting sensor readings. Recalibration may be required after tubing sterilization.

Type SONOFLOW CO.56 Pro V2.0	Zero point stability. Flow measurement drifts at zero flow in 24h less than:
1/4″ × 1/16″	0.02 l/min
1/4″ × 3/32″	0.02 l/min
3/8″ × 3/32″	0.02 l/min
1/2″ × 3/32″	0.05 l/min

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.

Parameter	Specifications	
Bubble threshold for bubble alarm (adjustable, contact our service)	Type SONOFLOW CO.56 Pro V2.0	Bubble threshold for alarm (Diameter of sphere)
	1/4″ × 1/16″	4 mm*
	1/4″ × 3/32″	5 mm*
	3/8″ × 3/32″	6 mm*
	1/2″ × 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	

* *factory default. Optional thresholds available upon request, subject to additional configuration.*

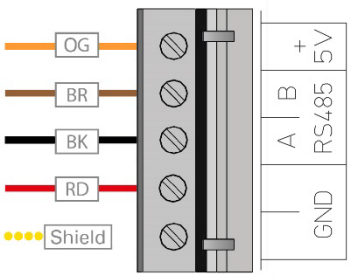
Technical data

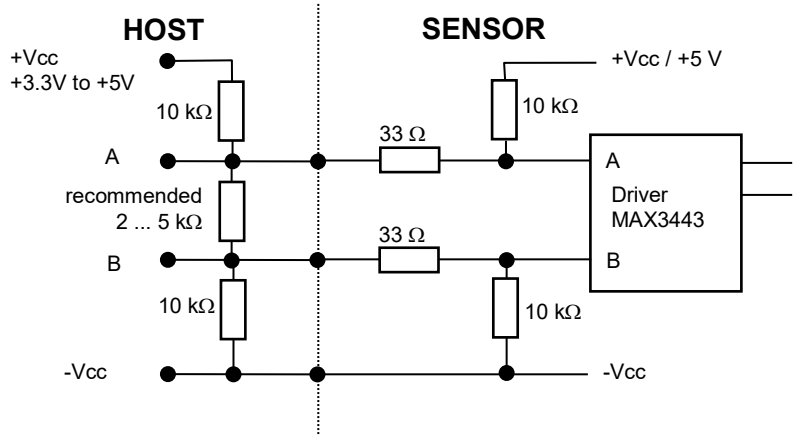
Parameter	Specifications
Measuring method	Ultrasonic transit time difference measurement in transmission with two redundant measurement paths, dry coupling, no couplant required
Mounting	Clamped on the tube, hanging freely or mounted into a medical device (cable outlet at the side of the sensor)
Tube 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) 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	Typically ca. 100 mA, max. 180 mA **NOTE:** If the power voltage is switched on and is raising up, the current could reach shortly higher values up to 180 mA. If the voltage is near 5 V, the current drops down to approx. 100 mA typically. Please consider that behave in your circuits of power supply. We recommend a raising up of power voltage as fast as possible. 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, slow reaction)
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 / 115 200 Bd / 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
Ambient temperature	+10 … +50 °C (see also chapter ‘Calibration and conditions of use’)
Media temperature	+15 ... +45 °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 sensor • 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

Parameter	Specifications
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 7cI/ IV 15, RoHS (EU) 2015/863 ▪ Acoustic emission: IEC 61157, suitable for use on human blood

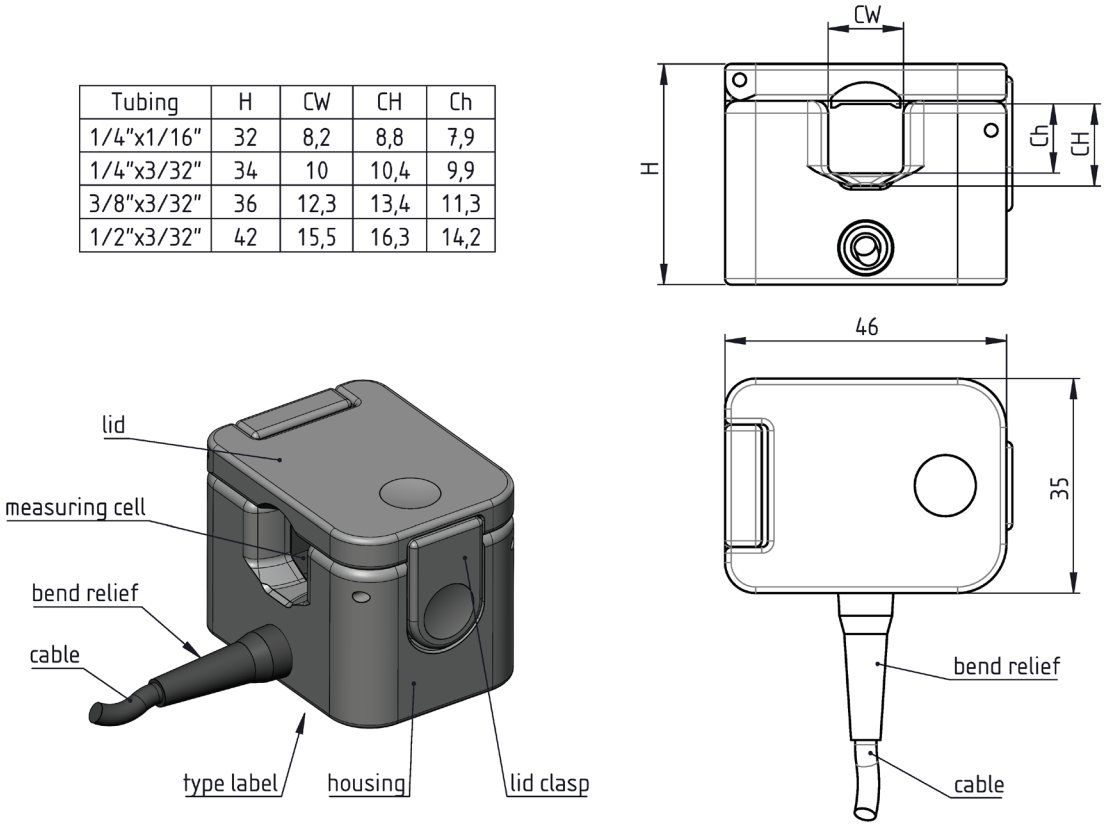
Use in medical devices and safety

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.

Parameter	Specifications
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!

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
1/2"x3/32"	42	15,5	16,3	14,2



Dimensions SONOFLOW CO.56 Pro V2.0

Drawings are not to scale. Dimensions in mm, unless otherwise specified. Information is subject to change without notice!
Registration according to ElektroG: WEEE Reg. No. DE 22125904. SONOTEC is a registered trademark.

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