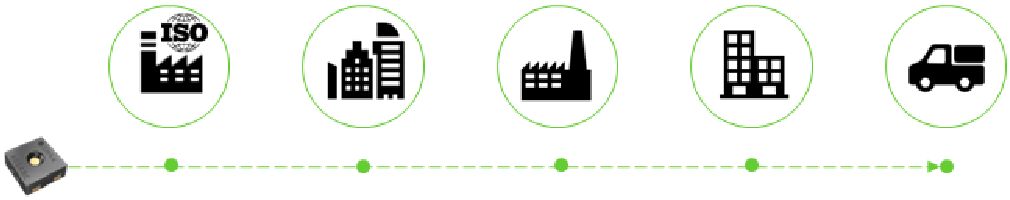
Certified Smart Tracking

Less complexity for the benefit of all -- Enabled by Sensirion



Highlights

- End to end monitoring
- ISO17025 certified | NIST traceable
- Efficient recertification
- Economical, time-saving & scalable
- Cloud access throughout the value chain
- Design-in guidelines

Sensirion is the first ISO17025-accredited Semiconductor company in the world, allowing Sensirion to issue certified sensors independently, which in turn enables customers to build a certified smart tracker without having to certify the entire device. This document showcases novel aspects of this approach and what design-in considerations should be considered to achieve the best results.

Sensors with ISO17025 certificate

Product	Details
STS33-DIS	3-point calibrated, ISO17025 certified temperature sensor
SHT33-DIS	3-point calibrated, ISO17025 certified, 0x44 & 0x45 I2C addr.
SHT43-ADCB	3-point calibrated, ISO17025 certified, 0x44 I2C addr.
SHT43-BDCB	3-point calibrated, ISO17025 certified, 0x45 I2C addr.

ISO 17025

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1 Novel Approaches for the Design of Calibrated and Certified Devices

The core innovation of Sensirion's Certified Smart Tracking is the redundancy of calibration of a device by certifying the sensor component itself. This approach allows for a leaner way of achieving reliable monitoring of environmental conditions. Traditional monitoring devices require calibration of the entire system, which can be very time-consuming and costly. With Sensirion Certified Smart Tracking solutions, the sensor components are calibrated and certified, eliminating the need for calibration of the assembled devices. This new approach to calibration and monitoring changes the classical value chain of End-to-end monitoring devices, enabling more efficient and accurate monitoring of environmental conditions.

1.1 Device versus Sensor Certification – Analog versus Digital

When calibrating an analog measurement device, all components that might affect the measurement must be considered for calibration, in particular the sensing element *(e.g.* a Pt100), its corresponding read-out equipment, and the signal path in-between. This is traditional approach is necessary due to the analog nature of signal transport and processing, which can be affected when temperatures, strain, or resistances change ever so slightly. Today, many manufacturers and institutions still stick to this approach for traditional reasons. However, new approaches would be enabled by the switch from an analog to a digital system (see Figure 1).

Digital sensors, such as the the SHT43, consist of an analog sensing element and on-chip read-out electronics which entails that calibration and certification of the digital sensor comprises the same elements also considered in the traditional approach. Since the signal processing happens in the digital sensor itself, it is not subject to change due to other electronics in the device, provided correct design-in of the sensor to avoid a bias by dissipative heat from other electronics in the sensors (see section 1.2). In addition, Sensirion's calibration and certification process is accredited in a way to account for the soldered state, so that manufacturing processes don't affect the validity of the certificate.

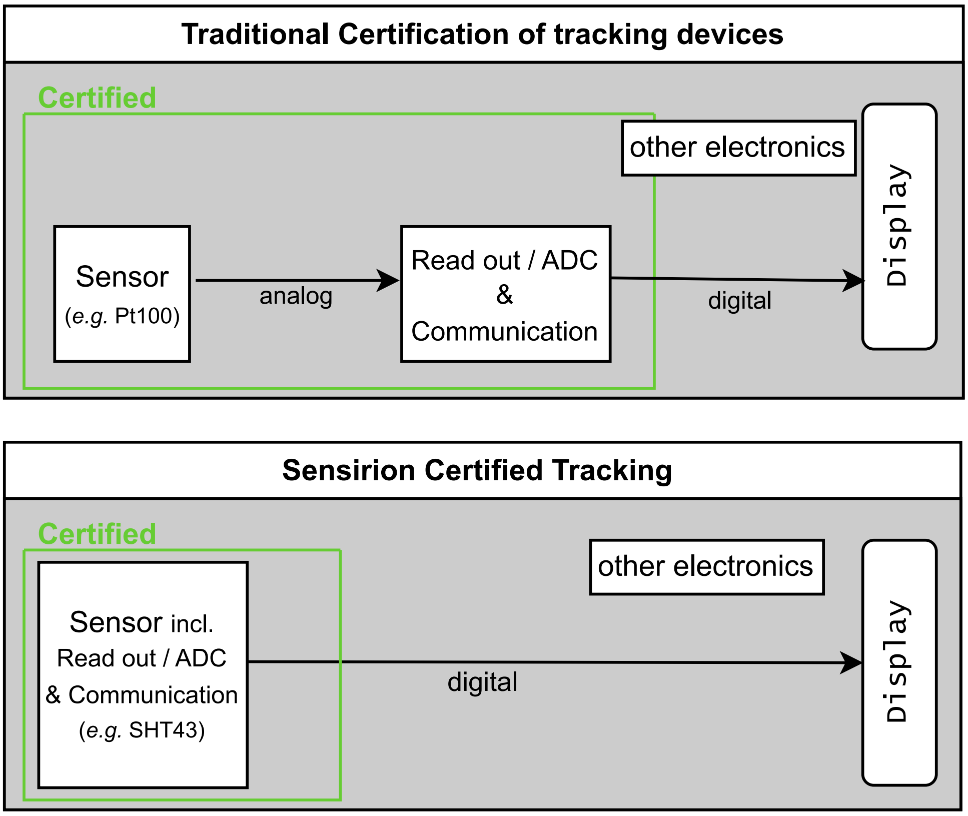

Figure 1. Comparison between traditional analog and digital sensor based (Sensirion) smart tracking devices.

1.2 Signal Stability and Transmission

When contrasting digital sensors and conventional analog sensors, one of the most prominent advantages of digital sensors lies in the simplification of signal transmission. Digital sensors convert the measured data into discrete digital values, which significantly reduces susceptibility to signal distortions during transmission. This inherent stability ensures data integrity and enables more accurate and reliable measurements. This is also the underlying reason why Sensirion can certify the sensors without the need of knowing their final application, provided the sensors are designed-in properly, which of course would also apply to analog sensors.

1.3 Design-in Guidelines

The SHT43 digital sensor has a compact design, which facilitates seamless integration into various applications. Unlike conventional analog sensors that require separate readout and analog-to-digital conversion components, our digital sensor seamlessly incorporates these functions into a single unit. As a result, customers can develop smaller and lighter tracking devices without compromising overall performance. The integration of readout and ADC functionality eliminates the need for extra circuitry, streamlining the design process and reducing the overall space requirements.

As the certified SHT43 makes a certification of the whole tracking device redundant, it is even more important to follow the guidelines, given in the design in guide [1], during the design phase of your device. Below you can find a summary of the most important recommendations from the Design Guide for Humidity and Temperature Sensors that can be found on our website.

Decouple the Sensor from other electronics and possible heat sources.

To ensure that the sensor is not affected by potential heat sources through conduction or radiation, it is necessary to thermally decouple the sensor from other electronics. There are various measures that need to be taken to achieve thermal decoupling. For instance, thin metal connections and sufficient distances between the sensor and heat sources are recommended. Furthermore, mill slits around the sensor on the PCB are advised. Additionally, thermal conduction can be mitigated by removing as much metal as possible from the PCB in proximity of the sensor. Another solution, and at the same time well-suited for recertification of a smart tracking device, is to mount the sensor on a separate removable flex-PCB.

Furthermore, since the housing of a device can influence any measurement taken, special care should be taken to reduce the influence from enclosed air by sealing the sensor compartment from the remaining housing. This avoids heat transport and ensures more representative sampling.

Design with a possible airflow

To ensure accurate values of the sensor, it is also important to consider the airflow and air exchange of the local air surrounding the sensor with the environment. The best solution is to ensure an airflow directly over the sensor. If this is not possible, we recommend reducing the dead volume around the sensor and have the largest possible aperture towards the environment of the device.

1.4 Difference between NIST traceability and ISO17025 certification

A NIST traceable calibration is when a manufacturer or laboratory can certify that the standards used to calibrate a device, and therefore the device itself, are traceable to standards used at NIST. This traceability can be established by a chain of intermediate transfer calibrations and transfer standards, each step increasing the overall measurement uncertainty. Even though the traceability of the reference standard is given by certification, this does not include any information on the calibration measurement itself (see **Figure 2** left).

- Each step increases the overall measurement uncertainty.
- No information on level of competence of staff and equipment.
- Reference standard traceable, the calibration itself however is not.

An ISO 17025 accreditation is a statement to the competence of the calibration laboratory. Given that the body performing the calibration is ISO 17025 accredited, the results are trustworthy, certified and are traceable to national and international standards (see **Figure 2** right).

- Accreditation by an official body member of ILAC MRA
- Highest standards with known measurement uncertainty
- Calibration performed by a certified body.

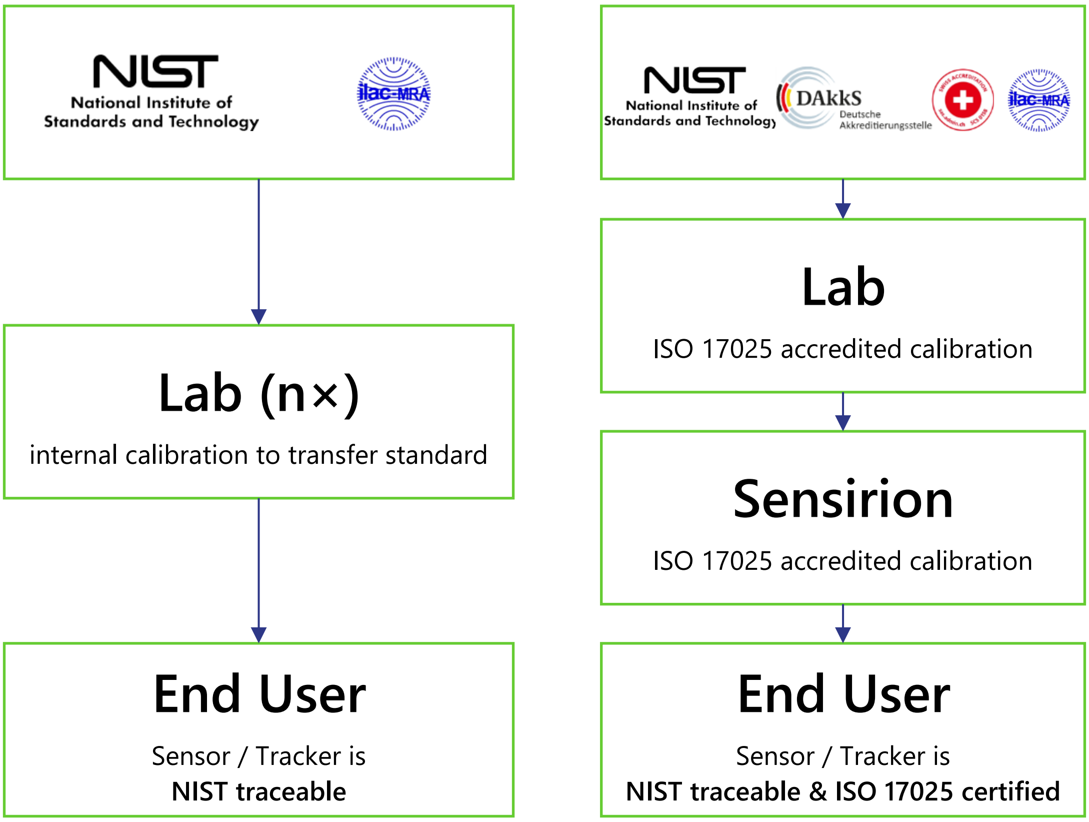

Figure 2. Schematic overview of steps taken to get a NIST traceable sensor (left) and an ISO17025 certified sensor (right).

Where 'NIST Traceable' meets the Metrological Traceability requirement, ISO17025 also requires a complete and sophisticated quality system ranging from process requirements to management system requirements including quality assurance of the calibration data, validity of the calibration method, maintenance of the equipment and competence of the staff. Hereunder the differences shown between the requirements of NIST traceability vs. ISO17025.

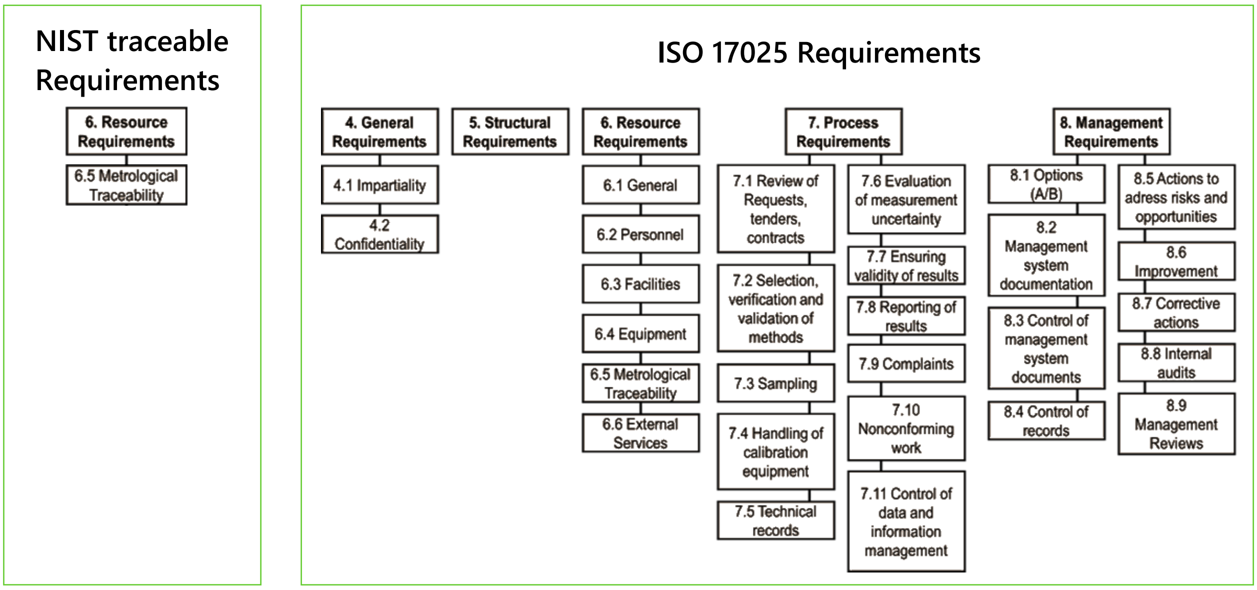

Figure 3. Comparison of the requirements for "NIST traceable" (left) and ISO 17025 (right).

2 Sensirion Certification Insights

2.1 Recertification

Any calibration certificate generally is valid only at the time of calibration due to the device under test leaving the controlled environment to the field, where damages cannot be fully excluded. The commonly used term "certificate validity" therefore does, in contrast to public perception, not indicate if the certificate is still valid, but instead refers to the often arbitrary time-period in which the device should be re-certified. To estimate this time-period, issuing companies and regulation bodies need to find a reasonable compromise between frequent calibration and lifetime in the field. To this end, a good strategy is to determine a typical application profile and estimate the drift of the measurement device to assess how long it remains within customer specifications. (Example: GDP Guidelines require ±0.5°C accuracy, SHT33 and SHT43 have max accuracy of 0.48 °C and <0.01 °C drift per year, which results in >2 years lifetime in the field.)

The second, more established, yet less pragmatic method is to arbitrarily demand re-certification every calendar year. This is often recommended in industry guidelines.

At Sensirion, the first ISO17025-certified semiconductor company in the world, sensors are certified in an in-house accredited calibration lab, which is optimized for efficiency and in line processes. Customer devices, which would require manual operations therefore cannot be re-certified as full devices at Sensirion. Instead, Sensirion recommends mounting the sensor on a removable board or better even a flex-PCB in the device, so that the sensor can easily be exchanged with a new certified sensor. This is not only time and cost-efficient but also has a lower impact on the environment.

2.2 Drift Estimation for Determining Re-certification Needs

Sensor drift is a phenomenon inherent to any measurement device due to material aging or any influence from the environment. Therefore, all reliable sensor manufacturers determine a drift that might be expected in the field. However, since the type of influence can only be estimated, worst case scenarios always consider drift in two directions. Sensirion therefore defines the drift specified in the datasheets as a widening of specs. Next to binding specification, Sensirion believes in transparency and performs accelerated aging tests to a simulated lifetime of 15 years in the field. This is achieved by THB tests, following the JESD22-A101 standard. While some companies assume THB to simulate 30 years, Sensirion takes a more strict and conservative approach assuming THB to simulate 15 years.

Example SHT33:

The drift specified in the datasheet (<0.01 °C per year) implies a widening of the specs from originally $S_{Original}$(-30°C to +70°C) = 0.48°C to 0.49°C after one year. Following this example, the maximum SHT33 accuracy specification after 15 years lifetime (S_{15y}) would therefore be:

$$S_{15y} = S_{Original} + 15 \times 0.01\ °C \quad \rightarrow \quad S_{15y}(\text{STS33 @25, 50°C}) = 0.63\ °C$$

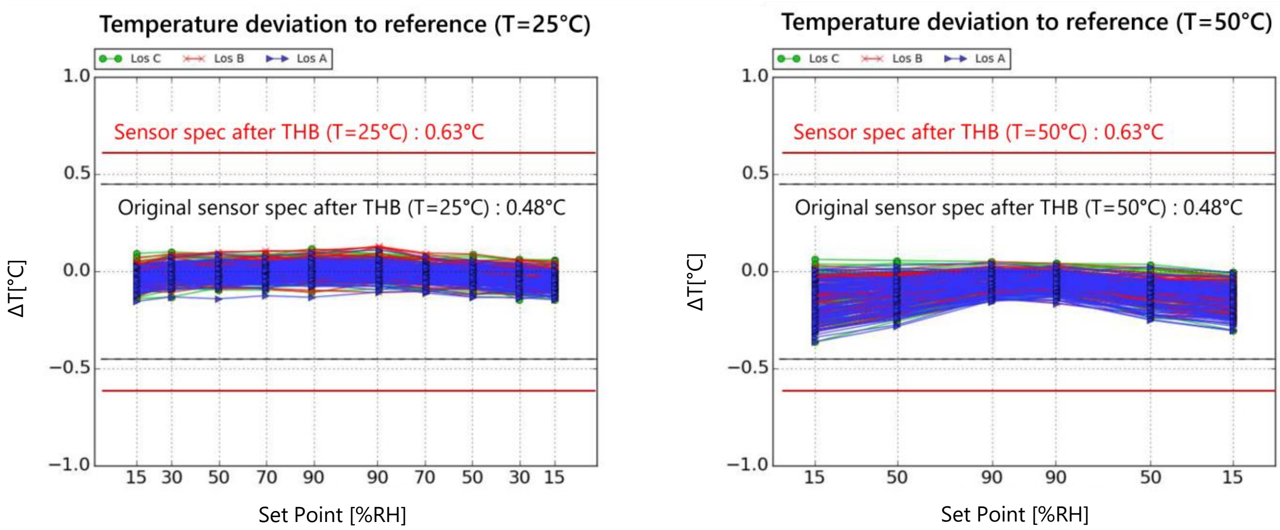

Figure 4. Steady-State Temperature-Humidity Bias Life Test (THB) test results according to JEDEC standard, with THB: 85 %RH, 85°C, 1000h; Standard JESD22-A101; 77 Sensors from 3 independent lots, total 231 Sensors.

This entails that even after 15 years simulated lifetime, the T performance is well within specs after THB (drift 0.01°C/y). Specifically, even within the original specs, which entails a yearly drift of <<0.01 °C.

2.3 Sustainability

Production and certification of an SHT43 at Sensirion is estimated to produce 6 g of CO_2 and consumes almost negligible amounts of resources. In contrast, transporting a batch of devices (about 20 kpcs) to a calibration lab could produce up to 12 g of CO_2. Knowing that this is rough estimation, it illustrates how a replacement of the certified sensor might be the most economical and ecological solution.

3 Glossary

Typical Accuracy

When plotting the accuracy (accuracy=device deviation from reference) distribution of a statistically significant number of sensors, the number of sensors in the μ±2σ range shows the typical accuracy. This equals 95.45% of all sensors.

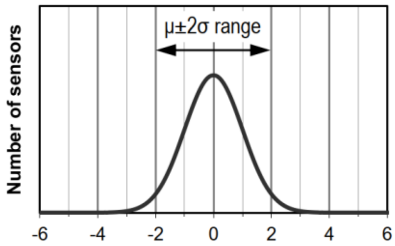

Figure 5. Visual representation of the μ±2σ range.

Maximum Accuracy

When plotting the accuracy distribution of a statistically significant number of sensors, the number of sensors in the μ±4σ range shows the typical accuracy. This equals 99.99% of all sensors. [2]

Allowed Tolerance

Allowed device deviation from a reference including maximum measurement uncertainty. In contrast to typical and maximum accuracy, not a statistical fraction, but every tested device, *i.e.,* 100% must fulfill the allowed tolerance. This is of particular interest for ISO17025-certified sensors.

Measurement Uncertainty

All measurements are subject to uncertainty determined through error propagation of all involved steps. Nevertheless, it is often neither estimated, nor reported, in contrast to ISO17025 measurements, where it is mandatory to add the measurement uncertainty to the measured value before evaluation of pass criteria.

ISO 17025

ISO17025 is an international standard that specifies the general requirements for the competence of testing and calibration laboratories. This standard was first published in 1999 by the International Organization for Standardization (ISO) and is now widely recognized as the highest level of accreditation that a laboratory can achieve. The purpose of ISO17025 is to ensure that laboratories perform tests and calibrations to a consistently high standard, producing accurate and reliable results. The standard covers all aspects of laboratory management, including the quality of the equipment and materials used, the qualifications and training of staff, and the procedures used to perform tests and calibrations. To achieve ISO17025 accreditation, laboratories must undergo a rigorous assessment process, which includes a thorough evaluation of their technical competence, quality management systems, and overall operational efficiency. This assessment is carried out by independent accreditation bodies, which are recognized by the International Laboratory Accreditation Cooperation (ILAC). Once a laboratory has achieved ISO17025 accreditation, it is required to undergo regular surveillance and re-assessment to ensure that it continues to meet the standard's requirements. This helps to ensure that the laboratory maintains its high level of competence and continues to produce accurate and reliable results.

4 Bibliography

5 Revision History

Date	Version	Pages	Changes
August 2023	1	all	Initial release
October 2023	1.1	1 7	Added SHT33-DIS to Sensor list Corrected typo

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Important Notices

Warning, Personal Injury

Do not use this product as safety or emergency stop devices or in any other application where failure of the product could result in personal injury. Do not use this product for applications other than its intended and authorized use. Before installing, handling, using or servicing this product, please consult the data sheet and application notes. Failure to comply with these instructions could result in death or serious injury.

If the Buyer shall purchase or use SENSIRION products for any unintended or unauthorized application, Buyer shall defend, indemnify and hold harmless SENSIRION and its officers, employees, subsidiaries, affiliates and distributors against all claims, costs, damages and expenses, and reasonable attorney fees arising out of, directly or indirectly, any claim of personal injury or death associated with such unintended or unauthorized use, even if SENSIRION shall be allegedly negligent with respect to the design or the manufacture of the product.

ESD Precautions

The inherent design of this component causes it to be sensitive to electrostatic discharge (ESD). To prevent ESD-induced damage and/or degradation, take customary and statutory ESD precautions when handling this product. See application note "ESD, Latchup and EMC" for more information.

Warranty

SENSIRION warrants solely to the original purchaser of this product for a period of 12 months (one year) from the date of delivery that this product shall be of the quality, material and workmanship defined in SENSIRION's published specifications of the product. Within such period, if proven to be defective, SENSIRION shall repair and/or replace this product, in SENSIRION's discretion, free of charge to the Buyer, provided that:

- notice in writing describing the defects shall be given to SENSIRION within fourteen (14) days after their appearance;
- such defects shall be found, to SENSIRION's reasonable satisfaction, to have arisen from SENSIRION's faulty design, material, or workmanship;
- the defective product shall be returned to SENSIRION's factory at the Buyer's expense; and
- the warranty period for any repaired or replaced product shall be limited to the unexpired portion of the original period.

This warranty does not apply to any equipment which has not been installed and used within the specifications recommended by SENSIRION for the intended and proper use of the equipment. EXCEPT FOR THE WARRANTIES EXPRESSLY SET FORTH HEREIN, SENSIRION MAKES NO WARRANTIES, EITHER EXPRESS OR IMPLIED, WITH RESPECT TO THE PRODUCT. ANY AND ALL WARRANTIES, INCLUDING WITHOUT LIMITATION, WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, ARE EXPRESSLY EXCLUDED AND DECLINED.

SENSIRION is only liable for defects of this product arising under the conditions of operation provided for in the data sheet and proper use of the goods. SENSIRION explicitly disclaims all warranties, express or implied, for any period during which the goods are operated or stored not in accordance with the technical specifications.

SENSIRION does not assume any liability arising out of any application or use of any product or circuit and specifically disclaims any and all liability, including without limitation consequential or incidental damages. All operating parameters, including without limitation recommended parameters, must be validated for each customer's applications by customer's technical experts. Recommended parameters can and do vary in different applications.

SENSIRION reserves the right, without further notice, (i) to change the product specifications and/or the information in this document and (ii) to improve reliability, functions and design of this product.

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