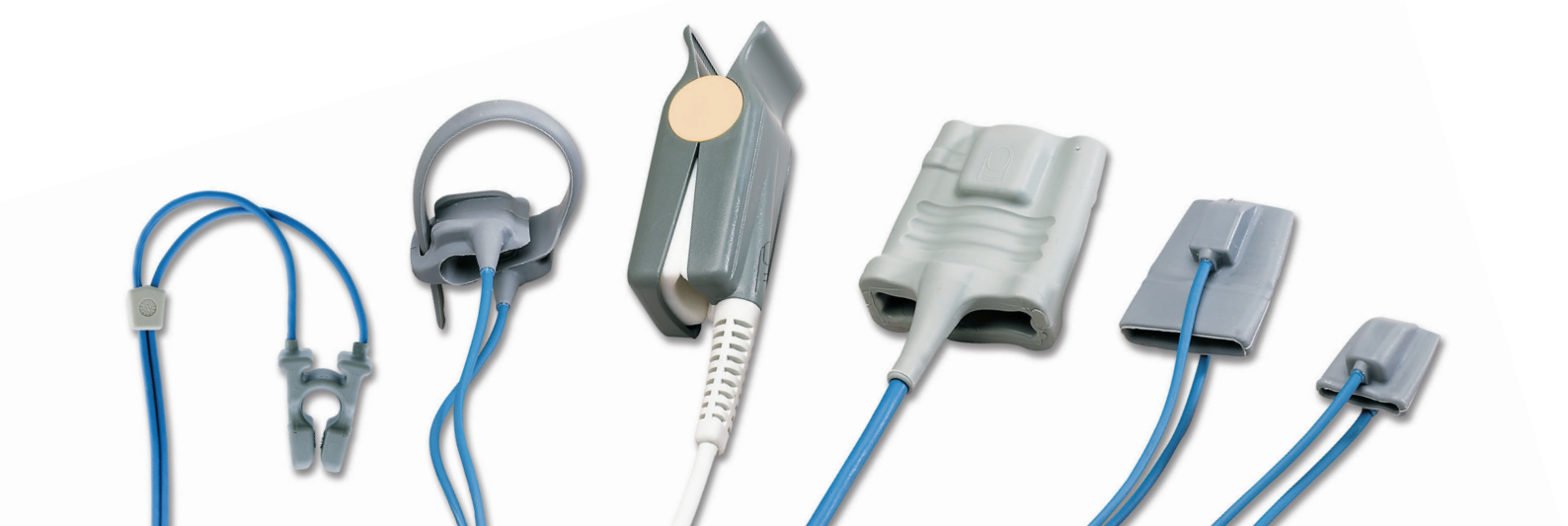
Our commitment to quality: SpO_2 sensor verification and validation testing

When you place a Philips sensor on a patient, you should be fully confident that it will perform accurately. That is why we design our high-quality SpO_2 sensors and cables to precise specifications. By meticulously following these specifications, our manufacturing facilities produce sensors and cables that advance the performance of Philips monitors, including the Philips FAST-SpO_2 technology. Rigorous verification and validation testing confirms that our cables and sensors deliver the quality and performance that we claim.



What do verification and validation mean?

Prior to the release of a medical device to the market or for clinical trials, the device must be verified and validated for compliance with the intended use and the claims made to customers. **Verification** activities demonstrate that the product meets the established design input requirements. **Validation** activities confirm that the design conforms to user needs in the intended use environment.

What standards do Philips SpO_2 sensors meet?

Our sensors meet applicable standards set by regulatory authorities (for example, U.S. Food and Drug Administration and the European Commission) and by standardization committees (for example, International Electrotechnical Commission and the International Standards Organization). See the chart on the next page listing applicable standards.

How does Philips verify sensors?

Our sensors undergo testing that simulates the conditions they will face in real-world healthcare settings. Environmental chambers replicate high and low temperature and humidity settings. Machines repeatedly bend or twist sensor cables, just as users might. Sensors are subjected to various cleaners and disinfectants, and are repeatedly plugged and unplugged.

In addition, controlled desaturation studies test that sensors read various O_2 saturation levels correctly. These studies involve inducing hypoxia (reducing the level of O_2 reaching body tissues) in healthy volunteers. Scientists measure many different O_2 saturation levels with a sensor-monitor combination, and compare those readings with invasive measurements from a co-oximeter. The standard specifies how many samples must be compared to confirm the accuracy claim.

How does Philips validate sensors?

Other evaluations, called user acceptance testing, are done in clinical settings to collect clinicians' views of the new product.

M1140A adult/pediatric alar sensor

M1131A adult/pediatric sensor

M1132A infant sensor

M1133A neonatal/infant/adult sensor

M1134A neonatal/infant/adult adhesive-free sensor

Why is it important to verify sensor compatibility?
Even though a sensor appears to work when plugged into a monitor or oximeter, it may be inaccurate and ineffective. Sensors shine different optical wavelengths through tissue to measure O_2 saturation, and the wavelengths must match with those that the oximeter is designed to accept. We make compatibility claims only after a sensor-monitor combination passes a full range of verification testing. Because of this rigorous testing, we confidently stand behind all claims we make about SpO_2 sensor or cable compatibility.

What products do we verify and validate?
Sensors are tested and validated for use on the vast majority of Philips monitors. Please refer to the individual Instructions for Use (IFU) or ask your sales representative for this information.

Examples of verification and validation testing

User requirement	Standard	Verification and validation
Accurate measurement of arterial O_2 saturation	Particular requirements for basic safety and essential performance of pulse oximeter equipment (ISO 80601-2-61, clause 201.12.1.101)	Verify accuracy by an invasive controlled desaturation study with healthy volunteers over the range from 70 to 100% SpO_2. Sensors are tested in combination with representatives of all compatible devices.
Accurate pulse rate	Particular requirements for basic safety and essential performance of pulse oximeter equipment (ISO 80601-2-61, clause 201.12.1.104)	Verify pulse rate accuracy with patient signal simulator for all sensor-monitor combinations for which we claim compatibility.
Proven intended-use, covering application sites and patient sizes	Philips requirement	Verify that sensors perform properly per claimed application sites and weight ranges.
Operates within intended electromagnetic environment within hospital	Particular requirements for basic safety and essential performance of pulse oximeter equipment (ISO 80601-2-61, clause 202) General requirements for basic safety and essential performance (IEC 60601-1, clause 17)	Verify that sensors perform properly when operated within intended electromagnetic environment at a care setting.
Wide range of approved cleaning and disinfecting methods for reusable sensors	Philips requirement	Verify that the products do not deteriorate if cleaned or disinfected using the specified cleaners and disinfectants.
Biocompatible with patient skin	Biological evaluation of medical devices – evaluation and testing (ISO 10993-1, part 5 and 10)	Verify biocompatibility of all patient-contacting materials.
Does not reach excessive temperature due to SpO_2 IR/red light	Basic safety and performance of pulse oximeter equipment (ISO 80601-2-61, clause 201.11)	Verify that the temperature of the part applied to the skin does not exceed 41° C (105.8° F) when used with all instruments with which we claim compatibility.
Withstands expected mechanical stresses during life of product	Philips requirement	Verify durability: mechanical performance, cycling, and connector tear-out.
Ambient light immunity	Philips requirement	Verify that sensors perform properly when operated under ambient light environment conditions.

Discover how Philips medical supplies and sensors can help you unlock the full value of your clinical monitoring systems at **www.philips.com/supplies**.

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