The role of validation and the value it provides

Philips Healthcare Supplies

Philips Healthcare offers high quality accessories and supplies that are designed to precise specifications. Philips manufacturing facilities meticulously follow these specifications to produce products that optimize the performance of Philips equipment and instrumentation. Philips then follows rigorous testing to ensure that the quality and performance we claim are delivered.

What does "Validation" mean?

Validation encompasses the necessary steps to confirm that a product performs as it has been specified and therefore ensures it is safe and will perform to a specified level of performance.

What standards do Philips SpO_2 Sensors conform to?

Philips meets a wide range of standards that have been set by regulatory authorities (e.g. FDA) and standardization committees (e.g. IEC, ISO). (See the accompanying chart that lists the standards).

What does the process of validation entail?

Some tests are performed in highly sophisticated laboratories with specific environmental conditions, for temperature and humidity to ensure that the products will perform properly under these conditions. Some of the tests can take up to three months to complete.

Other tests are done in a clinical environment to ensure that the customers' needs are met. One complicated step in the validation process is known as controlled desaturation studies (sometimes referred to as "Desats").

During studies, a controlled hypoxia (a deficiency in the amount of oxygen reaching body tissues) is induced in healthy volunteers and the readings of the pulse oximeter are compared to a CO-oximeter. The number of volunteers and data samples per volunteer has to be high enough to attain statistical significance to demonstrate that the instrument/sensor combination under test meets the specified accuracy.

Why is validation of sensor/device compatibility important?

Just because a sensor "appears" to work when plugged into a device, it does not mean that it is accurate or safe. Other devices may use different technology and software algorithms to synthesize the data. In addition, other sensors may use different optics for transmitting and receiving a signal. As a result, it is essential to determine that the various combinations meet Philips standards to ensure that clinicians will get clinically viable data. Because of the rigorous validation activities that Philips Healthcare undergoes with SpO_2 sensors, we can stand behind any claims that we make with regard to these products.

What products do we validate?

Before Philips sells any SpO_2 sensors or claims compatibility with any specific devices, the sensors go through rigorous validation testing. Sensors have been tested and validated for use on the vast majority of Philips (HP/Agilent) monitors as well as certain Nellcor and GE monitors. Please refer to the individual IFUs or ask your sales representative for this information.

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Examples of Validation Testing:

Customer Requirement	Standard	Validation of Requirement
Accurate SpO_2	Basic safety and performance of Pulse Oximeter Equipment (EN ISO 9919:2005 Clause 50.101)	Validate accuracy by an invasive controlled desaturation study with healthy volunteers over the range from 70 to 100% SpO_2. A representative set of sensors is used in combination with all instruments we claim compatibility with.
Accurate pulse rate	Basic safety and performance of Pulse Oximeter Equipment (EN ISO 9919:2005 Clause 50.104)	Validate pulse rate accuracy with patient signal simulator with all monitors we claim compatibility with.
Proven intended-use, covering application sites and patient sizes	Philips requirement	Validate sensors perform properly per claimed application sites and weight ranges.
Operates within intended electromagnetic environment within hospital	General requirments for safety - Electromagnetic compatibility (IEC 60601-1-2, Clause 36)	Validate that all compatible instruments when used with a Philips sensor have equal or better EMC performance than with original sensors specified for use with the instruments.
Wide range of approved cleaning and disinfection methods for reusable sensors	Philips requirement	Validate the products don't deteriorate, if cleaned or disinfected using the specified cleaners and disinfectants.
Protects patient skin from allergic, irritation or toxic reaction	Biological evaluation of medical devices - Evaluation and testing (ISO 10993-1-part 5 and 10)	Validate all patient-contact materials do not cause harm to patient skin.
Prevents skin burns due to SpO_2 IR/RED light	Basic safety and performance of Pulse Oximeter Equipment (EN ISO 9919:2005 Clause 42)	Validate the temperature of the part applied to the skin does not exceed 41° C in combination with all instruments we claim compatibility with.
Withstands expected mechanical stresses during life of product	Philips requirement	Validate mechanical performance, cycling, connector tear out.
Ambient light immunity	Philips requirement	Validate that when all compatible instruments are used with a Philips sensor there is equal or better ambient light performance than with an original sensor specified for use with the instruments.

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