The importance of validating invasive blood pressure supplies

Philips Healthcare Supplies

Philips Healthcare offers high quality accessories and supplies that are designed to precise specifications. The manufacturing facilities meticulously follow 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 necessary steps that confirm 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 TRANSPAC® 4 Disposable Pressure Transducer kits conform to?

Philips TRANSPAC® 4 transducers and accessories meet 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 for *Examples of Validation Testing* that list the standards.

What does the process of validation entail?

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

Why is validation of transducer/device compatibility important?

When connected to a device, a transducer and adapter cable may appear to function effectively, but may not necessarily be performing safely or accurately. Other transducers and adapter cables with different technologies may not have been validated on all required component combinations needed to truly claim compatibility with Philips monitors. It is essential to determine that all component combinations meet Philips' standards to ensure that clinicians consistently receive clinically-viable data. Philips Healthcare is able to stand behind its validated claims of safety and effectiveness based on the rigorous validation activities that are performed on its transducers and adapter cables.

What products do we validate?

Philips TRANSPAC® 4 disposable pressure transducer kits and reusable adapter cables go through rigorous validation testing. They have been tested and validated for use on the vast majority of Philips (HP/Agilent) monitors.

TRANSPAC® 4 Specifications

Operating Pressure Range:	-50 to 300mmHg	**Input Impedance**:	300-350 ohms
Overpressure Limits:	-400 to 5000mmHg	**Output Impedance**:	300 ohms ± 30 ohms
Sensitivity:	5.0 µV/V/mmHg ± 1% @ 6.0VDC and 22°C	**Shock Resistance**:	Withstands 5 falls from a height of 2 meters onto a concrete floor
Temperature Error Band of Sensitivity:	<± 1.5%	**Temperature Range**:	***Storage***: -15°C to 60°C ***Operating***: 15°C to 40°C
Temperature Error Band of Zero Pressure:	<± 4.5 mmHg	**Excitation**:	4 to 10VDC or rms AC up to 5 kHz
Temperature Coefficient of Sensitivity:	<± 0.1%/°C	**Leakage (Risk) Current**:	<2 µA at 115VAC, 60 Hz
Temperature Coefficient of Zero Offset:	<± 0.3 mmHg/°C	**Dielectric Breakdown**:	>10,000VDC for 1 second
Accuracy: Accurate within 1 mmHg for pressures up to 100mmHg and within ± 2.0% of reading for pressures from 101 - 200mmHg		**Defibrillator Withstand**:	5 discharges of 400 joules in 5 minutes across a 50 ohm load
Zero Offset:	<± 25mmHg	**Phase Shift**:	<5° to 5 kHz
Zero Drift:	<± 2mmHg in 8 hours	**Output Impedance**:	300 ohms+ 30 ohms
Warm up Time:	2 minutes	**Light Sensitivity**:	Transducer output is not affected by changing light conditions

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Examples of Validation Testing

Customer Requirement	Standard	Validation or Requirement
Accurate and real-time data	Basic safety and essential performance of invasive blood pressure monitoring equipment (EN/IEC 60601-2-34) American National Standard (ANSI/AAMI BP22): Blood Pressure Transducers	TRANSPAC® disposable transducer kits and reusable adapter cables were tested together in combination with Philips instruments with which we claim compatibility per standard requirements *Other factors:* TRANSPAC® transducers are 100% factory-tested for accuracy
Operates within intended electromagnetic environment within hospital	General requirements for safety - Electromagnetic compatibility (EMC) (IEC 60601-1-2, Clause 36)	TRANSPAC® transducers and reusable adapter cables were tested together in combination with Philips instruments and proven to perform properly under EMC conditions
Wide range of approved cleaning and disinfection methods for reusable adapter cables	Philips requirement	Validated that 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-parts 5 and 10)	Validated that patient-contacting materials do not cause harm to patient skin
Withstands expected mechanical stresses during life of product	Philips requirement	Validated mechanical performance, bend cycling, connector insert/removal forces
Sterile, single-use, non pyrogenic	Sterilization of health care products: Requirements for development, validation and routine control of a sterilization process for medical device (ISO 11135-1 or ISO 11137-1 as applicable)	Validation and routine quality audits of the sterilization procedures and process are performed

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Part No. 453564374101
Published June 2012