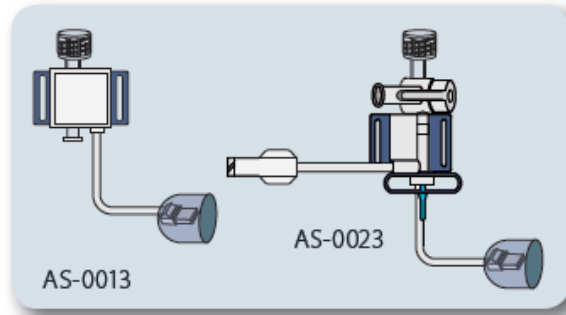


Art-Line™: DISPOSABLE PRESSURE TRANSDUCER

Code	Description
AS-0013	Disposable blood pressure Transducer
AS-0023	Integrated disposable blood pressure transducer with 3cc flush device



TECHNICAL SPECIFICATIONS

	BIOMETRIX
Sensitivity	5 μ V/V/mmHg \pm 1%
Operating pressure range	-30 to 300 mmHg
Non linearity & hysteresis	\pm 1 mmHg (-30-200mmHg) \pm 1.5mmHg (200-300 mmHg)
Zero thermal effect	\leq \pm 0.3mmHg/ $^{\circ}$ C
Zero drift with time	\leq 2mmHg/8 hr (drift)
Leakage current	<2uA
Overpressure protection	6464mmHg
Operating temp	+15 C to +40 C
Operating life	168 hr
Storage temp	-25 C to +70C
Output impedance	270 - 330 ohms

INSPECTION:

1. Incoming Inspection:

Sampling per Mil. Sts 105 E AQL 0.25 Level II, Inspection of Supplier documents of compliance and special attention to integrity of raw materials.

2. Final Inspection:

Sampling per Mil. Sts. 105E AQL 0.25 Level II, functional tests, integrity, pull-out tests and very detailed visual inspection of damages in the product.

A. Product Stability.

The products have been tested with satisfying results for 5 years shelf life when stored in an atmosphere of 25 C temp. max. with 30-60% relative humidity.

No significant light source is recommended/ allowed.

B. Compatibility.

Products are compatible with the Pharmaceutical products with which they are in contact in a day to day use, based on engineering testing and 10 years of experience of use in hospitals.

Biological evaluation of the product is per ISO-10993-1 –Biological evaluation of medical devices, Part 1: Guidance on selection of tests.

C. Sterilization:

By Ethylene Oxide sterilization process. Validation and routine control of the sterilization is complying with ISO 11135-1:2007 requirements.

D. Conformance

Conformance with ISO 13485:2003, ISO 9001:2008 and the Medical Devices Directive 93/42/EEC ANNEX II as amended per 2007/47/EC.