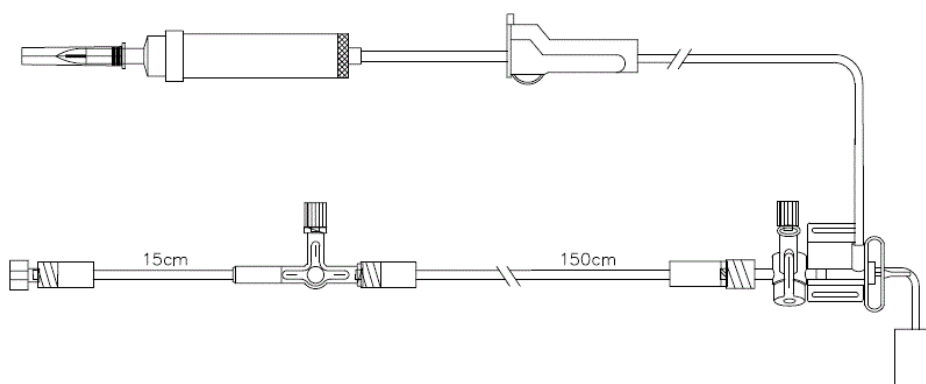


Art-Line™: Invasive Arterial Blood Pressure Set with Disposable Transducer

Code	Description
AB-0023	Single Channel Blood Pressure Monitoring Set



Contents:

1. DPT- disposable pressure transducer
2. Pressure lines 15, 150cm
3. 4 way stopcock
4. IV line

INTEND OF USE

The set permits continuous and accurate blood pressure reading during clinical invasive procedures without interfering the blood flow and pressure. These sets enable detection of patients' immediate response to medication, therapy and stress.

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 22 ± 2 C° temp 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.