Instructions for Use
Disposable Pressure Transducer

Manufactured by Mais India Medical Devices Pvt. Ltd.

PRODUCT OVERVIEW:
The disposable pressure transducer is intended for invasive monitoring of physiological pressures and is supplied sterile for single-use only.

INDICATIONS FOR USE:
This device is intended for continuous invasive monitoring of arterial pressure (AP), central venous pressure (CVP), pulmonary artery pressure (PAP), and atrial pressure.

CONTRAINDICATIONS:
There are no known absolute contraindications. Use with caution in patients with bleeding disorders or coagulopathies.

WARNINGS:

- Single-use device. Do not reuse, reprocess, or re-sterilize.
- Do not use if packaging is damaged or contaminated.
- Use only by trained medical personnel.
- Ensure removal of all air bubbles before use.
- Do not overtighten Luer connectors.
- Inspect system regularly for leaks or loose connections.
- Do not alter or modify the device.
- Lipid-based continuous infusions may weaken Luer components.

PRECAUTIONS:

- Maintain aseptic technique.
- Position transducer at mid-axillary line for zeroing.
- Inspect the system periodically for leaks, pressure, and flushing.
- Avoid heat or direct sunlight before use.

STORAGE & TRANSPORT CONDITIONS:

- Temperature: +10°C to +40°C
- Humidity: 50% ± 10%
- Store in a cool, dry place away from sunlight.
- Protect from moisture and physical damage.

SHELF LIFE & LIFETIME:

- Shelf life: 5 years.
- Lifetime: Single patient use, up to 72 hours.

SET-UP INSTRUCTIONS:
Refer to subsections below.

1- Preparation

- Turn the patient monitor ON.
- Open sterile packaging using aseptic technique.
- Verify connections and stopcock orientation.
- Ensure vented caps remain until filling.

2- Filling & Flushing the System

- Prepare sterile flush solution.
- Connect transducer set to solution bag.
- Purge air by squeezing bag.
- Insert solution bag in pressure cuff and hang 2 ft above patient.
- Eliminate all air bubbles.
- Pressurize cuff to 300 mmHg.
- Replace vented caps with non-vented caps.

3- Zeroing and Calibration

- Position transducer at mid-axillary level.
- Connect to monitor cable.
- Open stopcock to air and perform zero calibration.
- Close stopcock and replace vented cap.

4- Connection to Patient

- Connect monitoring line to cannula/catheter.
- Flush line to clear blood.
- Prevent flushing air or clots into the patient.

5- DYNAMIC RESPONSE TEST
Perform square wave test after system setup and allow 1 minute stabilization.

COLOR CODING (MULTIPLE TRANSDUCERS):

Red – Arterial
Blue – CVP
Yellow – PAP
Green – Atrial
White – Miscellaneous

MAINTENANCE:

No preventive maintenance required. Dispose per biomedical waste guidelines.

INCIDENT REPORTING:

Report serious incidents to the manufacturer and competent authority.

EXPLANATION OF SYMBOLS

Includes ISO 15223-1 standard symbols such as:

Manufacturer, Sterilized using EO, Do not reuse, Use-by date, Batch number, Catalogue number, Keep dry, Keep away from sunlight, Temperature limit, Humidity limit, Medical Device (MD), CE marking (if applicable), Authorized Representative in EU, UDI, Consult IFU.

Explanation of symbols used:

Symbols	Title of the Symbol	Symbols	Title of the Symbol
	Consult instructions for use (Indicates the need for the user to consult the instructions for use)		Latex free (Indicates a medical device that is Latex free)
	Caution (To indicate that caution is necessary when operating the device or control close to where the symbol is placed, or to indicate that the current situation needs operator awareness or operator action in order to avoid undesirable consequences.)		Date of manufacture (Indicates the date when the medical device was manufactured)
	Sterilized using ethylene oxide Single sterile barrier system (Indicates a medical device that has been sterilized using ethylene oxide)		Use-by date (Indicates the date after which the medical device is not to be used)
	Do not re-sterilize (Indicates a medical device that is not to be re-sterilized)		Batch Number (Indicates the manufacturer's batch number so that the batch or lot can be identified)
	Do not re-use (Indicates a medical device that is intended for one single use only)		Reference number (Indicates the manufacturer's catalogue number so that the medical device can be identified)
	Non-pyrogenic (Indicates a medical device that is non- pyrogenic)		Keep away from sunlight (Indicates a medical device that needs protection from light sources)
	Do not use if packaging is damaged and consult instructions for use. (Indicates a medical device that should not be used if its packaging has been damaged or opened, and that the user should consult the instructions for use for additional information)		Manufacturer (Indicates the medical device manufacturer) Manufacturing Unit: 525P, Sector-37, Pace City II, Gurgaon, Haryana-122001, India. Contact Details.: +91 8527589990 Fax No.: 0124 404 7533 Email ID: info@maisindia.com Website:www.maisindia.com
	Humidity limitation (Indicates the range of humidity to which the medical device can be safely exposed.		Temperature limit (Indicates the temperature limits to which the medical device can be safely exposed.

Symbols	Title of the Symbol	Symbols	Title of the Symbol
	Keep dry (Indicates a medical device that needs to be protected from moisture)		This way up
	Unique Device Identifier (Indicates a carrier that contains Unique Device Identifier information)		Medical device (Indicates the item is a medical device)
	Country of manufacture (To identify the country of manufacture of products)		Fragile, handle with care (Indicates a medical device that can be broken or damaged if not handled carefully)

Manufactured by:
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