Instructions for Use

MONITOR™

Pressure Monitoring Transducer Kits

Description:

MONITOR™ Pressure Monitoring Transducer Kits are single use devices used for monitoring of blood pressure required during invasive and minimally invasive medical procedures. The Pressure Transducers are available as kits along with accessories required for their effective use. The main components of the Pressure Transducer itself are a Protective cap, Perfusion valve, & Zero Tee. Accessories include Pressure Monitoring Line, 3-way Stopcock, I.V. Set & coloured sticker for identification.

A separate reusable interface cable is used with this system to connect the transducer to a pressure monitor. A fixing plate is available for attachment to a pole mount, or it may be used with a manifold or attached directly to the patient via a strap.

Indications for Use:

MONITOR™ Pressure Monitoring Transducer Kits are used on patients requiring intravascular, intracranial, or intrauterine blood pressure monitoring

Contraindications:

- None Known

Technical Specifications

a) Transducer incentive voltage: 1V-6V;
b) Incentive voltage rate: 5 KHz;
c) Transducer input impedance: 300Ω-400Ω;
d) Transducer output impedance: 250Ω-350Ω.
e) The range of input pressure: -30mHg-300mHg

Warnings:

1. Please read all packaging insert warnings, precautions, and instructions before use. Failure to do so may result in loss of blood and delay to the procedure.
2. Sterile by EO, Single Use: Do not reuse, reprocess or re-sterilize under any circumstance. Blood and other foreign material can collect in the inner parts of the product which cannot be removed.
3. Do not use if the packaging is damaged or opened unintentionally before use. This will lead to loss of sterility.
4. Rx Only. The products must be used by trained physicians
5. Connections should only be made with devices compliant to ISO 80369-7
6. If the transducer is used to measure left arterial pressure, an air eliminator filter must be installed between the solution source and the transducer

Precautions:

1. Aseptic techniques must be used wherever possible, especially during removal from packaging.
2. The connection should be hand tightened, but not over tightened as that can lead to cracks which may cause an embolism.
3. Check products carefully to ensure there is no entrapped air which can lead to an embolism
4. Ensure the connection is secure as insecure connections can lead to air in the system which can cause an embolism

Instructions for Use:

Connections

1. Using aseptic technique, open the package containing the sterile transducer.
2. Set-up according to hospital protocol for pressure monitoring procedures. Connect to other monitoring equipment (e.g. manifolds, stopcocks, flush devices, tubing administration sets, etc.)

CAUTION: Make sure that all connections are tight. To prevent stripping, do not overtighten.

3. Ensure that the connectors are dry.
4. Connect the MONITOR disposable transducer cable to the reusable monitor cable.
5. Extract all air from the flush solution container.

CAUTION: If air is not extracted from the solution container, air may be forced into the system when the fluid is depleted.

Fill Lines

1. Remove caps (if any) from stopcock on transducer and open the system.
2. Fill all lines with sterile flush solution until free of air bubbles.

NOTE: ALSPL recommends gravity filling the system rather than pressurizing the flush solution to avoid generating bubbles in the solution.

CAUTION: Verify that no air is trapped in any components of the fluid pathway. Air bubbles can cause serious patient harm and will negatively impact pressure wave forms.

3. Turn stopcock off.
4. Using sterile technique fix non-vented caps.
5. Repeat steps 1-4 for any additional stopcocks or ports.
6. Pressurize the I.V. solution source to 300 mmHg.

Zeroing The System

1. Zeroing should be performed after the system has been filled and mounted.
2. Turn the pressure monitoring system "off" to the patient.
3. Verify that the opening of the stopcock to be used for zeroing is positioned at the patient's mid-axillary level.
4. Being careful not to contaminate the zeroing port, turn the stopcock handle to open the port at the mid-axillary level to air.
5. Zero the transducer according to the monitor manufacturer's instructions.
6. Turn the stopcock handle "off" to the open port.
7. Turn the pressure monitoring system "on" to the patient.

CAUTIONS: Before injecting, turn the stopcock handle to the transducer off in order to isolate the transducer from pressure.

Connecting to the Catheter

1. Connect the monitoring kit pressure tubing carefully to the patient's catheter or sheath so that no air is introduced into the system.

Disposal:

Pressure Transducers can be a biological hazard if disposed incorrectly. They should be disposed using recognised medical procedures and industry best practices. Local laws and regulations should be taken into account during disposal

EMC Information

⚠ **Important Notice**

- Disposable Blood Pressure Transducer & Accessories meet the requirement of electromagnetic compatibility in IEC60601-1-2.
- The user needs to install and use according to electromagnetism compatibility information which is

attached with it.

- Portable and mobile RF communication devices may influence Disposable Blood Pressure Transducer & Accessories performance, so Disposable Blood Pressure Transducer & Accessories should be kept away from them during using.
- Guidance and manufacturer's declaration stated in the appendix.

⚠ **Warning:**

- Disposable Blood Pressure Transducer & Accessories should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the Disposable Blood Pressure Transducer & Accessories should be observed to verify normal operation in the configuration in which it will be used.
- Class A equipment is intended for use in an industrial environment. The Disposable Blood Pressure Transducer & Accessories may be potential difficulties in ensuring electromagnetic compatibility in other environments, due to conducted as well as radiated disturbances.

Table 1

Guidance and manufacturer's declaration –electromagnetic emissions

The Disposable Blood Pressure Transducer & Accessories are intended for use in the electromagnetic environments specified below. The customer or the user of the kit should assure that it is used in such environments.

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	Disposable Blood Pressure Transducer & Accessories use RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	Disposable Blood Pressure Transducer & Accessories is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not Applicable	
Voltage fluctuations /flicker emissions IEC 61000-3-3	Not Applicable	

Table 2

Guidance and manufacturer's declaration – electromagnetic immunity

The Disposable Blood Pressure Transducer & Accessories are intended for use in the electromagnetic environments specified below. The customer or the user of the kit should assure that it is used in such environments.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for powersupply lines	±2 kV for power supply lines	Mains power quality should be that of atypical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	Mains power quality should be that of atypical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % *U*T (>95 % dip in *U*T) for 0,5 cycle 40 % *U*T (60 % dip in *U*T) for 5 cycles 70 % *U*T (30 % dip in *U*T) for 25 cycles <5 % *U*T (>95 % dip in *U*T) for 5 s	<5 % *U*T (>95 % dip in *U*T) for 0,5 cycle 40 % *U*T (60 % dip in *U*T) for 5 cycles 70 % *U*T (30 % dip in *U*T) for 25 cycles <5 % *U*T (>95 % dip in *U*T) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Disposable Blood Pressure Transducer & Accessories requires continued operation during power mains interruptions, it is recommended that the Disposable Blood Pressure Transducer & Accessories be powered from an uninterruptible power supply or a battery.

Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE *U*T is the a.c. mains voltage prior to application of the test level.			

Table 3

Guidance and manufacturer's declaration – electromagnetic immunity

The Disposable Blood Pressure Transducer & Accessories are intended for use in the electromagnetic environments specified below. The customer or the user of the kit should assure that it is used in such environments.

Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3Vrms 150kHz to 80MHz 3V/m 80MHz to 2.5GHz	3Vrms 3V/m	Portable and mobile RF communications equipment should be used no closer to any part of the Disposable Blood Pressure Transducer & Accessories, including cables, then the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80MHz to 800MHz $d = 2.3\sqrt{P}$ 800MHz to 2.5GHz where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, [a] should be less than the compliance level in each frequency range. [b] Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1 At 80MHz and 800MHz, the higher frequency range applies.
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a	Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Disposable Blood Pressure Transducer & Accessories is used exceeds the applicable RF compliance level above, the Disposable Blood Pressure Transducer & Accessories should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Disposable Blood Pressure Transducer & Accessories.
b	Over the frequency range 150kHz to 80MHz, field strengths should be less than 3V/m.

Table 4

Recommended separation distances between portable and mobile RF communications equipment and the Disposable Blood Pressure Transducer & Accessories

The Disposable Blood Pressure Transducer & Accessories is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Disposable Blood Pressure Transducer & Accessories can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Disposable Blood Pressure Transducer & Accessories as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter m**		
	150kHz to 80MHz $d = 1.2 \quad P$	**80MHz to 800MHz** $d = 1.2 \quad P$	**800MHz to 2.5GHz** $d = 2.3 \quad P$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80MHz and 800MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Potential Complications / Adverse Effects

The clinical benefit of the product must be evaluated against the recognized risks and complications of the procedure which include but are not limited to:

- Air embolism.
- septicemia

Warranty and Limitations

Products are sold in 'as is' condition. The entire risk as to the quality and performance of the product is with the buyer. ALSPL disclaims all warranties, expressed or implied, with respect to its products, including but not limited to, any implied warranty of merchantability or fitness for a particular purpose. ALSPL shall not be liable to any person for any medical expenses or any direct or consequential damages resulting from the use of any product or caused by any defect, failure, or malfunction of any product, whether a claim for such damages is based upon warranty, contract, tort, or otherwise. No person has any authority to bind ALSPL to any representation or warranty with respect to its products.

Symbols Glossary

	Caution, Consult Indications for Use
	Date of Manufacture
	Do not re-use
	Do not use if package is damaged
	Sterilized using ethylene oxide
	Keep away from sunlight
	Batch code
	Catalogue Number
	Manufacturer
	Use-by date
	Keep dry
	Temperature Limit

 Manufactured By:

Advanced LifeSciences Pvt. Ltd.
D-22 Okhla Industrial Area Phase – 1,
New Delhi – 110020,
India
E-mail: customerservice@alspl.com
Phone: +91 9818237529