HITACHI
Inspire the Next

MXS1 Probe
Instruction Manual
Specification

MN1-6260 Rev.2

Notes for operators and responsible maintenance personnel

★ *Please read through this Instruction Manual as well as the separate Instruction Manual "Safety (MN1-5980)" and "Cleaning, Disinfection and Sterilization (MN1-5998)" carefully prior to use.*

★ *Keep this Instruction Manual together with the ultrasound diagnostic instrument for any future reference.*

CE 0123

Hitachi, Ltd.

Introduction

This is the instruction manual for MXS1 probe. The probe is available by connecting to Hitachi's ultrasound diagnostic instrument and can be mainly used for observation of cardiovascular.

Prior to use, read this manual as well as the separate instruction manual “Safety” in which information for safe use is provided.

The probe bears the CE mark but the mark is valid only when the probe is connected to the ultrasound diagnostic instrument bearing the CE mark.

Symbols used in this document

Safety information is classified into Danger, Warning, Caution, and Note according to the level of hazard. Those terms are used in safety information provided to prevent hazards and injuries to the operator or patient.

⚠ Danger
Indicates an imminently hazardous situation which, if not avoided, will result in death or serious injury to the operator or patient.

⚠ Warning
Indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury to the operator or patient.

⚠ Caution
Indicates a potentially hazardous situation which, if not avoided, may result in minor or moderate injury to the operator or patient, or property damage only.

⚠ Note
Indicates a strong request concerning an item that must be observed in order to prevent damage or deterioration of the equipment and also to ensure that it is used efficiently.

The type of safety information is indicated by the symbols below.

⚠	This symbol means that attention is required.
⃠	This symbol means that the described action is prohibited.
❗	This symbol means that the described action is mandatory.

CONTENTS

This instruction manual contains 4 pages of front matter and 8 pages of the main content.

1. General Information

General information for the probe is provided below.

1-1. Intended use

This probe is intended to be used by doctors or other qualified operators. The probe is placed on the body for observation of surrounding organs.

Please refer to the ultrasound diagnostic instrument instruction manual used with this probe for the probe intended use information.

Regarding with the connectable instrument, please refer to section 2-1. Specifications of this manual.

⚠ Warning
Do not use this equipment for other than its intended use. Otherwise it could cause burns or other injuries to the operator or the patient.
Do not performe a puncture. This probe doesn't support any puncture method .

1-2. Classification of ME equipment

This probe is classified as follows according to IEC60601-1.

Please refer to the section 2-1 for the applied part, the part treated as the applied part, and the range of IPX7.

- Classification based on the degree of protection against electric shock ····· Type BF applied part
- Classification for protection against ingress of liquids ····· IPX7 (Watertight equipment)
- Operation mode····· Continuous operation
- Method of sterilization····· Refer to the separate instruction manual "Cleaning, Disinfection and Sterilization"

1-3. Standard components

The standard components of MXS1 probe are as follows.

MXS1 Probe ····· 1 set
Storage case ····· 1 set
Instruction Manual
- Specification (MN1-6260) ····· 1 copy
- Safety (MN1-5980)····· 1 copy
- Cleaning, Disinfection and Sterilization (MN1-5998) ····· 1 copy

1-4. Options

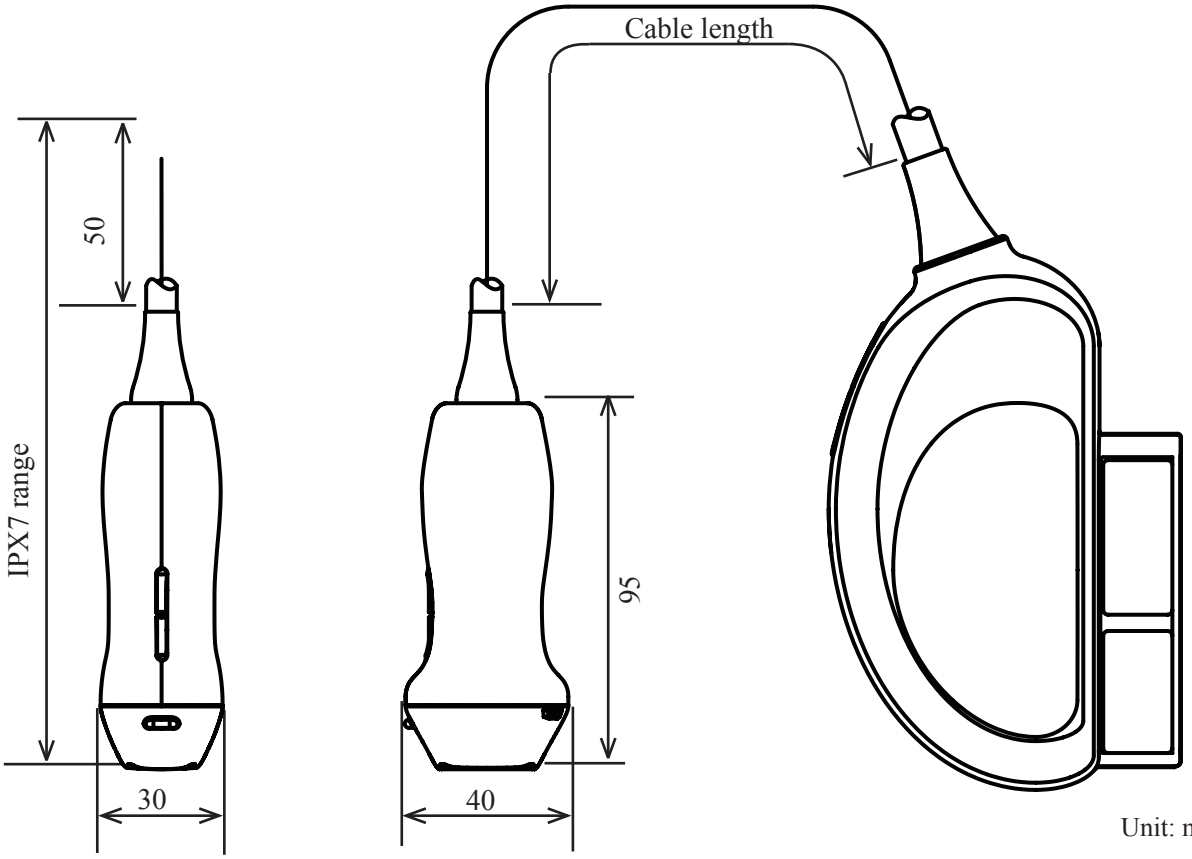
There is no option for MXS1 probe.

2. Specifications and Parts name

The specifications and the name of each part are provided below.

2-1. Specifications

Application:	Cardiovascular
Type of patient contact:	Surface
Connectable instruments:	ALOKA LISENDO 880,ALOKA ARIETTA 850 NOTE: At the time of publication of this manual, the connectable diagnostic ultrasound instrument or instrument software version available with this probe is different for each country, please refer to the instrument instruction manual or contact your local Hitachi representative.
Field of view:	90°
Frequency:	2.75 MHz
Cable length:	2.2 m
Service life:	3 years
Applied part:	Probe tip including ultrasonic radiation part, see the section 2-2
Part treated as Applied part:	Cable up to 1 m length from the probe tip
IPX7 range:	See Figure 1
Measurement accuracy:	Refer to the instruction manual of the ultrasound diagnostic instrument
External dimensions:	See Figure 1
Maximum surface Temperature of Probe tip	43°C



Unit: mm

Remark: The tolerance for the dimensions is ±10%.

Figure 1 External View

2-2. Name of each parts

The name of each part is shown in Figure 2 and the explanation for each part is listed in Table 1.

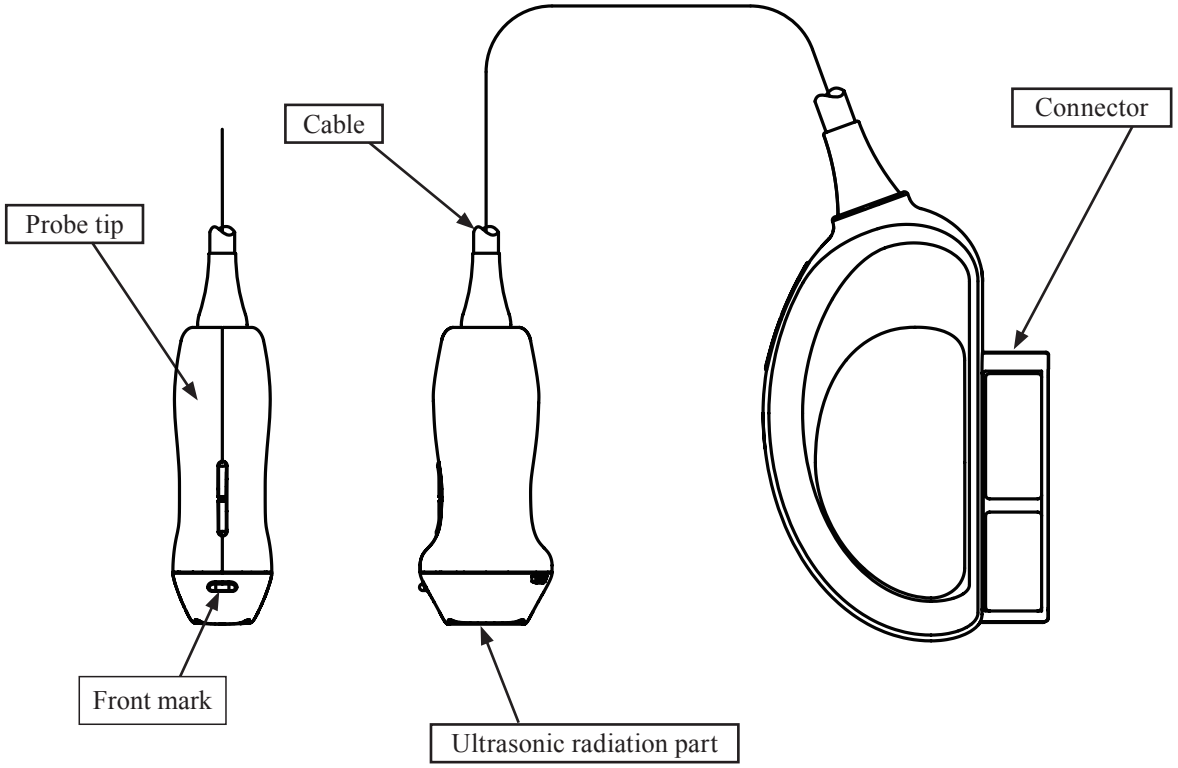


Figure 2 Name of each parts

Table 1 Name of each part and its explanation

Name	Explanation
Ultrasonic radiation part	Ultrasound is radiated from this part. The electronic sector transducer is integrated underneath this part.
Front mark	The side of the front mark corresponds to the side of the orientation mark on the image.
Probe tip	This part is gripped during operation.
Cable	Cable transfers electric input/output signals.
Connector	The connector is the part which is connected to the ultrasound diagnostic instrument.

⚠ Caution	
⃠	Do not pull, bend, twist, or apply excessive force to the cable. The probe may malfunction due to cable disconnection.
⃠	Do not subject the ultrasonic radiation part to hard impact. The impact may cause damage to the transducer, and that results in noise or no echo in the image. In most cases, the ultrasonic radiation part itself is not damaged because the part is made of elastic material.

3. Preparations before use

This chapter describes preparations needed to use the probe safely. Please prepare the probe prior to each use by following the instructions below.

3-1. Visual check

Visually check the probe tip, ultrasonic radiation part, cable, and connector.
If any holes, indentations, abrasion, cracks, deformation, looseness, discoloration, or other abnormalities are found, do not use the probe.

3-2. Confirmation of cleaning, disinfection, and sterilization

Confirm that the probe is certainly cleaned, disinfected, and sterilized. The degree of reprocessing depends on the intended use. Please refer to the separate instruction manual “Cleaning, Disinfection and Sterilization” for cleaning, disinfection, and sterilization procedure.

3-3. Operation check

Connect the probe to the ultrasound diagnostic instrument and check that the displayed scan type and frequency correspond to those of the probe. Check also that there is no abnormality in the image.
If any abnormality is found in the image, please refer to the picture at section “1-1-1 Warnings and cautions” of separate instruction manual “Safety”.

Remark: Please refer to the documentation supplied with the ultrasound diagnostic instrument for how to connect the probe and information displayed on the monitor.
If the probe is operated in still air, brightness on the top of the image may be non uniform, but this does not affect the performance of the probe.

⚠ Warning

Make preparations prior to each use.
The operator and the patient may be injured if the equipment has any abnormality.
If any abnormality is found in the equipment, stop using it and contact our office written on the back cover.

⚠ Caution

Do not use the probe if the displayed scan type and frequency do not correspond to those of the probe. Incorrect acoustic output can result in burns or other injuries to the patient. Contact our office written on the back cover.

4. Operation

Place the ultrasonic radiation part of the probe onto the skin surface. An image of the region of interest is displayed on the monitor of the ultrasound diagnostic instrument. For details on displaying and adjusting the image, refer to the documentation supplied with the ultrasound diagnostic instrument.

⚠ Caution
Do not operate the probe with excessive force. Use with excessive force could result in injury to the patient.
Scan for minimum time necessary at the lowest possible acoustic output. Acoustic output may affect the patient's internal tissues. For details about the acoustic output, please refer to the documentation supplied with the ultrasound diagnostic instrument.
Do not touch the connector terminal pin of the probe. Electrostatic discharge may result in malfunction of the probe.
Do not touch the probe connector of the ultrasound diagnostic instrument and the patient at the same time. It can cause electric shock to the patient.
Remove the probe after pushing the Freeze button Probe will be damaged when do not remove the probe after stopping the transmission.

4-1. Temperature Control System

The tip of the probe contains a temperature sensor. This sensor monitors the surface temperature at the tip of the probe in order to prevent damage to the body surface.

When the surface temperature exceed limit, the message appears on the equipment monitor.

1) When the surface temperature becomes 41°C

When the surface temperature becomes 41°C, the message "Probe temperature is higher than 41.0°C." appears on the equipment monitor.

2) When the surface temperature becomes 43°C

When the surface temperature becomes 43°C, the message "TTE thermal limit. Auto cooling mode in progress." appears on the equipment monitor and the acoustic output is automatically stopped. When surface temperature is below 40.5°C, This message disappears and restarts operation.

3 Under the following conditions, the probe tip gets hot easily and rapidly, so select "Saving".

The ambient temperature exceeds 30°C.

Patient has a high body temperature.

Prolonged use is expected.

See the equipment mannual for the detail.

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