SIGMAX

MEDICAL PRODUCTS

SIGMAX

NIPPON SIGMAX CO., LTD.

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Tokyo, 160-0023, JAPAN

HP https://www.sigmax-med.com/
Corporate HP https://www.siagmax.co.jp/english/index.html

Contact Information:

Company Name:

Email:

Phone:

Sophisticated Device for the Ideal Cold Therapy

ICING SYSTEM
CE4000

SIGMAX Accelerates Patient's Recovery and Shorten the Hospital Stay

We, Nippon Sigmax Co., Ltd., have been spreading our ICING SYSTEM in the Japanese Orthopedic field since 1997.
CE4000 is our 4th generation cold therapy device derived from the opinion of various clinical practitioners. We have pursued better usability from the viewpoint of the doctors and health-care professionals in order to accelerate the recovery of the patients.

Effectiveness of Cold Therapy

Cold therapy is the treatment approach well known from the 1950s in the sports medicine field which accelerate the recovery of the patient by icing the affected area. In the orthopedics field, it is used in many ways, preventing bleeding and swelling from the surgical incision or affected area, cooling down after the rehabilitation, and pain relieving after the surgery. CE4000 is the secure and safe cold therapy device with no side effects which surely keeps the preset temperature and enables the proper temperature management.

Efficiency

Less Bleeding
Cooling will cause vascular constriction and hypoperfusion which results in less bleeding.

Prevent and Limit Swelling
Less bleeding decrease the amount of blood remained in the tissue and prevents the swelling. Also, it will prevent tissue fluid remaining under the hypodermal tissue.

Pain Relief
Increase of sensory receptor threshold relief the pain. At the same time, reduction of metabolism will decrease production of the algesic substance, or the pain-producing substance.

Early Rehabilitation

Restoration of " Range of Motion "

Merit

For Patients
- Reduce burden of both physical and mental illness
- Reduce burden of medical expenses
- Early rising
- Early hospital discharge

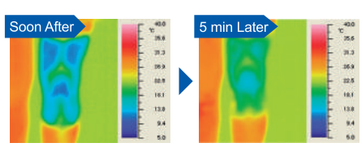
For Medical Professionals
- Increase in hospital bed turnover rate
- Decrease in medication
- Man-power saving
- Reduce hospital stay period

* Reference: Knight KL. Cryotherapy in sport injury management. 1995. Human Kinetics, Champaign, IL.

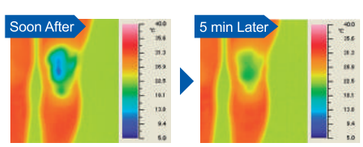
Difference in Effectiveness Between ICING SYSTEM and Ice Pack

Compared the dermal thermography of the knee joint cooling down for 20 min and leaving it for 5 min (ICING SYSTEM preset temperature 0°C with air compression level 2). Compared to the ice pack, ICING SYSTEM offers more wide and uniform effect on the affected area for prolonged time. * According to our research

ICING SYSTEM



Ice Pack

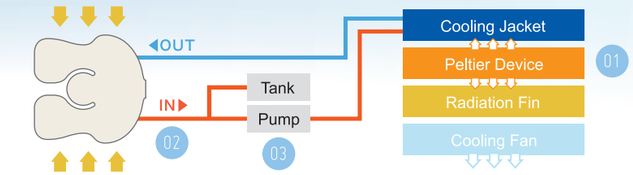


Great Difference in Cooling Efficiency and Cooling Effect Duration

Functionality

01 Cooling

Cooling Mechanism



01 Circulating Liquid in a cooling jacket is cooled by the peltier device.

02 The cooled liquid flows into the Cooling Pad through a hose and absorb heat while cooling the affected area.

03 After absorbing heat, the liquid is pumped back to the cooling jacket.

* Peltier device : A semiconductor with the feature that one side of the device is cooled and the other side heated when direct-current electricity is applied.

02 Temperature Management

Constant and Precise Temperature Management

CE4000 enables the secure temperature control, keeping the preset temperature constantly.
It will reach the preset temperature in 20 min* after the power is on.

* Note: Time reaching the preset temperature differs by the environmental condition such as room temperature.
It takes 20 min when the room temperature is 25°C and preset temperature at 5°C.

Temperature Adjustable Between 0°C to 13°C

In cold therapy, the ideal temperature varies based on the therapeutic purpose. With CE4000, you can control the temperature anywhere from 0°C to 13°C (or 32°F to 55.4°F) depending on the patient's symptoms.

03 Silent

Silent Design

Postoperative cold therapy has a beneficial effect in the case of cooling the affected area constantly. CE4000 is designed to be as quiet as possible not to disturb patient's sleep or others while in the multi-bed room.

04 Alarm

Error Alarm Function

In case of trouble, the error code will appear in the temperature display (TEMP.) and alarm sounds. Refer to the Error Code List in the Instructions for Use to identify the cause of the error.

05 Timer

Timer with Audible Alarm

Alarm will sound when it reached the setup time. Elapsed time is indicated in the time display (TIME).

CAUTION: This timer will NOT stop cooling. Timer ONLY announces the setup time and indicates the elapsed time of the treatment.

Convenience

01 Compact & Portable

Portable Size and Installable to the bed

CE4000 has a small compact body which is easy to carry around.

Two hooks are located on the back of the Main Unit which can be used to hook it on the bed side rails. CE4000 will occupy only minimum space in the hospital bed room.

02 Energy Saving

Low Power Consumption

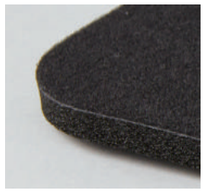
Cold therapy often requires constant use of the device after surgery. Using CE4000 is very economical even in the use of the device for a prolonged time.

03 Condensation Free

Condensation Free Hose and Pad

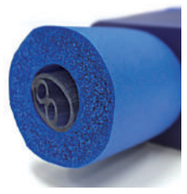
Cooling Pad and CE4000 Hose are covered by the insulation material to keep them free from condensation. Keeping them clean even in the long term use.

① Insulation material on CE4000 Universal Cooling Pad
② Pad Connector Cover



Thick insulation material to avoid condensation

Connecting Hose and the Main Unit



Cross-sectional surface of the CE4000 Hose

04 Easy Application

Easy-to-Wear Universal Pad

CE4000 Universal Cooling Pad is easy-to wear by wrapping it around the affected area and fixing it by the bands included in package. The pad can be applied to various parts of the body in various size and symptoms.

05 Operation

Easy Setup & Easy Operation

Setting up CE4000 and wrapping the Pad to the affected area is just simple. Turnning on the power, setting the temperature and adjusting the timer, all done on the operating panel at the front surface. CE4000 is universally designed that everyone can easily operate, and it will save a lot of time and labor in the medical practice.

Connecting Hose & Main Unit

Connecting Hose & Cooling Pad

Fixing the Pad

Adjusting temperature

06 Accessories

Accessories for Each Body Part and Therapeutic Purpose

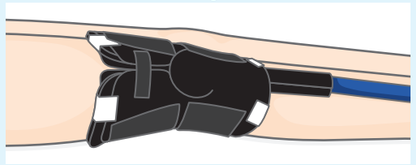
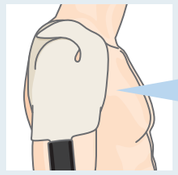
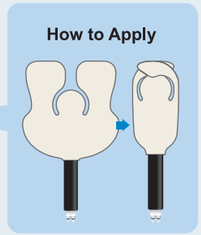
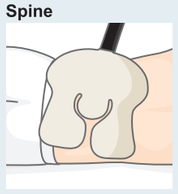
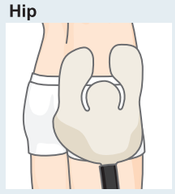
Place the CE4000 Pad Sheet on the inner surface of the Cooling Pad which touches the affected area directly in order to keep it hygienic. We also have different types of Cooling Pads for each body part to fit correctly to the body.

07 Storage

Hose Storage

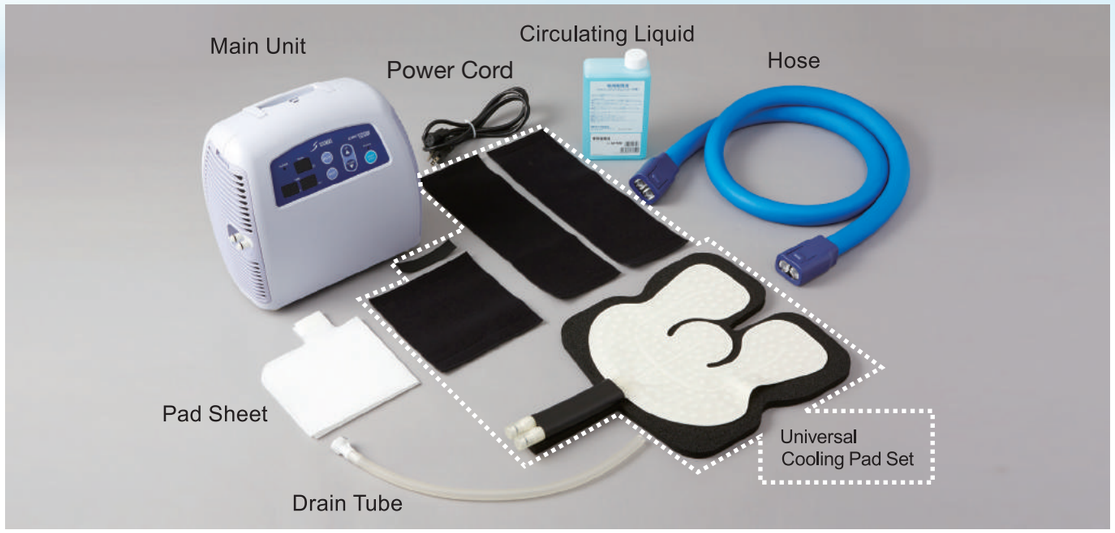
Wrap the Hose around the four hooks at the back of the Main Unit to keep it compact.

Cooling Pad Combination Pattern

	Cooling Pad	AIRFIT UNIT	Fixing Band	Pad Cover	Example of Fitting the Cooling Pad
Knee Joint	CE4000 Universal Cooling Pad 	–	CE4000 Pad Accessory 	CE4000 Pad Sheet 	CE4000 Universal Cooling Pad Set 
Other Joints	CE4000 Universal Cooling Pad 	–	CE4000 Pad Accessory 	CE4000 Pad Sheet 	Shoulder  eg. Universal Cooling Pad + Pad Cover  How to Apply
	Universal Cooling Pad (Large) 		Elastic Bandage, etc.	Pad Cover Large 	Spine  eg. Universal Cooling Pad (Large) + Pad Cover Large Hip  eg. Universal Cooling Pad (Regular) + Pad Cover Regular

* Image shown hereunder eliminating the Pad Cover. DO NOT place the Cooling Pad directly on the affected area.
* Combinations shown above are not the only way to wear. Please consult with your local distributor if necessary.

ICING SYSTEM CE4000

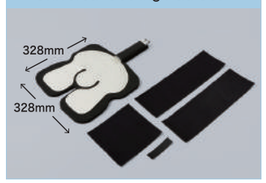


* Specification written is subject to change without notice. * Refer to the Instructions for Use for our Warranty Policy.

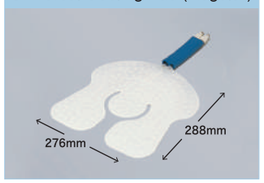
Accessories

Cooling Pad

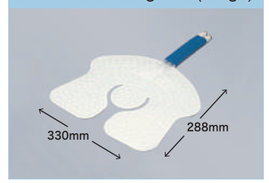
Universal Cooling Pad Set



Universal Cooling Pad (Regular)

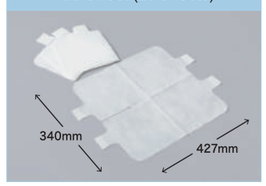


Universal Cooling Pad (Large)

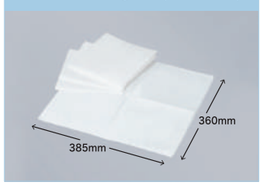


Others

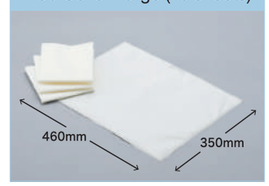
Pad Sheet (20 sheets)



Pad Cover Regular (20 sheets)



Pad Cover Large (10 sheets)



Circulating Liquid (1 bottle)

Hose

Pad Accessory

Technical Specification

*CE4000 has CE approval.

Product Name	ICING SYSTEM CE4000	Weight	Main body	4.5 kg
General Name	Cold Therapy Device		Hose	0.7 kg
Effect / Function	Decrease bleeding, swelling, pain caused by trauma or orthopedic surgery.		Pad	0.25 kg
		AC Power / DC Input		AC100V, 50-60Hz, 240VA
		Operating Temperature		10 - 30 °C (50 - 86 °F)
W x H x L (mm)	300 x 185 x 280	Target Temperature		0 - 13 °C (32 - 55.4 °F)

Accelerate Healing of the Fractured Bone with Accellus mini LIPUS (Low Intensity Pulsed Ultrasound) Treatment.

Accellus mini

LIPUS Acoustic Pressure Wave to the Fracture Site Help Forming New Bone.

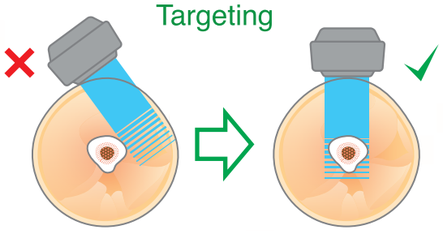
Concept

In recent years, LIPUS (Low Intensity Pulsed Ultrasound) stimulation therapy to accelerate the formation and union of fractured bone has been adopted to current medical practices.
Accellus mini is universally designed device which is easy to operate for both medical professionals and patients, and improves the efficiency of the fracture healing treatment. Accellus mini is the world's smallest and lightest LIPUS device.

Ultrasound Bone Healing with LIPUS

Ultrasound bone healing is therapeutic approach using low-intensity, high frequency, pulsed ultrasound to accelerate the fractured bone treatment.
This treatment is based on the "Wolff's Law" which states that bone will adapt to the loads under which it is placed, and it will remodel itself over time to become stronger to resist that sort of loading. ***"Accelerate the healing of the fractured bone by delivering mechanical stimulation caused by ultrasound to the fracture site."***
This is the basic theory of the Accellus Ultrasound Bone Healing System.

Targeting

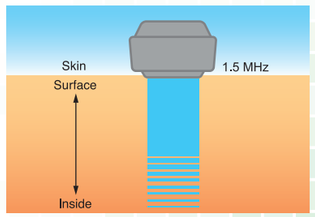


Place the transducer on the correct position and angle to gain the effective treatment. Since ultrasound signal is delivered only in a straight direction, incorrect position or angle of the transducer may result in not reaching the targeted fracture site.

What is Ultrasound?

Ultrasound is one kind of acoustic wave which is invisible and insensible even if it's directly radiated to the skin. Two major characteristics of ultrasound are "Straight Beam" and "Attenuation".

Attenuation



Ultrasound beam from the transducer has the constant rate of attenuation, or decrease in Hz.

The SMALLEST & LIGHTEST LIPUS Bone Healing System Ever.

20 Minutes Treatment Per Day. Safe & Non-Invasive.

Accellus mini

Features

Wireless, Compact and Smart Design

Ultrasound transducer and control unit are mounted on the same single device to achieve **"the World's 1st Wireless LIPUS Device"**.
No power cable and no transducer cable necessary. Accellus mini is universally designed for the every patient for their comfortable treatment.

Easy to Charge with Non-Contact Charging Cradle

Just place the Device on the Charger side of the Accellus mini Cradle and it will start charging its battery automatically. Simply rest the device on the Cradle after your treatment.

- **30-150 min. for full charge. (Depends on the remaining battery level)**
- **3-5 times treatment when fully charged. (Depends on the battery life)**

How to Charge

1) Plug the end of the Battery Charger into an electrical outlet. Then LED Light on the Cradle turns on.
2) Put the Logo surface of the device on the Charger side of the Cradle.
3) Changing status LED lightens up while charging the power, and it will automatically turns off when it's fully charged.

Ultrasound Output Checker

Since ultrasound wave is painless and insensible to human, you can check whether the transducer is working properly by placing it on the checker side of the Cradle. Check the ultrasound output before you start the treatment in order to gain the effective treatment.

How to Check

1) Plug the end of the Battery Charger into an electrical outlet. Then LED Light on the Cradle turns on.
2) Put the Ultrasound Gel on the Transducer surface of the Device.
3) Place the Transducer surface facing down on the checker side of the Cradle. Then turn on the power of the Device. Checking status LED lightens up if the ultrasound is properly radiated.

Simple 4 Steps to Start Your Treatment

STEP 1

Wrap the Silicon Strap around the fracture site and position the Holder over the site. Your doctor, or physician, might have marked the site with "X" for the accurate placement of the Device.
Wrap the strap securely using the Fastening Band located near the holder
DO NOT fasten the strap too tight.

STEP 2

Place moderate amount of Ultrasound Gel on the Transducer surface of Accellus mini Device.

STEP 3

Put Accellus mini Device on the Holder facing the Transducer surface down on the skin. Make sure you place the Transducer surface right on the fracture site. Built-in magnets in the Silicon Strap Holder stabilize the Device and the Holder.

STEP 4

Press the Power Button to start 20 min. treatment.
When the treatment is done, it will automatically stop the radiation and it will announce you by the vibration.

Treatment Tracking Manager

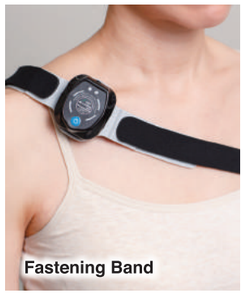
You will be able to know the freguency of the treatment.
* Treatment Tracking Manager is only available for the medical professionals.

Accellus mini can be Applied to Various Body Parts.

Accellus mini

Radius

Clavicle



Tibia

Femur

Metatarsal

Rib

Finger

Over the Cast

Product Specification

Accellus mini Device

Size	53 × 50 × 33 mm
Weight	81 g
Power Supply	DC 2.4 V, 650 mAh
Classification	Internally Powered Equipment Type BF Applied Part

Accellus mini Cradle

Size	140 × 80 × 35 mm
Weight	127 g
Power Supply	AC 100–240 V, 50/60 Hz, 3.25 VA
Classification	Internally Powered Equipment Type BF Applied Part

* Specification written is subject to change without notice.

Ultrasound Specification

Ultrasound Intensity (SATA)	30m W/cm²
Ultrasound Frequency	1.5 MHz
Repetition Rate	1 kHz
Treatment Time	20 minutes
Pulse Width	200 μs
Duty Factor	20 %
Effective Radiating Area (ERA)	5.30 cm²

Optional Item

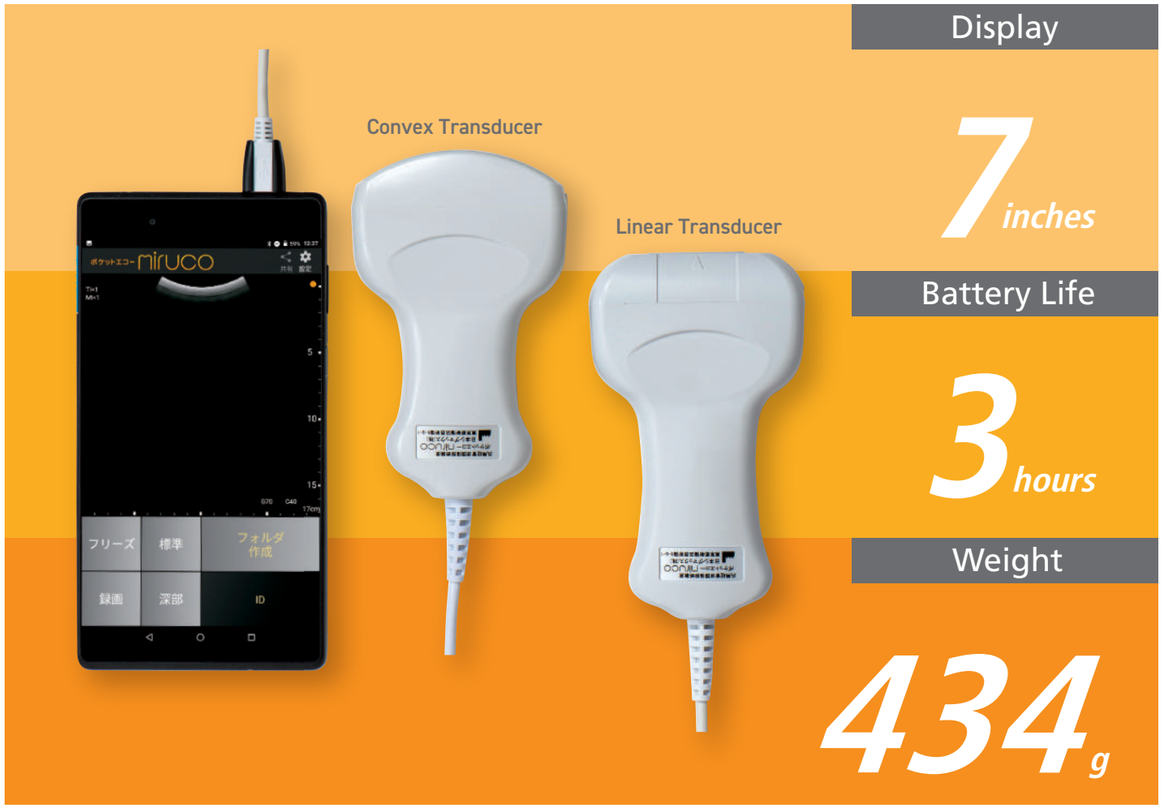
Product Name	Qty per Box
Ultrasound Gel	1
Silicon Strap	1

CAUTION:
Accellus mini Ultrasound Bone Healing System should only be used as prescribed by your doctor or other medical professionals.
Please read through the Instructions for Use completely before using the product.

General Ultrasound Imaging System

Pocket-sized Ultrasound Imaging Device

miruco



Display

7 inches

Battery Life

3 hours

Weight

434 g

Features

Portable & Compact

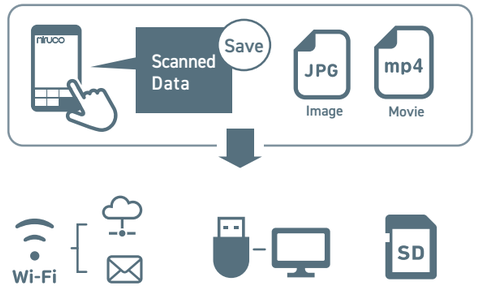
Compact device that can slide into your pocket. Battery lasts 3 hours that makes it available anytime anywhere you want.

Simple UI & Quick Boot-Up

Quick boot-up and simple UI give you an easy access to everyday POC practice.

Empower Point-Of-Care Assessment

Share and receive clinical images via email under Wi-Fi connection, and/or to save to your PC via USB connection for your assessment.



Multiple Purpose
Specially Designed for Everyday Point of Care

Overview

3.5 MHz Convex Transducer

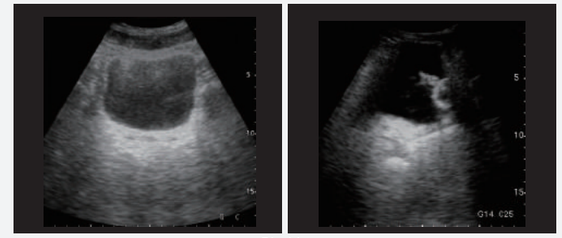
Designed for Everyday Point-Of-Care. Versatile 3.5 MHz Transducer.

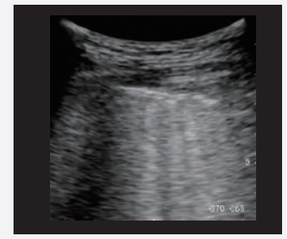
< Preset mode >

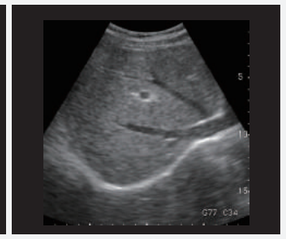
- Bladder Mode
Dehydration care, urinary care, etc.

- Lung Mode
Chronic cardiac failure, aspiration pneumonitis, etc.

- Deep Mode and User Settings
Abdominal observation, etc.


Bladder


Lung Mode


User Setting

10 MHz Linear Transducer

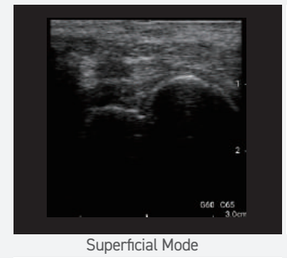
Designed for Assessment of Superficial Tissues 10 MHz Transducer.

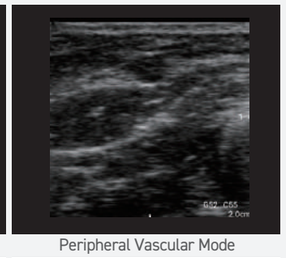
< Preset mode >

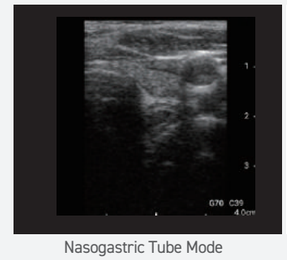
- Superficial Mode, Peripheral Vascular Mode
Vascular puncture, etc.

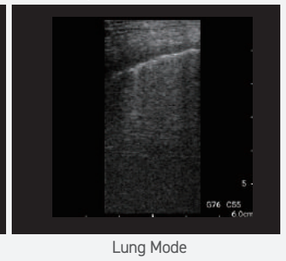
- Nasogastric Tube Mode
Nasogastric tube insertion , etc.

- Lung Mode
Pneumothorax, aspiration pneumonia, etc.
*MSK Mode, User Settings also available


Superficial Mode


Peripheral Vascular Mode


Nasogastric Tube Mode


Lung Mode