ISO 9001
EN ISO 13485

CE
1639

Digital Pneumatic Tourniquet system

DTS-3000

USER MANUAL

Indications for safety use

Read this manual carefully. This manual is for user's safety and previewing any property-loss. Before using our device, please read this manual inevitably.

This product is medical device using under doctor's instructors.

DS MAREF
DAESUNG MAREF CO.,LTD.

CONTENTS

1 Information

1-1. DTS-3000 Introduction

Thank you for purchasing DTS-3000. DTS-3000 is the surgery device blocking blood flow by wrapping the limbs with cuff and inflating the cuff. Thus, this device shall be applied under the instruction of a doctor.

This device has two channels with 4 ports that can connect two double cuffs at the same time. A double cuff prevents muscles, skin or blood vessels in the area stopping the bleeding from being damaged during the surgical operation taking long time.
During the surgical operation, the area to stop bleeding can be changed using the "Cuff Change" button.

Furthermore, the pressure can be adjusted depending on the areas to stop bleeding or patient's status in the pressure range of 20 to 700mmHg. Even in case of power failure due to blackout or contingencies, this device can be used in Emergency Mode for up to Max. 6 hours using the embedded battery when it is fully charged.

This User Manual contains the information related to application, storage and maintenance. It is strongly recommended to thoroughly read and understand the contents in this User Manual including control and connection method before using for successfully completing surgical operations and preventing failure of this device.

1-2. Intended use

A device intended to occlude the blood flow to obtain hemostasis field during limb(s) surgery.

1-3. Target treatment group of disease

- Kirschner wire removal
- Nerve injuries
- Tendon repair
- Bone grafts
- Amputations
- Replantations
- Reduction of certain fractures
- Tumor and cyst excisions
- Subcutaneous fasciotomy

- Total wrist joint replacement
- Replacement of joints in the fingers
- Knee joint replacements

1-4. Expected except group of treatment

- Open fractures of the leg
- Post-traumatic lengthy hand reconstruction
- Severe crushing injuries
- Elbow surgery (where there is excess swelling)
- Severe hypertension
- Skin grafts in which all bleeding points must be readily distinguished
- Compromised vascular circulation, e.g.peripheral artery disease.
- Diabetes mellitus
- The presence of sickle cell disease is a relative contraindication

1-5. Side effect

- A dull aching pain (tourniquet pain) may develop throughout the limb following use.
- Pathophysiologic changes due to pressure, hypoxia, hypercarbia, and acidosis of the tissues occur and become significant after about one and a half hours of tourniquet use.
- Symptoms of tourniquet paralysis are motor paralysis and loss of sense of touch, pressure, and proprioceptive responses.
- Intraoperative bleeding may be caused;

  • By the slight impeding effect exerted by an unpressurized cuff (and its padding, if used), which prevents venous return at the beginning of the operation.

  • By blood remaining in the limb because of insufficient exsanguination.

  • By inadequate tourniquet pressure (between systolic and diastolic blood pressure of the patient), or slow inflation and deflation, all of which allow arterial blood to enter while preventing venous return.

  • By blood entering through the nutrient vessels of the long bones, such as the humerus.

2 Information on Safety and Handling

2-1. Operation of the device

- In case of any abnormal smell, stop using this device. Turn off the power immediately and pull the power plug out of the outlet. And contact the Service Center. Continuing application may cause fire or electric shock.
- Unplug out the device in case of thunder, lightning, or power failure.
- The device is for indoor use only. Do not use the device in highly humid places, e.g., sauna or, bathroom.
  (Humid environment may result in mechanical defect or physical damage caused by an electric shock or scald.)
- When using or transporting this product please take care not to shake or drop this device as it may cause the device to malfunction or fail to operate.
- Do not put any objects on the device.
  (During operation, these objects may drop from the device and cause a fire or physical injury to the user.)
- Do not turn on the power switch before applying cuff to a patient. Connect the hoses after the cuff are applied to the patient. Turn the power on to the device after connecting the hoses to the air socket at front of device to ensure self check.
- To avoid the risk of electric shock, use the power supply with protective grounding.
  (There is a risk of fire and electric shock.)

- Do not put or pull out a power line from a socket with wet hands.
  (Fire or electric shock may occur.)
- Do not damage, process, bend, twist or heat the power cord. It may damage the cord and cause fire or electric shock.
- Do not change the fuse.
  (It may be dangerous. Ex. An electric shock or possible burn.)
- Install the power plug in a place where it can be easily removed.

- This Product is used to connect to a power source that is grounded. If you are connecting to a power source that is not grounded, it may occur to malfunction and problems protection circuit works when the device shorted.
- Do not use oil, benzene, alcohol, or any other chemicals to clean the device or cuff.
- Be cautious to prevent water or other foreign substances from getting into the inside of device.
  (It may cause failure, electric shock or fire.)
- Do not use the device in places with temperatures over 40°C or under 0°C.
  (Otherwise, it may cause mechanical problems, electric shock, fire physical damage, or property-loss.)

- Do not attempt to open, repair, or modify this device.
  Doing so may lead to a risk of fire, electric shock, or injury to the user.

2-2. Indications for use

- Use this device under the supervision or instruction by a doctor.
- Thoroughly read and understand the instruction to use this device including connection and operating method before application.
- Check the cuffs before using. Air leakage from a cuff due to any reasons including damage may cause incorrect operation including insufficient hemostasis.
- Put a cuff after putting a bandage around the application area.
- Do not use the air hose toward a nose, a mouth or ears. It may cause physical injury.
- Use the sleeves with wearing thin cloths.
  (It can cause an allergy to a person with sensitive skin.)

- Do not fold or bend the hose.
- For upper arm or thighs put the cuffs on the thickest areas. Turning the inflated cuffs or changing the application areas with inflated cuffs may damage the skin tissues on the application areas.
- Use the minimum pressure to stop bleeding to minimize the damage of blood vessel, nerve, muscle or skin.
- If you can not deflation even pressing the Deflation button after surgery , remove the hose from the device and forcibly deflated.
- The duration to stop bleeding shall not exceed generally 60 minutes for upper body and 90 minutes for lower body. If more time is required due to inevitable reasons, let blood flow for 15 minutes to minimize the inflammatory reason of skin tissues.
- Keep the cuffs after washing and suitable sterilizing after application.
- Keep monitoring body temperature, blood pressure and pain of a patient during hemostasis.
- When using two double cuffs, connect one cuff with the red hose and grey hose to ports of 1CH(red) first and then another double cuff with blue hose and grey hose to 2CH(blue). If Change button is pressed, the cuff bladder connected with gray hose is activated.
- For using LOP sensor, trim the nails of a patient. If a patient has a nail polish, remove it because it can interrupt LOP sensor to recognize.

- A cuff shall be the exclusive cuff for the model of DAESUNG MAREF. Do not use any cuffs from other manufacturers or for other models of DAESUNG MAREF.
- Do not operate this device before putting on a cuff. Putting the inflated cuffs may damage the cuffs and strain a body. Furthermore, putting the inflated cuffs may decrease the efficiency of hemostasis because the cuffs may not stick to the application area of a patient sufficiently.
- Do not press the deflate button during surgery.
  (There is a risk of bleeding when the cuff is deflated.)

- Select the proper cuffs depending on patients, application areas or types of operations. Improper cuffs may drop the efficiency of hemostasis or cause the failure in getting the intended effects from operations.
- Do not use the device in the area with strong magnetic field or electromagnetic field. It may cause an error of motor or valve.

2-3. Cuff safekeeping and maintenance

- Do not inflate a cuff without putting it on a body except the tests. It may damage a cuff or reduce its durability.
- Check the device and its parts on a regular basis.
- Do not keep out of heat sources including heaters or direct sunlight. It may cause breakdown, distortion or fire.
- Be cautious to prevent any sharp objects around including scissors from making a hole in a cuff or an air hose. The damage of an air chamber in a cuff or an air hose may cause improper operation of this device.
- Do not make oil, benzene, alcohol, gasoline or chemicals touch a cuff. It may reduce the durability of a cuff.

- Do not inflate a cuff without putting it on a body except the tests. It may damage a cuff or reduce its durability.
- Do not inflate a cuff with any other objects except this device. It may break down or damage a cuff.

2-4. Device safekeeping and maintenance

- Be cautious not to bend or fold the hose. It may cause improper operation. Immediately request maintenance to a vendor or customer service enter in case of any damage of the compressor case. (Doing so may lead to a risk of fire.)
- Prevent clips, staples, metals, food or liquid from getting into this device. It may cause heat. If such objects get into this device, ask your vendor or the store you purchase to check it.
- Keep in the safe place without influence by temperature, humidity or atmospheric pressure.
- Immediately request maintenance to a vendor or customer service enter in case of any damage of the device case. device.
- Once a year, please check the maintenance by a service center agent or distributor.
- When you install or carry the device be sure not to shake or drop the device.
- Inspect the device and accessories on a regular basis.

- Do not attempt to open, repair, or modify this device. Doing so may lead to a risk of fire, electric shock, or injury to the user.

2-5. Cautions for Battery safety

- Check a battery on a regular basis and replace it if it is not normal status. (Abnormal battery may prevent the device from operating for a long time in emergency situations.)
- Fully charge up the battery for more than 8 hours when using the device for the first time.
- Low temperature(below 0°C) may interrupt proper charge of the battery by reducing the battery function. Excessively high temperature(below 40°C) may interrupt proper charge of the battery by reducing the battery function or the battery life by excessive heat.

- Do not leave the rechargeable lithium ion battery to be completely discharged and kept as being discharged.
- Unplug the AC cord immediately if you smell anything.
- Remove the battery when not using it for a long time. Keeping the discharged battery for a long time may increase the risk of short circuit. Shorted battery may reduce the battery life and cause safety accidents.
- Keep the battery charged by about 30 to 50% at room temperature. It is recommended to charge the battery once a year during storage to prevent excessive discharge of battery.

- A battery replacement is available only in the customer service center or by your vendor. A battery shall be replaced or repaired only by the qualified service engineer.
- In case of any damage of the battery in use, leakage of battery fluid or foreign substances at the contact point of the battery, stop using the battery and purchase the new battery from the manufacturer.
- Do not disassemble the device for replacing a battery. Do not use any battery from other manufacturers. It may cause fire by the error of the device or overheating of the battery.
  (Warranty is not applied to the device using any batter from other manufacturers or for other models.)
- In case of the disposal of the device, separate the battery and dispose it in accordance with the rules and regulations on the disposal of battery in the relevant region.
- Do not keep the battery or the main unit under the direct sunlight or in the place of high temperature.
- Charge up the battery only at indoor spaces.
- Do not squash or make a hole on the body.
- Do not put the battery into fire or short out the contact point of battery.
- Do not expose the battery to water or other liquids.
- Strictly comply with the instructions on the user manual for charging up the battery.

2-6. Cleaning

2-6-1. How to clean the device

- If any foreign materials get on the device, first turn off the device and use a soft cloth to wipe the device with a bit of water or a neutral detergent.
  (It may cause discoloration, damage or malfunction.)
- If you sanitize product, first turn off the device and wipe off with soft cotton using neutral detergent.
  (It may cause discoloration, damage or malfunction.)
- Please be careful to prevent any liquid from going into the air socket or AC inlet.
  If liquid does get in operation errors, electric shock, and fire could occur due to do an affect of internal parts.
- Do not wipe the device with benzene, thinner, alcohol, etc or spray water directly on the device.
  (It may cause change of color, discoloration or damage.)

  * Use neutral detergent or the alkalescence for cleaning.
    Dilute in water if it is Alkali undiluted state.
    Drug use: be careful not to enter into the skin or eyes.

2-6-2. How to clean the hose

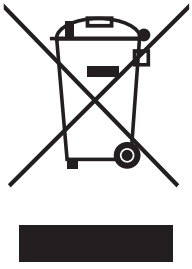
- If any foreign material gets on the hose, use a soft cloth to wipe the hose with a bit of water or a neutral detergent.
- Be careful of any liquid doesn't go into the hose.
  (It may cause the durability of the hose if water is inside of the hose, it could also break and cause a fire if and when water goes into the device from the hose.)
- Do not spray water directly on the hose or put the hose into the water.
- Do not wipe the hose with benzene, thinner, alcohol, etc.

2-6-3 How to clean the cuff

- Deflate the bladder completely before cleaning the cuff.
- the bladder completely before cleaning the cuff.
- Cover the hose with a rubber cap to prevent liquid from entering the cuff.
- Do not wipe the cuff with benzene, thinner, alcohol, etc.
- It may cause durability reduction or any change on the cuff if it is not completely dry.

2-7. WEEE marking

2-7-1. Correct Disposal of this product (Waste Electrical & Electronic Equipment)



As the market continues to expand and innovation cycles become even shorter, the replacement of equipment accelerates, making EEE a fast-growing source of waste. The content of hazardous substances such as mercury, cadmium, lead, hexavalent chromium in EEE is a major concern during the waste management phase.

The purpose of this Directive is to contribute to sustainable production and consumption by, as a first priority, the prevention of WEEE and, in addition, by the re-use, recyling and other forms of recovery of such wastes so as to reduce the disposal of waste and to contribute to the efficient use of resources and the retrieval of valuable secondary raw materials.

The Definitions of this Directive is dependent on electric currents or electromagnetic fields in order to work properly and equipment for the generation, transfer and measurement of such currents and fields and designed for use with a volage rating not exceeding 1000 volts for alternating current and 1500 volts for derect current. (Exemption of equipment desinged to be sent into space, large-scale stationary industrial tools and etc.)

Cunsumers have to actively contribute to the success of such collection and should be encouraged to return WEEE.

The Producer have to provide the information of re-usable, recyclable and recoverable rate. 75% shall be recovered, and 55% shall be prepared for re-use and recycled within category 2 (Small household appliances) and 8 (Medical devices).
DTS-3000 is a recoverability rate of 76.9% and a recyclability rate of 62.2%.

Information for treatment facilities shall be made available to centres which prepare for re-use and treatment and recyling facilities by producers of EEE. DAESUNG MAREF, whenever, is prepared to provide.

The symbol indicating separate collection for EEE consists of the cross-out wheeled bin, as shown below.

2-7-2. Correct disposal of batteries in this product

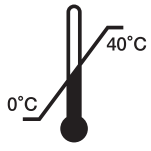
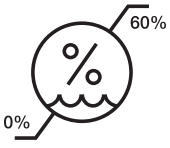
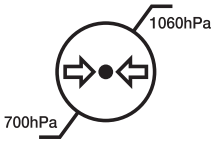
(1) Crossed-out wheeled bin applies to all batteries;

(2) Chemical symbols (Hg, Cd, Pb), indicating the heavy metal content of batteries, apply to batteries containing more than a given amount of these substances;

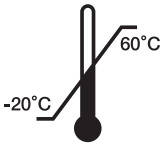
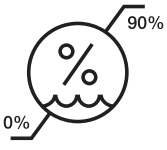
- Lead-acid batteries: recycle cadmium as far as technically feasible, and recycle a minimum of 75% of batteries by average weight;
- Nickel-cadmium batteries: recycle cadmium as far as technically feasible, and recycle a minimum of 75% of batteries by average weight;
- Other batteries: recycle a minimum of 50% of batteries by average weight.

2-8. Operating, storage and cleaning conditions

2-8-1. Operating conditions

Temperature (°C)	Relative humidity (%)	Atmospheric Pressure (hPa)
		

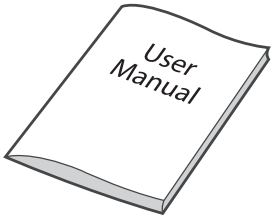
2-8-2. Storage conditions

Temperature (°C)	Relative humidity (%)
	

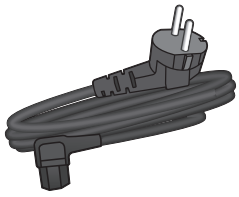
3 Product package

3-1. Device part

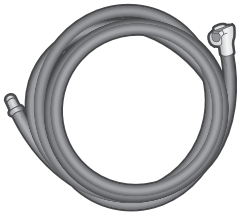
Main device



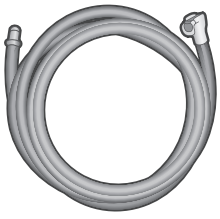
User manual



Power code



Air Hose (Blue) 1EA



Air Hose (Red) 1EA

Air Hose (Gray) 2EA

3-2. Cuff part

Select and purchase the cuffs depending on user's status or application areas.

Single Cuff

Double Cuff

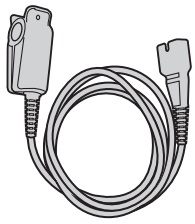
Cone Single Cuff

Cone Double Cuff

Silicone Bladder Cuff

* The cuff is a consumable product.
* The cuff is defined as the mounting part in IEC 60601-1.

3-3. LOP Sensor



The LOP sensor is defined as the mounting part in IEC 60601-1.

4 Product description

4-1. Device specifications

Items		Specification
Model		DTS-3000
Protection Type		Class II, BF-type Device
Rated Voltage		AC100-240V, 50/60Hz
Power Consumption		80VA
Rated Fuse		T3.15A/250V
Setting Pressure		20~700mmHg ± 4mmHg (Unit : 1, 5mmHg)
Setting Time		1~240min (Unit : 1min, 5min)
Dimension		180(W) x 200(D) x 260(H)mm
Weight		3kg
Rated Voltage of Battery		DC 14.4V
Current Consumption of Battery		2600mAh
Working Hours of Battery		About 6 Hours (varying on the battery status)
Certification	SAFETY	IEC60601-1
	EMC	IEC60601-1-2

Rx ONLY Setting pressure should be operated under doctor's instructions.

4-2. Device views

Back

Top

Left side

Front

Right side

4-3. Cuff specifications

Part no.	Cuff names and size	Part no.	Cuff names and size
DTC-S02	SINGLE CUFF 40 X 7cm	DTC-D06	DOUBLE CUFF 107 X 15cm
DTC-S04	SINGLE CUFF 52 X 7.5cm	DTC-D07	DOUBLE CUFF 57 X 15cm
DTC-S05	SINGLE CUFF 61 X 9cm	DTC-CD25	CONE DOUBLE CUFF 70 X 10cm
DTC-S06	SINGLE CUFF 80 X 9cm	DTC-CD26	CONE DOUBLE CUFF 90 X 12cm
DTC-S07	SINGLE CUFF 86 X 10cm	DTC-CD27	CONE DOUBLE CUFF 107 X 14cm
DTC-S08	SINGLE CUFF 107 X 10cm	DTC-SA01	SILICONE BLADDER CUFF 30 X 11cm
DTC-C25	CONE SINGLE CUFF 70 X 10cm	DTC-SA02	SILICONE BLADDER CUFF 46 X 11cm
DTC-C26	CONE SINGLE CUFF 90 X 12cm	DTC-SA05	SILICONE BLADDER CUFF 61 X 11cm
DTC-C27	CONE SINGLE CUFF 107 X 14cm	DTC-SA06	SILICONE BLADDER CUFF 76 X 11cm
DTC-D04	DOUBLE CUFF 57 X 10cm	DTC-SA07	SILICONE BLADDER CUFF 86 X 11cm
DTC-D05	DOUBLE CUFF 80 X 15cm	DTC-SA15	SILICONE BLADDER CUFF 52 X 7cm

4-4. LOP sensor specifications

Items	Specification
Model	Oxipulse RA01
Manufacturer	HUREV
Applicable patients	Adult (> 30kg)
Size	Reusable finger probe (1M cable)

4-5. Names and Functions of Parts

No	Name	Function
1	LCD Screen	Display the operating status of the device.
2	1CH Air Socket	- Socket for inserting red hose into 1ch when using single cuff. - Socket for inserting red hose and gray hose into 1ch when using double cuff.
3	2CH Air Socket	- Socket for inserting red hose into 2ch when using single cuff. - Socket for inserting red hose and gray hose into 2ch when using double cuff.
4	LOP Socket	Socket to connect LOP Sensor.
5	Alarm LED	LED indicating the operating status and errors. - Green: Standby, operating status. - Red: Errors
6	SD Card Slot	Slot to insert SD Card to save the operating status by a user.
7	Hose Holder	Holder for the air hose.
8	Holder fixing pin/ Handle	- Pin to fix the device on the holder. - Use the handle when moving the device.
9	Battery Cover	- Battery mounted on the device. - Do not open the battery cover and do not change the battery.
10	Power Inlet	Inlet to connect power cord.
11	Power ON/OFF Switch	Switch to turn power on or off.

4-6. Names and Functions of Control Panel

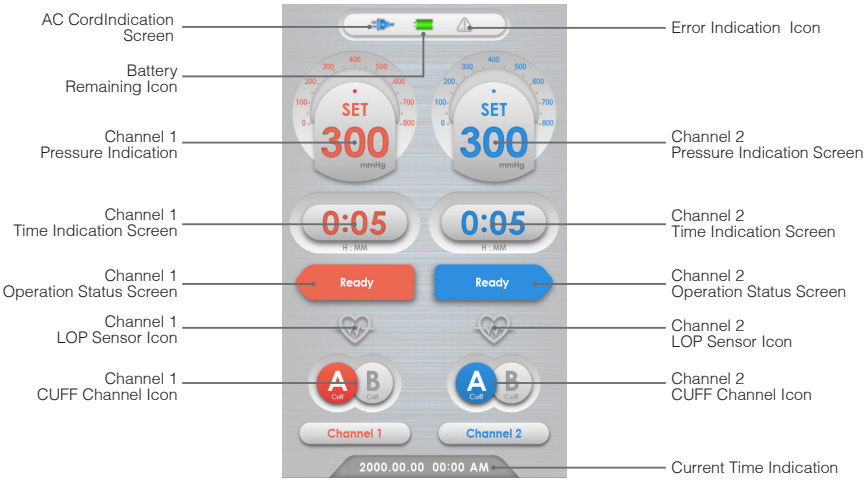
No	Name		Function
1	PRESSURE	1CH Pressure Control Button	**Control of Pressure of 1CH** The previous setting is saved and displayed. The pressure can be adjusted from 20 to 700mmHg depending on patient's status and application areas. Set the pressure using the Pressure button (▲,▼). Press for about 3 seconds. The pressure can be adjusted during operation. (Unit : 5mmHg (Long push), 1mmHg (Short push)) Furthermore, SET is displayed on the pressure value before pressure is applied. SET is changed to RUN when pressure is supplied and the current pressure value is displayed.

2	INFLATE	**1CH Inflation Button**	**Inflation of the cuff of 1CH** Press the Inflate button long (3 seconds) to apply preset pressure to a cuff. When pressure is applied to a cuff, LCD displays  . When pressure reaches to the preset value,  is displayed.
3	TIME	**1CH Time Setting Button**	**Time setting of 1CH** The previous value is saved and displayed. It can be adjusted to 1 to 240 minutes depending on patient's status or operation types. Press the Time Setting button (▲,▼) to set the time. User can change the set pressure during operation. (Unit : 5min (Long push), 1min (Short push)). The time displayed during operation indicates the elapse time. Time can be adjusted during operation using the button (▲,▼).
4	DEFLATE	**1CH Deflate Button**	**Deflate the cuff of 1CH** For deflating a cuff, press the Deflate button long (3seconds). LCD displays  during deflating.
5	CHANGE	**1CH Cuff Change Button**	**Change the hemostasis area while using double cuff of 1CH** When operation continues for a long time, change the hemostasis area while using double cuff to prevent damage of skin, nerve or muscle. Press the Cuff Change button long (3 seconds) while using the Cuff A. Pressure is applied to the Cuff B and then the Cuff A is deflated. In this case, LCD shows the change from the Cuff A to the Cuff B at the bottom of the screen. 
6	LOP	**1CH LOP Button**	**Set LOP of 1CH** LOP notifies the proper pressure for hemostasis by measuring of a patient's LOP. For using LOP, press the LOP button long (3 seconds) after putting a cuff on, and LOP measurement starts.

6	LOP	**1CH LOP Button**	Then, LOP automatically estimates and notifies the proper pressure for a patient. To start, press the Inflate button to activate. The icon below is activated on the LCD during LOP measurement. LOP icon color is changed as shown below. 
7	PRESSURE	**2CH Pressure Control Button**	**Control of Pressure of 2CH** The previous setting is saved and displayed. The pressure can be adjusted from 20 to 700mmHg depending on patient's status and application areas. Set the pressure using the Pressure button (▲,▼). Press for about 3 seconds. The pressure can be adjusted during operation. (Unit : 5mmHg (Long push), 1mmHg (Short push)) Furthermore, SET is displayed on the pressure value before pressure is applied. SET is changed to RUN when pressure is supplied and the current pressure value is displayed.
8	INFLATE	**2CH Inflation Button**	**Inflation of the cuff of 2CH** Press the Inflate button long (3 seconds) to apply preset pressure to a cuff. When pressure is applied to a cuff, LCD displays  When pressure reaches to the preset value  is displayed.
9	TIME	**2CH Time Setting Button**	**Time setting of 2CH** The previous value is saved and displayed. It can be adjusted to 1 to 240 minutes depending on patient's status or operation types. Press the Time Setting button (▲,▼) to set the time. User can change the set pressure during operation. (Unit : 5min (Long push), 1min (Short push)). The time displayed during operation indicates the elapse time. Time can be adjusted during operation using the button (▲,▼).

10	DEFLATE	2CH Deflate Button	**Deflate the cuff of 2CH** For deflating a cuff, press the Deflate button long (3seconds). LCD displays during deflating.
11	CHANGE	2CH Cuff Change Button	**Change the hemostasis area while using double cuff of 2CH** When operation continues for a long time, change the hemostasis area while using double cuff to prevent damage of skin, nerve or muscle. Press the Cuff Change button long (3 seconds) while using the Cuff A. Pressure is applied to the Cuff B and then the Cuff A is deflated. In this case, LCD shows the change from the Cuff A to the Cuff B at the bottom of the screen. 
12	LOP	2CH LOP Button	**Set LOP of 2CH** LOP notifies the proper pressure for hemostasis by measuring of a patient's LOP. For using LOP, press the LOP button long (3 seconds) after putting a cuff on, and LOP measurement starts. Then, LOP automatically estimates and notifies the proper pressure for a patient. To start, press the Inflate button to activate. The icon below is activated on the LCD during LOP measurement. LOP icon color is changed as shown below. 
13	RECORD	Record Button	**Record the history of application** Setting values or errors are saved during the application.
14		Power Button	**Power Button** Turn power on or off with this button.

4-7. LCD Screen



4-7-1. LCD Information

AC Cord Indication Screen	The icon of indicating the connection of AC cord to the product * Inactivate if there is no AC cord connection
Battery Remaining Icon	The icon of indicating battery remaining by 4 steps of marking
Error Indication Icon	Activated if there is an error in the product * Alarm LED at Errors: Red color
Pressure Indication Screen	-The screen of indicating pressure values by pressing PRESSURE ▲, ▼ button. - The screen of indicating pressure values of INFLATE
Time Indication Screen	- The screen of indicating time values by pressing TIME ▲, ▼ button. -Indicate the elapsed time while operating
Operation Status Screen	- When INFLATE (INFLATE) button is pressed, the READY icon is changed to the OK icon after compression.
LOP Sensor Icon	The LOP sensor icon is activated based on LOP sensor connection to the product.
CUFF Channel Icon	- In the use of DOUBLE CUFF, the compression is through CUFF A⇔ CUFF B when the CHANGE (CHANGE) button is pressed.
Current Time Indication	Indication of current date and time

4-7-2. Power Status

- Display the power status on the top of LCD.

4-7-3. Battery Status

- Display the battery status in four steps depending on the charging amount. The battery is automatically charged when AC power is supplied.

	Full Charge		External power connection
	Medium Charge		
	Charge Required (Supply Power)		External power Cutt-off
	No Power (Supply Power)		

* Disassembly and Replacement of Battery

- Open the battery cover at the back of the device and separate the connector connected to the battery.
- For replacement of battery, contact the service center of your seller.
- The battery is consumable. The warranty for battery is 6 months from the date when you purchase.

5 Product use and procedure

5-1. Before using a device

Use this device in accordance with the instruction from a doctor.
Select proper application area, types of cuffs and pressure level in consideration of a patient's status and operation area. Improper application may have adverse impact to patients during operation.

5-2. Use and install

1) Connect the cuff and the air hose.
2) Put a bandange on the application area of a patient and put the cuff on it.
3 Connect the power cord to the device.
4) Push the ON/OFF switch at the back of the device to ON. Touch the Power button on the front.
5) Set the pressure and time in accordance with a patient's status and operation area.
6) Touch the Inflate button long (3 seconds) to apply the pressure to the cuff.
7) When "OK" message is displayed on the LCD screen, the pressure is completely applied to the cuff. At this point, check the blood flow at the end of limbs and start operation.
8) For changing the hemostasis area while using the double cuff, touch the Cuff Change button long (3 seconds) to change the pressure area.
9) For deflating the cuff after the completion of operation, touch the Deflate button long (3 seconds) to deflate the cuff.
10) After the air is completely deflated from the cuff, disconnect the power cable and touch the power button to shut off the power completely.

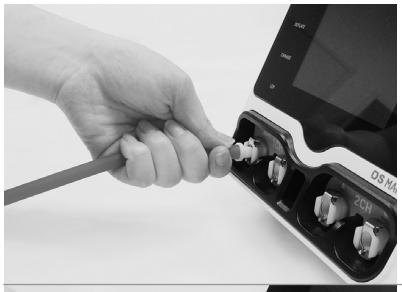
* Even when power is forcibly off, the cuff is not deflated.
(When power cord is pulled off, the device works with the battery so that power is not turned off).
* Do not press the deflate button during surgery.
(There is a risk of bleeding when the cuff is deflated.)

5-3. LOP Application

1) Connect the parts as described from Step No. 1 to 5 above in Application and Installation section.
2) Put the LOP sensors to the index finger of the limb where the cuff is applied.
3) Touch the LOP button long (3 seconds), and LOP starts measuring and displays the proper pressure value for a patient.
4) For using the recommended pressure value by LOP sensor, touch the Inflate button to apply the pressure to the cuff. Or set the pressure value as desired using the Pressure Control button without using the recommended pressure value.
5) After the pressurization is complete , remove the LOP sensor worn by the patient.

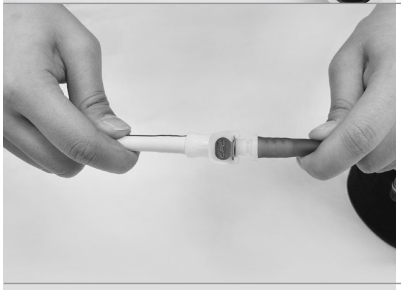
5-4. Cuff connection

5-4-1. Single cuff



- Connect the air hose to the channel until you hear the ‘click’ sound.
  (When the Lock Pin is not pressed in the air socket in the device, press the top to open it with the sound ‘click’)

- For separating the air hose from the device, pull the air hose as pressing the top of air socket, and the air hose is easily removed.



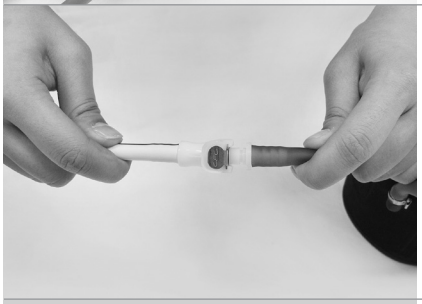
- Connect the single cuff to the other end of the air hose until you hear the ‘click’ sound

- Use the device after checking the proper connection.

5-4-2. Double cuff connection

- Connect the air hose to the channel until you hear the ‘click’ sound.
  (When the Lock Pin is not pressed in the air socket in the device, press the top to open it with the sound ‘click’)

- For separating the air hose from the device, pull the air hose as pressing the top of air socket, and the air hose is easily removed.



- Connect the double cuff to the other end of the air hose until you hear the ‘click’ sound

- Use the device after checking the proper connection.

5-5. LOP connection

- Connect the port of LOP Sensor to the device.

- Put the LOP Sensor to the index finger of the limb where the cuff is applied. Put a finger or a toe deep into the sensor. Use the LOP function after checking the proper connection.

* Remove all foreign substances including nail polish on fingers where the LOP Sensor is applied.

6 Troubleshooting

6-1. Alarm messages

No	Alarm Code	Description	Actions
1	⚠ Time Over	Indicate the set time is over.	- Take the follow-up actions in accordance with the instructions from a doctor. - Finish alarm rings after the set time. (However, the device is not turned off and cuffs are not deflated.) - Press the Deflate button to deflate the cuffs.
2	⚠ Leak Air	A certain pressure is detected, but pressure doesn't reach to the set value or a cuff is continuously deflated.	- Check the connection of a cuff and a hose. - Check air leakage of a cuff and a hose. - If the error persists even checking a cuff and a hose, contact your vendor.
3	⚠ No Cuff	A cuff is not connected to the device.	- Check the connection of a cuff and a hose. - If the error persists even checking the connection of a cuff and a hose, contact your vendor.
4	Low Battery	Voltage error while using the battery.	- Charge the battery by supplying AC power. - When the battery is used continuously without AC power supply, it may reduce the life span of device due to battery discharge.
5	⚠ LOP Check	Errors during LOP operation.	- Check the connection of LOP Sensor. - If the error persists even checking LOP connection, contact your vendor.

* When an alarm occurs, Alarm LED turns red.
Press the Alarm button, and alarm stops. However, Low Battery Alarm keeps ringing and Time Over Alarm is activated 30 seconds after the first alarm. Alarms occurred are displayed in the numbers as shown in the table above on the top of LCD. When the errors occur in both 1CH and 2CH at the same time, more urgent error is displayed.

6-2. General Troubleshooting

No	Problem	Cause	Solution
1	No electric power	Power connection alarm	Check that the plug is correctly inserted into the power outlet
		Rated power	Check if your power supply is in the range of AC100-240V, 50/60Hz
		FUSE shortcut	Check if FUSE is in the state of shortcut. (FUSE is located inside AC INLET.)
2	Power on but not operating	Power supply alarm	Turn power to the controller off and on
3	Noisy during operating	Setting condition	Check that the device is installed horizontally or fixed the screw hard-locking.
			Check that there is nothing laying on top of the device or underneath.
4	No air in the hose	Hose connection alarm	Check that the hose is inserted correctly into the device.
		Bent hose	Check that the hose is not bent.

6-3. Troubleshooting

No	Problem	Cause	Solution
1	Weak air injection	Air hose damage	Contact the seller if there is a defect in the inner hose or cuff connection.
		Air hose socket damage	
		Defect of Inner parts of cuff	
2	Power on but not operating	Defect of Inner parts	Check that the plug is correctly inserted into the outlet.

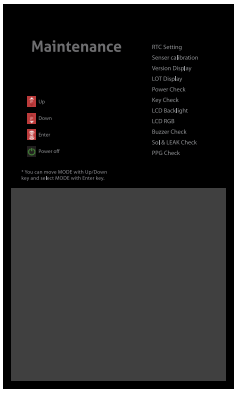
* We can't be responsible for any defect occurred from user's careless use, even though warranty period.
* Please contact your dealer or the place where you purchased the product for repairs or repurchase.
* If you can't solve the problem by this way, please contact our service center.
* If you can't solve the problem by this way, please check the Service Manual (DSM-SM-008).

7 Maintenance and safety instructions

Once a year, please check the maintenance by a service center agent or distributor.

7-1. Test mode Set-up

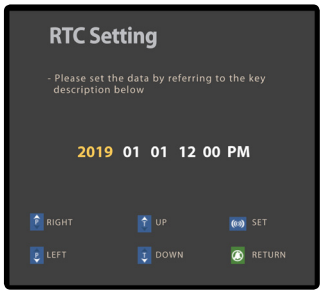
1) Remove the cuff and LOP sensor to DTS-3000, then connect the AC cord.
2) Turn on power switch ON/OFF located at the back of the device.
3) Press Alarm Button + Power Button together and go to Maintenance mode.
4) Press Power button with long key to quit Maintenance mode.



7-2. Test method

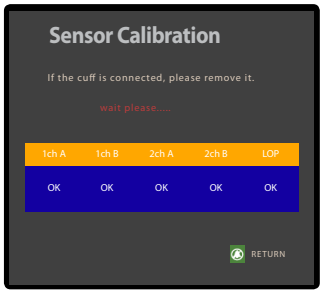
7-2-1. RTC Setting

- Enter the RTC Setting in the Maintenance mode to set the date and time of the device.
- After setting the time, press the RETURN button to return the maintenance mode.



7-2-2. Senser Calibration

- In maintenance mode, enter the Sensor Calibration to calibrate the device of pressure sensor and LOP sensor.
- After finishing the Sensor Calibration, press the RETURN button to return the maintenance mode.
- If there is no error in pressure sensor and LOP sensor, 'OK'
- 'Fail' if the pressure sensor and LOP sensor are faulty.



* If 'Fail' appears after calibration, please contact your dealer or service center. If you open the device arbitrarily, it can get a malfunction and injury.

7-2-3. Version Display

- If you enter Version Display in Maintenance mode, you can check the version of mainboard and sub-board of the device.
- After checking the version of the product, press the RETURN button to return the maintenance mode.

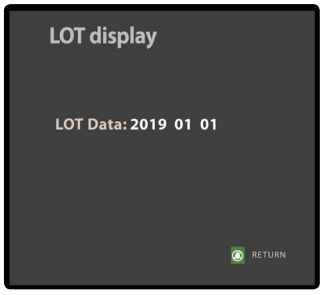
* Main board : It is mainly controls Drive that manipulate LCD display, Button input control, LOP control, SD DATA SAVE.

* Sub board : It is the board that will proceed for the order coming from Main board after giving command using UART communication.

* If there is communication error between Main board and Sub board, Sub board version won't be shown. In this reason user can notices if the data communicates or not.

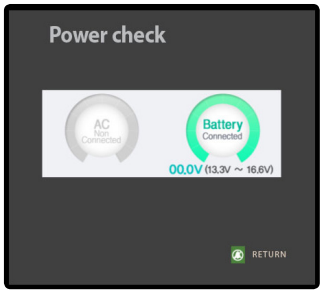
7-2-4. LOT Display

- When you enter the LOT Display in Maintenance mode, you can check the date of manufacture.
- After checking the version of the device, press the RETURN button to return the maintenance mode.



7-2-5. Power Check

- In maintenance mode, enter the Power check to check the power and battery status of the product.
- After checking the battery and pressing RETURN button, return to maintenance mode.



7-2-5-1. Power display

Display	Status	Test method
	AC cord not connected	After booting into maintenance mode with the battery in the device, disconnect and unplug the power cord and check that the 'AC Connected' and 'AC Non Connected' statuses are working properly on the LCD screen.
	AC cord connected	

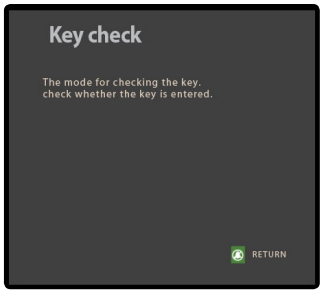
7-2-5-2. Battery indicator

Display	Status	Test method
	Battery is not connected	- After booting in maintenance mode with the power cord connected to the device, check that 'Battery Connected' and 'Battery Non Connected' are working properly on the LCD screen while removing the battery. - Make sure that the remaining capacity of the battery is within the permissible range. If the battery is below 13.3V, it is 'low battery', so you need to charge it and make sure that it is charged when the power is connected.
	- Battery is connected - Remaining battery capacity and permissible range indication	

* Check the service manual for battery specifications and replacement instructions.

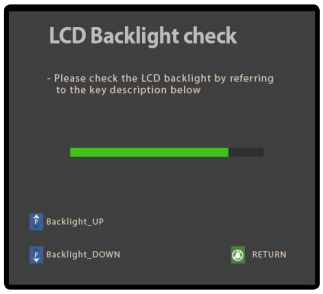
7-2-6. Key Check

- In maintenance mode, enter the Key check to check whether each button on the device is operating normally.
- After Key Check , press the RETURN button to return to maintenance mode.



7-2-7. LCD Backlight

- In maintenance mode, enter the LCD Backlight check to set the LCD brightness of the product.
- After completing the LCD brightness setting, press the RETURN button to return the maintenance mode.

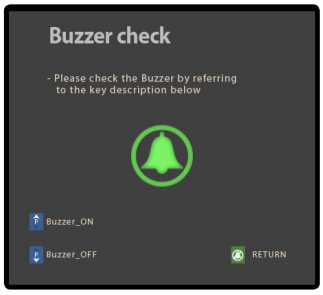


7-2-8. LCD RGB

- When you enter LCD RGB in Maintenance mode, red -> green -> blue are displayed.

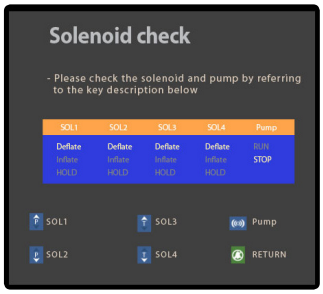
7-2-9. Buzzer Check

- In the maintenance mode, you can check whether the buzzer sound working normally when you enter Buzzer Check.
- After confirming that the Buzzer is working, press the RETURN button to return the maintenance mode.



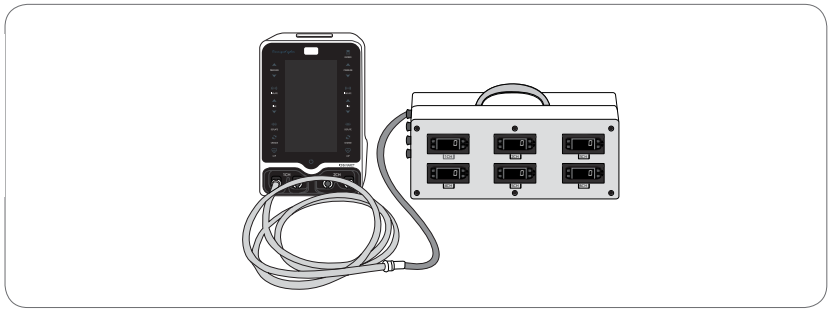
7-2-10. Sol & LEAK Check

- In maintenance mode, enter the solenoid Check to check the operation status of solenoid and pump of the device.
- Connect four cuffs to the CH 1 and 2 air socket before starting the test.
  (It is ok to connect the cuff to the socket that you want to test.)



1) Connect four cuffs to the CH 1 and 2 air sockets before starting the test.
   (It is ok to connect the cuff to the socket that you want to test.)
2) Press the Pump button to confirm that PUMP is working.
3) If you press the 1CH A button while PUMP is in operation, it will operate Deflate -> Inflate -> HOLD and check the solenoid status.
4) After completing the solenoid check, press the RETURN button to return the maintenance mode.
   (It is ok to connect the cuff to the socket that you want to test.)

7-2-10-1. Device LEAK Check



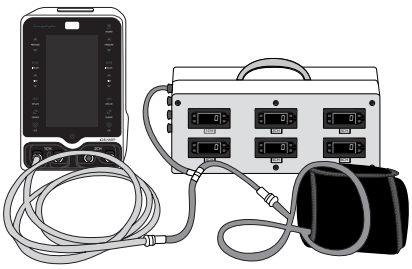
1) Connect the pressure gauge to the CH1, CH2 air socket before starting the test.
   (It is ok to connect the pressure gauge to the socket that you want to test.)
2) Press Pump button to activate PUMP.

3) While the PUMP is in operation, press the 1CH A button to set the HOLD and check the measured value of the pressure gauge.

4) Check the pressure gauge pressure after about 15 seconds.
If the pressure is more than 20mmHg below the pressure indicated in (3), there is a device leak. Please contact your dealer or service center. If you open the device arbitrarily, it can get a malfunction and injury.

5) After solenoid check, press RETURN button to return the maintenance mode.

7-2-10-2. Cuff leak check



1) Connect cuff and pressure gauge to CH1, CH2 air socket before test start.
(It is ok to connect the pressure gauge to the socket that you want to test.)

2) Press Pump button to activate PUMP.

3) While the PUMP is in operation, press the 1CH A button to set the HOLD and check the measured value of the pressure gauge.

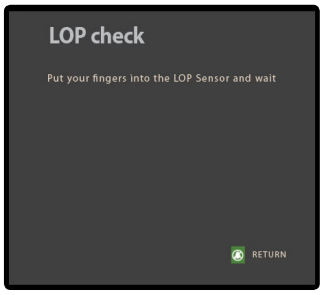
4) Check the pressure gauge pressure after about 15 seconds.
If the pressure is more than 20mmHg below the pressure indicated in (3), there is a leak to cuff.

5) After solenoid check, press RETURN button to return the maintenance mode.

7-2-11. LOP Check

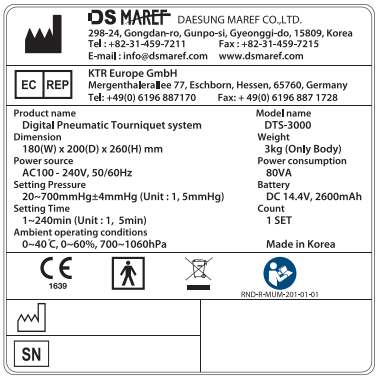
- If you enter LOP Check in Maintenance mode, you can check if the LOP sensor is operating normally.
- After confirming that the LOP sensor operates normally, press the RETURN button to return the maintenance mode.

* If you apply a nail polish during the LOP sensor check , please remove it because it makes a problem in LOP sensor recognition .



8 Labels

8-1. Label for main device

No	Label location and description	Label designs
1	 Left side of Device (Main Label)	
2	 Front of Device (Window Sheet)	
3	 Front of Device (Deco Window)	

4

Side of Device

SD CARD

5

Back of Device

WARNING
- DO NOT CHANGE THE BATTERY (OR COVER)
- THE EXCHANGE OF BATTERY IS POSSIBLE AT THE SERVICE CENTER OR SUPPLIER.

KEEP POWER CORD PLUGGED IN. BATTERY ONLY FOR USE DURING POWER EMERGENCY OR TEMPORARY PATIENT TRANSPORT.
ATTENTION : UNIT SHOULD BE PLUGGED IN 24 HOURS BEFORE USE TO PROPERLY CHARGE BATTERIES.

6

Back of Device

⚠ WARNING

FOR CONTINUED PROTECTION AGAINST FIRE HAZARD REPLACE ONLY WITH THE SAME TYPE AND RATING OF FUSE :

POWER INPUT: 80VA, 100-240V~, 50/60Hz,
FUSE: 250V~T3.15AH

9 Information on EMC

9-1. Guidance and manufacturer's declaration - electromagnetic emissions

The DTS-3000 is intended for use in the electromagnetic environment specified below.
The customer or the user of DTS-3000 should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The DTS-3000 uses 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	The DTS-3000 is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply net work that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ Flicker emissions IEC 61000-3-3	Complies	

9-2. Guidance and manufacturer's declaration – electromagnetic immunity

The DTS-3000 is intended for use in the electromagnetic environment specified below.
The customer or the user of DTS-3000 should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagneticenvironment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6kV contact ±8kV air	±6kV contact ±8kV 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	±2kV for power supply lines ±1kV for input/ output lines	±2kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.

Surge IEC 61000-4-5	±1kV differential mode ±2kV common mode	±1kV differential mode ±2kV common mode	Mains power quality should be that of a typical 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 0.5cycle 40% U_T (60% dip in U_T) for 5cycles 70% U_T (30 % dip in U_T) for 25cycles <5% U_T (>95% dip in U_T) for 5sec	<5% U_T (>95% dip in U_T) for 0.5cycle 40% U_T (60% dip in U_T) for 5cycles 70% U_T (30 % dip in U_T) for 25cycles <5% U_T (>95% dip in U_T) for 5sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the DTS-3000 requires continued operation during power mains interruptions, it is recommended that the DTS-3000 be powered from an uninterruptible power supply or a battery.
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	3A/m	3A/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.

9-3. Guidance and manufacturer's declaration – electromagnetic immunitytic immunity

The DTS-3000 is intended for use in the electromagnetic environment specified below.
The customer or the user of the DTS-3000 should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3Vrms 150kHz to 80MHz	3Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the DTS-3000, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = [\frac{3.5}{V_1}]\sqrt{P}$
Radiated RF IEC 61000-4-3	3V/m 80MHz to 2.5GHz	3V/m	$d = [\frac{3.5}{E_1}]\sqrt{P}$ 80MHz to 800MHz $d = [\frac{7}{E_1}]\sqrt{P}$ 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 deter-mined 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 80 MHz and 800 MHz, 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 DTS-3000 is used exceeds the applicable RF compliance level above, the DTS-3000 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the DTS-3000.

[b] Over the frequency range 150kHz to 80 MHz, field strengths should be less than [V_1] V/m.

9-4. Recommended separation distances between portable and mobile RF communications equipment and the DTS-3000

The DTS-3000 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the DTS-3000 can help prevent electromagnetic interference by maintaining a minimum distance bet ween portable and mobile RF communications equipment (transmitters) and the DTS-3000 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)		
	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2, 5 GHz
	$d = [\frac{3.5}{V_1}]\sqrt{P}$	$d = [\frac{3.5}{E_1}]\sqrt{P}$	$d = [\frac{7}{E_1}]\sqrt{P}$
0.01	0.117	0.117	0.233
0.1	0.369	0.369	0.738
1	1.167	1.167	2.333
10	3.689	3.689	7.379
100	11.667	11.667	23.333

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (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 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

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

10 Symbols Information

Symbols	Explanation	Reference
	Manufacturer	EN ISO 15223-1 5.1.1
	European Representative	EN ISO 15223-1 5.1.2
	Data of Manufacture	EN ISO 15223-1 5.1.3
	Serial Number	EN ISO 15223-1 5.1.7
	Batch code	EN ISO 15223-1 5.1.5
	The official mark of Europe Certificate	CE logo
	Type of applied part	IEC 60878 5333
	Refer to instruction manual	ISO 7010 M002
	Alternating current	IEC 60878 5032
	Alarm off Button	Custom Symbol
	Increase Button	Custom Symbol
	Decrese Button	Custom Symbol
	Inflation Button	Custom Symbol

	Deflate Button	Custom Symbol
	Cuff Change Button	Custom Symbol
	LOP Button	Custom Symbol
	Record Button	Custom Symbol
	"ON" (power)	IEC 60878 5007
	"OFF" (power)	IEC 60878 5008
	Power Button	IEC 60878 5009
	The official mark of Europe Certificate	CE logo
	Humidity limitation	EN ISO 15223-1 5.3.8
	This way up	ISO 7000 0623
	Do not hang on hooks in the box	ISO 7000 0622
	Temperature limitation	EN ISO 15223-1 5.3.7
	Load Limitation	ISO 7000 2403
	Fragile, handle with care	EN ISO 15223-1 5.3.1
	Keep dry	EN ISO 15223-1 5.3.4
	Symbol recommending the recycling of polluting components	EN ISO 60878 1135

	General warning, Caution	ISO 7010 W001
	General prohibition sign	ISO 7010 P001
	Do not take to pieces	Custom Symbol
	Symbol that indicates electrical and electronic components which must be collected separately.	EN 50419
	Symbol that indicates electrical and electronic components which must be collected separately.	EN 50419
	European Representative	EN ISO 15223-1 5.1.2
	Easy settings symbols	Custom Symbol
	Self Check system symbols	Custom Symbol
	Data Recording symbols	Custom Symbol

Warranty

Much appreciated on using our device. We, DAESUNG MAREF are doing our best to improve the quality of our products.

※ We can not be responsible for any defect occured from user's careless use or in case of followings, even though warranty period :

1. Disorder happened by strong impact.
2. In case user repair or reproduce internal part arbitrarily.
3. In case of using the device in prohibited place.
4. In case of against our <How To Use>
5. Cuff is articles of consumption.

DESCRIPTION	**Digital Pneumatic Tourniquet system**
MODEL NAME	**DTS-3000**
WARRANTY	**Device : 1 year**

DS MAREF
DAESUNG MAREF CO.,LTD.

RND-R-MUM-201-01-01 (Rev.3) 2019-09

COMPANY HISTORY

1990's

- 1986
  - Established DAESUNG Machinery Company
- 1994
  - Conversion to DAESUNG MAREF CO.,LTD.
- 1999
  - Registered DOCTOR LIFE
  - Registration of utility model for limb compression circulation therapy machine

2000's

- 2004
  - The 34th precious Technique bronze awards
  - Vice president award
  - Selected World class products
- 2006
  - Innovation management awards
  - KGMP registration
  - KFDA awards by Prime minister
- 2007
  - Authentication of Merit certificate
- 2008
  - Received a citation from the Chungbu Regional Tax Service Director
- 2009
  - Gunpo-si Mayor's Citation
  - Awarded by the Minister of Health and Welfare

2010's

- 2010
  - Awarded the Governor's Citation for Day of Commerce and Industry by Gyeonggi province
- 2011
  - President Award
  - Gold Listed at the Korea Precision Industry Technology Contest
- 2012
  - Selected an Global Small Giants Company
- 2013
  - A credit guarantee fund star company
  - Member of Trade Industry Forum
- 2014
  - Commissioned member of INNO-BIZ
  - Korean world-class product award in recognition of DVT prevention system
- 2015
  - The 8th medical devices day president award to industrial company
- 2017
  - Selected as a design innovation company
  - Grand prize of service satisfaction selected by consumers
- 2018
  - Official sponsor of Seoul E-Land FC
  - A citation from the Ministry of Employment and Labor

DS MAREF
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