

EN ISO 13485



KFDA



The Venous Assist System
DVT-2600

User Manual

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



Indications for Safety Use

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



DS MAREF
DAESUNG MAREF CO.,LTD.

www.dsmaref.com

1. Introduction

1.1 Operation of the controller

Thank you for choosing the DVT-2600. This product is a specialized Intermittent Pneumatic Compression (IPC) system designed to prevent DVT (Deep Vein Thrombosis) and PE (Pulmonary Embolism) by improving venous blood flow in high risk patients.

This system consists of the controller, tubing sets and cuffs. The DVT-2600 offers sequential inflation which promotes venous blood movement and metabolism. After deflation, there is a time interval before reinflation to allow the veins to refill. The operation of the inflation and deflation is repeated until the stop button is activated.

The DVT-2600 has an integrated self-checking system which includes checks for the digital sensor, cuff connection, and power supply. If an error code shows during initial operation of the DVT-2600, it can be checked against the error code key attached to the side of the DVT-2600 unit for convenient reference.

2. General contraindications and Cautions

2.1 Contraindications

The DVT-2600 system is not recommended for use with the following conditions:

- Pre-existing deep vein thrombosis, phlebothrombosis or pulmonary embolism
- Presumptive evidence of Congestive Heart Failure
- Inflammatory Phlebitis Process
- Severe arteriosclerosis or other ischemic vascular disease
- Decompensated cardiac insufficiency
- Carcinoma metastasis in the affected extremity
- Lymphatic return is undesirable
- Severe arteriosclerosis or active infection

2.2 Precautions

- If any pain or oedema occurs during use of the device, cease therapy and seek medical advice.
- Use caution with the device on patients with any prosthesis inserted.
- Assess skin integrity frequently during use in patients with diabetes or vascular disease.
- If any electronic shock is detected, remove device from power source and disconnect unit from patient.
- Manual settings should be adjusted under the advice of a medical practitioner.

2.3 Warnings

- Manual settings should be adjusted under the advice of a medical practitioner.
- Do not attempt to repair a faulty device or replace broken tubing connectors as abnormal inflation of the cuff may occur. Contact your local representative.
- Use the device with a suitable AC power cord observing the electronic standards for each local region. (Fire and electric shock are possible)

2.4 Clause 5

- 1) Type of protection against electric shock: Class I equipment.
- 2) Degree of protection against electric shock: Not classified - BF applied parts
- 3) Classify according to the degree of protection against ingress of water: IPX0, ordinary equipment.
- 4) This equipment is not suitable for use in the presence of flammable anaesthetics or oxygen.
- 5) Mode of operation - continuous operation

2.5 Information regarding potential electromagnetic or other interference

This equipment has been tested and found to comply with the limits for medical devices in IEC/EN 60601-1-2. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation.

This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation.

If this equipment does cause harmful interference to other devices, which can be determined by tuning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures :

- Reorient or relocate the receiving device.
- Increase the separation between the equipment.
- Connect the equipment into an outlet on a different circuit from that to which the other device(s) are connected.
- Consult the manufacturer or field service technician for help.

2.6 WEEE marking



This marking shown on the product or its literature, indicates that it should not be disposed of with other household waste at the end of its working life. To prevent possible harm to the environment or human health from uncontrolled waste disposal, please separate this from other types of waste and recycle it responsibly to promote the sustainable reuse of material resources.

Household users should contact either the place of purchase, or their local government office, for details of where and how they can take this item for environmentally safe recycling.

Business users should contact their supplier and check the items and conditions of the purchase contract. This product should not be mixed with other commercial waste for disposal.

3. Product Description

3.1 Summary and Specifications

► Composition

- The controller
- Air connectable hose
- AC power cord

► Operating principle

The operating principle is that the air from the controller will be delivered to the cuff with 3 air chambers and the air will sequentially pressurize the chambers from 1st to 3rd. After completion of pressurization to each chamber, the controller determines the interval time for vein refilling and the controller will restart to pressurize the chambers again. This operation will then be repeated.

► Intended Use

This product is an ancillary medical device to help with the treatment of DVT by accelerating blood circulation in the lower limbs. Please use this product in accordance with medical direction.

► How to connect the hose to the cuff

The controller has a self test function to automatically recognise the kind of cuff(s) connected to it during initial operation. Press the "START/STOP" button after turning on the power switch to initiate this self test feature.

► System features

- Self-test function of the controller

On device start up, the controller initiates an automatic check of the cuff connection and the type of cuff applied. The controller also detects any abnormal pressures encountered during regular operation.

- Manual setting program

The controller is designed to allow custom pressure values to be delivered to the patient.

3.2 The functions

(1) Name of each part



1. Leg Pressure Button

Sets the pressure to be delivered.

When the user presses the START/STOP button, the pressure is set according to the type of cuff connected. (LEG/CALF/BOOT CUFF: 40mmHg). This value is not able to be changed during operation.

Basic pressure is set at 40mmHg. This pressure setting can be changed at 10mmHg increments (ex. 40→50→60→20→30→40mmHg).

The LCD screen will remain turned off if the user does not apply the cuff, as the controller automatically selects the cuff when the START/STOP button is selected.

The controller has an automatic gradient pressure application which applies gradient pressure into each chamber of a cuff sequentially (+/- 5mmHg). For cuffs with 3 chambers such as the leg/calf/boot cuff; if 40mmHg is set, pressure will be delivered as 35/40/45mmHg to the three chambers.



2. Foot Pressure Button

This button sets the pressure at which the device will be operated. When the user presses the START/STOP button, the pressure will be selected according to the type of cuff. (Foot Cuff: 120mmHg). The pressure setting cannot be changed during operating.

Basic pressure is set as 120mmHg. The pressure setting can be changed by 10mmHg increments by pressing the button (ex. 120→130→140→120mmHg). The LCD screen will remain be off if the user does not apply the cuff, as the controller automatically selects the cuff when the START/STOP button is selected.



3. Interval Button

This button sets the interval time. The time value which the user sets will be saved. Default time is set at 48 sec, and it can be changed to 48→60→24→48 sec each time the interval button is selected. After initial inflation of pressure to each chamber the controller will then restart therapy with the interval time selected. This operation will be repeated and the setting cannot be changed during operation.



4. Mode Button

Sets the mode to be operated. The default setting is set to DVT Mode during initial power on.



5. START/STOP Button

Starts or stops the operation. It goes back to STOP mode when the user presses START/STOP button during the error mark on the screen.

6. LCD display screen

1) Batteries status indicator

DVT-2600 is equipped with a battery pack as standard. There are four battery status indicator LED's used to represent the charge level of the battery.

2) AC power indicator

AC power indicator (LED) represents one of power input or the fail of power input.

3) Battery charging indicator

Indicates whether batteries are charging. Indication of the battery charge level will not be displayed when the unit is off. The indicator for battery charging will be displayed only when the batteries are not fully charged.

	Battery fully charged		Power plugged in
	Battery is 50% charged		
	Battery needs to be recharged		Battery is charging
	Out of battery		

※ The batteries require the device to be powered on for charging. Warranty period for the batteries will be 6 months after the date of purchasing. Do not remove the batteries from the device.

4) Battery charging

To charge the batteries, please ensure the device is plugged in and the device power switch is on. The amount of power the batteries can deliver will vary according to a battery's condition and the settings of the device. Regular battery charging time is approximately 4 hours. Maximum running time is up to 8 hours.

5) Operation indicator

Shows normal operating condition and the type of applied cuffs. Initial self-test will detect the type of cuff.

When the device is turned on, the controller will check the type of cuff. During the controller check; the symbols below will be gradually encircled demonstrating progress of the check.



<Picture 1>

The operation indicator below displays the variety of cuff types which may be used. Please note if there is no cuff applied to the controller, an error code will be displayed.

Two feet	Two legs	Left foot & right leg	Left leg & Right foot
Right leg	Left leg	Left foot	Right foot

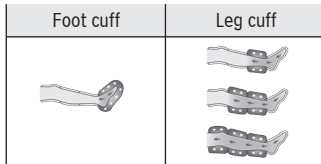
<Picture 2>

(2) Operating Mode

The operating mode is divided into DVT and LYMPH mode.
During normal operation, the operation indicator activates repeatedly.

1) DVT Operation Mode

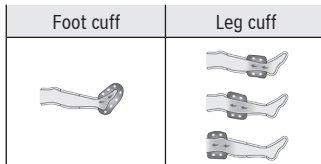
In DVT mode, the controller first pressurizes the cuffs. (Refer to picture 1). The interval time will start after pressurisation of both legs.



< Picture 1 >

2) Lymph Operating Mode

In Lymph Mode, the controller first pressurizes the cuffs. (Refer to picture 2). The Interval time will start after pressurisation of both legs.



< Picture 2 >









3) Interval Mode

After initial pressurisation, the interval time setting on the LCD (counter) will decrease gradually and will restart the pressurisation cycle at the end of the interval time.

(3) Error Description

If there is an error with the controller; the error mode will start with an alarm. The controller will revert back to Waiting Mode when the user presses START/STOP.

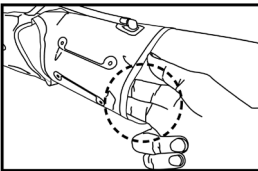
> Error Mode

Segment	Error information	Segment	Error information
Error 10 (Cuff connection error)	 <p>This error mark will be on the screen if there is no cuff connection to the controller.</p>	Error 30 (system error)	 <p>Vent error Pressure in cuff doesn't ventilate.</p>
			 <p>Pump error When the device pump has an error.</p>
			 <p>Device error When the device has an error.</p>
Error 20 (Pressure error)	 <p>Lower pressure error Under the 30% pressure has consecutively checked five times.</p>	Error 40 (Power error)	 <p>The voltage of the controller has an error after AC power is on.</p>
	 <p>High pressure error Over the 30% pressure has consecutively checked five times.</p>		 <p>Warning of low battery Connect the AC power.</p>

※ Error codes and instructions to follow

1) Code 10 (Cuff connection error)

- During power on the controller performs an automatic one cycle calibration to detect the cuff type and proper garment fit. If the controller fails to detect the cuff, it shows Error code 10 with an alarm sound.

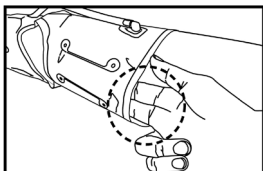


*Checking point

- ① Check the connection of the controller to the hoses (tubing).
- ② Check that each cuff is wrapped properly on the patient's leg.

2) Code 21 (Low pressure error)

- If pressures lower than 30% of the set value are detected more than 3 times during operation, it will indicate Error code 21.



*Checking point

- ① Check the connection of the controller to the hoses (tubing).
- ② Check that each cuff is wrapped properly on the patient's leg.
- ③ Check whether there is any leakage from a connected cuff.
- ④ Separate the cuff and hose, check air is leaving from the air socket of the controller.

3) Code 22 (higher pressure error)

- If pressures higher than 30% of the set value are detected more than 3 times during operation, it will indicate Error code 22.

*Checking points

- ① Check whether the hose is bent.
- ② Check if there is something blocking the hose.
- ③ Check whether air socket is blocked.

4) Code 31 (Ventilation error)

- If air is not ventilated (deflated) under 20mmHg during INTERVAL TIME, Error code 31 will be indicated.

*Checking points

- ① Check the inner solenoid valve (Exchange the valve)

5) Code 32 (Pump error)

- During the initial self detection test, if the pump is not operating normally, Error code 32 will be displayed.

*Checking points

- ① Check pump operation after opening the cover of the controller
- ② Check the wire connection in the controller.

6) Code 33 (System error)

- This error indicates the inner controller is damaged seriously.
- Please call your local representative.

7) Code 41 (Power supply error)

- Code 41 is displayed if the power supply from the outer AC power generates any problem.
- Please call your local representative.

8) Code 42

- Code 42 is displayed when there is a problem with the power supply generated by the inner batteries. Please call your local representative.

3.3 System description

(1) Main compositions








1) DVT-2600 controller







- Voltage and AC power : 100-200V~, 50/60Hz
- Power consumption : 25W(35VA)
- Output : 2
- Pressure range : LEG - 20~60mmHg
Foot - 120~140mmHg


2) DVT-2600 Accessories

>Single use cuff

Cuff		Size	Width	Code	
	Non woven				Soft fabric
Thigh cuff			Small	60cm	DS011 / DS211
			Medium	75cm	DS012 / DS212
			Large	93cm	DS013 / DS213
			X-Large	113cm	DS014 / DS214
Calf cuff			Small	50cm	DS021 / DS221
			Medium	62cm	DS022 / DS222
			Large	77cm	DS023 / DS223
			X-Large	97cm	DS024 / DS224
Foot cuff			One size	42cm	DS031 / DS231
Boot cuff			One size	63cm	DS041 / DS241

>Multi-use cuff

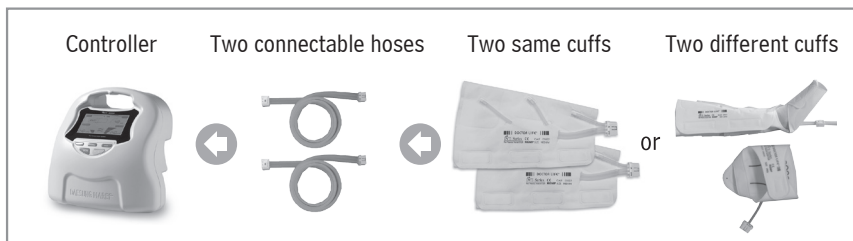
Cuff		Size	Width	Code
Thigh cuff		One size	80cm	DS111
Calf cuff		One size	66cm	DS121
Foot cuff		One size	42cm	DS131
Boot cuff		One size	63cm	DS141

Tubings	
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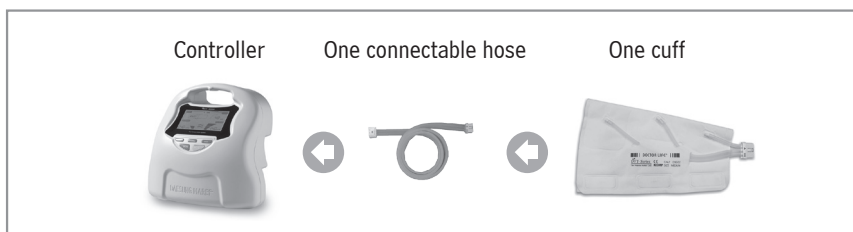
※ The dimensions given in the above table may deviate by 2~3cm depending on production conditions.

(2) Cuff usage and caution

1) Two cuffs + Controller



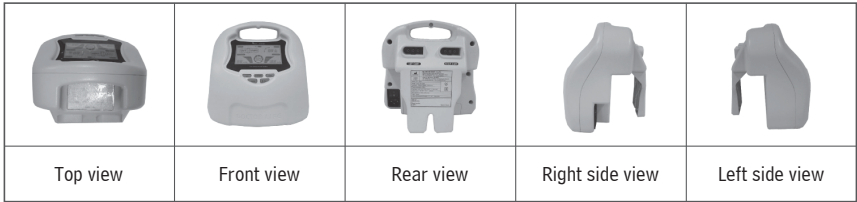
2) One cuff + Controller



(3) Cuff usage and caution

- 1) Do not turn on the power switch before applying cuff(s) to a patient. Connect the hoses after the cuffs are applied to the patient. Turn the power on to the device after connecting the hoses to the air socket at rear of device to ensure self check.
- 2) Do not operate with patient standing or sitting down. There could be a risk of malfunction of the device and cuffs.
- 3) The manufacturer recommends using basic pressure settings for initial use. Caution is recommended for manual pressure settings (Leg : over 50mmHg, Foot : over 140mmHg)

3.4 Controller views



3.5 Technique data

(1) Specifications and Dimensions









Test descriptions	Standard	Remarks
AC voltage	100-240V~, 50/60Hz	
Power consumption	25W(35VA)	
Air power consumption	below 5W	
Noise level	Above 2 KV	
Operation nose level	below 60dB	
Max. pressure level	140mmHg	
Controller weight	2kg	
Controller size	200(W) x 165(D) x 190(H) mm	

3.6 Products Label










(1) Copyright



(2) Label

	Caution		BF type medical equipment
	Europe certificate mark		Manufacturer mark
	Service supplier mark		Production date
	LOT NO		Serial No.

<Products information sticker>

	Daesung Maref Co.,LTD. DOCTORLIFE (www.dsmaref.com) 689-31, Geumjung-dong, Gunpo-shi, Geonggi-do, 435-862, Korea Tel: +82-31-459-7211 Fax: +82-31-459-7215
	SUPPLY MEDICAL SERVICE 18, CHEMIN DES COURSES 31100 TOULOUSE, FRANCE TEL: +33-(0)5-3450-4455 FAX: +33-(0)5-3450-4461
Model : DVT-2600	   
Weight : 2kg (only body)	
Dimension : 200(W) x 165(D) x 190(H)	
Power consumption : 35VA	
Power source : 100-240V~, 50/60Hz	
SMPS : T3, 15A 250V	
Place : Indoors	
Ambient temperature & Humidity : 0℃-40℃ / below 60%	
Made in Korea	
	IPX0
<ul style="list-style-type: none"> - When the problem happens, stop the operation immediately, then turn a power switch off. - When the machine is unfit for body, please stop using a machine. - The electricity is suddenly off, separate hoses from pad and eliminate the air. - Do not use under the high temperature places as sauna, bathroom or the place where humidity is very high. - Do not connect body with another machine or modify absolutely. - Plug off a power cord from socket when you don't use. - See accompanying documents - To avoid electrical shock, do not open the cabinet. Refer servicing to qualified personnel only. 	
	DATE OF MANUFACTURE
	SERIAL NUMBER

※ This label is attached on the rear of a controller.

4. Product composition

4.1 Package

DVT-2600 consists of a controller box and a cuff box.
The contents of each box are described below.

(1) Controller

- A. DVT-2600 main body
- B. The form for shock prevention of the controller
- C. Connectable hose
- D. AC cord
- E. Operation manual

(2) Cuff box (Optional items)

- A. Thigh cuff (large, Medium, Small)
- B. Calf cuff (Large, Medium, small)
- C. Foot cuff (One size)
- D. Boot cuff (One size)
- E. Multi-use cuff (Thigh, calf, foot and boot / One size)

4.2 Product checking

※ Caution : Do not open the box with a sharp knife or scissors. The product may be damaged.

(1) Composition inspection in a box

Check the accessories included are correct as ordered and that a user manual is included in the box.

1) Basic set

- A. DVT-2600 main body
- B. Connectable hose
- C. AC cord
- D. Operation manual

2) Optional items

- A. Thigh cuff (large, Medium, Small)
- B. Calf cuff (Large, Medium, small)
- C. Foot cuff (One size)
- D. Boot cuff (One size)
- E. Multi-use cuff (Thigh, calf, foot and boot / One size)
- F. User manual for cuffs
- G. Cuff package pack

► Check point of normal products

- A. Products model name (DVT-2600)
- B. Cuff size and material
- C. The right connection of a hose socket and outlet of a controller
- D. The right connection of a hose socket and outlet of a cuff hose
- E. AC cord for local voltage

(2) Products or package defect

- A. Please contact your local representative if products are found to be damaged or quantities/items are incorrect.

(3) Other Points to Note

- A. Damage during opening of the package by a user cannot be warranted.
- B. Store device in a safe place protected from dust or humidity. Unplug the unit when the device is not in use.

(4) Environmental conditions for transport and storage

Operating condition	Temperature (°C)	0-40
	Relative humidity(%)	10-90
	Atmospheric pressure (hPa)	700-1060
Transport and storage condition	Temperature (°C)	-20-60
	Relative humidity(%)	0-90
	Atmospheric pressure (hPa)	500-1060

5. Product use procedure

5.1 Before using a device

Use this device only under medical supervision.

5.2 Setup and use

- 1) Place the device on a hard and flat table, or hang on the bed and connect to a power outlet.
- 2) Ensure the cuff is the correct size and securely fitted to the patient.
- 3) Connect the cuff to the controller with the connectable hose(s).
- 4) Turn on the power switch at the rear of the controller.
- 5) Operate the controller by pressing the START/STOP button for the automatic setting DVT or enter pressure and interval time manually after initial inflation.
- 6) The controller will operate automatically utilizing the entered settings after the cuff self-test operation.
- 7) Press and hold the START/STOP button for 3 sec to stop therapy.
Check therapy parameters are in accordance with medical supervision.
- 8) Start the operation.

5.3 Before using a device

Do not use the device if the patient demonstrates any of the following symptoms:-

- 1) Oedema
- 2) Difficulty breathing
- 3) Uncomfortable pressure during cuff compression.
- 4) Pain during use of device.
- 5) Temporary numbness or Irritation caused by the cuff.

5.4 Setting and use

As DVT-2600 is a medical device for the purpose of assisting with venous therapy, DVT-2600 is to be used only under medical supervision.

The device is not recommended for long term use.

Over time the patient may become accustomed to the compression pressures and hence benefits from use of the device diminish.

6. Maintenance

▶ Device

- Use the device indoors in the temperature range of 0~40°C and under humidity of 60%. (Outside of these parameters there is a fire risk).
- Keep the device from heating equipment or direct light rays. (fire risk)
- Do not use the device in high humidity places such as bathrooms or saunas etc. (Fire, electric shock risk)
- Don't fold or bend air hose.
- Do not tamper or attempt to repair the device – contact your local representative (Fire, electric shock risk)
- Keep the device in a clean place and protect from dust.

▶ Cuff

- Disposable cuffs are for single use by one person only.
- Keep cuffs or hose away from water or dust.
- Do not blow air into the cuff while it is not fitted securely to the body (Damage, anti-endurance risk).
- Do not keep cuffs near sharps

▶ Battery

- Avoid dropping or shocking
- Prevent from being soaked in liquid
- Do not touch any material leaking from the battery pack.
- Do not open the cover of the battery pack or tamper with it in any way. (fire or explosion risk)
- Dispose of the battery properly according to local regulation.
- The warranty period for the battery is 6 months after the date of purchase.

7. Troubleshooting

7.1 Troubleshooting

No.	Condition	Cause	Solution
1	No electric power	Power connection error	Check that the plug is correctly inserted into the power outlet
2	Power on but not operating	Power supply error	Turn power to the controller off and on
3	Noisy during operating	Setting condition	Check that the device is installed horizontally
			Check that there is nothing laying on top of the device or underneath
4	No air in the hose	Hose connection error or bent hose	Check that the hose is inserted correctly into the device.
			Check that the hose is not bent
5	Air is going through the hoses in the wrong order	Connection fault	Check that the plug is correctly inserted into the outlet

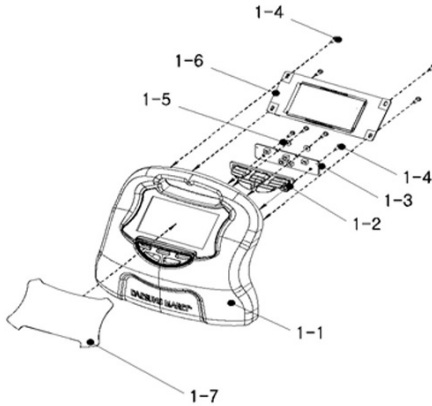
7.2 Others related to defect

No.	Condition	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

※ Manufacturer is not responsible for any defect incurred by user neglect.

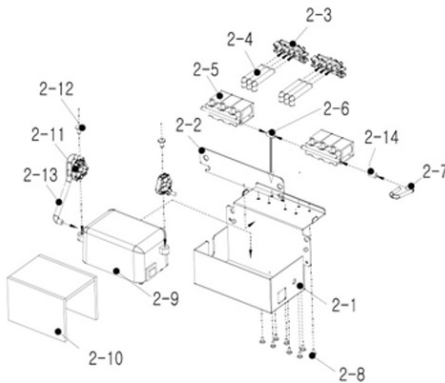
8. Schematics

1) Parts Assembly Diagram : SUB-ASM-FORNT



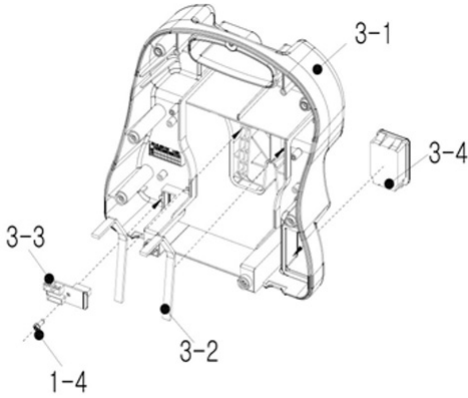
No.	Name
1-1	FRONT_COVER (1EA)
1-2	KNOB_BUTTON (1EA)
1-3	SUB_BOARD_KEY (1EA)
1-4	M3XL6 TT (8EA)
1-5	WASHER (2EA)
1-6	MAIN_BOARD_LCD (1EA)
1-7	WINDOW_SHEET (1EA)

2) Parts Assembly Diagram : SUB-ASM-FRAME



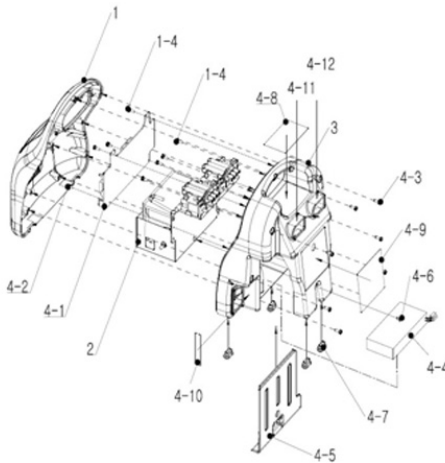
No.	Name
2-1	FRAME_MAIN (1EA)
2-2	SHEET_PLATE (1EA)
2-3	COVER_PLUG (2EA)
2-4	RUBBER_HOSE_ELBOW (6EA)
2-5	SOLENOID (2EA)
2-6	RUBBER_HOSE_CONNECTOR (1EA)
2-7	RUBBER_HOSE_PRESSURE (70mm)
2-8	M3XL5S (8EA)
2-9	PUMP (1EA)
2-10	SPONGE (3EA)
2-11	RUBBER_VIBRATION (2EA)
2-12	M4XL10 TP (2EA)
2-13	RUBBER_HOSE (120mm)
2-14	RUBBER_HOSE (20mm)

3) Parts Assembly Diagram : SUB-ASM-REAR



No.	Name
3-1	REAR_COVER (1EA)
3-2	RUBBER_PAD (2EA)
3-3	SUB_BOARD_CHARGE (1EA)
3-4	AC_INLET (1EA)

4) Parts Assembly Diagram : SUB-DVT-2600



No.	Name
1	SUB_ASM_FRONT
1-4	M3XL6 TT (9EA)
2	SUB_ASM_FRAME
3	SUB_ASM_REAR
4-1	SMPS (1EA)
4-2	M3XL5 S (2EA)
4-3	M3XL8 TT (8EA)
4-4	BATTERY (1EA)
4-5	CAB_BATTERY (1EA)
4-6	M3XL4 M (1EA)
4-7	RUBBER_FOOT (4EA)
4-8	STICKER (ERROR_CODE) (1EA)
4-9	LABEL (1EA)
4-10	STICKER (WARNING) (1EA)
4-11	STICKER (LEFT) (1EA)
4-12	STICKER (RIGHT) (1EA)

Warranty

We appreciate your use of our device. Daesung Maref will continue to improve the quality of our products.

※ We will not be responsible for any defect incurred due to neglect by the user or any of the following:

1. Malfunction caused by strong impact.
2. Unauthorised repair or parts.
3. Use of the device in a prohibited place.
4. Not following the user manual
5. Cuffs are articles of consumption and are not under warranty

DESCRIPTION	The Venous Assist System
MODEL NAME	DVT-2600
SERIAL NO.	
WARRANTY	Controller : 2 years
BUYING PLACE	
BUYING DATE	

DS MAREF
DAESUNG MAREF CO.,LTD.



History & Certificates

2011	President Award
2010	Anvisa in Brazil
2007	Authentication of Merit certificate
2006	Innovation management awards
2006	KOTRA B2B e-Trade awards
2006	KFDA awards by Prime minister
2006	KGMP registration
2004	The 34 precious Technique bronze awards
2004	Korean World class products award
2004	Vice president award
2004	SFDA in China
2003	Success Design product
2003	FDA in USA
2002	ISO9001/EN13485
2002	CE marks (DL series, MK series, DL1200, DVT-2600)
1986	DS MAREF is established

DS MAREF
DAESUNG MAREF CO.,LTD.

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