

PneumaPRESS®

User Manual



Intermittent Pneumatic Compression System

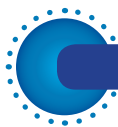
To ensure safe use of this device, it is essential that you read and fully understand the information contained within this manual.

Mechanical
prophylaxis for the
prevention of Deep
Vein Thrombosis

CE
0473

Caution: Federal (USA) and European Union law restricts this device to sale, distribution and use by or on the order of a physician.

G+N MEDICAL



1. Introduction

1.1 OVERVIEW OF THE SYSTEM

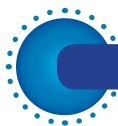
Thank you for choosing PneumaPress® DVT-2600. The product is a pneumatic compression system which is used to improve the blood circulation for patients with reduced mobility, therefore reducing the risk of DVT/VTE formation.

The product range comprises of a pump, connecting tubing and disposable cuff(s).

The pump has digital sensors to check the cuff connections, output and power supply. If an error code shows during the initial operation, check the error code sticker on top of the controller and action as advised.

This user manual contains information on how to use and maintain PneumaPress®.

Please read this manual to ensure you use this product correctly.



2. Clinical Information

2.1 RANGE OF APPLICATION AND EFFECT OF USE

Air from the pump is delivered to the cuff(s) via 3 air chambers in the thigh, calf and boot styles. The air will sequentially pressurise the chambers from 1st to 3rd. This applies pressure to the legs and the veins within them, forcing blood up towards the heart.

Please use this product as prescribed by medical staff and as per your Hospital/Trust DVT/VTE policy and only once you have undertaken training in its use.

2.2 CONTRA-INDICATIONS



PneumaPress® 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.
- Where lymphatic return is undesirable.
- Severe arteriosclerosis or active infection.

2.3 PRECAUTIONS

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

2.4 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).

2.5 CLAUSE 5

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

2.6 INFORMATION REGARDING POTENTIAL ELECTROMAGNETIC OR OTHER INTERFERENCE

This equipment has been tested and found to comply with the limits for medical devices in EC/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 interference to other devices, which can be determined by turning 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.
- Consult the manufacturer or technician for help.

2.7 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.

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 pump.
- Air connecting hose (tubing).
- AC cable (plug).
- Cuff(s).

Specification

- Model: DVT - 2600.
- Weight: 2 Kg (only body).
- Dimension: 190(W) x 200(D) x 162(H)mm.
- Power consumption: 35 VA.
- Fuse: Apply inside the AC inlet socket: F 3.15AL 250V.
- Place: Indoors.
- Ambient temperature & humidity: 0°C~ 40°C / below 60%.
- Power source: AC 100V - 240V, 50/60Hz.
- The information label sticker of DVT-2600 is attached on the rear of a controller.

Operating Principle

The pump will deliver air to the cuff(s) and sequentially pressurise them. Cuff(s) with 3 air chambers will be pressurised from the 1st chamber (nearest to the foot) to the 3rd chamber. Once the chambers are pressurised, the pump will provide an interval period for vein refilling before the pump starts to pressurise the chambers again.

These cycles will be repeated throughout the time the unit is in use.

Intended Use

This product is a medical device to help reduce the risk of DVT/VTE formation by increasing the flow of blood in the venous circulation from the legs back to the heart.

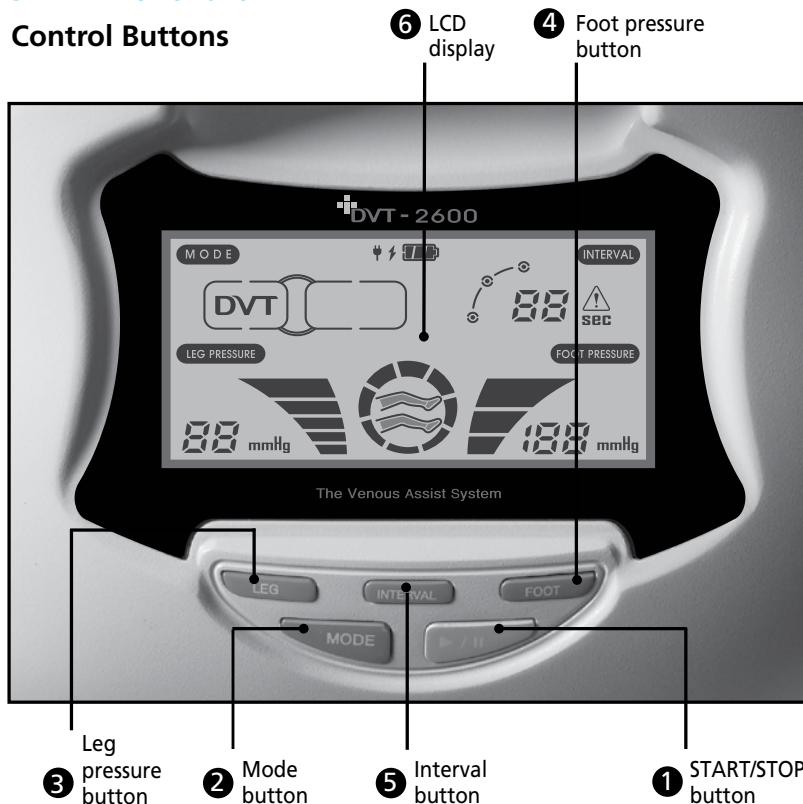
Please use this product under the guidance of medical staff and in line with your hospital(s) DVT/VTE policy.

System features

- **The Self-Test Function:**
On start up, the pump 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 pump is designed to allow custom pressure values to be delivered to the patient.

3.2 THE FUNCTIONS

Control Buttons



1. START/STOP: This button is used to start or stop the compression cycles. If an error occurs, the pump automatically stops. To restart cycles press once.

2. MODE: In the UK, PneumaPress® is only marketed to provide 'DVT/VTE prophylaxis'. The mode button does not have a use - use in DVT mode only.

3. LEG PRESSURE: This button is used to set the required pressure to be delivered to leg cuff(s). When the START/STOP button is pressed, the basic leg pressure will automatically be shown (LEG/CALF/BOOT CUFF: 40mmHg).

It is not possible to change these settings whilst the pump is in operation.

The basic pressure is set as 40 mmHg and the pressure setting will be changed by 10mmHg with each depression of the button (eg.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 pump has an automatic gradient pressure application that is applied into each chamber of a cuff sequentially (+/-5 mmHG).

For cuff(s) with three chambers such as leg/calf/boot; if 40mmHG is set, pressure will be delivered as 35/40/45mmHG to the three chambers.



4. FOOT PRESSURE: This button is used to set the required pressure to be delivered to a foot cuff. When the START/STOP button is pressed, the basic foot pressure will automatically be shown (FOOT CUFF: 120mmHg).

It is not possible to change these settings whilst the pump is in operation. The basic pressure is set as 120mmHg and the pressure setting will be changed by 10mmHg with each depression of the button (ex.120→130→140→120mmHg).

The LCD screen will switch off if the user does not apply a cuff, because the pump selects the cuff automatically when START/STOP is pressed.



5. INTERVAL: This button is used to set the interval (cycle) time.

When the START/STOP button is pressed, the default setting of 48 sec is shown and can be changed with each depression of the button: 60→28→48→60 sec.

Upon completion of pressurisation to each chamber, the pump has an interval period to allow time for the vein to refill with blood, before the pump restarts to pressurise the chambers again. These cycles will be repeated during the operating time set or until discontinued.

It is not possible to change these settings whilst the pump is in operation.



6. LCD DISPLAY SCREEN:

A) Battery status indicator

PneumaPress® DVT-2600 is equipped with a back up battery pack.
An LED indicator is used to represent the charge status of the battery
(as per diagram below).

B) AC power indicator

AC power indicator (LED) is used to show mains power is attached and in use. If not shown please check status of mains supply.

C) 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 PneumaPress® to be switched on for charging. Warranty period for the batteries will be 6 months after the date of purchasing.

D) Battery charging

To charge the batteries, please ensure PneumaPress® is plugged in and the 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.

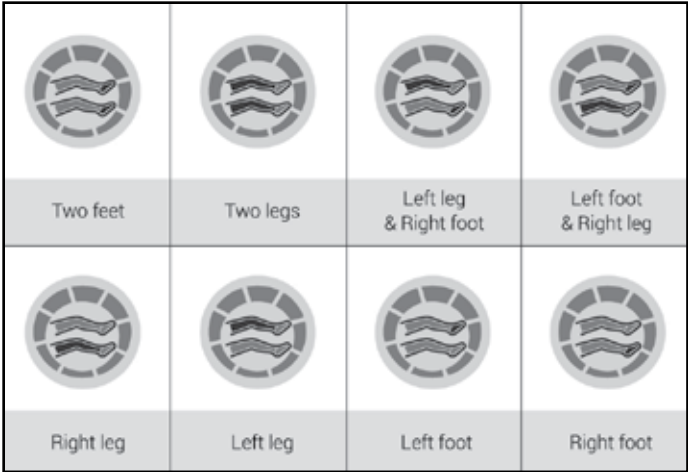
E) Operation indicator

This LED indicator shows the status and type of cuff(s) applied, following the self test application. It also shows if one or two legs are being compressed and to which leg different cuff(s) are being used (i.e. leg and foot).

A moving LED shows pump in operation following self check application.



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

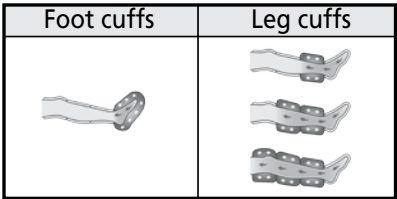


Operating Mode

The pump is able to provide two levels of therapy. For the UK, PneumaPress® is only marketed to provide DVT/VTE prophylaxis.

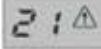
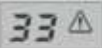
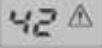
Diagram 1

1. DVT OPERATING MODE: In DVT mode, the pump pressurises the cuff(s), (see diagram 1). If different cuff(s) have been selected, pressure is applied to foot cuff first, then the leg cuff(s). Interval time will start after both legs/cuff(s) have been pressurised.

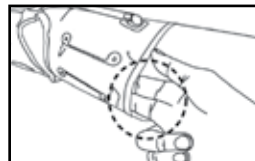


2. ERROR DESCRIPTION: If there is an error with the pump; the error mode will start with an alarm. The pump will stop and return to a waiting mode. Once the error is corrected the pump will restart when the user presses START/STOP.

Error Mode

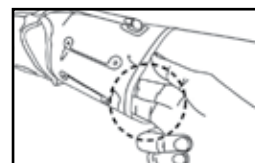
Segment	Error information	Segment	Error information
Error 10 (Cuff connection error)	 No cuff(s) connected to the pump.	Error 30 (system error)	 Vent error Pressure in cuff doesn't ventilate.
			 Pump error
Error 20 (Pressure error)	 Low pressure error 30% under pressure following 5 consecutive checks.		 Device error
			 AC cord (plug) error Power problem when using AC power.
	 High pressure error 30% over pressure following 5 consecutive checks.	Error 40 (Power error)	 Battery power error Power problem when AC power off and using battery.

1. CODE 10 (Cuff connection error): During power on, the pump performs an automatic one cycle calibration to detect cuff type(s) being used and confirm they are fitted to the limb(s). If the pump fails to detect the cuff(s) error code 10 will be displayed with an alarm sound.



- 1 Check the pump and cuff(s) to ensure the tubing is correctly fitted.
- 2 Check that each cuff is fitted correctly on the patient's leg.

2. CODE 21 (Low pressure error): If pressures lower than 30% of the set value are detected more than 5 times during operation, error code 21 will be displayed.



- 1 Check the pump and cuff(s) to ensure the tubing is correctly fitted.
- 2 Check that each cuff is fitted correctly on the patient's leg.
- 3 Check whether there is any leakage from a connected cuff.
- 4 Disconnect the cuff and tubing, check air is being pumped from the air outlets on the pump.

3. CODE 22 (High pressure error): If pressures higher than 30% of the set value are detected more than 5 times during operation, error code 22 will be displayed.

- 1 Check whether the tubing is bent.
- 2 Check if there is something blocking the tubing.
- 3 Check the pump air output sockets for blockages.

4. CODE 31 (Ventilation error): If air has not ventilated (deflated) under 20mm Hg during the INTERVAL TIME, error code 31 will be displayed.

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.

1 Check pump operation after opening cover of the pump.

2 Check the wire connection in the pump.

6. CODE 33 (System error): This error indicates serious damage to the inner pump. Please call your local representative.

7. CODE 41 (Power supply error): Code 41 is displayed if the power supply from the outer AC is causing a 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

Main Compositions

1. PNEUMAPRESS® DVT-2600 PUMP:

- Voltage and AC power: AC 100 ~ 240V, 50/60Hz.
- Power consumption: 25W(35VA).
- Output: 2.
- Pressure range: LEG 20 ~ 60mmHg, FOOT 120 ~ 140mmHg.



2. PNEUMAPRESS® DVT-2600 ACCESSORIES:

THIGH	PRODUCT CODE	SIZE	LENGTH OF CUFF	LENGTH OF CALF SECTION	CALF CIRCUMFERENCE	THIGH CIRCUMFERENCE	NHS CODES
	DS011	Small	53cm	31cm	26 - 40cm	50 - 76cm	EGD 7614
	DS012	Med	61cm	63.5cm	37 - 51cm	53 - 81cm	EGD 7615
	DS013	Large	65cm	38.5cm	45 - 66cm	56 - 87cm	EGD 7616
	DS014	X-Large	65cm	38.5cm	45-84cm	56-102cm	EGD 7617

CALF	PRODUCT CODE	SIZE	LENGTH OF CUFF		CALF CIRCUMFERENCE		NHS CODES
	DS021	Small	28cm		19 - 36cm		EGD 7618
	DS022	Med	33cm		29 - 46cm		EGD 7619
	DS023	Large	35cm		35 - 56cm		EGD 7620
	DS024	X-Large	35cm		Up to 97cm		EGD 7621

FOOT	PRODUCT CODE	SIZE				FOOT CIRCUMFERENCE	NHS CODES
	DS031	One size fits all				Up to 36cm	EGD 7622

BOOT	PRODUCT CODE	SIZE		LENGTH OF CALF SECTION	CALF CIRCUMFERENCE	FOOT CIRCUMFERENCE	NHS CODES
	DS041	One size fits all		33cm	27 - 46cm	Up to 28cm	EGD 7623

TUBING	NHS CODES
	EGD 7635

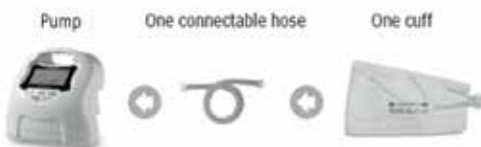
PUMP	PRODUCT CODE
	DVT -2600

Cuff usage and caution

TWO CUFFS & PUMP:



ONE CUFF & PUMP:



3. CUFF USAGE AND CAUTION

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

3.4 CONTROLLER VIEWS



3.5 TECHNICAL DATA

Specifications and Dimensions

TEST DESCRIPTIONS	STANDARD
AC voltage	100-240V~, 50/60Hz
Power consumption	25W(38VA)
Air power consumption	Below 5W
Noise level	Above 2KV
Operation noise level	Below 60dB
Max. pressure level	140mmHg
Pump weight	2kg
Pump size	200(W) x 165(D) x 190(H) mm

3.6 PRODUCTS LABEL

1. COPYRIGHT



2. LABEL

	Caution		BF Type Medical Equipment
	Europe Certification Mark	 Manufacturer	Manufacturer Mark
	Serial Number	 Date of Manufacture	Date of Manufacture
	LOT Number		Service Supplier Mark

4. Product Composition

4.1 PACKAGE

PneumaPress® DVT-2600 box consists of the following:

- PneumaPress® DVT-2600.
- Air connecting hose (tubing).
- AC cable (plug).
- Operations manual.

Cuff(s) are ordered separately and can be ordered in various sizes.

4.2 INSPECTION OF BOX

- Caution: Do not open boxes by using sharp implements.
- Ensure content matches above list.
- Check power cable is correct for your locality and use.

4.3 PRODUCTS OR PACKAGING DEFECTS

Please contact your representative if products are found to be damaged or items are missing from the packaging.

4.4 PLEASE NOTE

- 1 Damage caused by the user during the opening of the packaging is not covered by the warranty. Please take care.
- 2 Please ensure PneumaPress® is stored safely, away from dust and humidity after each use.
- 3 Ensure PneumaPress® is unplugged from the mains supply when not in use or being charged.

4.5 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 THIS DEVICE

Only use PneumaPress® under the direction of medical staff and as per your hospital's DVT/VTE policy. Do not operate this device unless you have been trained to do so.

5.2 SETTING UP AND USING THE DEVICE

- 1 Place the PneumaPress® on a hard, flat surface or hang using the bed hanger.
- 2 Connect to a suitable power supply.
- 3 Ensure the cuffs are the correct size and securely fitted to the patient.
- 4 Connect the applied cuff(s) to pump using connecting hose(s).
- 5 Turn on the power switch at the rear of the pump.
- 6 The pump will automatically self-test checking the cuff(s) attached.
- 7 Operate the pump by pressing "START/STOP" button to use the device's basic settings or the previously saved patient settings.
OR
Change the settings for the Mode, Pressure and Interval time as previously described in section 3.2 The Functions.
- 8 Press the "START/STOP" button to stop the controller operating.

Note: PneumaPress® is not recommended for long term use.

5.3 STOPPING THE DEVICE DURING OPERATION

Do not use PneumaPress® if the patient demonstrates any of the following symptoms.

- Oedema of the foot, calf or leg.
- Difficulty breathing.
- Patient complains that the compression is too strong.
- Patient complains of serious pain during use of the device.
- Temporary numbness or irritation caused by the cuff.

5.4 RECOMMENDATION

The PneumaPress® DVT-2600 is a medical device and must only be used as prophylaxis for the prevention of DVT/VTE formation and under the guidance of medical staff and as per the Hospital DVT/VTE policy.

Patients often feel that the compressions become weaker as time goes by but this is due to them becoming accustomed to the compression.



6. Troubleshooting

6.1 TROUBLESHOOTING

No	Problem	Cause	Solution
1	No electric power.	Power connection error.	Check the plug is inserted correctly.
2	Power on but not operating.	Power supply error.	Turn off and on at PneumaPress® power switch. Check cable is plugged in securely.
3	Noisy during operation.	Position of pump.	Check that that the pump is standing/ hanging correctly and not lying flat. Ensure there is nothing covering the device.
4	No air coming out of the hose(s).	Hose connection error or hose is bent or kinked.	Ensure hose(s) are correctly inserted into pump and cuff(s). Ensure all tubing and hoses lie straight.
5	Air is not inflating the cuffs in the correct sequence.	Connection error.	Stop the operation and reconnect the hose(s) to the pump and cuff(s).

6.2 OTHER RELATED PROBLEMS

No	Problem	Cause	Solution
1	Weak air injection.	Air hose damage. Air socket damage. Internal defect.	Ensure hose(s) are correctly inserted.
2	Power on but not operating.	Internal defect.	Return to hospital maintenance or supplier.

The user is responsible for any defect that occurs through careless use, even during the warranty period.

7. Maintenance

DEVICE

- Use PneumaPress® indoors in the temperature range of 0-40°C and under humidity of 90%. (Outside of these parameters there is a fire risk).
- Keep PneumaPress® away from heating equipment or direct sunlight. (Fire risk).
- Do not use PneumaPress® in high humidity places such as bathrooms or saunas etc. (Fire, electric shock risk).
- Do not fold or bend air hose(s).
- Do not tamper or attempt to repair PneumaPress® - contact your representative. (Fire, electric shock risk).
- Keep the device in a clean place and protect from dust.

CUFF

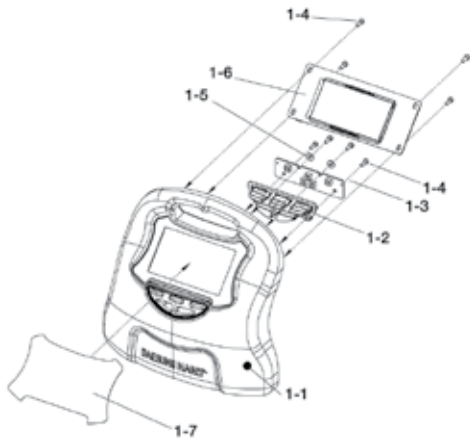
- Disposable cuff(s) are for single patient use only.
- Store cuff(s) and tubing away from water or dust.
- Inflate cuff(s) only when fitted to a limb, as this may cause problems to the sensors or pump.
- Caution should be used when using sharp implements near to cuff(s) and tubing.

BATTERY

- Avoid dropping.
- Prevent from being soaked in liquid.
- Do not touch any fluid 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 regulations.
- The warranty period for the battery is 6 months after the date of purchase.

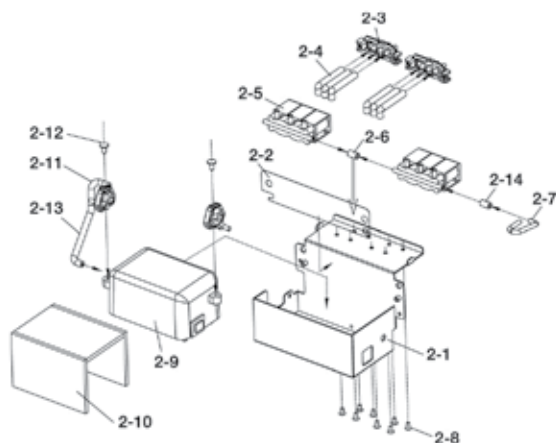
8. Troubleshooting

1) PARTS ASSEMBLY DIAGRAM: SUB-ASM-FRONT



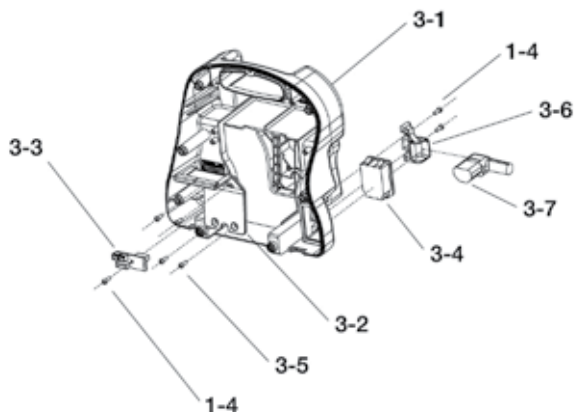
No.	Name
1-1	FRONT_COVER (1EA)
1-2	KNOB_BUTTON (1EA)
1-3	SUB_BOARD_KEY (1EA)
1-4	M3XL6 TT (8EA)
1-5	WASHER (2EA)
1-6	MAIN_BOARD_LCD (1EA)
1-7	WINDOW_SHEET (1EA)

2) PARTS ASSEMBLY DIAGRAM: SUB-ASM-FRAME



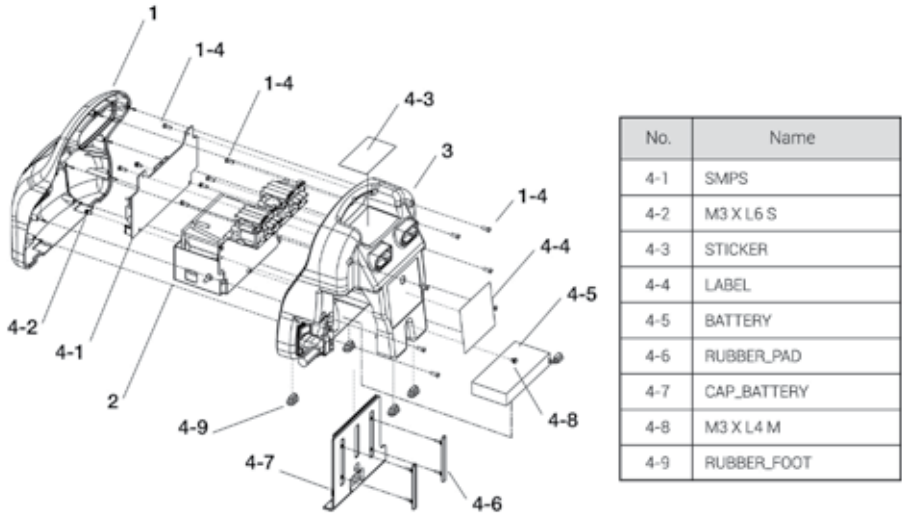
No.	Name
2-1	FRAME_MAIN (1EA)
2-2	SHEET_PLATE (1EA)
2-3	COVER_PLUG (2EA)
2-4	RUBBER_HOSE_ELBOW (6EA)
2-5	SOLENOID (2EA)
2-6	RUBBER_HOSE_CONNECTOR (1EA)
2-7	RUBBER_HOSE_PRESSURE (70mm)
2-8	M3XL5S (8EA)
2-9	PUMP (1EA)
2-10	SPONGE (3EA)
2-11	RUBBER_VIBRATION (2EA)
2-12	M4XL10 TP (2EA)
2-13	RUBBER_HOSE (120mm)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

3) PARTS ASSEMBLY DIAGRAM: SUB-ASM-REAR



No.	Name
3-1	REAR_COVER
3-2	RUBBER_PAD
3-3	SUB_CHARGE_PCB
3-4	INLET
3-5	M3 X L8 TP
3-6	HOLDER_CODE
3-7	AC_CODE

4) PARTS ASSEMBLY DIAGRAM: SUB-DVT-2600



WARRANTY

Thank you for purchasing and using PnuemaPress®. We constantly strive to improve the quality of our products and the support provided to our customers.

Note: In the following cases we are not able to repair our device free of charge, even during the warranty period:

- 1. Damage caused by a strong impact.
- 2. Unauthorised user repair or arbitrary part replacement.
- 3. Use of the device in unauthorised situations.
- 4. Used against manufacturer's manual instructions.

Pump: 1 year.

Cuff: N/A (Disposable item).



Manufactured by:

G+N Medical
Maydwell Avenue
off Stane Street
Slinfold, Horsham
West Sussex
United Kingdom
RH13 0GN

Tel: +44 (0) 845 263 8908
Email: medsales@gandn.com
Website: www.gandn.com

Product Manufactured in Korea
GANDN/PP/0308/1114