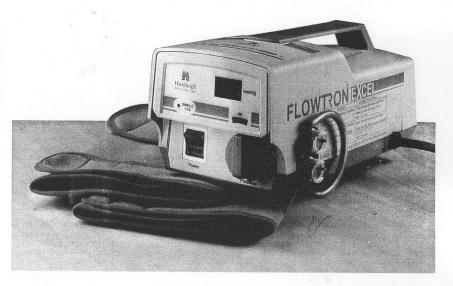
FLOWRONEXCE

External Pneumatic Compression System for DVT Prophylaxis



Operating Instructions • Model AC550

1. Description and Operating Principle

Flowtron® Excel is non-invasive prophylactic system for reducing the incidence of deep vein thrombosis (DVT). The application of external pneumatic compression has two effects:

- Augments venous blood flow velocity, thereby reducing stasis, and
- 2. Enhances fibrinolytic activity to reduce the risk of early clot formation.

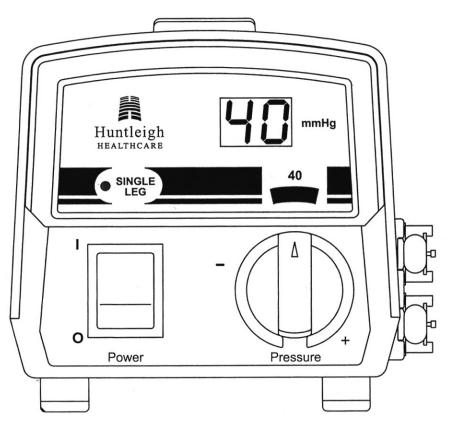
The Flowtron Excel system consists of a pump and a pair of calf or thigh length, single patient use garments. The pump provides intermittent cycles of compressed air which alternately inflate the single-chambered air garments. The compression applied on the extremity augments venous blood flow velocity and stimulates fibrinolysis.

The pump operates on a 60-second automatically timed cycle consisting of approximately 12 seconds of inflation followed by approximately 48 seconds of deflation.

The Flowtron Excel system may be used on patients at risk of developing deep vein thrombosis and in conjunction with systemic interventions (e.g., anticoagulation, Dextran, etc.) for the high risk patient.

Caution

Federal law restricts this device to sale by or on the order of a physician.



Flowtron® Excel Front View

2. Cautions and Contraindications

Cautions

- Proper application and connection to the pump is essential.
- 2. Garments should be removed if the patient experiences tingling, numbness or pain.
- 3. Interruption of external pneumatic compression for a substantial length of time is discouraged.

Contraindications

Flowtron Excel should NOT be used in the following conditions:

- Severe arteriosclerosis or other ischemic vascular diseases.
- 2. Known or suspected acute deep vein thrombosis.
- 3. Severe congestive cardiac failure.
- 4. Any local condition in which garments would interfere, for example:
 - Gangrene
 - Untreated, infected leg wounds
 - Recent skin graft
 - Dermatitis

3. System Set Up

The system is easy to set up:

- 1. Remove the pump and tubing from the carton.
- Plug pump into electric outlet DO NOT switch on at this time.
- 3. Insert tubing assembly into the snap-lock connectors at the side of the pump. Press firmly until a sharp 'click' is heard. Pull lightly to confirm proper connection.

WARNING

DO NOT use pump in the presence of flammable anesthetic gases.

4. Garment Application

- Check that the power switch on the pump is OFF. Remove the garments from the packaging and unfold.
- 2. Place the back of the patient's leg in the center section of the garment with the connector tubing pointing towards the foot.
- 3. Starting with the side that does not have the Velcro® tabs, wrap securely against the leg. While holding the garment snugly against the leg, wrap the taps over the top. Ensure that the garments are fitted snugly and are not 'wrinkled' or 'tucked'. The connector tubing should be pointing towards the patient's heel.
- 4. Snap-lock the garment connector to the tubing assembly. Ensure that a sharp 'click' is heard. Pull lightly to confirm a proper connection.
- To disconnect the garments from the tubing, press the snap-lock connector and pull apart.

IMPORTANT

If garments are not applied snugly, a Lo pump alarm may result. To correct the alarm, simply rewrap the garment snugly.

To Use One Garment

To use only one garment, connect a single tube to either connector. The snap-lock connectors on the pump are self-sealing and, unlike other systems, DO NOT require the unused garment to be attached.

Press the Single Leg button esqual to prevent the alarm system incorrectly indicating a fault. The system responds with a 'beep' and the LED on the button illuminates. If the Single Leg button is pressed by mistake with two garments connected, the system will reset itself to normal after two cycles.

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5. Pump Operation

Pre-Use Check

Before using the Flowtron Excel on the patient, ensure that:

- The pump has been set at 40 mmHg (or the pressure prescribed by the physician).
- Garments have been applied to patient's legs. correctly, snugly and without wrinkles.
- There are no kinks in the tubing.
- The pump is connected to an electrical outlet.
- All tubing connections are secure.

Operation

Turn the power switch ON which will illuminate green. The pump performs a two-second self test cycle where the display, LED's and alarm are tested. The compressor then proceeds directly to the inflation cycle.

The garments will inflate alternately. The first garment inflates for approximately 12 seconds and is deflated for approximately 48 seconds.

The second garment inflates 30 seconds after the inflation of the first garment and follows the same inflation/deflation cycle.

Verify that the display is indicating the desired output pressure. Refer to section 6 - Pressure Adjustment for specific pressure setting instructions.

6. Pressure Adjustment

The pressure control mechanism is located on the front of the pump and ranges from 30-60mmHg. The pressure exerted by the garments on the leg can be adjusted by turning this knob. Turning the knob clockwise increases the pressure; counterclockwise decreases the pressure.

The recommended pressure setting is 40 mmHg or the pressure prescribed by the physician.

The Flowtron Excel pressure monitoring system is independent of the pressure control and delivery system, providing added reliability and safety. The digital display indicates the actual pressure that is delivered to the garments, and furnishes immediate and continuous feedback regarding pump performance.

The pressure display is used for the following functions:

Pressure Output Check

After turning the pump on, check that the pressure display is showing the desired output pressure when the garments are inflated. Visually recheck the display at regular intervals.

Resetting the Output Pressure

Two methods may be used to reset pressure:

- Rotate the pressure control knob during the active inflation period until the required pressure is displayed OR
- Disconnect the garments from the pump and rotate the pressure control knob until the required pressure is displayed. Reconnect the garments.

System Calibration Check

To confirm the calibration accuracy of the pressure controland display, perform the following check each time the pump is turned on.

During normal operation when the display reads 40, the pointer on the pressure control knob should be located somewhere within the 40 mmHg arc on the front panel. If the pointer falls outside of this arc, the pump should not be used and returned for recalibration.

7. Troubleshooting

The Flowtron Excel system features an audible and visual alarm. If a problem occurs, the system will sense the fault and briefly flash a message on the display.

If the same fault continues for successive inflations, the audible alarm will sound and a flashing message will remain on the display until corrective action is completed. The exception to this is an 'F' fault which will alarm immediately.

Display	Problem	Corrective Action
	1. Loose garment fitting.	Rewrap snugly.
Lo	Hose disconnected at garment.	Check the hose connection at garment end.
	3. Garment leak.	Check garment and replace if faulty.
	4. Low Pressure.	4. Refer to service.
	Hose kinked causing a blocked tube.	Check hoses for kinks or obstructions.
HI	2. Hose disconnected at pump.	Check the hose connection at pump outlet.
	Single garment attached without pressing "Single Leg" button.	Press "Single Leg" button if only one garment is used.
		DO NOT USE PUMP.
	Pump failure.	Refer to service.
•		

In the unlikely event of a display electronics failure, the red LED on the top panel will rapidly flash (approximately four times a second). Do not use the pump: refer to service.

Alarm Cancel

After a fault has been corrected, the alarm can be cancelled by two methods:

- Switch the pump off, then on again, using the on/off switch.
- 2. Allow the pump to run until it senses a normal inflation; it will then reset itself.

Corrective Action Check (when using On/Off Reset)

To confirm that the fault has corrected, watch the display for about one minute. If everything is normal, there will be no HI or LO message flashing during that time.

Fuse Replacement

If the system fails to operate when plugged in and switched on, the fuse on the underside of the pump should be checked. To do this, disconnect the pump from the main power supply and remove fuse holder cap using a suitable screwdriver.

Important

To protect against fire hazard, replace blown fuse with identical type and rating - 0.5 Amp quick blow. If the fuse blows again, refer the pump for service.

8. Warranty and Service

Warranty

All Huntleigh Healthcare products shall conform to applicable specifications in effect from the invoice date to the end of the Warranty Period, and Huntleigh Healthcare reserves the right to change such specifications at any time with or without notice. The Warranty Period for Huntleigh Healthcare Products shall be as follows calculated from the date of invoice:

- a. Intermittent Compression Pumps: one year parts and labor.
- Single patient use garments have no warranty period, but Huntleigh Healthcare warrants that the Products meet the then current specifications as the date of receipt.

Huntleigh Healthcare's sole liability to the Customer for nonconformity of any Products to the specifications therefore, for any claim arising out of or in any way connected with the manufacture, sale, handling, or use of the Products, or for any other reasons, shall be, at Huntleigh Healthcare's sole option, limited to (i) the refund of the full purchase price for such Products, plus the invoice shipping charges, or (ii) replacement thereof, free of change to Customer, with Products conforming to the then current specifications, thereof. The parties agree that these remedies shall be exclusive. Huntleigh Healthcare, AND ITS AFFILIATES, SHALL HAVE NO LIABILITY FOR INCIDENTAL OR CONSEQUENTIAL DAMAGES OF ANY KIND OR, EXCEPT AS PROVIDED ABOVE, FOR ANY CAUSE ARISING OUT OF OR IN ANY WAY CONNECTED WITH THE MANUFACTURE, SALE, HANDLING OR USE OF SUCH PRODUCTS. EXCEPT AS SPECIFICALLY SET FORTH IN THIS PARAGRAPH, THERE ARE NO EXPRESS OR IMPLIED WARRANTIES, INCLUDING THE WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, AND THE FOREGOING PRÓVISIONS OF THIS PARAGRAPH ARE IN LIEU OF ALL OTHER WARRANTIES, EXPRESS OR IMPLIED.

Customer is solely responsible for the proper use of the Products. Huntleigh Healthcare Products should not be used in conjunction with those of any other manufacturers.

Service

The **Flowtron Excel** pump should be routinely inspected (not less than once a year) by a qualified biomedical service technician to assure proper operation of the pump and garment system. Inspection should verify that pressure output and timing cycle are within listed specifications and that the audible and visual alarms function. The **Flowtron Excel** pump should receive annual preventive maintenance.

All required servicing should be performed by Huntleigh Healthcare service personnel:

Service Department Huntleigh Healthcare Inc. 227 Route 33 East Manalapan, NJ 07726

Telephone: 1-800-223-1218

Fax: 1-732-446-1938

9. Cleaning Instructions

The outside pump casing is made from ABS plastic and should be cleaned using a soft damp cloth and a mild detergent. Hypocarbonate and Phenolic based cleaning solutions should NEVER be used as they cause this plastic to deteriorate.

The pump may be disinfected by wiping down with an EPA-approved, hospital grade disinfectant as per an appropriate protocol determined by the customer to be valid.

DO NOT SPRAY any disinfectant or detergent directly onto the pump.



The pump cannot be sterilized.

The garments are single patient use. Sterile garments are available from Huntleigh Healthcare.

Cleaning and reuse of garments is not recommended.

10. Ordering Information

Code	Description	Per Case
AC550	Flowtron Excel Pump with Tubing Assembly.	1 each
DVT10	Standard Calf Garment (up to 17" calf circumference).	10 pair
DVT10(S)	Sterile Standard Calf Garment.	10 pair
DVT20	Large Calf Garment (up to 23" calf circumference).	5 each
DVT30	Standard Thigh Garment (up to 28" thigh circumference).	10 pair
DVT30(S)	Sterile Standard Thigh Garment	10 pair
DVT40	Large Thigh Garment (up to 35" thigh circumference).	5 each
L550	Connector Tubing (60" length)	5 pair
L552	Connector Tubing (120" length)	5 pair

To order, contact:

Huntleigh Healthcare Inc. 227 Route 33 East Manalapan, NJ 07726

Telephone: 1-800-223-1218.

11. Technical Data

Size:

 $5\frac{1}{4} \times 6 \times 10^{3}$ 4 inches

Weight:

6 lbs

Pressure range:

 $30-60 \text{ mmHg} \pm 5 \text{ mmHg}$

Cycle time:

Inflation 12 seconds (approx.)

Deflation 48 seconds (approx.)

Indicators:

2-digit 7-segment red LED that indicates:

- garment pressure in 5 mmHg steps

fault conditions (Hl. LO. F)
Single garment amber LED.

Power on:

green illuminated switch and

green LED on top panel.

Fault:

red LED on top panel.

Rated voltage:

 $120V\,\pm\,10\%$

Rated frequency:

60Hz

Rated input power:

20 Watts

Fuses: Tested to: F500mA

UL544 - double insulation, external metal

grounded.

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HNE Healthcare Inc 227 Route 33 East, Manalapan, New Jersey 07726 Telephone: 800-223-1218/908-446-2500





External Pneumatic Compression System for DVT Prophylaxis

HNE HEALTHCARE FLOWTRON MODEL AC500/DVT

OPERATING INSTRUCTIONS

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