

User Manual





CONTENTS

- **Device Description** 2
- 4 **General Warnings and Precautions**
- Operating instructions 5
- **Aviafit Specifications** 10
- 10 **Troubleshooting**

Copyright ©2007 by FlowMedic Ltd (FlowMedic)
The FlowMedic Aviafit™ should only be used in the manner prescribed in this user manual. Changes or modifications to the Aviafit not expressly approved by FlowMedic or use of the Aviafit in any other manner than indicated in this manual could void authority to operate the FlowMedic Aviafit.

Neither FlowMedic nor any of its shareholders, directors, employees or affiliates, shall be held responsible in any manner for any bodily injury and/or property damage arising from operation or use of the Aviafit other than that which adheres to the instructions and safety precautions contained herein and in all supplements hereto and according to the terms of the limited warranty.

FlowMedic and Aviafit are trademarks owned by FlowMedic Limited and are pending registration in several jurisdictions. Several patent applications have been filed covering the technology embedded in the FlowMedic Aviafit. All Rights Reserved

DEVICE DESCRIPTION

Purpose of the Device (Indications for Use)

- Improves blood circulation in the lower limbs.
- Helps prevent Deep Vein Thrombosis (DVT).
- Helps prevent swollen ankles and leg discomfort.
- Aviafit[™] may be used during long periods of immobility such as continuous sitting at home, at the office and/or during longhaul flights.

Device Overview

Aviafit[™] is a battery operated portable device which is placed around the calf and held in place by a strap.







The product package contains two Aviafit devices (one for each leg), two straps, a handy storage bag, User Manual, Quick Start and four AA batteries (optional).

The Aviafit strap is available in two sizes. For the most effective results, ensure that you choose the correct size.

When the device should not be used (contraindications) You should not use the Aviafit under the following conditions:

- Any kind of skin injury in the application area of the Aviafit™.
- A blood clot (thrombolitic) event in the last 6 months, with or without complications (such as pulmonary embolism, DVT ect').
- If your calf is insensitive to pain.
- You are under 18 years of age.

Risks and Benefits

DVT (Deep Vein Thrombosis) is the medical term for the formation of a blood clot ("thrombus") in a deep vein. These blood clots mostly occur in the lower limbs. There may be no symptoms referable to the location of the DVT, but the classical symptoms of DVT include pain, redness, tenderness, or sudden swelling in the leg. DVT in some cases, when left untreated, may cause irreversible damage to your veins. The blood clot may travel through your blood stream and cause pulmonary embolism, a high risk medical condition which requires urgent treatment and in some cases may be fatal.

All individuals experiencing several hours of immobility increase their chances of developing DVT. Additional known risk factors for DVT that increase the probability even further include: age over 60, overweight, smoking, birth control pills or hormone therapy and pregnancy.

Walking or other physical activity provides the best protection for DVT. However in some situations it is hard to achieve the level of exercise needed to effectively reduce the risk. The **Aviafit**TM effectively stimulates blood circulation in the legs and reduces the risk for DVT while at the same time it provides you with a pleasant massage like feeling.

Possible risks associated with the use of the **Aviafit™** include ineffective therapy due to incorrect assembly, application or operation of the device or inappropriate use by contraindicated individuals.It is recommended that you read the entire User Manual prior to using the device.

GENERAL WARNINGS AND PRECAUTIONS

WARNINGS



- Do not open the Aviafit[™] housing in order to eliminate the risk of injury.
- Keep the Aviafit™ away from liquids or food. The Aviafit™ is not waterproof.

PRECAUTIONS



- Read the User Manual prior to using the device in order to ensure safe and effective operation of the Aviafit™
- Do not attempt to use the Aviafit™ on any other location of the body other than the calf as this will result in ineffective therapy.
- Do not over-tighten or loosen the **Aviafit™** as this may result in ineffective therapy or may cause discomfort.
- The Aviafit™ is intended for use with healthy legs. If you suffer from one of the following we recommend that you consult your physician before using the device:
 - o Undesirable increased venous return (such as, congestive heart disease, pulmonary hypertension)
 - o Muscle disease or compartment syndrome
 - o Recent calf operation (such as, bypass, skin graft etc')
 - o Calf inflammation or infection (such as, thrombophlebitis, cellulitis, osteomyelityis, ulcers etc')
- The **Aviafit™** should be kept for your personal use in order to maintain personal hygiene.
- Do not use rechargeable batteries to ensure effective operation of the Aviafit™.
- Do not use a damaged Aviafit™ or attempt to fix the device yourself as this may result in ineffective operation of the device.
- Contact your local distributor if the Aviafit™ does not operate properly, or if it fails to respond in the manner described in the User's Manual.

How the Aviafit™ Device Works

This section describes what to expect when using the Aviafit™

Once attached to the calves of your legs and turned on, the Aviafit periodically pulls in the straps causing a tightening action of the calf muscles, approximately every minute and lasts for about five seconds. This is similar to the action that occurs when walking. In this manner, the Aviafit assists in keeping the blood flowing properly in your legs while sitting or not moving.

The first tightening may occur after a short delay and may take a few cycles to get used to. In between each action of the Aviafit you will not feel any tightening. You may only hear a guite humming of the motor. While operating normally, the green led

is constantly **ON**.

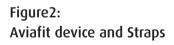


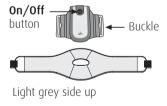
Figure 1: Aviafit Device

Attaching the Aviafit™ to your Legs (Calf Muscle)

The following steps demonstrate how the Aviafit™ is applied around your calf: over your trousers, nylons or directly against your skin:

1. Remove the Aviafit™ devices and straps from the package.





2. Place the strap on a flat surface (with light grey side facing up) as shown in **Figure 2** above.

Figure3: Insert and Fasten One End of Strap

3. Make sure the On/Off button is facing you. Insert one end of the strap through one buckle of the Aviafit™ device and secure it using the fastener as shown in **Figure 3** above.

Figure4: Place Device on Shin and Wrap Strap around Calf

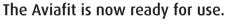


4. Place the Aviafit™ device in the upright position with the **ON/OFF** button facing upward on your calf as shown in **Figure 4** above.

5. Wrap the strap around the thickest part of your calf as shownin

Figure5: Insert and Fasten the Other End of the Strap

- 6. Insert the other end of the strap through the second buckle on the AviafitTM as shown in **Figure 5**.
- 7. Pull the strap until the Aviafit fits comfortably on the leg and then secure using the fastener as shown in **Figure 5**.



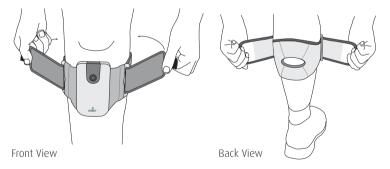


Figure 6: Tightening the Strap (Front and Back view)

PRECAUTION



Do not over-tighten or loosen the Aviafit™ as this may result in ineffective therapy or may cause discomfort.

8. If the straps seem loose, or the Aviafit™ starts sliding down your leg, release one or both of the straps and pull until it fits comfortably on your leg as shown in **Figure 6** above.

Turning-on the Aviafit™

The green LED (Figure 1) turns ON.

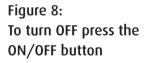
1. Using **Figure 7** below as a guide, press the **ON/OFF** button located on the front of the device.



- **ON/OFF Button**
- 2. Wait for the device to tighten around the calf muscle. This may take up to 60 seconds. Tightening will last for approximately 4-10 seconds. The sensation caused by the tightening of the device may take a few cycles to get used to.
- 3. The Aviafit™ device will repeat the tightening action approximately every 60 seconds until the device is switched **OFF**.

Removing the Aviafit™ from your Leg

1. While the device is on and using **Figure 7** as a guide, press the **ON/OFF** button to turn-off the device power.





While powering-off, the green LED continues to blink for up to 60 seconds. During this time another tightening action may occur.

When the Aviafit is in the process of powering-off you may remove it from your leg.

- 2. Release the fastener of one end of the strap.
- 3. Pull the strap out of the device buckle and remove the units
- 4. Store the devices in their storage bag.

Replacing the Batteries

When the Orange LED turns on (see **Figure 1** on page 8) you must replace the 2 x 1.5V AA batteries. If NO action is taken the device turns **OFF** automatically after approximately 10 minutes from when the Orange LED turns on. The battery compartment is located on the back of the unit as shown in **Figure 9**.

Figure 9: Replacing the Batteries

- 1. Make sure the device is turned **OFF**.
- 2. Slide the battery compartment cover off the device.
- 3. Insert two fresh 1.5V AA Alkaline batteries as described in the battery compartment.
- 4. Reinstall the battery compartment cover to its original position.



PRECAUTION Do not use rechargeable batteries to ensure effective operation of the Aviafit™.

General Battery Information

- A set of fresh batteries should provide you with up to 20 hours of continuous operation.
- When the Orange LED is lit, replace the batteries.
- It is recommended to remove the batteries from the device if not used for an extended period of time.
- In most countries, used batteries may not be discarded with household refuse.
- Please dispose batteries in compliance with local environmental laws and regulations.

Preventative Maintenance

The Aviafit™ is designed to be trouble and maintenance-free

- Keep the Aviafit™ clean and dry at all times.
- Replace the batteries when necessary.

Cleaning the Aviafit™

- Gently wipe the exterior of the Aviafit using a soft, slightly damp cloth avoiding excessive liquid
- The Aviafit strap may be hand-laundered with a gentle detergent and line-dried.



WARNING Keep the AviafitTM away from liquids or food. The AviafitTM is not waterproof.

SYMBOL INFORMATION

Laundering Symbols









Do NOT Wring

Warnings and Precautions Used in this Document

The information found in this section is part of the BF requirements.



WARNING

Warning means that the situation described can cause personal injury or death to you or someone else if the safety information is not obeyed.



PRECAUTION

Caution means that the situation described may cause personal injury to you or someone else or damage to the equipment if this information is not obeyed.

Other Symbols

Symbol	Description
i	Consult accompanying documents
†	Type BF applied part
Ţ	Fragile, handle with care
*	Keep dry
\sim	Manufacturer

AVIAFIT SPECIFICATIONS

Item	Specification
Weight including strap	270 gr.
& batteries	
Batteries (per unit)	2 x 1.5V AA Alkaline batteries
Operation	On/Off button
LED Indicators:	Green - Normal operation /
	Orange - Attention required
Operating temperature range:	10C (50F) to 40C (104F)
Operating humidity range:	5% to 95% R.H.
Storage temperature range:	-20C (-4F) to 45C (113F)
Storage humidity range:	10% to 95% R.H.
Latex Free Material	The FlowMedic Aviafit is made
	of latex free material.

Available Aviafit Strap Sizes

Size	Calf Circumference
Small	11.6-14.8 inches
Large	14.8-19.7 inches

TROUBLESHOOTING

Problem: Aviafit does not start to work

Solution: Check battery polarity and if this does not help install new batteries. If the problem persists, contact your local distributor.

Problem: Aviafit does not turn OFF and the Green LED blinks **Solution:** Allow approximately 2 minutes for the device to turn off. If the device does not turn off after 2 minutes, remove the batteries and contact your local distributor.

Problem: Orange LED Lit

Solution: Replace the batteries and turn on the device. If this problem persists, contact your local distributor.

Problem: When operating none of the LEDs are Lit

Solution: Contact your local distributor.

Problem: Aviafit strap opens during operation

Solution: Clean the strap surface of any debris, hair or foreign objects. Contact your local distributor if the problem persists.

Problem: Aviafit Stops in the "tight" position

Solution: Release one of the strap attachments to remove the device and contact your local distributor.

Limited Warranty

- (a) FlowMedic warrants that the Product, with which this manual was delivered, will be free from defects in design, materials, and workmanship for a period of 1 year from the date of purchase of the Product. If the Product contains a defect in design, materials or workmanship and such Product is returned to FlowMedic within 1 year of delivery of the Product, FlowMedic will repair or replace the Product, or issue a credit for the purchase price of the Product, with the choice to repair, replace or credit being within the sole discretion of FlowMedic. The foregoing repair, replacement or credit remedy will be the sole remedy for breach of the warranty set forth in this Section.
- (b) <u>Limitation of Warranties</u>. The warranties contained in Section (a) above do not cover damage to the Products caused by accident, misuse, abuse, negligence, failure to install in accordance with FlowMedic's installation instructions, failure to operate under conditions of normal use and in accordance with the terms of the documentation accompanying the Product, failure to maintain in accordance with applicable documentation accompanying the Product, alteration or any defects not related to materials or workmanship, or in the case of Products, design, materials or workmanship. This warranty does not cover damage which may occur in shipment. This warranty does not apply to Products that were not purchased new. Any repair or service of the Product by anyone other than FlowMedic or a person or entity authorized by FlowMedic to repair Products will invalidate the warranty and may cause the Product to malfunction.

FlowMedic hereby disclaims, with respect to the Products, all other warranties and conditions, whether express or implied, including, but not limited to, any warranties or conditions of or related to merchantability, fitness for a particular purpose, accuracy or completeness of information, lack of negligence and negligence and correspondence to description.

Limitation of Liability

- (a) To the maximum extent permitted by applicable law, except for damages arising under section (a) of the Limited Warranty above, in no event shall FlowMedic be liable to you for damages in excess of the purchase price paid for the Product. The foregoing limitation shall be applicable regardless of whether the action giving rise to such damages is in tort, contract, strict products liability, or otherwise.
- (b) In no event shall FlowMedic be liable for any special, incidental, indirect or consequential damages whatsoever arising out of or in any way related to the use of or inability to use the Product, or the provision of or failure to provide support services by FlowMedic, even if FlowMedic has been advised of the possibility of such consequential damages shall be applicable regardless of whether the action giving rise to such damage is in tort, contract, strict products liability, or otherwise.

The information in this document is subject to change without notice.

This document contains proprietary information, which is protected by copyright. No part of this document may be photocopied, reproduced, or translated without the prior written consent of FlowMedic.

How to Contact Us FlowMedic (USA) Inc.

89 Headquarters Plaza North 4 Speedwell Avenue, Suite 1417 Morristown, NJ 07960

Tel: 1-888-356-9639, 1-888-FLOWMDX

Fax: 1-973-993-4381 info@flowmedic.com