FLOWOX

FLOWOX BY OTIVIO

Information for patients





Information on the usage of the FlowOx[™] system.

FlowOx™ is used for the treatment of Peripheral Arterial Disease (PAD), e.g. Intermittent Claudication and Critical Limb Ischemia, as well as, diabetic and pressure wounds.



FlowOx $^{\text{\tiny{TM}}}$ is a medical device that operates using cyclical negative pressure (-40 mmHg).

What is PAD, Intermittent Claudication and Critical Limb Ischaemia?

You can develop a condition called PAD when the arteries in your legs become blocked and your legs don't receive enough blood or oxygen. An early stage of PAD is called Intermittent Claudication (IC). IC is characterized by discomfort or pain when you walk, and it stops when you rest.

Critical Limb Ischemia is an advanced PAD stage characterized by chronic pain and/or chronic wounds. The cause of these symptoms is an undersupply of oxygen to your legs, even at rest. This can cause you to feel pain in your toes and feet even when you are not walking.

How does the FlowOx[™] system work?

FlowOx™ generates pulsating negative pressure inside the boot which draws blood down into the leg, improving skin blood flow and oxygenation. This is due to a combination of dilatation of the arterioles and increased arteriovenous pressure gradient.

What are the benefits of using FlowOx $^{\text{\tiny TM}}$?

- Non-invasive, safe and easy to use
- Suitable for home use
- Can be used in addition to surgical intervention or where surgery is contraindicated
- May be used on limbs with existing wounds if they are bandaged

When should FlowOx[™] not be used?

In case of skin infections in the area of application

If during the treatment there are any changes to your medical condition, contact your doctor or responsible wound therapist.

How do I use FlowOx™?

Sit comfortably, place the leg on the positioner and keep the leg in the center of the pressure chamber during the initiation of the treatment. Once the padding is inflated, you can stretch your leg out if desirable.

Information on the individual parts, assembly, application and error messages of the device can be found in the FlowOx $^{\text{\tiny{M}}}$ operating manual included in the packaged product.

How often should I use FlowOx™?

Your Surgeon, Vascular Nurse or Clinical Specialist will advise you about usage, which is usually two hours per day. This can be split over multiple treatment sessions.

How do I deflate the pressure chamber when I've finished?

Make sure you can reach the blue button on the side of the pressure chamber once it is on your foot.

This blue button will open the one-way valve which will allow you to deflate the padding using your hand, pushing it towards the wall of the pressure chamber.

How do I clean the FlowOx[™] device?

The control unit can be dusted with a damp cloth. Don't use any corrosive cleaners, just water. The pressure chamber can be wiped with antibacterial cleaning wipes. Allow the pressure chamber to dry thoroughly before use.



Troubleshooting

What do I do if the pressure chamber becomes misted or clouded?

You have been provided sachets (small bags) to help with moisture control. If your pressure chamber becomes misted or clouded, simply place sachets inside the pressure chamber during use.

Troubleshooting - Continuation

What does an E2 error message mean?

An E2 message is for a major air leakage. Here's what to do:

- 1. Turn off the device and remove the foot.
- 2. Reposition the foot back into the device. Ensure the padding is intact and in the correct position.
- 3. Place seal around leg, checking the seal for integrity. If there's visible damage, replace with a new seal.
- 4. Check blue strap around the seal is firmly in place.
- 5. Turn device on and it will run through a self-test mode.





The E2 error isn't going away...

- 1. Remove the foot. Check integrity of padding and seal.
- Check padding and air vents are still engaged with air holes in the pressure chamber.
- 3. Place foot in the pressure chamber again and switch on once padding and seals are in normal place for operation.

Still getting an error message? Please contact your clinical specialist or Otivio.



Who should I contact if I have any concerns?

If during the treatment your medical condition worsens, contact your clinical specialist or responsible wound therapist.

For technical issues, contact your local customer service team. \\

Otivio GmbH, Fürstenrieder Straße 279a, 81377 München, Germany

E-Mail: hallo@otivio.com Tel: +49 151 28 27 35 36

www.flowox.com



