

live your life.



Patient Information for Use document:
DMO® Essentials Vest



www.dmorthotics.com

Our products

DM Orthotics is a world-leader in the design and manufacture of its patented Dynamic Movement Orthoses® (DMO®).

The DMO® use biomechanical panelling and strategic reinforcements to improve postural alignment and increase proprioception. These factors then stimulate and adjust the neurosensory system training muscles to work with improved tone, strength, and performance.

The DMO® Essentials vest is a pre-sized fabric orthoses and a good cost effective option if you want to test whether a custom orthosis will be of benefit to a patient. They work effectively as an entry level single measurement product.

Created to provide improved comfort, posture, and range of movement to the user. Designed to be worn next to the skin, the enhanced proprioceptive feedback and biomechanical positioning of these designs help train muscles to work; leading to improved tone, strength, and performance.

All these benefits work towards a single goal – to improve function and encourage independence for the user.

DMO® Essentials are a pre-sized product that is made to set sizes for both children and adults and are a combination of our compression/sensory fabric and combined with a number of reinforcement panels that are strategically placed to benefit the patient. They are not alterable and further reinforcements are not permitted. They can be recommended by a clinician where a standard off the shelf product may be of benefit, or can be ordered direct from our website with only one measurement being required.

Get in Touch

To find out more about our DMO® Product ranges, contact your local DMO® provider or distributor or DM Orthotics directly to find out who that is. Email: admin@dmorthotics.com visit: www.dmorthotics.com call: +44 (0) 1209 219205

How we intend our products to be used by patients

DMO Orthotic Essential products are intended to help support and correct posture and joint alignment where further individual adjustment or additional reinforcements are not required.

All DM Orthotics custom made orthoses are medical devices as defined by the EU MDR (2017/745) and are declared to conform to the regulations according to Annex II and III EU MDR, are covered under the definition of an orthotic device: a brace, splint, or other artificial external device serving to support the limbs or spine or to prevent or assist relative movement.

The devices are custom made (according to Annex XIII MDR) and comply with the applicable requirements of the MDR (Medical Devices Regulation) (2017/745) : Custom Made Product

Date of Issue

Our medical devices are manufactured and issued with a date of manufacture on the accompanying declaration form that is sent with your product. This is for the end user to keep for their records.

Contents

● Wear instructions	P3
● Washing instructions	P4
● Contraindications and precautions	P5

Essentials Vest

● Intended purpose	P6
● Intended patient population	P7
● Intended users	P7
● Effective for patients	P8
● Use with other orthotics	P7
● How to put on and take off	P9
● Disposal of Device Statement	P14
● Serious Incident Statement	P14
● Explanation of symbols used	P15

Wear instructions

Follow the care instructions carefully. By taking care of your orthosis you will **prolong its wear and prevent damage.**

DO

- Put the orthosis on and off as advised by your therapist/ supplier. See website: www.dmorthotics.com/productcare
- Take care when putting it on and taking it off, follow the instructions in this booklet carefully– pulling it on and off roughly and long finger nails can cause damage.
- It is important to build up wear time as per your individual instructions.
- Follow the washing instructions carefully or it can become damaged.

DO NOT

- Do not put on or take off your product roughly - this can cause damage to the product with ladders or tears or holes in the fabric.
- Do not put on or take off with long finger nails, this can also damage the fabric.

FIT OR SAFETY CONCERNS

Contact your therapist / supplier **IMMEDIATELY** if it is getting really tight, causing red marks or has developed ladders and /or holes.

DMO® products are designed to complement therapy and physical exercise, so should not be removed for exercising unless advised by your therapist, or you have any other concerns that they can help you with.

Wearing time

DO

- Build up wearing time slowly over the first week, as stated below, doubling the amount of time daily until the orthosis is worn throughout the working day.

e.g. 1st day - 1 hour

2nd day - 2 hours

3rd day - 4 hours

4th day - 8 hours

5th day - all day, during the day. Thereafter, wear all day and every day during the day.

DO NOT

- Wear all day immediately. Wear needs to be built up to ensure sensory input, biomechanical changes and fit are monitored.
- Do not wear your DMO at night time unless recommended by your doctor or clinician e.g. in the case of EDS patients, where this can be beneficial.

Washing instructions

Follow the care instructions carefully. By taking care of your orthosis you will **prolong its wear and prevent damage**.

DO

- The orthosis should be washed at least every 2-3 days.
- The orthosis can be hand washed cool or machine washed at 30°C degrees.
- Wash separately
- Short spin only or roll up in a dry towel to remove excess moisture.
- Allow to completely dry overnight by hanging up indoors.

DO NOT

- DO NOT dry in strong direct sunlight or on a radiator.
- DO NOT WRING OUT– it will stretch out of shape and will cause damage to the materials.
- DO NOT IRON.
- DO NOT USE BLEACH, OR WHITENING AGENTS
- DO NOT USE FABRIC CONDITIONER
- DO NOT DRY CLEAN.
- DO NOT TUMBLE DRY– it will shrink.

For further help and support, we have added how to put on and take off your orthosis to our website please visit: www.dmorthotics.com/productcare.

Regular and correct care of the orthosis will prevent it from developing odour and keep the material supple. If your orthosis is silver treated, this will need to be re-applied after 100 washes as the silver ions start to disperse after 50 washes.

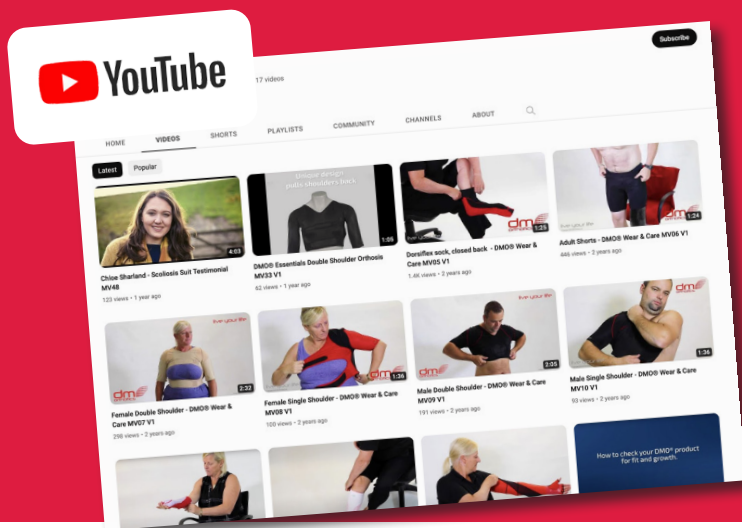


Wearing our products

We have created a range of video guides to help our customers to get the best out of their product. These guides include helpful tips and tricks to wearing our products and how you can best care for them when putting on or taking off.

To view them visit: www.dmorthotics.com/productcare

DMO® products should be worn next to the skin. It is important to build up wear time slowly over the first week, doubling the amount of time daily until worn throughout the day. e.g.



CONTRAINDICATIONS AND PRECAUTIONS/CONSIDERATIONS

Contraindications

There are no known contraindications for using a DMO®. The assessment for a DMO® product should be undertaken by an authorised medical professional with the correct professional qualifications.

Precautions/Considerations

The following is a list of possible precautions to consider before going ahead with the prescription of a DMO® product. This should be discussed with your professionally qualified medical professional.

Poor temperature regulatory control

A DMO will have no affect on the temperature regulatory centre of the body. However, DMO should be treated as a layer of clothing and clothing layers will need to be adjusted for hot or cold climates accordingly.

Primary circulation disorders

Certain primary respiratory problems where muscles are growing weaker due to deterioration of the nerves/muscles, will need careful consideration and may require discussion with the patients medical practitioner - Secondary circulation problems associated with Cerebral Palsy can be improved due to improved posture of the trunk/body and improved position of the ribs.

Skin conditions

Skin conditions that might be exacerbated by close contact with synthetic materials for prolonged periods may require further consultation with a healthcare professional who is overseeing the patient's dermatological treatment but this is rarely a contraindication.

Skeletal fragility/brittle bones

Some conditions can be well supported by a DMO® product but this should be discussed with your medical practitioner.

DMO® Essentials Vest

Intended Purpose

The intended purpose of the DM Orthotics Essential Vests is to provide trunk, shoulder and upper limb stabilisation and realignment. They also provide sensory and proprioceptive feedback.

Indications

Children or adults who present with low or high muscle tone which require stabilisation of the effected joints and also realignment of the joints/trunk. This realignment can help with function and prevent contractures. The vests can help reduce pain and help manage fatigue.

Intended Patient Population

Male and female adults or children who present with low or high muscle tone who require assistance with posture and alignment of their trunk, shoulder and upper limbs.

A carer may be required to assist with donning and doffing the vest, depending on the functional capabilities of the wearer.

Intended Users

The Essentials vests can be prescribed by a competent healthcare professional, or chosen by the wearer, carer or parent.

The wearer of the vest will typically be a lay person.

The wearer's carer who may be involved in the donning and doffing of the product, the washing of the product and the reporting of any issues with the product will typically be a lay person.

The DMO® Essentials Vest offers benefits similar to the DMO® Custom made-to-measure vest but in a variety of pre-determined sizes. The DMO® Essentials Vest is designed to influence posture of the shoulders, trunk and arms.

Effective for:

- Cerebral Palsy
- Stroke
- Multiple Sclerosis
- Cerebellar Ataxia
- Ehlers-Danlos Syndromes

Provides:

- Shoulder retraction
- Improved shoulder complex position
- Improved posture
- Improved distal function
- Trunk support
- Reinforcement panelling



DMO® Essentials Vest

UDI-DI & Basic UDI-DI

PRODUCT IDENTIFICATION			
Product Name	Catalog Number	UDI-DI	Basic UDI-DI
Essentials Vest			
Adult Vest – XS	VA1	5054522001538	5054522SPINALV9
Adult Vest – S	VA2	5054522001545	5054522SPINALV9
Adult Vest – M	VA3	5054522001552	5054522SPINALV9
Adult Vest – L	VA4	5054522001569	5054522SPINALV9
Adult Vest – XL	VA5	5054522001576	5054522SPINALV9
Adult Vest – XXL	VA6	5054522001583	5054522SPINALV9
Child Vest – 1	VC1	5054522001590	5054522SPINALV9
Child Vest – 2	VC2	5054522001606	5054522SPINALV9
Child Vest – 3	VC3	5054522001613	5054522SPINALV9
Child Vest – 4	VC4	5054522001620	5054522SPINALV9
Child Vest – 5	VC5	5054522001637	5054522SPINALV9
Child Vest – 6	VC6	5054522001644	5054522SPINALV9
Child Vest – 7	VC7	5054522001651	5054522SPINALV9
Child Vest – 8	VC8	5054522001668	5054522SPINALV9
Child Leggings – 8	SLC8	5054522001811	5054522LOWERLIMBMF

live your life.

Precautions:

- Ensure the zip liners are in place over the skin prior to pulling up zips and not rolled back.
- The vest should be removed if the patient is sick or has a temperature.
- If there are any concerns with fit i.e. extremities turning blue or feeling overly cold to the touch, then please remove and inform your clinical team (if you have one involved with your care and has recommended this product) immediately for further assessment.

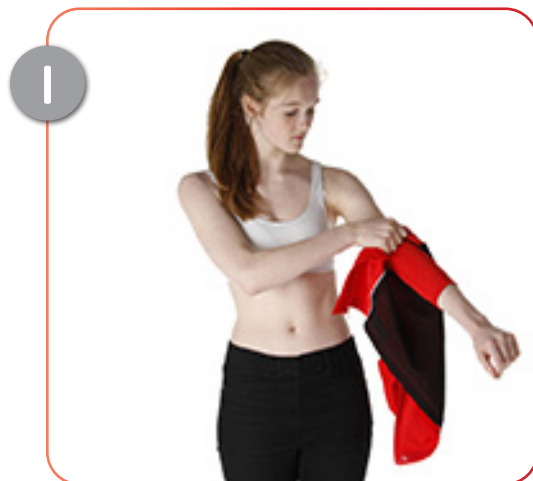
To check the fit:

- The vest should be a tight fit, but you should be able to fit your index finger under the bottom of the sleeves & around the neck line.
- When removed, the stitching/ ends of the orthosis may leave red marks in the skin. If overly red after 20-30 mins of removal, then it may be too tight.
- If in any doubt, as to its appropriate fit, then please notify your therapist immediately, or return to DM Orthotics if purchased from the website.

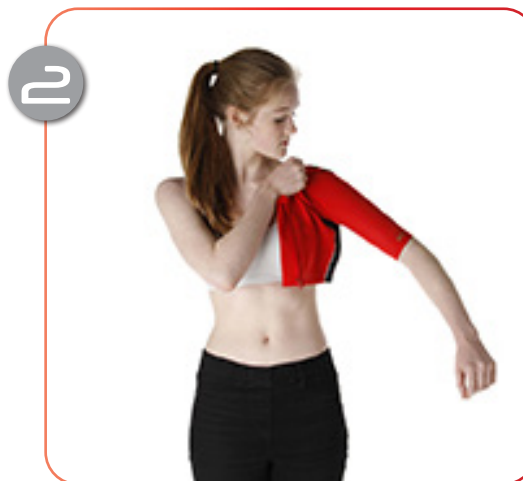
DMO® Essentials Vest application instructions

How to apply the DMO® Essentials Vest.

The DMO Essentials vest is put on and taken off the same way as the DMO Custom vest, which has been used for illustrative purposes.



It may be better for you to place your affected arm in the orthosis first.



Pull well up to the shoulder.



Take orthosis behind back and feed other arm into the other sleeve behind your back.



Pull front panel round.

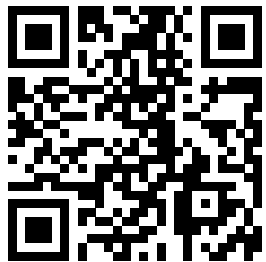


Fasten front zip taking care to protect the skin from entrapment.

Please note. Your orthosis may be longer than the one shown here. Ensure when you have fastened the zip that you gently pull your orthosis down to ensure it is covering your body well.

live your life.

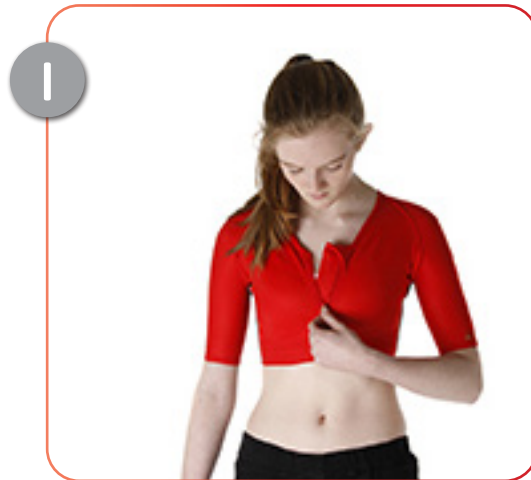
How the Essentials Vest should look when on:



Use the QR code above to access our wear and care videos or go to:

www.dmorthotics.com/productcare

How to remove the DMO® Essentials Vest orthosis.



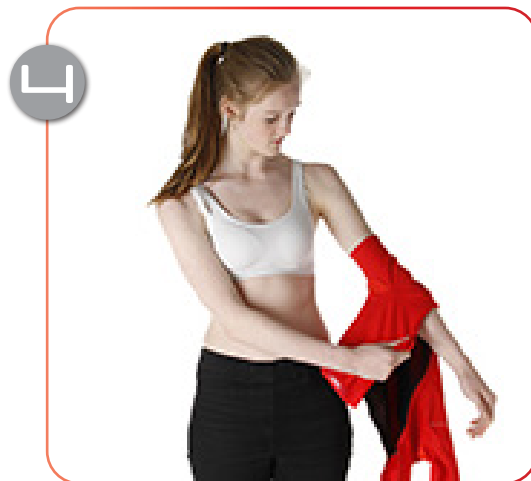
Undo the front zip taking care to protect the skin from entrapment.



Open vest at front.



Remove one arm from orthosis.



Remove the other arm and slide orthosis off over the hand.

Disposal of Device Statement

The devices manufactured by DM Orthotics are class 1 / custom made orthotic devices. There are no precautions required to be taken to dispose of DMO® devices. The materials used for manufacture can be disposed of in line with your local arrangements for clothing / materials disposal. We do ask that you please wash the device before disposal.

Serious Incident Statement

If any serious incident occurs in relation to your DMO® device, you should report it immediately to the manufacturer (DM Orthotics) and the competent authority responsible for medical devices in your Member State for example in the UK this would be the Medicines and Healthcare products Regulatory Agency MHRA.

Manufacturer



Patient identification



Product/model ID



Manufactured in Britain



Distributor



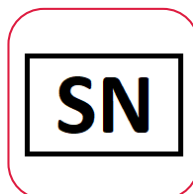
MedEnvoy Global BV
Pr. Margrietplantsoen 33
Suite 123
2595 AM Den Haag
Netherlands



Clinician name



Order number



Medical Device



Please note user modification is not recommended and by altering the orthosis yourself your warranty can be affected or deemed void. Please contact your clinical specialist or DM Orthotics for information on alterations and product modifications.



Manufacturer:
DM Orthotics Ltd
Unit 2 Cardrew Way
Cardrew Industrial Estate
Redruth
Cornwall, UK
TR15 1SS

+44 (0) 1209 219205
www.dmorthotics.com
admin@dmorthotics.com



Designed and constructed in the UK

Basic UDI-DI: 5054522SPINALV9

UDI-DI:

Adult Vest – XS	VA1	5054522001538
Adult Vest – S	VA2	5054522001545
Adult Vest – M	VA3	5054522001552
Adult Vest – L	VA4	5054522001569
Adult Vest – XL	VA5	5054522001576
Adult Vest – XXL	VA6	5054522001583

Child Vest – 1	VC1	5054522001590
Child Vest – 2	VC2	5054522001606
Child Vest – 3	VC3	5054522001613
Child Vest – 4	VC4	5054522001620
Child Vest – 5	VC5	5054522001637
Child Vest – 6	VC6	5054522001644
Child Vest – 7	VC7	5054522001651
Child Vest – 8	VC8	5054522001668



Manufacturer: DM Orthotics Ltd
Unit 2 Cardrew Way
Cardrew Industrial Estate
Redruth, Cornwall, UK
TR15 1SS



EC

REP

MedEnvoy Global BV
Pr. Margrietplantsoen 33
Suite 123
2595 AM Den Haag
Netherlands