PHYSIOLAB

USER MANUAL

REPAIR · RECOVER · PERFORM

www.physiolab.com

REPAIR · RECOVER · PERFORM

CONTENTS

REPAIR · RECOVER · PERFORM

1.1 INDICATIONS FOR USE

Always follow the recommendations of a qualified healthcare practitioner.

The Physiolab® S1 System combines cold and compression therapies. It is intended to aid soft tissue recovery post-exercise and treat soft tissue injuries in their early (acute) stage.

Cold and compression can help to reduce pain and swelling. They also help to reduce an excessive inflammatory response to an injury which helps to limit further damage.

It can be used as part of a holistic sports injury prevention strategy when used pre and post activity.

The system is designed to be used in hospitals, outpatient clinics, athletic training settings or home settings.

⚠ CAUTION - OPERATION OF THE PHYSIOLAB® S1 SYSTEM BY THE USER RECEIVING THERAPY

As the user receiving therapy, you may operate the S1 Control Unit but only after:

- You have read in their entirety and thoroughly understood all the instructions for use, contraindications and warnings, and
- If there is anything that you do not understand, please contact a qualified healthcare professional or your Physiolab® representative. Alternatively you can refer to the Physiolab® contact information found in section 3.10.

1.1 INDICATIONS FOR USE

⚠ WARNING – PROLONGED OR EXCESSIVE USE

Improper application or excessive/prolonged use of the Physiolab® S1 System could result in tissue damage such as frostbite.

The repeated application of cryotherapy can result in permanent tissue and/or nerve damage. The treatment area should be given sufficient time to recover between repeat treatments.

Always wait for skin to return to normal temperature; as a minimum wait 2 hours before administrating another therapy.

Discontinue use immediately if you experience or observe any of the following:

- Increased pain
- Burning
- Itching
- Increased swelling
- Blisters
- Skin discolouration
- Increased skin redness
- A raised, itchy rash.

It is **ESSENTIAL** that you read section 3.4, which contains all warnings and cautions, in detail before using the Physiolab® S1 System.

1.1 INDICATIONS FOR USE

The Physiolab® S1 System is intended for the application of cryotherapy and intermittent pneumatic compression therapy via a Therapy Pack by the user and, when advised, by a qualified healthcare practitioner for the treatment of soft tissue injury.

It is important to always follow the recommendations of a healthcare practitioner.

The Physiolab® S1 System combines cryotherapy and intermittent pneumatic compression therapies and is intended for the treatment of post-surgical and musculoskeletal injuries during both the acute and sub-acute phases.

Therapy results may vary from person to person and may not be the same or have the same effect. Please consult your healthcare practitioner regarding treatment and individual results.

CRYOTHERAPY:

Cryotherapy is intended for use during the early (internal) bleeding and inflammation stages of an injury, where the aim is to reduce the detrimental effects of excessive bleeding and inflammation.

INTERMITTENT PNEUMATIC COMPRESSION THERAPY (IPC):

Intermittent pneumatic compression therapy is intended for use during the inflammation and proliferation stages of an injury, where the aim is to reduce swelling, in order to prevent the detrimental effects of excessive swelling and to improve function in order to increase the rate of healing.

If any problems or unexpected operation errors are detected during the setup, use or maintenance of the Physiolab® S1 System, please contact your Physiolab® representative. Alternatively, you can refer to the Physiolab® contact information found in section 3.10.

1.2 INTENDED USERS

The Physiolab® S[1] System is intended for use by individuals and healthcare practitioners.

The user receiving therapy may also become the operator of the S[1] Control System but only once they have read in their entirety and thoroughly understood all of the instructions for use, warnings and cautions.

If there is anything you do not understand, please contact a qualified healthcare practitioner or your Physiolab® representative. Alternatively, you can refer to the Physiolab® contact information found in section 3.10.

1.3 CONTRAINDICATIONS

⚠ WARNING

The Physiolab® S[1] system SHOULD NOT be used on individuals who have:

- Diabetes.
- A loss of sensation in the intended therapy area, such as numbness/ paraesthesia caused by nerve damage.
- A confirmed or suspected tissue infection in the treatment area.
- Previously had frost bite on the affected limb or treatment area.
- Previously experienced an adverse reaction to cold, such as development of hives or welts, itchiness and swelling (e.g. cold induced urticaria or acute paroxysmal cold haemoglobinuria or cryoglobulinemia).
- A condition which could be exacerbated as a result of cold (e.g. multiple sclerosis, rheumatoid arthritis, spinal cord injury, clotting abnormalities, peptic ulcer).
- Experienced slow wound healing in the past.
- Any known circulatory or cardiac conditions (e.g. acute stages of inflammatory phlebitis, Raynaud's phenomenon, hypertension, extreme low blood pressure, arteriosclerosis or other vascular ischemic disease).
- An unstable fracture in the treatment area.
- A tumour in the treatment area.

1.3 CONTRAINDICATIONS

- Deep vein thrombosis (DVT) and/or pulmonary embolus - either current or in the past – or any recent factors which may increase the risk of DVT (e.g. you have been bed bound or on a long haul flight).
- A localised skin condition in the intended therapy area (e.g. dermatitis, vein ligation, gangrene, skin graft).
- Muscle tightness with a reduced ability to stretch, caused by nervous system damage (e.g. decompensated hypertonia).
- Cognitive impairment / disabilities or communication barriers, whether temporary due to medication or permanent.

Please note: There may be some instances where your healthcare practitioner may decide that cold and compression therapy are appropriate for individuals who have some of the above conditions. This decision is always a clinical judgment call and must always be made by a suitably qualified practitioner.

⚠ WARNING

If you are under 18 you must seek advice from a healthcare practitioner before using the Physiolab® S[1] system.

2.1 SYSTEM OVERVIEW

THE PHYSIOLAB® S¹ SYSTEM:

2.2 ACCESSORIES

A range of Physiolab® Therapy Packs are available for use with the S[1] Control System. This includes Therapy Packs for key anatomical locations and a range of Tubular Therapy Packs of different sizes that can be used on any limb location. For a full list of the Therapy Packs that are currently available, please contact your local Physiolab® Sales Representative.

Shoulder (Left) Therapy Pack

Lower Back Therapy Pack

Groin (Right) Therapy Pack

S540 (Tubular) Therapy Pack

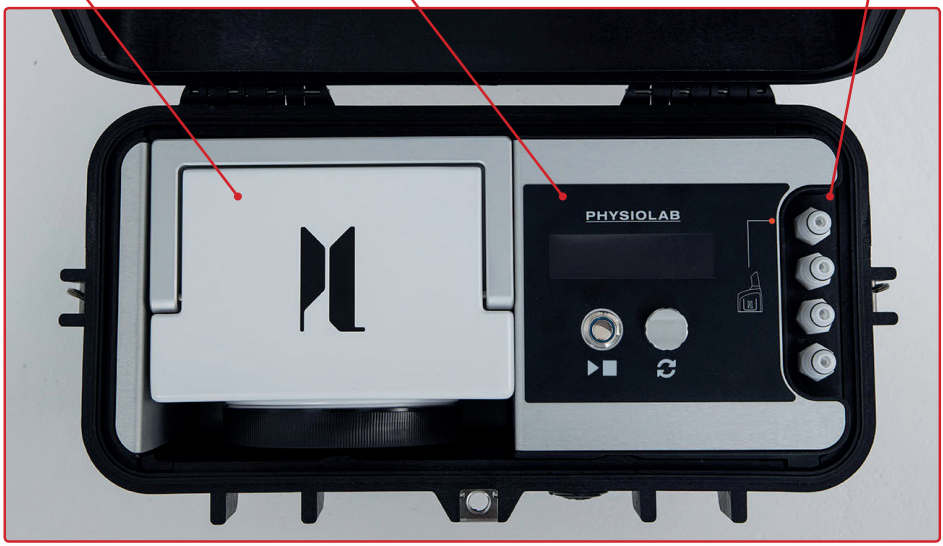
M540 (Tubular) Therapy Pack

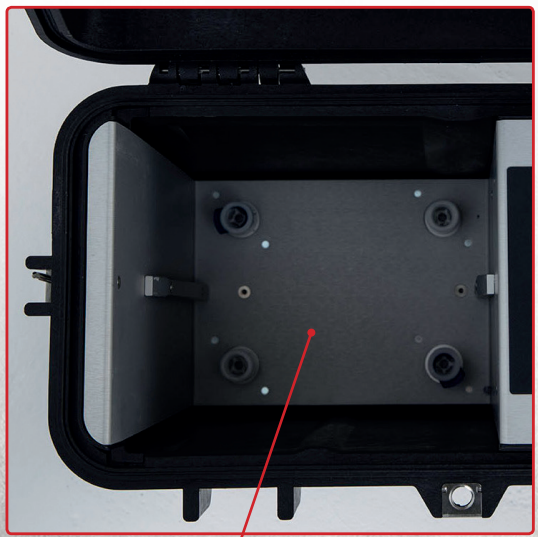
Ankle Boot Therapy Pack

⚠ WARNING

Only use Therapy Packs and accessories supplied by Physiolab® Technologies Ltd. Do not use other manufacturer's Therapy Packs and accessories.

2.3 DEVICE FEATURES

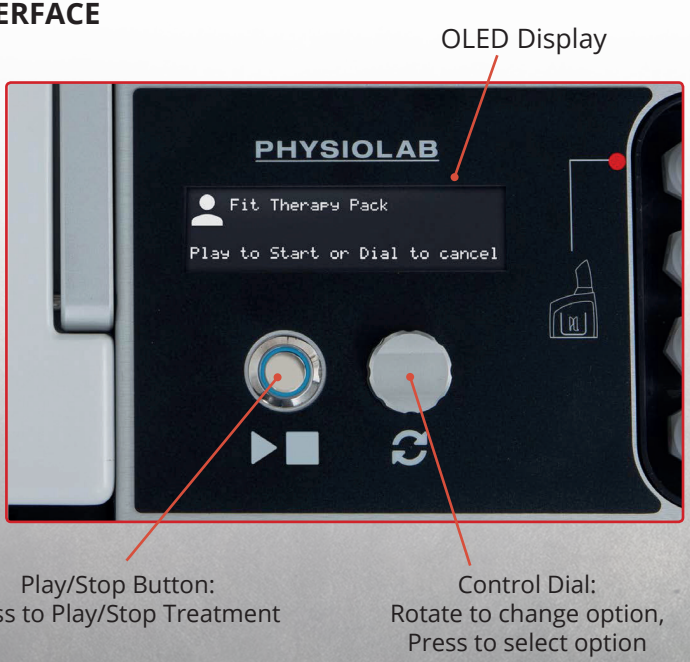




2.4 DISPLAY AND CONTROLS

Settings Adjustment	User Warning	Action Required	Error/ Warning
Treatment Running	Treatment Complete	Sleep Mode Cycle Time	Low Ice Indicator

USER INTERFACE



2.5 GETTING STARTED

1. If assistance is required at any time when setting up, using or maintaining the Physiolab® S1 System, please contact your Physiolab® representative.
2. Before choosing a location to setup the device, please consider the following:

⚠ WARNING

Do not position the device so that it is difficult for the patient and/or user to:

1) View the display
2) Press the Stop Button
3) Disconnect the Therapy Pack
4) Disconnect the Power Supply from the mains socket.

⚠ WARNING

Position the system to minimize the risk of tripping over the S1 Control Unit, Therapy Pack tubeset or Power Supply and cables.

⚠ WARNING

Liquid may drip from the underside of the device due to condensation. If excessive water pools beneath this may instead be due to unforseen obstruction. In this event, remove the device from use and contact your Physiolab® representative.

⚠ WARNING

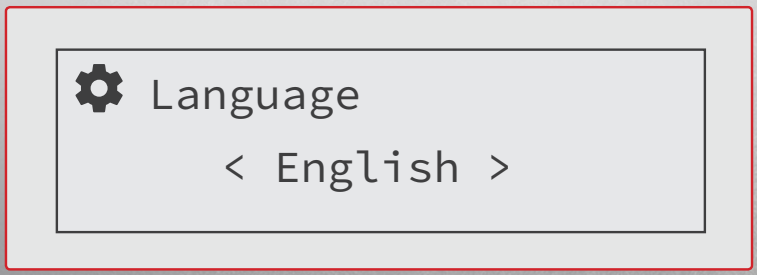
Position the Power Supply out of the way so that liquid will not be dripped on it or pool nearby during use. Drips and spillages may occur when connecting and disconnecting Therapy Packs or by filling and emptying the Cartridge.

2.5 GETTING STARTED

3. Always setup the device in an up-right position on a level surface. Open the lid fully.

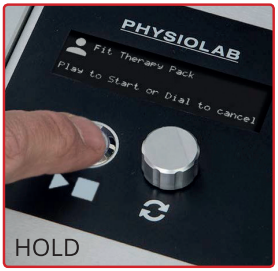
4. Connect the Power Supply to the Power Port on the device by inserting fully and twisting the collar clockwise to engage. Once engaged, connect the power supply to the mains outlet socket.

5. Once connected, the device will automatically power on. When using the device for the first time, the user will be required to select the operating language. To proceed, select Exit on the User Options screen.

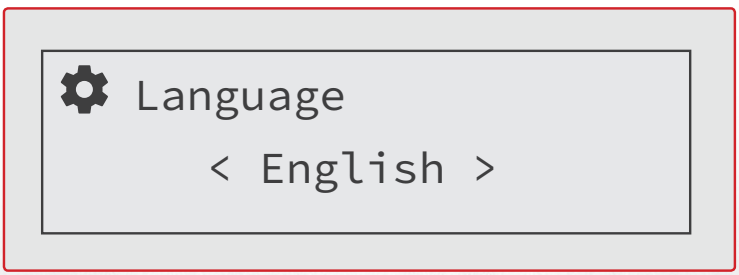


2.5 GETTING STARTED

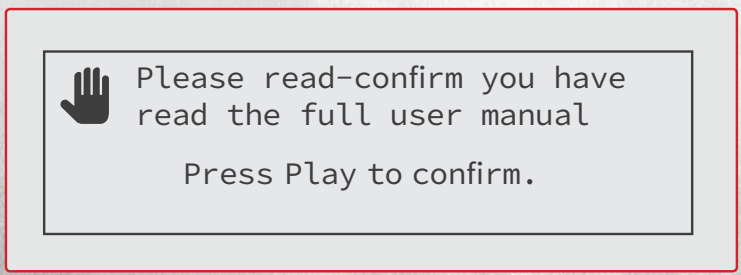
6. To reset the operating language at any time: Hold down the Play/Stop button, disconnect the Power Supply and reconnect the Power Supply.



7. Once the device re-powers on, release the Play/Stop Button. The Language screen will be displayed again. If the Physiolab® S[1] User Manual is required in a different language, please contact your Physiolab® representative.



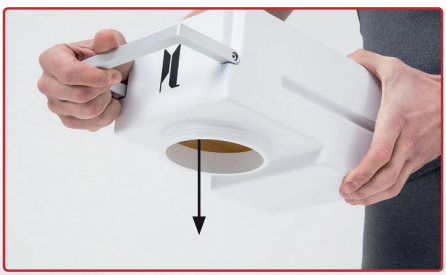
8. Before each use, the user must first confirm that you have read the full user manual. Press the flashing Play button to confirm.



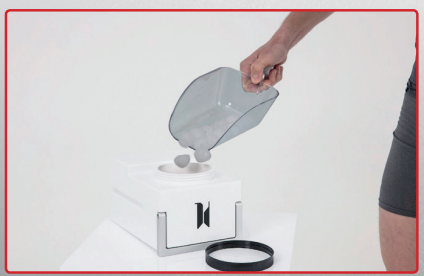
2.6 FILLING THE DEVICE

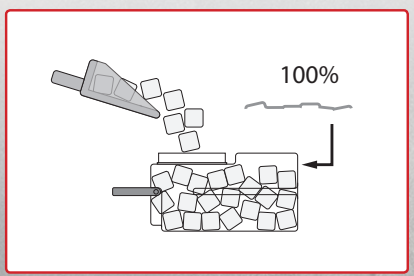
1. To fill the device, remove the Cartridge from the Cartridge Port.

2. Unscrew the cap and check to see that the Cartridge is empty.
   If the Cartridge contains any water from previous use, pour away.



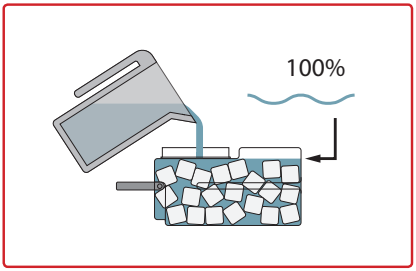
3. Fill the Cartridge to the top with ice.





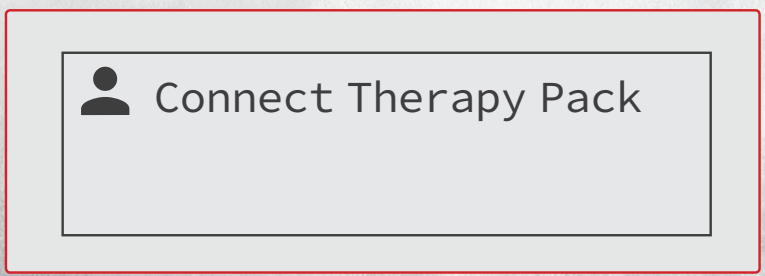
2.6 FILLING THE DEVICE

4. Fill the Cartridge to the top with water (3.2 litres).



5. Screw the cap back on. Carry the Cartridge upright using the handle this avoids water exiting the air breather hole nearest the lid. Place the Cartridge into the Cartridge Port.

6. Once replaced, the device will prompt the user to connect the Therapy Pack.



2.7 CONNECTING A THERAPY

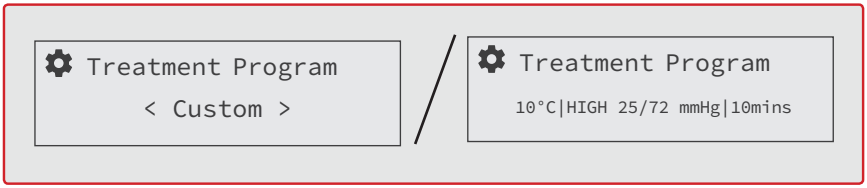
1. Connect the Therapy Pack Connector to the device's Therapy Pack Connector Port.

2. The Therapy Pack Connector can only be connected in the orientation shown below (Therapy Pack Tubeset closest to Control Unit lid):

3. Once the Therapy Pack has been connected, the system will automatically recognise the Pack and the Treatment Program can then be selected.

2.8 SETTING UP A TREATMENT

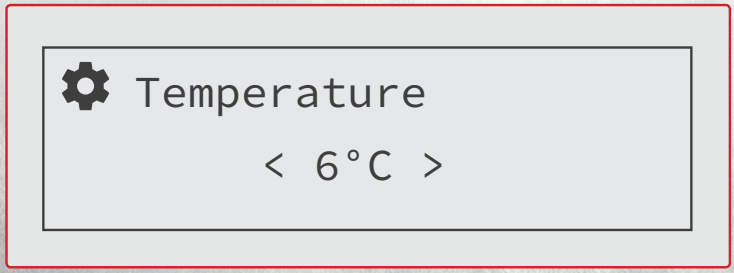
1. There is the choice between Custom Program or a Quick Start Program.



2. Instead of manually setting a treatment, the following preset Quick Start Programs are available for selection:

6 °C| HIGH 25 / 75 mmHg | 10 mins
8 °C| HIGH 25 / 75 mmHg | 10 mins
10 °C | HIGH 25 / 75 mmHg | 10 mins
12 °C | HIGH 25 / 75 mmHg | 10 mins
- - - - | HIGH 25 / 75 mmHg | 10 mins

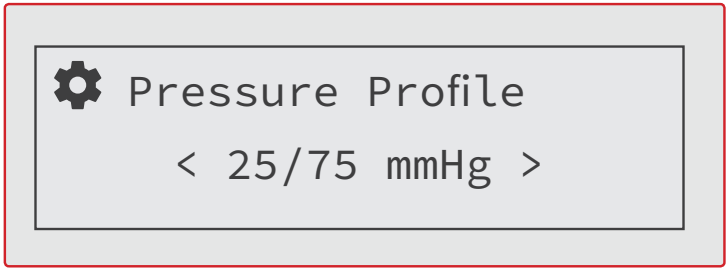
3. If the Manual Treatment Program has been selected the system will then require a temperature value (6-12 °C).



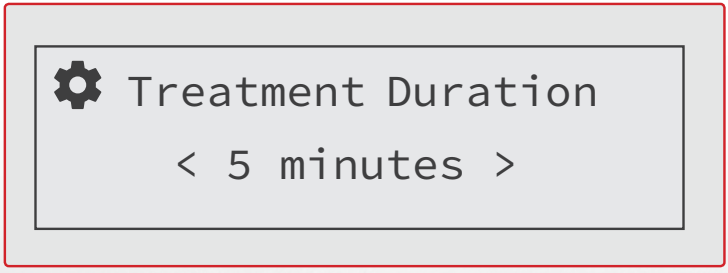
2.8 SETTING UP A TREATMENT

4. Select the Pressure Profile (25-75 mmHg). If 25/50 or 25/75 mm Hg is selected, a Cycle Time* (60, 90 or 120 sec) will need to be specified:

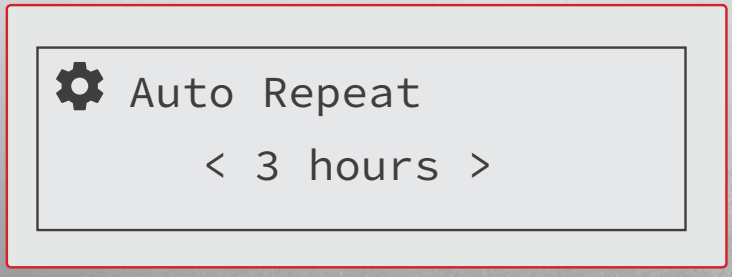
(*E.g. Cycle Time of 60 sec = 30 sec @ 25mmHg, 30 sec @ 50 or 75mmHg)



5. Select the Treatment Duration (5-30 minutes).



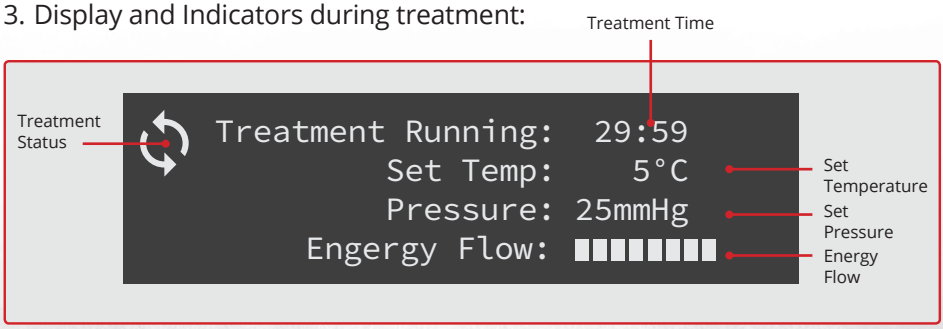
6. Select the Auto Repeat period ('Off', 2, 2.5 or 3 hours). This is the duration between the end of a treatment and the auto repeat cycle of the same treatment: (Auto Repeat is only available for selection in Custom mode)



2.9 DURING TREATMENT

1. Fit the Therapy Pack to the intended treatment area and hold in position. Press the flashing Play/Stop Button to begin treatment.

2. The Therapy Pack will autogrip to the limb/treatment area. The device will then perform a purge and prime cycle. This is done to optimise the Therapy Pack's performance for treatment.
3. Display and Indicators during treatment:



4. To stop treatment at any time, press the Play/Stop Button:

⚠ WARNING

If during treatment there is an increase in pain, or if you are concerned in any way, **STOP THERAPY IMMEDIATELY AND REMOVE THE THERAPY PACK.**

2.10 END OF TREATMENT

1. When the treatment is complete, the Therapy Pack will release. Remove the Therapy Pack.

2. Select to perform another treatment. When repeating a treatment, please note:

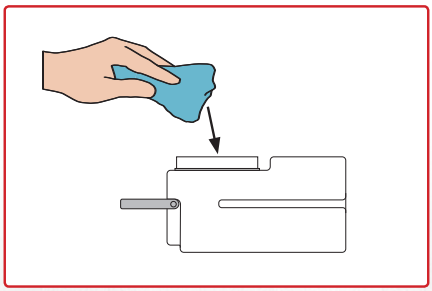
> **⚠ WARNING - RISK OF PERMANENT INJURY:**
>
> Re-applying cryotherapy treatments before the tissue has recovered can result in permanent tissue and / or nerve damage. Do not re-apply therapy until the skin has returned to normal temperature and always wait a minimum of 2 hours.

3. If finished with the current Therapy Pack, disconnect from the device. Press the side button of the connector and pull to disconnect.

2.11 AFTER USE AND STORAGE

1. Before storing the device, always check that the Cartridge is empty. Pour away any remaining water or ice.

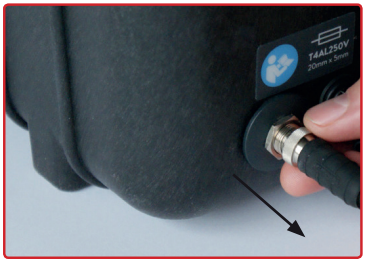
2. Wipe off any excess fluid from the inside of the Cartridge using a clean dry disposable cloth.



3. Screw the cap back on and then replace the Cartridge into the Cartridge Port.

2.11 AFTER USE AND STORAGE

4. To power down, twist the collar of the Power Supply plug anti-clockwise to disengage from the Power Port and disconnect.



5. Close the lid securely using the front clips.
   Store the device away in a safe location until its next use.

6.

> **⚠ CAUTION**
>
> Please note - If power is lost or the device is powered down during treatment, the selected treatment program and any treatment progress will be lost. The treatment program will need to be set up again each time the device is powered up.

7. See section 3.6 for full storage and transportation guidelines.

8. The Physiolab® S[1] Control Unit and Therapy Packs must be cleaned and disinfected before being put back into clinical use. See section 3.1 for full cleaning and disinfecting instructions.

3.1 CLEANING AND DISINFECTING

CLEANING AND DISINFECTING THE PHYSIOLAB® S¹ CONTROL UNIT

On receipt or after periods of storage, the Physiolab® S¹ Control Unit must be cleaned and disinfected before being put into clinical use.

Before every use, the Physiolab® S¹ and Physiolab® Therapy Packs should be cleaned and disinfected as appropriate to avoid cross infection, particularly when individuals have compromised immunity.

⚠ WARNING

Before cleaning, disconnect from the mains electrical supply. Do not use the device during cleaning, servicing and maintenance.

⚠ WARNING

No part of the S¹ Control Unit or Therapy Pack should be immersed in water or other liquids during cleaning or disinfection.

⚠ CAUTION

Disinfectant products are corrosive in nature; failure to properly wipe and dry the surfaces could leave a corrosive residue which may cause latent damage:

- Do not use cleaning or disinfecting solutions which contain Phenol, Bleach or Chlorine on any part of the S¹ Control Unit or the Therapy Packs.
- Do not steam clean or jet wash any areas of the S¹ Control Unit or Therapy Packs.

3.1 CLEANING AND DISINFECTING

RECOMMENDED CLEANING STEPS FOR OUTSIDE OF UNIT:

1. The Physiolab® S¹ Control Unit must be turned off and disconnected from the mains supply before any cleaning.
2. Clean and disinfect the screen with Alcohol wipes only.
3. Remove the Cartridge. Wipe all surfaces of the S¹ Control Unit, Cartridge, Power Supply (and cables) using a disposable cloth dampened with detergent diluted with water as per the manufacturer's instructions. Apply the liquid to the disposable cloth and squeeze out surplus liquid.
4. Disinfect all surfaces of the S¹ Control Unit, Cartridge, Power Supply and cables (disconnected from a mains supply) using a disposable cloth dampened with disinfectant, which is indicated for use on plastic and metal, and is diluted as per the manufacturer's instructions. Apply the liquid to a disposable cloth and squeeze out surplus liquid.
5. After the specified contact time wipe dry with a clean and dry disposable cloth. Make sure all surfaces are completely dried before reconnecting the Physiolab® S¹ Control Unit, power supply and cables to a mains supply.

RECOMMENDED CLEANING STEPS FOR S¹ CONTROL UNIT CARTRIDGE AND CONNECTED PACK:

1. The S¹ Control Unit Cartridge must be cleaned twice every month using the supplied Cleaning Tablets, or an available alternative with the following ingredients: TROCLOSENE SODIUM (CAS: 2893-78-9): 19.5% W/W.
2. Remove the Cartridge from the S¹ Control Unit and follow the steps instructed on the Cleaning Tablet packaging and place the solution in the cartridge.
3. Screw the cap back on and then replace the Cartridge into the Cartridge Port, connect a Therapy Pack to the S¹ Control Unit and run a treatment. This will clean the internals of the S¹ Control Unit and the internals of the connected Therapy Pack.

3.1 CLEANING AND DISINFECTING

CLEANING AND DISINFECTING THE PHYSILOAB® THERAPY PACKS:

⚠ CAUTION

- Physiolab® Therapy Packs must be cleaned and disinfected after each use, particularly when used to treat more than one individual in accordance with good cross infection prevention practice.
- Physiolab® Therapy Packs should be cleaned and disinfected only using an appropriate medical device CE marked disinfectant diluted to the manufacturer's instructions and including the appropriate contact time before drying or rinsing off.

RECOMMENDED CLEANING STEPS:

1. Disconnect the Therapy Pack from the S1 Control Unit.
2. Clean the Therapy Pack using a disposable cloth dampened with detergent, diluted with water as per the manufacturer's instructions. Apply the liquid to the disposable cloth and squeeze out surplus liquid. Do not apply liquid directly to the Therapy Pack. It is recommended that the Therapy Pack is cleaned in the following order: 1) Therapy Pack Connector, 2) Outer surface of Therapy Pack, 3) Inner surface of Therapy Pack.
3. Disinfect all surfaces of the Therapy Pack using a disposable cloth dampened with disinfectant which is indicated for use on PU coated Nylon and is diluted as per the manufacturer's instructions. Apply the liquid to a disposable cloth and squeeze out surplus liquid. Do not apply liquid directly to the Therapy Pack. It is recommended that the Therapy Pack is cleaned in the following order: 1) Therapy Pack Connector, 2) Outer surface of Therapy Pack, 3) Inner surface of Therapy Pack.
4. After the specified contact time, wipe dry with a clean dry disposable cloth.

3.2 MAINTENANCE

Ensure that the Physiolab® S1 Control Unit, its parts (Cartridge, Power Supply, cables) and the Therapy Packs are in good condition before use and that there is no leakage of fluid.

⚠ WARNING

Before each use, ensure the device's functions operate correctly. Also visually inspect the device for any loose or damaged parts.

If the device's performance or mode of operation changes from that specified or required, the device should be taken out of service immediately.

Request maintenance before returning the device to clinical use.

⚠ CAUTION

Before use, check that the Cartridge is not damaged or leaking. Any part of the Physiolab® S1 System that is damaged or worn should be replaced.

⚠ CAUTION

Do not use the device during cleaning, servicing and maintenance.

⚠ CAUTION

Any servicing or maintenance beyond what is stated in this document should only be undertaken by Physiolab® or Physiolab® approved service personnel.

3.2 MAINTENANCE

EXPECTED SERVICE LIFE

The device has an expected service life of 3 years, subject to an annual Physiolab® approved service.

MAINS ISOLATION

To isolate the equipment from the mains power, disconnect the power supply from the supply mains.

RECURRENT TESTING

The system should be electrically safety tested on an annual basis in accordance with EN IEC 62353:2014.

ESSENTIAL PERFORMANCE

In fault state, the device ensures the user remains safe by monitoring for low output temperatures and high output pressures. In the event that any potentially hazardous events are detected, the device will stop functioning and an error message will be displayed.

FUSE

The S[1] Control Unit includes a user-replaceable T3.15AL250V fuse. This can be found on the side of the device, next to the power port. To replace the fuse, firstly disconnect the Power Supply from the Control Unit's Power Port. Use a flat head screwdriver to unscrew the fuse holder cap.

⚠ WARNING

Ensure that the unit's fuse T3.15AL250V is replaced using one of the same specification.

3.3 TROUBLESHOOTING

MESSAGE	DESCRIPTION	MEANING	SOLUTION
⚠ **ERROR 103**	Safety System permanent lock	Unexplained error	Phone Physiolab® for Technical Support
⚠ **ERROR 110**	Time-out waiting for action	No action taken	Disconnect and reconnect power
⚠ **ERROR 200**	Time-out current state time-out	Therapy Pack/ Air pump has timed out.	Ensure that the Therapy Pack is orientated with the pipes facing down. Press the Cartridge fully down. Press the Therapy Pack connector fully down. Check for contaminants in the liquid connections. Try to keep the S[1] and the Therapy Pack level - place the unit on a table or floor as required.
⚠ **ERROR 400**	Tank Switch Open	Cartridge is not inserted correctly	Ensure the Cartridge is fully inserted into the Cartridge Port.
⚠ **ERROR 500**	Accelerometer out of bounds	The system has been knocked or is positioned on an unstable surface	Move the device to a flat, level surface for operation.
⚠ **ERROR 809**	Pack pressure too high	Pressure error	Keep S[1] unit and pack within 1.5 metres of each other

3.3 TROUBLESHOOTING

MESSAGE	DESCRIPTION	MEANING	SOLUTION
⚠ **ERROR 810**	Pack pressure too low	Pressure error	Keep S[1] Unit and Pack within 1.5 metres of each other
⚠ **ERROR 2000**	Tank level too high	Too much liquid in system due to poor liquid flow in the Therapy Pack	Empty enough liquid from the cartridge to allow for residual liquid from the Therapy Pack to drain into the Cartridge
⚠ **"LOW WATER" OR "TOO MUCH LIQUID IN THE SYSTEM" DISPLAYED**	Water level check	Too much liquid or too little liquid	Check that the water level is to the bottom of the neck of the Cartridge. Insert and remove the Cartridge 10 times
⚠ **UNABLE TO SELECT TREATMENT**	An instruction has been missed or skipped	User selection may not have been recognised	Follow the selection instructions in Section 2.4 Display & Controls- "Control Dial"
⚠ **"POOR LIQUID FLOW" OR "THERAPY FAILED" DISPLAYED**	Current state time-out	Therapy Pack/ air pump has timed out	Ensure the Therapy Pack is orientated with the pipes facing down. Press the Cartridge fully down. Press the Therapy Pack connector fully down. Check for contaminants in the liquid connections. Try to keep the S[1] Unit and Therapy Pack level - place the S[1] Unit on a table or floor as required.

3.3 TROUBLESHOOTING

MESSAGE	DESCRIPTION	MEANING	SOLUTION
⚠ **"LEAK FROM THE UNIT" DISPLAYED**	Liquid error	Liquid may have leaked. Cartridge fill error.	Check cartridge lid is tight. The S¹ unit will produce condensation in use - a small number of liquid drips is to be expected.
⚠ **ERROR CODE NOT LISTED**	Unexpected error	Error not defined	Phone Physiolab® for Technical Support.

If any problems or unexpected operation errors are detected during the setup, use or maintenance of the Physiolab® S¹ System, please contact your Physiolab® representative. Alternatively you can refer to the Physiolab® contact information in section 3.10.

3.4 WARNINGS AND CAUTIONS

⚠ A WARNING

is given when the personal safety of the user may be affected and when disregarding this information could result in permanent injury.

⚠ A CAUTION

is given when special instructions must be followed. Disregarding this information could result in permanent damage being caused to the Physiolab® S[1] System and Therapy Packs.

⚠ WARNING

The repeated application of Cryotherapy can result in permanent tissue and nerve damage. Skin should always be allowed to return to normal temperature and, as a minimum, wait 2 hours.

The recovery time will be dependent on a number of factors such as the type and severity of injury, treatment duration, treatment area, thickness of adipose tissue and stage of healing. ACPSM guidelines (Bleakley et al, 2010) advise that this is typically 2 hours.

Your healthcare practitioner will use their clinical judgement when recommending a treatment protocol.

⚠ WARNING

Using the Physiolab® S[1] System contrary to instructions, or using incorrectly fitting Therapy Packs may result in permanent tissue damage.

It is important when using the Physiolab® S[1] System to regularly view and monitor the skin in and around the area being treated, particularly the digits of the extremities, for any increased swelling, burning, or pain.

'Bleakley, C.M. and Davison, G., (2010). 'Management of acute soft tissue injury using Protection Rest Ice Compression and Elevation: Recommendations from the Association of Chartered Physiotherapists in Sports and Exercise Medicine' ACPSM [Executive Summary]. Association of Chartered Physiotherapists in Sports and Exercise Medicine.

3.4 WARNINGS AND CAUTIONS

- In the event that any of these symptoms are observed or if there is any unexpected change to the appearance of the skin (including: non-reactive hyperaemia, cyanosis, blistering), therapy must be stopped immediately and a healthcare practitioner must be informed.
- If elevation of the limb is undertaken during therapy, the clinician should look for signs of reduced blood flow/perfusion in the foot/hand and toes/fingers, and if observed, the treatment should cease immediately.
- Physiolab® Therapy Packs are not sterile and as such should not be brought into contact with any rash, sore, open wound, infection, or sutures (stitches). Therapy Packs may be applied over a dressing or clothing upon the assessment and advice of a healthcare practitioner.
- Physiolab® Therapy Packs are available for a wide range of anatomical locations but are not intended for all possible orthopaedic uses. The Therapy Pack should only be used for the anatomical area indicated on the Therapy Pack and corresponding instructions. It is important for the appropriate Therapy Pack to be selected for suitable fit to the individual's own limb and anatomy.

⚠ WARNING
No modification of this equipment is allowed.

⚠ WARNING
Ensure the Cartridge is filled with water and ice only.

⚠ WARNING
Keep the device and any cables or hoses out of the reach of children to prevent the risk of strangulation.

3.4 WARNINGS AND CAUTIONS

⚠ CAUTION

Do not add water and ice directly to the device during therapy operation. Ensure that only the Cartridge is filled with the water and ice and then placed into the device.

⚠ CAUTION

Any servicing or maintenance beyond what is stated in this document should only be undertaken by Physiolab® or Physiolab® approved service personnel.

⚠ WARNING

Do not use device if the Power Supply or Power Supply cable appears damaged.

⚠ CAUTION

Ensure to wipe up all spillages which occur during use with the unit.

⚠ WARNING

Do not fill Cartridge with hot water. If misused in this way, the S[1] may warm the Therapy Pack to the temperature of liquid in the Cartridge.

⚠ CAUTION

Do not crush Therapy packs during use.

3.5 EMC COMPLIANCE

The following information is based on the requirements of EN 60601-1-2:2015. The S[1] System has been supplied with a mains lead of length 1.8 metres. Use of accessories or cables other than those supplied with the unit may result in increased emissions or decreased immunity to EMI.

The S[1] System should not be used directly adjacent to, or stacked, with other equipment. If adjacent or stacked use is necessary, the equipment should be observed to verify normal operation in the configuration in which it will be used.

Portable and mobile RF communications equipment can affect medical electrical equipment. The Physiolab® S[1] System may be interfered with by other equipment, including equipment that complies with CISPR emission requirements.

All tests have been performed on the Enclosure and / or AC Power Ports as applicable. The Physiolab® S[1] System has no user accessible DC Power, Signal or Patient Coupling Ports or outdoor cables.

Guidance and manufacturer's declaration - electromagnetic emissions	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 2	The Physiolab® S[1] System must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
RF emissions CISPR 11	Class B	The Physiolab® S[1] System is suitable for use in all establishments, including domestic establishments and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions EN61000-3-2:2004	N/A Power <75W	
Voltage fluctuations / flicker emissions EN61000-3-3:2013	N/A Power <75W	
ETSI EN 302 291-1 V1.1.1 and ETSI EN 302 291-2 V1.1.1	Complies	

3.5 EMC COMPLIANCE

Guidance and manufacturer's declaration - electromagnetic emissions	IEC 60601 test level	Compliance	Electromagnetic environment - guidance
Electrostatic discharge (ESD) EN 61000-4-2:2009	8kV contact 15kV air	Class B	
Electrical fast transient/burst EN61000-4-4:2012	± 2 kV for power supply lines	Class B	Mains power quality should be that of a typical commercial or hospital environment.
Surge EN61000-4-5:2006	± 1.0 kV lines to lines ± 2.0 kV lines to earth 20s	Class B	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips and interrupts EN61000-4-11:2004 at 240VAC and 100VAC	30% UT for 500ms @ 0°0% UT for 20ms @ 0°0% UT for 10ms @ 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315° 0% for 5s	Class B Class B Class B Class C	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Physiolab® S[1] System requires continued operation during power mains interruptions, it is recommended that the Physiolab® S[1] be powered from an uninterruptible power supply or a battery.
Power frequency Magnetic Field EN61000-4-8:2010	30 A/m		If there is a reduction in delivery performance it may be necessary to position the Physiolab® S[1] System further from sources of power frequency magnetic fields or to install magnetic shielding. The power frequency magnetic field should be measured in the intended installation location to assure that it is sufficiently low.

NOTE UT is the A.C. mains voltage prior to application of the test level

3.5 EMC COMPLIANCE

Guidance and manufacturer's declaration - electromagnetic emissions	IEC 60601 test level	Compli-ance	Electromagnetic environment - guidance
Conducted RF EN61000-4-6: 2014	3V rms (1kHz 80%) 150kHz - 80MHz 6V rms ISM and amateur radio bands	Class A	Portable and mobile RF communications equipment should be used no closer to any part of the Physiolab® S¹ System including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separatio distance d = 0.6√P for frequencies at the 10V/m test level d = 0.22√P for frequencies at the 27V/m test level d = 0.67√P for frequencies at the 27V/m test level where P is the maximum output power rating of the transmitter in watts (W) according to the trans-mitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, (a) should be less than the compliance level in each frequency range (b) Interference may occur in the vicinity of equipment marked with this symbol
Radiated RF EN61000-4-3: 2006	10V/m (1kHz 80%) 80MHz -2.7GHz 385 MHz 27 V/m PM 18 Hz 450 MHz 28 V/m FM 1 kHz sine 710 MHz 9 V/m PM 217 Hz 745 MHz 9 V/m PM 217 Hz 780 MHz 9 V/m PM 217 Hz 810 MHz 28 V/m PM 18 Hz 870 MHz 28 V/m PM 18 Hz 930 MHz 28 V/m PM 18 Hz 1720 MHz 28 V/m PM 217 Hz 1845 MHz 28 V/m PM 217 Hz 1970 MHz 28 V/m PM 217 Hz 2450 MHz 28 V/m PM 217 Hz 5240 MHz 9 V/m PM 217 Hz 5500 MHz 9 V/m PM 217 Hz 5785 MHz 9 V/m PM 217 Hz	Class A	

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

(a) Field strengths from fixed transmitters, such as base stations for radio (cellular / cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Physiolab® S¹ System is used exceeds the applicable RF compliance level above, the Physiolab® S¹ System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Physiolab® S¹ System.

(b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 10 V/m.

3.5 EMC COMPLIANCE

RF TRANSMITTERS WITHIN THE DEVICE			
Technology	Transmission frequency (MHz)	Effective Radiated Power (pW)	Modulation Scheme
NFC / RFID	13.56	2.7	ASK

RF RECEPTION FREQUENCY BANDS		
Technology	Reception frequency (MHz)	Bandwidth (MHz)
NFC / RFID	13.56	0.02

3.6 ENVIRONMENT, STORAGE AND TRANSPORTATION

The Physiolab® S[1] System is intended for use in healthcare environments, (e.g. hospitals, outpatient clinics), athletic training settings and at home. When used in home settings, avoid placing or using the device near fireplaces or heaters.

Please ensure the device is not used in areas of high humidity such as a shower room.

The device can be used outdoors but only when used with the portable battery pack accessory (supplied separately). The device should not be stored outdoors.

ENVIRONMENTAL OPERATING CONDITIONS:	
Ambient Temperature	1°C - 40°C
Humidity	15% - 90% non-condensing
Altitude	Sea level to 3000m

IP RATINGS:	
S[1] Control Unit	IP23: May be used outdoors in light rain. Avoid excessive splashing or submersion in water. Not protected against dust ingress.
Power Supply	No IP rating
	⚠ **WARNING** Device is not to be used outside with the Power Supply.

STORAGE AND TRANSPORTATION CONDITIONS BETWEEN USE:	
Ambient Temperature	1°C - 70°C
Humidity	10% - 90% non-condensing
Atmospheric Pressure	70kPa - 106kPa

Please note: If stored above 40°C, you may need to allow up to 90 minutes for the device to cool down to the normal operating temperature before use.

3.7 TECHNICAL SPECIFICATION

PART NO / REF:	
S[1] Control Unit	2101
Power Supply	2001, 2001.1
Cartridge	2002

MECHANICAL SPECIFICATION:	
External Dimensions (mm)	244 (h) x 430 (w) x 341 (d)
Weight (empty)	9.1 Kg
Weight (full Cartridge)	13.4 Kg

THERAPY DELIVERY:	
Temperature	6°C - 12°C (+/- 1.0°C)
Pressure	25mmHg - 75mmHg (+/- 10mmHg @ 25mmHg)
Pressure Cycle Time	60 sec, 90 sec or 120 sec
Therapy Duration	30 minutes maximum

THERMAL SYSTEM:	
Total Volume	4.2 L
Volume of Water	3.2 L
Quantity of Ice	1 Kg (approx.)

ELECTRICAL POWER SOURCE:	
Power Supply	Input - Universal 100 ~ 240Vac, single phase, 50 ~ 60 Hz Output - 12.00V, 7A Max or 12.00V, 5A Max
	⚠ **WARNING** Designed for use with Physiolab® Power Supply 2001 Series. Do not use with any other Power Supply.

3.8 DISPOSAL

This symbol on the products and / or accompanying documents means that at the end of life, electrical and electronic products should not be mixed with general waste.

Disposing of this product correctly will save valuable resources and prevent any potential negative effects on human health and the environment which could otherwise arise from inappropriate waste handling.

If you are unsure of your national requirements with respect to disposal please contact your local authority, dealer or supplier for further information.

The above information is based on the European waste electrical and electronic equipment directive 2012/19/EU.

3.9 SYMBOLS

The following symbols apply to the product:

Warning or Caution,
read the instructions for use

Manufacturers name and address
(see section 3.10 for details)

Date of manufacture

IP23

S1 Control Unit has an ingress protection rating of IP23

Electronic Waste
(see section 3.10 for details)

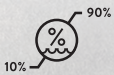
CE
0086

Compliant to the Medical Device Directive 93/42/EEC with 0086 as the Notified Body reference number.

Supply Mains Rating -
Class II

Supply Frequency

Fuse Value



Packaging -
Humidity Limit

Packaging -
Keep Away from Rain

Read the instructions for use

Mandatory to read
instructions for use

The device's Reference or Model Number (Type)

The device's unique Serial Number

Applied Part Type BF or Applied Part Type BF Connection

Therapy Pack Type Example shown is the Shoulder (Right) Therapy Pack - additional therapy packs are available for other anatomical locations

Period after opening

Do not use Phenol-based cleaning solutions

Do not expose the device to temperatures below 1 °C

Packaging - Atmospheric Pressure Limit

Packaging -
Temperature Limit

Packaging - This Way Up

3.10 MANUFACTURER / CONTACT

Physiolab Technologies Ltd
Unit 2 Centurion Court,
Brick Close,
Kiln Farm,
Milton Keynes,
MK11 3JB,
United Kingdom

Tel: +44 (0)1908 263 331
Email: contact@physiolab.com
Website: www.physiolab.com

3.11 WARRANTY

Warranty options are available for the Physiolab® S[1] System. For further information, please contact your Physiolab® representative.

CE
0086

Conforms to the Medical Device Directive 93/42/EEC and also the RoHS Directive 2011/65/EEC.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