PHYSIOLAB

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USER MANUAL

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CONTENTS

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.

The system is designed to be used in hospitals, outpatient clinics, athletic training settings or at home under the direction of a health care professional.

WARNING - 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 1 hour 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 sections 1.3 and 3.4, which contain all the 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 and post orthopaedic surgery.

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® S1 System is intended for use by individuals and healthcare practitioners.

The user receiving therapy may also operate the S1 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.

> **⚠ WARNING**
>
> If you are under 18 you must seek advice from a healthcare practitioner before using the Physiolab® S1 system.

1.3 CONTRAINDICATIONS

⚠ WARNING

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

- Cold urticaria/cold allergy
- Known haematological conditions that affect clotting
- Regenerating nerves under the intended therapy area
- Tissues affected by tuberculosis in the intended therapy area
- Acute thrombophlebitis, current or suspected deep vein thrombosis (DVT) and/or pulmonary embolus
- Muscle tightness with a reduced ability to stretch, caused by nervous system damage
- Cognitive impairment / disabilities or communication barriers
- Significantly impaired circulation in the intended therapy area
- Chronic wounds near the intended therapy area
- Malignant tumour in the affected limb or therapy area
- Haemorrhaging tissue or a patient with any untreated haemorrhagic disorders

Additionally, patients with the following conditions must be assessed prior and then regularly by a healthcare professional. Therapy should be discontinued if not tolerated

- Diabetes
- A loss of sensation in the intended therapy area
- A confirmed or suspected tissue infection in the treatment area
- Previously had frost bite on the affected limb or therapy area
- An unstable fracture in the treatment area
- An unstable localised skin condition in the intended therapy area
- Heart failure
- Raynaud's phenomenon or cold hypersensitivity

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 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.

Limb Pack

Hip Pack

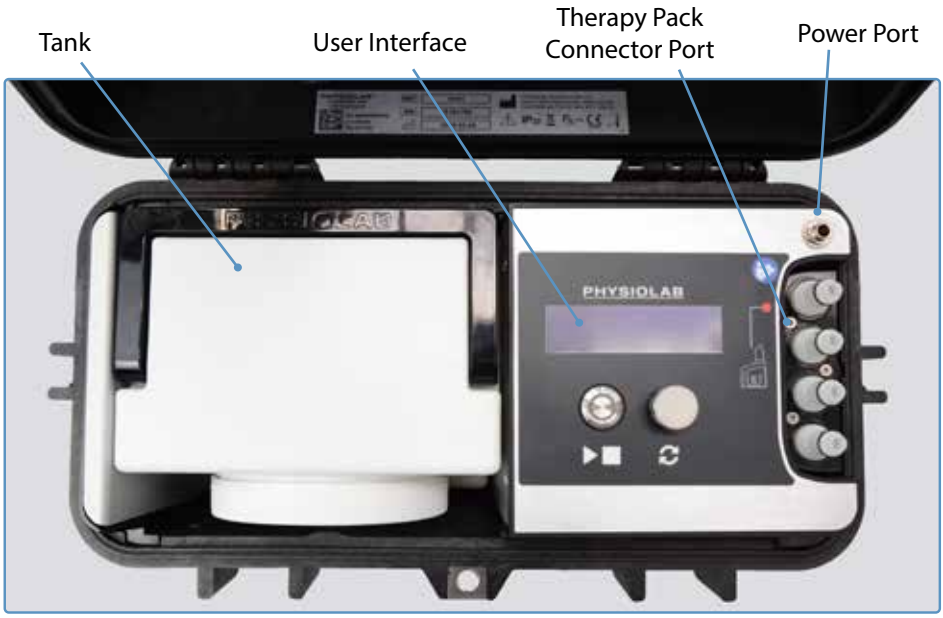
Shoulder Pack

Ankle Pack

⚠ WARNING

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

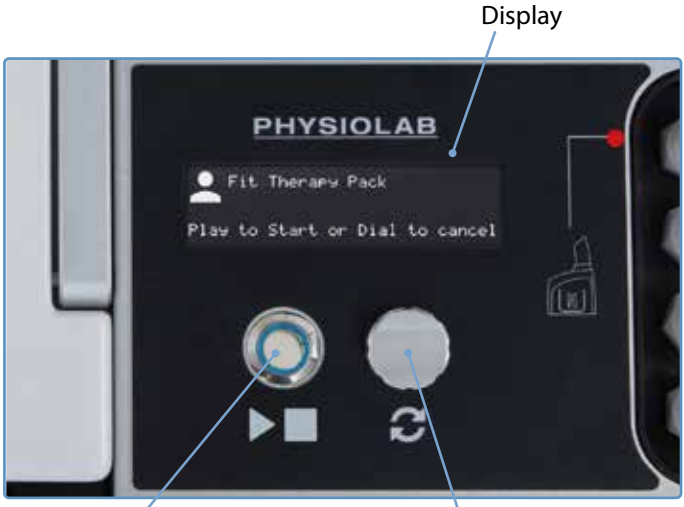
2.3 DEVICE FEATURES



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, Hose or Power Supply and cables.

⚠ WARNING

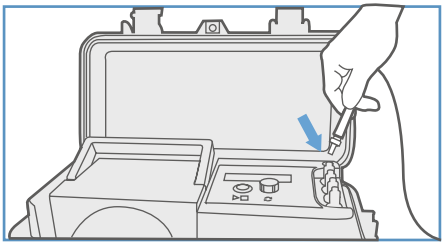
Liquid may drip from the underside of the device due to condensation, always position the device on a wipeable surface. If excessive water is identified then this may be due to an internal leak. In this event, remove the device from use and contact your Physiolab® representative.

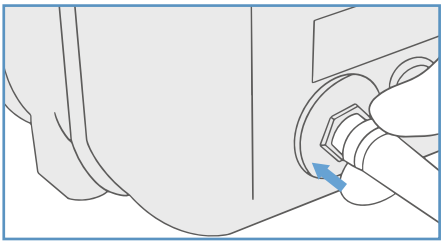
⚠ WARNING

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 Tank.

2.5 GETTING STARTED

3. Open the case. Make sure the unit is plugged in and switched on at the wall, with the power jack screwed into the socket in the top right-hand corner of the unit. The unit will auto power up.

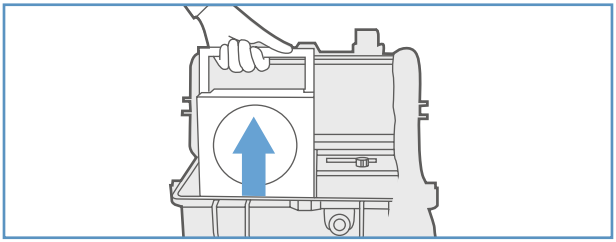




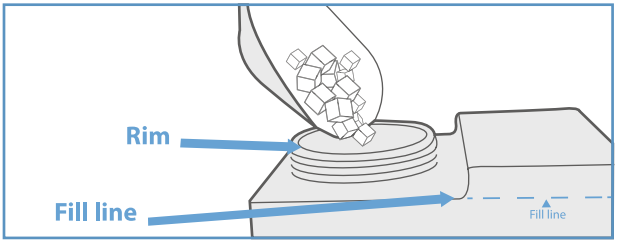
*Location of power socket varies depending on your device. It will be in either of the locations shown above.

2.6 REMOVAL & FILLING OF THE TANK

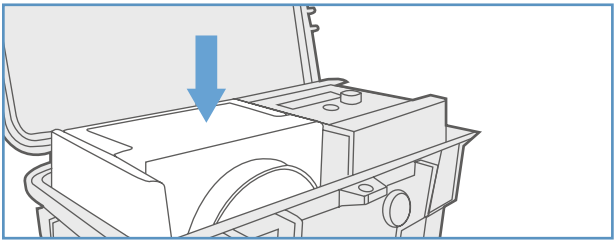
1. Raise the handle and remove the tank from the unit. If the tank is stiff, please pull firmly.



2. Place the tank on a flat surface with the lid facing upwards. Unscrew the lid and fill with ice (approx. 2 kilo bag) to the top of the rim. Then, fill the tank with water up to the fill line indicated on the side of the cartridge (approx. 3.2 ltr).



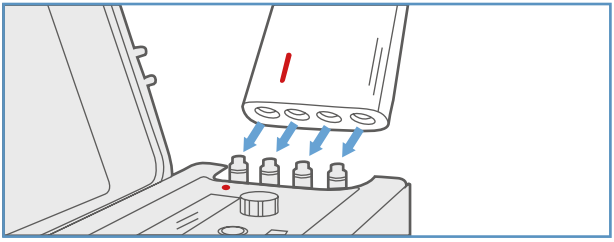
2.6 REMOVAL & FILLING OF THE TANK



3. Put the lid back onto the tank and screw it closed tightly. Gently lower the tank back into the unit and push down fully until it is firmly in place.

2.7 TREATMENT SET-UP

1. Select your chosen therapy pack. Attach your pack to the unit, aligning the red line with the red dot. Push firmly downwards until you hear a click.

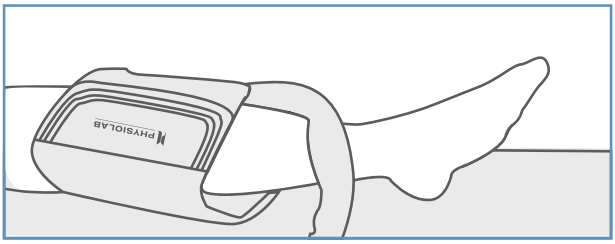


2. Connect your chosen therapy pack to the hose by aligning the white parts of each connector.

3. Place the therapy pack around the injured area, leaving any wound dressings in place.

2.7 TREATMENT SET-UP

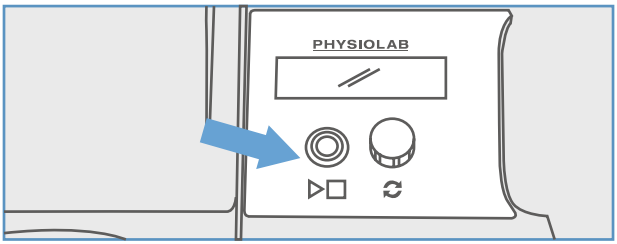
The pack can be applied over a thin layer of clothing or onto bare skin as preferred or advised. Ensure that the tube is not twisted or stretched.



2.8 TREATMENT SET-UP
SELECTING YOUR TREATMENT

Press the (▷□) start/stop button on the unit to begin the setup of your treatment.

You are able to select a pre-set protocol dependent on the body part you are treating. Alternatively, select 'custom' to set up your own treatment and manually select your temperature, pressure, dwell time and duration. You can also choose to activate the auto-repeat setting. To view the different options turn the dial clockwise. To select an option, press down on the dial.



Once your chosen treatment has been selected, press the flashing play button to begin your treatment.

The pack will start to inflate and treatment will begin.

2.8 TREATMENT SET-UP
SELECTING YOUR TREATMENT

At any point during the treatment you can press the Start/Stop button to stop your treatment.

2.9 TREATMENT SET-UP
DURING YOUR TREATMENT

During your treatment you can expect to feel the pack inflating and deflating as it applies compression to the desired area. Your skin will gradually get cooler until it reaches the temperature set, effectively managing your pain relief. The S1 unit will make a clicking sound during the treatment - this in indicative of the valves working to deliver your treatment.

To view the temperature of the water going in/out of the pack and compression levels during your treatment, click the dial button once the treatment has started.

Click the dial once more to change temperature and / or compression levels.

⚠ WARNING

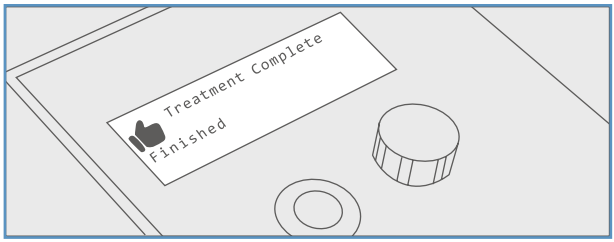
During treatment, ensure blood flow is not restricted to the point of inadequate perfusion; signs would be pins and needles in the extremity of foot or hand, “dead leg/arm”, pain developing in hand/foot, or significantly pale foot/arm in comparison to the other limb.

If uncomfortable at any point during treatment stop and remove the therapy pack and inspect skin; contact a healthcare professional for advice before continuing.

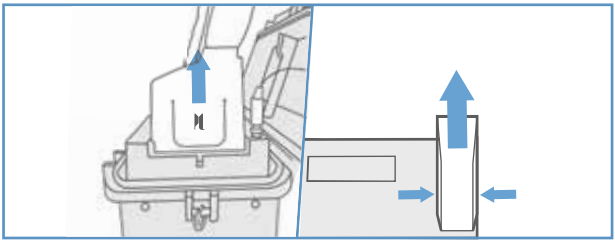
If in doubt stop treatment and contact your healthcare professional for advice.

2.10 AFTER YOUR TREATMENT

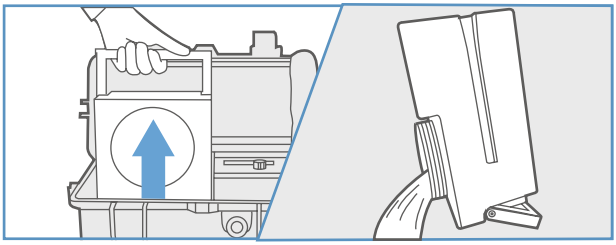
1. Once your treatment is complete the screen will display FINISHED. You can then remove the therapy pack.



2. To remove the therapy pack from the unit, push the bottom of the logo on the outside of the connector and pull it upwards.



3. Remove the tank, unscrew the lid and empty the ice/water mix.

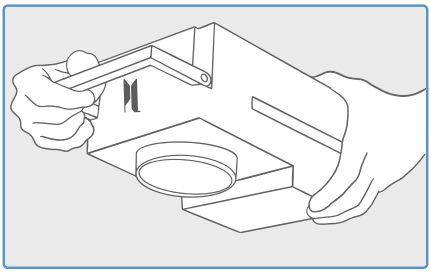


⚠ WARNING

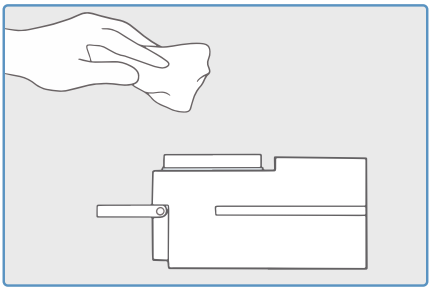
Reapplying cryotherapy treatments before the tissue has recovered can result in permanent tissue and/or nerve damage. Do not re-apply therapy until the skin has returned to normal temperature and always wait a minimum of 1 hour.

2.11 AFTER USE AND STORAGE

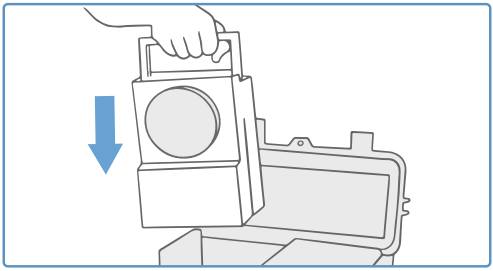
1. Before storing the device, always check that the Tank is empty. Pour away any remaining water or ice.



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

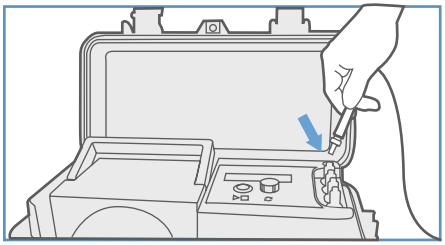


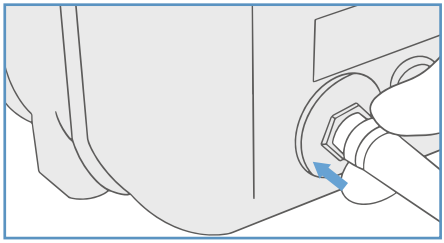
3. Screw the cap back on and then replace the Tank into the Tank Port.



2.11 AFTER USE AND STORAGE

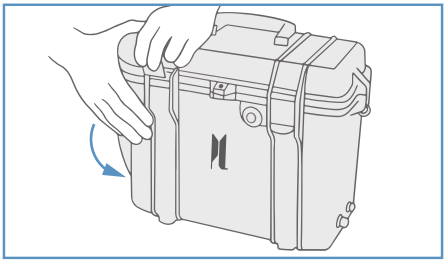
4. To power down, twist the collar of the Power Supply plug anti-clockwise to disengage from the Power Port and disconnect.





*Location of power socket varies depending on your device. It will be in either of the locations shown above.

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® S1 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.

> **⚠ 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.

> **⚠ WARNING**
>
> 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® S[1] 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 Tank. Wipe all surfaces of the S[1] Control Unit, Tank, 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 S[1] Control Unit, Tank, 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® S[1] Control Unit, power supply and cables to a mains supply.

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

1. The S[1] Control Unit Tank must be cleaned twice every month using a cleaning tablet containing: 780 mg NaDCC / TROCLOSENE SODIUM (CAS: 2893-78-9).
2. Remove the Tank from the S[1] Control Unit and follow the steps instructed on the Cleaning Tablet packaging and place the solution in the Tank.
3. Screw the cap back on and then replace the Tank into the Tank Port, connect a Therapy Pack to the S[1] Control Unit and run a treatment. This will clean the internals of the S[1] Control Unit and the internals of the connected Therapy Pack.

In clinical settings where the device needs to be cleaned without a therapy pack attached, a cleaning attachment accessory is available. Enquire for further information.

3.1 CLEANING AND DISINFECTING

CLEANING AND DISINFECTING THE PHYSIOLAB® THERAPY PACKS:

⚠ WARNING

- 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.

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 (Tank, 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.

⚠ WARNING

Before use, check that the Tank is not damaged or leaking. Any part of the Physiolab® S1 System that is damaged or worn should be replaced. Always place the device on a wipeable surface.

⚠ WARNING

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.

3.3 TROUBLESHOOTING

EVENT	DESCRIPTION	SOLUTION
S1 DOES NOT TURN ON	The S1 is not receiving power.	Check the power jack is pushed in and the collar is tightened as described in section 2.5. Check the power supply is connected to the mains and wall socket switched on. If the S1 is still not operational phone Physiolab® for technical support.
'CARTRIDGE REMOVED' DISPLAYED	Tank is not detected as being in place.	Ensure the tank is filled to the level shown in section 2.6. Push the tank down firmly to click it into place.
WATER POOLING UNDERNEATH UNIT	Water spillage / leaking.	Please note that condensation can create small amounts of water. This can be expected and is normal. If there is a large amount of pooling, check you have tightened the tank lid fully. If leak continues contact Physiolab for technical support.
THERAPY PACK GETTING COLD	Cold water is not flowing through the therapy packs.	Check that the tank has been filled with ice and water as described in section 2.6. Check the hose and pack are connected firmly. Check the hose and pipes are not kinked.
ERROR 103 DISPLAYED	Safety system stopped therapy.	Disconnect and reconnect the power jack to restart the S1 then retry therapy. If the fault is persistent phone Physiolab® for technical support

3.3 TROUBLESHOOTING

EVENT	DESCRIPTION	SOLUTION
ERROR 106 OR ERROR 806 DISPLAYED	Pressure measurement too high.	Check the hose and therapy pack are connected firmly. Check the hose and pipes are not kinked.
ERROR 110 DISPLAYED	An existing error has occurred.	Disconnect and reconnect the power jack and retry applying therapy.
ERROR 206 DISPLAYED	Therapy pack inflation took too long.	Check therapy pack connectors are fully clicked together. Ensure therapy is wrapped snuggly around the patient, with velcro secured.
ERROR 851 DISPLAYED	No warming detected on the therapy pack.	Ensure the therapy pack is applied to the skin without heavy clothing.
ERROR XXX OTHER NON-LISTED ERROR NUMBER DISPLAYED		Contact 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 WARNING, CAUTIONS AND SIDE EFFECTS

⚠ 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® S1 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 1 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

No modification of this equipment is allowed.

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

'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 WARNING, CAUTIONS AND SIDE EFFECTS

⚠ WARNING

Using the Physiolab® S1 System contrary to instructions, or using incorrectly fitting Therapy Packs may result in permanent tissue damage.

It is important when using the Physiolab® S1 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.

- 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

Ensure the Tank is filled with water and ice only.

3.4 WARNING, CAUTIONS AND SIDE EFFECTS

⚠ WARNING

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

⚠ WARNING

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

⚠ WARNING

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

⚠ WARNING

Do not use in the presence of flammable gases, or in oxygen rich environments.

⚠ CAUTION

Tighten the Tank lid fully to ensure it does not drip. Always place the device on a wipable surface. Wipe up any spillages which do occur during use with the unit.

⚠ 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® S[1] 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 transmitter 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® S[1] System is used exceeds the applicable RF compliance level above, the Physiolab® S[1] 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® S[1] 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® S1 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 should not be stored outdoors.

> ⚠ **WARNING**
> Do not use outside listed operating conditions.

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

IP RATINGS:	
S1 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
Tank	2002

MECHANICAL SPECIFICATION:	
External Dimensions (mm)	244 (h) x 430 (w) x 341 (d)
Weight (empty)	7.8 Kg
Weight (full Tank)	13.4 Kg

THERAPY DELIVERY:	
Temperature	6°C - 12°C (+/- 1.0°C)
Pressure	15mmHg - 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 L (approx.)
Quantity of Ice	2 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)

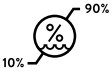
CE 2797

Compliant to the Medical Device Directive 93/42/EEC with 2797 as the Notified Body reference number.

Supply Mains Rating -
Class II

Supply Frequency

Fuse Value



Packaging -
Humidity Limit

Packaging -
Keep Away from Rain

Expiry Date YYYY-MM-DD

Read the instructions for use

Mandatory to read
instructions for use

REF

The device's Reference or Model Number (Type)

SN

The device's unique Serial Number

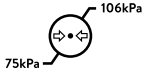
Applied Part Type BF or Applied Part Type BF Connection

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

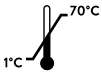
Period after opening

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

EC	REP

Medical Device Management Ltd
Block B, The Crescent Building,
Northwood, Santry, Dublin 9, D09 C6X8, Ireland

3.11 WARRANTY

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

CE
2797

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

PHYSIOLAB

REPAIR • RECOVER • RESTORE

ORIGINAL INSTRUCTIONS

PHYSIOLAB® S[1] – USER MANUAL DOCUMENT DI1-006 ISSUE 1.0.36