

STRAVA SPLINT BATH USER MANUAL

SMART Model

REF 100.600 (U.S. Plug)

REF 100.600E (Euro Plug)

REF 100.600A (Australia Plug)

REF 100.600UK (U.K. Plug)

Basic Model

REF 100.601 (U.S. Plug)

REF 100.601E (Euro Plug)

REF 100.601A (Australia Plug)

REF 100.601UK (U.K. Plug)

This manual must be given to the user of the product. Before using this product, this manual must be read and saved for future reference.



Manufactured by:
PIVOTAL HEALTH SOLUTIONS
3003 9th Ave SW
Watertown, SD 57201 USA



PATENT PENDING

CONTENTS

Inspection	3
Contents of Box	3
Safety	3
Symbols	4
The Purpose of this Manual	5
Instructions for Proper Use	5
Indications for Use	5
Product Description	5
Responsibility of the User	5
Technical Data	6
Safety Certifications	6
Instructions	7
Initial Set Up	7
Cleaning Instructions	10
Troubleshooting	12
Replacement Parts	12
Warranty/Replacements	13
Service Life	13
Storage and Handling	13
Contact the Manufacturer	13

STRAVA SPLINT BATH USER MANUAL

Inspection

Prior to shipment, the water baths are subjected to a thorough safety-related and functional quality control and are carefully packed.

Check **ALL** parts for shipping damage. If shipping damage is noted, **DO NOT USE**. Contact dealer/manufacturer for further instruction.

Products may only be returned in undamaged cardboard packaging - primarily the original cardboard packaging.

Contents of Box

- 1. Splint Bath Standard REF 100.600
- 2. User Manual REF 400.600
- 3. One of the following:

Power Cord (US) REF 300.107

Power Cord (Euro) REF 300.154

Power Cord (UK) REF 300.155

Power Cord (AU) REF 300.153

(do not use a detachable mains power cord with inadequate ratings to the Strava cord)

- 4. 6 ft Drain Hose REF 200.101
- 5. Strainer REF 300.131
- 6. Priming Bulb REF 300.173 (SMART Model)
- 7. Inline Filter 300.231 (Qty 2)

Safety

The safety section contains important information for the safe operation and use of this product. Read this information, the Care Card, and any other safety information included with the product before using the splint bath.



WARNING

To avoid electric shock, connect the instrument to properly earth-grounded, GFCI protected, 3-prong receptacles only. Failure to observe this precaution can result in severe injury.

The Electric Shock Symbol is used to indicate a hazard arising from dangerous voltage. Any mishandling could result in severe injury or death. The Exclamation Symbol appears in Warning and Caution statements.

SYMBOLS



Signal words are used in this manual and apply to hazards or unsafe practices which could result in personal injury or property damage. See the information below for definitions of the signal words found either on the splint bath or in this manual.

See page 6 for safety certifications



This symbol designates where personal injury or damage to the equipment is possible.



DANGER!

Danger indicates an imminently hazardous situation which, if not avoided, will result in death or serious injury.



WARNING!

Warning indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury.

** Failure to follow these instructions could result in damage to your new heating appliance and/or injury



CAUTION!

Caution indicates a potentially hazardous situation which, if not avoided, may result in property damage or minor injury or both.



Electric Shock

The Electric Shock Symbol is used to indicate a hazard arising from dangerous voltage. Any mishandling could result in severe injury or death.



Caution, consult the instructions for use.



Keep dry



Refer to User Manual



Year of Manufacture



Catalog Number

THE PURPOSE OF THIS MANUAL

This User Manual is mainly focused on the set up, cleaning, operation and routine maintenance of the Strava Splint Bath. These instructions help avoid dangers and repairs while increasing product reliability. Keep this manual for future reference.

Instructions for Proper Use



Please read these instructions carefully before using the water baths. These instructions will help avoid dangers, unnecessary repair costs and down times. Following these instructions will increase the reliability and life of the product.

The water bath is only intended for the heating of thermoplastic material for medical use.



- This water bath is not suitable for direct heating without using water.
- The heating of food and drinks, as well as other pharmaceutical and medical products, is not allowed and constitutes improper use.
- Direct application on the patient is not allowed.

Indications for Use

The Strava Splint Bath is intended for use as a reservoir in hospitals, clinics and other medical facilities to heat and soften thermoplastic used in the splinting process. The device is intended for indoor use only.

Product Description

Strava Splint Bath is a reservoir made of a thermoset composite material that holds and heats water. The water bath allows for thermoplastic splint sheets to be softened and made pliable to form to the body. Both models (SMART and BASIC) feature a custom LCD touch display for accurate water temperature readings, user controlled water temperature and time

settings, water evacuation, stainless steel hinged lid, low water sensor, thermostat water temperature regulator (+/-2F), and holds approximately 5 gallons of water. The SMART version additionally has thermoplastic sheet presets, user presets, two independent filtration mechanisms and dual disinfection systems: UV-C germicidal kill light, and a high-heat sanitation cycle that heats the water temperature to kill levels.

Responsibility of the User

This product guarantees safe operation if installed, operated and maintained in accordance with general safety rules. The operator of this device must read and understand this manual and be trained in occupational therapy methods. All operators are to be aware of the relevant dangers of using a hot water bath and exercise measures to avert such dangers. In case of spillage of hazardous materials on or inside the bath, operator must properly decontaminate the unit.



TECHNICAL DATA

Technical Specifications Strava Splint Bath

Strava SPLINT BATH	UM	Spec
Operating Temperature Range	F	140° - 180° F
	С	60° - 82° C
Sanitation Mode	F	185°
	С	85°
Temperature Variability	F/C	2°
Set Time	Seconds	30 - 180
Over Voltage	W	11
Frequency	Hz	50/60 Hz
Mains Voltage (+/- 10% of nominal voltage)	V	100-120 VAC, 200-240 VAC
Power Consumption	W	1100W
AC Current (Max)	A	12 amps
Water Fill Capacity	Gallons	5.2 G
	Liters	20 L
Water Fill Height	in	5"
	cm	12.5 cm
Unit Weight	lbs	35 lbs
	kg	15.9 kg
Unit Dims Outer (LxWxH)	in	22.625"L x 19.75"W x 10"H
	cm	60cm L x 52cm W x 25.5cm H
Unit Dims Inner (LxWxH)	in	19"L x 12"W x 6"H
	cm	48cm L x 30cm W x 15cm H
Unit Shipping Weight	lbs	47 lbs
	kg	21 kg
Unit Shipping Dims (LxWxH)	in	26.5"L x 23"W x 16"H
	cm	67cm L x 59cm W x 41cm H
Standard		IEC 61010-1, -2
		UL 61010-1, -2
		CSA C22.2#61010-1, -2
		CB SCHEME
Environment (Altitude)		
Operation (Max)	ft	16,732 ft
	m	5100 m
Storage (Altitude)	ft	16,732 ft
	m	5100 m





Safety Certifications

European Union CE mark.

The CE mark indicates that this product satisfies the relevant requirements of EC Directives.

Waste Electrical and Electronic Equipment (WEEE)



This symbol on the product or on its packaging indicates that this product must not be disposed of with regular waste. Instead, it is the user's responsibility to dispose of waste equipment according to the local laws. Separate collection and recycling of the waste equipment at the time of disposal will help conserve natural resources and ensure it is recycled in a manner that protects human health and the environment. For information about where the user can drop off the waste equipment for recycling, please contact your local waste collection authority.



Production Certification Mark

PATENT PENDING

INSTRUCTIONS

Tap water is required for the **unit to run correctly.** Follow these proportions if you are in a hard-water environment and require distilled water.



WARNING: Do not start the unit if the cable or plug is damaged, or if there are obvious, visible defects to the unit.



FILLING THE SPLINT BATH

TAP WATER IS REQUIRED FOR THE UNIT TO RUN CORRECTLY. FOLLOW THESE PROPORTIONS IF YOU ARE IN A HARD-WATER ENVIRONMENT AND REQUIRE DISTILLED WATER.



Initial Set Up

- Unpack the splint bath and place on a level surface that is capable of bearing the bath and water load. Be sure there is adequate space between the vent and wall for ventilation. Make sure that all packaging materials are cleared from the reservoir.
- 2 Plug the Strava supplied power cord (do not use any other power cord other than supplied by Strava) into the back of the unit and a dedicated wall receptacle. (Protective Earthing - a dedicated electrical circuit is required).
- Fill the reservoir with water just above the water sensor (approximately 2"/5cm).
- Turn unit on flip the switch at the back of the unit to turn the unit "on." At initial powering up of the bath, the start up wizard will display on the LCD screen to prompt user to set

time, day of the week, and temperature mode.

- Unit must be primed before operation (SMART model). Squeeze the supplied priming bulb (outside of the water) until it is fully deflated and hold. Then insert it into the priming port located at in the water tub. Release the bulb to pull water from the port until it is fully inflated then remove it from the port. You should see the water start to bubble at the port. If this doesn't occur, repeat up to 3 times. Once the water bubbles, the unit is primed. This process removes any trapped air in the tubes and allows the pump to engage.
- Continue filling the tank to desired water level or to the bottom of the internal hinge line.

General Use:

- Once the unit is filled to desired water level, the power is on, the preset is fixed, and the set temperature has been reached, the unit is ready for the thermoplastic materials.
- Insert the splinting material into the reservoir, being careful not to splash hot water outside the tank.
- Press start (green button with arrow on home screen). At any time during a session, the timer can be paused and restarted from the beginning or from the time the unit was paused.
- To maintain an accurate water temperature, retain heat, and minimize evaporation, keep lid closed.
- Use caution when retrieving the material from the bath. Apply the material to the patient as per the splint manufacturer's instruction.
- Maintain sufficient water level at all times. (approx 3"/7.62cm deep).



Water Sensor

Priming Bulb

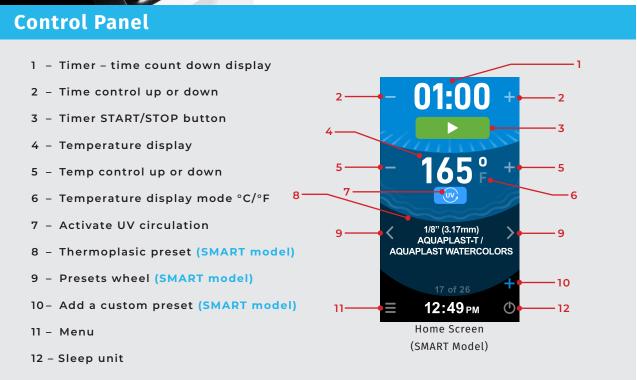


INSTRUCTIONS



Touchscreen LCD Display

The touchscreen LCD display lights up when the unit is turned on. The control panel functionality provides the user with options to customize the device for their needs.

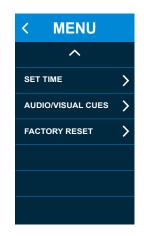


Home Screen

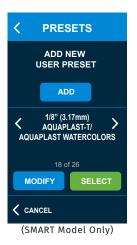
The home screen consists of the session timer, water temperature, UV circulation (SMART model only), thermoplastic presets (SMART model only), menu, and sleep icon.

Note: Presets are factory installed temperature and time suggestions that are specific to the thermoplastic selected and only available on the SMART model. These are recommendations provided by the thermoplastic manufacturer. Time and temperature can be changed prior to or during a session by depressing – or + on the home screen. View all factory presets with the horizontal scroll on the home screen with < or >.











Menu

Set auto on/off – this feature automatically sets "off" time (sleep) and "on" time (wake) for specific days of the week. Factory default is off. This feature preheats the water to reach set temperature prior to a session starting and to save energy in the evening when not in use. Power must be on for this function to work properly.

Sanitation cycle (SMART Model) – The sanitation cycle is an optional, secondary disinfection of the unit by increasing the water temperature to an extreme high heat for 5 minutes to kill microbes. Strava highly recommends daily sanitation of the splint bath. The sanitation cycle factory default is "off".

- A nightly sanitation cycle can be set by engaging the "auto sanitation" feature to set days and time. After the sanitation cycle is completed, the unit will return to last preset used or sleep mode if auto on/off has been set.
- You may also manually activate the sanitation cycle when the "start" button is depressed and sanitation water temperature is reached. At the conclusion of the cycle, the water temperature last used will be resumed.
- RISK OF SEVERE BURN!
- Keep the lid closed during sanitation cycle. Do not insert any thermoplastics or any other materials into the bath during sanitation cycle. Do not put hands or appendages in the water.

Helpful Tips – this screen provides the user with helpful tips and information about the Strava splint bath.



Presets (SMART Model) – in addition to the factory presets, the user can program desired presets by name. Up to 50 user-defined presets can be stored in the unit. The default time for a new user preset is 1:00 minute and the default temperature is 155° F/68° C.

- Add a new user preset two ways: 1. go to presets in the menu, click +, enter the material size (if desired), the sheet name, and adjust the time and/or temperature with and +. Click save after each selection. 2. From the home screen, click the + in the bottom right corner beside the displayed preset. Enter the material size (if desired), the sheet name, and adjust to the desired time and/or temperature with the and +. Click save.
- To modify an existing preset: go to presets in the menu, click on modify, make desired time and/or temperature change with and +. Click save.
- Note: factory preset names cannot be changed or deleted. User defined presets can be removed.

Temp settings – set in degrees Fahrenheit (F) or Celsius (C). Factory default is F.

Set Time - set the real time clock with scroll wheel in either 12 hour or 24 hour time display. Factory default is 12 hour display mode.

Audio/Visual – adjust the screen brightness and the volume of auditory signals. A beeping sound engages the last ten seconds of a session to alert the user.

Factory Reset CAUTION! by clicking reset, all factory defaults will be restored and all user-defined presets will be erased.

INSTRUCTIONS CONT.

Cleaning the bath



Frequency – Two or more times monthly. Strava recommends each facility determine its cleaning frequency based on usage, water grade, visual inspection, and sanitation protocols that apply to your facility and/or JCAHO. Consult manufacturer if there is any doubt of the compatibility of decontamination or cleaning agents.

Strava SMART Splint Bath



TURN UNIT OFF FROM THE SWITCH ON THE BACK OF THE UNIT AND EVACUATE



See pg. 11 for procedure.



ADD WATER & CLEANING SOLUTION

Fill unit just above the water sensor with a 2:1 ratio of tap water to cleaning solution.



Cleaning Solution = Vinegar -OR- Coffee Machine Commercial Descaler



TURN THE UNIT BACK ON and leave it running for 20-30 minutes to allow the water/cleaning solution mixture to heat.



EVACUATE WATER

Wait 10 minutes then evacuate water. See pg. 11 for procedure.



TURN UNIT OFF

Unplug and allow unit cool down before proceeding.



CLEAN BI-FOLD LID & INSIDE WATER BASIN



Using a Scotchbrite® Scour Pad or cloth, wipe the inside tub with warm water. To remove scum, waterlines, mineral deposits, etc., add a mild detergent. Be sure to <u>rinse thoroughly</u> and wipe dry. Do NOT use bleach, ammoniabased cleaning products, or extra abrasive products such as steel wool.



CLEAN INLINE FILTER

Remove the thermocouple inline filter found inside the water basin beneath the grate to clean debris. See pg. 11 for procedure for removal and cleaning. Return the cleaned inline filter to the thermocouple.



REFILL WITH WATER

Fill unit to operating level with tap water. See initial set up section if you use distilled water.



9 TURN UNIT ON

• Repeat procedures if necessary

Strava BASIC Splint Bath



TURN UNIT OFF FROM THE SWITCH ST ON THE BACK OF THE UNIT AND **EVACUATE WATER**



See pg. 11 for procedure.



ADD WATER & CLEANING SOLUTION

Fill unit just above the water sensor with a 2:1 ratio of tap water to cleaning solution.



Cleaning Solution = Vinegar -OR- Coffee Machine Commercial Descaler



TURN THE UNIT BACK ON and leave it running for 20-30 minutes to allow the water/cleaning solution mixture to heat.



EVACUATE WATER

Wait 10 minutes then evacuate water. See pg. 11 for procedure.



TURN UNIT OFF

Unplug and allow unit cool down before proceeding.



CLEAN BI-FOLD LID & INSIDE

WATER BASIN

Using a Scotchbrite® Scour Pad or cloth, wipe the inside tub with warm water. To remove scum, waterlines, mineral deposits, etc., add a mild detergent. Be sure to rinse thoroughly and wipe dry. Do NOT use bleach, ammoniabased cleaning products, or extra abrasive products such as steel wool.



REFILL WITH WATER

Fill unit to operating level with tap water. See initial set up section if you use distilled water.



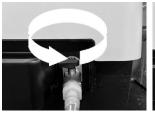


8 TURN UNIT ON

• Repeat procedures if necessary

Water Evacuation

- Turn unit off using the power switch at the back.
- Allow the water to cool before water evacuation.
- Be sure that the supplied drain hose is properly inserted at the back the unit.
- Turn the quarter turn valve counter-clockwise to release the water.





Inline Filter Cleaning (SMART Model Only)

Your Strava Splint bath is fitted with a small inline filter which protects against small impurities and debris which can accumulate over time and clog the system

- 1. Evacuate the water
- 2. Using the supplied Allen key, loosen the filter (an additional inline filter is included in the side storage bin)
- 3. Wiggle the filter off of the thermocouple
- 4. Clean all debris from the screen (hint: run under water and remove debris with toothbrush or toothpick)
- 5. Fit the cleaned filter back on the thermocouple by wiggling it into place (screw head facing out)
- 6. Using the supplied Allen key, tighten the filter ensuring that it is properly aligned and close to the hole

Annual Recommended Maintenance

Annual maintenance, or more frequently based on usage, sanitation protocols, and type of thermoplastic materials used.

Cleaning the Secondary Inline Filter (SMART Model)

The secondary inline filter will catch any remaining debris that the basin stainless steel filter may not have caught

1 REMOVE BACK PANEL

While the unit is off, drained of water, remove the four screws the back panel exposing the secondary inline filter.

2 LOOSEN THE CAP

Loosen the cap by turning counter clockwise to the left by hand.

3 CLEAN THE MESH STRAINER

Pull the mesh strainer out to check for any debris collection. Clean mesh strainer by rinsing it under water. Use a toothbrush if needed to remove any stuck-on matter.

4 REMOVE RESIDUAL WATER

Using the provided priming bulb (SMART model only), suck out any residual water/debris pooled at the bottom of the filter bowl. This may take several squeezes of the priming bulb.

5 REASSEMBLE

Replace the mesh strainer into the reservoir. Tighten cap back on by turning clockwise to the right. If the gasket becomes wrinkled, loosen and reassemble or order a new one. Screw the back panel into place. Replacement gaskets are available.











Changing the UV-C Bulb (SMART Model)

Visit the service area at www.stravasolutions.com for video instructions on changing the UV bulb.

Carefully remove the black rubber boot from UV housing allowing the lamp to slide out of the housing. Disconnect the lamp from connection on both ends.

Troubleshooting



Over temp:

If the unit exceeds 195°F (91°C) turn off main power and contact technical service at technicalsupport@stravasolutions.com.



Low water:

- 1. If there is water in the reservoir, make sure that the tank is NOT filled exclusively with distilled water. The unit must have (1) cup of tap water per (1) gallon of distilled water for the sensor to register the water level. If there is tap water in the reservoir, turn off the main power and contact technical service.
- 2. If there is no water in the reservoir, turn off the main power and investigate possible causes water evaporation or unit leakage.
 - Water evaporation always maintain adequate water volume in the tank.
 - Water leakage turn off main power and contact technical service.

UV lamp defective (SMART Model):

Turn main power off. Unplug cord from unit and wall. Remove rear access panel via 4 screws. Carefully remove black rubber boot from UV housing, allowing the lamp to slide out of the housing. Disconnect lamp from connectors on both ends. Replace bulb. Reconnect at both ends and insert new bulb back into the housing. Attach rear access panel. Dispose of defective bulb according to local regulation. In the event the error message "UV Lamp Defective" remains after the new bulb replacement, contact technical service to obtain a software upgrade. Visit the service area of www.stravasolutions.com for bulb changing video.

Pump occlusion (SMART Model):

Refers to blockage in the water system.

- 1. If evacuating the water, stop evacuation mode and contact technical service.
- 2. In standard operation, turn off the main power and contact technical service.

Temp sensor error:

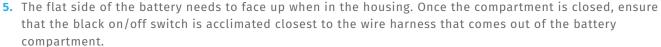
Refers to the water temperature exceeding 195°F (90.5°C). If the over temp error message displays:

- 1. While evacuating the water, pause evacuation, wait for the water to cool, then resume evacuation. Unplug cord from unit and wall. Contact technical service.
- 2. During standard operation, unplug cord from unit and wall. Contact technical service.

Replacing the battery:

It is recommended to replace the battery annually to prevent loss of all custom settings.

- 1. Turn the unit off with the switch at the back of the unit.
- 2. Remove the (5) m4 screws on top of the display bezel.
- 3. Carefully tilt the bezel on its side, insuring the black USB cable remains intact.
- Proceed to open the plastic battery housing and replace with a fresh battery LIR2032 rechargeable battery.







Check the power cord and plug for excessive wear or fraying. Replace as needed. Do not use a detachable mains power cord with inadequate ratings. Only replace with a Strava power cord.

Software Upgrades:

In the event a software upgrade is required, the manufacturer will provide you with a new version of software to upload via USB stick.

- Make sure unit is off
- Remove the back panel of the unit by removing the four screws with a #2 Phillips screwdriver
- · Locate the USB connector
- Insert the USB stick into the connector
- Turn the unit on
- •The software upgrade is complete when the set up wizard appears on the screen

Warranty/Replacements

Strava warrants that its products are free from defects in material or workmanship. Under normal use and following all guidelines defined in this manual, Strava splint baths are warrantied for a period of one year from when product is received (two years outside the USA). Should replacement or repair be required, purchaser must notify dealer or manufacturer in writing. After obtaining an RA (returned goods authorization), product must be returned in original packaging.

Service Life

We estimate a service life of five years for this product, provided it is used in strict accordance with the intended use as set out in this document and all maintenance and service requirements are met. The estimated service life can be exceeded if the product is carefully used and properly maintained, and provided technical and scientific advances do not result in technical limitations. The service life can also be considerably reduced by extreme or incorrect usage. The fact that we estimate a service life for this product does not constitute an additional warranty. Strava will provide replacement parts for up to 10 years from date of purchase.

Storage and Handling

It is recommended the following guidelines are used whenever this system is being stored or transported to another location:

Pollution degree	2
Environment (Temperature)	Operation: 32° F – 104° F (0° C – 40° C)
	Storage: 32° F – 140° F (0° C – 60° C)
Environment (Humidity)	Operation: Up to 80%
	Storage: Up to 90%, non-condensing

Contact the Manufacturer

General Information:

email: info@stravasolutions.com

tel: 800.743.7738

Technical Service:

email: technical support @strava solutions.com

tel: 800.743.7738

www.stravasolutions.com





MANUFACTURED BY:

Pivotal Health Solutions

3003 9th Ave SW

Watertown, SD 57201 USA

TEL:800.743.7738

EMAIL: info@stravasolutions.com

technical support @strava solutions.com

www.stravasolutions.com