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Owner's Manual

PAK2-P

"Pelican case" iv fluid warmer, by *Smithworks*

FDA 510K #K060851 CE

Read all information carefully **before** installation and use!

This manual should accompany the unit

and be held as a reference tool by the end user.

Visit our website:

www.smithworksmedical.com

Email: sales@smithworksmedical.com

The PAK2-P iv fluid warmer, by *Smithworks* is a rugged, water resistant iv fluid warmer, built for service where rugged durability is of paramount concern. The PAK2-P is housed in a Pelican Case™ (model 1450), and uses the time proven electronics of *Smithworks*.

The PAK2-P iv fluid warmer, by *Smithworks* is 40 watt, 12 volt dc and draws 3 amps intermittently. Cool fluid is warmed by conduction. The thermal rate of rise is ½° Fahrenheit per minute. Once heated to 99°F - 101°F (37.2°-38.3°C); the unit maintains that temperature until the iv solution is removed from the heating surface, or when power to the device is inadequate, absent, or when the unit is turned off.

User Information for the PAK2-P™ iv fluid warmer "rev 6"

The following information will serve as a guide to most of the questions concerning the installation, operation, and maintenance of the PAK2-P iv fluid warmer, by Smithworks.

- ***Special note: Units ordered with the optional 120 vac to 12 vdc adapter (part# 12VRFE) are not subject to the installation instructions listed as 1B, 1C, and 4. Only use power cord sets or converters supplied by Smithworks Medical, Inc. Any alterations or substitutions will void our product liability insurance coverage.***

1) ***Installation***
   A. The PAK2-P iv fluid warmer, by *Smithworks* is a portable compact case measuring 16" X 13" X 6.9". The warmed area inside is designed to warm 3 liters, & measures 10.5" X 8.75" X 3.25".
   B. This unit comes standard with a 12 vdc power cord set. The 12 volt cord set has a barrel jack connector on one end that plugs into quick disconnect barrel jack in the side of the Pelican box. The other end of the cord set has a standard fused cigarette lighter jack. This end should be plugged into a fused receptacle (7 amp fuse recommended).
   C. We recommend that the receptacle be connected to the 12 vdc output side of your battery conditioner. Be certain to have a 7 amp in line fuse between the battery conditioner and the cigarette lighter receptacle. Failure to equip your emergency vehicle with a battery conditioner could result in a vehicle under voltage issue, preventing the vehicle from starting. If you intend to use 12 vdc, you need a battery conditioner. Failure to follow these guidelines will void the warranty and disqualify the user from our product liability insurance coverage.
   D. After establishing "full time power" (the female cigarette lighter power jack should be powered up at all times), plug the fused cigarette lighter jack into the receptacle. Plug the other end of the cord set into the iv fluid warmer. Inside the unit is a green power switch. Rock the power switch to the "ON" position. The green switch should be lit, & the unit should be operational. Heater ramp up time should take approximately five minutes with no iv fluid bags loaded in the iv fluid warmer.
   E. Position the PAK2-P iv fluid warmer, by *Smithworks* in the desired location. Some care should be taken to assure the unit will not slide around during response.

2) ***Design***
   A. The PAK2-P iv fluid warmer, by ***Smithworks*** is designed to operate on 12 vdc and draws 3 amps intermittently. The power draw frequency and duration will vary due to ambient temperatures and frequency of loading cool fluids on the unit to be warmed.
   B. The heating element is fixed to the underside of the iv fluid warmer. A thermister and thermal fuse are built into the heating element. A circuit board controller is mounted within the enclosure, below the switch.
   C. Three (3) liters may be in the concave area of the iv fluid warmer.
   D. Always be sure to use crystalloid fluids only. Normal saline and ringers lactate are examples. Do not warm any protein based fluids. These will deteriorate rapidly and may become toxic to your patient. **Appropriate fluids (crystalloid) should remain in the double bag as received by the manufacturer. Do not remove the outer bag until you are ready to use it. Only use iv fluids that are double bagged.** Fluids should not be intentionally warmed beyond a two-week period. Date the outer bag when it is loaded onto the iv fluid warmer. If 2 weeks pass and the bag is unused, rotate it into an area where it will not be intentionally re-warmed.

3) ***Maintenance***
   A. Daily confirm the temperature of the fluids. The PAK2-P iv fluid warmer has a digital temperature readout located above the switch. This displays the temperature of the warmer. Newly loaded fluids may be cool, while the temperature indicator remains at the set point. A properly warmed iv fluid bag can be judged by its relative temperature to your hand. It will feel warm but not uncomfortable.
   B. **Clean the surface of the warmer with mild soap and water only.** Use a moistened towel or sponge. Do not soak the unit.
   C. Weekly check iv fluids for solution clarity and expiration date(s) marked.

4) ***Important information***
   - Use the appropriate power cord set as supplied. Do not alter any of the equipment, including the cord set. If you choose to use a 120 vac to 12 vdc power converter, use only our equipment. The part number is “12VRFE”. Failure to follow this guideline will void any warranty and disqualify the product liability insurance coverage.

*Thank you for selecting the PAK2-P iv fluid warmer by **Smithworks**!*

Douglas M. Smith, President

Warranty

3 year limited warranty

- The PAK2-P iv fluid warmer, by ***Smithworks*** is built to the highest attainable standards of ***Smithworks Medical, Inc.***
- Any unauthorized alterations or service of the equipment voids the warranty and disqualifies the end user from our product liability insurance coverage.
- Any evidence of disturbance of the internal workings or entry to the internal workings will void the warranty and disqualify the end user from our product liability insurance coverage.
- Failure to use the specified power (12 vdc) or any alterations to power supply delivery systems will void the warranty and disqualify the end user from our product liability insurance coverage.
- Physical abuse or water damage will void the warranty and disqualify the end user from our product liability insurance coverage.
- Any alterations or penetrations of this equipment will void the warranty and disqualify the end user from our product liability insurance coverage.

What is our policy on warranty? In all cases, follow the above parameters for use or service.

1st year we will cover parts, labor, & freight. Outside Contiguous USA (lower 48), freight charges to be paid by the customer.

2nd year we will cover labor, & freight. Outside Contiguous USA (lower 48), parts, & freight charges to be paid by the customer.

3rd year we will cover ½ the labor cost. Parts, freight & ½ labor to be paid by the customer.

This warranty is designed to protect the buyer and the manufacturer. We are confident no problems will arise; however, we extend a three (3) year limited warranty "the unit will function as represented." Should a failure occur, we will repair the unit. This warranty covers the repair or the replacement of the unit and is limited to such.

Indications for use

- 20% of all trauma patients become hypothermic. The 2 major causes include exposure to the environment and/or the infusion of below normal body temperature of iv fluids.
- Geriatric patients who are sick or injured often become hypothermic due to the reasons listed throughout this text, plus a slower metabolism.
- Pediatric patients have a relatively fast metabolism but a small body mass and are susceptible to exposure in moderate to inclement weather conditions.
- Burn patients require rapid cooling of the burn area and may require large infusions of fluid due to plasma loss through the burned areas of the body. They are at high risk of lowered body core temperatures.
- Patients exposed to moderate temperatures may easily develop hypothermia. Even inside a home in the summer, an elderly patient with a hip fracture, lying on a tile floor can rapidly become hypothermic.
- An immersion into a cold body of water (70° F or lower) leads to very rapid loss of body temperature. Heat travels to cold and the body is in direct contact with a circumferential heat sink. Hypothermia is a high hazard for these patients.
- Patients without hypothermia may develop mild to moderate hypothermia from a below normal body temperature infusion of iv fluids.
- For each degree Fahrenheit that a patient's body core temperature drops, medications are 10% less effective. Infusion of cold iv solutions may result in a moderate body core temperature drop that may have a significant detrimental effect in the patients that require medications during these efforts.

When a sick or injured patient described above becomes hypothermic, the body will divert energy to attempt thermoregulation, further compromising the patient, possibly worsening the outcome of the attempted patient care rendered by personnel.

It is in the best interest of the patient and the care provider, to initiate therapy that has the greatest potential of a favorable outcome. This includes the use of warmed iv fluids in the care of the sick or injured patients if you have access to a warm iv solution, provided it falls within your scope of practice.

Special Circumstance Protocol Recognition

We recognize “good patient care” advancements and protocols are addressing “post-resuscitation” induced hypothermia, to decrease morbidity and mortality outcomes.

In addition, protocols are being developed and implemented to address spinal cord injuries as it pertains to reduced patient core temperatures.

These new protocols and treatment efforts will require new advanced equipment development.

Smithworks Medical, Inc. is dedicated to addressing these issues. We pledge our efforts to nothing less than excellence.

Douglas M. Smith, President

Trouble Shooter

This is a supplementary document to the Owner's Manual for the PAK2-P iv fluid warmer, by *Smithworks*.

If the unit fails to operate properly during initial installation or develops trouble while in operation, please refer to this document. Often times the trouble found is associated with inadequate vehicle voltage or a broken power cord set. The unit is designed to operate at 12.0 vdc – 14.0 vdc. If the power source drops below 12.0 vdc, the unit will not operate.

Special note: If any of the procedures below are beyond your ability, please present this information to a qualified mechanic.

We just installed the unit and the unit doesn't heat. The green switch is not lit.

1. Assure that the power source is 12.0 volt direct current or higher (12v – 14v).
2. Check for current at the barrel jack end of the cord set.
3. If there is power at the source but absent at the end of the cord, check the fuse in the cigarette lighter jack.
4. Check for an in line fuse (recommended safety installation feature).
5. If trouble persists, return the entire unit and cord set for evaluation.

The unit overheats the solution.

1. Be sure the solutions remain double bagged. The double bagging has an "R factor" and is calculated into the set point of the iv fluid warmer.
2. Check the actual temperature of the solution in question. The fluid should measure 99°F - 101°F.
3. If the fluid temperature is higher than 102°F, return the entire unit for service.

Call 1-800-576-3454 for a "*Return Materials Authorization"* number.

Address all returns to:

Douglas M. Smith

Smithworks Medical, Inc.

18512 US Hwy. 69 North

Lindale, TX 75771

**Please include the Return Materials Authorization (RMA) number and a note or a work order describing the nature of the problem. Include your agency, agency's address, and a contact person's name and phone number.*