

TSC LIFE

Innovation with purpose

Note: Always consult the latest User and Technical Manual of the Fluido Compact.

1. Internal Testing Document: FLC-2015-TS-01
2. Internal Testing Document: 570-0010 PQ Summary Report
3. Internal Testing Document: FLC-2017-TR-06

The use of our medical equipment is solely intended for the use of healthcare professionals. Healthcare professionals have the obligation to exercise their own professional clinical judgment when determining the suitability of a specific product for treating an individual patient. TSC Life does not provide medical advice and strongly advises healthcare professionals to undergo training on the usage of any specific product before using it. Healthcare professionals should consistently refer to the package insert, product label, and/or instructions for use, including guidelines for cleaning and sterilization (if applicable), before utilizing any product supplied by TSC Life. The information presented aims to display specific products and the extensive range of offerings from TSC Life. Availability of products may vary across markets due to regulatory and/or medical practices specific to each region. For inquiries regarding the availability of specific TSC Life products in your area, please reach out to your TSC Life representative

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TSC LIFE

Technical Datasheet

FLUIDO[®] COMPACT SYSTEM



Your everyday, user-friendly
blood and fluid warming solution

[tsc-life.com](https://www.tsc-life.com)

FLUIDO® COMPACT SYSTEM

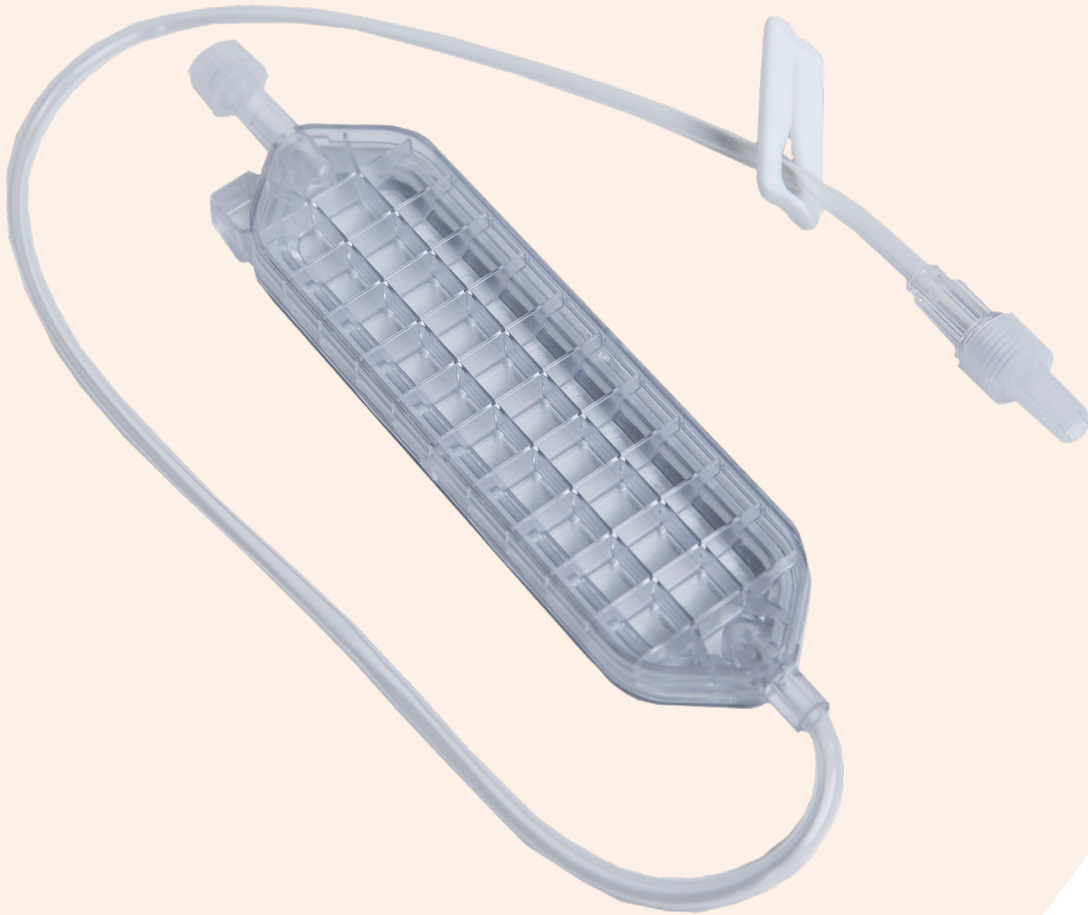
Description	<p>The Fluido® Compact System (REF 650000-US)</p> <p>The Fluido Compact System consists of the Fluido Compact Control Module (REF 650100-US) and Fluido Compact Warming Module (REF 650200).</p> <p>The Fluido Compact System and the Fluido Compact single-use sets are intended for use exclusively with each other.</p> <p>Optional: Fluido Compact Holder for Warming Module (REF 660700), an accessory which holds the Fluido Compact Warming Module in a safe and stable position next to the patient.</p>
Intended Use	<p>The Fluido Compact System can be used in adult patients that need fluid warming prior to administration of blood products and intravenous (IV) fluids, to help prevent hypothermia. The system is intended to be used by healthcare professionals, e.g. nurses, medical specialists, doctors. Only medical professionals shall interact with the system. The devices must only be used on the order of a physician.</p>
Indications for Use	<p>The device can be used with the following products:</p> <ul style="list-style-type: none"> • Plasma • Packed red blood cells • Crystalloid intravenous (IV) fluids • Synthetic Colloid intravenous (IV) fluids <p>The system is indicated to be used in hospitals to help prevent hypothermia. The devices can be used in the full clinical environment.</p>
Single-Use Sets	<p>The Fluido Compact single-use sets:</p> <ol style="list-style-type: none"> 1. Fluido Compact Standard Set 2. Fluido Compact Standard Set with Drip Chamber <p>are for single-use only and can be used for a maximum of 24 hours. These single-use sets shall be used with the Fluido Compact System.</p>

Name, Article Number, Dimensions and Weight

Name	Article Number/REF	Size (height, width, depth)	Weight
Fluido Compact System	650000-US		4.74lb
Fluido Compact Control Module	650100-US	11.22 × 4.72 × 7.68in	3.75lb
Fluido Compact Warming Module	650200	6.50 × 2.95 × 1.97in	0.99lb
Fluido Compact Holder for Warming Module	660700	8.50 × 6.02 × 3.2in	0.66lb



Description	Specification
Article Number/REF	650000-US (Fluido Compact System)
Cleaning and Disinfecting	According to the Technical/User Manual
GMDN	47616
GTIN-14 Code	18719867001554

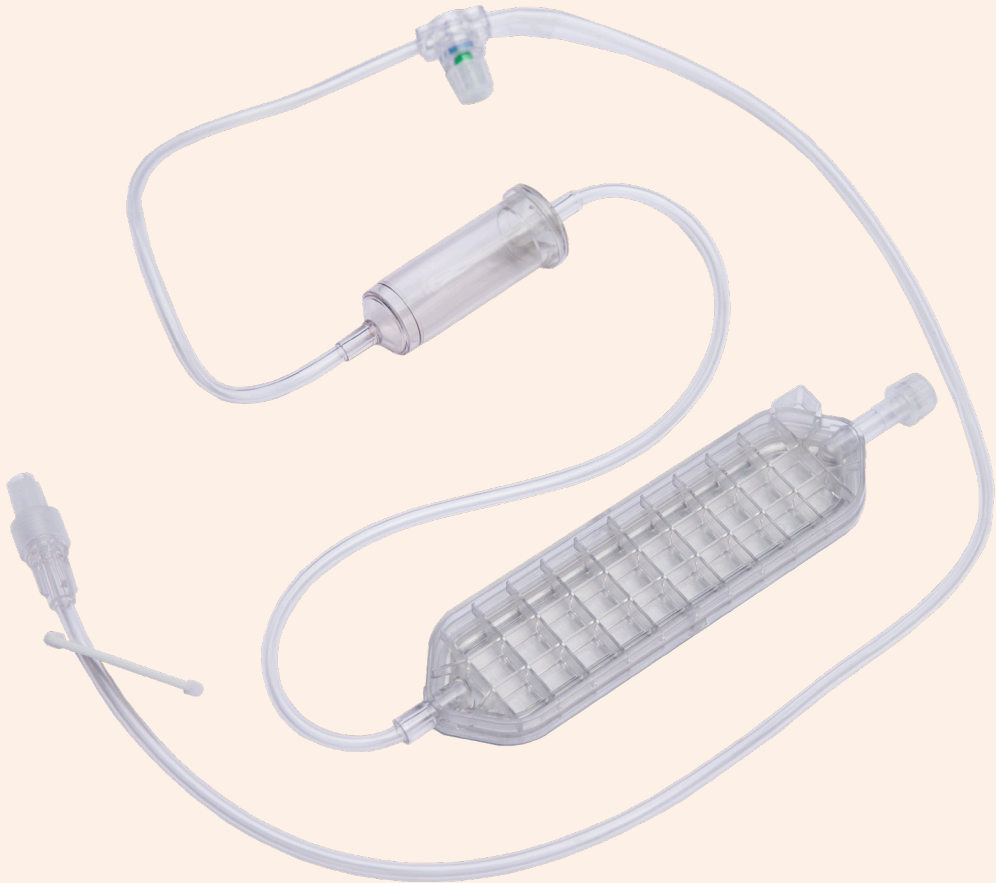


Single-Use Fluido Compact Standard Set

Description	Specification
Article Number/REF	672000
Patient Line	15.75in
Maximum Pressure	300mmHg
Maximum Flow	400mL/min or 24L/hour ¹
Filling Volume	4mL ¹
Storage Volume	5mL with 300mmHg ¹
GMDN Code	47618
GTIN-14 Code Outer Box	18719867001790
Coating	Parylene C coating 4 – 8.5µm ²
Sterilization Method	Ethylene Oxide (EO) Sterilization

Single-Use Fluido Compact Standard Set with Drip Chamber

Description	Specification
Article Number/REF	672100
Patient Line	27.56in
Maximum Pressure	300mmHg
Maximum Flow	500mL/min or 30L/hour ³
Filling Volume	15mL ³
Storage Volume	16mL with 300mmHg ³
GMDN Code	47618
GTIN-14 Code Outer Box	18719867001820
Coating	Parylene C coating 4 – 8.5µm ²
Sterilization Method	Ethylene Oxide (EO) Sterilization





Fluido Compact Holder for Warming Module (Optional)

Description	Specification
Article Number/REF	660700
Materials	Reinforced PA6 (polyamide) and stainless steel
Compatible with	OR table and armrests, IV pole and DIN rail
Drip Chamber Holder	Optional
Multiple positions	Yes
Lock	Spring lock with sound
GMDN Code	61952
GTIN-14 Code	18719867001561

Safety Properties of Fluido Compact Sets

DEHP free.

Does not contain latex or latex components.

No medicinal substances, animal tissue and/or human blood derivatives.

Biocompatible according to ISO 10993, for the intended use.

Packaging

Fluido Compact System

Fluido Compact Control Module:

Carton packaging box, dimensions 14.05 x 10.24 x 10.04in.

Weight 5.51lb.

User Manual, Power supply cord (length 157.48in) and box and unit label are included.

Fluido Compact Warming Module:

Carton packaging box, dimensions 14.05 x 10.24 x 4.53in

Weight 1.98lb

Interface Cable (length 70.87in), Clamp, Instruction Card & Short Instructions for Use (SIFU) and box and label are included.

Fluido Compact Holder for Warming Module

Carton packaging box, dimensions 31.50 x 59.06 x 74.80in.

Weight 0.73lb.

SIFU and box and unit label are included.

Single-Use Fluido Compact Standard Set

Each single-use set is packed in a Tyvek paper peel pouch supplied with a pouch label indicating sterilization by EO process.

4 inner boxes, each containing 30 peel pouches are placed in the carton outer box, containing 120 units total.

The inner boxes are supplied with a box label including an EO indicator sticker.

The outer box is supplied with one IFU and a box label including an EO sterilization indicator sticker.

Dimensions outer carton box 22.83 x 12.60 x 8.07in, weight outer box 13.23lb, weight inner pouch 0.09lb.

Fluido Compact Standard Set with drip chamber

Each single-use set is packed in a Tyvek paper peel pouch supplied with a pouch label indicating sterilization by EO process.

4 inner boxes, containing 15 peel pouches are placed in the outer box carton containing 60 units total.

The inner boxes are supplied with a box label including an EO sterilization indicator sticker.

The outer box is supplied with one IFU and a box label including an EO sterilization indicator sticker.

Dimensions outer carton box 22.83 x 12.99 x 8.86in, weight outer box 10.58lb, weight inner pouch 0.13lb.

Regulatory Information

FDA 510(k) clearance, Class II device.

Classification IEC 60529:

Fluido Compact Control Module IPX1

Fluido Compact Warming Module IPX4

Classification IEC 60601-1

Fluido Control Module Class II Body Floating

Fluido Warming Module Class II Body Floating

Fluido Compact Holder for Warming Module N/A

Electrical Safety Certified Body Certificate by UL.

Recommended Storage Conditions

Fluido Compact System

All components shall be stored in a dry and dark place under warehouse conditions, between -40°C – 50°C (-40°F – 122°F), the atmospheric pressure 50kPa - 106kPa. Keep away from sunlight and rain. The relative humidity shall remain between 10 – 90%. The lifetime of the devices is 7 years.

Recommended Storage Conditions

Fluido Compact Sets

All components shall be stored in a dry and dark place under warehouse conditions, between -20°C – 40°C (-4°F – 104°F), the atmospheric pressure 50kPa - 106kPa. Keep away from sunlight and rain. The relative humidity shall remain between 10 – 90%. The shelf life of our single-use sets is 3 years. Both the manufacturing date and the use by date is indicated on the pouch label.

Waste disposal

According to hospital practice and/or local legislation.

Manufacturer

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