

TSC LIFE

Innovation with purpose

Note: Always consult the latest User and Technical Manual of the Fluidio 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

TSC Life

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TSC LIFE

Technical Datasheet

FLUIDIO® COMPACT SYSTEM



Your everyday, user-friendly
blood and fluid warming solution

tsc-life.com

FLUIDO® COMPACT SYSTEM

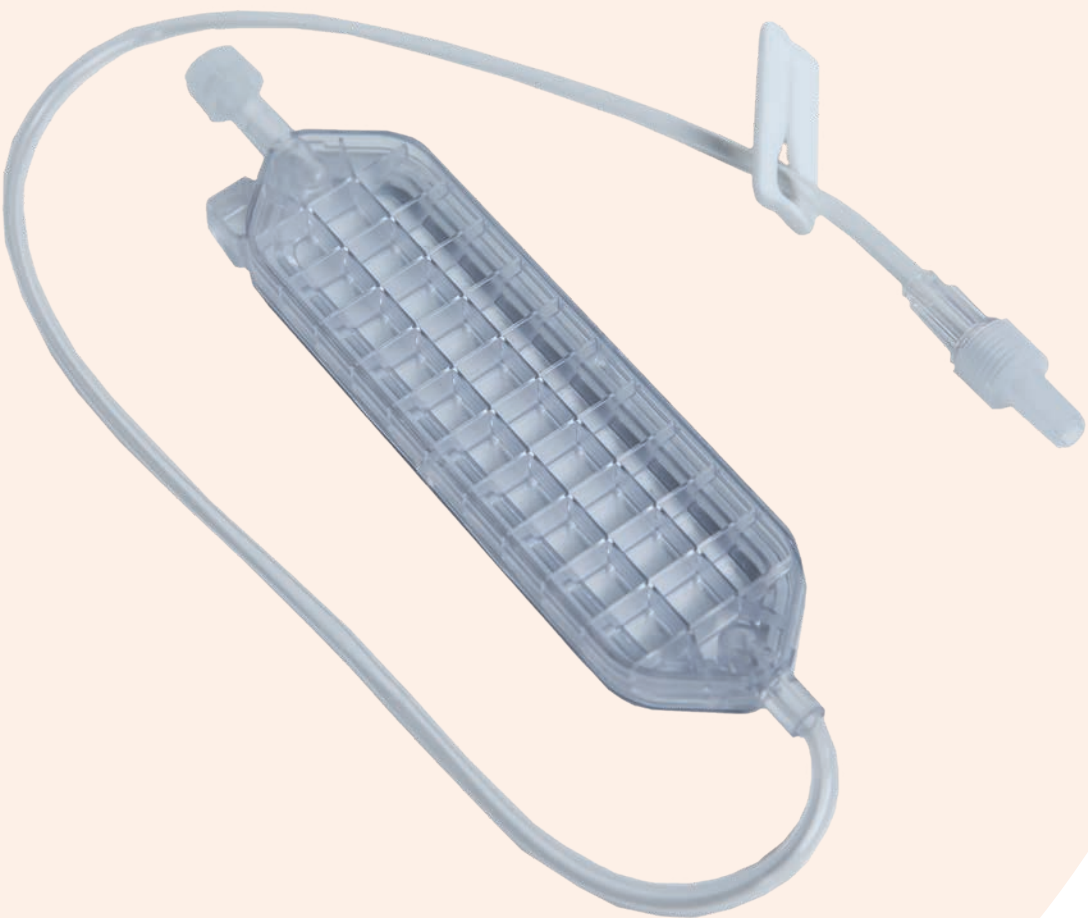
Description	The Fluido® Compact System
	The Fluido Compact System consists of the Fluido Compact Control Module and Fluido Compact Warming Module
	Optional: Fluido Compact Holder for Warming Module, an additional accessory which holds the Fluido Compact Warming Module in a safe a stable position next to the patient.
Indications for Use	The device is developed to supply warm fluids to a patient. The Fluido Compact Standard Set is developed for adults. Use the device for warming: • Crystalloid IV-fluids • Synthetic Colloid IV-fluids • Packed red blood cells
Single-Use Sets	The Fluido Compact single-use sets: Fluido Compact Standard Set, Fluido Compact Standard Set with Drip Chamber, 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.

Name, Article Number, Dimensions and Weight

Name	Article Number/REF	Size (height, width, depth)	Weight
Fluido Compact System	650000		
Fluido Compact Control Module	650100	285 x 120 x 195 mm	1,7 kg
Fluido Compact Warming Module	650200	165 x 75 x 50 mm	0,45 kg
Fluido Compact Holder for Warming Module	660700	216 x153 x 82 mm	0,3 kg



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

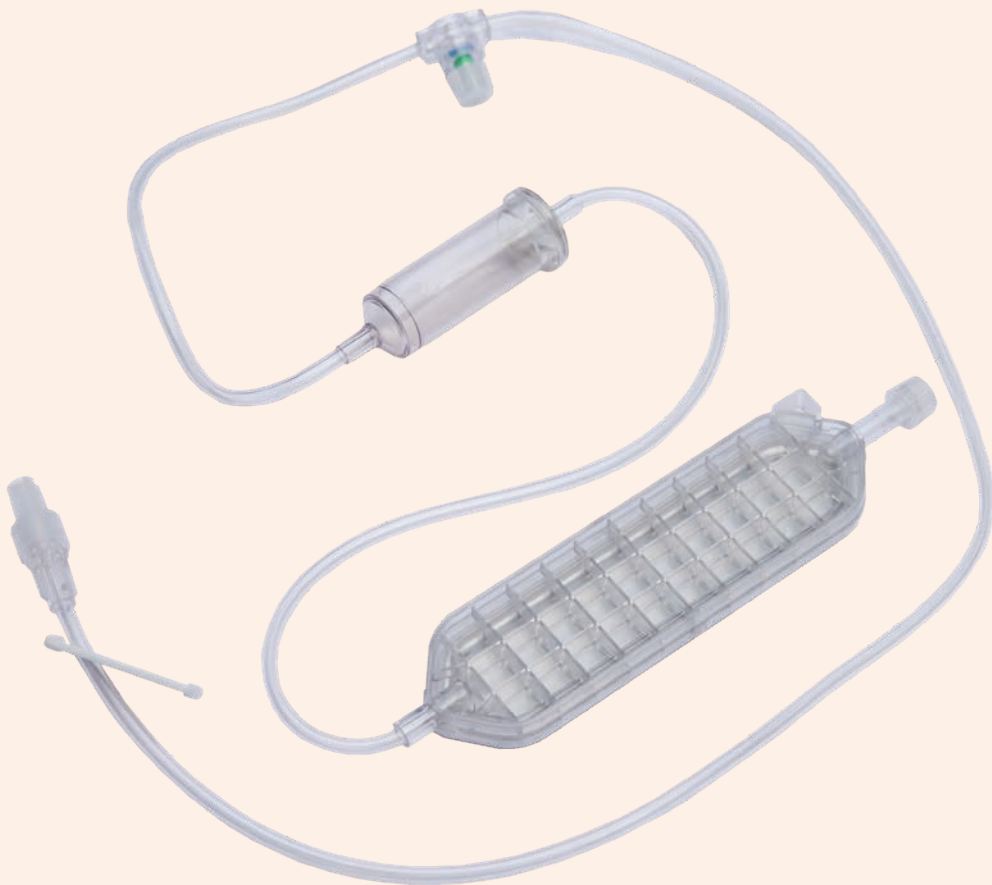


Single-Use Fluido Compact Standard Set

Description	Specification
Article Number/REF	672000
Patient Line	4 cm
Maximum Pressure	300 mmHg
Maximum Flow	400 mL/min ¹
Filling Volume	4 mL ¹
Storage Volume	5 mL with 300mmHg ¹
GMDN Code	47618
Coating	Parylene C coating 4 – 8,5 µm ²
Sterilization Method	Ethylene Oxide (EO) Sterilization

Single-Use Fluido Compact Standard Set
with Drip Chamber

Description	Specification
Article Number/REF	672100
Patient Line	7 cm
Maximum Pressure	300 mmHg
Maximum Flow	500 mL/m ³
Filling Volume	15 mL ³
Storage Volume	16 mL with 300 mmHg ³
GMDN Code	47618
GTIN-14 Code Outer Box	18719867001820
Coating	Parylene C coating 4 – 8,5 µm 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 365 x 260 x 255 mm.
Weight 2,5 kg.
User Manual, Power supply cord (length 400 cm) and box and unit label are included.

Fluido Compact Warming Module:
Carton packaging box, dimensions 365 x 260 x 115 mm.
Weight 0,9 kg.
Interface Cable (length 180 cm), Clamp, Instruction Card & Short Instructions for Use (SIFU) and box and label are included.

Fluido Compact Holder for Warming Module

Carton packaging box, dimensions 800 x 1500 x 1900 mm.
Weight 0.33 kg.
SIFU and 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 including 30 peel pouches are placed in the carton outer box, 120 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 indicator sticker.

Dimensions outer carton box 580 x 330 x 225 mm, weight outer box 6,4 kg , weight inner pouch 43 gr.

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, including 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 580 x 330 x 225 mm, weight outer box 4,78 kg, weight inner pouch 59 gr.

Regulatory Information

Fluido Compact Holder for Warming Module, Class I

MDD Classification:
Fluid Control Module, Class IIb
Fluido Warming Module, Class IIb
Fluido Compact Standard Set, Class IIa
Fluido Compact Standard Set with drip chamber, Class IIa

Classification IEC 60529:
Fluido Compact Control Module IPX1
Fluido Compact Warming Module IPIX4

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

All components shall be stored in a dry and dark place under warehouse conditions, preferably between 2°C – 30°C. Keep away from sunlight, rain and high humidity. The lifetime of the devices is 7 years. The shelf life of our single-use sets is 3 years, and the use by date is indicated on the pouch.

Waste disposal

According to hospital practice and/or local legislation.

Manufacturer

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