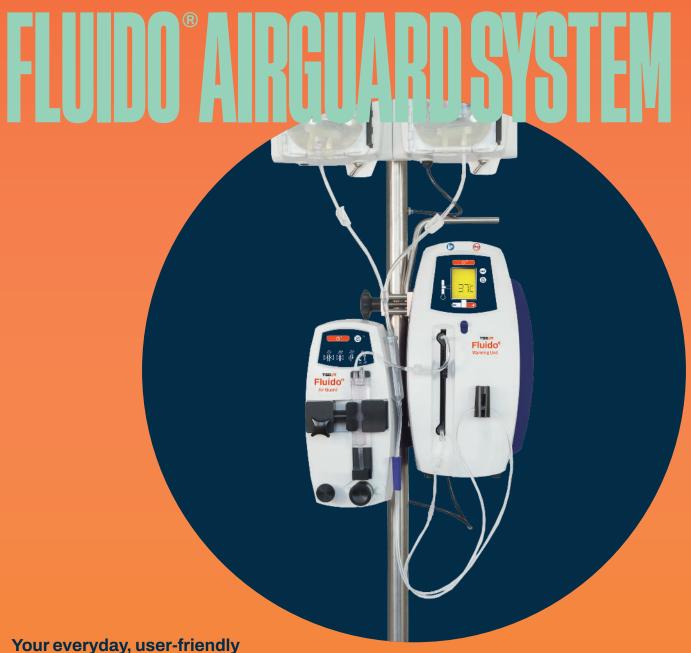
## TSC LIFE

## **Technical Datasheet**



Your everyday, user-friendly blood and fluid warming solution

# FLUIDO® AIRGUARD SYSTEM

| Description     | The Fluido AirGuard System is indicated for warming blood and fluids before IV administration to patients in variety of clinical situations.   |
|-----------------|--|
| Intended use    | The Fluido® AirGuard System is developed to supply warm fluids to adult patients. The system can be used to warm the following fluids:  • Crystalloid Intravenous (IV) fluids  • Synthetic Colloid Intravenous (IV) fluids  • Packed red blood cells, Plasma, and other blood components |
| Single-Use sets | The Fluido AirGuard single-use sets: Fluido Standard Set, Fluido Trauma Set, 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 AirGuard System.   |

## Name, Article Number, Dimensions and Weight

| Name                                      | Article Number/REF | Size (height, width, depth) | Weight |
|---|--------------------|-----------------------------|--------|
| Fluido® AirGuard System (230 Volt)        | 655230-C           |                             |        |
| Fluido® Blood and Fluid Warmer (220-240V) | 651230             | 435 x 250 x 315 mm          | 9.5 kg |
| Fluido® Air Guard (220-240V)              | 660400             | 310 x 150 x 190 mm          | 4.5 kg |
| Fluido® Pressure Chamber                  | 660300             | 370 x 400 x 150 mm          | 4.2 kg |
| Fluido® Compressor (100-240V)             | 660200A            | 210 x 150 x 150 mm          | 1.3 kg |
| Fluido IV-Pole                            | 660500-B           | 1830 x 70 x 70 mm           | 13 kg  |

| Description               | Specification                          |                |  |
|---------------------------|--|----------------|--|
| Article Number / REF      | 655230-C (Fluido® AirGuard System)     |                |  |
| Cleaning and Disinfecting | According to the Technical/User Manual |                |  |
| GMDN Code                 | Fluido* Blood and Fluid Warmer         | 47623          |  |
|                           | Fluido <sup>®</sup> Air Guard:         | 47040          |  |
|                           | Fluido* Pressure Chamber               | 38468          |  |
|                           | Fluido <sup>®</sup> Compressor         | 31253          |  |
|                           | Fluido* IV-Pole                        | 36069          |  |
| GTIN-14 Code              | Fluido* Blood and Fluid Warmer         | 18719867001592 |  |
|                           | Fluido* Air Guard                      | 18719867001639 |  |
|                           | Fluido® Pressure Chamber               | 18719867001622 |  |
|                           | Fluido Compressor:                     | 18719867001615 |  |
|                           | Fluido <sup>®</sup> IV-Pole:           | 18719867001653 |  |



#### Fluido Standard Set

| Description          | Specification                     |
|----------------------|-----------------------------------|
| Article Number/REF   | 671200                            |
| Patient Line         | 150 cm                            |
| Maximum pressure     | 300 mmHg                          |
| Filling Volume       | 90 ml (40°C)                      |
| Storage Volume       | 91 ml (40°C, 300 mmHg)            |
| GMDN Code            | 47622                             |
| Sterilization Method | Ethylene Oxide (EO) Sterilization |

### Safety Properties of Fluido® Sets

Does not contain latex or latex components.

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

Biocompatible according to ISO10993 on cytotoxicity, acute systemic toxicity, sensitization, irritation, and hemocompatibility, for the intended use.

#### **Packaging**

#### Fluido Blood and Fluid Warmer

Carton packaging box, dimensions 41 x 35 x 57 cm.

Weight 11,70 kg.

User Manual, Power supply cord and box and unit label are included

#### Fluido AirGuard

Carton packaging box, dimensions 41 x 35 x 57 cm.

Weight 11,70 kg.

User Manual, Power supply cord and box and unit label are included

#### Fluido Pressure chambers

Carton packaging box, dimensions 56 x 50 x 35 cm.

Weight 6,59 kg.

User Manual and box and unit label are included

#### **Fluido Compressor**

Carton packaging box, dimensions 25 x 22 x 25 cm.

Weight 1,70 kg.

User Manual, Power supply cord and box and unit label are included

#### Fluido IV pole

Carton packaging box, dimensions pole  $7 \times 7 \times 183$  cm and dimensions base  $72 \times 70 \times 15$  cm.

Weight 4,3 kg (pole) and 10,8 kg (base).

User Manual and box and unit label are included

#### Fluido Standard Set

Each single-use set is packed in a Tyvek paper peel pouch. 2 inner boxes, each including 20 peel pouches are placed in the carton outer box, 40 units total.

The inner boxes are supplied with a box label and IFU.

The outer box is supplied with a box label.

Dimensions outer carton box 57 x 37 x 31 cm,

weight outer Box 6,39 kg, weight inner pouch 134 gr

#### Fluido Trauma Set

Each single-use set is packed in a Tyvek paper peel pouch.

#### Fluido Trauma Set

| Description          | Specification                     |
|----------------------|-----------------------------------|
| Article Number/REF   | 671500                            |
| Patient Line         | 150 cm                            |
| Maximum pressure     | 300 mmHg                          |
| Filling Volume       | 160 ml (40°C)                     |
| Storage Volume       | 165 ml (40°C, 300 mmHg)           |
| GMDN Code            | 47622                             |
| Sterilization Method | Ethylene Oxide (EO) Sterilization |

2 inner boxes, each including 15 peel pouches are placed in the carton outer box, 30 units total.

The inner boxes are supplied with a box label and IFU.

The outer box is supplied with a box label.

Dimensions outer carton box 57 x 37 x 31 cm,

weight outer box 7,62 kg, weight inner pouch 232 gr

#### **Regulatory Information**

#### MDD Classification:

Fluido Pressure chamber, Class Ila Fluido Standard Set, Class Ila Fluido Trauma Set, Class Ila

#### **Classification IEC 60529**

Fluido Blood and Fluid Warmer, IPX1 Fluido AirGuard IPX1 Fluido Compressor IPX1

#### Classification IEC 60601-1

Fluido Air Guard and Fluido Blood and Fluid Warmer Class I, Cardiac floating

Fluido Compressor Class I, Cardiac floating 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  $2^{\circ}\text{C} - 30^{\circ}\text{C}$ , 10-90% RH and 50 - 106 kPa.

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 and boxes. Transport conditions single-use sets is between -20°C and +40°C, 10-90%RH, 50-106 kPa.

#### Waste disposal

According to hospital practice and/or local legislation.

#### Manufacturer

The Surgical Company International B.V. Beeldschermweg 6F 3821AH Amersfoort The Netherlands



## Innovation with purpose

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