

# FLUIDO® AIRGUARD SYSTEM



**Your everyday, user-friendly  
blood and fluid warming solution**

# FLUIDO® AIRGUARD SYSTEM

<b>Description</b>	The Fluido AirGuard System is indicated for warming blood and fluids before IV administration to patients in variety of clinical situations.
<b>Intended use</b>	The Fluido® AirGuard System is developed to supply warm fluids to adult patients. The system can be used to warm the following fluids: <ul style="list-style-type: none"> <li>• Crystalloid Intravenous (IV) fluids</li> <li>• Synthetic Colloid Intravenous (IV) fluids</li> <li>• Packed red blood cells, Plasma, and other blood components</li> </ul>
<b>Single-Use sets</b>	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
<b>Fluido® AirGuard System (230 Volt)</b>	655230-C		
<b>Fluido® Blood and Fluid Warmer (220-240V)</b>	651230	435 x 250 x 315 mm	9.5 kg
<b>Fluido® Air Guard (220-240V)</b>	660400	310 x 150 x 190 mm	4.5 kg
<b>Fluido® Pressure Chamber</b>	660300	370 x 400 x 150 mm	4.2 kg
<b>Fluido® Compressor (100-240V)</b>	660200A	210 x 150 x 150 mm	1.3 kg
<b>Fluido IV-Pole</b>	660500-B	1830 x 70 x 70 mm	13 kg

<b>Description</b>	<b>Specification</b>	
<b>Article Number / REF</b>	655230-C (Fluido® AirGuard System)	
<b>Cleaning and Disinfecting</b>	According to the Technical/User Manual	
<b>GMDN Code</b>	Fluido® Blood and Fluid Warmer	47623
	Fluido® Air Guard:	47040
	Fluido® Pressure Chamber	38468
	Fluido® Compressor	31253
	Fluido® IV-Pole	36069
<b>GTIN-14 Code</b>	Fluido® Blood and Fluid Warmer	18719867001592
	Fluido® Air Guard	18719867001639
	Fluido® Pressure Chamber	18719867001622
	Fluido® Compressor:	18719867001615
	Fluido® 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 x 7 x 183 cm and dimensions base 72 x 70 x 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 IIa

Fluido Standard Set, Class IIa

Fluido Trauma Set, Class IIa

#### 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°C – 30°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

# TSC LIFE

## Innovation with purpose

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**TSC Life**

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