

# SafMed

## Heat Sealer Range



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## The Importance of a Validated Heat-Sealing Process:

Packaging is a critical part of the decontamination of surgical instrument, as the step before sterilization, with smaller surgical items that are often packaged in small, laminated reel pouches which are sealed either manually or through a heat-sealing process. Having a validated heat-sealing process provides assurance to maintain sterility after the sterilization process, ensuring that the seal is intact, there are no channels, punctures, and tears in the seal as well as no material delamination or separation that may cause exposure.

According to ISO 11607-2 the sealing process needs to be validated. A rotary heat sealer with parameter control is an important when it comes validation. Parameter control enables a heat-sealing machine to constantly monitor the three seal parameters (**Temperature, Speed & Force**). If any one of these parameters is incorrect, the machine will give an audible warning and stop sealing.

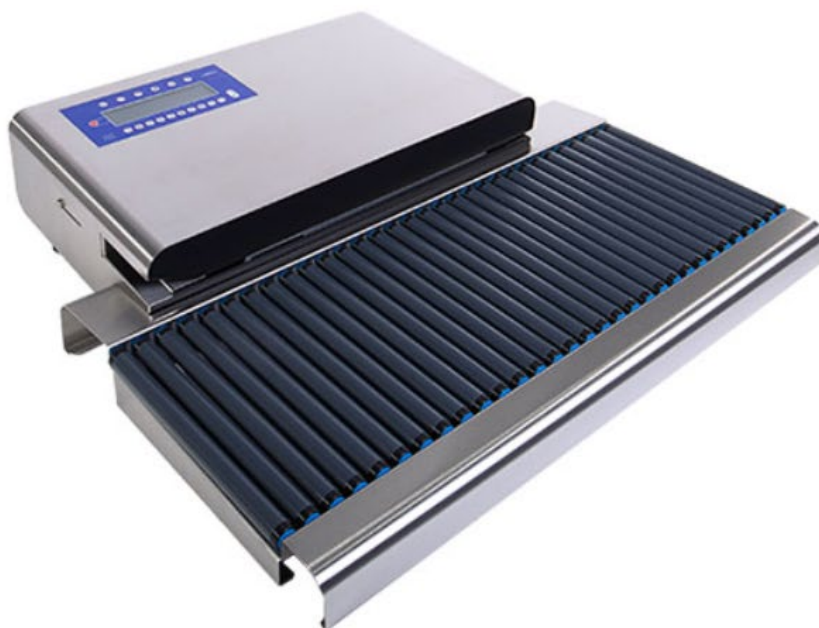


*Health Technical Memorandum 01-01: 2016 Management and decontamination of surgical instruments Part A: Management and provision DOH UK Crown.*

### Famos Protec Heat Sealer Range: PROTEC Series

The Famos PROTEC Heat Sealing range has an innovative design. The housing of the Famos rotary heat sealers has been designed so that surface disinfection and cleaning can be easily done due to the round corners and closed housing. Another unique feature is that the machines can be easily opened and serviced without the use any tools. The feed-in guide is now integrated into the machine and can be simply adjusted by an easy clicking system (0-40 mm).

PROTEC has been derived from the word “protect” and symbolizes the high level of protection that is created by the seal made with the Famos heat sealers.



The Famos PROTEC Heat Sealing range has various accessories such as roller front tables and front tables with a flat surface, label printers etc. To complement the PROTEC heat sealers Famos offers various roll holders with different cutting lengths.



**F108 PROTEC SERIES**

The F108 PROTEC series have a menu-controlled operation and microprocessor-controlled system. Each model has an accurate sealing temperature setting which can be set by a keyboard and which is being displayed on a LCD display with a good visual read out. The F108TX and F108TX-P/USB are additionally equipped with an automatic transport start and reverse transportation feature, which not only ensures safety, but which also prevents both instruments and the sealer itself from getting damaged. Both models are equipped with another safety feature that stops the machine from sealing when there is more than a 5°C deviation from the set temperature.

A production counter with audible alarm is also integrated in the F108 TX and F108 TX-P/USB. Moreover, the F108TX-P is equipped with parameter control and USB connection. Optionally an Ethernet connection can be integrated. In addition, all models are equipped with a RS232 communication port for easy software updates.

The F108 models are not equipped with an internal printer. The F108 PROTEC series consists of 3 models:

- F108
- F108 TX
- F108 TX-P/USB.

Each model is available in two versions:

- The first version is equipped with a grooved pressure roller (rib seal) to accommodate a controlled opening of the pouch and is suitable to seal laminate pouches and paper pouches.
- The second version is equipped with a pressure roller without grooves (flat seal) and is especially suitable for Tyvek pouches.

A front table with rollers is available as an optional accessory.

**F108 PROTEC SERIES**

Item No.	Product Model	Description	Tyvek Model
30.100.550	F108 PROTEC	<b>F108 PROTEC</b> Heat sealer, Rib seal. Dimensions: 438 x 289 x 137 mm (LxWxH) 220-240 VAC, 50/60 Hz	30.100.551
30.100.554	F108 TX PROTEC	<b>F108 TX PROTEC</b> Heat sealer, Rib seal. Dimensions: 438 x 289 x 137 mm (LxWxH) 220-240 VAC, 50/60 Hz	30.100.555
30.100.558	F108 TX-P/USB PROTEC	<b>F 108 TX-P /USB PROTEC</b> Parameter Control, Rib seal. Dimensions: 438 x 289 x 137 mm (LxWxH) 220-240 VAC, 50/60 Hz	30.100.559
30.100.620	Roller Front Table	<b>Roller Front Table:</b> Compatible with the All F108 PROTEC Series Models including Tyvek Models	Compatible

**F110DEP PROTEC SERIES**

According to DIN ISO 11607-2 the sealing process needs to be validated. The F110 series is equipped with parameter control which makes the sealer DIN ISO 11607-2 compliant. As a result, the parameters temperature, speed, and pressure are constantly being checked with each seal. If one of these parameters is incorrect, the machine will stop sealing and will notify the user by a warning message and a sound alarm. The monitoring of the parameters can be done in real time on a pc by means of external parameter monitoring software (included in delivery).

The F110DEP-P/USB is equipped with an automatic transport start, reverse transportation feature and a production counter with alarm. It is also equipped with an integrated internal printer which can print various data on the pouches. Each sealer can print the packing date, expiry date and a code the F110DEP-P/USB can print one line of text.

The F110DEP-P/USB has the following additional features:

- Storage of 2.000 texts with 30 characters each.
- Connection for external label printer to print various data on labels.
- Connection to a pc to program texts. Software and cable included in delivery.
- USB connection to connect a USB drive to upload the texts that have been programmed on a pc. In addition, when a USB drive is connected to the sealer, a log will be made of the parameters of each seal.

F110DEP-P/USB sealer is available with a grooved pressure roller (rib seal) for laminated or paper pouches or a pressure roller without grooves (flat seal) which is especially suitable to seal Tyvek.

**F110DEP PROTEC SERIES**

Item No.	Product Model	Description	Tyvek Model
30.100.574	F110DEP-P/USB PROTEC	<b>F110DEP-P/USB PROTEC</b> Heat Sealer, Rib seal. Dimensions: 527 x 314 x 162 mm (LxWxH) 220-240 VAC, 50/60 Hz	30.100.575
30.100.619	Roller Front Table	<b>Roller Front Table:</b> Compatible with the F110DEP and Including the Tyvek Model.	Compatible



**F220DEP PROTEC SERIES**

The F220DEP-P/USB PROTEC is equipped with parameter control which makes the sealer DIN ISO 11607-2 compliant. As a result, the parameters temperature, speed, and pressure are constantly being checked with each seal. If one of these parameters is incorrect, the machine will stop sealing and will notify the user by a warning message and a sound alarm. Software is supplied with the units and can be installed on a pc. Using the software program the parameters can be monitored in real time, the data will be recorded and this information can be saved. The F220 PROTEC series have an automatic transport start, reverse transport feature and production counter with alarm. An internal printer is integrated in this series as well. The F220DEP-P/USB can print the packing date, expiry date, a code and one line of text which can consist of up to 30 characters.

F220 DEP-P/USB PROTEC model has the following extra features:

- Storage of 3.000 texts with 30 characters each.
- Connection for external label printer to print various data on labels.
- Connection to a pc to program texts. Software and cable included in delivery.
- USB connection to connect a USB drive to upload the texts that have been programmed on a pc. In addition, when a USB drive is connected to the sealer, a log will be made of the parameters of each seal.
- An Ethernet connection is available as an option on this model
- The F220 PROTEC series is the only series of the Famos range that is equipped with a large graphical LCD-display.

F220 DEP-P/USB PROTEC is available with a grooved pressure roller (rib seal) for laminated or paper pouches or a pressure roller without grooves (flat seal) which is especially suitable to seal Tyvek packaging material.

**F220DEP PROTEC SERIES**

Item No.	Product Model	Description	Tyvek Model
30.100.600	<b>F220DEP P/USB PROTEC</b>	<b>F220 DEP-P/USB PROTEC</b> heat sealer, rib seal. Dimensions 527 x 314 x 162 mm (LxWxH) 220-240 VAC, 50/60 Hz	<b>30.100.601</b>
30.100.619	<b>Roller Front Table</b>	<b>Roller Front Table:</b> Compatible with the F220DEP and including the Tyvek Model.	<b>Compatible</b>

**Famos Roll Holder and Cutting Device**



Famos has designed various roll holders including cutting device to create the length of packaging material that is required. The rotary knife of the cutting device is made from the highest quality hardened steel and is self-sharpening which ensures years of maintenance free use.

All roll holders are available in two versions:

- Table model which can also be attached to the wall (only applicable for roll holders without extension).
- Model which can be hung onto an upright partition of a packing table or workstation.

Item No.	Product Model	Description
50.100.140	TS600	<b>Roll holder with cutting device:</b> Storage capacity: 600 mm, Dimensions: 820 x 420 x 110 mm
50.100.138	OZ600	<b>Extension for Roll holder:</b> Storage capacity: 600 mm, Dimensions: 603 x 255 x 105 mm

**Famos Sterilization Wrap Trolley**



Sterilization Wrap stands and trolleys are widely used for storage of sterilization wrap. The Famos Sterilization Wrap Trolleys have been specially designed to store sterilization wrap to have them within reach when ever required. The trolleys are made from AISA 304 stainless steel ensuring durability for the lifespan of the product.

The durable Sterilization Wrap trolley is made of stainless steel round tubes and stands on four swivel castors for easy maneuverability. It is equipped with 4 frames making is possible to store four different sterilization wrap configurations. It is equipped with four anti-static Ø 75 mm swivel castors of which two have a brake.

Item No.	Description	Dimensions in mm LxWxH
50.101.082	<p><b>Paper Trolley:</b>                      4 frames up to 4 different materials,                      4 castors Ø 75 mm (2x with brakes 2x Swivel)</p>	1225x600x900

# ABOUT SafMed

➤ B-BBEE Level 1 Contributor

➤ ISO 13485 Accredited

➤ Member of SAMED

➤ Medical Device Licence Numbers:

- Cape Town - 00000243MD (Manufacture/Distribute)
- Johannesburg - 00000227MD (Manufacture/Distribute)
- Cape Town - 0000680MD (Wholesale)
- Johannesburg - 00000643MD (Wholesale)



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