



# Validatable Doboy Band Sealer for Medical and Clean-room Environments



#### **Precision Control for a Precise Process**

Designed to meet FDA validation requirements, the B-550M medical sealer regulates, monitors and displays temperature, pressure and speed. The result is a secure, error free seal essential for medical pouches and other sterile packaging.

#### **Outstanding Features:**

#### **Temperature Control**

The B-550M features Watlow™ digital controllers with high and low set points combined with externally mounted thermocouples. The B-550M delivers precise control of the sealing process.

#### **Heating and Cooling Bars**

Both the heating and cooling bars have a super hard (60 Rockwell™) surface treatment that virtually eliminates wear. Both heating and cooling bars are pneumatically controlled to provide consistent pressure. Air pressure is electronically monitored to assure operation within specified parameters.

#### **Operator Interface/ PLC**

The heart of the B-550M is the integrated HMI/ PLC. All sealing parameters are monitored and fault conditions are displayed. There is a screen for setting the machine speed and a screen for alarm history with date stamp. A digital screen for troubleshooting is also incorporated.

#### **Bag Top Control**

Full length 12mm urethane timing belts grip the bag top and provide positive timing and speed control throughout the entire length of the sealer.

#### **AC Frequency Variable Speed Drive**

Machine speed can be adjusted from the control panel, with no belts or pulleys to adjust. In addition, the main drive is gear driven, so there are no chains or sprockets to wear out.

#### **Easy Accessibility**

Open frame design allows easy access for production and maintenance personnel. The B-550M has been designed to provide rapid band changes, with no tools required. Bands can be replaced in under two minutes!

#### **Sanitary Construction**

The main frame components are constructed of stainless steel and aluminum anodized plates, QPQ Melonite and other sanitary materials. The durability of these materials allows the B-550M to meet the demanding requirements of sanitary and sterile applications.

## **Doboy B-550M Medical Band Sealer**

Quality. Accuracy. Repeatability.

#### Validating the B-550M

Terminally sterilized medical device packaging is made easier with Bosch Packaging Technology as a partner. Count on our experienced staff to help translate ISO 11607-2 requirements to help you develop a sterile barrier system.



#### Installation Qualification (IQ)

- ► Each order includes a one day factory acceptance test (FAT) at our facility. Customer attendance is encouraged, but not required.
- ▶ The FAT will be used to demonstrate critical design specifications and verify function of the equipment.

#### Operational Qualification (OQ)

- ▶ A machine set up sheet will be provided for each product outlining nominal settings for machine speed, heat bar temperature, and sealing pressure.
- ▶ The set up sheet can then be used to derive high and low settings for each critical parameter.
- Seals can be tested using our calibrated Instron® peel testing equipment to verify that quality targets are being met.

#### Performance Qualification (PQ)

- ▶ The B-550M is supplied with a temperature verification port for each of the two sealing bars. These ports enable ongoing process checks without stopping production.
- ▶ The B-550M's PLC monitors machine speed, sealing pressure and heat bar temperature continuously to insure process reliability.
- Deviations from any validated set point result in a visual alarm and a reversing of the B-550M's direction of travel to clear potentially flawed seals. The sealer will continue to run in reverse until all parameters have been satisfied.

Speed Encoder



Temperature Controls



Temperature Ports



# **Doboy B-550M Medical Band Sealer**Total Process Control

The B-550M band sealer has the features you want when repeatability and quality are essential to your sterile barrier system.

#### **Speed**

- ▶ Digital speed control with speeds ranging from 100-1000 inches per minute
- Speed is monitored via a 500 position encoder for precise control
- High and low speed alarm set points are established through the HMI
- Variable speed AC drive and motor for enhanced accuracy and durability

#### **Temperature**

- ▶ Two precision digital temperature controllers
- ▶ Controllers programmable with high and low set points
- ▶ Controllers can be locked out for process security
- ► Surface mounted thermocouples for temperature sensing near the contact point on the pouch
- ► Temperature ports allow for ongoing process checks without stopping production

#### **Pressure**

- Air pressure is applied to the heat bars, compression wheels and cooling bars providing control of the complete sealing process
- Pressure is adjustable via an analog dial
- Alarm for low pressure
- Sealing bar gap can be mechanically adjusted to eliminate premature sealing band failure

#### Security

- ► Touchscreen operator interface allows for two user levels with password protection
- Fault conditions are listed and date stamped



B-550M with horizontal orientation

Pressure Gauge



Operator Interface



Sealing Section



## **Doboy B-550M Medical Band Sealer**

## Mechanical Specifications

#### A wide range of options:

- Markem Touch Dry Ink Coder
- Emboss style coder
- Bag top trimmer
- Bag counter
- ▶ Light tower
- Bag top guide
- ▶ High product detection
- ▶ Band break detection
- ▶ Tapered infeed
- Casters
- ▶ 9mm or 12mm seal width
- ▶ .87" long x 10" wide width conveyors
- ▶ 220 volt transformer





**Ink Coder** 

**Emboss Coder** 

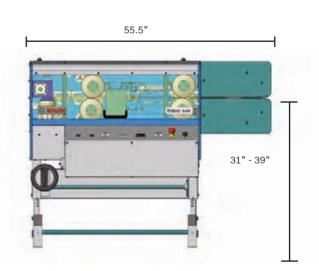
#### **Specifications**

Machine Size	Vertical	Horizontal
Length	55.5 <sup>"</sup>	55.5 <sup>"</sup>
Width	26"	26.5 <sup>"</sup>
Height (Variable) floor to belt	28" - 45.5"	31" - 39 <sup>"</sup>
	*Add 5 <sup>"</sup> for casters	*Add 5 <sup>"</sup> for casters
Weight	325 lbs.	310 lbs.
Specifications		
Production Speed	Up to 1000" / minute	
Product Range	All heat sealable materials, tube style or gusseted	
Sealing Bands	Glass Teflon	
Sealing Width	.25 <sup>"</sup> standard	
Heat Bars	1 pair 7.5" long	
Compression	Adjustable pressure roller	
Cooling	1 pair of air cooled bars	
Main Drive	AC drive / frequency control	
Temperature Control	One precision digital control	
Electrical	110 volt, 60 hz, 1 phase	

#### **Vertical Format**

# 28" - 45.5"

#### **Horizontal Format**



Add 5" if equipped with casters

### **Bosch's Family of Doboy Medical Sealers**

# Validatable sealers for medical and clean-room environments

All pharmaceutical and medical products require high integrity handling and packaging to satisfy hygiene requirements and meet validation parameters to ensure hermetic packaging is achieved. Based on years of experience and continual customer input, Bosch's extensive line of medical grade heat sealing equipment is highly reliable and is ideal for a wide range of medical and pharmaceutical applications. In addition to the B-550M, Bosch's family of Doboy medical sealers include the models below:

#### **CBS-DM Medical Band Sealer**

The CBS-DM is a high speed industrial duty medical sealer. Intended for multiple shift medical packaging operations or demanding medical sealing applications, the CBS-DM features comprehensive controls and diagnostics to satisfy stringent FDA standards. All CBS-DM band sealers feature stainless steel guards, enclosures and elevating stands. Special attention has been given to assure sanitary design and reliable continuous band sealer operation at speeds up to 1,200 inches per minute.



#### **Hospital Sealer**

Light on Weight. Heavy on Performance. The Hospital Sealer is a rotary sealer designed for sealing pouches or bags for sterile or disposable instruments at the point of use. It assures consistent and reliable sealing.



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Packaging Machines

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