

Intended Purpose:

The V-PRO Max Low Temperature Sterilization System with VAPROX HC Sterilant is a vaporized hydrogen peroxide Sterilizer intended for use in the terminal Sterilization of properly cleaned, rinsed and dried reusable metal and non-metal medical devices used in Healthcare Facilities. The pre-programmed Sterilization Cycles (Lumen Cycle, Non Lumen Cycle and Flexible Cycle) operate at low pressure and low temperature and are thus suitable for processing medical devices sensitive to heat and moisture.

Product Features:

<p>AMSCO® V-PRO® Quick Reference Guide</p>	
Sterilizer	V-PRO™ maX
Usable Volume (ft³)	4.8 (136Lt)
Chamber Shape	Rectangular
Cycle Time (mins)	55 Lumen 35 Flexible 28 Non-Lumen
Cycles/Cassette	15
Cycles/Case	45
H₂O₂ Concentration	59%
Configurations	Cabinet, In-wall
Dimensions (W x D x H)	33"x37"x75"
Voltage	208/230V, 60Hz, 3ph, 16 Amp
Stainless Steel, Single channel	1mm X 125mm
	2mm X 250mm
	3mm X 400mm
Flexible, Single channel	1mm X 1050mm (Max 2 per load)
Flexible, Dual Channel	1mm X 998/850mm (Max 2 per load)
Flexible, Plus Load	1 Scope (single or dual) up to 24 Lbs. of Non-Lumen Load
Max Lumens/Load	20


Technical Specifications:

Specification	V-PRO™ maX
Total (Usable) Volume (L)	136L
Chamber Volume (L)	136L
Chamber Shape	Rectangular
Chamber Dimensions (W x D x H) mm	432 x 826 x 381
Cycle Time (mins)	55 Lumen 35 Flexible 28 Non Lumen
Conditioning phase and moisture test	Yes, in every cycle
Cycles/Cassette	15
H ₂ O ₂ Concentration	59%
Sterilization temperature	48.5 to 51.5°C
Plasma	Not Required
By-products	Vaporized Water & Oxygen
Configurations	Cabinet, In-wall double door
Outside Dimensions (W x D x H) cm	84 x 94 x 191
Voltage	208/230V, 60Hz, 3ph, 16Amp
Venting requirements	None
Utility requirements	None
Packaging requirements	Polypropylene Wrap or Tyvek Pouches
Lumen Claims	
Stainless steel, single-channel (ID x length)	≥.77mm X ≤500mm
Stainless steel, dual-channel (ID x length)	≥.77mm X ≤527mm
Stainless steel, triple-channel (ID x length)	≥1.2mm X ≤310mm (or) ≥2.8mm X ≤317mm
Flexible, single-channel (ID x length)	≥1mm X ≤1050mm (Max 2 Per Load)
Flexible, dual-channel (ID x length)	≥1mm X ≤998/850mm (Max 2 Per Load)
Flexible, Plus Load	1 Scope (single or dual) and non-lumened load up to 11 kg

Max Stainless Steel lumens/load	20
Maximum weigh per load	Flexible cycle: 11kg Lumen cycle: 8.9kg Non Lumen cycle: 22,7kg
Connectivity	
Networking capability	●
Color-coded touch screen	●
Standards / Directives	
European (CE)	●
ISO14937	●
USA (FDA)	●

Daily Maintenance:

The following steps must be performed daily prior to V-PRO Max Low Temperature Sterilization System usage:

<p>1. Ensure chamber interior is clean.</p> 	<p><i>The entire chamber should be wiped down and rinsed following any spills or other soiling.</i></p> <ol style="list-style-type: none"> 1. Ensure door is open and Sterilizer power is OFF. 2. Remove shelf assembly before cleaning chamber by pulling shelves out to stop, tilting front of shelves up, removing from chamber. 3. Wash inside of chamber and shelf assembly with a damp cloth. Only use water (Deionized or RO preferred) to clean chamber. 4. Once chamber is clean, replace shelf assembly using reverse of appropriate procedure given in Step 2.
2. Close sterilizer door.	
3. Ensure VAPROX HC Sterilant Cup is installed:	
4. Verify printer is supplied with sufficient amount of paper. A coloured warning stripe is visible when paper roll is near the end.	<p>Load or replace printer paper roll as follows:</p> <ol style="list-style-type: none"> 1. Open front cover as follows <ol style="list-style-type: none"> a. A touch latch mechanism is used to hold front cover to main

enclosure. Press on dots to release latch.

b. To completely disengage front cover, pull cover out away from main enclosure.

c. Gently swing cover down 180° until it rests against equipment panel.

2. Release paper cover as follows:

a. Press on indentation on right side-wall of paper cover.

b. Gently pull to release.

c. Swing door to left until it is open.

d. Remove old roll if necessary.

3. Cut leading edge of paper roll straight and square with sides as shown in

4. Mount paper roll on paper-roll-holder as follows:

a. Position paper roll on both plastic protrusions shaped like domes, inside paper compartment.

b. Paper must curl up as shown in

c. Paper roll core must properly align with paper-roll-holder. Ensure paper-roll-holder fits inside paper core and paper roll turns freely.

5. Hold both edges of paper and insert it straight into paper slot of printer mechanism. Printer feeds paper automatically.


6. Press **FEED** button until 8" (20 cm) of paper exits print mechanism. Do not pull paper in either direction through printer mechanism.



7. Remove take-up spool. Make a slight bend in paper edge and place bent paper edge into slot on take-up spindle. Wrap paper around spool two or three times tightly and reinstall take-up spool in printer.

8. First ensure gear on take-up spool aligns with gear on printer

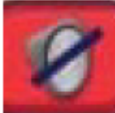


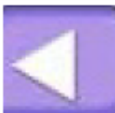






	<p>and then press other shaft end so it snaps into metal frame.</p> <p>9. Close printer paper cover. Close front cover.</p>
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Sterilant Cup Installation:

 <p>The screenshots show the following messages:</p> <ul style="list-style-type: none"> Cup Invalid: Sterilant cup invalid. Install new cup. DOOR CLOSED. 08/18/14 01:18:28P. Cup Expired: Sterilant cup expired. Unload chamber. Close door. Touch to start cup dispose cycle. DOOR CLOSED. 08/25/14 03:03:25P. Cup Empty: Sterilant Cup Empty. Install New Cup. Wear Chemical Resistant Gloves when Removing or Installing Sterilant Cup. DOOR CLOSED. 08/27/14 10:21:44A. 	<p>The following displays shall appear to prompt the use to install a new sterilant cup</p> <p>The steps to follow:</p> <ol style="list-style-type: none"> 1. Put on Personal Protective Equipment (PPE) using chemical-resistant gloves when removing or installing Sterilant Cup. 2. Open Cup interface door. 3. Remove and properly discard spent Cup. 4. Remove new Cup from carton. Ensure Cartridge is not past expiration date (printed on label; Sterilizer does not permit expired sterilant to be used in a cycle). 5. Place new Cup into Cup interface (see and close door. Cup only fits one way in interface).
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 <p>Data Matrix Code, Lot Number, Expiration Date</p>	<p>1) VAPROX HC Sterilant Cups contain high-purity 59% hydrogen peroxide and are filled under controlled conditions to assure effectiveness through the expiration date</p>
	<ul style="list-style-type: none"> • Install or remove VAPROX HC Sterilant Cup • Always wear chemical resistant gloves

Information for Use:

Symbol	Definition
	Silence Alarm Touch Pad
	Abort Touch Pad
	STATUS Screen Touch Pad
	Go to Previous Screen or Alarm Acknowledge Touch Pad
	IN STANDBY Screen Touch Pad
	VAPROX HC Sterilant Cartridge (Cup) Empty Icon [Cup Level Indicator]
	VAPROX HC Sterilant Cartridge (Cup) Full Icon [Cup Level Indicator]
	Vacuum Pump and Filter Preventive Maintenance Required – Maintenance Past Due (Red)
	Vacuum Pump and Filter Preventive Maintenance Required – Maintenance Required Shortly (Yellow); Unit at 90% of Total Maintenance Cycle.
	Acknowledge Touch Pad. Enables user to dismiss alarm window and prevents alarm notification from continuously displaying while triggering condition remains active.

Selection of a program cycle

	<p>Display Menu</p> <p>Select any of the following three program cycles</p> <ul style="list-style-type: none"> • Lumen Cycle • Non Lumen Cycle • Flexible Cycle
	<p>Press the Status Screen button and the following details shall appeal on the display screen once a cycle has been selected and started.</p>
	<ul style="list-style-type: none"> • Once you have loaded your lumen instruments into the chamber. • Press the Lumen Cycle icon. The following screen will display before the cycle starts. • The Lumen Cycle is 60 minutes
	<ul style="list-style-type: none"> • Once you have loaded your Non Lumen instruments into the chamber • Press the Non Lumen Cycle icon. The following screen will display before the cycle starts. • The Non Lumen Cycle is 38 minutes

		<ul style="list-style-type: none"> • Once you have loaded your flexible scope(s) into the chamber. • Press the Flexible Cycle icon. The following screen will display before the cycle starts • The Flexible Cycle is 28 minutes
		<p>At the end of every passed cycle the following screen shall appear to appear</p>