

FEATURE SUMMARY

- Chamber volume from 47 to 162 liters
- Low temperature process of less than 55 °C
- No hazardous or odorous emissions
- No utilities needed except electricity
- Sophisticated Bacsoft control system, with 7" multi-color touch screen display (also on back side of two door configurations)
- Automatic sterilizer refilling
- Equipment tracking application software for an easy follow-up of endoscopes history
- Ethernet connection port for direct PC access
- USB port to download cycle data to USB memory device
- Diagnostic In/Out test (enables technician to check each component separately)
- Built-in thermal printer
- Aluminium chamber and door
- Foot activated Kick Switch allows hands-free door operation
- Stainless steel and polypropylene piping
- Process Challenge Device kit (PCD) integrated
- Conforms to standards: ISO 9001:2008, ISO 13485:2003, ISO 14937, EN 61010-2-040, EN 61010-2-040:2005, EN ISO 14971:2012
- Medical Device Directive 93/42/EC
CE Medical Device Mark 0344

PRODUCT DESCRIPTION

The PlazMax is a low temperature sterilizer designed to cover a large field of applications for hospitals, CSSD, Gastro Clinics and medical centers.

The PlazMax sterilizers series has a chamber volume range from 47 liters to 162 liters.

The sterilizer operates at low temperature (less than 55 °C), with Hydrogen Peroxide, H₂O₂, as the sterilizing agent (Class 5.1 UN Number: UN2014).

The combined use of H₂O₂, vapor and plasma, safely sterilizes medical instruments and materials. The PlazMax sterilizer offers an effective, safe, fast and economical sterilization method.

APPLICATIONS

Central Sterilizing Supply Department (CSSD)
Operating Theater
Gastro Clinic
Out Patient Clinic

DEVICE PICTURE



PlazMax - Low Temperature Sterilizer

Information furnished by Tuttnauer is believed to be accurate and reliable. However, no responsibility is assumed by Tuttnauer for its use.

This specification is subject to change without notice.

PRODUCT SPECIFICATION

CHAMBER VOLUME & SIZE

MODEL	CHAMBER DIMENSIONS (mm)			VOLUME (liter)
	Width	Height	Depth	
P50	420	180	624	47
P80		320		83
P110		420		110
P160		420	924	162

DOOR SELECTION

- Single door
- Double door (pass through)
- Automatic vertical sliding door

SERVICE ACCESS

From loading side. All the components can be accessed for maintenance from left or right side of the sterilizer.

INSTALLATION SELECTIONS

- Standalone with cabinet for single or double door machines
- Installed through two walls for double door machines

VOLTAGE SUPPLY

Frequency: 50/60 Hz

MODEL	VOLTAGE (V)	PHASES	POWER (kW)
P50	220/230 V	1	3.1
P80	220/230 V	1	3.4
P110	220/230 V	1	4.3
P160	220/230 V	1	4.3

LANGUAGE

The operator display is available in different languages. For languages not included, a translation process of the interface is required.

STANDARDS AND CODES

Tuttnauer products meet the following international provisions and standards. The PlazMax was developed in accordance with the below norms and directives:

Standards

- ISO 9001:2008 - Quality Management Systems
- EN ISO 13485:2003 - Medical Devices - Quality Management Systems - Requirements for Regulatory Purposes
- EN ISO 13485: 2012 “Quality Management System” – Medical Devices
- EN ISO: 14971:2012 - Medical Devices: Application of risk management to medical devices
- ISO: 14937:2009 - Sterilization of health care products -- General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices
- ISO 61010-2-040: 2005 Particular requirements for sterilizers and washer-disinfectors used to treat medical materials
- EN 61326-1: 2006 — Electrical equipment for measurement, control
- IEC/EN 61010-1:2010— electrical equipment for laboratory use; general requirements
- IEC 62304:2006- Medical device software – Software life-cycle

Directives

- Medical Device Directive 93/42/EC
- 2006/42/EC Machinery Directive
- 2006/95/EC, Directive, Electrical equipment
- 2004/108/EC, Electromagnetic compatibility

Patent

- The Low Temperature Sterilizer and its processes are protected under Patent N.º PCT/PT2007/000029

CHAMBER CONSTRUCTION

Materials

The sterilizer chamber is constructed from solid, high quality materials. Chamber and door thickness is no less than 10 mm. All panels and covers are made from stainless steel.

Standard Configuration Materials:

Chamber + Door: Aluminium 6061

Chamber Design

An aluminium strainer protects the drain port from blockage by debris. The chamber is mounted on a stainless steel framework.

Door Gasket

Manual hinged door and vertical sliding door gasket: a silicone gasket is permanently fixed in the door.

Chamber Heating

The chamber is pre-heated by electric heaters to 50- 55 °C.

Insulation

The sterilizer and door are completely insulated in order to save energy. The sterilizer is always cool on the outside.

SAFETY FEATURES

Door Safety Systems

- Chamber door cannot be opened when the cycle is active
- H₂O₂ cannot penetrate into the chamber when the door is open
- A cycle cannot start if the door is open or not properly locked
- Double door safety is implemented through interlocks which prevent both doors from being opened simultaneously
- The vertical sliding door movement will stop immediately if any object obstructs it
- The operator has no contact with the sterilant agent

HIGH PERFORMANCE VACUUM PUMP

The vacuum pump effectively removes most of the air from the chamber, leaving a pressure of 0.1 mBar (almost absolute vacuum). The pump is mounted on shock absorbers to minimize vibration.

PIPES & COMPONENTS

The piping system of the sterilizer consists of an electrically operated ball valve, air inlet valve, vaporizer valve and dosing pumps, which control the flow of H₂O₂ in and out of the chamber, and the vacuum inside the chamber.

Standard configuration:

Piping and fittings:	316 tri-clamp stainless still and polypropylene tubes
Components:	Stainless steel
Dosing Pump:	Plastic and silicone

VALIDATION PORTS

The chamber is provided with two 1" tri-clamp connector for optional vacuum/pressure gauges and test sensors. The Validation Port is found on the left side of the sterilizer, from the control side.

AIR FILTER

An HEPA air filter is provided to filter all air entering the sterilizer chamber. The filter is rated for a particle size of 0.2 µm.

CONTROL SYSTEM

The control system is based on microcomputer technology. The sterilizer has a Bacsoft controller, which includes a touch screen on the front panel. The system controls and monitors the physical parameters of the sterilization process and performs the operation sequence of the machine, according to the selected program and features:

- Digital inputs and outputs for sterilizer control
- Analog inputs from multiple temperature and pressure
- Measures chamber pressure and temperature
- USB and Ethernet connection port
- Thermal Printer
- Built in Flash memory and real-time clock history backup cycle data for at least 200 cycles even if there is a power failure
- Diagnostic In/Out test (enables technician to check each component separately)

The control system controls and displays all system functions, monitors system operations and audibly alerts the operator of cycle malfunctions.

TEMPERATURE AND PRESSURE SENSORS

The temperature and pressure measuring circuits are both linear and designed with components having a high precision. The PT100 sensors conform to Class A of the IEC751 standard.

The control system allows for the calibration of temperature and pressure to be performed digitally.

Each sensor circuit is calibrated with individual constants to correct the deviation in manufacturing and aging.

CONTROL PANEL

The operators control panel is found on the loading side and on the unloading side for double door models.

The control system is operated via the Bacsoft fully automated menu driven, multi-color touch screen display allowing the user to easily operate, browse programs or set the sterilizer.

30 identification Codes and Passwords are provided to control access/operation of the machine preventing unauthorized access. These access levels are customizable. Access control can be applied to functions, such as running test cycles, setting parameters, calibration, service and maintenance, cycle selection, cycle start and door control.

The software can easily be upgraded at no additional cost every time that a new version is available.

With the standard factory configuration, calibration of the temperature circuits and calibration of the pressure circuits require an access code.

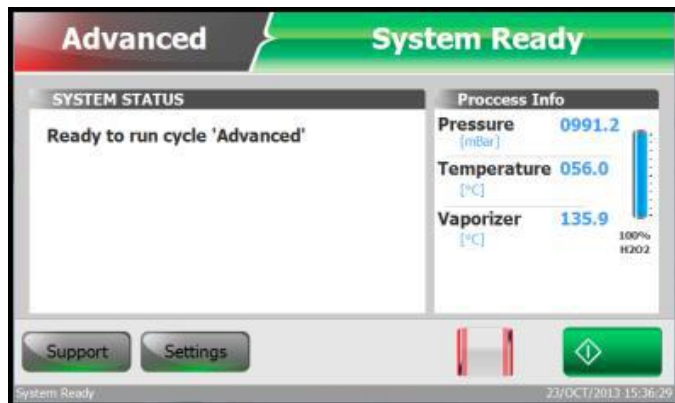
TECHNICAL SPECIFICATION

PlazMax – Low Temperature Plasma Sterilizer

MULTI-COLOR TOUCH SCREEN DISPLAY

Human Machine Interface (HMI) has been designed with the following features:

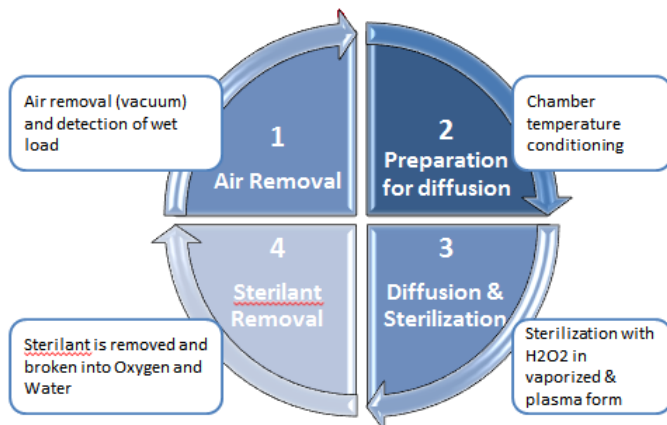
- Multi-color touch screen for easier reading from a distance
- Built-in view of historical cycle data
- Graphical display of pressure graphs
- Multilingual interface



Operators Control Panel (Touch Screen)

The following information is displayed:

- Sterilizer status: as shown in the image below
- Process info
- Selected Program
- User messages



Sterilizer Status

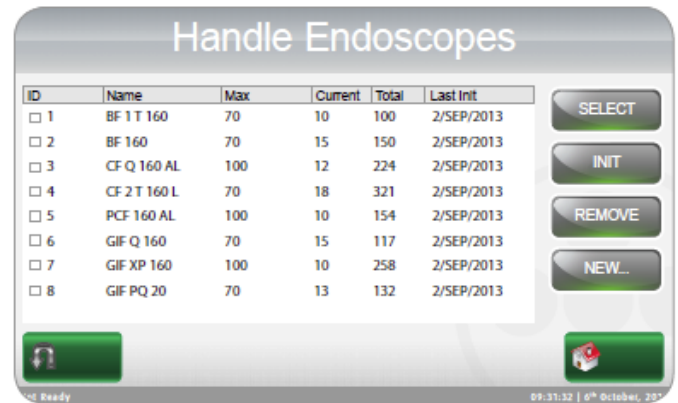
ALARMS

The sterilizer uses both audible and screen messages. Automatic process checking and failure detection are provided by the control system. In the event of a failure during and after the diffusion phase the machine will aerate the chamber to avoid residual H₂O₂, the system enters an alarm phase which will safely end the process automatically. The range of alarms includes:

- Temperature & pressure sensor failure in case of out of range parameters
- Door(s) not properly closed
- Power failure

EQUIPMENT TRACKING & MAINTENANCE NOTIFICATION

Equipment tracking software, at no additional costs, provides a detailed sterilization history of each endoscope tracked. The software will notify when the equipment needs to be delivered for evaluation and maintenance.



CYCLE DOCUMENTATION - PRINTER

The sterilizer is equipped with a thermal printer which prints a detailed history of each cycle performed by the equipment.

The printing format is 24 characters per line. The following information and set parameters are printed when the sterilization cycle begins:

- Sterilizer serial number and load number
- Software version
- Real time
- Selected program
- Sterilization temperature, pressure and time
- Alarms

Thereafter, the sterilizer starts performing the sequence of operations of the cycle. The measured values of temperature and pressure are printed at fixed time intervals, according to various phases of the sterilization process.

The data is printed from the bottom up, beginning with the date and ending with "CYCLE ENDED" for a complete cycle or "CYCLE FAILED" for an aborted cycle.

LOADING EQUIPMENT

Two Pull Out Trays

Stainless steel trays equipped with tracks for easy loading and unloading. The trays are made of durable AISI 304 stainless steel. Model P50 is supplied with one Pull out Tray.

STERILIZER DOCUMENTATION

A number of copies of the manuals are provided. Operator and Service manuals are in English. Manuals include electrical and piping diagram.

Furthermore, the sterilizer is provided containing the following:

- Operators manual
- Technical manual
- Serial number for specific sterilizer
- Factory test report prior to shipping

TECHNICAL SPECIFICATION

PlazMax – Low Temperature Plasma Sterilizer

STERILIZATION PROGRAMS

The sterilizer is supplied with 3 sterilization programs and 2 test programs. The cycle programs are summarized as follows:

Note: For loads which its manufacturer declares to be in compliance with the following sterilization conditions using an H₂O₂ sterilizing agent (Class 5.1 UN Number: UN2014).

Model	Normal Cycle	Advanced Cycle	Endoscope Cycle
	Non-hollow loads	Hollow loads	Two endoscopes
	Time (min.)	Time (min.)	Time (min.)
P50	35	40	28
P80	35	40	28
P110	45	50	30
P160	50	55	45

Note:

- Cycle time may change according to the load and the condition of the sterilizer (hot/cold).
- Endoscope cycle temperature range 50°C to 55°C.

TEST CYCLE PROGRAMS

Program: Penetration Test

This program is intended to test the efficiency of air removal from the chamber.

Test parameters:

- Sterilization temperature 50 °C to 55 °C
- Cycle time 25min
- Sterilizing agent H₂O₂ (Class 5.1 UN Number: UN2014)

Program: "Air Leakage Test" (Vacuum Test)

This program is intended to test air leakage from the chamber through the door seal or any other seals. The program also tests the vacuum pump performance.

PROCESS CHALLENGE DEVICE (PCD)

The lumens PCD kit simulates sterilization conditions in terms of length, diameter and channel type (open on one or both sides). The kit includes lumens that are more difficult to penetrate than regular loads. The PCD allows knowing with certainty that the lumen loads, like endoscopes, are fully exposed to the H₂O₂ sterilizing agent.

The PCD kit includes 1mm diameter lumens with lengths of 4m (both sides open) and 1.4 m (one side open).



A comprehensive study by Endomobil, an independent German laboratory, determines that a wide range of endoscopes withstand extended PlazMax sterilization cycles.

The complete Endomobile document:

<http://www.tuttnauer.com/files/endomobile.pdf>

MAINTENANCE / SERVICE PLAN

A global network of skilled service specialists can provide periodic inspections and adjustments to help assure low-cost peak performance. A detailed service and maintenance plan is included in the operator manual.

PACKAGING AND SHIPMENT

The sterilizer is packed in a wooden crate for shipping/transportation.

Transportation of sterilizing agent (H₂O₂) is only by sea or land. Minimum quantity per order: 48 bottles.

WARRANTY

Tuttnauer warrants that each device is carefully tested, inspected and that it leaves the factory in proper working condition.

Tuttnauer certifies that the device is guaranteed to be free from defects in material and workmanship, for one year from installation date but not more than 18 months from shipping date, against faulty components and assembly. Extended warranty periods are optional.

The warranty does not include and does not replace routine treatment and preventive maintenance to be performed according to "Preventive and Periodical Maintenance" instructions mentioned in the device's accompanying manual.

UTILITY DATA / REQUIREMENTS

The user must ensure that all utilities used, including the water, meet all the specifications mentioned in the operator manual.

The user is subject to the full warranty statement found in the documentation delivered with the equipment.

Ventilation

10 air replacements per hour.

Ambient Temperature

Plant room temperature should be in the range from 15 to 30 degrees Celsius and 80% RH (relative humidity).

Sterilizing Agent

Number of cycles per machine from one bottle of sterilizing agent.

Model	No. of Cycles
P50	12-15
P80	10-12
P110	8-10
P160	4-6

The numbers of cycles is an estimate and can change according to the load and also depends on the machine starting from a hot or cold condition.

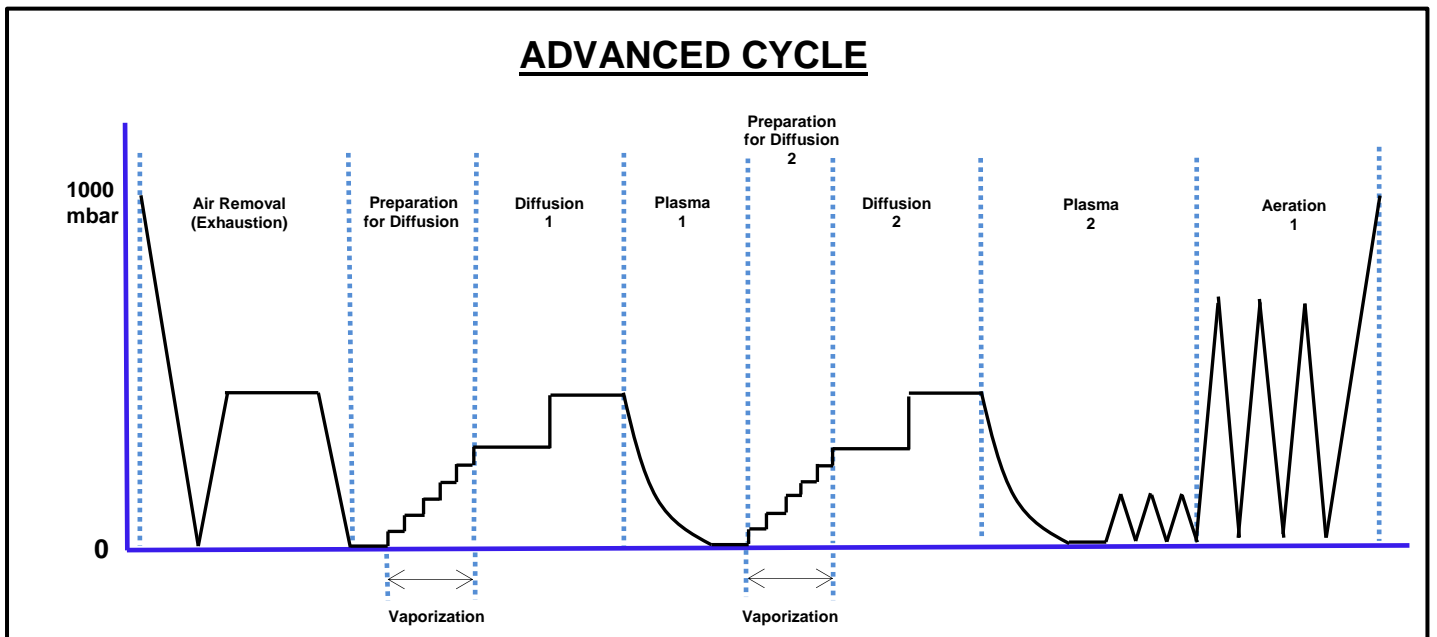
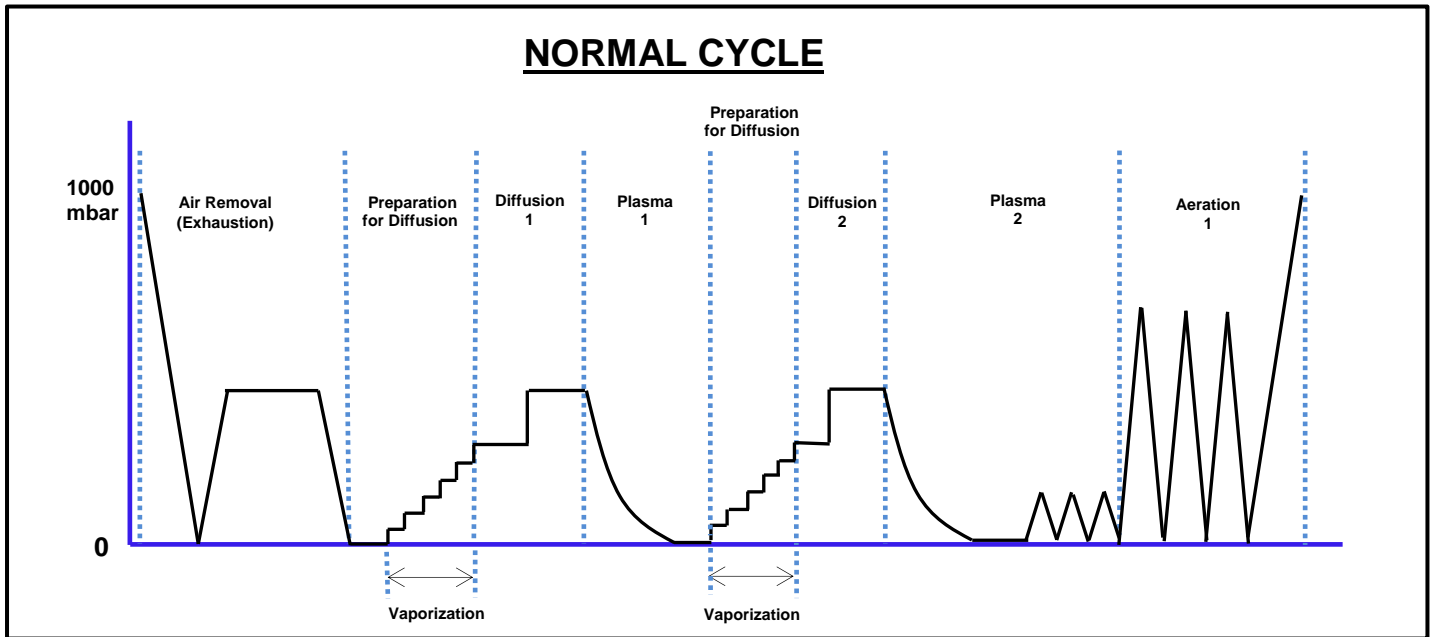
Note: Users must follow storage instructions for the sterilizing agent.

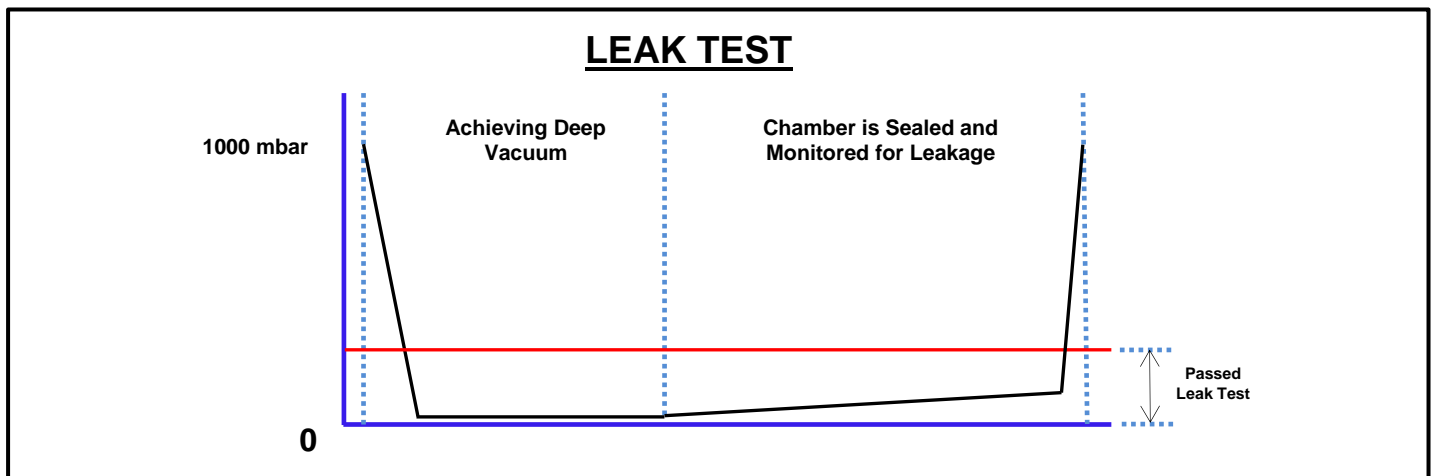
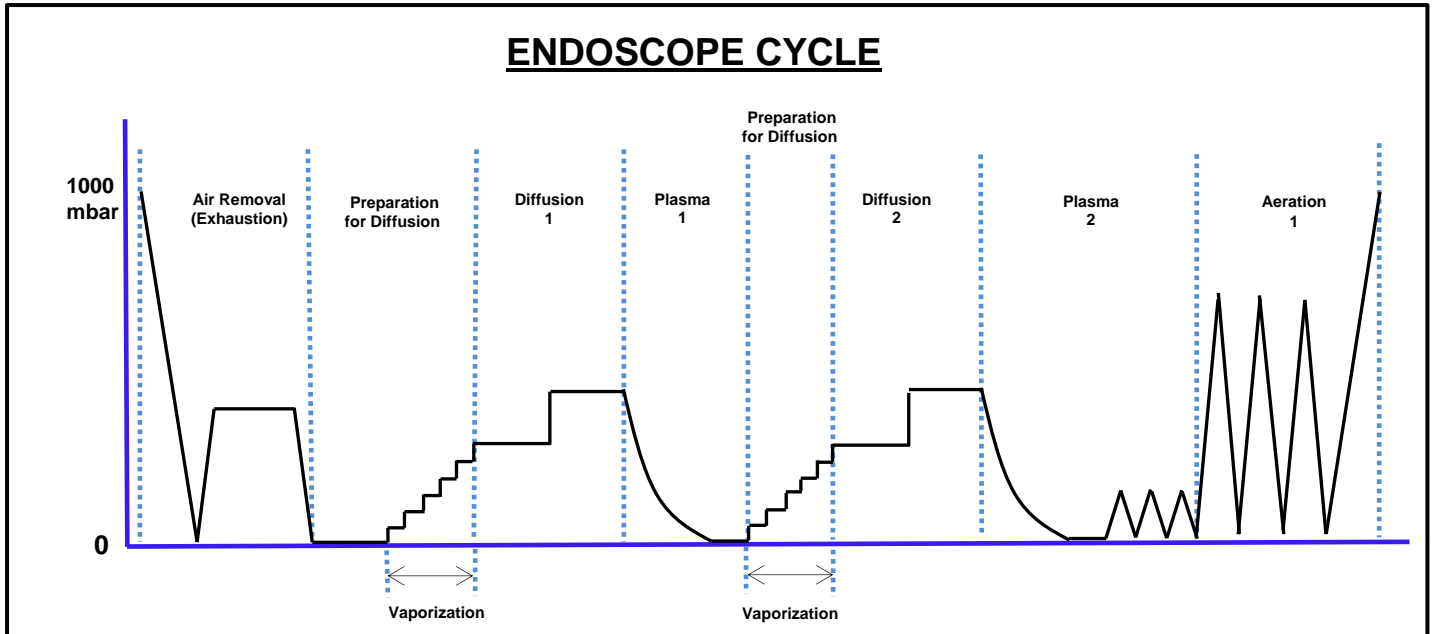
TECHNICAL SPECIFICATION
PlazMax – Low Temperature Plasma Sterilizer

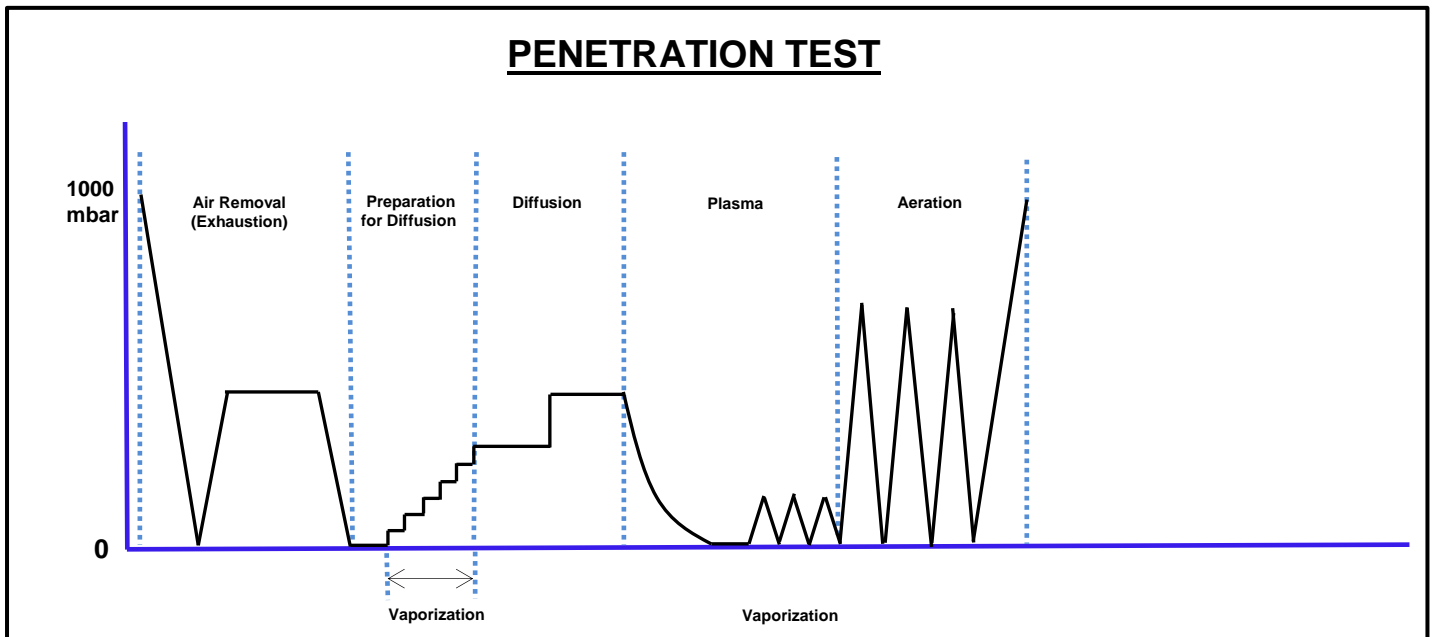
TECHNICAL DATA

MODELS		P50		P80		P110		P160	
Doors		1	2	1	2	1	2	1	2
Total volume (Liter)		47 Lt	47 Lt	83 Lt	83 Lt	110 Lt	110 Lt	162 Lt	162 Lt
Tray Dimensions (mm)	W	400	400	400	400	400	400	400	400
	L	600	600	600	600	600	600	600	600
Chamber Dimensions (mm)	W	420	420	420	420	420	420	420	420
	H	180	180	320	320	420	420	420	420
	D	624	624	624	624	624	624	924	924
Sterilizer External Dimensions (mm)	W	702	702	702	702	702	702	702	702
	H	1528	1528	1668	1668	1768	1768	1768	1768
	D	729	736	729	736	729	736	1029	1036
Weight (Kg)		170 Kg	170 Kg	200 Kg	200 Kg	210 Kg	210 Kg	252 Kg	260 Kg
Power Supply	Voltage (V)	230 V	230 V	230 V	230 V	230 V	230 V	230 V	230 V
	Frequency (Hz)	50/60 Hz	50/60 Hz	50/60 Hz	50/60 Hz	50/60 Hz	50/60 Hz	50/60 Hz	50/60 Hz
Power (kW)		3,1 kW	3,1 kW	3,4 kW	3,4 kW	4,3 kW	4,3 kW	4,3 kW	4,3 kW

PROGRAM CYCLE DATA (SCHEMATIC DIAGRAM)







SPECIAL OPTIONS AND ACCESSORIES

Independent Alphanumeric Recorder

Two Additional Sensors (Temperature & Pressure) for Secondary Measurements and Printing. The analog signal from the additional sensors are transferred to the controller (via an additional analog input extension board) and are printed by the control system printer.

R.P.C.R Software

Software that is installed on a network connected PC. Allows for remote monitoring and download of cycle data from the sterilizer connected to the same network. Software gives access to: cycle data graph, numeric cycle data, print-outs, measured values table, parameter table, and more.

Remote Automated Cycle Data Recording

- Automatic recording of cycle information to any PC on the same Ethernet network
- Convenient access to graphs and tables
- Generate PDF reports

Real-Time Remote Monitoring

- See real-time autoclave display on network connected PC
- Monitor all activity for up to 8 sterilizers

Remote Access

Provides technician ability to monitor autoclave via Internet (requires R.P.C.R, and local SIM card for Internet connection).

Two Color Printer

Printer IDP3550 Serial dot impact, two colors black/red, high speed printing 3.6 lines/sec, 7 X 9 matrix 40 columns, 76mm roll paper, paper auto loading.

Chart Recorder (Independent Microprocessor Control)

A high-speed chart recorder, with independent microprocessor control and power supply, is suitable for independent cycle documentation. This multi-range input recorder can record 12 points at once from RTDs and DC voltage input signals, producing analog trend records and print-outs. Simple

operation with an easy-to-view display allows one to key-in various items of set data. The unit operates independently of the autoclave (obligatory for meeting EN285).

Process Workflow Management Data Connection

Provides real-time data to any process workflow management system supporting Modbus.

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