CellPreserv
kolplast

Instruction Manual

Slide Processor
TPK FÊNIX

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INSTRUCTION MANUAL

This *Instruction Manual* describes the installation, application, operation and maintenance of the **SLIDE PROCESSOR** model **TPK Fenix**. Reading and understanding is recommended before operating the equipment. Always keep it close for any queries.

KOLPLAST reserves the right to modify the project and the information contained in this *Instruction Manual*, without prior notice.

If requested, KOLPLAST will make available circuit diagrams, parts list and other information that can assist users.

MODEL: TPK FÊNIX REF.10.1249 / 10.1411

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SUMMARY

1 SYMBOLS

Symbol	Description	Symbol	Description
	Fragile		Attention, potential danger
	This side up		Important installation, operation or maintenance information
	Keep Dry	~	Alternating Current
	Maximum stacking allowed		Protection class against electric shock - Applied part type B
	Attention! Consult ACCOMPANYING DOCUMENTS	**IPX1**	Degree of harmful water penetration
	Manufacturer	**SN**	Serial number
	Temperature		Moisture
IVD	In Vitro Diagnostic Product		Follow the instructions for use
	Class I of electrical insulation		Atmospheric Pressure

Table 1 - Symbols

2 PRESENTATION

2.1 Introduction

We are pleased that you have chosen the **SLIDE PROCESSOR** model **TPK FENIX**. To ensure the best performance of your product, carefully read the guidelines in this *Instruction Manual*.

2.2 Technical Standards Used in the Project

- NBR IEC 60601-1: Electromedical Equipment - General requirements for basic safety and essential performance;
- NBR IEC 60601-1-2: Electromedical Equipment - Electromagnetic disturbances;
- INMETRO Ordinance No. 384, of December 18, 2020;
- NBR ISO 13485:2016 – Requirements for a Quality Management System for Health Products;
- NBR ISO 14971:2020 – Application of Risk Management to Health Products;
- RDC ANVISA No. 848, of March 06, 2024 - Essential safety and efficacy requirements applicable to health products;
- RDC ANVISA No. 665, of March 30, 2022 - Provides for Good Manufacturing Practices for Medical Products and In Vitro Diagnostic Products.

2.3 Equipment Overview

Figure 1 - TPK FENIX model overview

2.4 Indication of Use and Purpose

The **SLIDE PROCESSOR** has the purpose of processing gynecological and non-gynecological samples of collected cellular material, separating blood, mucus and other debris, allowing the preparation of a mono layer slide. During processing, the cells are homogenized and dispersed, bringing cellular representativeness to the slide prepared. It is a non-invasive equipment, intended for Pathological Anatomy and Cytopathology Laboratories, Clinical Analyses and Hospitals.

There are no contraindications for this system. The system can be used to replace the conventional gynecological smear method. It can be widely used in clinical medicine, biochemistry, free immunology and other related fields.

The SLIDE PROCESSOR allows the installation of a remote access module (optional item), which allows technical support remotely.

3 IDENTIFICATION OF EQUIPMENT, ACCESSORIES AND INPUTS

The **TPK FENIX SLIDE PROCESSOR** operates with CellPreserv inputs, configuring a system that comprises:

Equipment:

- 1 Cabinet;
- 1 Power cable.

Accessories:

- 1 Residue System (Residue Vial and Residue Hose);
- 1 Fixation Vial
- 1 Maintenance Kit.

Inputs:

- 1 Pre-Filter;
- 4 Absorbents;
- 1 Silicone based grease.

Inputs purchased separately:

- Filter;
- Common/Standard Glass Slide (25x75 mm ± 1 mm). **DO NOT** use the silanized glass slide;
- Preservation Solution, with cell sample.

☞ Only ACCESSORIES supplied by KOLPLAST may be used. If you need to purchase any component, please contact KOLPLAST through the communication channels. The use of any component not supplied by KOLPLAST may result in increased emissions or reduced immunity of the electromedical equipment.

3.1 Equipment:

3.1.1 Cabinet:

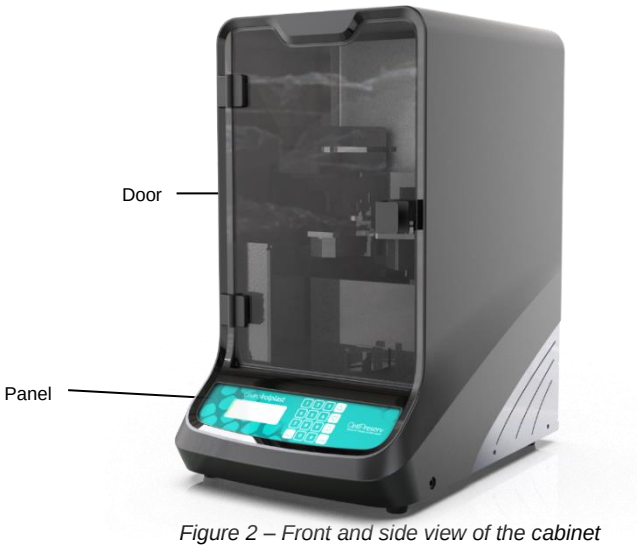

Figure 2 – Front and side view of the cabinet

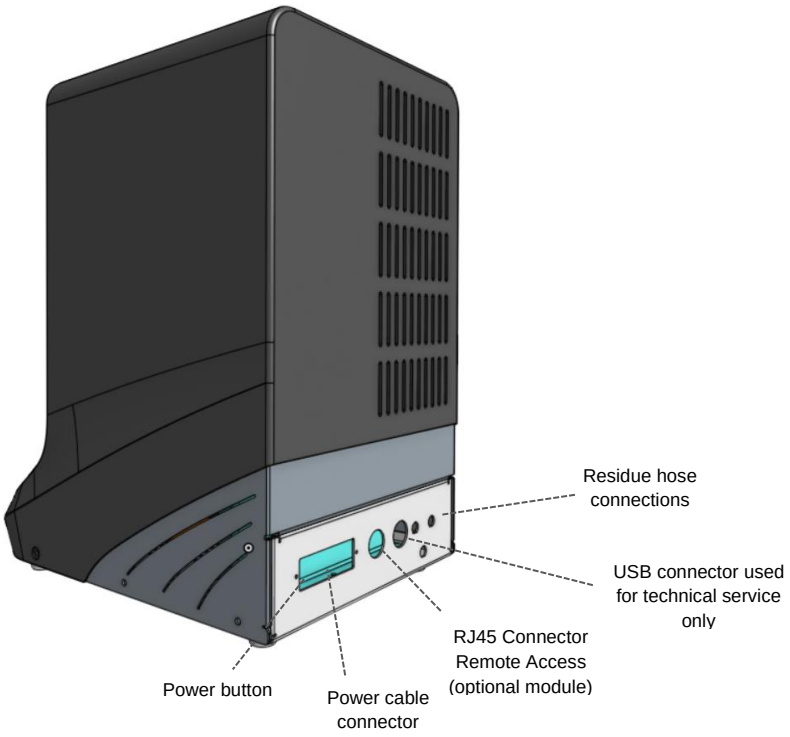

Figure 3 – Rear view of the cabinet

3.1.2 Panel

The panel has an LCD DISPLAY, where messages are displayed during gynecological and non-gynecological samples processing.

Figure 4 – Panel

Brief description of the function of the main command buttons:

START: Starts processing

STOP: Stops processing

ENTER: Restarts the process after finding an operation or execution error

DOWN ARROW / UP ARROW: Selects the operating mode

3.1.3 ON/OFF button

Located on the rear side of the CABINET.

3.1.4 Power cable

Before connecting the cable plug to the mains, check the voltage of the equipment and the mains.

Connection A must be made to the mains and connection B to the equipment, on the lower rear face.

Figure 5 – Power Cable

3.2 Accessories

3.2.1 Residue System

The RESIDUE SYSTEM consists of VIAL and HOSE, and is supplied as an accessory. The RESIDUE VIAL must be kept in its SUPPORT.

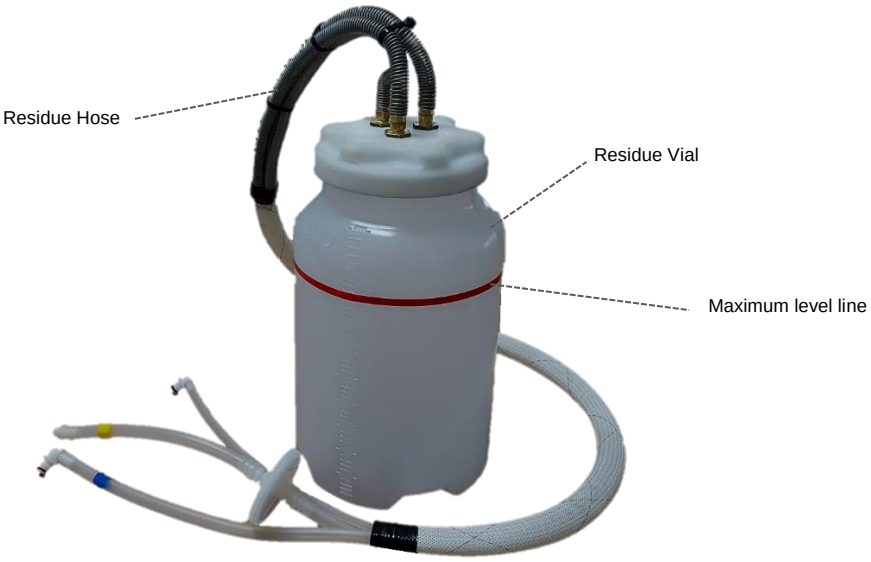

Figure 6 – Residue System

3.2.2 Fixation Vial

Used to receive the slide after processing and must contain liquid for preservation, according to the institution's protocol.

Figure 7 – Fixation Vial

3.2.3 Green Filter

Used when necessary, as directed by the Kolplast Technical Team.

Figure 8 – Green Filter

3.3 Inputs

3.3.1 Pre-Filters

Used to couple the FILTER to the equipment.

Figure 9 – Pre-Filter

3.3.2 Absorbent

Used to absorb potential liquids during processing.

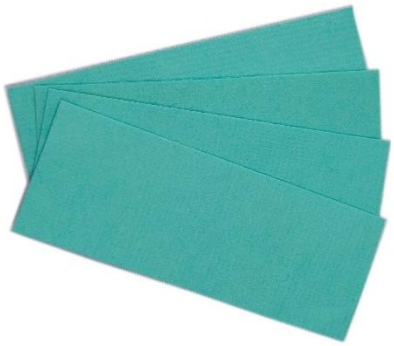

Figure 10 - Absorbents

3.3.3 Silicone Based Grease

Used to lubricate the o-rings present in the PRE-FILTER.

3.4 Inputs purchased separately:

3.4.1 Filter

Used to filter the SOLUTION and transport the cells to the SLIDE.

Figure 11 - Filter

3.4.2 Common/Standard Glass Slide

Used to transport the sample after processing.

Figure 12 - Slide

3.4.3 Preservation Solution

Used for preserving, transporting and processing the gynecological and non-gynecological samples.

Figure 13 - Preservation Solution

Use only supplies supplied by KOLPLAST, the use of supplies not supplied by Kolplast can damage the processor.

4 ASSEMBLY AND INSTALLATION

The PROCESSOR must be assembled and installed after understanding this *Instruction Manual*. In case of doubt, contact KOLPLAST

The correct assembly and installation of the equipment entitles the customer with the right to the product warranty against manufacturing defects

The installation in the electrical network must be done using a "No Break" of at least 200VA, according to the specifications established in the item 10.2 General Specifications, otherwise, the warranty will be void.

4.1 Pre-Checks

- Check if the box used in the transport and that contains the equipment shows signs of impact or perforation, it is convenient to contact KOLPLAST for joint evaluation of any damages in the equipment;
- Regardless of the existence or not of external signs (on the packaging), if any irregularity occurred during transportation, storage or handling is found, the procedure should be the same as indicated in the previous item;
- Carefully remove the equipment from the box;
- Place the PROCESSOR on a stable, level bench, preferably where it will be installed;
- Check if all items that make up the equipment are present (item 3 of this Manual).

Attention, the equipment may contain colored markings (yellow or green) on screws or specific points, which is part of the verification control of fixation, assembly and tightening of screws during the production process.

4.2 Assembly and Installation

The equipment is bivolt!

ATTENTION! The RESIDUE SYSTEM must be positioned in a safe place and free from interference

Do not share the bench with equipment that emits mechanical vibration, such as centrifuges, vortexes, among others;

- Place the PROCESSOR on the workbench where it will be installed, and it must support the weight of the equipment, be stable and level;
- Place the RESIDUE VIAL on the SUPPORT and place the set in a safe place - avoid places that make it difficult to see the liquid level and avoid places with potential risk of damage, falls, excessive movements or accidents;

Figure 14 – Residue VIAL

The set of RESIDUE VIAL and SUPPORT must be positioned below the level of the CABINET, taking care not to bend any of its hoses

- Screw the cap on the HOSE into the RESIDUE VIAL and make sure that the cap has been completely closed. In this process, the hoses do not need to be moved because the cap rotates independently;
- Connect the other end of the HOSE to the CABINET, according to the colors identified both on the HOSE connectors and on the back of the CABINET;
- Connect the POWER CABLE to the CABINET and then to the mains;
- Turn on the equipment using the ON / OFF BUTTON. When the equipment is turned on, the system will automatically calibrate, and the system is ready for operation from the “Ready to use” message displayed on the PANEL.

If you encounter any difficulties or the system displays any different messages, contact Kolplast immediately.

5 OPERATION

Make sure that the assembly and installation have been carried out in accordance with the item ASSEMBLY AND INSTALLATION. Check if there is any abnormal situation with the POWER CORD.

Use the POWER CABLE provided with the equipment

Turn on the equipment and wait for the “Ready for use” message. The inputs must be positioned as detailed below, following the order presented.

5.1 Inserting the Solution Vial

- Remove the vial cap;
- Check if the sample level is within the matte range of the VIAL. Adjust as necessary;
- Position the SOLUTION vial on the elevator support as shown in Figure 15 – Vial ;

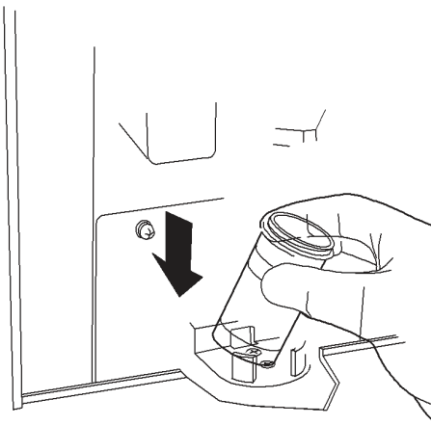

Figure 15 – Vial elevator

5.2 Inserting the FILTER

ATTENTION! Do not touch the FILTER membrane!

The FILTER must be fitted from the opposite end - hollow end

Any failure to insert the FILTER may cause processing errors

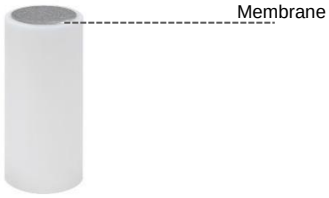

Figure 16 - Filter

- Carefully fit the empty end of the FILTER (face that does not contain the membrane) to the PRE-FILTER, with rotating movements, until the end of the stroke - as shown in Figure 19 - Positioning the filter in the pre-filter;
- If you encounter difficulties in fitting the FILTER with the PRE-FILTER, lubricate the rubber rings with the GREASE the base and silicone indicated by Kolplast;
- Insert the set between the rollers and make sure the part is centered, as shown in Figure 20 – Positioning the Filter + Pre-Filter set;

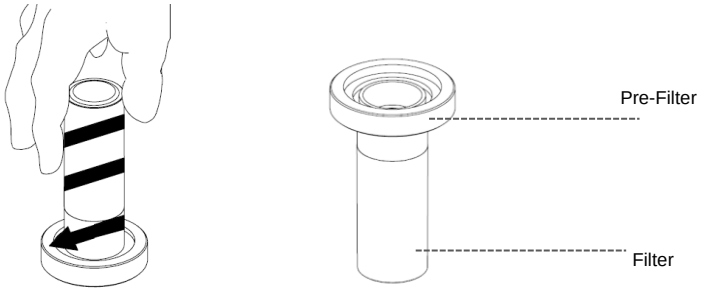

Figure 17 – Positioning the filter in the Pre-filter

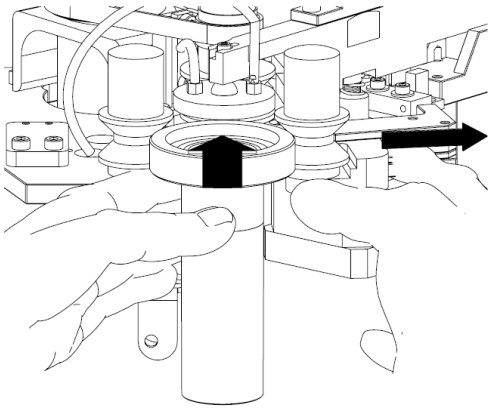

Figure 18 – Positioning the Filter + Pre-Filter set

5.3 SLIDE insertion

ATTENTION! Do not touch the engraved face of the slide
SLIDE must be fitted face down

- Carefully fit the SLIDE into the slide SUPPORT and keep the print facing down and to the right as shown in Figure 19 – Positioning of the slide;
- Fit the SLIDE until it is completely covered by the support structure;

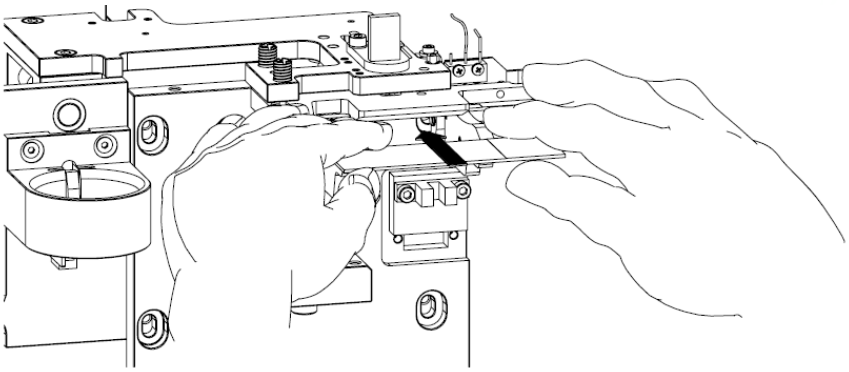

Figure 19 – Positioning of the slide

5.4 Inserting the FIXATION VIAL

ATTENTION! Fill with fixing solution up to the vial level mark
Replace the solution after every 100 slides processed

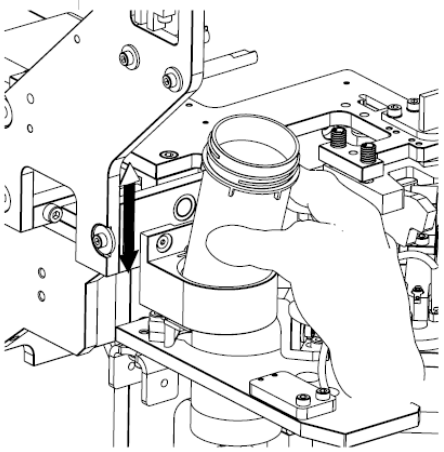

Figure 20 - Positioning of the Fixing Flask

- Check that the solution level is correct;
- Position the FIXATION VIAL on the support.

Close the door

ATTENTION! The equipment does not operate with the door open

5.5 Operation Modes

The TPK Fenix PROCESSOR features 2 modes of operation designated by 1 and 2. Each mode operates in order to guarantee the adequate cellularity of the slide always preserving the mono-layer concept.

The PROCESSOR is installed with operating mode 1 selected. Mode 2 can be used if the operator, in front of hypercellular samples, wants a lower cell density “printed” on the slide

To select mode 2, press the “up” indicator button to the desired mode, and then press the ENTER button for confirmation. The selected mode will appear on the display before each processing.

To select mode 1, press the “down” indicator button to mode 1, then press the ENTER button for confirmation. The selected mode will appear on the display before each processing.

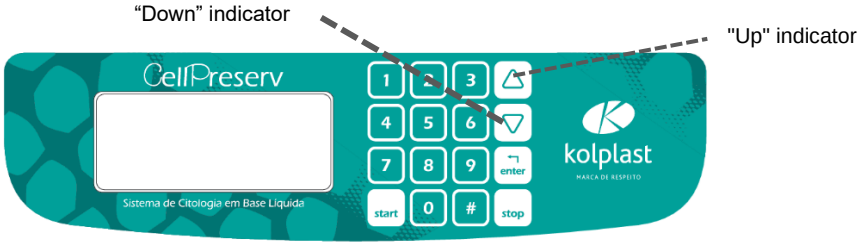

Figure 21 – Panel

5.6 OPERATION

- Press the “START” button and the system will automatically start the cycle;
- At the end of the cycle, the system will show the message “Pending - Remove Inputs”, informing which inputs should be removed;
- Open the door and remove the elements in the following order:
- Remove the FIXATION VIAL (which contains the slide):

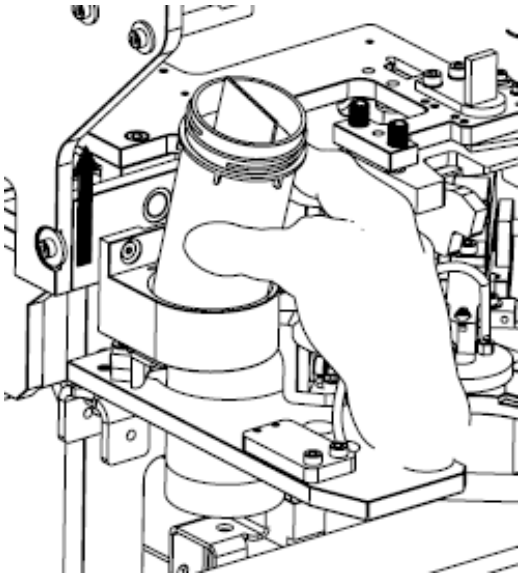

Figure 21a - Removal of the Fixing Vial

- Remove the PREFILTER + FILTER assembly;

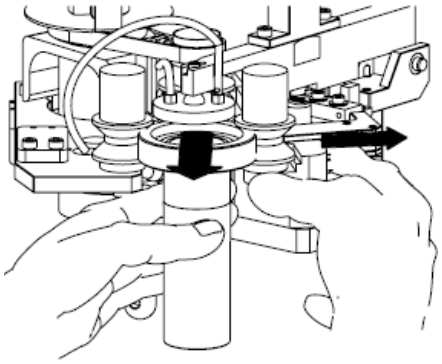

Figure 21b - Removal of Prefilter + Filter

- Remove the Solution Vial from the vial elevator;

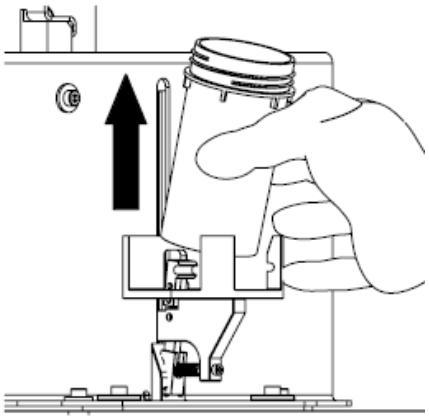

Figure 21c - Removal of the Solution Vial

- Remove the slide from the fixation vial and immediately place it in the multi-slide fixation container. The microscope slides should be fixed for at least 10 minutes prior to staining;
- The Solution Vial and the SLIDE must be stored appropriately according to the institution's protocols; The used filter must be disposed in accordance with the institution’s protocols.

Do not turn off the equipment during operation.

If the door is opened during the operation, the system will stop operating and the inputs must be discarded in sequence.

Check the level of residue on the residue vial daily, as it should not exceed the red line on the vial.

5.7 Sample Conservation

SAMPLE-FREE SOLUTION: Store between 15°C and 30°C according to the expiry date printed on the vial.

SAMPLE SOLUTION: Store between 4°C and 37°C for up to 6 weeks. After this period, the solution can be refrigerated at -2°C for 6 months for Molecular Biology tests.

LIMITATION: Gynecological samples should be collected using endocervical brushes and plastic spatula

6 CLEANING

Do not use abrasive, steel wool, organic solvents, thinner, xylene or corrosive compounds

6.1 Daily Cleaning / At the end of the Routine

Operation with Gynecological Sample

- Remove all inputs and then type on the display the keys **1 # ENTER**
- The equipment will enter Cleaning Mode and perform several movements and calibrations, until the message “Waiting for Cleaning” is displayed on the DISPLAY;
- Open the TPK FENIX door, clean the Seal Cover (item 6.3 of this Manual) and, if necessary, perform the Residue Depletion Disposal (item 6.4 of this Manual).
- After carrying out all the Cleaning processes, close the TPK FENIX door and press the STOP key;
- On the DISPLAY will be the message “Ready to use”, then perform the Liquid Cleaning Mode (DLMV) (item 6.3 of this Manual);

Operation with <u>NON Gynecological</u> sample

- Remove all supplies;
- Insert 1 FILTER into the PRE-FILTER and position it;
- Insert 1 VIAL with alcohol or CELLPRESERV SOLUTION – ATTENTION CANNOT HAVE A SAMPLE IN THIS SOLUTION;
- Type on the display the keys **2 # ENTER**
- The equipment will enter Suction Cleaning Mode and perform various movements and calibrations, until the message “Remove Inputs” is displayed on the DISPLAY;
- Open the TPK FENIX door, remove the FILTER and VIAL and discard;
- Close the door;
- On the DISPLAY will be the message “Ready to use”.

6.2 PreFilter Cleaning

- Remove residual grease;
- Clean with alcohol preferably alcohol;
- Apply grease to the upper seal ring;

6.3 Cleaning the Sealing Cap (capseal) 1# ENTER and Liquid Cleaning (DLMV) 4# ENTER

- With the equipment off, remove all inputs (pre-filter, fixation vial, slide), close the equipment door, turn on the equipment and enter the cleaning mode (press the control buttons on the panel, in this sequence: **1#** and ENTER;
- After the equipment is positioned correctly and the display indicates the message “waiting for cleaning”, open the door and clean the sealing cap with alcohol, preferably absolute alcohol;
- Clean the holes in the part with the cleaning brush to clear them;

- At the end of the procedure, close the door, press “STOP” and wait for the machine to reposition itself.
- To activate **Liquid Cleaning Mode** (Differential Low Mechanic Vacuum), the Processor must indicate on the screen “Ready for use”, then connect the green filter to the pre-filter, insert it into the equipment, close the door, type the command 4# ENTER . The processor will position the filter at 180°and activate the pneumatic pump for 1 minute, sucking any liquid residue from the hoses directly into the waste tank.
- Wait for the cleaning to take place (approximately 2 minutes) (Only in firmware version 6.2K and above) until the message “Remove Pre-filter” appears on the SCREEN, open the door, remove the Pre-filter with the green filter, wipe any liquid residue from the sealed filter and the pre-filter with a paper towel, close the door and turn off the Processor.

6.4 Residue Depletion

Depletion should occur when necessary, not exceeding the 3500 ml mark (red line identified in the Residue Vial, Figure 23- Residue Via), and the residue must be disposed in accordance with the institution’s protocols.

NEVER allow liquid to exceed the maximum level line on the Residue Vial

NEVER allow liquid to access the hoses when moving the VIAL

When turning the lid of the RESIDUE VIAL <u>NEVER</u> turn the hoses

Figure 22 – Residue Vial

- With the equipment off, remove all inputs (pre-filter, fixation vial, slide), close the equipment door, turn on the equipment and enter the cleaning mode (press the control buttons on the panel, in this sequence: **1 #** and ENTER;

- After the equipment is correctly positioned and the display indicates the message “Waiting for Cleaning”, unplug the RESIDUE VIAL, keeping it in an upright position, carefully rotating the cap and not the vial or the hoses, not allowing the hoses to move and empty the Residue Vial;
- Lubricate the cap ring;
- Position the cap again;
- At the end of the procedure, press “STOP” and wait for the machine to reposition itself.

Any unwanted movement or operation in the VIAL causes residue to return through the hoses, clogging the residue filter, which may cause damage to the internal components and the consequent interruption in the operation of the equipment, which requires technical intervention.

6.5 Door Cleaning

- With the equipment off, clean the DOOR with alcohol, preferably absolute alcohol;
- Never use xylol in this process.

6.6 General cleaning

- With the equipment off, perform a general cleaning on the fairing using alcohol preferably absolute;
- Never use xylol in this process.

6.7 Changing the Absorber

- Change the absorbent if you notice a hardening of part of it or entirely with a new one.

6.8 Cleaning the Optical Keys

- With the equipment off, use a rod or swab dipped in alcohol, preferably absolute, to clean each of the optical keys present;
- Cleaning must have a focus on the optical window present in the component;
- Only turn on the equipment when making sure that all clean components are dry.

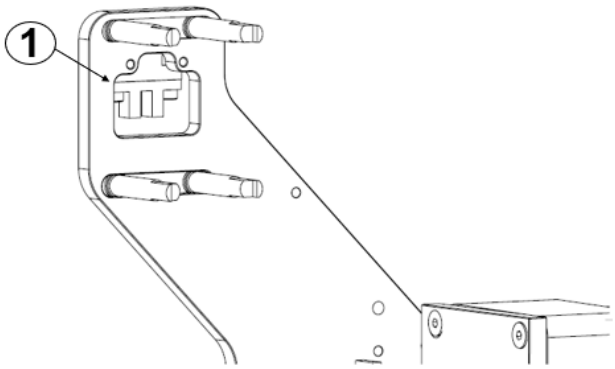

Figure 23 – Positioning the sensor 1 slide ejection

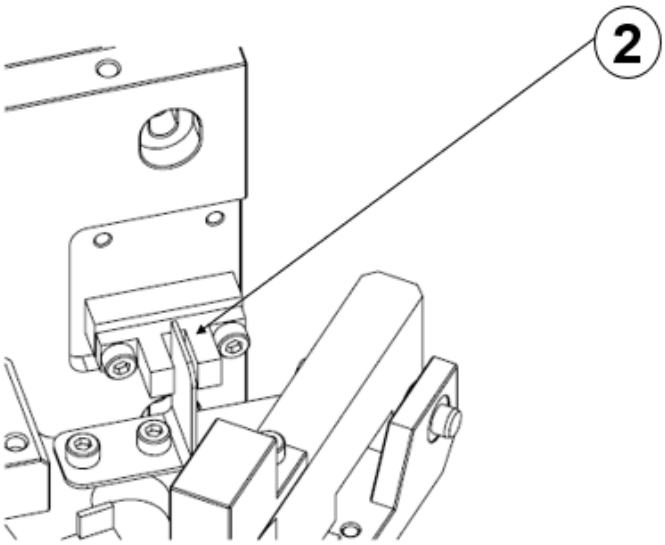

Figure 24 – Positioning sensor 2 on the rotation plate

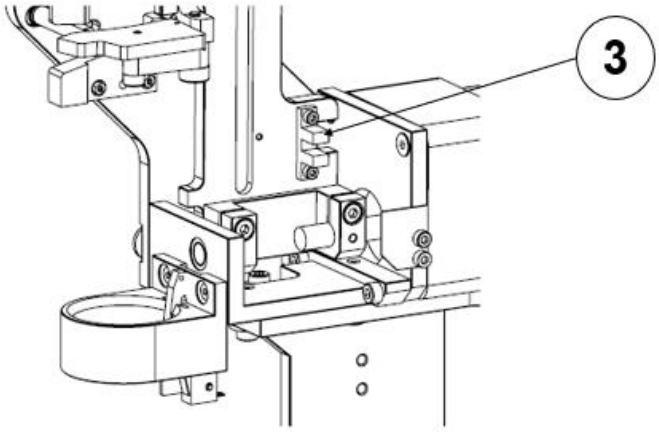

Figure 25 – Positioning sensor 3 of the slide handler

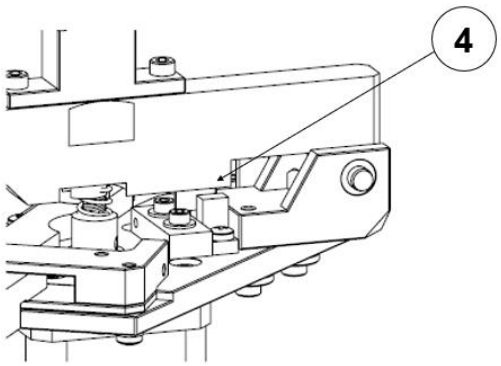

Figure 26- Positioning sensor 4 of sealing

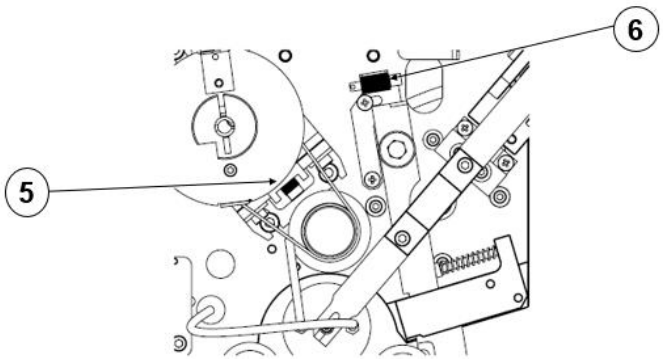

Figure 27 -Positioning sensor 5 of dispersion motor and sensor 6 of the prefilter

6.9 Cleaning the Front Hoses

- With the equipment off, disconnect all front hoses;
- Clean each one using an empty syringe;
- Reconnect them back to their proper points.

7 PREVENTIVE AND CORRECTIVE MAINTENANCE

7.1 Preventive Maintenance

Preventive maintenance must be performed by Kolplast, or by an authorized network company. It must be carried out every 12 (twelve) months.

7.2 Corrective Maintenance

In case the equipment is abnormal, KOLPLAST must be contacted and must evaluate the equipment to identify the actions required.

For both Preventive and Corrective Maintenance, the Electromedical Equipment should not be in use with the patient.

8 TROUBLESHOOTING

The table below lists the potential main problems that may occur before or during the operation of the equipment:

Failure	Cause	Solution
Insert Pre-Filter	Equipment did not detect the insertion of the filter	Insert the pre-filter with the filter
Insert Slide	Equipment did not detect the insertion of the slide	Insert a new slide
Insert new vial	Equipment did not detect the insertion of the slide ejection vial	Insert the slide ejection vial
No filter	Equipment did not detect the liquid in the sample vial	Make sure the solution is in the matte range
Sample overflowing during processing	CellPreserv sample vial volume is greater than 21 ml	If it is necessary to reduce the sample vial volume to between 17 ml and 21 ml, store excess fluid in a suitable container and continue the processing. If not solved, the equipment should contact Kolplast Technical Assistance
	Dispersion speed above specified	Contact Kolplast Technical Support
	Equipment malfunction	Contact Kolplast Technical Support

Table 2 - Problems Solution

9 SAFETY SPECIFICATIONS

9.1 Warnings and/or Precautions with the Users

- Before putting the equipment into operation, consult this *Instruction Manual*;
- The equipment must be operated only by suitably trained personnel;
- Do not use the equipment when it is damaged.
- The equipment may contain colored markings (yellow, green or white) on screws or specific points, which is part of the control of verification of fastening, assembly and tightening of screws during the production process.
- Switch off the equipment safely by disconnecting the power cable from the mains.

9.2 Warnings and/or Precautions during Use

- Use the equipment exclusively for the purposes described in this *Instruction Manual*;
- It cannot be used in conjunction with high frequency equipment;
- Always support the equipment on a flat surface, clear of other equipment with centrifugal technology;
- Do not wrap the power cable around the equipment;
- The user does not need to adjust any controls that have not been described in this *Instruction Manual*;
- If the equipment malfunctions, switch off the equipment safely by disconnecting the power cable from the mains and contact KOLPLAST.

9.3 Warnings and/or Precautions about Explosion Danger

- The equipment is not suitable for use in the presence of flammable anesthetic gases or other flammable materials, such as some types of cleaning fluids.

9.4 Electrical Care Warnings and/or Precautions

- If the equipment is not going to be used for a long time, it must be placed in a suitable place, disconnected from the mains and covered to prevent damage caused by dust.
- Switch off the equipment safely by disconnecting the power cable from the mains.
- To avoid risk of electric shock, this equipment should only be connected to an earthed mains supply for protection.

The use of accessories, transducers and cables other than those specified or supplied by the manufacturer of this equipment could result in increased electromagnetic emissions or reduced electromagnetic immunity of this equipment and result in improper operation.

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should not be used within 30cm of any part of the TPK Phoenix Slide Processor, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment may occur.

9.5 Warnings and/or Precautions during Transport and Storage

- The equipment must be protected from moisture (do not expose to rain, splashes, etc.);
- Because it is delicate, care must be taken not to let it tip or fall to the floor.

9.6 Warnings and/or Precautions during Corrective Maintenance

- Do not attempt to repair, assemble defective and inoperative components or replace parts with another device. KOLPLAST does not supply the original electrical and mechanical parts to other companies that are not members of the authorized maintenance network. Only KOLPLAST and members of the authorized network can carry out repairs with original parts;
- Only with the use of original parts and technical specifications can the safety of the device be guaranteed.

9.7 Warnings and/or Precautions during Preventive Maintenance

- KOLPLAST is responsible only for the technical safety features of this equipment, according to the legal provisions if the maintenance, repair and modifications of this device are carried out by the company itself or by an authorized agent.

9.8 Warnings and/or Precautions during Cleaning

- Autoclaving or high temperature sterilization is not permitted. For cleaning and disinfection refer to the specific item in this *Instruction Manual*.

9.9 Special Specifications

- This equipment requires special precautions regarding its electromagnetic compatibility and must be installed and operated in accordance with the electromagnetic compatibility information provided in this Instruction Manual;
- Portable and mobile RF communication equipment may affect the equipment;
- The equipment must not be used near or stacked on top of other equipment. If necessary, it is recommended that the equipment be observed to verify normal operation in the configuration to be used;
- Do not turn off the equipment while it is in operation;
- When the system is running, when opening the front door, the system will stop and pause; close the door and the system will return to its operation;
- The residue solution vial should be placed with the cap facing up. Do not turn it in the opposite direction;

- Clean the residue vial when it reaches the specified level

9.10 Disposal

Electro-Electronic Equipment

Dispose of them separately from other objects in the establishment. Check the local regulations for electronic waste

Incorrect disposal may affect the environment

Attention: The use of any part, accessory or material not specified or provided for in this *Instruction Manual* is under the user´s sole responsibility

10 TECHNICAL SPECIFICATIONS

10.1 Compatibility with other Medical Products

Not applicable

10.2 General Specifications

Constant fluctuations in the power supply that occur in several cities in the country can jeopardize the correct functioning of the Kolplast **SLIDE PROCESSOR**. This condition is particularly prevalent in homes or buildings that were not previously built and equipped specifically for the activities developed in a doctor's office or clinical analysis laboratory. As a result of this situation, Kolplast requests that the EQUIPMENT be supported by a UPS device with a minimum power of 200VA.

Equipment does not have an alarm

10.3 Equipment Classification According to NBR IEC 60601-1 Standard

- Type of Protection against Electric Shock: **Class I equipment;**
- Degree of Protection against Electric Shock of the Applied Part: **Type B;**
- Degree of Protection against Harmful Water Penetration of the Equipment: **IPX1;**
- Degree of protection against use in the presence of flammable anesthetics with air, oxygen or nitrous oxide: **not suitable**;
- Mode of Operation: **Continuous.**

Technical specifications:

Rated Voltage: 85V to 230Vca

Frequency: 50/60Hz

Input Power: ≤160VA

Fuse: 2A

10.4 Environmental conditions specifications

Best condition for Equipment Operation:

Room temperature: 15°C to 22°C.

Relative humidity: 10% to 80%, non-condensing;

Atmospheric pressure: 700hPa to 1.060hPa.

Storage and Transportation Conditions;

Room temperature: 2°C to 45°C;

Relative humidity: 10% to 95%;

Atmospheric pressure: 700hPa to 1.060hPa.

10.5 Specifications According to NBR IEC 60601-1-2

The equipment requires special precautions regarding Electromagnetic Compatibility (EMC) and must be installed and connected in accordance with the EMC information contained in this *Instruction Manual*.

The equipment may affect and cause electromagnetic interference to other electro-medical equipment.

The equipment must not be used next to, on or under other equipment. If it is necessary to use it in one way or another, check the correct operation of the device in the type of configuration used.

MANUFACTURER'S GUIDE AND DECLARATION - ELECTROMAGNETIC EMISSIONS		
The TPK FENIX SLIDE PROCESSOR is intended for use in the electromagnetic environment described below. The purchaser or operator of the TPK FENIX PROCESSOR should ensure that it is in use in such an environment.		
Emission Tests	**Compliance**	**Electromagnetic Environment - guidance**
RF emission CISPR 11	Group 1	The TPK FENIX SLIDE PROCESSOR uses RF energy only for its internal operation. Thus, its RF emission is very low and it is not likely to cause any interference to other nearby electronic equipment.
RF emission CISPR 11	Class B	The TPK FÊNIX SLIDE PROCESSOR is intended for use in in all establishments other than residential and those directly connected to the public low-voltage electricity distribution network that supplies buildings for domestic use.
Harmonic emission IEC 61000-3-2	Class A	

Voltage fluctuation / Flicker emission IEC 61000-3-3	Compliant	

Table 3 - Electromagnetic Emissions

Phenomenon	**Basic EMC standard or test method**	**IMMUNITY TEST LEVELS**	
		Professional health care environment	**HOME HEALTH CARE ENVIRONMENT**
ELECTROSTATIC DISCHARGE	ABNT NBR IEC 61000-4-2	± 8 KV contact ± 2 KV, ± 4 KV, ± 8 KV, ± 15 KV air	
Radiated RF EM fields at	ABNT NBR IEC 61000-4-3	3 V/m f 80 MHz – 2.7 GHz b 80 % AM a 1 kHz c	10 V/m f 80 MHz – 2.7 GHz b 80 % AM a 1 kHz c
Fields in the vicinity of RF wireless communication equipment	ABNT NBR IEC 61000-4-3	See 8.10.	
Magnetic fields at the DECLARED supply frequency d e	IEC 61000-4-8	30 A/m g 50 Hz or 60 Hz	

[a] The interface between the PATIENT physiological signal simulation, if used, and the EM EQUIPMENT or EM SYSTEM shall be located within 0.1 m of the vertical plane of the uniform field area in one orientation of the EM EQUIPMENT or EM SYSTEM.

[b] EM EQUIPMENT or EM SYSTEMS that intentionally receive RF electromagnetic energy for the purposes of their operation shall be tested at the receiving frequency. Testing at other modulation frequencies identified by the RISK MANAGEMENT PROCESS is possible. This test evaluates the BASIC SAFETY and ESSENTIAL PERFORMANCE of an intentional receiver when an ambient signal is in the passband. It is understood that the receiver might not achieve normal reception during the test.

[c] It is possible to perform tests on other modulation frequencies identified by the RISK MANAGEMENT PROCESS.

[d] Applies only to EM EQUIPMENT and EM SYSTEMS with components or circuits sensitive to magnetic fields.

[e] During the test, the EM EQUIPMENT or EM SYSTEM may be switched on at any NOMINAL input voltage, but at the same frequency as the test signal (see Table 1).

[f] Before the application of modulation.

[g] This test level assumes a minimum distance between the EM EQUIPMENT or EM SYSTEM and the magnetic fields at the supply frequency of at least 15 cm. If the RISK ANALYSIS shows that the EM EQUIPMENT or EM SYSTEM will be used less than 15 cm away from magnetic

fields at the supply frequency, the IMMUNITY TEST LEVEL shall be adjusted as appropriate for the minimum expected distance.

Table 4 - Cabinet Interface

GUIDELINES AND MANUFACTURER'S DECLARATION - ELECTROMAGNETIC IMMUNITY			
The TPK FENIX SLIDE PROCESSOR is intended for use in the electromagnetic environment specified below. The purchaser or operator of the TPK FENIX SLIDE PROCESSOR should ensure that it is in use in such an environment.			
Immunity Testing	**IEC 60601 Test Level**	**Level of Compliance**	**Electromagnetic Environment - guidance**
RF Conducted IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 V	Portable and mobile RF communications equipment should not be used closer, to any part of the TPK FENIX LAMP PROCESSOR, including cables, than the recommended separation distance calculated from the applicable equation for the frequency of the transmitter. Recommended separation distance $d = 1,2.\sqrt{P}$ $d = 1,2.\sqrt{P}$ 80 MHz to 800 MHz $d = 2,3.\sqrt{P}$ 800 MHz to 2.5 GHz Where P is the maximum output power of the transmitter in watts (W), according to the transmitter manufacturer, and d is the recommended separation distance in meters (m).
RF Irradiated IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	The field generated by fixed RF transmitters, as determined by a study of the electromagnetic field at the site[a], should be lower than the compliance level in each frequency band.[b] Interference may occur in the vicinity of equipment with the following symbol: 
NOTE 1: in the 80 MHz and 800 MHz band, the highest frequency of the band applies.			

NOTE 2: This procedure may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.
The intensity of fields generated by fixed transmitters such as base stations for telephones (cellular/cordless) and land mobile radios, amateur radios, AM, FM and TV broadcasting stations cannot be theoretically predicted accurately. To assess the electromagnetic environment due to fixed RF transmitters, a study of the electromagnetic field at the site should be considered. If the measured field strength at the location in which THE TPK FENIX SLIDE PROCESSOR is used exceeds the above compliance level, THE TPK FENIX SLIDE PROCESSOR should be observed to verify that it is operating normally. If abnormal performance is observed, additional measures may be required, such as reorientation or relocation of the TPK FENIX SLIDE PROCESSOR. a. Above the frequency range 150 kHz to 80 MHz, the field strength should be less than 3 V/m.

Table 5- Electromagnetic Immunity

Recommended Separation Distances between Portable and Mobile RF Communication Equipment and the TPK FENIX SLIDE PROCESSOR			
The TPK FENIX SLIDE PROCESSOR is intended for use in an electromagnetic environment in which RF disturbances are controlled. The purchaser or operator of the TPK FENIX SLIDE PROCESSOR can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the TPK FENIX SLIDE PROCESSOR as recommended below, according to the maximum output power of the communications equipment.			
Maximum declared output power of the transmitter (W)	Separation Distance According to Transmitter Frequency		
	150 kHz to 80 MHz $d = 1{,}17\sqrt{P}$	80 MHz to 800 MHz $d = 1{,}17\sqrt{P}$	800 MHz to 2.5 GHz $d = 2{,}3\sqrt{P}$
0.01	12 cm	12 cm	23 cm
0.1	37.9 cm	37.9 cm	72.7 cm
1	1.2 m	1.2 m	2.3 m
10	3.8 m	3.8 m	7.3 m
100	12 m	12 m	23 m
For transmitters with the stated maximum output power not listed above, the recommended separation distance (d in meters) can be determined using the equation applicable to the frequency of the transmitter; where P is the maximum output power of the transmitter in watts (W) according to the transmitter manufacturer. NOTE 1: at 80 MHz and 800 MHz, the separation distance for the higher frequency applies. NOTE 2: this procedure can apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

Table 6 - Recommended separation distance

Phenomenon	Basic EMC standard	IMMUNITY TEST LEVELS	
		Professional health care environment	HOME HEALTH CARE ENVIRONMENT
Electrical fast transients/bursts at l o	ABNT NBR IEC 61000-4-4	± 2 KV 100 kHz repetition frequency	
Line-to-line surges	IEC 61000-4-5	± 0.5 kV, ± 1 kV	
Surge a b j k o line-to-ground	IEC 61000-4-5	±0.5 kV, ±1 kV, ±2 kV	
Conducted disturbances induced by RF fields c d o	IEC 61000-4-6	3 V m 0,15 MHz – 80 MHz 6 V m em bandas ISM entre 0,15 MHz e 80 MHz n 80 % AM a 1 kHz e	3 V m 0,15 MHz – 80 MHz 6 V m em bandas ISM e de radioamador entre 0,15 MHz e 80 MHz n 80 % AM a 1 kHz e
Voltage drops f p r	IEC 61000-4-11	0 % UT; 0,5 ciclo g A 0°, 45°, 90°, 135°, 180°, 225°, 270° e 315° q	
		0 % UT; 1 ciclo e 70 % UT; 25/30 ciclos h Monofásico: a 0°	
Voltage interruptions f i o r	IEC 61000-4-11	0 % UT; 250/300 cycles h	

a The test may be performed at any power input voltage within the DECLARED voltage range of the ME EQUIPMENT or ME SYSTEM. If the ME EQUIPMENT or ME SYSTEM is tested at a power input voltage, it is not necessary to retest at additional voltages.

b All cables to the ME EQUIPMENT and ME SYSTEM are connected during the test.

c Calibration for current injection clamps shall be performed on a 150 Ω system.

d If the frequency step skips an ISM or amateur radio band, as applicable, an additional test frequency shall be used on the ISM or amateur radio band. This applies to each ISM and amateur radio band within the specified frequency range.

e Tests may be performed at other modulation frequencies identified by the RISK MANAGEMENT PROCESS.

f ME EQUIPMENT and ME SYSTEMS with a dc power input intended for use with ac to dc converters shall be tested using a converter meeting the specifications of the ME EQUIPMENT or ME SYSTEM MANUFACTURER. The IMMUNITY TEST LEVELS are applied to the ac power input of the converter.

g Applicable only to ME EQUIPMENT and ME SYSTEMS connected to the single-phase ac mains.

h For example: 10/12 means 10 periods at 50 Hz or 12 periods at 60 Hz.

i ME EQUIPMENT and ME SYSTEMS with a DECLARED input current greater than 16 A/phase shall have the voltage interrupted once per 250/300 cycles at any angle and on all phases at the same instant (if applicable). ME EQUIPMENT and ME SYSTEMS with battery backup shall resume operation on line power after the test. For ME EQUIPMENT and ME SYSTEMS with a DECLARED input current not exceeding 16 A, all phases shall be interrupted simultaneously.

j ME EQUIPMENT and ME SYSTEMS that do not have a surge protection device in the primary power circuit may be tested only line(s) to ground with ± 2 kV and line(s) to line(s) with ± 1 kV. k Not applicable to Class II ME EQUIPMENT and ME SYSTEMS. l Direct coupling shall be used. m r.m.s., prior to the application of modulation. n The ISM (industrial, scientific and medical) bands between 0.15 MHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz. The amateur radio bands between 0.15 MHz and 80 MHz are 1.8 MHz to 2.0 MHz, 3.5 MHz to 4.0 MHz, 5.3 MHz to 5.4 MHz, 7 MHz to 7.3 MHz, 10.1 MHz to 10.15 MHz, 14 MHz to 14.2 MHz, 18.07 MHz to 18.17 MHz, 21.0 MHz to 21.4 MHz, 24.89 MHz to 24.99 MHz, 28.0 MHz to 29.7 MHz, and 50.0 MHz to 54.0 MHz. o Applicable to ME EQUIPMENT and ME SYSTEMS with a DECLARED input current less than or equal to 16 A/phase and ME EQUIPMENT and ME SYSTEMS with a DECLARED input current greater than 16 A/phase. p Applicable to ME EQUIPMENT and ME SYSTEMS with a DECLARED input current less than or equal to 16 A/phase q At some phase angles, applying this test to ME EQUIPMENT with mains power input from the transformer may cause an overcurrent protective device to open. This may occur due to magnetic flux saturation of the transformer core after the voltage drop. Should this occur, the ME EQUIPMENT or ME SYSTEM shall provide BASIC SAFETY during and after the test. r ME EQUIPMENT and ME SYSTEMS that have multiple voltage settings or automatic voltage change capability, the test shall be performed at the minimum and maximum DECLARED input voltage. ME EQUIPMENT and ME SYSTEMS with a DECLARED input voltage range less than 25% of the DECLARED input voltage shall be tested at a DECLARED input voltage within the range. See Table 1 -ABNT NBR IEC 60601-1-2:2017 - Note c) for example calculations

Table 7 - AC power input INTERFACE

10.6 Dimensions and Weight

Model	Weight (kg)	Dimensions (cm)		
		Length	Width	Height
TPK FENIX	18	46	33	57

Table 8 - Dimensions and Weight

11 AFTER SALES SERVICE

KOLPLAST CI Ltda

Technical Assistance

Estrada Municipal Benedito de Souza, number 418

Bairro da Mina - Itupeva – SP - Brazil

CEP 13299-364

Tel.: +55 11 4961-0900

at@kolplast.com.br

12 WARRANTY

To request any service, have the equipment serial number ready.

1. Your KOLPLAST product is guaranteed against manufacturing defects for a period of 12 months from the issuance of the invoice to the consumer, namely:
   - 3 months - legal warranty;
   - 9 last months - special warranty, granted by Kolplast - Electromedical Unit.

The Special Warranty does not cover:

- Displacement for service of products installed outside the Kolplast Service Network, which may charge a technician's transportation fee, previously approved by the consumer, according to the km table informed by Kolplast - Electromedical Unit;
- Any and all apparent manufacturing defects of easy verification;
- Parts subject to natural wear, consumables, as well as the labor used in the parts and the consequences arising from these occurrences.

2. During the warranty period, defective parts will be replaced or repaired, at KOLPLAST's discretion, and at no charge to the buyer. All expenses for transporting the equipment (round trip) will be borne by the buyer, for the purpose of remittance for repair to Technical Assistance. If the visit of a technician is necessary to carry out maintenance on-site, the costs of transportation, accommodation and other expenses related to this will also be borne by the buyer;
3. KOLPLAST reserves the right to collect replaced parts and components under warranty;
4. Excluded from the warranty are any and all objects subject to deterioration, natural wear or consumption, such as: batteries, dry batteries, rubber or plastic object, including protection, cables in general, etc;
5. Exceptions are also made for defects or damage resulting from accidents, such as: fire, flood, mains voltage accidents, mechanical or thermal shocks, maintenance, cleaning, improper use of the equipment or negligence;
6. The warranty will automatically expire at the end of the periods mentioned in this agreement;
7. If modifications, repairs, coupling of equipment, installation of parts of another brand by third parties, use of consumables from another brand or manufacturer other than that specified in this *Instruction Manual* are carried out on the equipment, without consent by KOLPLAST in writing, the warranty will be terminated immediately;
8. Any indemnifications for loss of profit, personal accidents and distinct assets are excluded from the warranty.
9. For maintenance carried out after the warranty period has elapsed, labor will be billed, as well as parts and/or components that may be defective.
10. General considerations:

Kolplast – Unidade de Eletromédicos does not authorize any person or entity to assume on its behalf, any other responsibility related to the warranty of its products other than those explained here.

Kolplast – Unidade de Eletromédicos reserves the right to change general, technical and aesthetic characteristics of its products, without prior notice.

This warranty agreement is valid for products sold and installed in the Brazilian territory. For peace of mind, keep the Instruction Manual with this Warranty Agreement and the purchase receipt of the product in a safe and easily accessible place.