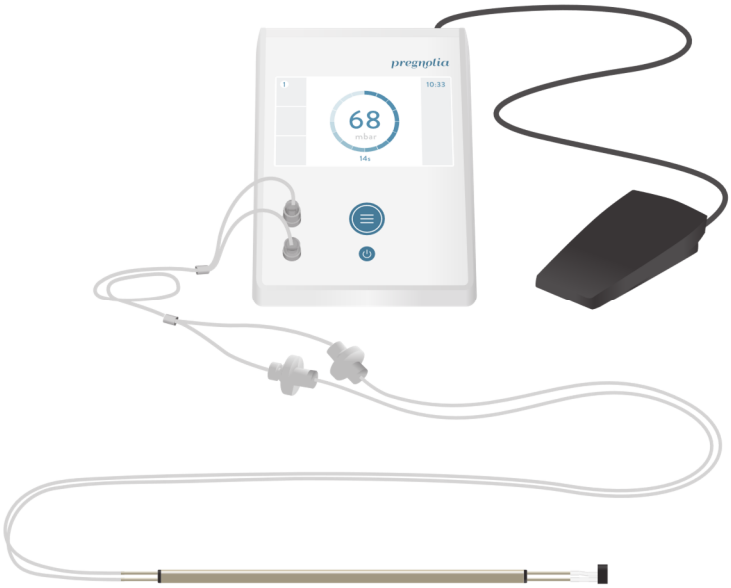
pregnolia®

INFORMED
PREGNANCY
CARE

PREGNOLIA SYSTEM

Cervical stiffness assessment

Instructions for Use



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Pregnolia System - Cervical stiffness assessment
Instructions for Use
P/N 100041-F
2021-09-06

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The latest version of these Instructions for Use is available online at
www.pregnolia.com/instructions

The translation of this manual in other languages is available online at
www.pregnolia.com/instructions

ABOUT THESE INSTRUCTIONS FOR USE

This manual provides instructions and information on the use of the Pregnolia System, ensuring subject and user safety. Read this manual carefully before operating the system. The user is responsible for operating the system as indicated in these Instructions for Use.

This manual uses the following conventions:

WARNING	A situation which, if not avoided, could result in death or serious injury.
CAUTION	Potentially hazardous situation which, if not avoided, may result in minor or moderate injury to the user or patient or damage to the equipment or other property.
NOTE	Note statements include additional important information for the user which is not hazard-related.

Symbol Legend

The following symbols are used in the product labelling.

Symbols on the Pregnolia Probe label:

	Manufacturer		Caution
	Catalogue number		Use-by-date
	Do not use if package is damaged		Type BF applied part
	Keep away from sunlight		Batch code
	Keep dry		Sterilized using ethylene oxide
	Temperature limit		Do not resterilize
	Humidity limitation		Do not re-use
	Atmospheric pressure limitation		Consult Instructions for Use
	EU Authorized Representative	UKRP	United Kingdom Representative
	Compliant with the essential requirements / general safety and performance requirements		

Symbols on the Pregnolia Control Unit labels:

	Manufacturer		Type BF applied part
REF	Catalogue number		Class II equipment
	Keep away from sunlight		Foot switch
	Keep dry		Center-positive polarity
	Temperature limit	EXT	Extension port
	Humidity limitation	SN	Serial number
	Atmospheric pressure limitation		Date of manufacture
	Caution		For indoor use only
CE	Compliant with the essential requirements / general safety and performance requirements		Do not dispose by dumping in garbage. Use a separate collection for electrical and electronic equipment
	Follow Instructions for Use	IP20	Protected against ingress of solid objects greater than 12.5 mm
	Direct current	EC REP	EU Authorized Representative
		UKRP	United Kingdom Representative

Symbols on the *power supply* label:


Class II equipment


Center-positive polarity


For indoor use only

CE
Affirms the product's conformity with European health, safety, and environmental protection standards


Do not dispose by dumping in garbage. Use a separate collection for electrical and electronic equipment

IP22
Protected against ingress of solid objects greater than 12.5 mm and against harmful effects due to the ingress of water


Recognized components for Canada and United States


Level VI efficiency standard

Symbols on the *foot switch* label:


Class II equipment


Recognized components for Canada and United States

IPX7
Protected against short durations of water immersion

CE
Affirms the product's conformity with European health, safety, and environmental protection standards

Other symbols used in this manual:


Pay attention


Single audio signal


Continuous beeping


No audio signal

Stop


When visible

The Pregnolia Control Unit and the Pregnolia Probe are certified by TÜV SÜD (CE 0123).

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TABLE OF CONTENTS

1. INTRODUCTION

1.1 System Overview

The Pregnolia System assesses the stiffness of the cervical tissue in pregnant and non-pregnant women to determine the biomechanical properties of the tissue.

The Pregnolia System is composed of two products: an active *control unit* (Pregnolia Control Unit) and a single-use *sterile probe* (Pregnolia Probe) (FIGURE 1).

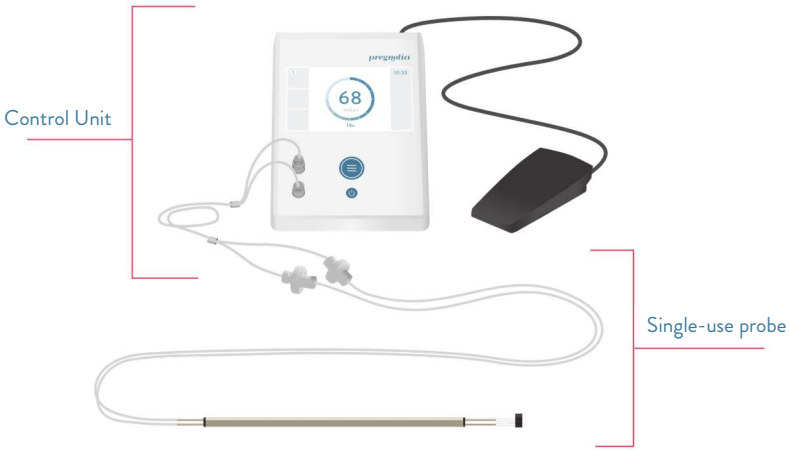


FIGURE 1: System components: *control unit* and single-use *probe*.

The *control unit* is an active device with a *power supply* and an integrated pump that generates vacuum. The single-use *sterile probe* is connected to the *control unit* through a *connector cable*. Air *filters* on the *probe* prevent microbiological contamination of the *control unit*.
The *probe* is transvaginally applied on the anterior lip of the cervix with the aid of a speculum and, if necessary, an external light source (FIGURE 2).

CAUTION	Do not use *probes* from a third-party supplier as this will result in abnormal device functionality and may cause harms to the subject.

To determine the tissue stiffness, the *control unit console* generates a weak vacuum and the cervical tissue is slowly deformed into the *probe tip* (FIGURE 2, INSET). The vacuum level required to displace the tissue into the *probe tip* by a fixed distance characterizes the tissue stiffness. This vacuum level is called the closing pressure (p_{cl}), or Cervical Stiffness Index (CSI), in mbar.

NOTE	The system turns itself off at a maximum vacuum pressure of 475 mbar. This minimises any potential risk to the woman.

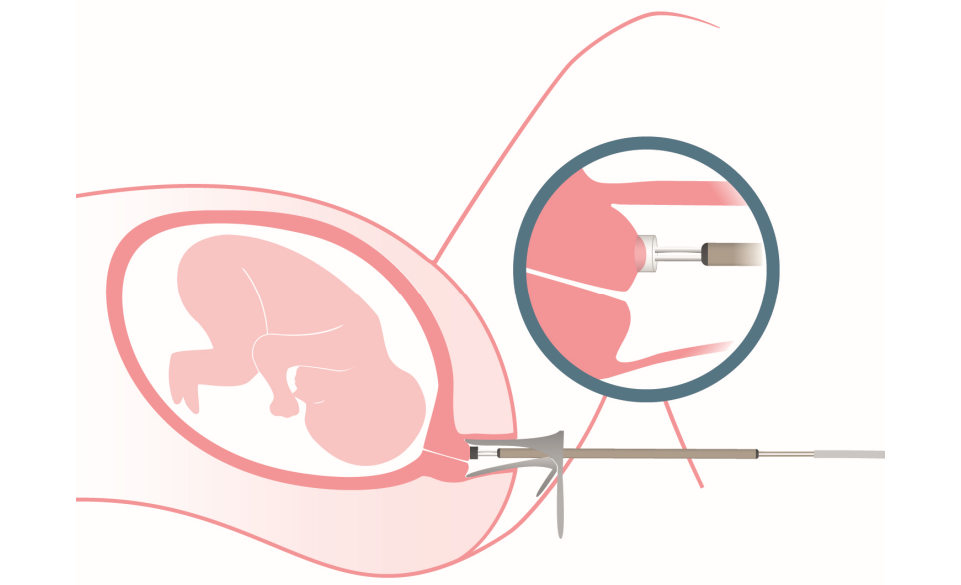


FIGURE 2: Operation Overview. The *probe* is placed on the anterior lip of cervix with the aid of a speculum. INSET: A weak vacuum deforms the cervical tissue into the *probe tip* by a fixed distance of 4mm.

The *probe* is designed to minimise the contact interaction between the user and the woman during the measurement. The *probe handle* (see ***Chapter 2.5 - Probe*** for probe description) slides freely, so the user does not impart contact force on the cervix during the measurement and to prevent the influence of woman movement (FIGURE 3).

FIGURE 3: *Probe handle* slides freely to minimise contact interaction during measurement.

1.2 User Assistance Information

For technical information or assistance, the user should consult this manual or the online electronic material available **at www.pregnolia.com/instructions**, or contact Pregnolia AG at **support@pregnolia.com**.

1.3 Intended Use

The intended use of the Pregnolia System is to provide information about the mechanical properties of the uterine cervix by assessing the tissue stiffness through a proxy parameter (the closing pressure, denominated CSI, or Cervical Stiffness Index, in mbar). The Pregnolia System is intended to be used in conjunction with the information obtained from the clinical evaluation of the patient and in addition to other standard examinations. It does not substitute them.

1.4 Medical Conditions

Any clinical situation where the quantitative determination and monitoring of the uterine cervix stiffness can be beneficial, in order to gather supportive data for diagnostics and characterisation of cervical remodelling. In particular, during pregnancy, when an atypical cervical remodelling condition can be a symptom or a precursor to an abnormal course of pregnancy.

1.5 Indications

Assessment of tissue stiffness of the uterine cervix during gynaecological examinations, indicated in any situation where the quantitative determination and monitoring of the uterine cervix stiffness can be beneficial, in order to gather supportive data for diagnostics and characterisation of cervical remodelling. In particular, during pregnancy, where an atypical cervical remodelling condition can be a symptom or a precursor to an abnormal course of pregnancy.

1.6 Patient Population

The intended patient population are all pregnant and non-pregnant women for which the assessment of the uterine cervix is indicated. Refer to ***Section 1.10 – Contraindications***.

1.7 User Group

The Pregnolia System is intended to be used by healthcare professionals with medical expertise in the fields of gynaecology or obstetrics, such as gynaecologists and midwives. The user must be familiar with speculum-based vaginal examinations. The user must have read these Instructions for Use. The system is not intended to be used by the patient.

1.8 Use Environment

The Pregnolia System is designed for use in a gynaecological examination room equipped for speculum-based vaginal examinations. In addition, noise levels should be moderate so as not to obscure the audio signals emitted by the system. Please refer to ***Section 1.14 – Training***. The system is to be used with the aid of a speculum and, if necessary, an external illumination source. Furthermore, the use of standard medical accessories is necessary, such as gloves to handle the *sterile probe* and swabs and saline solution to clear the cervix of excessive mucus or the possible presence

of ultrasound gel. The patient shall be seated and positioned in a manner consistent with routine practice for speculum-based vaginal examination.

1.9 Performance

The intended clinical performance of the Pregnolia System is to:

- Provide users with a proxy value for the uterine cervix stiffness of a woman, designated as closing pressure (p_{cl}), or Cervical Stiffness Index (CSI), and expressed in mbar;
- Allow users to understand the proxy value (p_{cl}) by comparison to a stiffness guidance chart (FIGURE 4 and TABLE 1) with relevant physiological values.

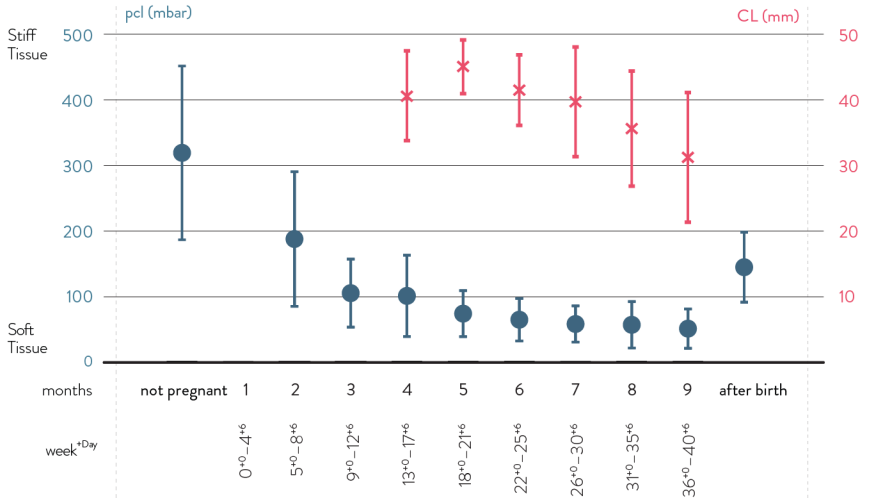


FIGURE 4: Collective results of closure pressure p_{cl} of the non-pregnant group and during gestation assessed with the Pregnolia System in the clinical investigation *Cervical Insufficiency* (Badir et al., *Prenatal Diagnosis*, 2013, 33, 737-741). Closure pressure p_{cl} of non-pregnant and pregnant women during singleton pregnancy (months 2–9) and post-partum (6-16 weeks at regular post-partum visit) are shown as blue dots – pink crosses indicate cervical length (CL), and the values refer to the second vertical axis on the right. For all values, means, and standard deviations are reported. The population is European, women are 18 years or older. Nulliparous and parous non-pregnant women (n=50) with and without contraception at different states in the menstrual cycle were included. For the pregnant women, nulliparous and parous women with singleton pregnancies are represented (n=42).

Table 1: Percentiles for each week of pregnancy (p_{el} in mbar). Data extrapolated from the clinical investigation *Cervical Insufficiency* (Badir et al., *Prenatal Diagnosis*, 2013, 33, 737-741).

week	5%	10%	25%	50%	75%	90%	95%
5	86	90	139	154	230	297	471
6	78	83	126	143	213	278	429
7	71	77	115	133	197	261	393
8	65	71	106	124	183	246	360
9	59	66	97	116	170	232	331
10	54	61	90	109	159	219	305
11	50	57	83	102	148	207	283
12	46	53	77	96	139	196	262
13	43	50	72	91	131	186	244
14	40	47	67	86	123	176	228
15	37	44	63	81	116	168	213
16	35	42	59	77	110	160	200
17	33	39	56	73	105	153	188
18	31	37	53	70	100	146	178
19	29	35	50	67	95	140	168
20	27	34	48	64	91	134	160
21	26	32	46	61	87	129	152
22	25	31	44	59	84	124	145
23	24	30	42	57	81	119	139
24	23	29	41	55	78	115	134
25	22	28	40	53	76	111	129
26	21	27	39	52	74	108	124
27	21	26	38	50	72	104	120
28	20	26	37	49	70	101	117
29	20	25	36	48	69	99	114
30	19	25	36	47	68	96	111
31	19	24	35	46	66	94	109
32	19	24	35	45	66	92	107
33	18	23	35	45	65	90	106
34	18	23	35	44	64	88	104
35	18	23	35	44	64	86	104
36	18	23	35	43	64	85	103
37	18	23	35	43	64	84	103

The assessment of the cervical stiffness on the same cervix, on the same location by the same user and after intervals of 2-3 hours gives a measurement variability with a standard deviation of up to approximately 15% of the reference value (first measurement) (Badir et al., *Prenatal Diagnosis*, 2013, 33, 737-741).

Viscoelasticity and immediate repeated measurements

The tissue of the cervix has viscoelastic properties. Viscoelastic materials have a time-dependent mechanical behaviour: after unloading, the tissue does not immediately recover back into its initial state. The recovery needs time. Due to viscoelasticity, immediate and repeated tests on the same location on the cervix are possible, but not representative of the native tissue response. Therefore, the user should record the order in which the sequential measurement results were obtained, for future reference and/or comparison purposes, and consider the result from the first measurement as representative of the native tissue.

1.10 Contraindications

The Pregnolia System has been designed to minimise any foreseeable risks when correctly used. However, the user must assess the appropriateness of using the system on a case-by-case basis, and evaluate the overall risk posed by its usage to the woman or, if applicable, to the foetus.

The use of the Pregnolia System is contraindicated in the following situations:

- Severe vaginal bleeding;
- Light bleeding (if the bleeding can be stopped, it is no longer a contraindication);
- *Placenta praevia totalis* with haemorrhage (irrespective of severity);
- Rupture of membranes before 34 weeks;
- Cervical dilation $\geq$ 3 cm.

1.11 Precautions

While repeated measurements are not harmful, they may temporarily alter the properties of the cervical tissue, yielding different results. It is recommended to note the order in which measurements were taken for future reference and comparison purposes.

Special care should be exercised in cases of:

- Female genital mutilation;
- *Placenta praevia* without bleeding;
- Müllerian anomalies with two cervices: a direct comparison to the guidance chart may not be possible as the two cervices may have a different stiffness value;
- Psychological reasons;
- Suspected or visible cervical and vaginal bacterial infections and viral infections: to minimize the possibility of damaging the cervical mucus plug and the spread of bacteria leading to ascending infection. Further, in case of suspected or visible cervical and vaginal infection, the stiffness value may not be representative of the native tissue.

Special care during the measurement should also be exercised in presence of one of the following conditions as the tissue may bleed if manipulated:

- Ectopy and cervical polyps;
- Nabothian cyst;
- Squamous intraepithelial lesion;
- Conization/LEEP[1]/LLETZ[2];
- Cervical endometriosis;
- Cervical carcinoma;
- Cervical myomas;

[1] Loop Electrosurgical Excision Procedure

[2] Large Loop Excision of the Transformation Zone

- Cervical condylomas;
- Cervical tears, scar tissue;
- Cervical dysplasia.

If any of the above conditions are present at the measurement location, the stiffness value may not be representative of the native tissue as those conditions may influence the tissue stiffness. If possible, measure on a location around 12 o'clock where the tissue is native (for example, at 11 o'clock or 1 o'clock).

Data presented in FIGURE 4 and TABLE 1 are for pregnant and non-pregnant women aged 18 years or older. Stiffness data for underaged women are not available, so a direct evaluation of the results is not possible.

1.12 Potential Complications

- Irritation and sensitization of mucosal tissue.
- Infection of the vaginal or mucosal tissue.
- Tissue abrasion and vaginal discharge.
- Spotting, light bleeding.
- Pulling sensation on the cervix.
- Superficial lacerations or minor tissue abrasions.
- Cardiac arrhythmia, heart attack: the Pregnolia System has been designed to minimise any foreseeable risks when correctly used. The use of the Pregnolia System as specified in the Instructions for Use reduces the risk of this potential complication.
- Under or over-treatment: undetected potential (pregnancy) complications or unnecessary treatment (such as progesterone administration) with possible adverse effect

1.13 Important safety information

- Make sure to use the Pregnolia Probe only in conjunction with the Pregnolia Control Unit.
- Upon system delivery, inspect the integrity of the *control unit case*. Do not use the *control unit* if external damage is visible. Immediately contact Pregnolia AG if shipping defects are observed.
- Do not dispose of the *control unit case*.
- Use the included *foot switch* only.
- Do not use any *power supply* from a third-party supplier.
- Do not use the system if no audio signal is emitted. Consult ***Chapter 6-Troubleshooting***.
- Do not use *probes* from a third-party supplier as this will result in abnormal device functionality and may cause harm to the subject.
- Do not use the demo probe on women as it is not sterile and may cause infections and/or harms to the woman.
- Prior to each usage, inspect the integrity of the *probe sterile pouch*. Do not use the *probe* if the *probe sterile pouch* looks damaged or open, since sterility may be compromised.
- Make sure the *probe* expiration date has not passed as the use of expired *probes* might lead to harm to the subject.
- No reuse or re-sterilization of the *probe* is allowed as this is out of the intended use and may lead to contamination or abnormal device functionality.
- Use gloves while handling the *sterile probe* to prevent contamination of the *probe*.
- Do not entirely remove the *probe* from the pouch during assembly in order to prevent the *probe* from contacting non-clean surfaces.
- Do not dispose of the *probe sterile pouch* before the measurement session is complete as it contains necessary reference information in case of issues with the device.
- If necessary, use external illumination. The placement region shall be visualized correctly.

- Remove excessive mucus before the measurement.
- Do not measure directly on the cervical canal.
- Use care when placing the *probe* on the cervix.
- Do not forcefully push the *probe handle* completely to the front as this may influence the measurement result.
- Do not pull the *probe handle* completely to the back as this may influence the measurement result.
- After each measurement, immediately dispose of the *probe* including the *filters and the probe sterile pouch.*
- Do not use any cleaning agent other than isopropyl alcohol.
- Never rinse the *control unit* with water or other fluids as this may damage the device.
- Always use the *control unit case* to ship or transport the *control unit*.
- No modification of the equipment is allowed.
- The Pregnolia System should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the Pregnolia System should be observed to verify normal operation.
- Use of components and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm to any part of the Pregnolia System, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment may occur.
- If subjected to strong electromagnetic fields or strong electrostatic discharge, the system may switch itself off. This is considered normal and does not affect the safety of the system. If such an event occurs, simply switch the system back on and re-start the measurement. In rare cases the system might get damaged and cannot be switched on again. If this occurs, unplug the system and contact Pregnolia AG for assistance.

- Follow the information contained in ***Chapters 4*** *and* ***5*** of this Instructions for Use for the maintenance and storage of the Pregnolia System products.

1.14 Training

CAUTION	Do not use the demo probe on women as it is not sterile and may cause infections and/or harms to the woman.

- Before the first usage, read these Instructions for Use in their entirety and complete the self-training by watching the training videos provided online at **www.pregnolia.com/instructions**.
- Training material is provided together with the *control unit*, inside the *control unit case*. It consists of a non-sterile demo probe (P/N 100060), a demonstration cervix (P/N 100059) and instructions on how to use the training material for familiarisation with the system.
- Use the training material to perform a familiarization test, following the instructions included in the *control unit case*:
  - Watch the Instructional video;
  - Follow the Instructional video step by step and use the training material to familiarize yourself with the system;
  - Watch the Training video.
- Do not use the non-sterile demo probe on women.
- During the familiarization test the user should verify that the audio signals emitted by the *control unit* can be heard over the ambient noise level. Do not use the system if the audio signals are not audible.

2. COMPONENTS DESCRIPTION

2.1 Control Unit Case

CAUTION	Follow the information contained in Chapters 4 and 5 of this Instructions for Use for the maintenance and storage of the Pregnolia System products.

CAUTION	Upon system delivery, inspect the integrity of the *control unit case*. Do not use the *control unit* if external damage is visible. Immediately contact Pregnolia AG if shipping defects are observed.

The *control unit case* contains the Pregnolia Control Unit (REF 100058 – see ***Section 2.2***) and the training material.

The training material consists of:

- Demonstration cervix (P/N 100059),
- Non sterile demo probe (P/N 100060),
- Instructions for self-training (P/N 100065).

If necessary, store the *control unit* inside the *control unit case* after each usage. If the *control unit* must be returned to Pregnolia AG, use the *control unit case* to pack the *control unit*.

CAUTION	Do not dispose of the *control unit case*.

2.2 Control Unit

The Pregnolia Control Unit (REF 100058) consists of (FIGURE 5):

- Pregnolia Control Unit – Console (REF 100044),
- Connector Cable (P/N 100035),
- Power Supply (P/N 100031),
- Foot Switch (P/N 100030),
- Instructions for Use (P/N 100041)

CAUTION	Use the included *foot switch* only.

CAUTION	Do not use any *power supply* from a third-party supplier.

- The *foot switch* is used to start and stop the application of vacuum by the *control unit console*. Press and release the *foot switch* to start the vacuum. If the vacuum has to be stopped any time during the measurement, press and release the *foot switch* again.
- The *power supply* is used to power the *control unit console*.
- The *connector cable* connects the *control unit console* to the *sterile probe*.

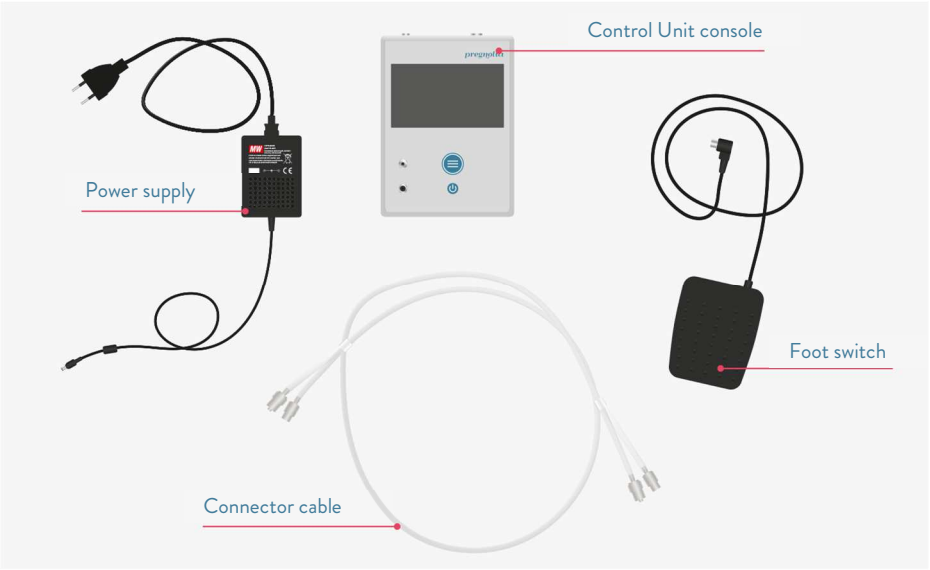


FIGURE 5: *Foot switch*, *connector cable*, *power supply* and *control unit console*.

2.2.1 *Control unit console – front*

The front of the *control unit console* is displayed in FIGURE 6.

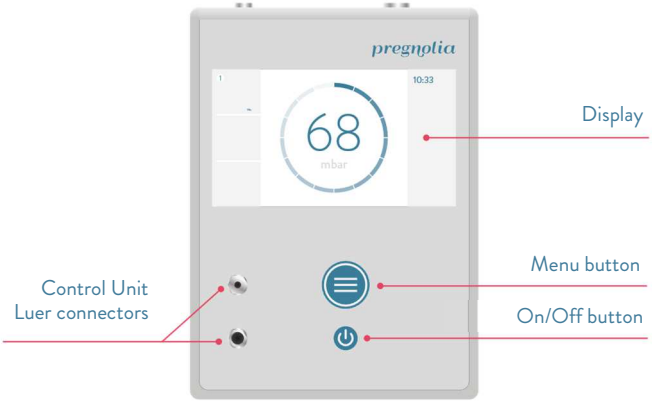


FIGURE 6: Front of the *control unit console*.

- On/Off button: turns on/off the *control unit console*.
- Menu button: shows the measurement screen on the Display.
- Control unit Luer connectors: enable connection of the *connector cable* to the *control unit console*.
- Display: shows the measurement values and enables interaction of the user with the *control unit console* through the menu.

2.2.2 Display screens

NOTE	The *control unit* records the latest three (3) measurement sessions, with up to three (3) measurements per session. Older measurement results are not accessible for the user anymore, and therefore the device should not be used for data backup purposes.

The main screen shows the following information:

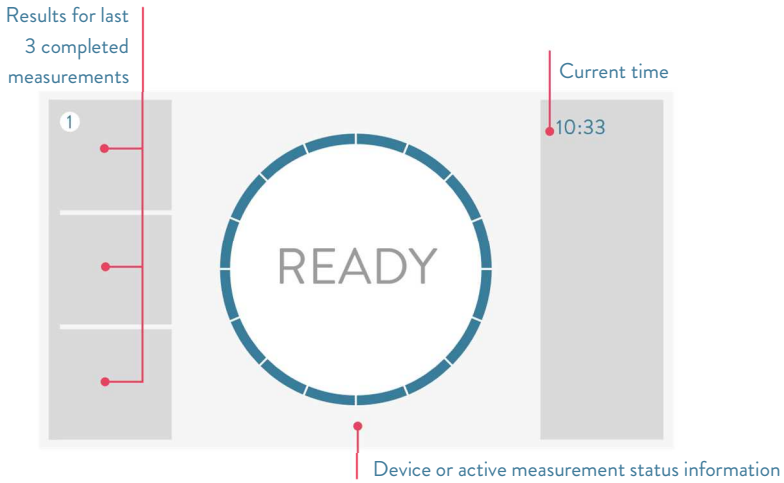
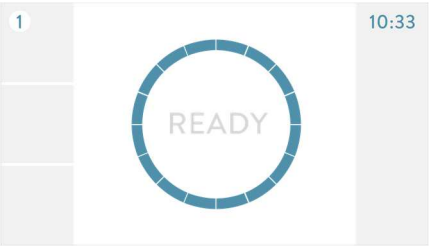
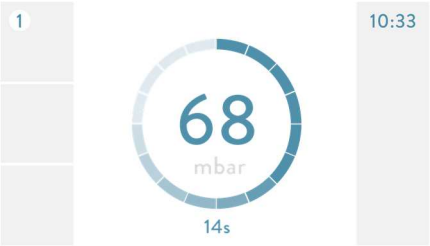


FIGURE 7: Main screen of the *control unit console*.

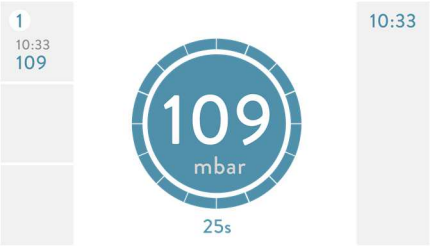
The main screen can display the following screens:



1. **Ready for the measurement.**
The system is ready for the measurement to be started.



2. **A measurement is running.**
The measurement is running. Current pressure and elapsed time are displayed.



3. **A measurement is complete.**
The measurement is finished. The final pressure value is displayed in the centre and stored on the left. If the displayed result is “Low”, the measured pressure is below 25 mbar. If the displayed result is “High”, the measured pressure is higher than 400 mbar.

4. **Three measurements are complete.**
Up two three measurements can be performed in one session. The pressure values of all three measurements are displayed on the left (in mbar).

5. **Past measurements screen.**
To recapitulate the past measurements (up to nine) access the measurements screen by pressing the Menu button. To return to the initial screen, press the Menu button again. Results are displayed in mbar, along with date and time of measurement. The column to the left contains the results of the last measurement session (up to three).

2.2.3 Control unit console - back

The back of the *control unit console* is displayed in FIGURE 8.

FIGURE 8: Back of the *control unit console*.

- *Foot switch inlet*: enables connection of the *foot switch* to the *control unit console*.
- *Power supply inlet*: enables connection of the *power supply* to the *control unit console*.

2.3 Probe Box

The *probes* are shipped in a box (*probe box*) containing 10 *sterile probes*. Each *sterile probe* is packed individually, in a sterile pouch (see ***2.4 – Probe Sterile Pouch***).

2.4 Probe Sterile Pouch

Each single-use, disposable *probe* is packed in a sterile pouch (*probe sterile pouch*), as shown in FIGURE 9. The *probes* have been sterilized using Ethylene Oxide. The opening side of the *probe sterile pouch* is indicated by an "Open Here" label (FIGURE 9).

FIGURE 9: *Probe sterile pouch.* Image for reference only.

2.5 *Probe*

The *probe* is displayed in FIGURE 10.

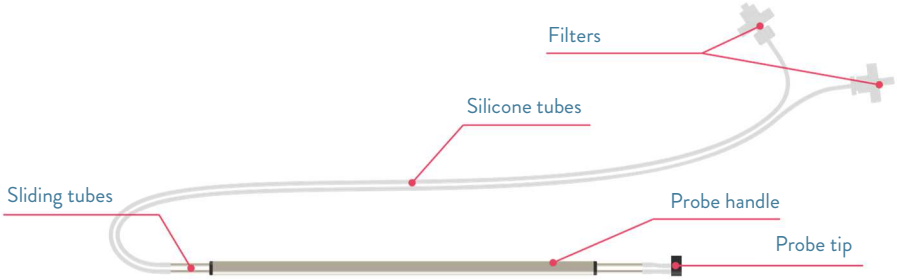


FIGURE 10: *Probe.*

The *probe* is connected to the *connector cable* through the *filters*. *Filters* prevent microbiological contamination of the *control unit*. The *probe tip* is the part of the *probe* to be placed in contact with the cervix. Note that the short *silicone tubes* connecting the *probe tip* to the *sliding tubes* are designed to allow the *probe tip* to orient itself according to the geometry of the cervix, in order to create airtight contact with the tissue.

3. OPERATION

3.1 System Setup

1) Place the *control unit console* on a stable surface close to the examination area.

2) Plug the *power supply* into the power outlet and connect it to the *control unit console* (*power supply inlet*, FIGURE 11). The green light on the *power supply* indicates that the *control unit* is powered.

3) Connect the *foot switch* to the *control unit console* (*foot switch inlet*, FIGURE 11).

FIGURE 11: Back of the *control unit console*. Connect the *foot switch* to the inlet on the left and the *power supply* to the inlet on the right.

4) Place the *foot switch* on the floor, where it can be reached during the measurement.
5) Connect the *connector cable* to the Luer connectors on the *control unit console* (control unit Luer connectors, refer to FIGURE 13).

NOTE	Verify that the control unit Luer connectors are properly assembled and aligned, as shown in FIGURE 12.

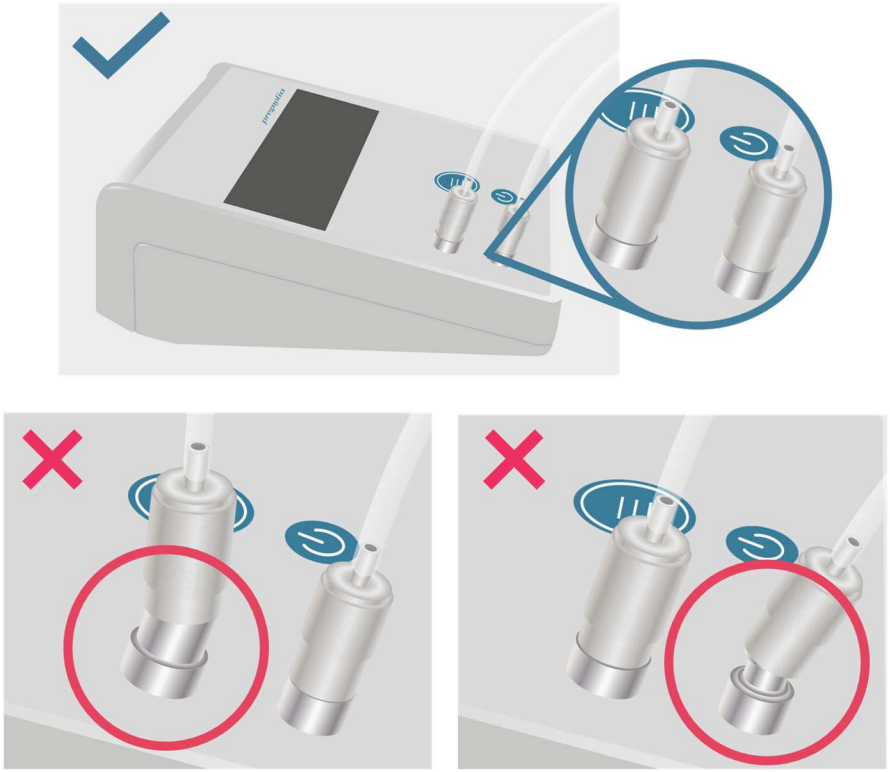


FIGURE 12: Top: correct attachment of the Luer connectors between the *control unit console* and the *connector cable*. Bottom: tilted or incomplete insertion of the Luer connectors may cause air leakages.

6) Turn on the *control unit console* (On/Off button, FIGURE 13). The *control unit console* will emit an audio signal[3].

[3] Refer to the training videos or use the training material to familiarise yourself with the audio signal.

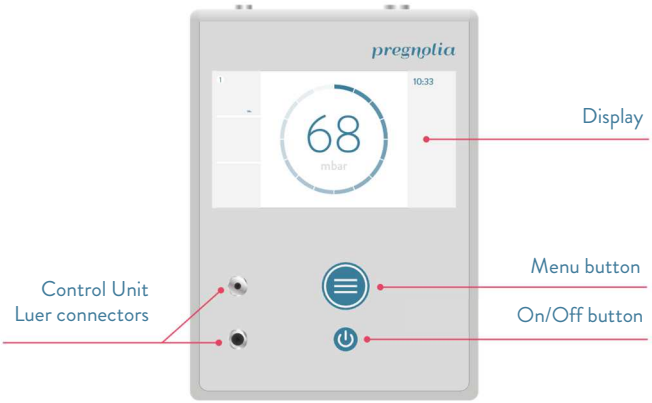


FIGURE 13: Front of the *control unit console*.

CAUTION	Do not use the system if no audio signal is emitted. Consult chapter ***6-Troubleshooting***.

7) Verify that the *connector cable* reaches the measurement area without being fully stretched. Refer to FIGURE 14 for the assembled *control unit*.

8) Take one packed *probe* from the *probe box*.

CAUTION	Prior to each usage, inspect the integrity of the *probe sterile pouch*. Do not use the *probe* if the *probe sterile pouch* looks damaged or open, since sterility may be compromised.

CAUTION	Make sure the *probe* expiration date has not passed as the use of expired *probes* might lead to harms to the subject.

CAUTION	Make sure to use the Pregnolia Probe only in conjunction with the Pregnolia Control Unit.

FIGURE 14: Assembled *control unit*.

3.2 Subject Preparation

1) Prepare the woman for a speculum-based vaginal examination.

2) Prepare the speculum, the swabs, and the saline solution for the examination.

3.3 Measurement Preparation

CAUTION	Do not dispose of the *probe sterile pouch* before the measurement session is complete as it contains necessary reference information in case of issues with the device.

CAUTION	Do not entirely remove the *probe* from the *pouch* during assembly in order to prevent the *probe* from contacting non-clean surfaces.

CAUTION	Use gloves while handling the *sterile probe* to prevent contamination of the *probe.*

1) Open the *probe sterile pouch* from the side indicated by the “Open Here” label.

2) Pull the *filters* and the *silicone tubes* out of the *pouch* while keeping the *probe* inside the *pouch* to ensure it remains sterile.

3) Connect the *filters* to the *connector cable*, while leaving the *probe* inside the *sterile pouch* (FIGURE 15).

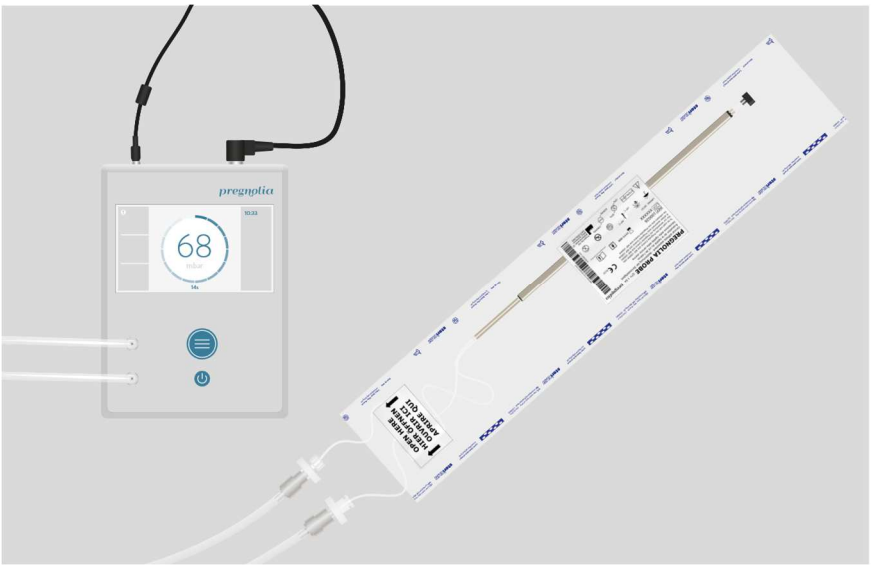


FIGURE 15: Step 3. Connect the *filters* to the *connector cable*, while leaving the *probe* inside the *sterile pouch*.

NOTE	Verify that the probe Luer connectors are correctly connected and aligned at all four locations, as shown in FIGURE 16 left.

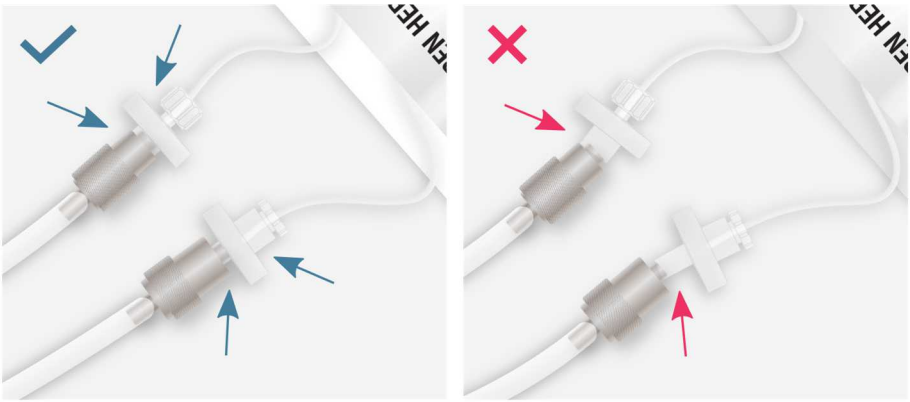


FIGURE 16: Left: correct attachment of the Luer connectors between the *probe* and the *connector cable*. Right: tilted or incomplete insertion of the Luer connectors may cause air leakages.

4) Insert the speculum in the vaginal canal and ensure that the cervix is clearly visible.

CAUTION	If necessary, use external illumination. The placement region shall be visualized correctly.

5) In case of excessive mucus, clean the cervix with a swab and/or saline solution, as in routine practice.

6) Evaluate if the *probe* can be placed on the anterior lip of the cervix at the 12 o'clock position (as shown in FIGURE 17).

7) Inspect the measurement location for any contraindication (***1.10 - Contraindications***). Abort the measurement if any contraindication is identified or the location is not accessible (see FIGURE 17).

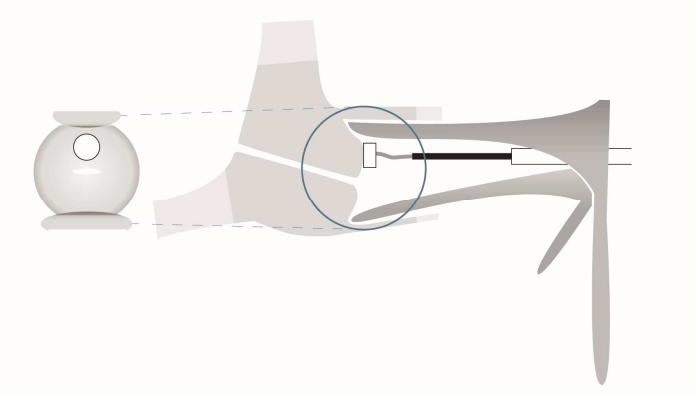


FIGURE 17: The measurement location is on the anterior lip of the cervix, at 12 o'clock position.

3.4 Measurement

CAUTION	Remove excessive mucus before the measurement.

CAUTION	Do not measure directly on the cervical canal.

NOTE	Do not manipulate nor clean mucus away from the cervix with the *probe* as the *probe* may become unusable. If the *probe* is blocked by the mucus, the measurement cannot be performed, and a new sterile *probe* has to be used.

NOTE	Do not squeeze the *filters* in the hand and do not bend the *tubes* at any time.

NOTE	Hold the *probe handle* by the end furthest from the *probe tip*, as indicated in FIGURE 18.

1) Hold the *probe* and the *filters* as shown in FIGURE 18. Do not touch the *probe tip*.

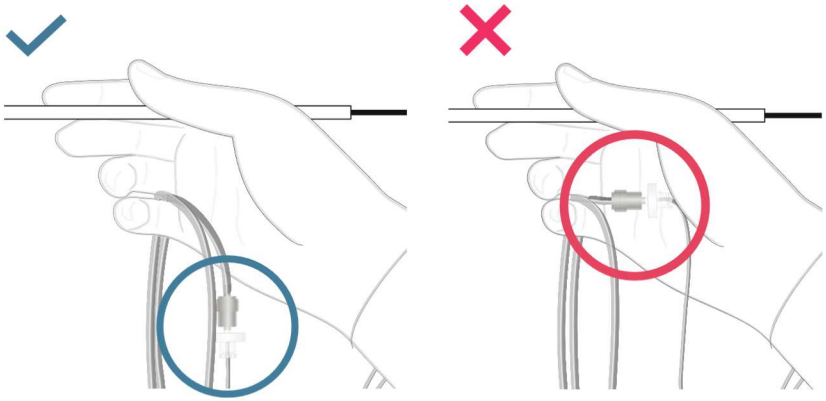
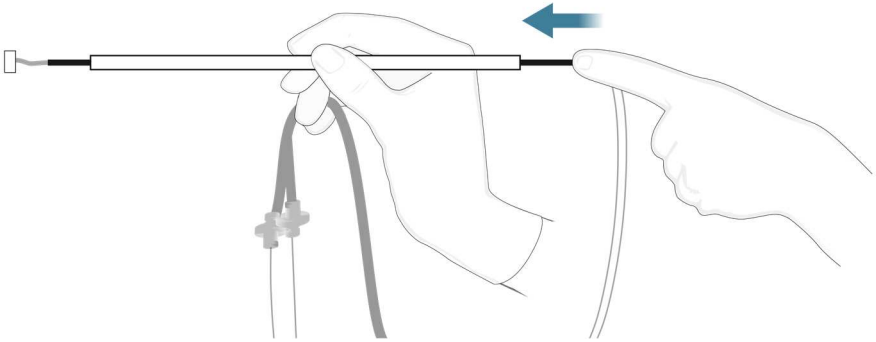
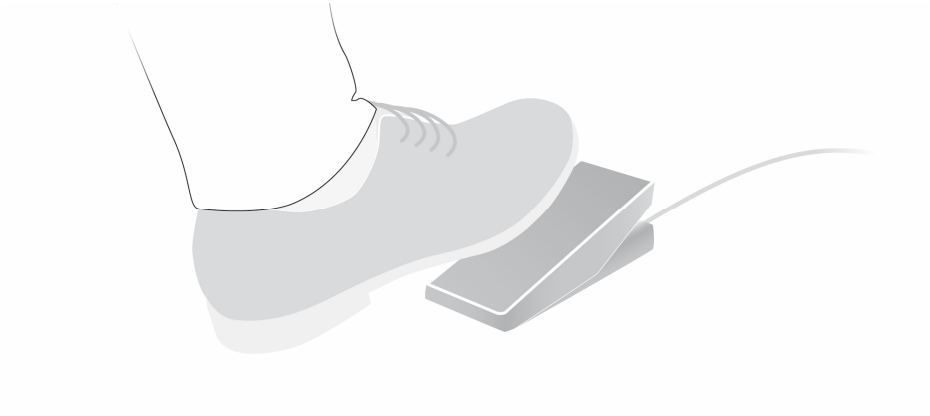


FIGURE 18: Left: correct *probe* holding. The *filters* are supported by holding the *connector cable* in the hand. Do not squeeze the *filters* in the hand. Right: incorrect *probe* holding.

2) Push the *probe sliding tubes* completely inward before inserting the *probe* in the vaginal canal.

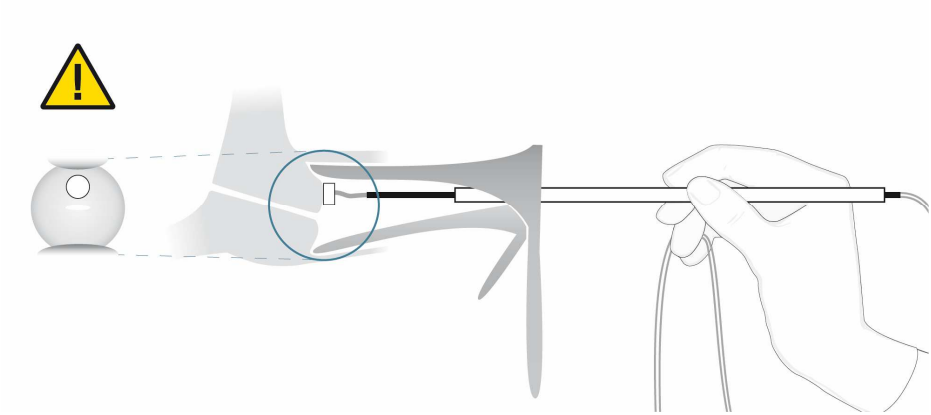


3) Press and release the *foot switch* to start the pump before inserting the *probe* into the vaginal canal.



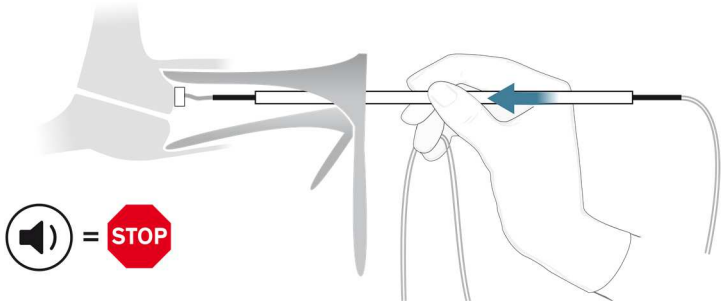
CAUTION	Use care when placing the *probe* on the cervix.

4) Gently place the *probe tip* through the speculum on the anterior lip of the cervix at the 12 o'clock position.



CAUTION	Do not forcefully push the *probe handle* completely to the front as this may influence the measurement result. When the *probe handle* is completely to the front, the result displayed could be lower than the real cervical stiffness.

5) Gently push the *probe handle* inward until the first audio signal is heard (be-beep[4]), then stop pushing the *probe*. The audio signal means that an airtight contact has been established between the *probe tip* and the tissue.

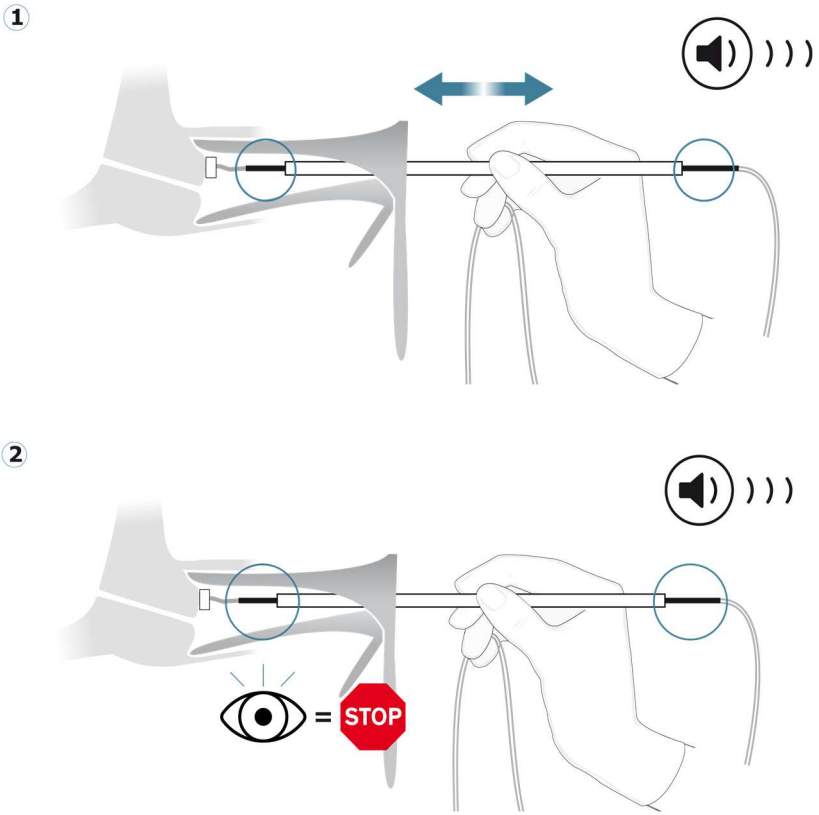


CAUTION	Do not pull the *probe handle* completely to the back as this may influence the measurement result. When the *probe handle* is completely to the back, the result displayed could be higher than the real cervical stiffness.

NOTE	During this phase of the measurement, the *probe handle* is free to slide, and not sitting against the front or back ends, in case the woman moves.

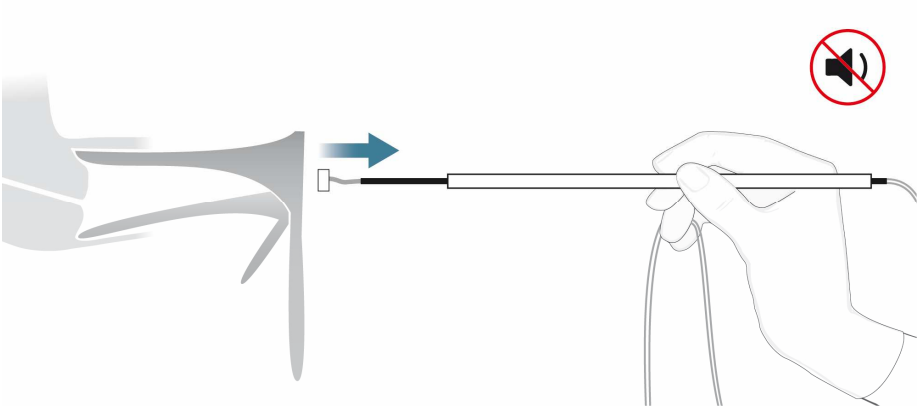
[4] Refer to the training videos or use the training material to familiarise yourself with the audio signal.

6) As soon as the tissue starts to be pulled into the *probe tip*, a continuous beeping is emitted (beep-beep[5]). Position the *handle* approximately in the centre of the *probe (step 1 of figure below)*. The *handle* is centred when you see roughly the same length of free *probe sliding tube* in the front and in the back. Hold this position until the measurement finishes (be-be-beep[5], *step 2 of figure below*).



[5] Refer to the training videos or use the training material to familiarise yourself with the audio signal.

7) When the audio signal stops the measurement is completed. Gently remove the *probe* from the vaginal canal.



8) If the measurement is to be repeated, return to *Step 2* (Measurement) (refer to ***1.11 – Precautions***).

3.5 Post Measurement

CAUTION	No reuse or re-sterilization of the *probe* is allowed as this is out of the intended use and may lead to contamination or abnormal device functionality.

CAUTION	After each measurement, immediately dispose of the *probe* including the *filters* and the *probe sterile pouch*.

1) Disconnect the *probe*, including the *filters*, from the *connector cable*.

2) Dispose of the *probe*, including the *filters*, and the *probe sterile pouch*.

3) Note down the measurement values and LOT number of the *probe*.

4) Turn off the *control unit console* (On/Off button).

5) Disconnect the *power supply*, *connector cable* and *foot switch*.

6) If necessary, clean and store the *control unit* as described in ***Chapters 4*** and **5**.

NOTE	Do not dispose of the *connector cable* or the *foot switch*.

4. MAINTENANCE

4.1 Cleaning of the Control Unit

When necessary:

1) Make sure that the *control unit* is turned off and that the *connector cable*, *foot switch* and *power supply* are unplugged.

2) Place the *control unit console* on a clean surface.

3) Carefully wipe the exterior of the *control unit console* and of the *connector cable* with isopropyl alcohol wipes.

CAUTION	Do not use any cleaning agent other than isopropyl alcohol.

4) Let the *control unit console* dry.

5) Store the *control unit* as described in ***Chapter 5 – Use, Storage and Transport***.

CAUTION	Never rinse the *control unit* with water or other fluids as this may damage the device.

NOTE	If necessary, the *foot switch* and the *power supply* can be cleaned in the same way.

4.2 Disposal of the Probe

CAUTION	No reuse or re-sterilization of the *probe* is allowed as this is out of the intended use and may lead to contamination or device functionality.

The *probe* is a single-use, disposable item. No cleaning or disinfection applies to the *probe*. After usage, dispose of it according to the local regulations.

4.3 Maintenance of the Control Unit

The *control unit* requires no maintenance by the user. The *control unit* and its parts are not user serviceable.

NOTE	In case of doubt regarding the performance of the *control unit*, contact Pregnolia AG.

4.4 Disposal of a Broken/ Old Control Unit

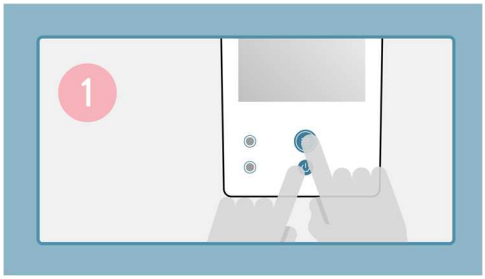
If a broken or old *control unit* has to be disposed of, either return it to Pregnolia AG or dispose of it in accordance with your local and/or internal regulation.

4.5 Return Guidelines

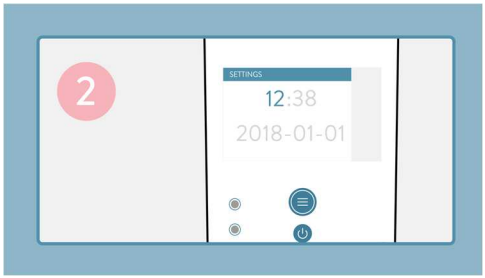
If the *control unit* must be returned to Pregnolia AG, always use the original *control unit case* to protect the *control unit* during transportation.

CAUTION	Always use the *control unit case* to ship or transport the *control unit*.

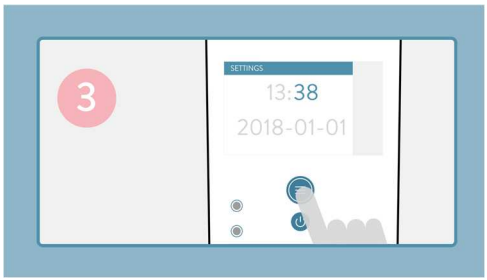
4.6 Set or change time/date in the Control Unit Console



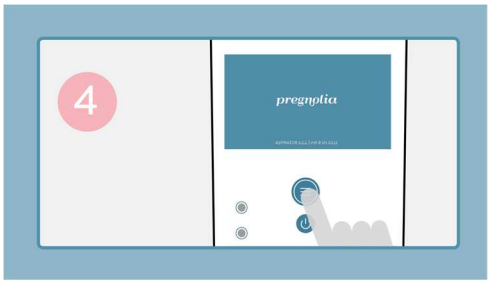
With the system off, press the Menu button and the On/Off button simultaneously.



The setting menu will appear.



Press the Menu button once to increase number, hold the Menu button to move on.



Hold the Menu button on the last number to finish. The device will start.

5. USE, STORAGE AND TRANSPORT

5.1 Use and Storage of the Control Unit

Upon delivery and, if necessary, between usages, store the *control unit* inside the *control unit case*. Storage and use environmental conditions are temperature between 10°C and 40°C, relative humidity between 10% and 80% and atmospheric pressure between 620 hPa and 1060 hPa.

5.2 Storage of the Sterile Probes

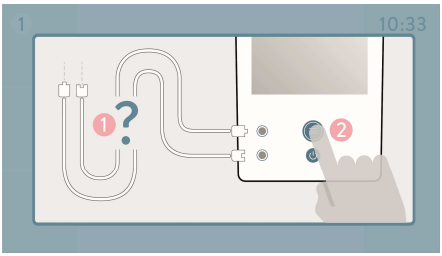
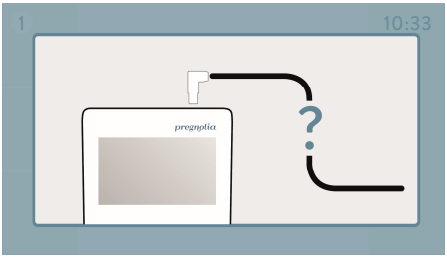
Upon delivery, store the *probes* inside the *probe box*. Keep the *probes* and the *probe box* away from direct sun light and UV radiation exposure. Keep the *probes* and the *probe box* at temperatures in the 10°C – 40°C range, relative humidity values in the 10% - 80% range and atmospheric pressures in the 620 hPa – 1060 hPa range. The same conditions apply to the use of the *probes*.

5.3 Transport of the Control Unit and of the Sterile Probes

Transport conditions are temperature between -10°C and +40°C, relative humidity between 10% and 95% and atmospheric pressure between 620 hPa and 1060 hPa.

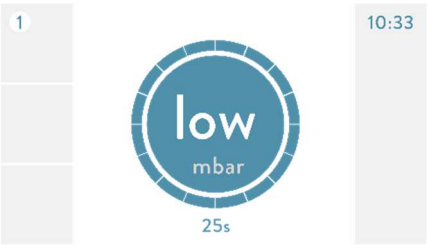
6. TROUBLESHOOTING

This section reports simple steps that can be performed by the user to solve basic problems which may be encountered while operating the system.
If the problem is not solved after performing the actions described in this section, follow the instructions in ***1.2 – User Assistance Information***.

Error message / problem	*Cause / action*
Control unit console displays *connector cable* error message: 	The *connector cable* is not properly connected. 1) Ensure that the *connector cable* is well connected and fastened. 2) Press the Menu button. If the error message persists: 1) Disconnect and reconnect the *connector cable*. 2) Press the Menu button.
Control unit console displays *foot switch* error message: 	The *foot switch* is not properly connected. 1) Ensure that the *foot switch* is correctly connected to the back of the *control unit console*. If the error message persists: 1) Disconnect and reconnect the *foot switch*.

Error message / problem	*Cause / action*
The start-up audio signal is not emitted after turning on the *control unit* using the On/Off button.	1) Disconnect the *power supply* and connect it again. 2) Turn on the *control unit* once more and check whether the audio signal is emitted.
Airtight contact between the *probe tip* and the tissue cannot be achieved (the first audio signal is not emitted).	The issue can be due to a leak or an obstruction. Proceed as follows: 1) Turn off the vacuum using the *foot switch*. 2) Disconnect the probe Luer connectors and the control unit Luer connectors and connect them again. 3) Ensure that the *filters* are not squeezed in the user's hand and that the tubes are not kinked. 4) Make sure that the cervix is cleaned of excessive mucus and/or ultrasound gel. 5) Try again to obtain airtight contact between the cervical tissue and the *probe tip*. If the problem is not solved, dispose of the *probe* and try the measurement with another *sterile probe*.

Error message / problem	*Cause / action*
The continuous beeping is emitted but the measurement repeatedly restarts.	The Luer connectors are not correctly assembled. Proceed as follows: 1) Turn off the vacuum using the *foot switch*. 2) Disconnect the probe Luer connectors and the control unit Luer connectors and connect them again. 3) Turn on the vacuum again using the *foot switch*. Refer to FIGURE 19 for the correct connection of the Luer connectors.
The measurement is interrupted but neither results nor error messages are displayed.	1) Start the pump again by pressing and releasing the *foot switch*. 2) Repeat the measurement. 3) If the error persists, disconnect the probe Luer connectors and the control unit Luer connectors and connect them again. 4) Turn on the vacuum using the *foot switch* and repeat the measurements.

Error message / problem	*Cause / action*
Control unit console displays “High” value: 	The measured pressure is higher than 400 mbar. The pump automatically stops, and the “high” value is displayed.
Control unit console displays “Low” value: 	The measurement is valid, but the measured pressure is lower than 25 mbar. Proceed as follows: 1) Try to perform the measurement again, taking care that the tubes are not kinked at any location. If the “low” value is displayed again, it means that the cervix is extremely soft and outside of the measurement range of the device.

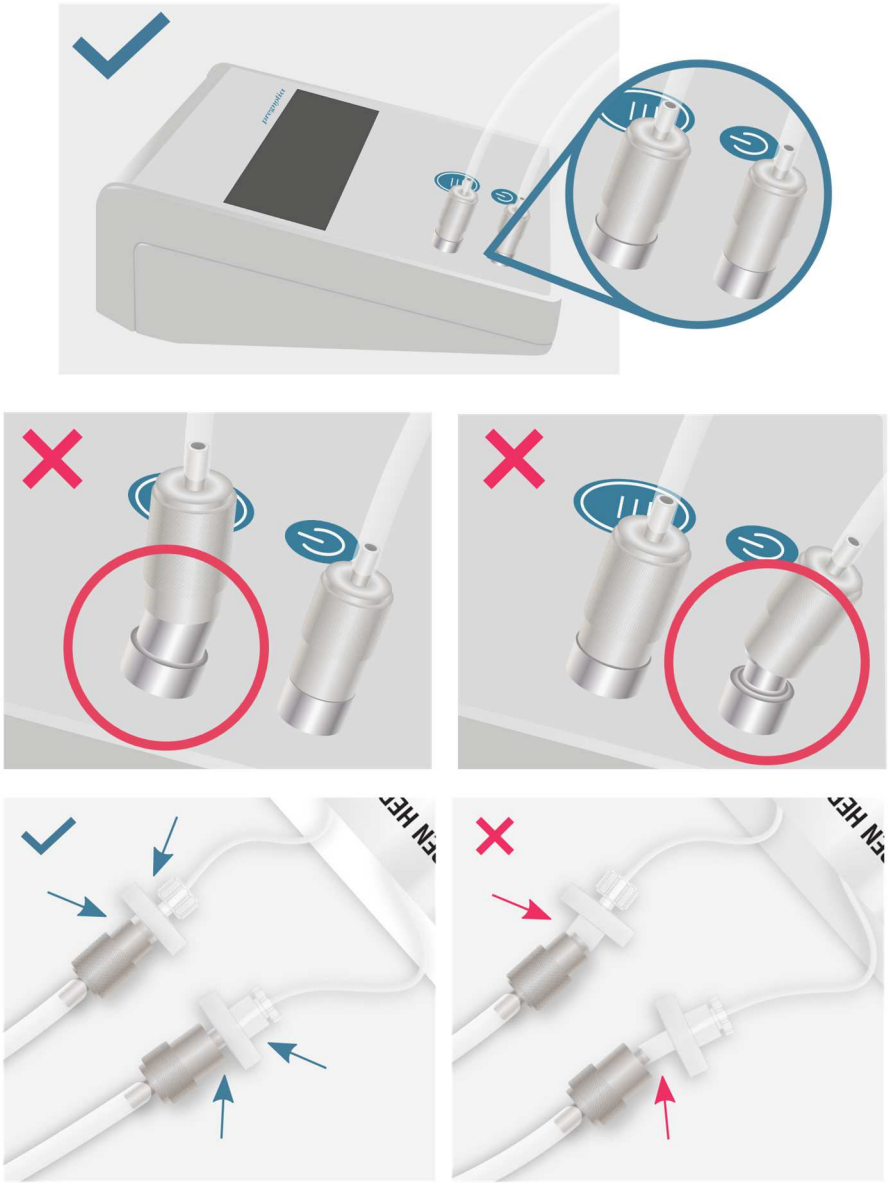


FIGURE 19: Top and centre: control unit Luer connectors. Bottom: probe Luer connectors. Correct assembly of the Luer connectors requires that they are well aligned and pushed all the way in.

7. SAFETY

The Pregnolia System is approved exclusively for the use as described in these Instructions for Use.

The subject should be informed on how the measurement is performed.

Always use the Pregnolia Control Unit with the Pregnolia Probe.

Purchase from Pregnolia AG or from approved retailers only.

8. WARRANTY

Correct operation of the *control unit* should be verified no later than during setup. Any defects must be immediately reported to Pregnolia AG. Failure to do so will void all warranty. In the event that a product defect covered by warranty is discovered and reported within the statutory warranty period (2 years), Pregnolia AG will replace the defective *control unit* at no cost.

Pregnolia AG's liability is excluded for the use of the system, including the *control unit* and the *probe*, beyond the scope of the intended use set out in these Instructions for Use. Furthermore, Pregnolia AG's liability is excluded when the *control unit* is used with other equipment than the Pregnolia Probe and when warnings and/or safety precautions set out in these Instructions for Use are not followed.

9. TECHNICAL DESCRIPTION

WARNING	No modification of the equipment is allowed.

The *control unit case* includes the Pregnolia Control Unit (REF 100058) and the training material.

The Pregnolia Control Unit (REF 100058) consists of:

- Pregnolia Control Unit – Console (REF 100044),
- Connector Cable (P/N 100035),
- Power Supply (P/N 100031),
- Foot Switch (P/N 100030),
- Instructions for Use (P/N 100041),

to be used with the Pregnolia Probe (REF 100026).

The training material consists of:

- Demonstration cervix (P/N 100059),
- Non sterile demo probe (P/N 100060),
- Instructions for self-training (P/N 100065).

Probe (type BF applied part)	
Length (excluding silicone tubes)	311 mm
Probe handle diameter	8.2 mm
Probe tip diameter	12 mm
Filter pore diameter	0.22 µm

Connector Cable	
Length	1500 mm
Luer connectors diameter	3.175 mm

Control Unit Console	
Length	125 mm
Width	177 mm
Maximum height	69 mm
Weight	600 g

Display	
Diagonal size of display area	4.3"
Dimensions	95.0 x 53.9 mm
Resolution	480 x 272
Technology	TFT

Foot Switch	
Model	Black, switch type

Power Supply	
Input voltage	80 ~ 264 VAC or 113 ~ 370 VDC
Frequency	47 ~ 63 Hz
Output	18 W, 12 V, 1.5 A

Closing Pressure	
Range	Vacuum generation range 0-475 mbar, minimum displayed value 25 mbar
Accuracy	10%
Precision	10%
Resolution	1 mbar

Use and Storage Conditions - Probe	
Temperature range	10°C – 40°C
Relative humidity range	10% - 80%
Atmospheric pressure range	620 – 1060 hPa

Use and Storage Conditions – Control Unit	
Temperature range	10°C – 40°C
Relative humidity range	10% - 80%
Atmospheric pressure range	620 – 1060 hPa

Transport Conditions –Probe and Control Unit	
Temperature range	-10°C – +40°C
Relative humidity range	10% - 95%
Atmospheric pressure range	620 – 1060 hPa

Control Unit	
Lifetime	5 years

10. ELECTROMAGNETIC COMPATIBILITY

WARNING	The Pregnolia System should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the Pregnolia System should be observed to verify normal operation.

WARNING	Use of components and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

WARNING	Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm to any part of the Pregnolia System, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment may occur.

10.1 Essential performance

Failure of the Pregnolia System to perform its intended use poses no unacceptable risk for the user and/or patient when used according to the Instructions for Use.

10.2 Emissions

This system was tested according to the emission test levels specified in IEC 60601-1-2:2014 4th Edition for medical electrical equipment for use in a professional healthcare environment.

NOTE	The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

10.3 Immunity

This system was tested according to the immunity test levels specified in IEC 60601-1-2:2014 4th Edition (according clause 8 and 9, tables 4 to 9) for medical electrical equipment for use in a professional healthcare environment.

CAUTION	If subjected to strong electromagnetic fields or strong electrostatic discharge, the system may switch itself off. This is considered normal and does not affect the safety of the system. If such an event occurs, simply switch the system back on and re-start the measurement. In rare cases the system might get damaged and cannot be switched on again. If this occurs, unplug the system and contact Pregnolia AG for assistance.

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