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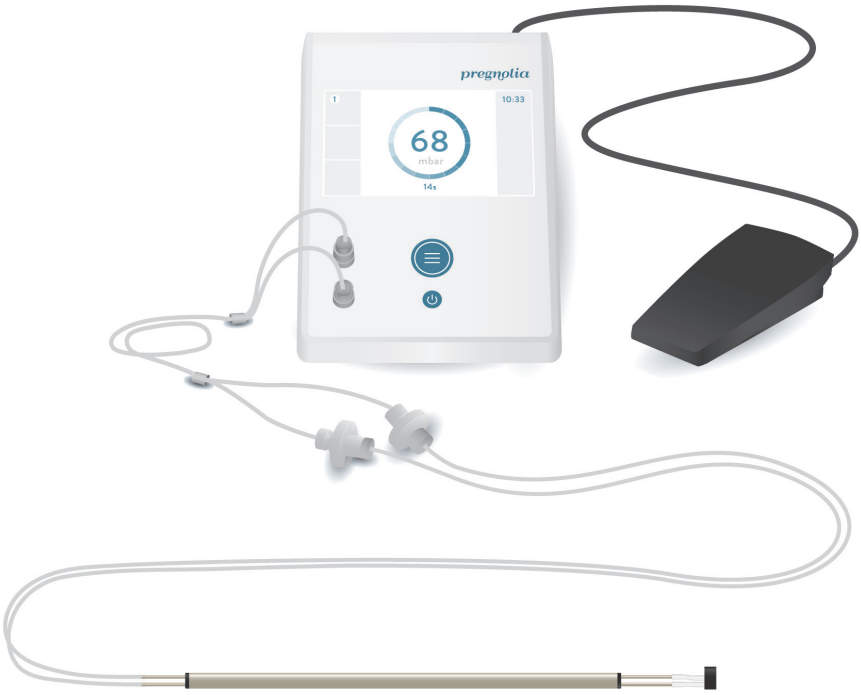
PREGNOLIA SYSTEM

Cervical stiffness assessment

Instructions for Use



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Pregnolia System - Cervical stiffness assessment
Instructions for Use
P/N 100041-E
2019-04-02

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 how to use the Pregnolia System, ensuring patient 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	Warning statements indicate a hazard that could lead to patient harm.
CAUTION	Caution statements indicate a hazard that could lead to equipment damage.
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 *probe* label:


Manufacturer

Catalogue number


Do not use if package is damaged


Keep away from sunlight


Keep dry


Temperature limit


Humidity limitation


Atmospheric pressure limitation


Caution


Compliant with the essential requirements of the Council Directive 93/42/EEC


Use-by-date


Type BF applied part

Batch code

Sterilized using ethylene oxide

Do not resterilize


Do not re-use


Consult Instructions for Use

Symbols on the *control unit console* labels:


Manufacturer


Catalogue number


Keep away from sunlight


Keep dry


Temperature limit


Humidity limitation


Atmospheric pressure limitation


Caution


Compliant with the essential requirements of the Council Directive 93/42/EEC


Follow Instructions for Use


Direct current


Type BF applied part


Class II equipment


Foot switch


Center-positive polarity

EXT
Extension port


Serial number


Date of manufacture


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


For indoor use only

IP20
Protected against ingress of solid objects greater than 12.5 mm

Symbols on the *power supply* label:


Class II equipment


Center-positive polarity


For indoor use only


Compliant with the essential requirements of the Council Directive 93/42/EEC


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


Compliant with the essential requirements of the Council Directive 93/42/EEC

Other symbols used in this manual:


Pay attention


Single audio signal


Continuous beeping


No audio signal

Stop


When visible

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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: a reusable *control unit* (Pregnolia Control Unit) and a single-use *sterile probe* (Pregnolia Probe) (FIGURE 1).

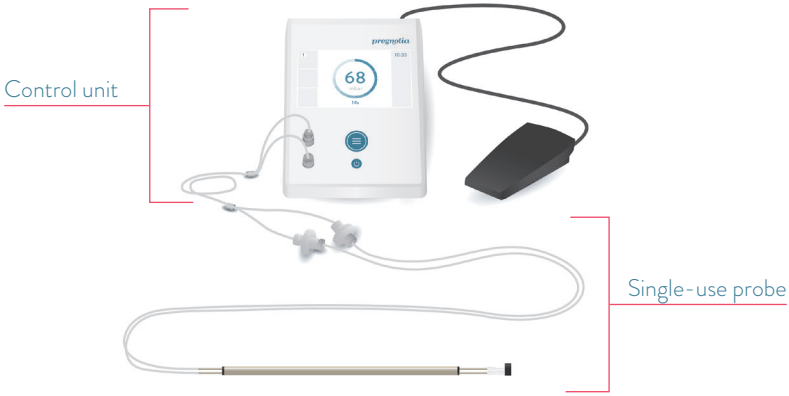


FIGURE 1: System components: *control unit* and single-use *probe*.

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).

WARNING	Do not use *probes* from a third-party supplier.

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, and it is defined as closing pressure (p_{cl}) and expressed in mbar.

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

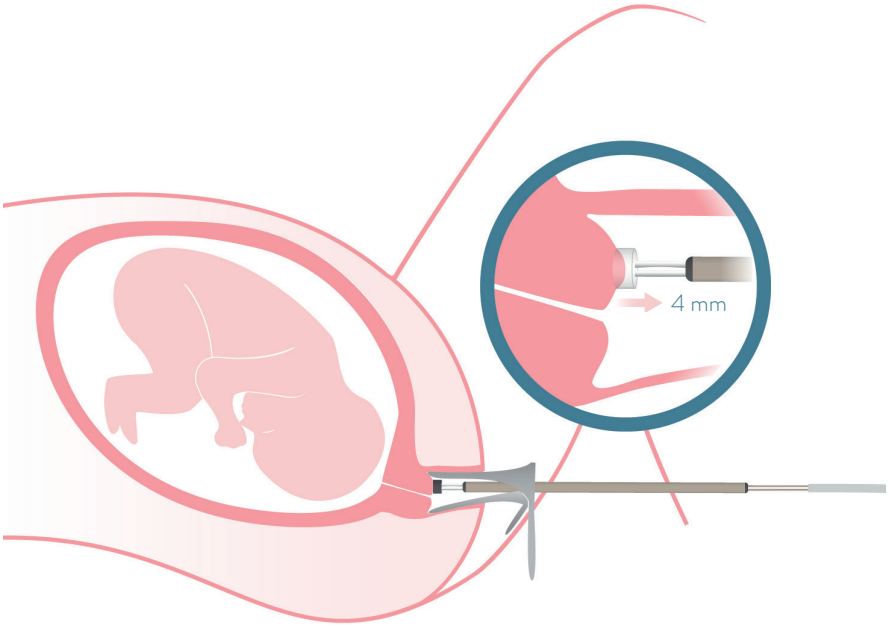


FIGURE 2: Operation Overview. The *probe* is placed on the anterior lip of cervix with the aid of a speculum. INSET: A weak vacuum deforms the cervical tissue into the *probe tip* by a fixed distance of 4mm.

The *probe* is designed to minimise the contact interaction between the user and the patient during the measurement. The *probe handle* (see ***Chapter 2.5 - Probe*** for probe description) slides freely, such that the user does not impart contact force on the cervix during the measurement, and to prevent the influence of patient movements (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 Statement

The Pregnolia System is used to provide information about the mechanical properties of the uterine cervix by assessing the tissue stiffness through a proxy parameter (the closing pressure, in mbar).
Cervical stiffness can be assessed during routine examinations - along with other parameters, such as cervical length measured by ultrasound - in order to gather supportive data for diagnostics in the field of obstetrics and gynaecology, in particular about cervical remodelling.
The Pregnolia System is intended to be used in addition to other standard examinations and does not substitute them.

1.4 Indications

Assessment of tissue stiffness of the uterine cervix during pregnancy and gynaecological examinations.

1.5 Patient Population

The intended patient population are all pregnant and non-pregnant women, aged 18 years old or older, for which the assessment of the uterine cervix is indicated.

1.6 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.

1.7 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 **1.13 – 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.
The patient shall be seated and positioned in a manner consistent with routine practice for speculum-based vaginal examination.

1.8 Performance

The intended clinical performance of the Pregnolia System is to:

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

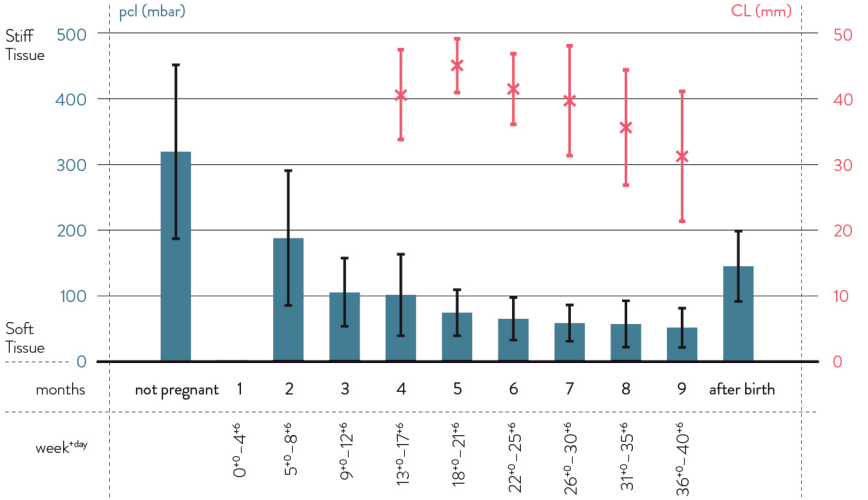


FIGURE 4: Collective results of closure pressure p_{cl} of the non-pregnant group and during gestation assessed with the Pregnolia System in the clinical investigation *Cervical Insufficiency* (Badir et al., Prenatal Diagnosis, 2013, 33, 737-741). Closure pressure p_{cl} of non-pregnant and pregnant women during pregnancy (months 2–9) and post-partum (6-16 weeks at regular post-partum visit) are shown as vertical bars – 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. 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 are represented (n=42).

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 an expected variability of approximately 15% in the clinical setting (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.

1.9 Contraindications

The Pregnolia System has been designed to minimise any foreseeable risks when correctly used on healthy women. 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 measurement must be conducted on native cervical tissue.

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);
- Lack of consent for vaginal examination by the patient;
- Rupture of membranes before 34 weeks and without contractions;
- Cervical dilation;

- Cervical carcinoma;
- Known HIV[1];
- Visible, symptomatic cervical or vaginal infections (this excludes treated, asymptomatic infections);
- Müllerian anomalies with two cervices;
- If one of the following conditions is present on the cervix at the 12 o'clock position:
  - Nabothian cyst;
  - Cervical myomas;
  - Cervical condylomas;
  - Squamous intraepithelial lesion;
  - Conization/LEEP[2]/LLETZ[3];
  - Cervical endometriosis;
  - Cervical tears;
  - Cervical dysplasia;
  - Large ectopy, for which it is not possible to find a suitable location near the ectopy where native tissue is present;
  - Large scar tissue, for which it is not possible to find a suitable location near the scar where native tissue is present.

1.10 Precautions

A repetition of the measurement is not harmful for the patient. However, repeated measurements can temporarily alter the properties of the cervical tissue, yielding different results. Therefore, the user should record the order in which the sequential measurement results were obtained, for future reference and/or comparison purposes.

1 Human Immunodeficiency Virus
2 Loop Electrosurgical Excision Procedure
3 Large Loop Excision of the Transformation Zone

Special caution should be exercised in the presence of:

- Female genital mutilation;
- *Placenta praevia* without bleeding;
- Active *herpes genitalis*;
- Psychological reasons or issues.

Special cautions should also be exercised if one of the following conditions is present outside the site of measurement (12 o'clock position):

- Ectopy and cervical polyps;
- Nabothian cyst;
- Squamous intraepithelial lesion;
- Conization/LEEP/LLETZ;
- Cervical endometriosis.

1.11 Warnings

- Do not measure directly on the cervical canal.
- Remove excessive mucus before the measurement.
- If an ectopy is visible at the 12 o'clock position, do not measure on the ectopy itself but find a location near the ectopy: either at the 12 o'clock position, avoiding the ectopy itself, or at positions 11 o'clock or 1 o'clock.
- 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.
- 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.
- Do not dispose of the *probe sterile pouch* before the measurement is over as it contains necessary reference information in case of issues with the device.
- After each measurement, immediately dispose of the *probe*

and the *probe sterile pouch*.
- Never reuse or re-sterilize a *probe* since this can lead to contamination or device abnormal functionality.
- Never use a *probe* from a third-party supplier.
- Use gloves while handling the *probe*.
- Make sure the *probe* expiration date has not passed.
- Do not manipulate nor clean mucus away from the cervix with the *probe*.
- Do not forcefully push the *probe handle* completely to the front.
- Do not pull the *probe handle* completely to the back.
- Do not use the demo probe on patients.
- Follow the information contained in **Chapters 4** and **5** of this Instructions for Use for the maintenance and storage of the Pregnolia System products.
- No modification of the equipment is allowed.

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: 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.
- User and patient dissatisfaction.

1.13 Training

WARNING	Do not use the demo probe on patients.

- Before the first usage, read these Instructions for Use in their entirety and watch the training videos provided online at **www.pregnolia.com/instructions**.
- A demo-kit is provided together with the *control unit*. It contains a non-sterile demo probe (P/N 100060), a demonstration cervix (P/N 100059) and instructions on how to use the demo-material for familiarisation with the system.
- Use the material in the demo-kit to perform a familiarization test, following the instructions included in the demo-kit:
  - Watch the Instructional video;
  - Follow the Instructional video step by step and use the demo-kit to familiarize yourself with the system;
  - Watch the Training video.
- Do not use the non-sterile demo probe on patients.
- 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.
- For further details, consult the instructions in the demo-kit.

2. COMPONENTS DESCRIPTION

2.1 Control Unit Case

The *control unit* and the demo-kit are contained inside the *control unit case*. 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 *control unit* comprises four components: the *foot switch*, the *connector cable*, the *power supply* and the *control unit console* (FIGURE 5).

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*.

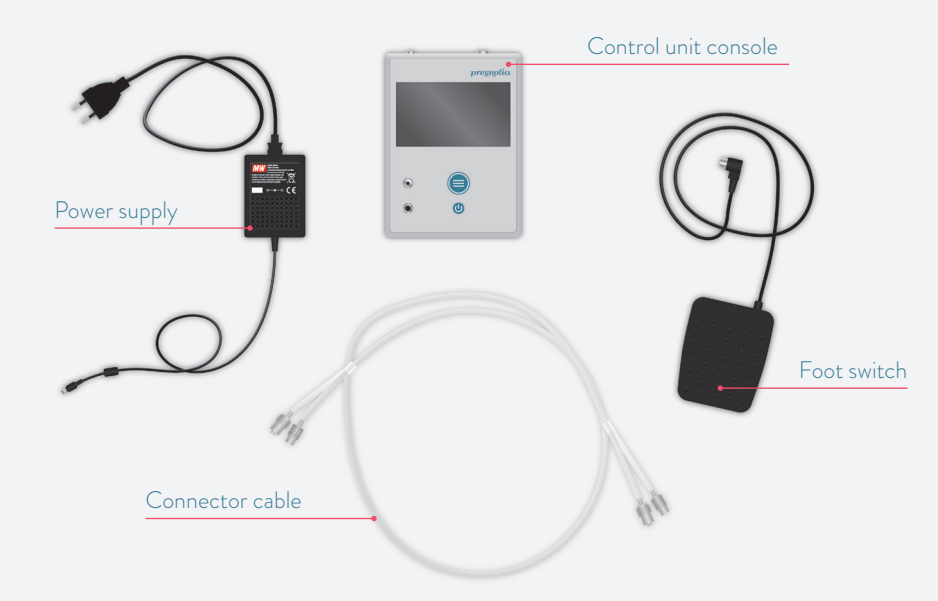


FIGURE 5: *Foot switch*, *connector cable*, *power supply* and *control unit console*.

2.2.1 Control unit console - front

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

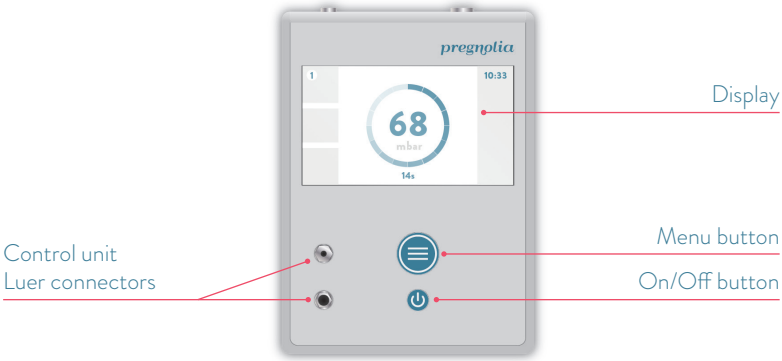


FIGURE 6: Front of the *control unit console*.

- 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

CAUTION	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:

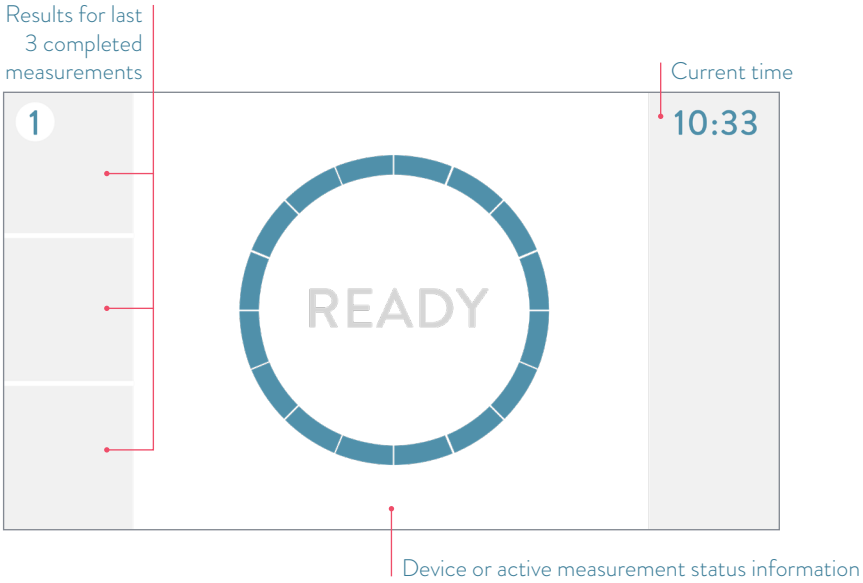
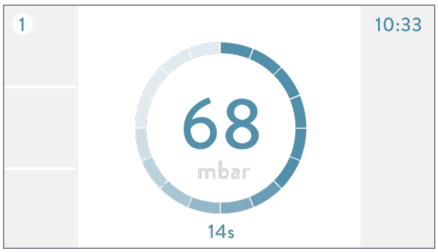


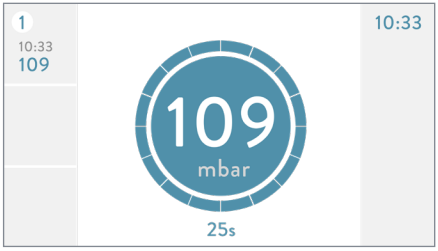
FIGURE 7: Main screen of the *control unit console*.

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.

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).

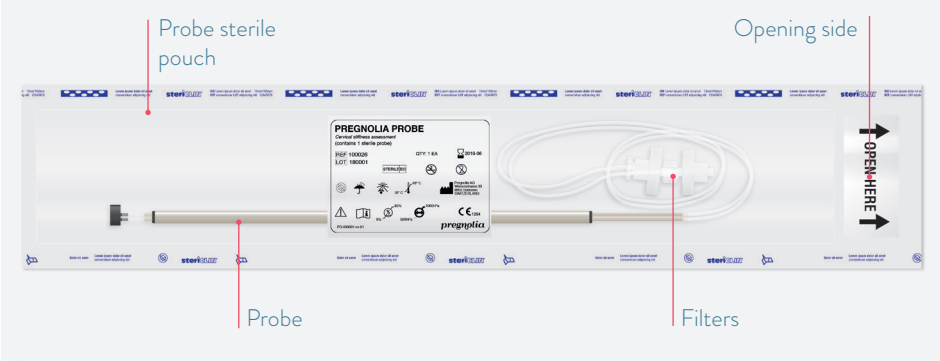


FIGURE 9: *Probe sterile pouch.*

2.5 Probe

The *probe* is displayed in FIGURE 10.

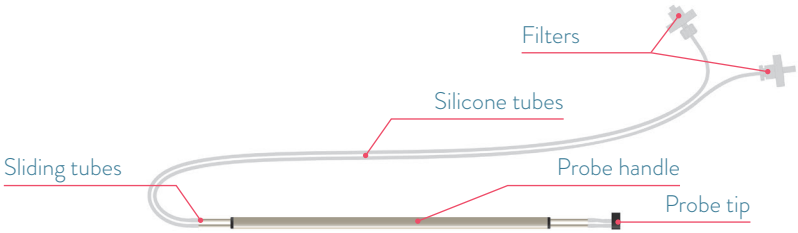


FIGURE 10: *Probe*. The *probe* is connected to the *connector cable* through the *filters*. *Filters* prevent microbiological contamination of the *control unit*. The *tip* is the part of the *probe* which will be placed in contact with the cervix.

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).

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

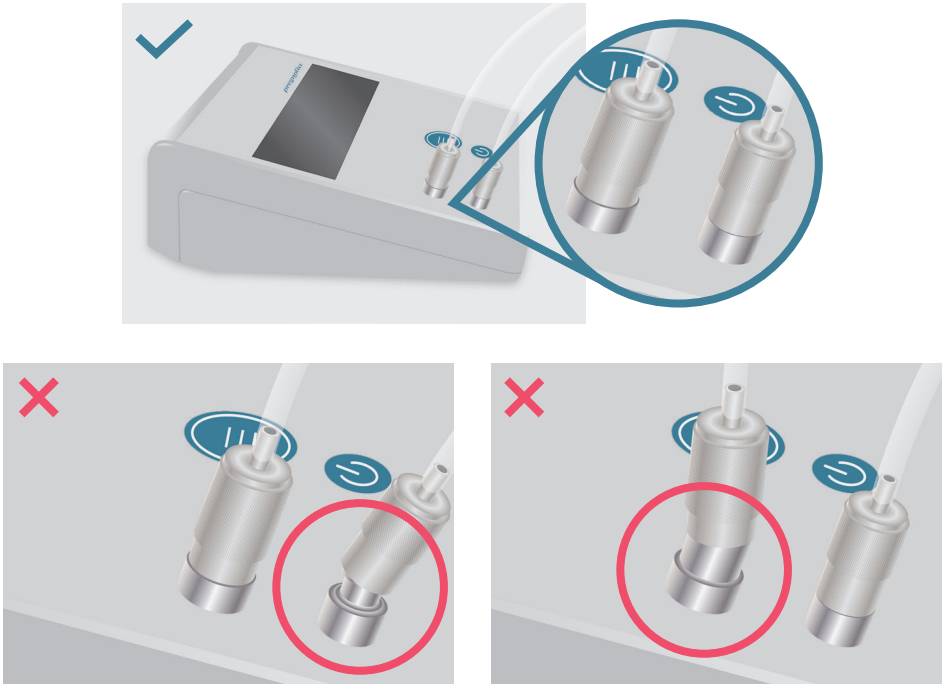


FIGURE 12: Top: correct attachment of the Luer connectors between the *control unit console* and the *connector cable*. Bottom: tilted or incomplete insertion of the Luer connectors may cause air leakages.

6) Turn on the *control unit console* (On/Off button, FIGURE 13). The *control unit console* will emit an audio signal[4].

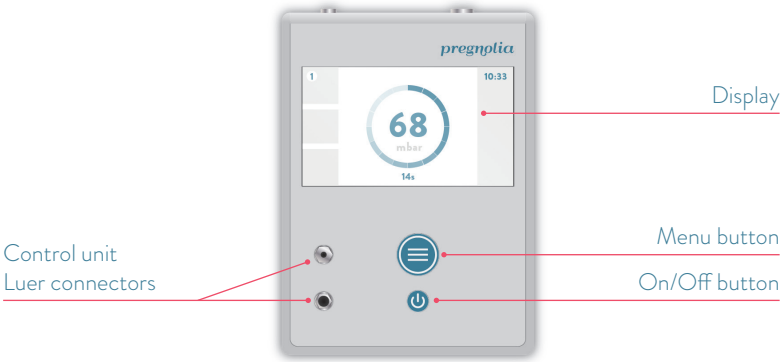


FIGURE 13: Front of the *control unit console*.

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*.

WARNING	Make sure the *probe* expiration date has not passed.

4 Refer to the training videos or use the demo-kit to familiarise yourself with the audio signal.

FIGURE 14: Assembled *control unit*.

3.2 Patient Preparation

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

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

3.3 Measurement Preparation

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.

WARNING Use gloves while handling the *probe*.

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

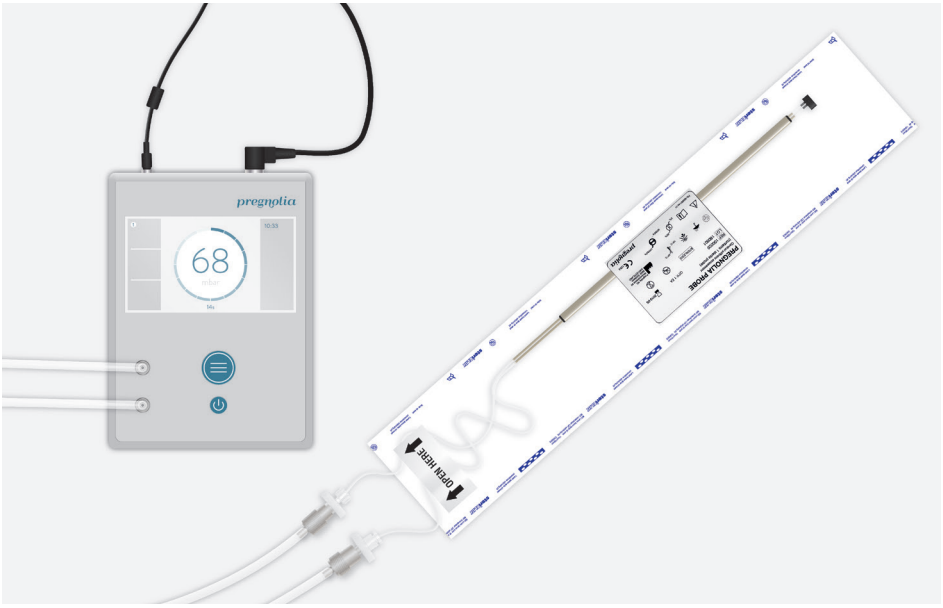


FIGURE 15: Step 3. Connect the *filters* to the *connector cable*, while leaving the *probe* inside the *sterile pouch*.

CAUTION	Verify that the probe Luer connectors are correctly connected and aligned, as shown in **FIGURE 16**.

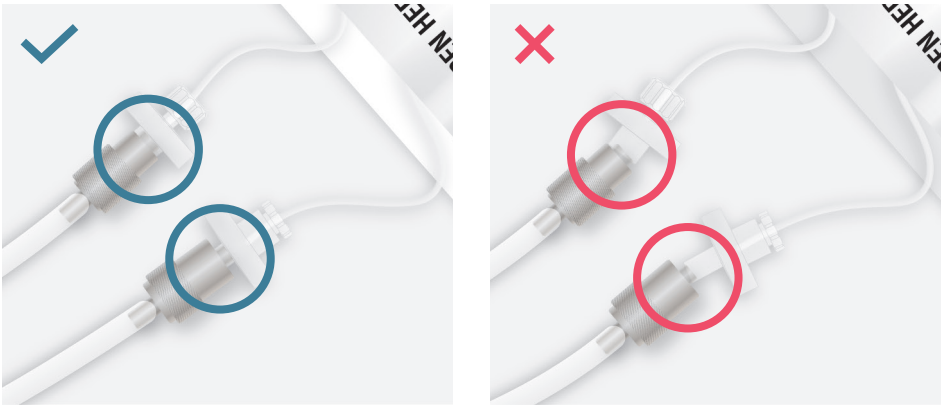


FIGURE 16: Left: correct attachment of the Luer connectors between the *probe* and the *connector cable*. Right: tilted or incomplete insertion of the Luer connectors may cause air leakages.

4) Insert the speculum into the vaginal canal and ensure that the cervix is clearly visible. If necessary, use external illumination. Do not touch the *probe tip*.

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

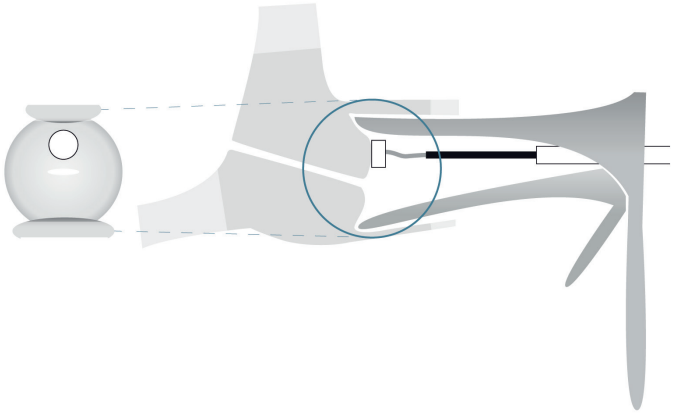


FIGURE 17: The measurement location is on the anterior lip of the cervix, at 12 o'clock position.

3.4 Measurement

WARNING	Do not manipulate nor clean mucus away from the cervix with the *probe*.
CAUTION	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*.

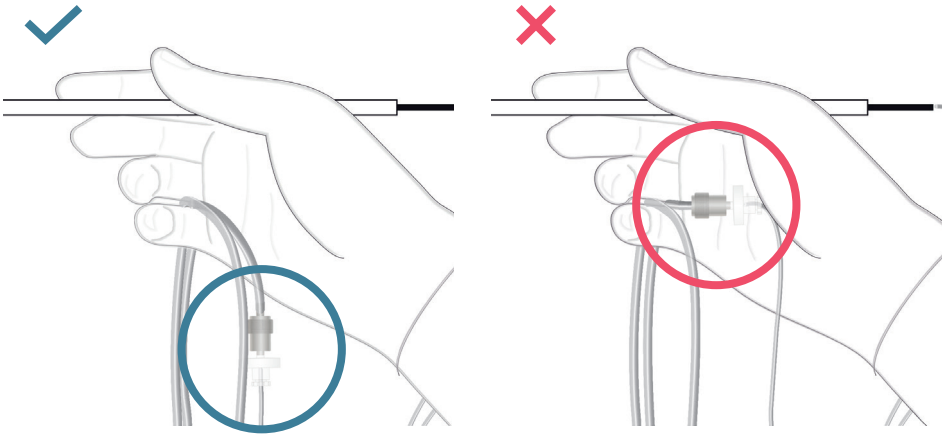
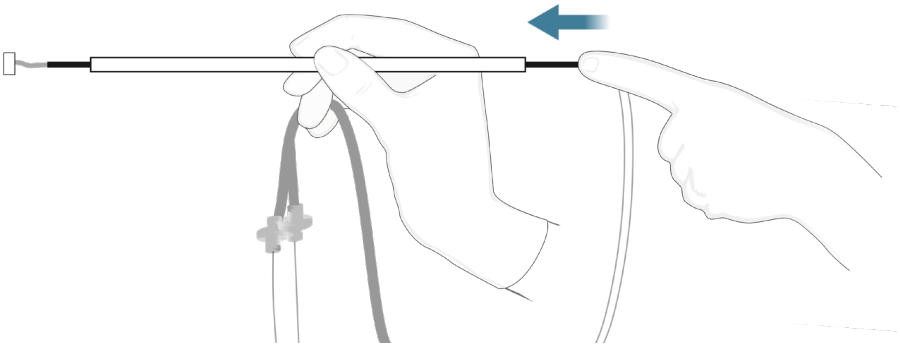
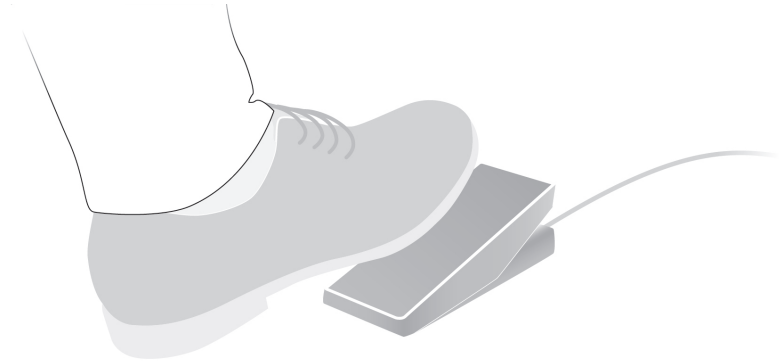


FIGURE 18: Left: correct *probe* holding. The *filters* are supported by taking the *connector cable* in the hand. Do not squeeze the *filters* in the hand. Right: incorrect *probe* holding.

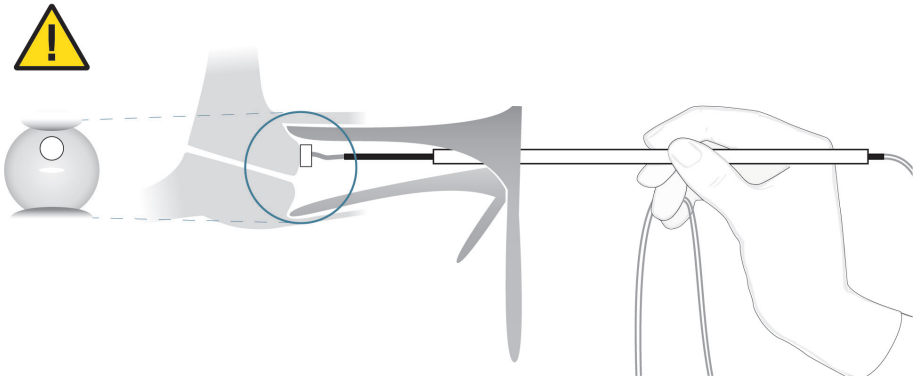
2) Push the *probe sliding tubes* completely inward before inserting the *probe* in the vaginal canal.



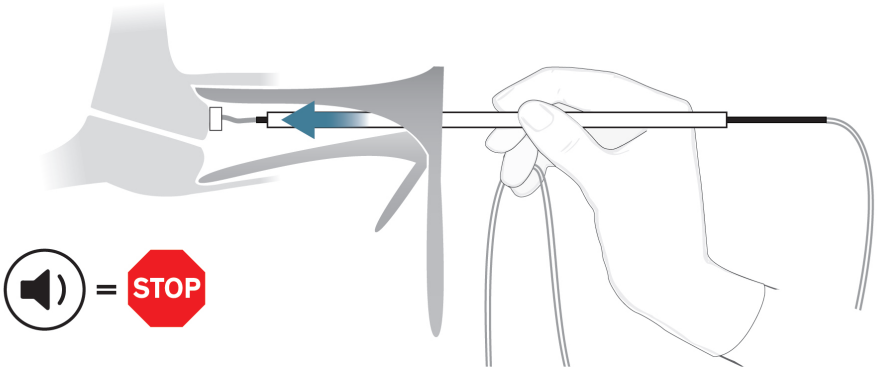
3) Press and release the *foot switch* to start the pump before inserting the *probe* into the vaginal canal.



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



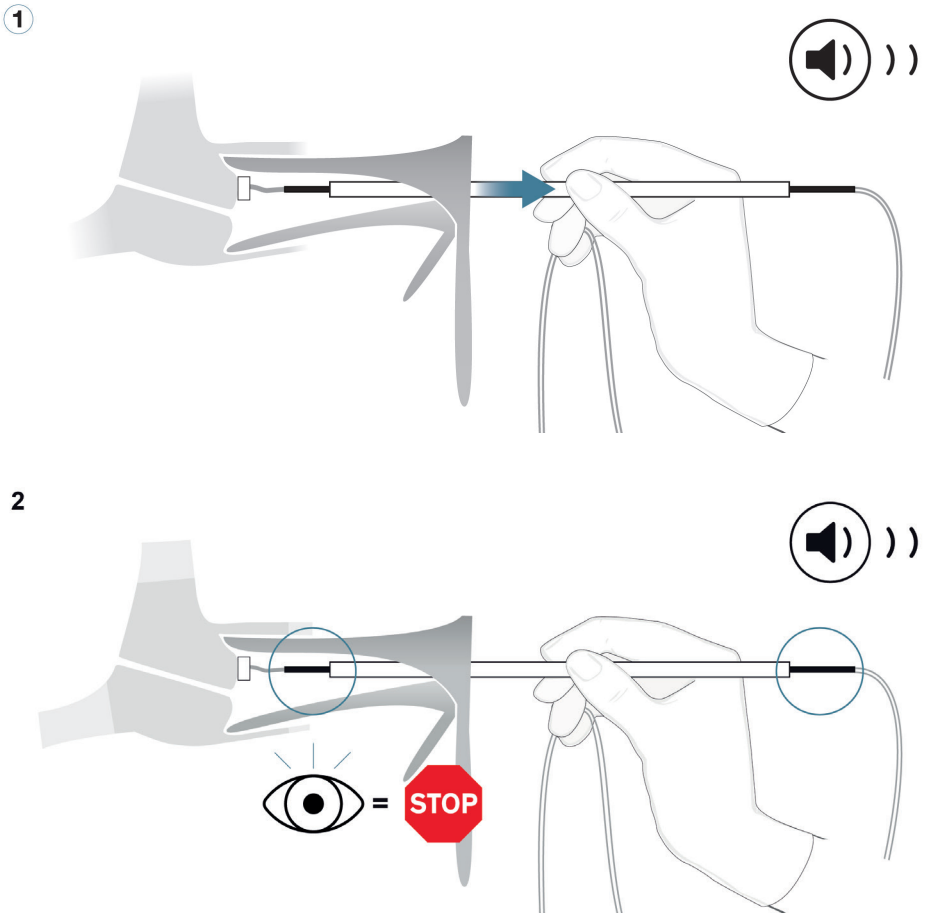
5) Gently push the *probe handle* inward until the first audio signal is heard (be-beep[5]), then stop pushing the *probe*. The audio signal means that an airtight contact has been established between the *probe tip* and the tissue.



WARNING	Do not to forcefully push the *probe handle* completely to the front.

5 Refer to the training videos or use the demo-kit 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[6]). Position the *handle* approximately in the centre of the *probe*. 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[6]).

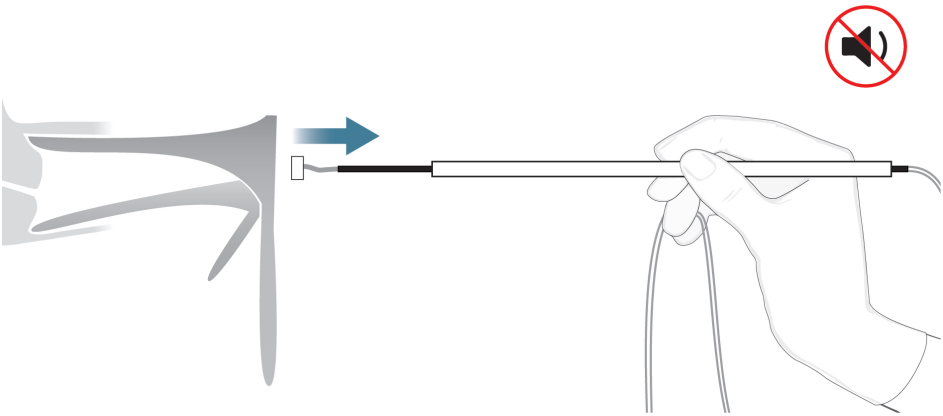


6 Refer to the training videos or use the demo-kit to familiarise yourself with the audio signal.

WARNING	Do not pull the *probe handle* completely to the back.

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 patient moves.

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 ***1.10 – Precautions***).

3.5 Post Measurement

WARNING	Do not reuse or re-sterilize the *probe* since this can lead to contamination or device abnormal functionality.

1) Disconnect the *probe* from the *connector cable*.
2) Dispose of the *probe* and the *probe sterile pouch*.
3) Note down the measurement values.
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***.

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

4.2 Disposal of the Probe

WARNING	Do not reuse or re-sterilize the *probe* since this can lead to contamination or device abnormal functionality.

The *probe* is a single-use, disposable item. No cleaning or disinfection apply 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 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*.

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 75% and atmospheric pressure between 620 hPa and 1060 hPa.

5.2 Storage of the Sterile Probes

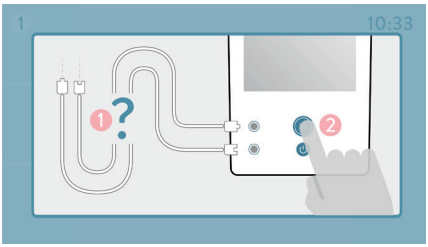
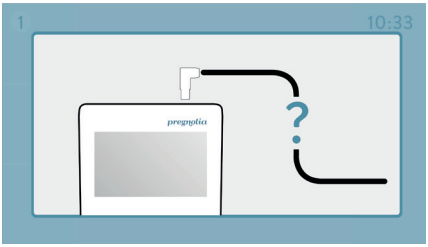
Upon delivery, store the *probes* inside the *probe box*. Keep the *probes* and the *probe box* away from direct sun light and UV radiation exposure. Keep the *probes* and the *probe box* at temperatures in the 10°C – 40°C range, relative humidity values in the 10% - 85% range and atmospheric pressures 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 connected. First, ensure that the *connector cable* is well connected and fastened and then press the Menu button. If the error message persists, disconnect and reconnect the *connector cable*, then try again.
Control unit console displays *foot switch* error message: 	The *foot switch* is not connected. Ensure that the *foot switch* is correctly connected to the back of the *control unit console*. If the error message persists, disconnect and reconnect the *foot switch*, then try again.

Error message / problem	*Cause / action*
The continuous beeping is emitted but no pressure rises during the measurement.	The Luer connectors are not correctly assembled. Turn off the vacuum using the *foot switch*. Disconnect the probe Luer connectors and the control unit Luer connectors and connect them again. Turn on the vacuum again using the *foot switch*. Refer to FIGURE 19 for the correct connection of the Luer connectors.
Airtight contact between the *probe tip* and the tissue cannot be achieved (the first audio signal is not emitted).	Either excessive mucus is present on the tissue, or the user is squeezing the *filters* in the hand, or the user is kinking one of the tubes. Ensure that the *filters* are not squeezed in the user's hand and that the tubes are not kinked. Try again to obtain airtight contact between the cervical tissue and the *probe tip*. If this does not solve the problem, remove any excess mucus from the cervix using saline solution and/or a swab.
The start-up audio signal is not emitted after turning on the *control unit* using the On/Off button.	Disconnect the *power supply* and connect it again. Turn on the *control unit* once more and check whether the audio signal is emitted.

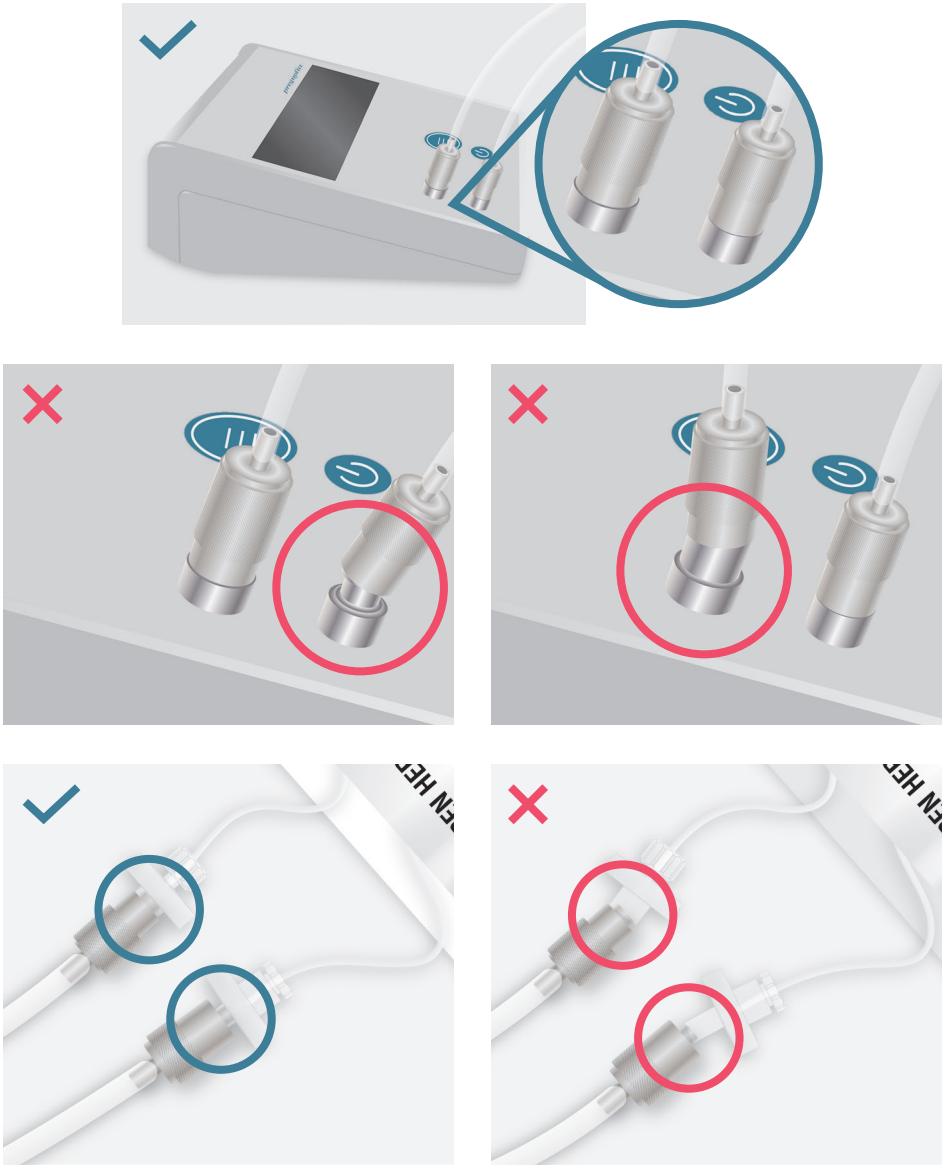


FIGURE 19: Top and centre: control unit Luer connectors. Bottom: probe Luer connectors. Correct assembly of the Luer connectors requires that they are well aligned and pushed all the way in.

7. SAFETY

The Pregnolia System has been used so far in two clinical trials to measure the cervical stiffness on 545 women (a total of 2853 measurements have been performed). No serious adverse events related to the Pregnolia System or to the interventions related to the use of the Pregnolia System were reported. There have been no reported adverese device effects (side effects).

The patient 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 Pregnolia Control Unit (REF 100058) consists of:
- Pregnolia Control Unit – Console (REF 100044),
- Connector Cable (P/N 100035),
- Power Supply (Mean Well GSM18B12-P1J),
- Foot Switch (Herga 6226-ACBB-ZBZZ-000),

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

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	Herga 6226-ACBB-ZBZZ-000

Power Supply	
Type	Mean Well GSM18B12-P1J
Input voltage	80 - 264 VAC or 113 - 370 VDC
Frequency	47 - 63 Hz
Output	18 W, 12 V, 1.5 A
Closing Pressure	
Range	25 – 475 mbar
Accuracy	10%
Precision	10%
Resolution	1 mbar

Use and Storage Conditions Probe	
Temperature range	10°C – 40°C
Relative humidity range	10% - 85%
Atmospheric pressure range	620 – 1060 hPa
Use and Storage Conditions – Control Unit	
Temperature range	10°C – 40°C
Relative humidity range	10% - 75%
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

CAUTION	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.

CAUTION	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.

CAUTION	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.

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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