

### **USER GUIDE**



### model Mobile\_S

including sensor module

with USB cable connection to App



Msys B.V. has the right to change the content of this manual as well change the properties of the product described. Specification of the product may change without notice.

Reading guide, "Pelvictrainer<sup>®</sup>" in this document means Pelvictrainer<sup>®</sup> model Mobile\_S using the sensor module with USB connection.

The content of this manual does not contain promises, a proposal, or a legal contract.

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Pelvictrainer<sup>®</sup> Mobile\_S

No charging Operation using a USB cable

Document Id : Msys-PTS-401



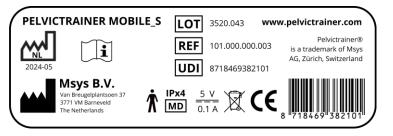


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## 1. Symbols



Symbol for country of production, including country code inside symbol. Symbol of Manufacturer Symbol to instruct the user to read and understand this user guide before using the Pelvictrainer. Symbol for type B applied parts. Symbol for batch code. LOT Symbol for product reference number. REF Unique Device Identifier UDI Symbol IP-code (International Protection rating), Splash-proof IPx4 Symbol to indicate Medical Device MD Symbol for DC Current. See technical data on page 38. The Pelvictrainer shall be disposed of as an electronic device, in conformance with European WEEE directive, or according national or local regulations. CE The CE-Marking indicates that the Pelvictrainer® complies with the EU Medical Device Regulations.



On sensor module 101.000.000.003 USB, you find the **LOT/Serial number** (important for Service).



### 2. Introduction

Congratulations with your purchase of the Pelvictrainer<sup>®</sup>! We are confident that it will fulfil your expectations.

For proper use, we recommend that you read this user guide in-depth before usage.

#### **2.1.** Functional principle

The Pelvictrainer<sup>®</sup> is a device for easy and comfortable training of the pelvic floor muscles. The Pelvictrainer<sup>®</sup> shows you to which extent you are contracting your pelvic floor muscles during training and creates insight in performance and progress.

#### 2.2. Purpose

The Pelvictrainer<sup>®</sup> is a medical device for the treatment of functional disorders related to the pelvic floor muscles. A functional disorder of the pelvic floor muscles may lead to problems like erectile dysfunction, incontinence, sexual disorder, instability of the pelvis.

The Pelvictrainer<sup>®</sup> can also strengthen the pelvic floor muscles in order to prevent a functional disorder.

The Pelvictrainer<sup>®</sup> shall be used while wearing clothes, between the contact area of the body and the device.

Best option is to wear a trainer or a pair of pants.

The Pelvictrainer<sup>®</sup> shall be used indoors; at home, in a gym or in a clinical environment.

The Pelvictrainer<sup>®</sup> shall not be used in contact with injured skin.

The Pelvictrainer<sup>®</sup> sensor module shall not be used inside the body (mouth, vagina, anal).

As all electronic devices, the Pelvictrainer<sup>®</sup> has electronic fields around the electronics, which may have an effect on other devices, for instance a pacemaker.

Please assure, in case you have a pacemaker, that it allows the usage of electronic devices within the range of the cable of the Pelvictrainer<sup>®</sup> and the connected computer.

Technical data on EMC you can find on page 38.

The purpose of the Pelvictrainer<sup>®</sup> is training of the pelvic floor muscles. Other usage may cause harm to you or the device.

The intended operators of the Pelvictrainer<sup>®</sup> are:



- medical practitioner (e.g. physio therapist) with experience regarding pelvic area and the training of pelvic muscles. Setting-up of the Pelvictrainer<sup>®</sup> and providing guidance to the patient.
- patient, suffering from issues in the pelvic area. The patient can use the Pelvictrainer<sup>®</sup> as described in this manual. Or patient can follow the instructions provided by the medical practitioner and follow the feedback from the PelvicTrainer<sup>®</sup>.

#### 2.3. Safety

Please follow the following instructions:

- 1. Bodyweight of the user shall not exceed 135 kg.
- 2. The Pelvictrainer<sup>®</sup> is not a toy. Please keep it safe from children and pets.
- 3. As all electronic devices, the Pelvictrainer<sup>®</sup> has electronic fields around the electronics, which may have an effect on other devices, for instance a pacemaker.

Please assure, in case you have a pacemaker, that it allows the usage of electronic Devices within the range of the cable of the Pelvictrainer and the connected computer.

Avoid direct or close contact of a mobile device with the sensor unit.

Technical Data on EMC you can find on page 38.

- 4. Only use the cable provided with the Pelvictrainer<sup>®</sup>.
- 5. Do not bend or twist the sensor module.
- 6. In the following cases (which may be incomplete) we advise to consult a medical practitioner:
  - a. If you are uncertain, whether your condition is good enough for moderate training. For instance in case you have a weak heart, a pacemaker or very complex problems in the pelvic area.
  - b. If you are under the age of 18.
  - c. If you already have been treated for pelvic floor related problems in the past.
  - d. If you are uncomfortable or have pain during or after training with the Pelvictrainer<sup>®</sup>.
  - e. If you do not understand how to use the Pelvictrainer®.
  - f. If you want to know if training with the Pelvictrainer<sup>®</sup> is likely to improve your personal health situation.

### **M**<sup>sys</sup>

#### 2.4. Warranty

Msys B.V. provides a warranty of two years on the Pelvictrainer<sup>®</sup> for product failures caused by manufacturing errors.

Dysfunction or damage because of improper use are excluded. The exact description of the guarantee you find in the separate guarantee brochure.

#### **2.5.** Legal protection

The Pelvictrainer<sup>®</sup> and the Pelvictrainer logo are registered trademarks of Msys B.V. Granted patents for the Pelvictrainer<sup>®</sup>: Patent US7473214, EP1747048 and NL1025526.

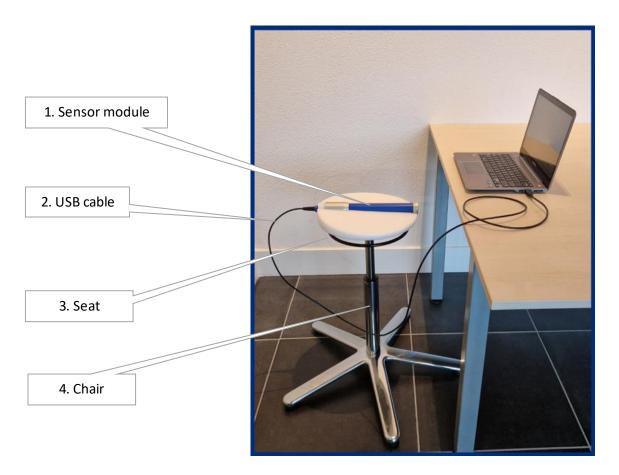




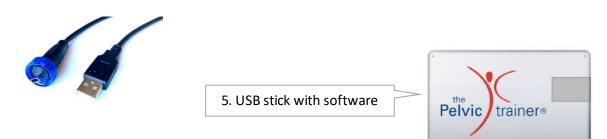
### 3. Start

#### **3.1.** Content of Delivery

The Pelvictrainer<sup>®</sup> contains from the following parts:



The connection between the sensor module and a device (PC, laptop) can by an USB cable connection.



For PC and laptop a USB stick with software is available.

The software can also be downloaded from the website www.pelvictrainer.com.

Applied parts are:

- (top of) Seat
- Sensor module assembly with sensor inside



#### 3.2. First Start

The Pelvictrainer<sup>®</sup> is almost ready after unpacking. Before first usage, please proceed as follows: In case of a PC or laptop take the USB stick and turn (flip) it open.



#### 3.2.1. Software Installation

(required a PC or Laptop; Windows 10 and higher + Intel processor)

- 1. Put the USB Stick in the USB port of your laptop/tablet.
- 2. Copy the Pelvictrainer software from the USB Stick to the laptop/tablet.
- 3. Start the program: **SetupPelvicTrainer-1.0.241** and follow the Instructions (only first time installation), see also step 1 in chapter Connect Application to Pelvictrainer
- 4. Now you can use the software (see software instructions).

Similar steps shall be followed when the software was downloaded from the website www.pelvictrainer.com.

#### 3.2.2. Install equipment Pelvictrainer<sup>®</sup>

#### Power supply of Pelvictrainer<sup>®</sup> sensor module

In case of an USB cable connection, the USB cable supplies electric power to the Pelvictrainer<sup>®</sup> sensor module, which allows immediate use.

In order to provide power to the cable it has to be plugged in the USB port of your PC/laptop.

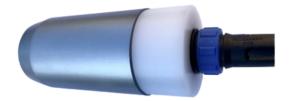


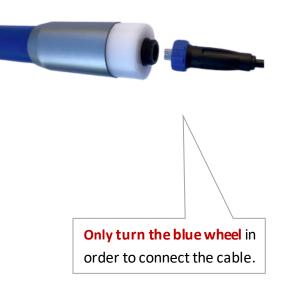
#### Cables

The USB cable connects the sensor module with the PC/laptop.

Put the connector of the cable into the plug of the sensor module and **fixate the blue wheel by turning it.** 

**Caution! Don't twist the cable**, as you can damage the interiors of the connector.





Plug USB cable in PC/laptop.





#### Set up of Pelvictrainer® sensor module

In order to place the sensor module into the seat, the sensor module has to slide from the back into the groove.

To remove the sensor module from seat, lift the sensor module at the front, and shift it towards the rear. Don't pull at the cable.



#### **Storage**

If you do not use the Pelvictrainer<sup>®</sup>, keep it protected (do not put sharp objects on the sensor module).

#### **3.3.** Software updates

The trainings software is stored on a USB stick, provided with the Pelvictrainer<sup>®</sup>.

Future updates will be provided free of charge by download from the website (www.pelvictrainer.com).

Installation of updates will replace the training program in your computer, without elimination of the database.



# 4. Connect application to Pelvictrainer<sup>®</sup>

After downloading and installation of the software program the following steps are carried out

#### A user licence will be effectuated.

For mobile devices, there is a single-user licence. No further actions are needed.

For other devices, a multi-user licence applies. An administrator is registered with password access. Other users can be added if necessary. To do this, the administrator goes through the following steps:

 first create a password. Once an unlock code is created, you can save and print it. If you forget your password, the account can be reset with this unlock code.

PelvicTrainer - v1.0.177		- [	×	
Bestand Help				
Petvic trainer*	elvictrainer - Setup	И	( <u>*</u>	
Minimur Password	administrative password for future access n password length is 6 characters d:			i1. Check correctness of Password.
and want to regain access to the u	code. You will need it in case you forgot you Iser and reporting database 067-45F0A08-8E6E41D-CA4A91	ur passwo	ord ] 🗊	<b>i2</b> . <b>Print</b> unlock code for administration.
		Volg	jende	



 $\circ$   $\;$  Next time administrator has to log in with the password.

PelvicTrainer - v1.0.180		– 🗆 X	
File Help	Pelvictrainer - Authenticate	M <sup>sys</sup>	
	Password: Login		i3. Login with password

#### $\circ$ $\;$ Add and remove multiple users

0

⑦ PelvicTrainer - v File Help	/1.0.180		- 🗆 X		
Pelvic trainer*	Pelvictrainer -	· Select User	M <sup>sys</sup>		
	Select	USEF Search:			i4. Search for user.
Id		Description			
0	Default				<b>i5</b> . Select user by double
1	Test user 1				
2	Test user 2		<		click.
3	Test user 3				
					Default user is
Add	Remove				administrator.
			Next		i6. Add and Remove user.
Open the	e main screen.				
		i7. Select Next	to open ma	in screer	for selected user.

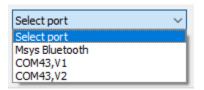


#### Make a connection between application and Pelvictrainer®

Sensor Connection: COM43,V2 Framecount: 2381 Framerate: 12 Battery: i8. Select protocol for connection. The current protocol is shown. I9. Check if you receive a signal from the tube (frame count increases).

On the settings screen a block represents the sensor module connection:

In case the connection doesn't start automatically you can choose the right protocol (V1 or V2) by selecting the corresponding port.



#### Protocol COM43, V1

This protocol is for use with a USB cable connection (Pelvictrainer<sup>®</sup> manufactured in 2020 or earlier). This connection starts immediately after connecting cable in sensor module and USB port of PC or laptop.

Protocol COM43, V2

This protocol is for use with a USB cable connection (Pelvictrainer<sup>®</sup> manufactured in 2021 and later). This connection starts immediately after connecting cable in sensor module and USB port of PC or laptop.



#### Start main screen

On the main screen you see some activities that can be performed:

- Start a training. Default a Basic training is selected.
- Start a Run test in order to indicate to what extend and accuracy you use the pelvic floor muscles
- Open menu option Switch User of 'File' in order to switch to another user.
- Open menu option Save 'File' in order to save all measurement values of last training sessions.

For a good exercise sit straight in the middle of the seat and:

- Move forward or backward as little as possible.
- Move the knees and legs in and out as little as possible.
- Relax and breathe calmly.
- Use your abdominal muscles as little as possible when tightening your pelvic floor muscle.
- Do not use abdominal air pressure.
- Check if the signal goes up and down sufficiently. If not, raise your chair (if adjustable).

For more information see next pages Preparation body position and Software instructions.



# 5. Preparation body position

You can now start your training.

#### Beware!

Maximum bodyweight shall not exceed 135 kg!

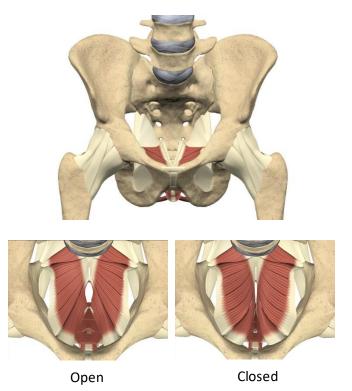
#### Training

Training with the Pelvictrainer<sup>®</sup> is most effective if:

You sit in the middle of the seat of the Pelvictrainer<sup>®</sup> and slide down to the front, until you feel the sensor module having good contact with your pelvic floor.

Only when you sit relaxed, painless and far enough to the front a good contact between the pelvic floor muscles and the elevation of the Pelvictrainer<sup>®</sup> seat is created.

Schematic front view of pelvic floor





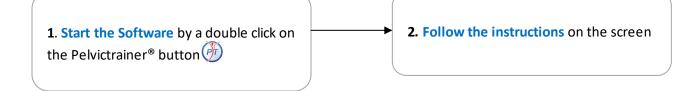
To prevent contamination, it's advised to do training with your clothes on.

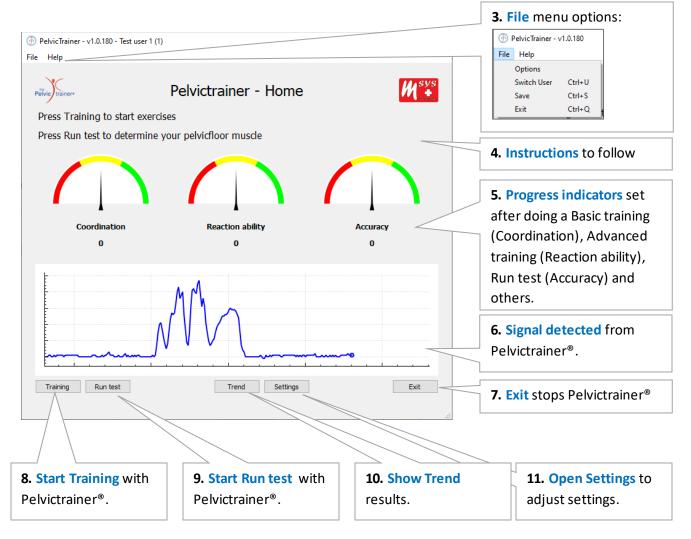


### 6. Software Instructions

#### 6.1. Main Screen







Open menu option Switch User of 'File' in order to switch to an other user.

Open menu option Save 'File' in order to save all measurement values of last training sessions.



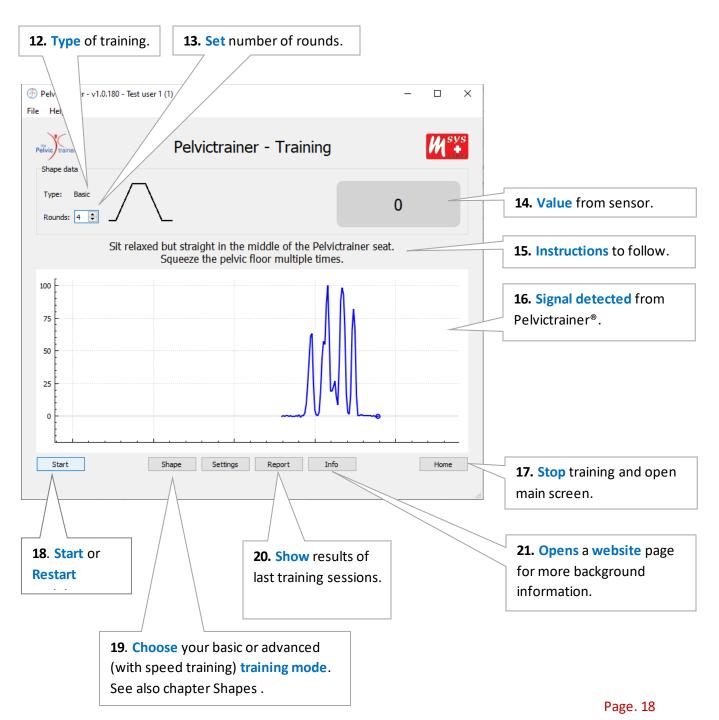
#### 6.2. Training

Each training has three phases:

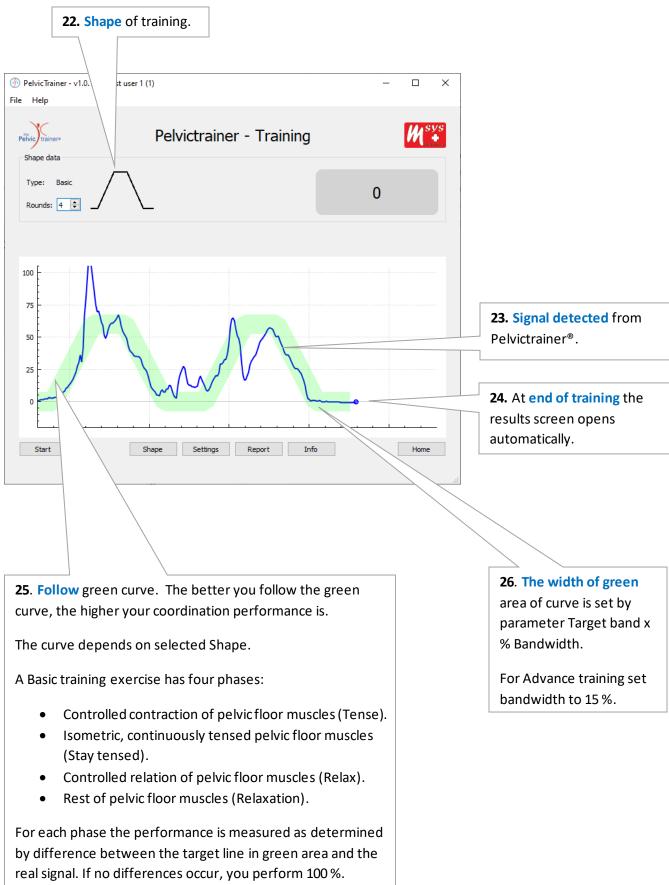
- Initialize,
  - o first 1 second to determine reference point (calibration for level zero).
  - then 5 seconds where you can squeeze pelvic floor muscles in order to determine the offset of maximum strength and scaling of the graph.
- Exercise: try to follow the pattern of the presented shape by squeezing the pelvic floor muscles.
- Show report of exercise results, details and trend.

#### 6.2.1. Basic training

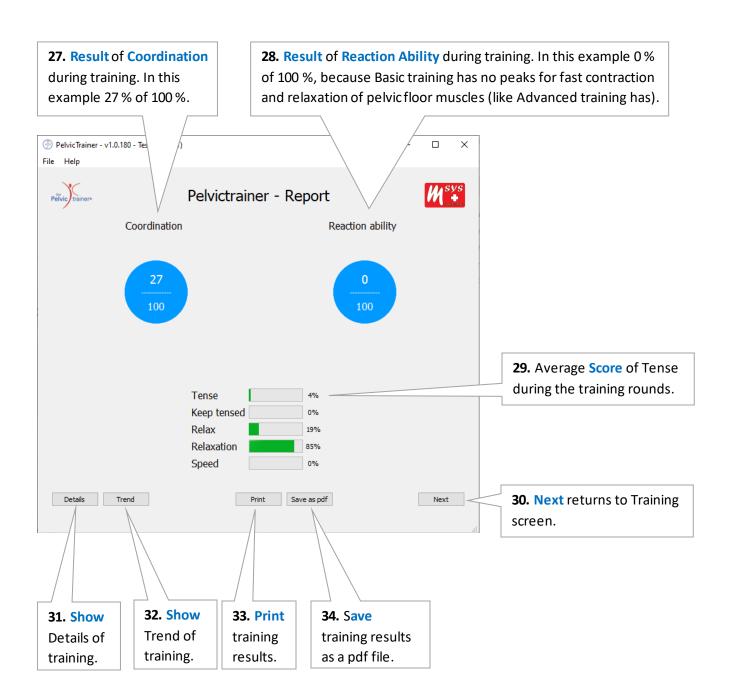
Default a Basic training is started.



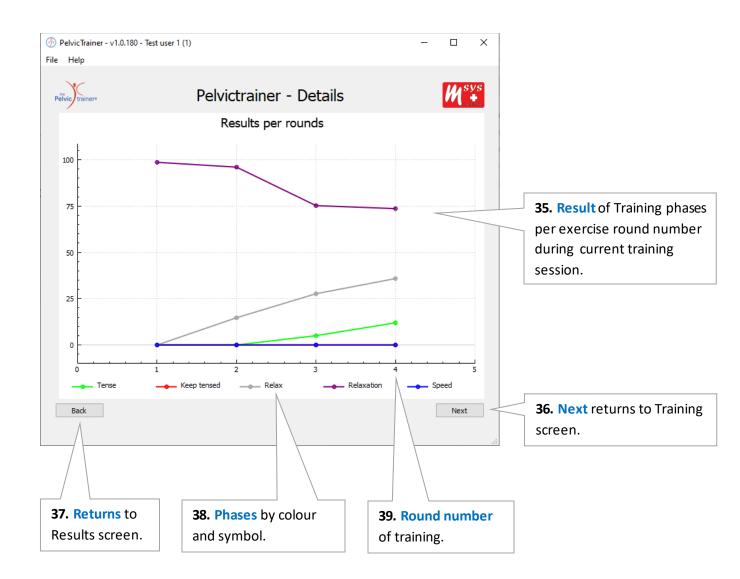














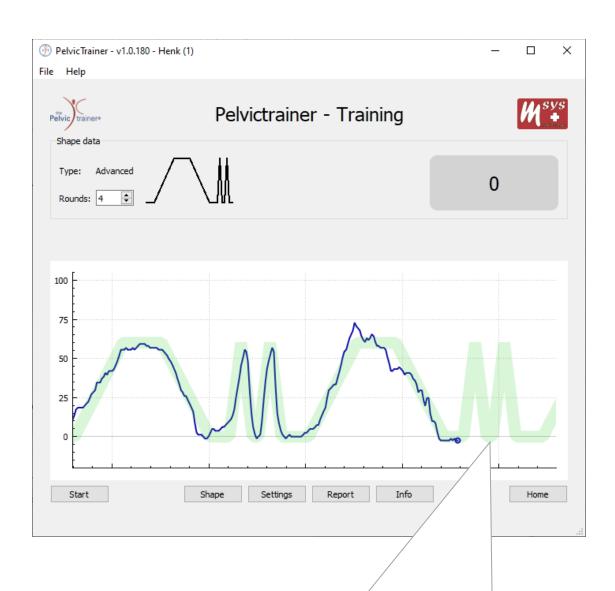
#### 6.2.2. Advanced training

While starting an Advanced training of the pelvic floor muscle you:

- Select Shape Advanced Training.
- Change Band width in Setting screen to 15%.
- Start Training.

<b>40. Type</b> of training.			
Pelvie v1.0.180 - Henk (1)		– 🗆 X	
Petvic trainer*	Pelvictrainer - Training	M <sup>sys</sup>	
Type: Advanced	.₩	0	
Sit relaxed b S	out straight in the middle of the Pelvictrainer seat iqueeze the pelvic floor multiple times.	-	<b>41. Instructions</b> to follow.
100			
75			
25			
Start	hape Settings Report Info	Home	





42. Follow green curve. The better you follow the green curve, the higher your coordination performance is.

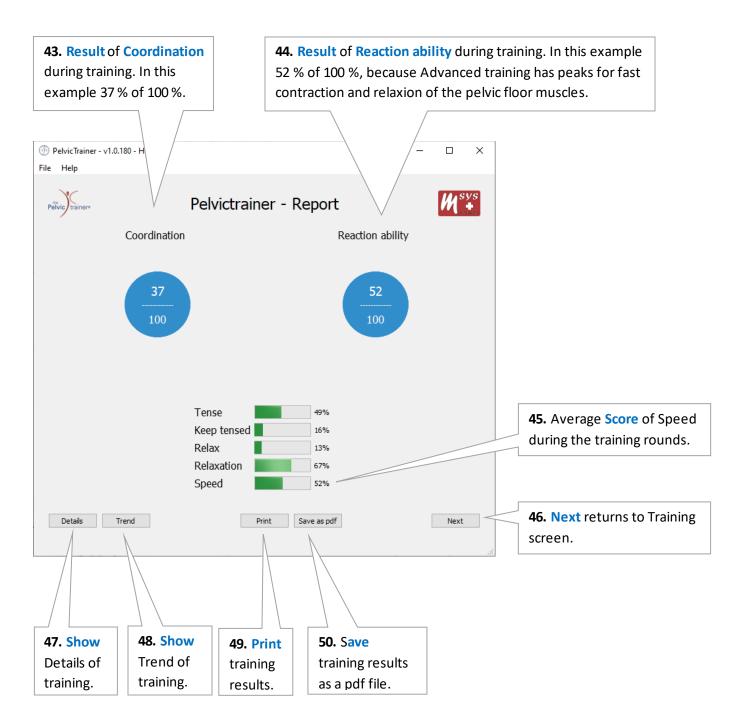
The curve depends on selected Shape.

An Advanced Training exercise has five phases:

- Controlled contraction of pelvic floor muscles (Tense).
- Isometric, continuous tensed pelvic floor muscles (Stay tensed).
- Controlled relaxion of pelvic floor muscles (Relax).
- Rest of pelvic floor muscles (Relaxation).
- Fast contraction and relaxation of pelvic floor muscle (Speed).

For each phase the performance is measured as determined by difference between the target line in green area and the real signal. If no differences occur, you perform 100 %.







#### 6.3. Run test

The Run test has two challenges combined:

- A special training curve with three levels with an indication on how accurate you use your pelvic floor muscles.
- A game to collect as many coins as you can. You receive coins if you use the pelvic floor muscles accurately and if you tense your pelvic floor muscle near the target line (see Settings screen) within coin limits.

To give an indication how the pelvic floor muscles are being used, the signal from the sensor is compared to a statistical configured learning model; a so called Machine Learning model. It is stored in the Application and determined from many training data. Ten times a second your training behaviour is compared to this model. The more the model has learned from trainings performed by several persons, the better the indication will be.

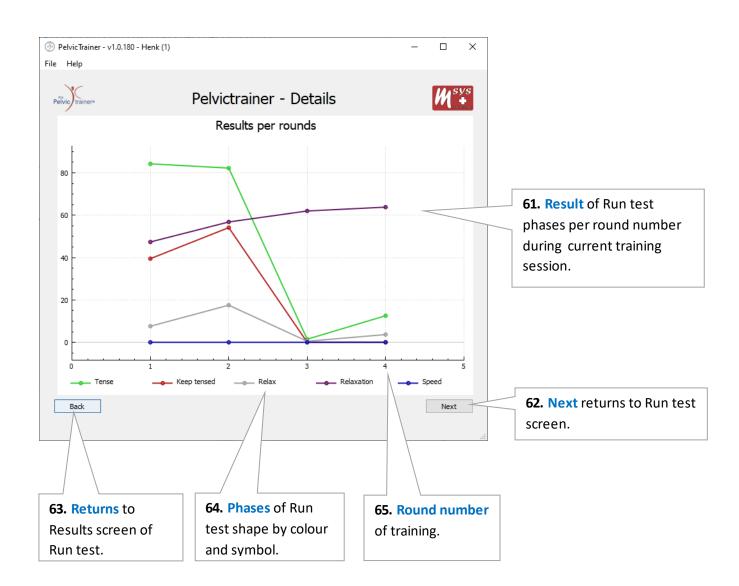
It is important to know that the model only provides an indication and does not makes absolute statistical statements. In case you want to help to make the model more accurate, please contact us.







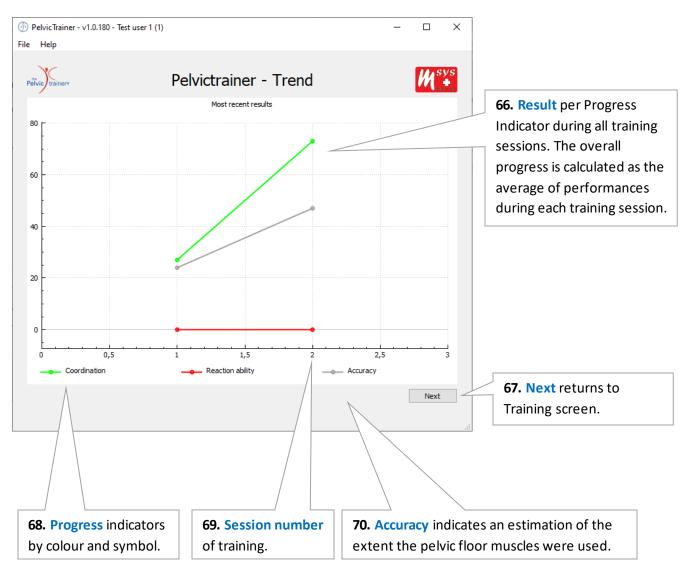






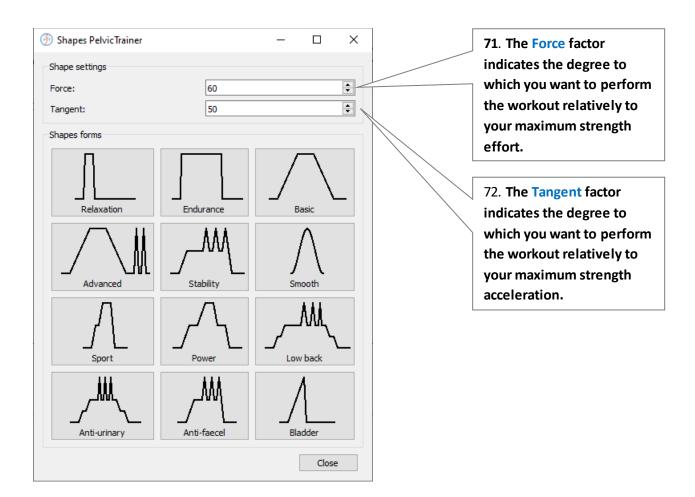
#### 6.4. Show Trend Progress

Show Trend of progress as result of action 10.





### 7. Shapes and Treatment



Although Basic and Advanced training cover most needs, you can always set up your individual training mode from these extra 10 trainings modes; they reflect the experience of a pelvic floor rehabilitation specialist.

#### 1. Relaxation

It is not only important that you can contract your pelvic floor muscles; many people have challenges to relax those sufficiently or fast enough. In this training mode you can train fast relaxation after fast contraction. For instance, if you suffer from Vaginismus you may profit from this training mode after a few rounds of Basic training.

#### 2. Endurance

The pelvic floor muscles with its mostly slow muscles fibres aren't made for endurance purposes. This training mode is recommended as extra mode after Basic and Advanced training if you have erectile disfunction.

#### 3. Basic



Basic Training is ideal to start with as it contains the 4 phases of traditional training: Concentric Phase (Upwards contraction), Isometric Phase (Holding), Eccentric Phase (Let go contraction) and Relaxation (Let go maximally)

#### 4. Advanced

If Basic training is mastered, Advanced training offers the extra challenge of controlled fast contraction which not only offers force and coordination training but also offers more activation of fast muscle fibres that are used by fast response of the whole body and especially by high impact loads as lifting or jumping, running and sports like tennis, golf etc.

#### 5. Stability

As the pelvic floor is situated in the lower end between the two pelvic bones (Ilium) it has much leverage on the whole of the pelvis and therefore offers a major contribution on the dynamic stability of the whole pelvic girdle including the lower spine. The stability training mode offers an extra challenge for people that need extra stability in this area.

#### 6. Smooth

The Smooth training mode offers an extra challenge of coordination because it has no straight lines you can follow.

#### 7. Sport

If every day's activities are supplemented by sports activities, the pelvic floor muscles are used on a higher level. The Sport mode is an extra mode after you finished Basic and Advanced training.

#### 8. Power

Just like the Sport mode the power mode is meant as extra mode after you finished you Basic and Advanced training if everyday life or sports involve lifting.

#### 9. Low back

As the pelvic floor is situated in the lower end between the two pelvic bones (Ilium) it has much leverage on the whole of the pelvis and therefore offers a major contribution on the dynamic stability of the whole pelvic girdle including the lower spine. The Low back training mode offers an extra challenge for people that need extra stability in this area.

#### 10. Anti-urinary

Although Basic and Advanced Training must be mastered first to master this extra training mode it can be an important one for people that in high impact situations loose urine.

#### 11. Anti-Faecal

Although Basic and Advanced Training must be mastered first to master this extra training mode it can be an important one for people that in high impact situations loose stool.



#### 12. Bladder

The bladder is a hole muscle and can be too tense or suffer from lack of tension. This extra training mode offers an overflow training of the pelvic floor muscles onto the bladder, to influence bladder hypertension or -relaxation.

Note that the patterns are based on best practises and suggested way of movements.

#### Suggested build-up of training and treatment

Step 1. Ensure that the pelvic floor muscles can be relaxed. Use shape Relaxation.

Step 2. Ensure that the pelvic floor muscles can be tightened at a lower force effort for a long period of time. Use shape Endurance.

Step 3. Train to tighten, keep tensed and relax the pelvic floor muscle in a coordinated manner. Use shape Basic.

Step 4. Train to tighten the pelvic floor muscles quickly and relax them quickly. Use shape Advanced

Depending on the issue(s) regarding the pelvic floor or fitness goal, use the other shapes:

- Sport : Stability, Sport, Power.
- Medical : Smooth, Low back.
- Incontinence : Anti-urinary, Anti-faeces and Bladder.



### 8. Settings

73. Select language	74. Select Style of	75. Show received messages
Options - PelvicTrainer	×	
System Settings		
Preferred language:	Amèrican English	
Style:	Natural Green	
Sensor		76. Set time for
Connection:	Select port  Debug	
	Framecount:	preparation before start
	Framerate Battery:	of training
Application defaults		77. Set number of rounds
Autostart after calibration	5 🚖 seconds	during training cycles
Number of rounds	3 🔄 rounds	
Target band	30 Sandwidth	
FFT Settings		78. Set width of allowed
Coin limit	40 %	deviation in training
IIR filter	0.5	pattern
Storage		
Trend reporting	10 Records	79. Set width of allowed
	reset	deviation in test run
Company info		pattern to receive coins
Address details	Details A	
Address details		
		80. Reset numbers to
?	Close	original manufacturers
/ /		data.
81. Set number of results	82. Add your identity to	
for determining the	print and pdf file.	
progress indicators		



#### **8.1.Print and save results**

You can **print** the training results or trend reports after every training, on your printer or store as PDF file.

💮 Pri	Print Preview ?				
$\leftrightarrow$	100.7% 💌		1 /1 🔿 🔷 📃 📗 📄 🖶		
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	Description	: Henk	My address My telephone number My Social identity		L
	Coordination	: 83 %			
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	Tense	: 87 %	Shape :		
	Keep tensed	: 86 %	Rounds : 3		н.
	Relax	: 71 %	<i>→</i>		
	Relaxation	: 87 %			
	Speed	:0%			
•					•

If you chose to **print as PDF** then the software will ask you where on your computer you want to save the file.

The generated PDF File name, that you can change at any time, will always contain **Time information**.

Bestandsnaam:	PelvicTrainer_Report-220311-1607	
Opslaan als:	PDF files (*.pdf)	



# 9. Cleaning & disinfection

Clean or disinfect your Pelvictrainer<sup>®</sup> with a soft and moist cleaning cloth. Do not use aggressive or abrasive detergent.

If you want to clean your PC or laptop screen, follow the cleaning instructions of the respective manufacturer.

The Pelvictrainer<sup>®</sup> is not waterproof and will get damaged when submerged in water or other liquid.

#### Beware!

If you clean the Pelvictrainer<sup>®</sup>, assure yourself that you disconnected any power source so that there is no voltage on the device.

#### 9.1. Transport and storage

The Pelvictrainer<sup>®</sup> must be stored in a safe way, so that you can be sure, that no damage to the device can occur, which can change the functionality or the safety of the device.

During transport and storage the following requirements must be fulfilled:

- Temperature between -25 °C and 70 °C.
- Air pressure between 700 hPa und 1200 hPa.
- Humidity between 5 % und 95 %.
- Prevention of bumping.

If the Pelvictrainer<sup>®</sup> is stored in a cold room, the device should be allowed to adapt to the environment for at least two hours, before usage.

The proper usage of the computer you use for the Pelvictrainer<sup>®</sup> Software you find in the manual of your computer.

#### 9.2. Disposal



The Pelvictrainer<sup>®</sup> is made of materials that can be recycled. So please follow the rules and regulations of your country concerning the recycling of electronic devices.



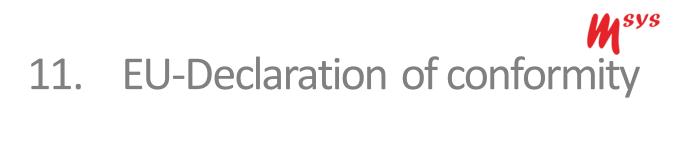
## 10. Problem solving

If you have questions or requests, please visit our Homepage: <u>www.pelvictrainer.com</u> Frequently asked questions can be found there.

Some problems that could occur and possible solutions.

- 1. The Pelvictrainer software does not function or does not function correctly:
  - Test if the connection cable is in the USB-port.
  - Test if the connection on Settings screen is set to COM V2. The moment connection is built and active, the Frame count and Framerate starts to publish figures.

Please contact the customer service of the company, where you bought the Pelvictrainer. See pg. 37.



EU- DECLARATION OF CONFORMITY.

The legal manufacturer, Msys B.V. in the Netherlands, hereby declares that the Pelvictrainer<sup>®</sup> fulfils the requirements of regulation (EU) 2017/745 on medical devices.

Msys B.V.

The Netherlands





### 12. Contact & Support

Any serious incident that has occurred in relation to the PelvicTrainer<sup>®</sup> should be reported to Msys B.V. and the competent authority of the Member State in which the user and/or patient is established.

#### 12.1. Customer care

If you have any issue, please contact your local supplier or distributor (the one who sold you the Pelvictrainer).

For general issues concerning the Pelvictrainer<sup>®</sup> please contact your trained and authorized reseller or one of the other addresses below.

Do not try to repair the Pelvictrainer<sup>®</sup> by yourselves. This can be dangerous and your warranty will get void.

Contact a service centre below to have your Pelvictrainer<sup>®</sup> repaired.

Only use original parts delivered by Msys or an authorized reseller as replacement.

#### 12.2. Service centers EU

Msys B.V.	Msys Technology GmbH
Van Breugelplantsoen 37	Klausstrasse 44
NL- 3771VM Barneveld	CH-8008 Zürich
the Netherlands	Switzerland
service@msys.nl	service@msys-international.ch
For further Information:	

Please visit www.pelvictrainer.com



## 13. Technical Data

Internal power consumption	5V +/- 5%, nominal current < 4 mA
EMC-Level	CISPR 11, Group 1, Class B (according to IEC 60601-1-2)*
Total weight	7 kg (Sensor module: 0,35 kg, Seat: 0,8 kg, Frame 5.85 kg)
Dime	nsions
Chair	Diameter = 76 cm, H = 50 - 76 cm
Seat	L = 27 cm, W = 20 cm, H = 1,5 cm
Sensor module	L = 27 cm, D = Ø 4,1 cm
Maximal allowed load by user	1350 [N] (135 kg)
<b>Operating temperature</b> (tolerable range)	10 – 40°C
Storage temperature (tolerable range)	-25 – 70°C
Relative humidity (tolerable range)	5– 95% (without condensation)
Air pressure (tolerable range)	700 – 1200 hPa
Magnitude of shock forces (tolerable range)	< 100 cm



\* The Pelvictrainer<sup>®</sup> fulfils the requirements for medical devices conform safety standards IEC 60601-1 and IEC 60601-1-2.

Please use the problem-solving area (pg. 35), visit our homepage: www.pelvictrainer.com or contact us if the device should not work properly.

#### **Classification of the Pelvictrainer**®

According to EN/IEC 60601-1:

USB: Device with external low-voltage DC power supply
Class II
Applied part Type B
IPx4
Non sterile medical device
Continuous usage
Indoor use