

MyotonPRO Digital Palpation Device USER MANUAL

Device model: 1B, device firmware v.1.8.1 Myoton Desktop Software v.5.0.0.261

For Research Use Only

Revision 32 10th July 2024





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WARRANTY

The materials and technological appliances of the MyotonPRO (hereinafter referred to as "the Device") have a two years warranty period if not agreed otherwise starting from the selling date of the item.

During the warranty period, Myoton AS undertakes to repair and/or replace the defective parts of the Device.

No other warranties will apply to the Device

Myoton AS will apply the warranties mentioned above only for the purposes described below.

Myoton AS will take responsibility for the safety and reliability of service of the Device only if:

 the Device is assembled or dismantled, changed or repaired by people authorised by Myoton AS; the Device is used in accordance with the guidelines provided in the product user manual.

WARRANTY RESTRICTIONS

The warranties described above will not apply to defects that have been caused to the Device by:

- improper storage by the buyer; or
- mishandling;
 or
- use of the Device outside the environment described in the specification of the product.

In addition to the restrictions described above, the warranty will not be extended to the cable, battery, power adapter or skin marker.

Warranty will NOT apply if the Device housing has been opened or any change has been made, or damage done to the Device.

MAINTENANCE

The Manufacturer guarantees the device DOES NOT need regular maintenance or re-calibration.

Repair, battery change, calibration and testing can be performed ONLY by the Manufacturer. Depend on Device usage the battery may need replacement with new one in every 5 to 10 years of service.

Global Medical Devices Nomenclature (GMDN)

The five-digit GMDN code is defined in "EN ISO 15225, Annex A, Code 04 (Electro-mechanical medical devices)".

European Legislation on Medical Devices

The MyotonPRO Digital Palpation Device is FOR RESEARCH USE ONLY. The Device conforms essential safety requirements of MDD 93/42/EEC + 2007/47/EC.

The Device is designed and manufactured in accordance with EN 60601-1-2: 2007; EN 55011: 2007 + A2: 2007; EN 61000 Part 3 and Part 4.

Storage of the product and opening of the package

When unpacking, please check that the package has not been damaged during the shipping. In case of any damage to the package, please contact the Manufacturer.

Open the package and compare its contents with the list of product items in the documentation.

One package contains one set of the Device. If the content of the package does not conform to the list of documentation, contact the Manufacturer immediately.

Manufacturer:

Myoton AS, Address: Lootsa Str.8A, Tallinn 11415, Estonia

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Terminology

Following terminology used in the User Manual, Software and Device:

- **Device** the MyotonPRO Digital Palpation Device, also called in the literature as Myotonometer, Myometer, Myoton technology;
- **Software** the Myoton Desktop Software;
- Computer a computer with Myoton Desktop Software installed for Microsoft Windows;
- Subject a person being measured;
- Operator a person performing measurements;
- Pattern a Measurement protocol consisting: Pattern name, Measurement mode, Object names, and Measurement profiles;
- **Measurement** a Measurement series that consist of single measurements, conducted under the measurement mode;
- Measurement mode the mode in which the Measurement is conducted, Triplescan or Multiscan;
- **Triplescan** a measurement mode consists of three single measurements. The device displays the median of the Frequency parameter. Other parameters: S, D, R, and C, displayed on the device screen, correspond to that particular single measurement.
- **Multiscan** a measurement mode which consists of more than three single measurements (by default five single measurements). The Device displays the average value.;
- CV Coefficient of Variation of the Measurement, to describe relative dispersion of data points;
- **Tissue** the soft biological tissue;
- **Tissue layer** a set of different types of tissues located under the Probe and being involved in the Measurement (e.g. skin, adipose fat, fascia, skeletal muscles, tendons);
- Object the Latin name of a tissue being measured (a skeletal muscle, tendon, skin, etc.);
- Muscle a superficial skeletal muscle;
- **Tendon** a superficial skeletal tendon;
- Accel.Graph the raw acceleration signal of an Object's natural oscillation;



- **Co-oscillation** an oscillation consisting of an Object, pre-compressed subcutaneous tissues, the Probe and the Device measurement system;
- Measurement set a list of Subjects and Patterns selected for upload to the Device;
- Measurement result a result containing the set of measured parameters (chapter 1.4.1);
- **Upload** a transfer of the Measurement set from the Software to the Device;
- **Download** a transfer of the Measurement results from the Device to the Software;
- **Probe** the flat end cylindrical polycarbonate rod (standard diameter 3mm);
- **Probe disk** the probe disk attachment (chapter 1.3);
- **Measurement position** is the Probe position within the range of 3mm, indicated with the green light, and where the Device automatically conducts the Measurement;
- **Delay** the time delay preceding the first measurement impulse of a Measurement (default Delay 0.7 seconds);
- Tap time¹ the measurement impulse time duration (default impulse 15ms);
- **Tap Interval** the interval between the measurement impulses in a Measurement Series (default value 0.8 seconds);
- Measurement profile a list of aspects of how an Object is measured (see below);

The Measurement profile consists of:

- **1. Tissue** the type of Object being measured:
 - Muscle
 - Tendon
 - Ligament
 - Skin, Other
- **2. Object** the Latin name of an Object being measured;
- **3. Position** a Subject position when measured:
 - Lying
 - Sitting
 - Standing
- **4. Side** the body side being measured:
 - Left
 - Right

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¹ The standard Tap time of 15 milliseconds is optimal for most of the measurements. By changing the Tap time, the Impulse Force will be changed as *Impulse Force * impulse duration*. The impulse force is not separately adjustable.



- Centre (Axial)
- **5. Location** anatomical location of the measurement point on Object:
 - Central on the middle part, e.g. on the muscle belly
 - Superior on the upper part
 - *Inferior* at the lower part
 - Medial on the side of the centre line of the body
 - Lateral on the side of the outward line of the body
- **6. State** the state of the Object being measured:
 - Relaxed (complete relaxation, full rest)
 - Contracted (low, medium, sub-maximum, maximum)

System requirements

The Device and Software is a stand-alone system.

Running on Windows

The Software is for Windows Operating System starting from Windows XP or later versions (32 or 64-bit Operating System).

Running on Mac

The Software can be operational on a Mac computer equipped with Windows OS as the mandatory operation system. Mac and Windows OS can be simultaneously used via Parallels Desktop Software. Read for more at https://www.parallels.com.

Disk space

Installation of the Software requires at least 25Mb of free disk space. Software database files (file extension .sdf) will require additional disk space. The size of database files depends on the amount of collected data which may be up to the 10th of Mb.

Display size

The minimum required display size is 12-inch.

Analytics

For the automatic export of Measurement results for analytical purposes, it is recommended to install Microsoft Excel as a part of the MS Office package.

The Software contains a feature of an automatic data export to MS Excel (chapter 3.7.1.). MS Excel provides comprehensive tools for data processing, statistics and visualisation of the results.

Communication

The Device connects to the computer via USB cable (chapter 3.2.2).



1. General information

1.1 Icon glossary

Symbol	Description	
	Symbol for CE Mark. This symbol certifies that MyotonPRO palpation device is	
	designed, manufactured and in full compliance with the following standards:	
CE	EN 60601-1-2: 2007 – Medical Electrical Equipment Part 1-2	
6	EN 55011:2007+A2:2007 – Industrial, scientific and medical (ISM) radio	
	frequency equipment	
EN 61000 Part 3 and Part 4 – Electromagnetic compatibility (EMC)		
SN	Serial number. Indicates the manufacturer's serial number so that a specific device can be identified.	
0°C - 50°C	Operating temperature limits.	
-10°C -55°C	Transportation temperature limits.	
15°C 30°C	Suggested operating temperature limits.	
★	According to the IEC 60601-1 MyotonPRO is a type B device which has a protection against electric shock. The leakage current of the device remains within the valid norms.	
[]i	Attention, Follow instructions for use!	
	Do not disassemble or modify this Device.	

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NON STERILE	Non-sterile. Indicates a device that has not been subjected to a sterilization process.
	Do no use if the package is damaged or opened. Please contact the local representative or manufacturer.
KEEP DRY	Keep dry.
FRAGILE	Fragile - handle with care.
	Do not discard with household waste. Waste handling according to local rules.
	Transport package is made of a recyclable material.

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1.2 Contents of the package

The package consist:	Photo
Digital Palpation Device – for the non-invasive measurement of biomechanical and viscoelastic properties of soft biological tissues. See Appendix 3 – Technical Specification	Manufacture for seasons to the seaso
USB cable, A plug to Type-C plug – for charging the battery and the Device and Software communication.	
2. AC Power Adapter with USB DC socket – for charging the battery from the mains power supply. See Appendix 3 – Technical Specification	
3. Medical Skin Marker – for marking measurement points on the skin. ALL SKIN, with prep resistant ViXL ink, 1447XLB	Skie Harkey Justice

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1.3 Accessories

Following accessories can be separately ordered. Please contact Myoton AS for quotation.

De	scription	Image
1.	Probes disks – increases the contact area and tissue's ability to respond to the measurement impulse and/or reduces the depth of measurement. (chapter 2.3.1 and 2.3.2). 1. the probe with the disk attached; 2. disk D=10mm; 3. disk D=12mm; 4. the standard probe D=3mm.	2
2.	The L-shape skin probe (medium arm) – The probe enables isolated measurements from deeper underlying adipose layers or muscles tissues.	
3.	Double sided skin tape – attaches the skin probe to the skin and prevents the probe from sliding on the skin surface (chapter 2.3.3). The stickers are available in roles. One role consists of 500 stickers. Sticker diameter is 12mm, thickness 0,1mm.	332228888888



For thin tissues, increase the probe contact area by using the Probe disk D=10mm. The Probe disk reduces the measurement depth or helps thin facial Muscles better to respond to the measurement impulse (chapter 1.3 p.1).



1.4 Device description

The Device is for the non-invasive measurement of biomechanical and viscoelastic properties of superficial soft biological tissues. Skeletal muscles or tendons can be measured at different regions, at full rest or in contraction.

The Device measurement system enables measurements in any direction to the vector of the gravity and in weightlessness (zero gravity).

Mathematically, the measurement result describes the property of the tissue layers involved in the measurement as a weighted average.

The tissue types that can be measured:

- single superficial skeletal muscles or different regions,
- tendons and ligaments,
- fascia and underlying fibrous layers,
- skin (experimental use),
- other superficial soft biological tissues.

The Device features:

- non-invasive and painless,
- reliable, reproducible, repeatable,
- fully automatic measurement sequence,
- measures at any angle to the vector of the gravity,
- functional in different gravity fields (from Earth's gravity to zero gravity),
- the depth of measurement 20-30mm, depending on dampening of underlying tissue structures,
- measures underlying tissues in 3D (three dimensionally);
- hand-held, cost-effective, quick and easy to use.

1.4.1 Measurable parameters

The Device measures (computes simultaneously) the following five parameters²:

- State of tension:
 - 1. F Natural oscillation frequency [Hz] characterising TONE³ or state of tension;

• Biomechanical properties:

- 2. S Dynamic STIFFNESS [N/m];
- 3. D Logarithmic Decrement, characterising ELASTICITY or dissipation of natural oscillation;

• Viscoelastic properties:

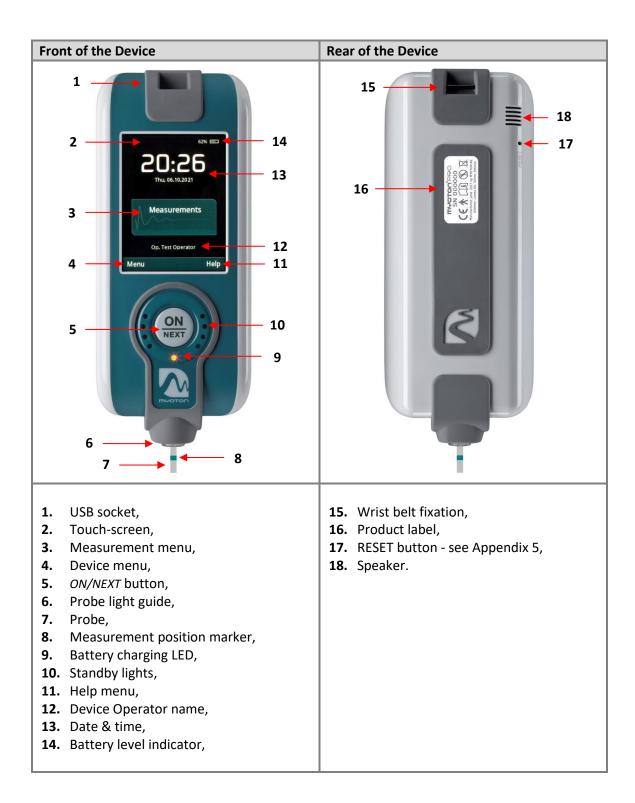
- **4.** R Mechanical Stress Relaxation time [ms];
- 5. C ratio of Relaxation time to Deformation time, characterising CREEP (Deborah number).

² Definitions of parameters – see Appendix 1.

³ Muscle Resting Tone must be measured at full rest. Muscle measurement in contraction characterises the state of functional tension. **Classification of tone:** Passive Tone, Resting Tone, Postural Tone.



1.4.2 Device overview



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1.4.3 Areas of application

MyotonPRO Digital Palpation Device is for research use only!

The Device can be used for basic science research, clinical research and other types of research.

Potential application areas:

1. Clinical medicine:

- monitoring the changes in tissues caused by health disorders,
- disease progression monitoring;
- obtaining supplementary information for health or disease diagnosis,
- intervention efficacy evaluation,
- physiotherapy or rehabilitation outcome monitoring;

2. Sports medicine:

- monitoring of key Muscles training efficacy,
- detection of fatigue and Muscle's overtraining,
- determination of the optimal training load for Muscles,
- prevention of Muscle and tendon injuries;

3. Occupational health care:

- prevention of trauma caused by Muscle overload due to uncomfortable positions assumed when working over a prolonged period,
- monitoring the changes to Muscle condition due to uncomfortable working positions assumed over a prolonged period,
- obtaining supplementary information when diagnosing Muscle diseases;

4. Veterinary medicine:

- prevention of Muscle and tendon injuries,
- evaluation of the applied interventions or treatments.

1.4.4 Method of measurement

The Device measurement method is non-invasive, safe and painless, easily applicable anywhere on the field, cost-effective and practical in clinical ward settings.

The method consists of recording the damped natural oscillation of soft biological tissue in the form of an acceleration signal and the subsequent simultaneous computation of the parameters, including State of Tension, Biomechanical and Viscoelastic properties.

To measure:

- 1. place the Probe perpendicular to the skin surface over an Object in interest;
- 2. lower the Device towards the skin until green light illuminates;
- 3. hold the Device gently and steadily in the Measurement position;



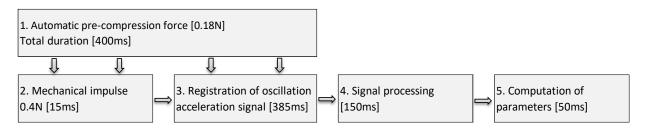
4. the Device performs the pre-defined Measurement automatically.

The Measurement series consisting of single measurements is executed with an interval of 0.8 seconds.

The Measurement consists of following automatic stages:

- 1. Pre-compression of subcutaneous adipose tissues throughout the measurement;
- 2. Mechanical impulse followed with quick release;
- 3. Registration of tissue response to the mechanical impulse in the form of acceleration signal of damped natural oscillation;
- 4. Processing of the raw acceleration signal;
- 5. Simultaneous computation of parameters.

A diagram of the measuring process:



The duration of the measurement impulse is 15ms and involves minimal force (pre-load 0.18N + 100mpulse 0.42N = 0.60N), hence, it does not cause residual mechanical deformations nor neurological reactions of the tissues being evaluated.

1.4.5 Limitations

The Device cannot measure:

- Isolated tissues or tissue layers;
- Muscle groups;
- Thin muscles or tissues (close to the skin surface, supported by bone surfaces), but below <
 2mm of its thickness;
- Small muscles between other muscles other tissue layers;
- Un-palpable deep Muscles or tissues located below other tissue layers;
- Muscles covered by subcutaneous fat over >20mm of its thickness;
- Tissues that are not classified as soft biological tissue.

The following can compromise meaningful measurement results:

- the Muscle or tendon is measured at its maximum or minimum length;
- visual or gentle palpatory test of a Muscle location is obstructed with a thick subcutaneous fat layer;
- the Subject's body position is not convenient for full relaxation;
- continuous muscle tremor due to a neurological condition;
- an Operator's device holding hand is not supported and trembles.



2. Important information

2.1 Device safety and precautionary measures

- Do not attempt to disassemble the Device under any circumstances! Unauthorised disassembly
 of the Device will void the warranty and cause damage to the Device!
- Do not place heavy items on it, Do not drop or apply strong shock.
- Do not place the Device near strong permanent magnets or strong electromagnetic fields.
- Do not submerge⁴, rinse, or spray excessive amounts of any liquids to clean the device.

The device can be sterilized only in a UV Sterilizer Cabinet, without heat and moisture. Cold sterilization, using approved liquid sterilants and disinfectants, is allowed only for the probe.

Cleaning the Device by Alcohol Wipes:

The device housing can be cleaned on the outside using semi-dry medical cotton wipes containing either isopropyl or isopropanol alcohol. Retrieve an alcohol wipe and unfold it. Gently and thoroughly wipe the surface of the device with the alcohol wipe. Ensure all surfaces of the device are wiped, paying attention to crevices, corners, and any areas that are touched frequently. Extend the probe by pressing the "Probe" button, pull out the probe, clean it thoroughly with a separate alcohol wipe, and position it back into the device. Press Done.

Do not store the Device:

- under direct sunlight, dusty or salty environments,
- on inclined surfaces, or subject to vibration and or shock,
- in freezing or high temperatures or high humidity.

Precautions:

- Disconnect the Device from the adapter and mains power supply before use.
- Do not use the Device if damaged and contact the manufacturer.
- The repair or battery change, re-calibration or testing can be performed ONLY by the manufacturer.
- To ensure the best use of the Device, it is recommended to take training from trainers authorised by the manufacturer.

2.1.1 Data protection measures

Use confidentiality and data protection measures, such as:

- Ensure that any confidential personal data contained in the Software and the Device will not be disclosed or accessed by unauthorised third parties;
- storage of the Device in a secured place, not accessible to unauthorised personnel;
- download the results and delete the entire measurement history before handing the Device over to third parties (chapter 3.8.2).

⁴ Rinsing or submerging the device in any liquid will cause permanent damage to its electronics and inevitable malfunction, making repair impossible and voiding the warranty.



2.2 Requirements for the measurement process

This chapter focuses on the information and procedures of reliable measurement results.



Please read the following instructions carefully!

2.2.1 The range of measurement axis

Description		Figure
1.	When measuring, keep the Probe always perpendicular to the skin surface above the Object being measured.	20:26 The skylazy Measurements Go, factore pur Menu Help 90°
2.	Avoid ⁵ the angle of measurement exceeding 100° from the vertical position. A – Device side view B – an Object cross-section view	Vertical position O° The vector of the gravity A < 100° < 100° The vector of the gravity

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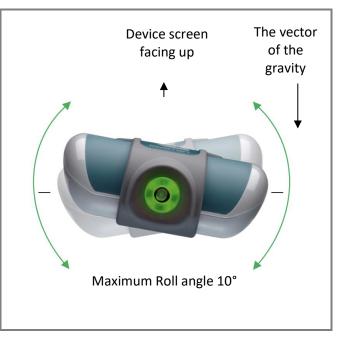
⁵ Avoid measurements opposite to the vector of gravity, i.e. the Probe facing up. The force of the gravity suppresses the measurement impulse and subsequent oscillation of an Object being measured.



3. When measuring horizontally, keep the Device screen facing upwards ±10°.

If the Device is rolled more than 10°, a warning notice Rotate! will be displayed.

Roll the Device round the probe axis until the notice disappears.



2.2.2 Environmental requirements

The measurement environment should be favourable for conducting measurements with minimal external disturbances. Avoid disturbing factors such as bright light, loud noises, vibration, too hot or cold ambient temperature or participation of unauthorised persons.

The most suitable temperature for measurements is room temperature, e.g. 22C° (72F).



For eg. hot temperature decreases the stiffness of tissues, but cold temperature increases the stiffness.

2.2.3 Subject preparation

Explain to new Subjects the measuring procedure is non-invasive, painless, and convenient. The explanation aims to ensure the person feels good and relaxed.

Instruct the Subject to arrive in good time for at least five minutes before the session. If necessary, instruct Subjects to avoid intensive physical activities or consume medications for at least three hours before the measurement session. Some medicines may affect the measurements results.

The long-term monitoring measurements are advisable to conduct approximately at the same time of the day and environments so that the Subject's condition would be as similar as possible throughout the measurement program.

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1. Ensure following:

- the Subject's position allows to be fully relaxed and is easily reproducible in subsequent measurement sessions. Use an examination or massage table if possible;
- allow the Subject to rest for at least 5 minutes prior to the measurements (use this time for preparatory activities, e.g. marking the measurement points);
- clothes or items are not in contact with the Tissue being measured, as it may obstruct free oscillation and influence results;
- the Muscle is not measured at its maximum or minimum length⁶;
- the Object is supported, either naturally⁷ by the skeleton or by artificial⁸ means;
- repetitive or comparative measurements are always taken at the same measurement point and the constant Muscle length;
- when positioning the Subject, ensure the repetitive or comparative measurements are always taken at the same angle;
- during the measurements, the Subject focuses on full rest.

2. On establishing and marking the measurement point:

- establish the location and contours⁹ of the Object and mark the measurement point by the **Medical Skin Marker** (chapter 1.2);
- in case of a muscle measurements, mark the measurement point above the Muscle belly (above the biggest cross-section);
- ensure that the measurement points are marked symmetrically when measuring the same Object on either side of the body;
- check immediately before measuring, by both the palpatory test and questioning the Subject, whether the Object being measured is fully relaxed.



Whenever necessary, take a photo of the Subject's body position to reproduce the same body position for subsequent measurement sessions.

2.2.4 Device requirements

When measuring with the Device ensure:

- 1. the characteristics of the mechanical impulses of repetitive or comparative measurements are always identical **The Probe**¹⁰ standard probe diameter 3mm.
- Tap time default value 15ms,
- **Tap interval** default value 0.8 sec,

⁶ Unless if it is the aim of the study.

⁷ Natural support – an Object being measured is supported by the skeletal system.

⁸ Artificial support – an Object being measured is supported by an artificial supporting means. For more detailed information, don't hesitate to get in touch with the manufacturer.

⁹ For establishing the location and contours of the Muscle, use simultaneously the manual palpation and resistance to the limb movement to cause medium contraction of the Muscle in interest (e.g. ref. Kendall, et al. 2005 "Muscles Testing and Functions with Posture and Pain").

¹⁰ In the case of experimental measurements, the standard Probe can be replaced with custom made probes or with a bigger diameter or/and length. For more detailed information please contact the manufacturer.



- 2. nothing but the Probe is in physical contact with the skin surface located directly above the Object being measured;
- 3. the Probe is always perpendicular to the skin surface;
- 4. the Device is held as stable as possible within the range of the measurement position indicated by the:
- green light,
- probe marker,
- "Hold position!" instruction on the Device screen;
- 5. the measurements are performed at the same measuring point;
- 6. during the measurement impulse, the Probe does not slide on the skin surface;
- 7. the Device holding hand, is well supported to ensure stability of the Device and comfortable measuring positions throughout the session;
- 8. the Device is held gently without gripping it tightly¹¹;
- 9. the focus on the Probe while conducting the measurements.



Re-measure, if any of the above listed aspects where not maintained.

2.2.5 Evaluation of the measurement variability

The Device offers the Coefficient of Variation for all five Parameters (hereinafter – "CV"). The CV describes the relative dispersion (variability) of the Measurement series.

The CV of the measurement depends on the Subject, Object, Operator, Device and the measurement environment.

The lower the CV, the higher the stability of the Measurement.



On the Device screen evaluate the results CV. If the CV is above 3% tap "Re-measure", otherwise tap "Next" or "Save".

The CV above 3% is show in red.

If the CV remains above 3%, try to determine the source of higher variability and make corrective actions.

However, higher CV > 3% may also be caused by the Subject's neurological condition and tremor. In this case, the variability reflects the current health condition and should be accepted.

¹¹ A tight grip of the Device may cause the hand tremor and decrease the accuracy of the results.



2.3 Measurement interference detection system

The Device contains an automatic interference detection¹² system. Measurement raw signals are verified for:

- 1. required datapoints that are mandatory for parameters computing;
- 2. optimal impulse time (Tap time);
- **3.** probe jump-off (loss of contact with the skin surface).
- 4. non-inherent frequencies;

On detection of the above-listed interferences, the following notices are displayed on the device screen¹³:

- **1.** Measurement data invalid!
- 2. Optimizing impulse!
- **3.** Probe jump-off detected!
- 4. Excessive noise detected!

2.3.1 Evaluation of a Tissue oscillation signal

For computing all five Parameters, the oscillation acceleration signal must contain at least two positive peaks a₁ and a₃ (Appendix 2).

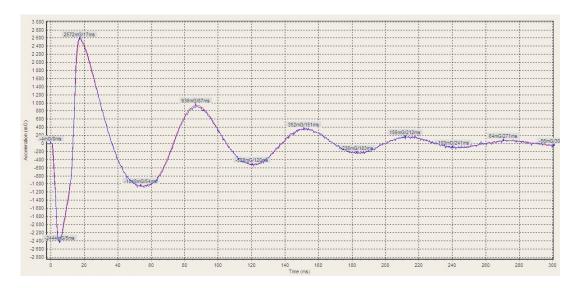


Figure 1: A typical soft tissue oscillation acceleration signal. The blue line - raw acceleration signal.

The acceleration signal with at least three positive peaks is typical for a tissue natural oscillation.

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¹³ See also chapter 3.5.1 p.7.



2.3.2 Optimal measurement impulse time

The measurement's standard impulse time (Tap time) is 15 milliseconds in duration.

The Device contains Optimal impulse time identification system. In case of non-optimal impulse Device provides "Optimizing impulse" notice while optimising the impulse automatically.

2.3.3 Probe jump-off

In the event of the Probe jump-off, the Probe disconnects from the skin surface. The short-term disconnection may occur when a tissue oscillates more forcefully than the Device measurement system can physically follow.

The phenomenon may occur while measuring contracted tendons or muscles (see Figure 2).

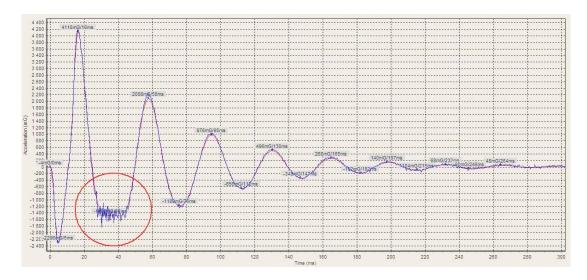


Figure 2: A typical Probe jump-off.



Due to the computation algorithms, parameters F, S, R and C are not affected by the Probe jump-off phenomenon.

To avoid Probe jump-off decrease the impulse time duration by adjusting the Tap time, e.g. from 15ms to 10ms.

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¹⁴ "Optimizing impulse" system is available from November 2022, MyotonPRO device, Model 1B, device firmware v. 1.6.2.



2.3.4 Non-inherent frequencies

The acceleration signal may contain non-inherent frequencies, which may influence the results and increase the measurement variation.

Non-inherent frequencies or Excessive noise may occur e.g.:

- a) during the oscillation the Probe is in contact with the Device probe opening (see Figure 3),
- b) A damaged¹⁵ Device, measurement system or loose components.

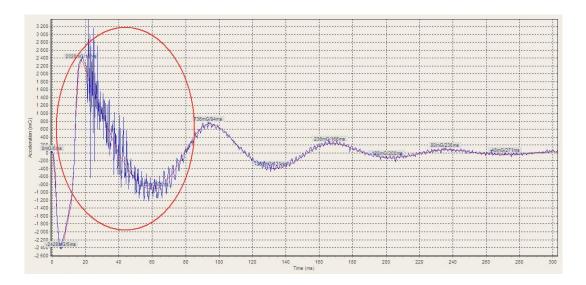


Figure 3: A raw acceleration signal with excessive noise. The figure illustrates a measurement signal while the Probe was in contact with the probe opening of the Device.

A signal of good quality is shown in the Figure 1.



Possible damage to the Device measurement system can be identified using the test mode by generating a raw acceleration signal - blue line (see also chapter 3.3.2).

In the event of damage to the Device, don't hesitate to contact the manufacturer.

¹⁵ The Device may be damaged as a consequence of it having been dropped.



3. Application of MyotonPRO

3.1 Quick instruction

The measurement process consists of the following steps:

- 1. Use the Myoton Desktop Software to prepare and upload the Subjects and Patterns.
- **2.** Mark the measurement point with the skin marker on the skin surface directly above the Object (e.g. muscle or tendon) being measured.
- 3. Press the ON/NEXT button or tap the "Measurements" label on the screen.
- **4.** Press the ON/NEXT button or select the Subject and the Pattern on the screen.
- **5.** Press the ON/NEXT button or tap the "Perform new measurement" label, or view previous measurements.
- **6.** Place the Probe perpendicular to the pre-marked measurement point above the Object being measured.
- 7. Move the Device towards the skin until the green light indicates the measurement position.
- **8.** Hold the Device gently and keep it steady within the measurement position until the Device automatically performs the Measurement.
- **9.** Press the ON/NEXT button to continue with measurements until all Subjects and Patterns have been completed.
- 10. Download the results to the Myoton Desktop Software for further analysis.



3.2 Preparations for use

This chapter describes the procedure for the application of the Device.



Use of the Device requires the Myoton Desktop Software for Windows.

The Software is not freeware. Download and use of the Software are only permitted for MyotonPRO device users.

The Software updates and the User Manual are available under the toolbar section "User Manual & About".

The main functions of the Software:

4.1 – 3.4.2
+.1 - 3.4.2
4.3
3.2
6.1
5.2 – 3.6.7
7

3.2.1 Charging the battery

The Device is provided with an internal Lithium Polymer battery, which at the time of delivery has been charged to approx. 40%.

Charge the battery before use of the Device. The charging time for an empty battery with the current of 1A is up to 3 hours.



Charge the battery before performing the measurements to at least 20% of capacity. The maximum voltage of fully a charged battery of 100% is 4.2V. The battery level is provided on the Device screen.

The battery can be charged either:

- a) with the USB cable from a computer,
 NB! If the Device is charged through a general computer, it is required to make sure that it is compatible with the standard IEC 60950 and it is done outside the patient area.
 or
- b) from the mains power supply with the AC-DC 5V/1A USB adapter delivered by the manufacturer (see technical specification).

NB! When charging the battery from the mains power supply, the charger should be positioned for easy disconnection.



Description	Photo
Charging the battery from the computer, connect the Device to the computer with the USB cable. Ensure the computer is switched ON for the duration of charging.	
2. Charging the battery from the adapter, connect the Device to the adapter with the USB.	
3. The battery is fully charged when the LED below the ON/NEXT button turns GREEN.	ON NEXT



During the process of charging or use, the Device may become warm. To check the temperature of the Device, press *Menu* and *System info*. If the temperature of the Device is over 50 °C (122°F), turn off the Device and wait until it cools down to avoid possible damage to the battery or the Device.

Charge the battery from the mains power supply ONLY with the adapter and USB cable delivered by the manufacturer. Remove the adapter from the mains power supply if not in use. The charging LED turns RED in case of required maximum voltage level of 4.2V has not been reached within 5 hours of charging.

In this case, repeat the charging process one more time. In case the LED remains RED after the second charging process, this indicates the battery should be replaced.

Never fully discharge the battery. For prolonged storage, charge the battery in every 6 months.



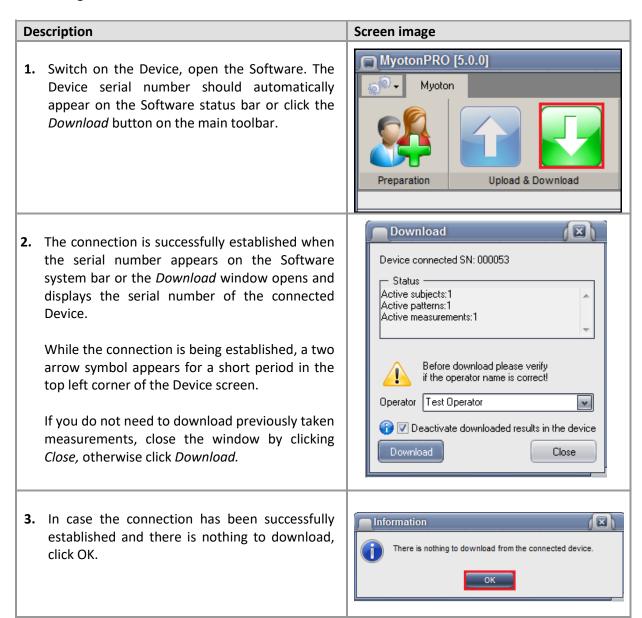
If the Device does not start, charge the battery for 15 minutes and try again. If the problem persists, please contact support.

The battery can be replaced ONLY by the manufacturer!

3.2.2 Connecting the Device to the computer

To establish the connection, connect the Device to the computer with the USB cable and open the Software.

For checking the connection:





4. If the connection was not established, the Device connection window will open after clicking on the Download button.
Wait for 5–10 seconds or unplug and plug the USB wire again when using the USB connection.





If there is no connection with the computer, the following actions may help.

- UNPLUG and PLUG the USB cable between the Device and computer. If necessary, try different USB sockets of the Computer if available.
- Check that the USB cable is properly connected to the Device and computer.
- Check that the Device is turned on and showing the main screen.
- Close and open the Software and repeat the actions above to establish the connection.
- Check the USB cable is not broken.



3.3 Test mode

The Device and Software allow to perform test measurements in the Test mode provided with the image of the acceleration signal of the Tissue's natural oscillation.

Test mode is used for the following:

- to study the measurement procedure,
- to evaluate the Co-oscillation (chapter 2.3),
- to test that the Device is functioning properly.

There are two options to start the Test mode:

- on the Device (chapter 3.3.1),
- in the Software (chapter 3.3.2).

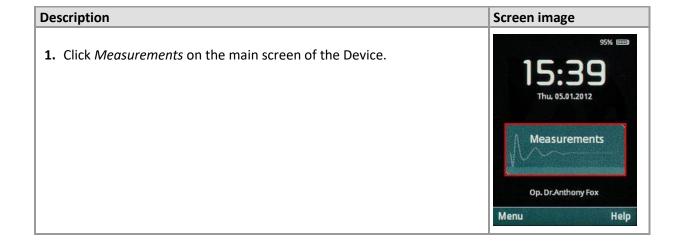
The benefits of using the Test mode in the Software are:

- display of the test measurement protocol on the computer screen, printing and saving the test result in JPG format;
- display of the raw and filtered acceleration signal of the natural oscillation of an Object (blue and red line);
- the possibility to examine the acceleration signal in detail (zoom-in and out);
- the possibility to export the values of the raw and filtered signals;
- display of other measurement related parameters.

3.3.1 Activation of Test mode in the Device



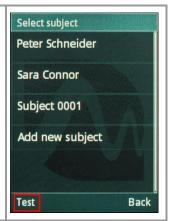
If the Test mode is started on the Device, detailed information is not displayed on the computer screen. The Test mode in the Device can be used only for general assessments.



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2. Click Test on the bottom left of the Select subject screen.



3. The *Test mode* screen opens, where the instructions to the Operator are displayed: Move into position!

Place the Probe perpendicular to the skin surface above the premarked measurement point on the Object. Move the Device towards the skin surface until the Measurement position¹⁶ is indicated by the green light.



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 $^{^{16}}$ The information regarding measurement position is provided in chapter 2.2.4, point 4.



4. Keep the Device steady within the measurement position. The Device performs the measurement automatically.

Follow the instructions displayed on the screen:

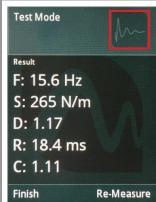
- Move into position! move the Device towards the Object;
- Hold position! hold the Device within the range of 3mm of the measuring position;
- Move back! move the Device away from the skin surface; Rotate! Roll the Device around its longitudinal axis (chapter 2.2.1 p3).



5. After the measurement, the results are displayed.

If necessary, the Tissue oscillation acceleration curve can be checked by clicking the Signal icon on the top right of the screen.

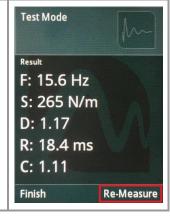
Observation of the acceleration signal allows for the evaluation of the natural oscillation of the tissue (chapter 2.3).



6. To navigate back, click the *Results* icon on the top right of the screen.



7. To repeat the measurement, click the Re-Measure icon.

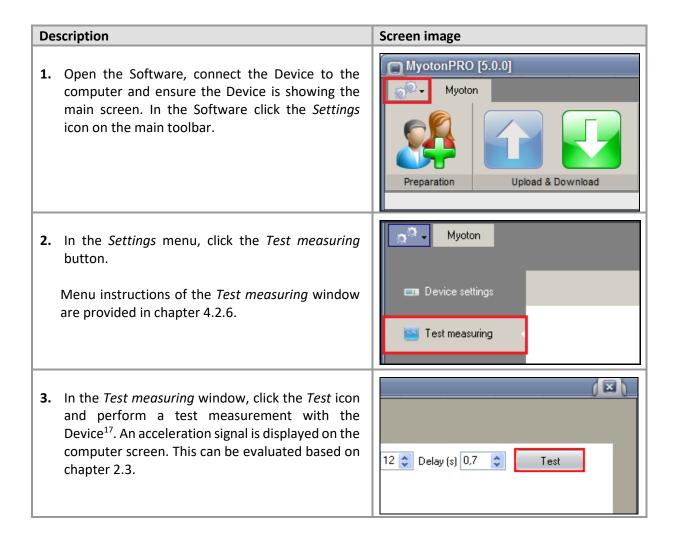




Test Mode 8. If necessary the Tap time can be changed by clicking on the Tap time Move into position! Single scan, 1/1 Cancel **Test Mode** 9. Click the "up/down" arrows on the Set Tap Time window and confirm by clicking OK. **Set Tap Time** Test Mode **10.** To exit the Test mode, click Finish. Result F: 15.6 Hz S: 265 N/m D: 1.17 R: 18.4 ms C: 1.11 Finish Re-Measure



3.3.2 Activation of the Test mode in Software



¹⁷ Chapter 3.3.1, points 3 to 5.



3.4 Preparation of the Measurement Set

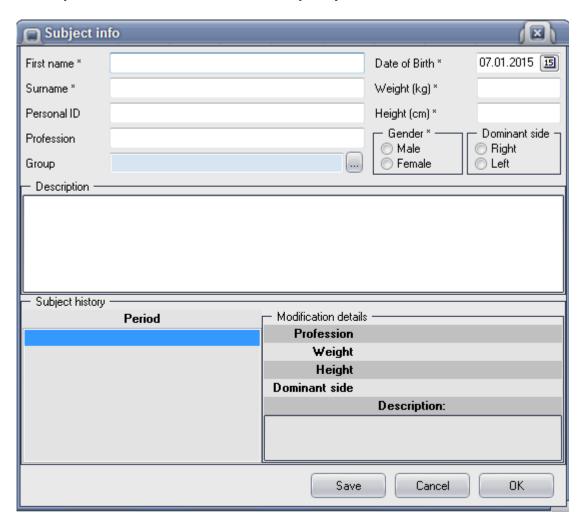
This chapter describes the preparation of the Measurement set for uploading to the Device. The Measurement set contains at least one Subject and one Pattern. It is possible to upload a maximum of 50 Subjects and 50 Patterns to the Device.

There are two inputs needed to compose a measurement set:

- 1. Subject information (chapter 3.4.1)
- **2.** Pattern information (chapter 3.4.2)

3.4.1 Input of Subject's data

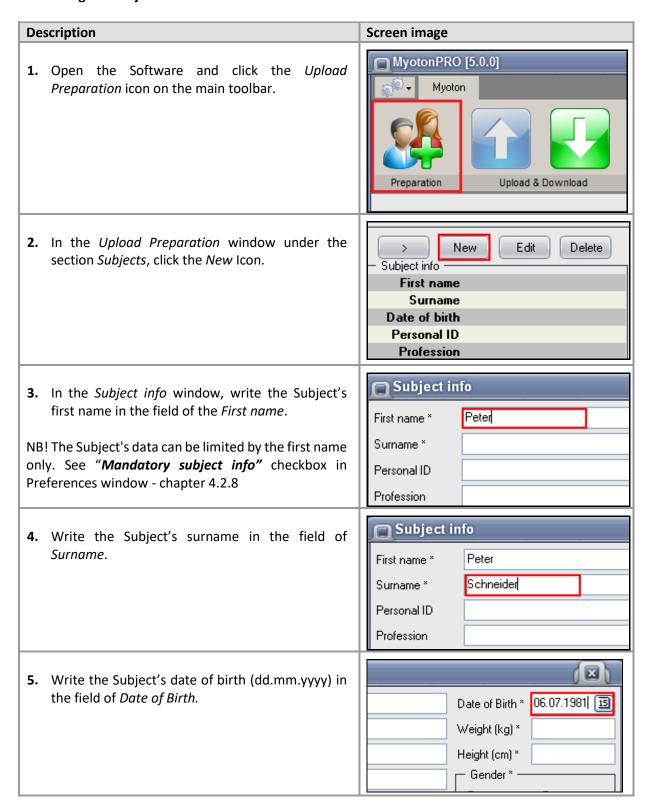
The Subject's data should be entered in the Subject info window:



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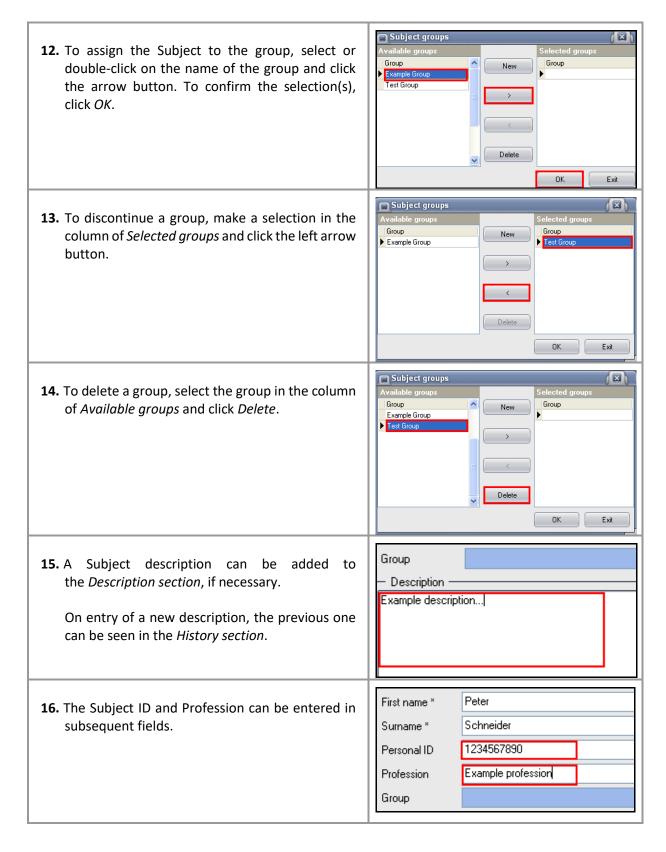
For entering the Subject's info:





6. Write the Subject's weight in kg in the field of Weight.Conversion: 1kg = 2.2pounds 1pound = 0.45kg	Date of Birth * 07.03.1981
 7. Into the field Height, write the Subject's height in cm. Conversion: 1cm = 0.0328feet 1foot = 30.48cm 	Date of Birth * 07.03.1981 3
8. Assign the Subject's gender in the section <i>Gender</i> .	Date of Birth * 07.03.1981
9. If necessary it is possible to mark the Subject's Dominant side.	Date of Birth * 07.03.1981 15 Weight (kg) * 80 Height (cm) * 180 Gender * Dominant side - Right Female Left
10. If necessary to group the Subjects (e.g. different conditions, locations, genders), it is possible to assign a group for the Subject. Start assigning the group from the button shown on the image.	First name * Peter Surname * Schneider Personal ID Profession Group Description
11. To create a new group, click the <i>New</i> icon, enter the Group name and click <i>OK</i> .	Subject groups Available groups Group New New New New Cancel







17. Click Save and OK, to finish entering the Subject information.

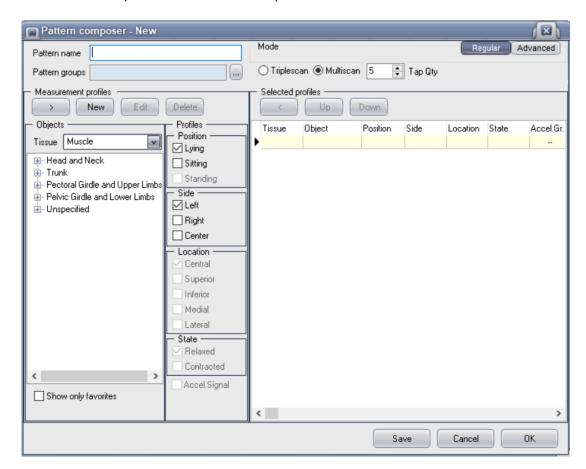
Profession
Weight
Height
Dominant side

Description:

3.4.2 Composing Patterns

Patterns contain Objects and the profile of how they are to be measured.

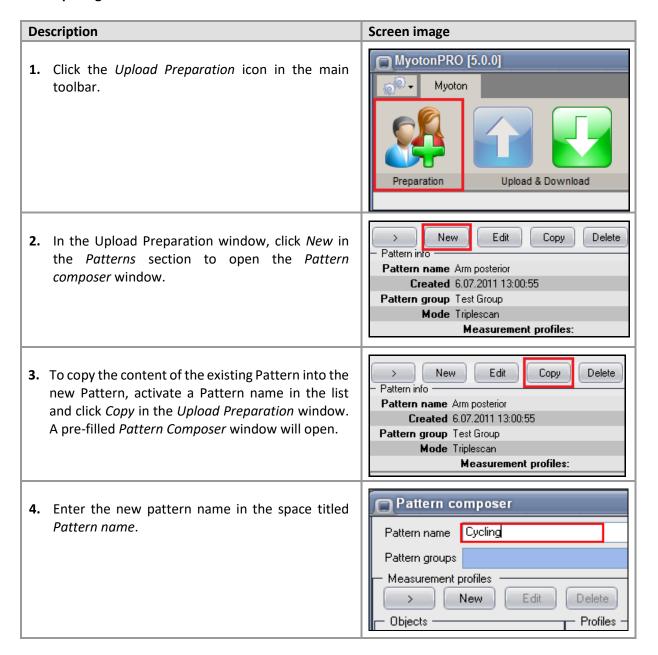
Patterns are composed in the Pattern Composer window:



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For composing a Pattern:



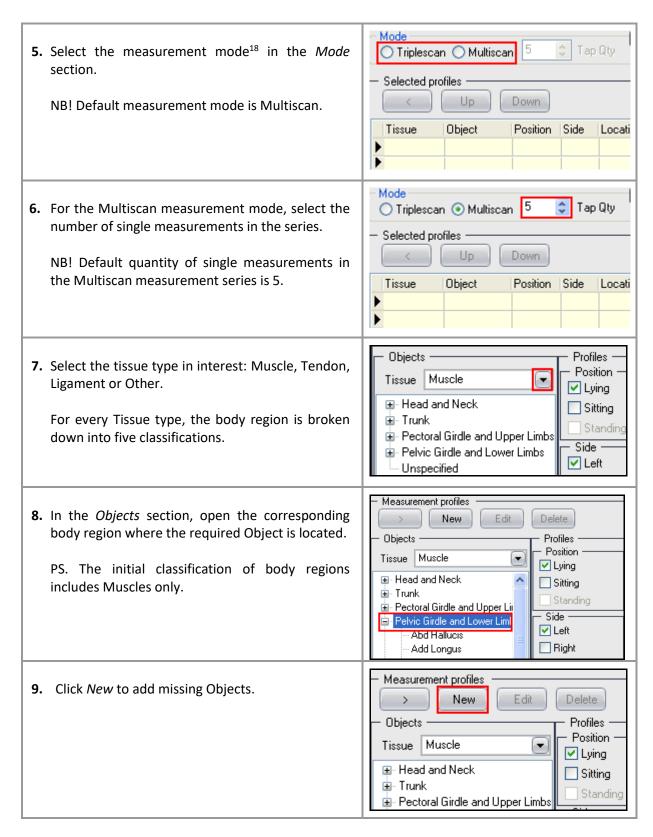


Create Pattern names containing some info about the study design or measurement program (e.g. PRE interv......; POST interv.......; t0; t1; etc).

Describing Pattern names is an important source of information for identifying the measurement results later in statistical analysis.

Up to 32 characters for Pattern and Object names are displayed on the Device screen.





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¹⁸ Measurement modes (Triplescan and Multiscan) are explained in the chapter "Terminology".



Object X **10.** Enter a new Object name¹⁹, select the appropriate Tissue type and Body region and confirm by Save. Example object Object Muscle Tissue Body region Unspecified Favourite object <u>S</u>ave Close Objects Profiles **11.** Set up the Object's measurement Profile by Position -Tissue Muscle checking relevant check-boxes in the Profiles Lying ■ Head and Neck section: Sitting Standing ■ Pectoral Girdle and Upper Limbs (Body position, Body Side, Location of the Side -Left measurement point and State of activation). - Unspecified Right Center **12.** To activate disabled options (Location, State and Advanced Regular Accel. Signal²⁰), click the Advanced button on the upper right corner of the Pattern composer Tap Qty window. Down Sartor ast p Location -Sartor prx p **13.** Select the Object(s) for the Pattern by double-✓ Central Semitend clicking or highlighting and then clicking on the Superior Tens Fas Lat right arrow button above the Objects. Tibialis Ant[*] Inferior Vastus It Medial A maximum of 50 Objects for one Pattern can be Vastus m Lateral selected. Unspecified State -Relaxed Selected profiles **14.** Click *Up* or *Down* buttons to set the order in which Down Up the Objects are measured. Tissue Object Position Side Location Muscle Vastus It Lying Left Central NB! The aim is a minimal disturbance to the Muscle Vastus m Lying Right Central Subject. Muscle Vastus m Left Central Lying Right Central Muscle Vastus It Lying

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¹⁹ Up to 32 characters for Pattern and Object names are displayed on the Device screen.

²⁰ The check-box *Accel. Signal* saves a raw acceleration signal that consists of 1280 rows of data for every measurement result. To avoid slowed data transfer and save the memory, activate the *Accel. Signal* only if necessary!



Selected profiles values **15.** To change the measurement < Up Down characteristics (Tap time and Interval), 21 click the Advanced button first. You can change Tap time and Interval below: Tap time(ms) Interval(s) Tissue Object **NB!** Do not change these values unless **12 \$** 1 Muscle Vastus It necessary! 12 1 Muscle Vastus It Pattern composer 16. To assign Patterns a Pattern group²², click the Pattern name Cycling button shown on the image. Pattern groups Measurement profiles New Edit Delete Objects -Profiles Position Tissue Muscle X 17. To create a new group, click New, enter the group name and click OK. ▶ Test Group Group name X Name Example group.. <u>0</u>K Cancel

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²¹ "Tap time" and "Interval" are explained in the chapter "Terminology".

²² The patterns relevant to a particular study, health condition, field or activity can be selected for the group (e.g. Physiotherapy).



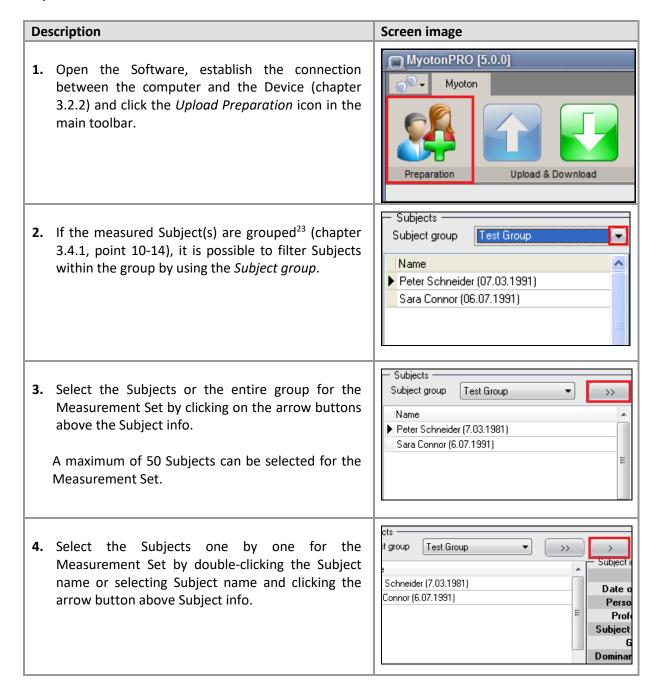
Pattern groups 18. To assign the Patterns to the group, select or double-click on the name of the group and click Example group the arrow button. To confirm the selection(s), click OK. > Delete Exit X Pattern groups **19.** To delete a group, select the group in the column Group of Available groups and click Delete. New Example Group Delete Exit 20. Click Save and OK, to finish composing the Pattern. Save Cancel 0K



3.4.3 Uploading the Measurement Set

To perform measurements, the Measurement Set has to be prepared and uploaded to the Device. The Measurement Set consists of at least one Subject and one Pattern (see also *Upload Preparation* chapter 4.2.2).

To upload the Measurement Set:



²³ Subjects can be added to or removed from the groups at a later stage.



Patterns 5. If the Patterns are grouped²⁴ (chapter 3.4.2, point Pattern group Test Group 17-20), it is possible to filter Patterns within the Pattern group. Arm posterior Cycling Patterns 6. Select the Patterns or entire group for the Pattern group Example Group Measurement Set by clicking on the arrow buttons Pattern above Pattern info. Example Triplescan Multiscan 10* Ξ Example Multiscan* A maximum of 50 Patterns can be selected for the Warnings update* Measurement Set. Example Group 7. Select the Patterns one by one for the Measurement Pattern Set by double-clicking the Pattern name or selecting Pattern Triplescan Pattern name and clicking the arrow button above n 10* the Pattern info. Pattern Multiscan* gs update* Tissue Muscle 8. Enter or select the address where the measurements are performed in the box titled Address on the left bottom of the screen. Address Example Address Muscle Ext Digitor Lying Left Cer **9.** Enter the person's name performing the Muscle Ext Digitor Lying Right Cer measurements in the box titled Operator in the middle bottom of the screen. NB! The Operator name is mandatory. Operator Example Operator

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²⁴ Patterns can be added to or removed from the groups at a later stage.



10. The measuring order²⁵ of the Subjects and Patterns can be changed by *Up* or *Down* buttons below the *Selected Subjects* or *Selected Patterns*.

11. Upload the Measurement Set to the Device by clicking *Upload* at the bottom right-hand side of the screen or the Upload icon in the main toolbar.



Before uploading the Measurement Set, download the previous Measurement results from the Device first (chapter 3.6.1).

By the new upload, the previously uploaded Measurement Set will be deactivated.

Whenever necessary, the deactivated or active data can be downloaded to any database of the Software (chapter 3.8.1)

For upload or download, the Device must be on the main screen and connected to the computer (chapter 3.2.2).

²⁵ It is important to consider the order in which Patterns are uploaded, to minimise disturbance to the Subject, thus reducing dispersion of the results.

If the sequence is correct, the Operator can only use the *ON/NEXT* button to seamlessly conduct all the measurements (chapter 3.5.1).



3.5 Device measurement mode

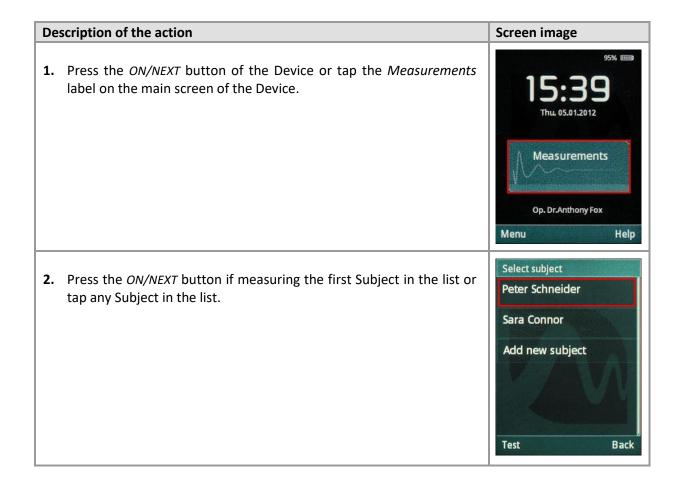
3.5.1 Measurement with the Device



Before performing the measurements, read carefully the chapter 2.2.

COMMENT

The measurements can be performed by using only the *ON/NEXT* button. For this, make sure the Measurement profiles, Subjects, and Patterns have been uploaded in the correct order. Make sure that also the Objects inside the Patter are listed in the correct order!



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3. Press the *ON/NEXT* button if using the first Pattern in the list or tap any Pattern in the list.



4. Press the *ON/NEXT* button to Perform new measurements or tap on this label.



5. The probe exerts, and the Measurement screen instructs: *Move into position*!

Place the Probe perpendicular to the skin surface on the pre-marked measurement point directly above the Object. Move the Device towards the skin surface until the Measurement position²⁶ is achieved and indicated by the green light.



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²⁶ The information regarding measurement position is provided in chapter 2.2.4, point 4.



6. Keep the Device steady in the range of the acceptable measurement position. There is a *Delay* of 0.7sec before the Device automatically starts the Measurement.

Follow the instructions displayed on the screen:

- Move into position! move the Device towards the Object;
- *Hold position!* hold the Device within the range 3mm of the measuring position;
- Move back! move the Device away from the skin surface;
- Rotate! roll the Device around the Probe axis (chapter 2.2.1 p3).



7. If the Device has detected an oscillation interference, a sound signal will be played, the probe light changes to red, and the Device screen displays an interference notification (chapter 2.3).

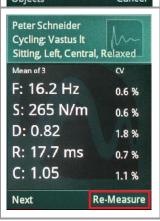
If the interferences occur repeatedly, identified the cause and make corrective actions applied.



8. After completing the Measurement, the Measurement results²⁷ are displayed with the variation coefficient (CV).

Before pressing the *ON/NEXT* button to proceed, verify whether the CV of all the Parameters is less than 3% (chapter 2.2.5).

If the CV is not satisfactory, tap *Re-Measure* to repeat the measurement.



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²⁷ In case of Triplescan or Multiscan modes the Measurement result to be displayed is calculated by using different statistical methods (chapter "Terminology").



9. To measure the next Measurement profile, press the *ON/NEXT* button or tap *Next*.

NB! After pressing the ON/NEXT button or taping *Next*, the Measurements results will be saved and cannot be replaced. However, the Measurement can be repeated (see point 11).

Unwanted measurement results can be deleted only in the Software after being downloaded to the Desktop Software.

Peter Schneider Cycling: Vastus It Sitting, Left, Central, Relaxed Mean of 3 cv F: 16.2 Hz 0.6 % S: 265 N/m 0.6 % D: 0.82 1.8 % R: 17.7 ms 0.7 % C: 1.05 1.1 % Next Re-Measure

10. To finish the Pattern, press the *ON/NEXT* button or tap *Save*.

NB! After pressing the ON/NEXT button or taping *Save*, the Measurements results will be saved and cannot be replaced. However, the Measurement can be repeated (see point 11).

Unwanted measurement results can be deleted only in the Software after being downloaded to the Desktop Software.



11. To continue with measurements, select Next Pattern, Next Subject or Repeat Pattern and follow above described measuring process until all the measurements have been conducted.



12. To finish the measurements, press *ON/NEXT* button or tap *Finish* on the Device screen.





3.5.2 Display of the Acceleration signal

After completing the Measurements, it is possible to display Acceleration signals for evaluation²⁸ purposes.

Description of the action	Screen image
In the window for Measurement results (chapter 3.5.1, point 8) on the Acceleration signal icon on the top right of the screen.	Peter Schneider Cycling: Vastus m Lying, Right, Central, Flelaxed Mean of 3 CV F: 16.2 Hz 0.6 % S: 265 N/m 0.6 % D: 0.82 1.8 % R: 17.7 ms 0.7 % C: 1.05 1.1 % Save Re-Measure
2. To view all Acceleration signals of every single measurement, ta the LEFT/RIGHT icons.	Peter Schneider Cycling: Vastus m Lying, Right, Central, Relaxed 1/3 P: 16.3 Hz S: 267 N/m D: 0.85 R: 17.5 ms C: 1.03 1/ 15 ms Save Re-Measure
3. To navigate back to the Measurement results window, tap the on the top right again.	Peter Schneider Cycling: Vastus m Lying. Right, Central, Polaved 1/3 P: 16.3 Hz S: 267 N/m D: 0.85 R: 17.5 ms C: 1.03 U 15 ms Save Re-Measure

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²⁸ The evaluation criteria for the natural oscillation of Tissues are provided in chapter 2.3.



3.5.3 Input of new Subjects

It is possible to enter new Subjects directly in the Device. To use this functionality, activate the *Enabled* option in the *Add new subject in the device* section of the *Preferences* window (chapter 4.2.8) before uploading the Measurement Set (chapter 3.4.3).

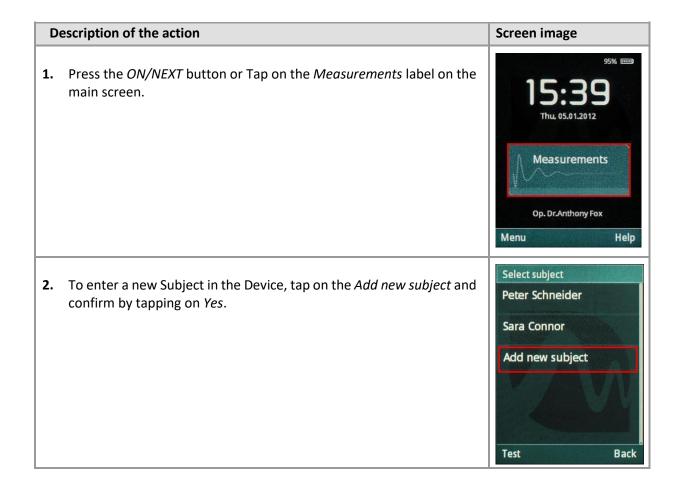
COMMENT

It is recommended to always use the Software for the input of New Subjects (chapter 3.4.1).



Should the newly created Subjects be used for the conduct of measurements, the Subject data (chapter 3.4.1) has to be filled in later during the download process of the measurement results (chapter 3.6.1, point 3).

In order to match the right Subjects with the right personal data, it is important to write down the unique identification numbers shown for each Subject on the Device screen.



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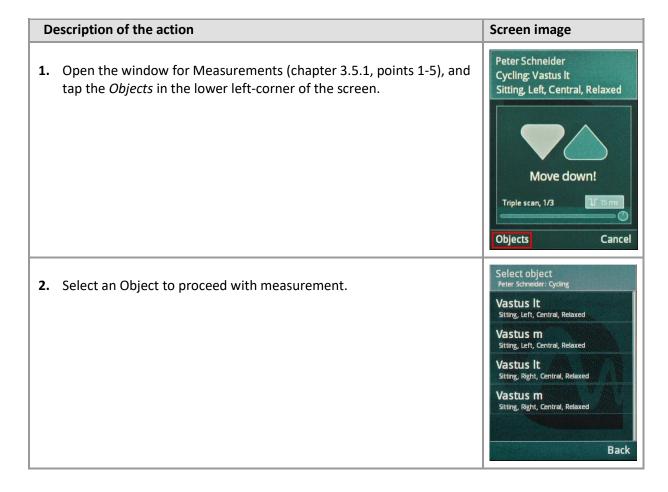
3. To select an added Subject, tap on Subject 0001.

Each added Subject will be displayed with a new ID number – e.g. *Subject 0002*, etc.



3.5.4 Selection of Objects in a different order

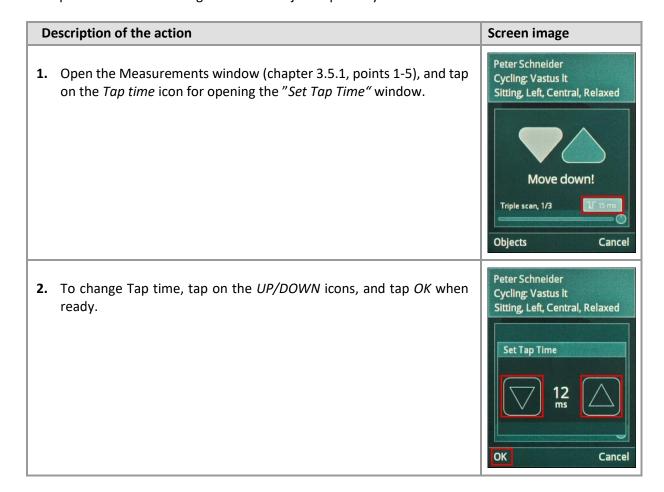
During the measurement, it is possible to measure Objects in a different order than in uploaded order.





3.5.5 Change of the impulse time

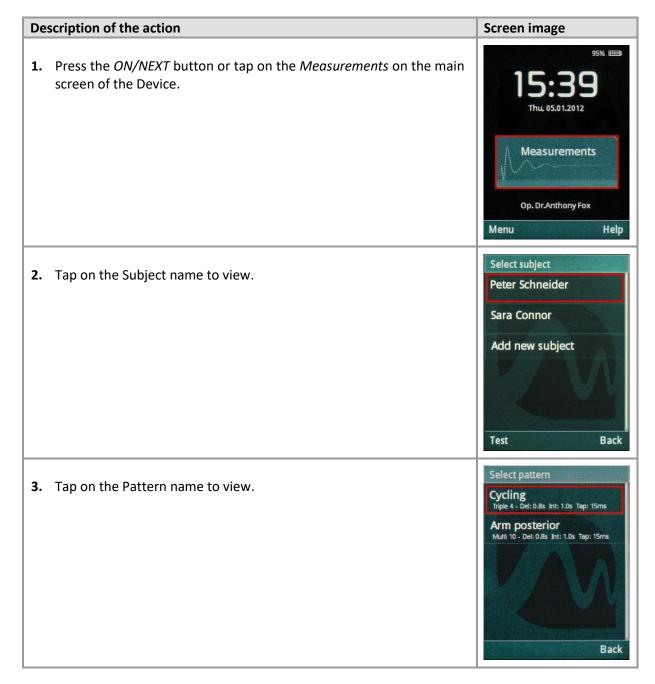
If necessary, it is possible to change the duration of the measurement impulse directly in the Device. The impulse time can be changed for each Object separately.





3.5.6 View of previous measurement results

It is possible to view the completed Measurement results directly on the Device screen.



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Select measurement **4.** Tap on the measurement *Date/Time* to view. Perform new measurement 16.04.2011 16:16 16.04.2011 16:16 16.04.2011 16:15 16.04.2011 16:15 16.04.2011 16:13 16 04 2011 16:00 Select object **5.** Tap on the *Object* to view. Vastus It Sitting, Left, Central, Relaxed Vastus m Sitting, Left, Central, Relaxed Vastus It Sitting, Right, Central, Relaxed Vastus m Sitting, Right, Central, Relaxed Back Peter Schneider 6. The measurement result²⁹ and the CV of the Measurement will be Cycling: Vastus It Lying, Right, Central, Relaxed displayed. Mean of 3 cv F: 16.0 Hz 0.1 % S: 263 N/m 0.9 % D: 0.89 0.7 % R: 17.9 ms 0.3 % C: 1.06 0.5 % Next Back

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²⁹ The Measurement measured in the Triplescan or Multiscan mode, are displayed on the Device screen as the median or average value (see also chapter "Terminology").



3.6 Visualisation of measurement results in the Software

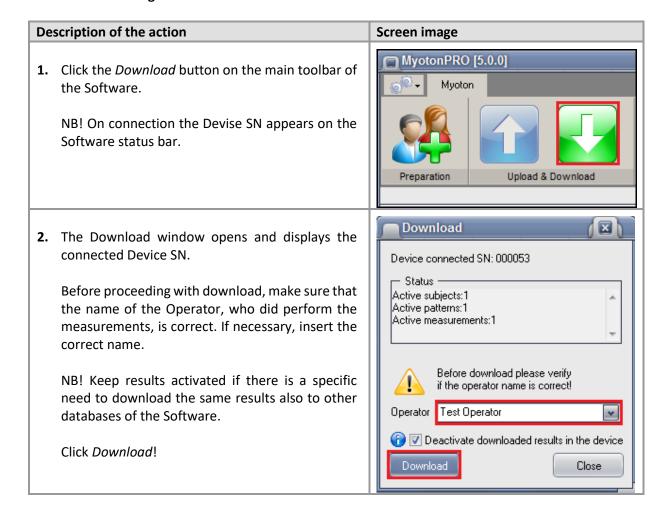
This Chapter describes the options for the visualisation of Measurement results in the Software.

The Software contains a feature of automatic export of the measurement results to Microsoft Excel for further data analysis or manual export to CSV format.

3.6.1 Download of measurement results

For download of the results, open the Software, and connect the Device to the computer via USB (chapter 3.2.2).

Perform the following actions:





3. If new Subjects were added to the Device during the measurements, the window *Subject info* will open.

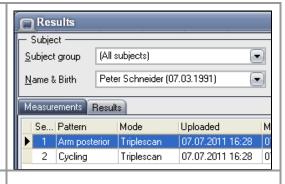
Enter the Subject (chapter 3.4.1) and click *OK* to continue with the download.





Do not disconnect the Device until the Download is completed.

4. Upon completed Download, the Software Results window will open with the downloaded results (chapter 4.2.3).



5. In case there is nothing to Download, the following window will open. Click OK.

NB! The Device automatically stores the entire measurement history as a backup until deleted (chapter 3.8.1).





Before uploading the Measurement Set, download the previous Measurement results from the Device first (chapter 3.6.1).

The upload of a new Measurement set deactivates previously measured results waiting for download!

Both active and inactive results as a backup of the entire measurement history can be downloaded in the Software under the Device settings (chapter 3.8.1).



3.6.2 Composing the Symmetry report

The Symmetry report offers the absolute values and Difference % of the left and right sides of the body.



Myoton AS MyotonPRO palpation device Symmetry Report

Subject info: Pattern info:

 Name:
 Peter Schneider
 Pattern name: ExampleTriplescan

 DOB:
 7.03.1981
 Mode:
 Triplescan

 Profession:
 not specified
 Tap Qty:
 3 taps

 Group:
 Example Group; Test Grou
 Uploaded:
 17.06.201116:26:26

 Gender:
 Male
 Measured:
 17.06.201116:27:24

 Dominant side:
 Unknown
 Downloaded:
 1.07.201112:59:47

 Weight:
 80 kg
 Operator:
 Example Operator

 Height:
 180 cm
 Device SN:
 000024

 BMI (kg/m2):
 24,7
 Address:
 Example Address

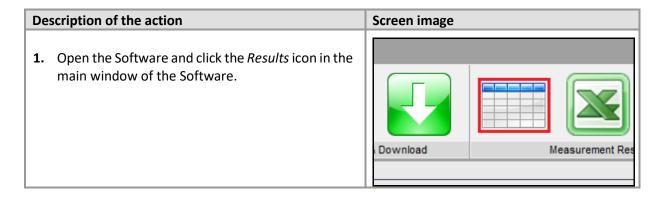
Measurement profile					Measurement series				Results					
Tissue	Object	Position	Side	Location	State	Angle	Tap time	Interval	Delay	Freq Hz	Stiff N/m	Decr	Relax ms	Creep
Muscle	Ext Digitor	Lying	Right	Central	Relaxed	И	15 ms	0,8 s	0,7 s	31,1	710	1,26	6,9	0,45
Muscle	Ext Digitor	Lying	Left	Central	Relaxed	71	15 ms	0,8 s	0,7 s	32,1	736	1,22	6,5	0,43
Symmetry index (%):							3,16	3,60	-3,23	-5,97	-4,55			

Description:

COMMENT

The Difference in Symmetry report above 5% is shown in orange and above 10% is shown in red. The Difference is computed: (y-x)/((y+x)/2)*100.

To compose a Symmetry report:





Results 2. Open the Measurements tab in the Results Subject window. (All subjects) Subject group Ŧ Name & Birth Peter Schneider (07.03.1991) -Measurements Results Se... Pattern Mode Uploaded Measurements Results 3. Select any Measurement row to compose the Row | Pattern Mode report. Arm posterior Triplescan Triplescan Arm posterior Triplescan Arm posterior Arm posterior Triplescan Arm posterior Triplescan Address Operator Accel. Graph **4.** Click the *Report* button in the *Results* window. Example Addres: Dr. Anthony Fox Export Example Address Dr. Anthony Fox If the Show description on the report was not Example Addres: Dr. Anthony Fox Graph Example Addres: Dr. Anthony Fox activated in the Preferences window (chapter Estim. Graph 4.2.8), the report will open. Report (X) Description **5.** If the <u>Show description on the report</u> was Name Peter Schneider OK activated, the Description window opens prior to the report. Example description... Cancel Enter the description info and click OK to open the report.



Composing the Multiscan Analysis report

The Multiscan Analysis is the report where two Multiscan Measurements of a Subject are statistically compared.



Myoton AS MyotonPRO palpation device **Multiscan Analysis Report**

Subject info:		Pattern info (set 1):	Pattern info (set 2):			
Name:	Peter Schneider	Pattern name: ExampleMultiscan	Pattem name: ExampleMultiscan			

DOB: 7.03.1981 Mode: Mode: Multiscan Multiscan Profession: not specified Tap Qty: 5 taps Tap Qty: 5 taps Example Group; Test Grou Uploaded: 13.05.201610:24:48 Uploaded: 13.05.201610:24:48 Group: Measured: 13.05.201610:25:11 Measured: 13.05.201610:26:05 Gender:

Downloaded: 13.05.201610:26:24 Dominant side: Right Downloaded: 13.05.201610:26:25 Weight: 80 kg Operator: Dr. Anthony Fox Operator: Dr. Anthony Fox Height: 180 cm Device SN: 000053 Device SN: 000053 BMI (kg/m2): 24,7 Address: Tallinn,Estonia Address: Tallinn,Estonia

Set of	Measurement profile		Measurement series		Results						
measure					Statistics	Freq Hz	Stiff N/m	Decr	Relax ms	Creep	
	Tissue:	Muscle			Average:	15,9	261	0,99	18,5	1,10	
	Object:	Ext Digitor	Angle:	И	Standard deviation:	0,1	4	0,02	0,2	0,01	
1	Position:	Sitting	Tap time:	15 ms	Variation coefficient %:	0,9	1,7	2,0	1,0	1,2	
	Side:	Left	Interval:	0,8 s	Minimum:	15,7	255	0,95	18,2	1,08	
	Location:	Central	Delay:	1s	Maximum:	16,1	266	1,01	18,7	1,12	
	State:	Relaxed			Median:	16,0	263	0,99	18,7	1,10	
	Tissue:	Muscle			Average:	16,9	281	0,82	16,7	0,98	
	Object:	Ext Digitor	Angle:	И	Standard deviation:	0,1	2	0,02	0,1	0,01	
2	Position:	Sitting	Tap time:	15 ms	Variation coefficient %:	0,3	0,8	2,2	0,8	1,1	
	Side:	Left	Interval:	0,8 s	Minimum:	16,9	278	0,80	16,5	0,97	
	Location:	Central	Delay:	1s	Maximum:	17,0	285	0,85	16,9	1,00	
	State:	Relaxed			Median:	16,9	281	0,82	16,7	0,98	
	Difference of averages (%):							-18,8	-10,2	-11,5	
				Signifi	cance by T-test (p < 0,05):	TRUE	TRUE	TRUE	TRUE	TRUE	

The Multiscan Analysis report, offers the statistics for all five parameters of the Measurement:

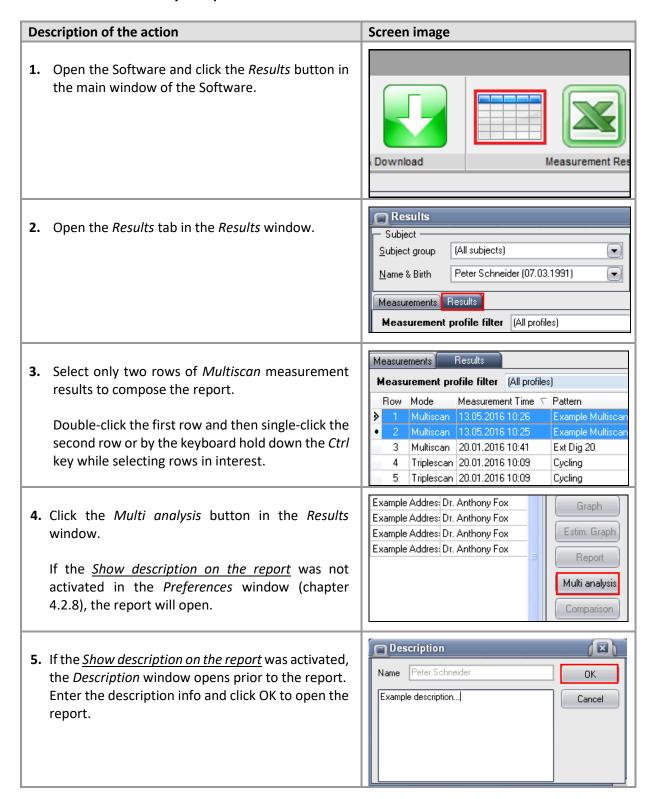
- Arithmetical average;
- Standard deviation;
- Variation coefficient (%) (CV);
- Minimum value;
- Maximum value;
- Median;
- Difference of averages (%);
- Significance by Student's T-test (sign. 5%).





The *Multiscan Analysis* report can be composed only for the measurements performed in the Multiscan mode (chapter 3.4.2).

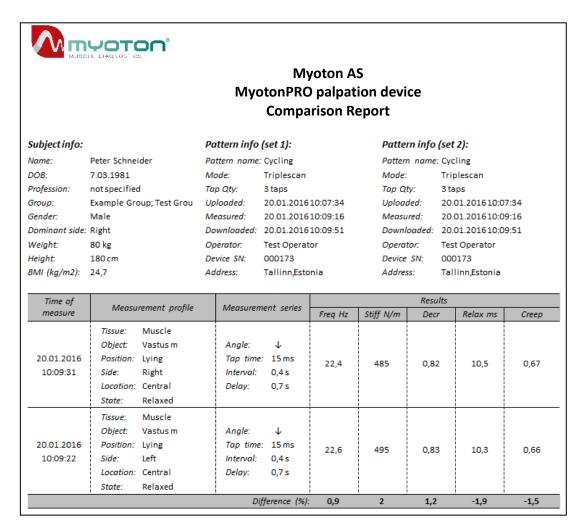
To create a Multiscan Analysis report:





3.6.4 Composing the Comparison report

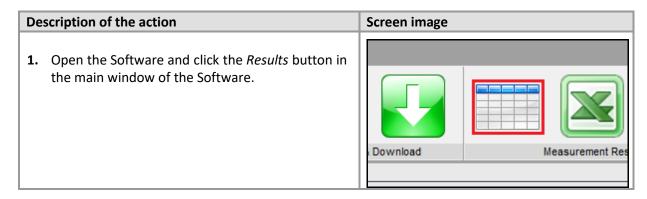
The *Comparison report* offers the absolute values and Difference (%) of any two selected measurements.



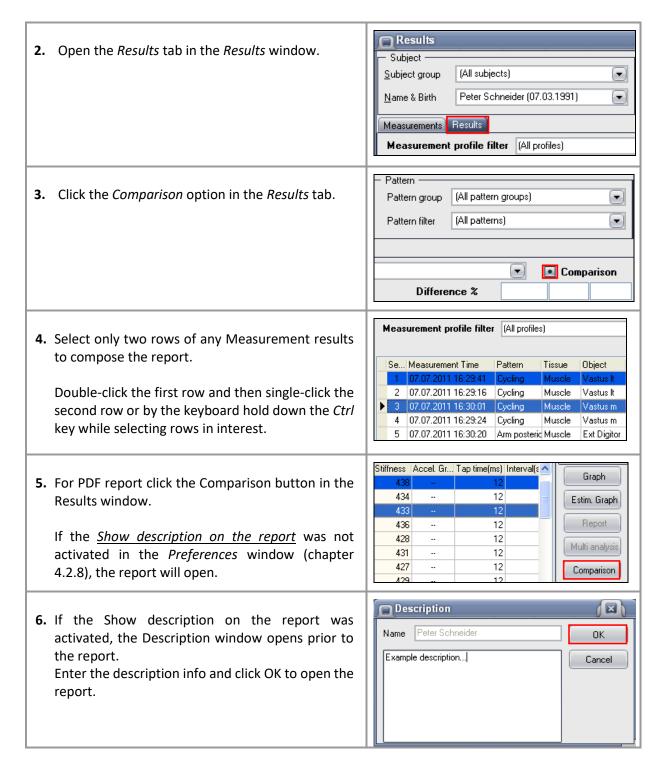
COMMENT

The Difference in Symmetry report above 5% is shown in orange and above 10% is shown in red. The Difference is computed: (y-x)/((y+x)/2)*100.

To compose a Comparison report:



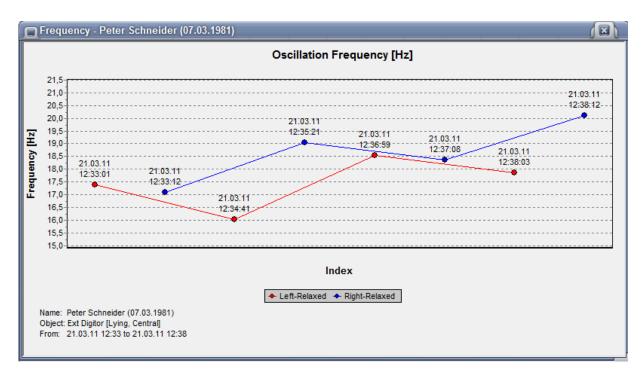






3.6.5 Composing the graphs

It is possible to compose basic graphs for each parameter of the Measurement Profile of the selected Subject. The graph displays one Measurement Profile of the left and the right side of the body, both in relaxed and contracted states.



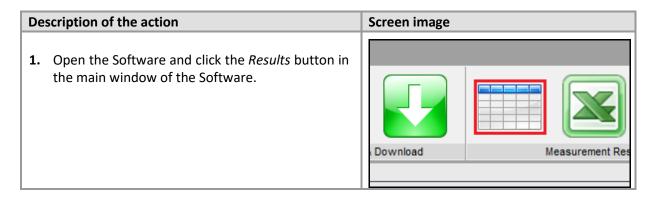
On the graph making the right-click with the mouse button opens the options for:

- Copy
- Print
- Save

COMMENT

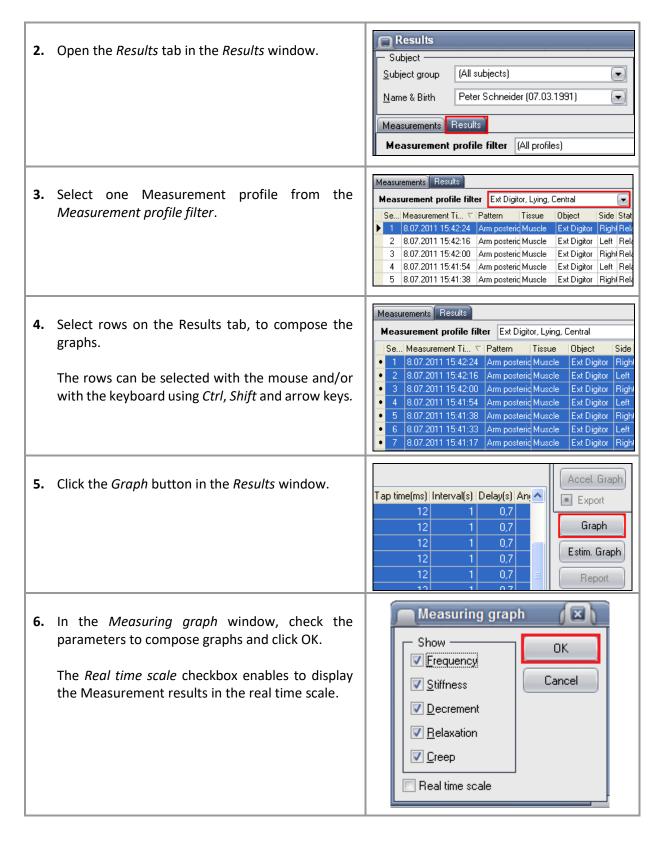
To zoom in on an area on the graph, mark the area from left to right. To zoom out, mark any area from right to left. The limit values of the Y-axis can be changed in the Software *Preferences* window (chapter 4.2.8).

For the composing of graphs:



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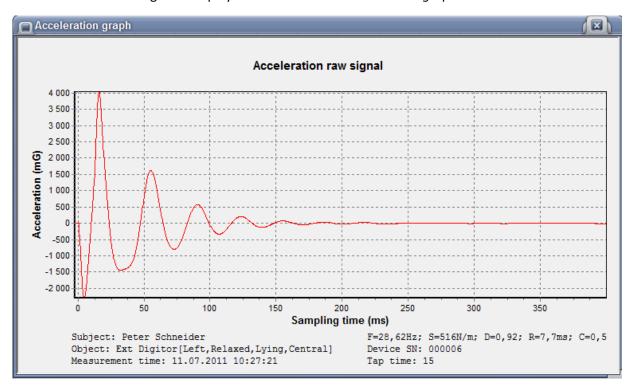




3.6.6 Display of the acceleration signal

It is possible to store the raw acceleration signal of the oscillation for every single Measurement. The raw signal consists of 1280rows of data and can be exported to CSV file format if necessary.

The raw acceleration signal is displayed in the Software Acceleration graph window:



On the graph making the right-click with the mouse button opens the options for:

- Copy
- Print
- Save

COMMENT

To zoom in on an area on the graph, mark the area from left to right. To zoom out, mark any area from right to left.



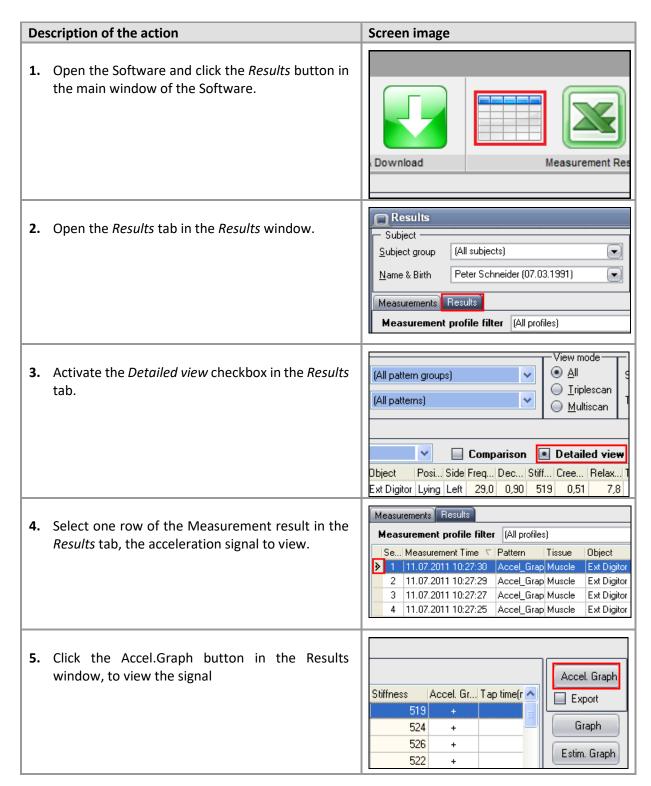
To enable the functionality of storing the raw acceleration signal:

- Activate the Accel. Signal checkbox during composing of a new Pattern (chapter 3.4.2, point 12).
- Upload the new Measurement set with the composing Pattern to the Device.

To save memory, do not activate Accel. Signal unless certainly needed!

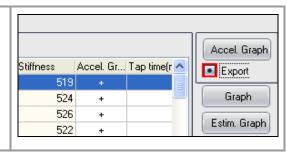
To display the raw acceleration signal:







6. To export the signal, activate the *Export* option and click the *Accel.Graph* button.



COMMENT

In the *Results* tab, column *Accel.Graph*, rows marked with "+", show the measurements for which the acceleration signal has been stored.

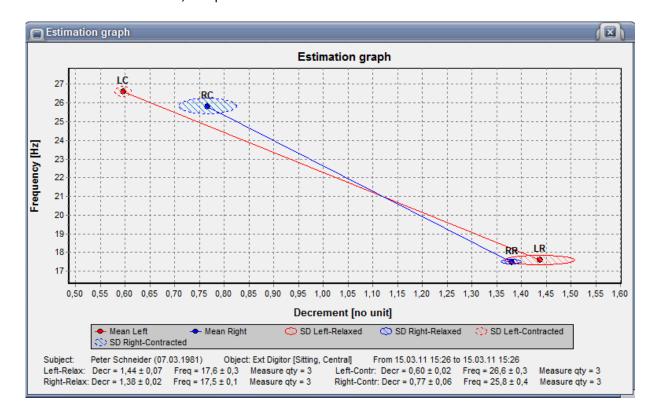
3.6.7 Muscle function Estimation graph

The *Estimation graph* enables to evaluate the muscle function as an indication of the muscle health condition.

The Estimation graph describes the muscle function by the relocation of the intersection point of two parameters, the Frequency (F) and Decrement (D), in a relaxed vs contracted state.

The criteria of healthy muscle condition:

The results plotted on the following graph demonstrate the healthy muscle condition by the inverse relocation of the Frequency and Decrement. Therefore, the F value increases in the contracted state, and the D value decreases, compared to the results measured in a relaxed state.





NB! The larger the difference and relocation of the intersection points of F and D parameters (relaxed vs. contracted state), the higher the muscle function.

The Estimation graph displays four intersection points:

- LC Left Contracted
- RC Right Contracted
- RR Right Relaxed
- LR Left Relaxed

On the graph making the right-click with the mouse button opens the options for:

- Copy
- Print
- Save

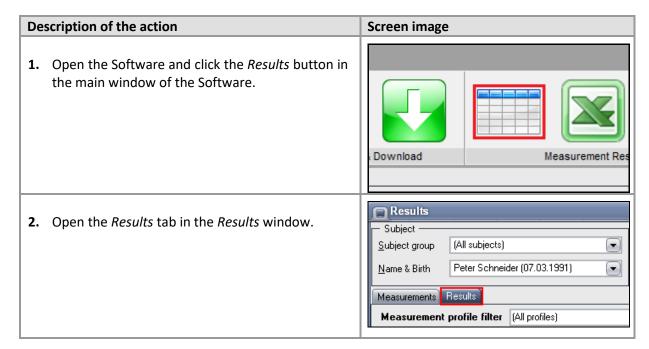
COMMENT

To zoom in on an area on the graph, mark the area from left to right. To zoom out, mark any area from right to left. The limit values of the Y-axis can be changed in the Software *Preferences* window (chapter 4.2.8).

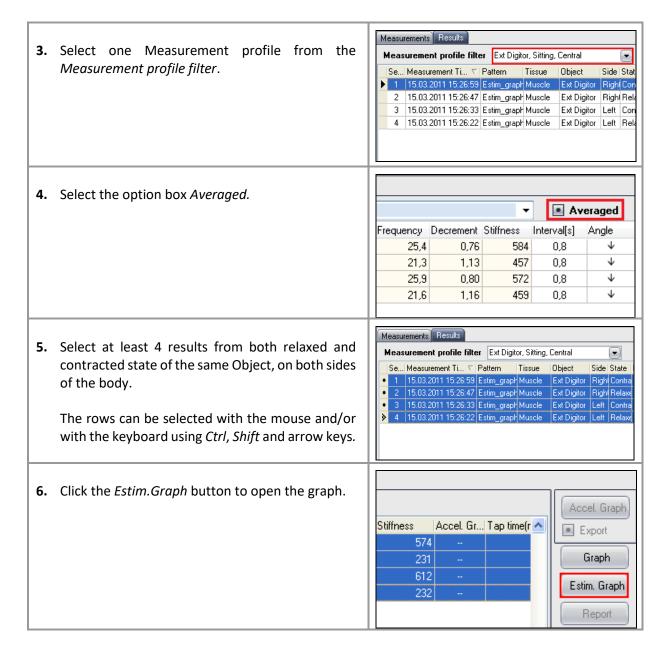


Composing the Estimation graph requires the muscle in interest measured on both body sides, first in a fully relaxed and then in contracted state, thus requiring four measurements.

To create the Estimation graph:









3.7 Export of the measurement results

The Software contains an important feature of automatic export of measurement results to Microsoft Excel for further data analysis, statistics and visualization in the form of charts. Automatic export to Excel is compatible with Excel 2010 and later versions.

There are two options to export the Measurement results:

- Automatic export to the XLSM file format (chapter 3.7.1),
- Manual export to the CSV file format (chapter 3.7.2).

3.7.1 Automatic export to Microsoft Excel

The Software contains a convenient feature of Automatic data export from the connected database into Microsoft Excel for Windows for further analysis and visualization.

The Excel file of Automatic export contains a macro (the pre-programmed task) for data import and refresh of Pivot tables.

In Excel file the imported Measurement results are located in the sheet "Database", where columns Z to AD contain some prepared formulas containing functions for data processing tasks.



Automatic export enables to keep the Excel reports up-to-date every time when data is being downloaded from the connected device.

NB! Automatic export is compatible only with the Microsoft Excel for Windows.

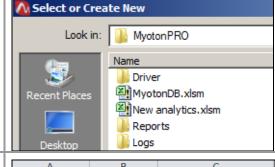
For the automatic export of results:

Description of the action 1. Open the Software, click the Automatic export on the main toolbar. Wait until the export is completed and the Excel file opens automatically. Measurement Results



2. For connecting the Excel file with the Myoton database, click the *Automatic export* button, select an Excel file (*.xlsm) and click OK.

To create a new Excel file, write a name of the new file name at the bottom of the window and click OK.



- **3.** The "Database" sheet contains following preferences:
 - Auto import on opening the file the data is imported automatically.
 - On check AVG only average values of measurements will be imported.
 - Auto re-fresh of Pivot tables.

Α	В	С
Database	Import	✓ Auto import ✓ AVG Auto refresh Pivot tables
Measurement identity -	Measureme nt iteratic ▼	Measurement time
5,95353E+18	10	4.12.2013
5,95353E+18	10	4.12.2013
5,95868E+18	20	18.12.2013

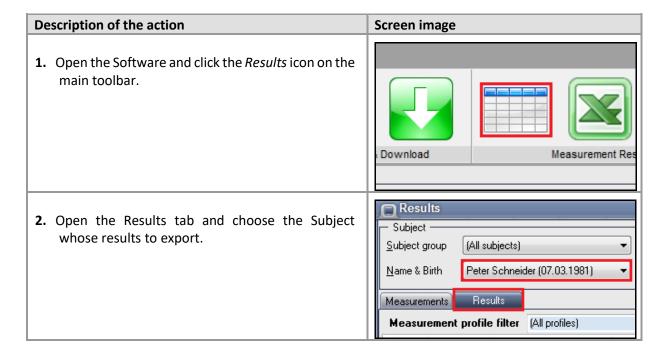
3.7.2 Manual export

The manual export offers an option to export the data to the CSV file format (chapter 4.2.4).

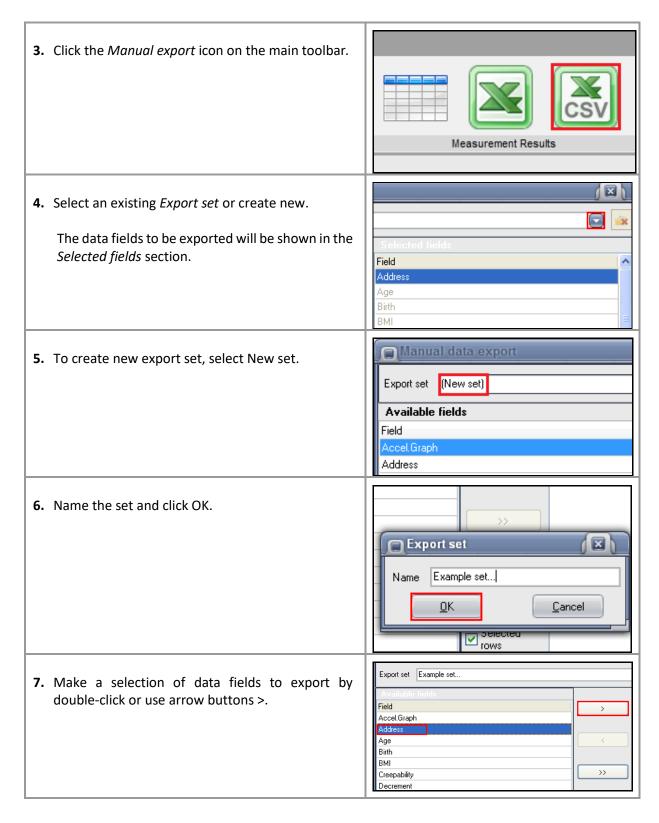
COMMENT

To export the entire database, click Manual export icon without opening the Results tab. To export selected results, open the Results window first, make a selection of the results and then click the Manual export icon.

For the manual export of selected Results to the CSV:









8.	To export results displayed in the Results tab, click Export data of filtered results. The Manual export window closes automatically on completed export.	Selected rows Export data of filtred results Export full database
9.	To export the entire content of the connected database click <i>Export full database</i> .	Selected rows Export data of filtred results Export full database



3.8 Data management

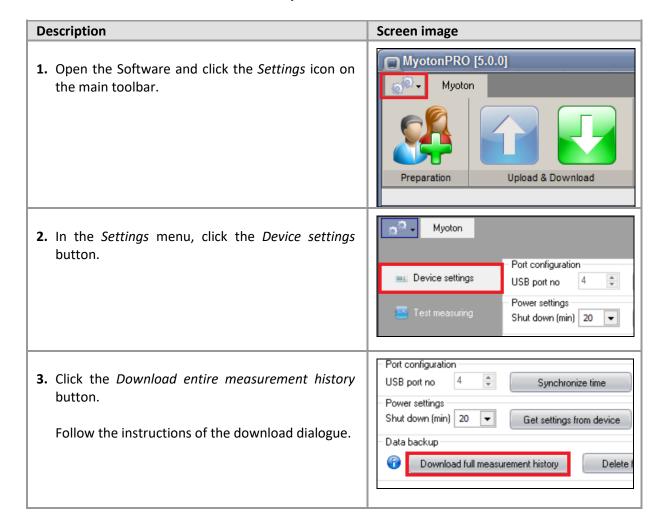
3.8.1 Data backup of the Device

The Device contains the **entire measurement history as a backup**. The backup can be downloaded to a new or to any existing database of the Software.

COMMENT

In the Device measurement history, all single measurements of the Measurements are stored separately.

To download the entire measurement history:





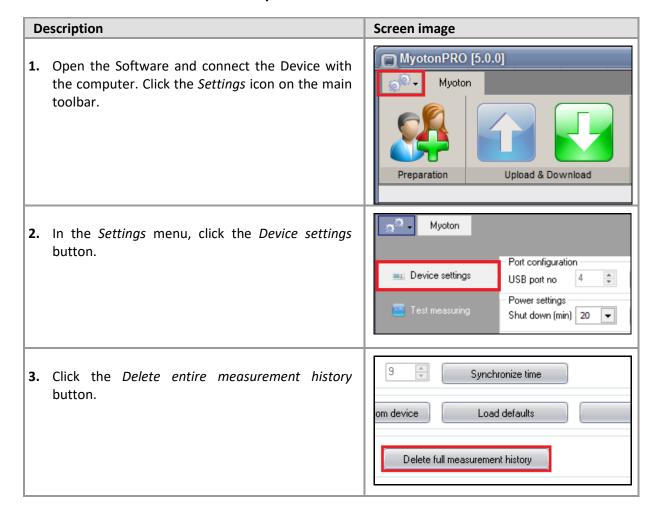
3.8.2 Deletion of backup from the Device

The entire measurement history of the Device can be deleted in the *Device settings* window located under the *Settings* menu (chapter 4.2.5).



Before delete, make sure all Measurement results are downloaded (chapter 3.8.1). Delete of the measurement history permanent and cannot be undone!

To delete the entire measurement history from the connected Device:



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4. Click the Delete button.

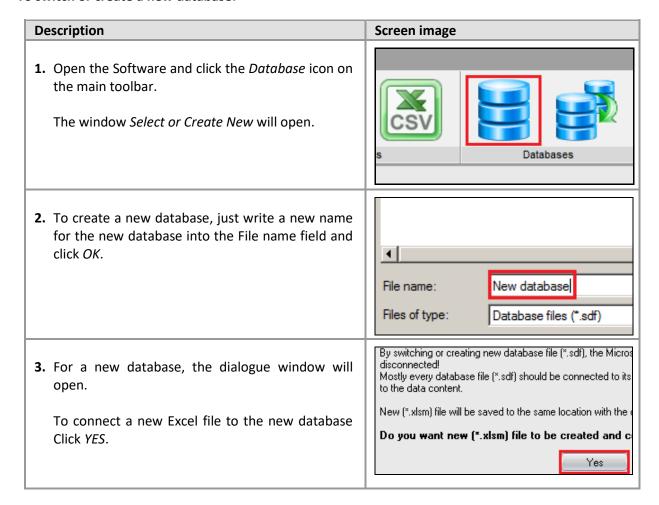
After the deletion is completed click Close.



3.8.3 Software database management

Multiple databases can be used in the Software. It is recommended to create a new database for every research project.

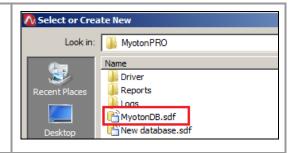
To switch or create a new database:





4. To switch the database, click the database icon on the main toolbar and double-click any database file (extension *.sdf) in the window *Select or Create New*.

NB! Database files can be saved to any location of the computer.

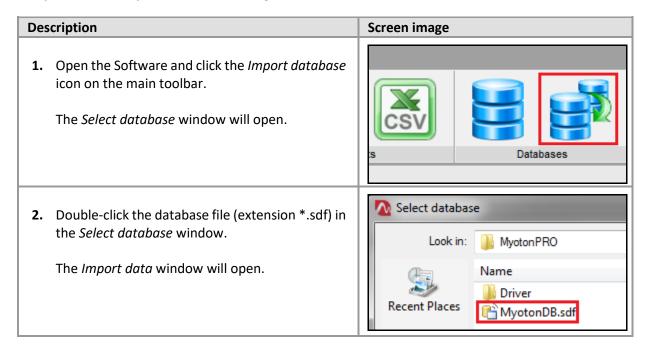


3.8.4 Import of database

Import of database enables data import from any Myoton database (*.sdf).

The feature can be used for a multicentre study, where separate devices and computers have been used to collect measurements. The function enables the consolidation of all results from different database files into one database before statistical analysis.

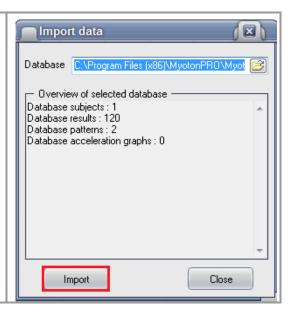
To import database, perform the following actions:





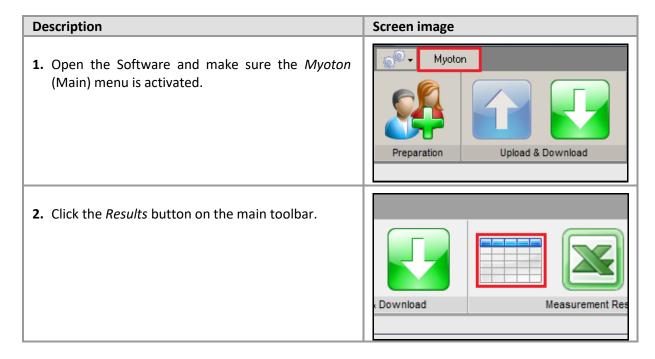
3. Click *Import* button in the *Import data* window to start the import.

Wait until the import is successfully completed and click *Close*.



3.8.5 Deletion of measurement results from the Software

Measurement results can be deleted from the Software in the Results window (chapter 4.2.3):



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Results 3. Choose a Subject from the Name & Birth field Subject whose Measurement results you want to delete. (All subjects) Subject group Peter Schneider (07.03.1991) Name & Birth Measurements Results Measurement profile filter (All profiles) Row Mode Measurement Time ▽ Pattern Results **4.** Open the *Measurements* tab in the *Results* Subject window. (All subjects) Subject group Peter Schneider (07.03.1991) Name & Birth -Measurements Results Se... Pattern Mode Uploaded Measurements Results **5.** Select row(s) to delete. Row Pattern Mode Arm posterior Triplescan Triplescan Arm posterior Arm posterior Triplescan Arm posterior Triplescan Arm posterior Triplescan **6.** Open the *Pop-up* window with the right-click Select all Ctrl+A 3 Ar mouse button and click on Delete measurements 4 Ar Clear selection Ctrl+D row. 5 Ar Export filtered results 6 Ar Delete measurements row C₃ 7 Field chooser 8 Ar Restore field size



If a row of measurements is deleted from the *Measurements* tab, then that row's measurement results will also be deleted automatically from the *Results* tab.

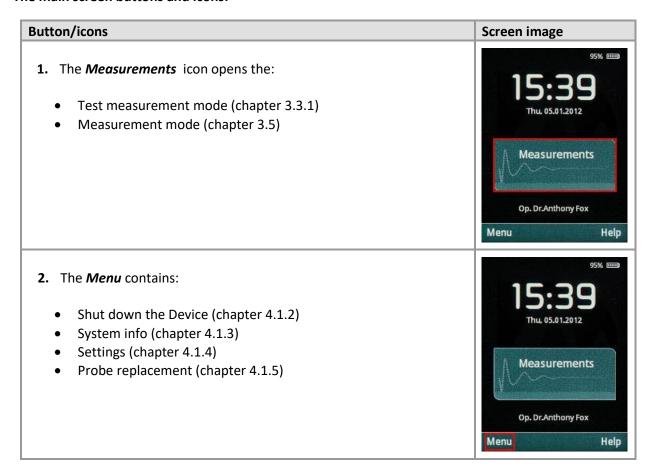


4. Menu instructions

4.1 Device menu

4.1.1 The main screen

The main screen buttons and icons:





- 3. The *Help* contains the following items:
 - ATTENTION!
 - User manual
 - Quick instruction for use
 - Measurable parameters
 - Important information
 - ON/NEXT button



4. The Date & time format: d dd.mm.yyyy hh:mm.

The date and time are automatically synchronised when connecting the Device to the Software (chapter 3.2.2) or synchronised manually (chapter 4.2.5).



5. The battery icon at the top-right corner of the Device screen provides a visual indication of the battery level. A yellow lightning mark over the icon shows the battery is being charged.



6. The Operator name is uploaded to the Device from the Software together with the Measurement Set (chapter 3.4.3).



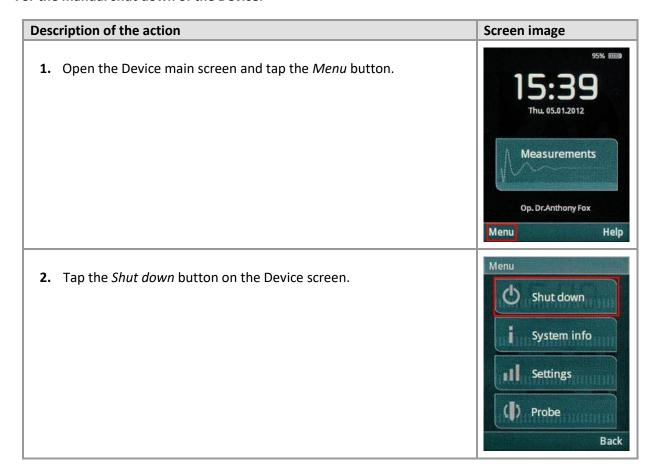


4.1.2 Device Shut Down

By default, the Device is shutting down in 10 minutes. The default values can be changed in the Software under the Device settings (chapter 4.2.5). The manual shut down locates under the Device menu.

Time	1 min	1 min	Shut down time - 8 min
Display	ON	Dim	Off
System	Operational		
Lights	0	Off 30sec interval	

For the manual shut down of the Device:



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4.1.3 Device system info

To display the Device system info:

Description of the action	Screen image
1. Open the Device main screen and tap the <i>Menu</i> button.	15:39 Thu, 05.01.2012 Measurements Op. Dr.Anthony Fox Menu Help
2. Tap the System info in the Menu window.	Menu Shut down System info Settings Probe Back
 3. The System information of the Device: Serial number - Device SN Manufactured - manufacturing date; Calibrated - date of calibration³⁰; Hardware rev - hardware version; Application FW - firmware version number; Myoton device FW - firmware version number; Battery - battery voltage V Device temp - Device temperature C° 	System Information Serial number: 1B211053 Manufactured: 17.01.2022 Calibrated: 16.01.2023 Hardware rev: 1 Application FW: 1.7.3 Myoton device FW: 1.4.0 Battery: 4.04V (95%) Device temp: 25.9°C
beview temperature o	Statistics Back

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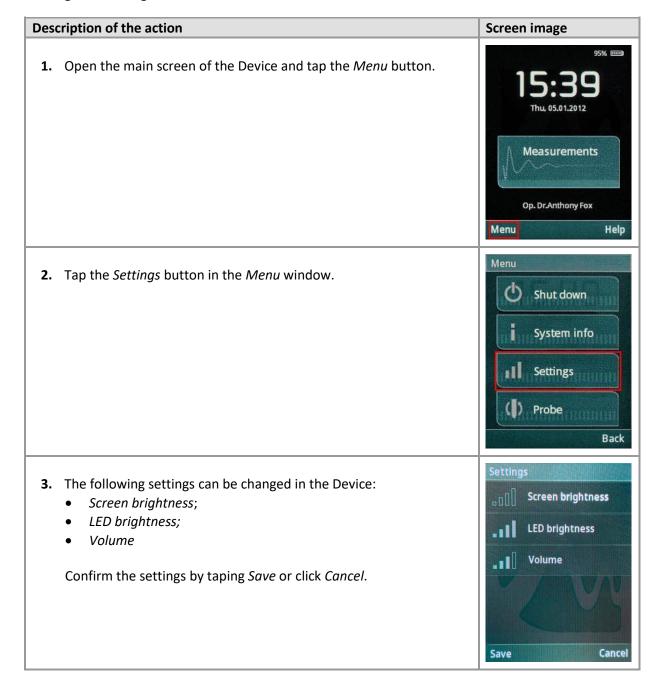
³⁰ The Device does not require re-calibration.



4.1.4 Device settings

The settings are set in the Device and the Software (chapter 4.2.5).

To change the settings in the Device:



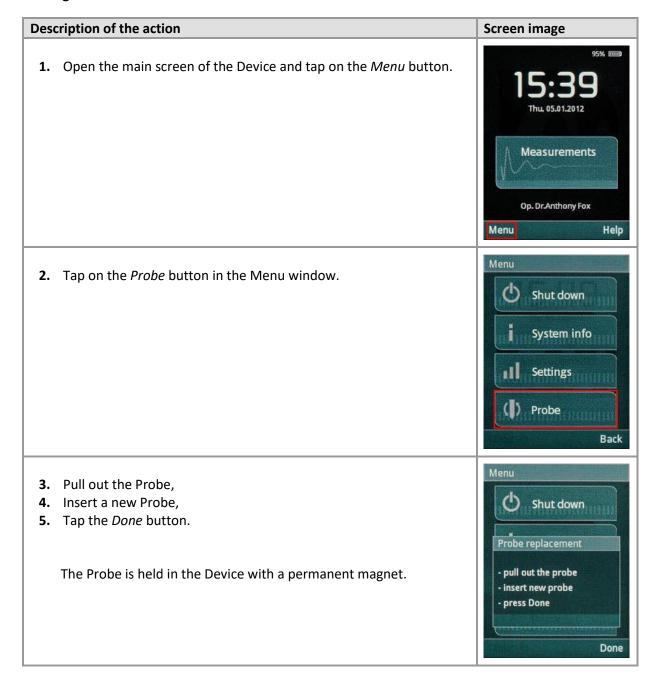


4.1.5 Device probe replacement

The Device probe can be replaced:

- with the skin probes or long probes that are suitable for tissues difficult to access,
- for sterilization purposes (e.g. if tissues with mucous membrane are measured).

To change the Probe:

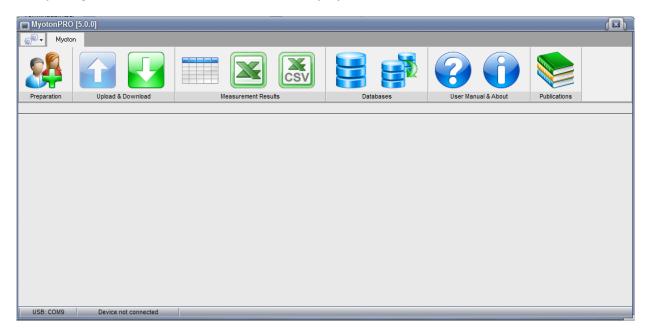




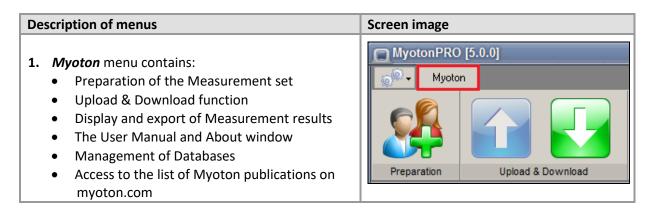
4.2 Software menu

4.2.1 The main window

On opening the Software, the main window is displayed:



There are two tabs in the main window of the Software (Settings and Myoton):

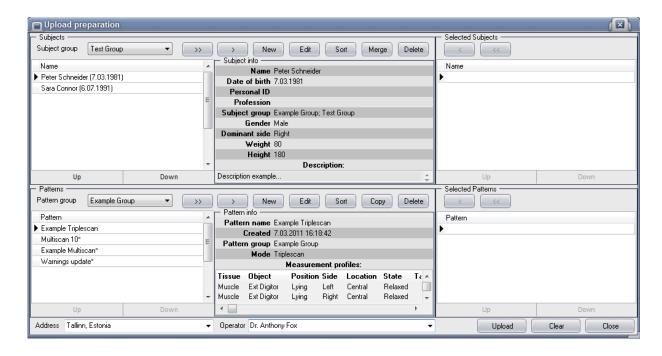




- 2. Settings menu enables to open:
 - Device settings
 - Test measuring
 - Locations
 - Preferences
 - Deleted items



4.2.2 Upload Preparation window



To open the Upload Preparation window, click the following icon in the main toolbar:



The Upload Preparation window contains:

- Entering the Subject information (chapter 3.4.1),
- Composing and handling of Patterns (chapter 3.4.2),
- Upload the Measurement set (chapter 3.4.3).



The mouse right-click pop-up menu for Subjects or Patterns:

- **Select subject/pattern** sends either the activated Subject or Pattern into the section Selected Subjects or Selected Patterns;
- **New subject/pattern** opens either the Pattern Composer or Subject info window to enter the information of the new Pattern or Subject;
- **Edit subject/pattern** opens either the Pattern Composer or Subject info window to change the information of the activated Pattern or Subject;
- **Sort** enables to sort Subjects and Pattern in the alphabetic or date order;
- **Change groups** opens either the Subject Groups or Pattern Groups window to change the groups of the activated Subject or Pattern;
- **Delete** subject/pattern deletes either the activated Subject or Pattern.

Functions of the buttons in the *Upload Preparation* window:

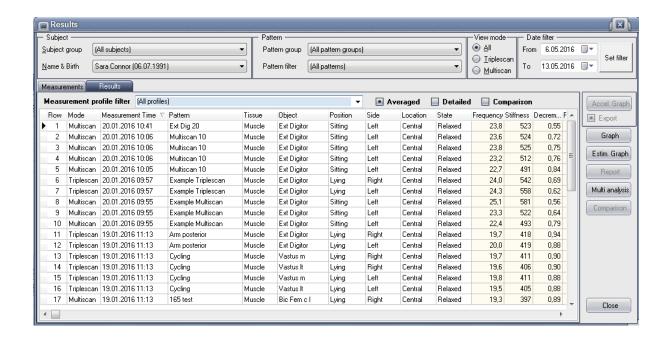
- Arrow right > either sends the selected Subjects or Patterns from the Subjects or Patterns section
 into the Upload section;
- **Double arrow right >>** either sends the entire group of Subjects or Patterns from the Subjects or Patterns section into the Upload section;
- **Arrow left** < either sends the selected Subject or Pattern from the Upload section back to the Subjects or Patterns section;
- **Double arrow left** << either sends all Subjects or Patterns from the Upload section back to the Subjects or Patterns section;
- **New** opens either the Pattern Composer or Subject info window to enter the information of the new Pattern or Subject;
- **Edit** opens either the Pattern Composer or Subject info window to change the information of the activated Subject or Pattern;
- **Sort** enables to sort Subjects and Pattern in the alphabetic or date order;
- *Merge* enables to merge³¹ two or more Subjects, including their measurement results under one Subject name.
- **Copy** enables to copy the content of existing Pattern into a new Pattern with a different name e.g. for PRE and POST data collection;
- Delete deletes either the activated Subject or Pattern;
- **Up** moves either the name of the selected Subject or Pattern upwards within the respective section;
- **Down** moves either the name of the selected Subject or Pattern downwards within the respective section:
- Upload button performs the upload of Subject and Patterns onto the Device;
- **Clear** sends the Subject and Patterns from the sections Selected Subjects and Selected Patterns back to the section Subjects and Patterns;
- Close closes the Upload Preparation window.

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³¹ Enables to merge two or more Subjects and their measurement results in case a user has created the same Subject more than once and has collected the measurement results under different names of the same Subject.



4.2.3 Results window



To open the Results window, click the following icon in the main toolbar:



In the Results window, the measurement results are displayed in two different tabs:

- **1.** *Measurement* tab,
- 2. Results tab.

Filters in the Results window:

- **Subject group** (filter for Subject groups) only the Subjects belonging to the selected group are displayed in the list Name & Birth;
- Name & Birth the name and birth date of the Subject whose measurement results are displayed
 on the Measurements and Results tabs;
- Pattern group (filter for the Pattern groups) only the Patterns belonging to the selected group
 are displayed in the Pattern filter list and only the measurement results belonging to the selected
 group are displayed on the Measurements and Results tabs;
- Pattern filter only the measurement results of the selected Pattern are displayed on the Measurements and Results tabs;
- **Date Filter** measurement results are displayed according to the determined interval:
 - Since start date of the filter,
 - To end date of the filter,

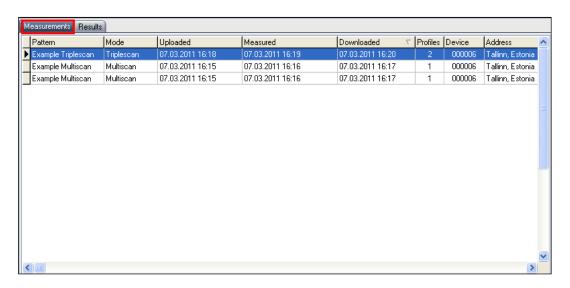


- Set filter/Clear applies or clears the filter;
- **View Mode** filter for the measurement mode:
 - o All all measurement results are displayed,
 - o **Triplescan** only **Triplescan** measurement results are displayed,
 - o *Multiscan* only *Multiscan* measurement results are displayed.

Measurements tab

On the *Measurements* tab, the measurement results of the selected Subject are displayed by the Patterns used. Each row on the tab shows the time when a particular Pattern was used.

To open the Measurements tab, click the Measurements button in the Results window:



The Measurements tab is used for:

creating a Symmetry report (chapter 3.6.2);

The mouse right-click pop-up menu on the for *Measurements* tab:

- Select all selects all rows that are displayed on the Measurements tag;
- Clear Selection deselects selected rows;
- Export filtered results exports selected rows into a file format that can be opened with MS Excel;
- **Delete measurements row** deletes the selected rows of measurements;
- Field chooser opens the window columns where the columns to be displayed can be selected.



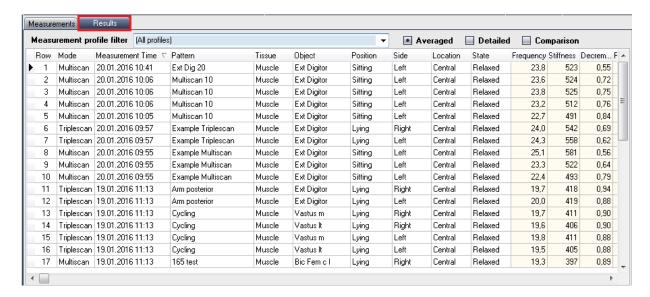
If a row of measurements is deleted from the Measurements tab, then that row's measurement results will also be deleted automatically from the Results tab.



Results tab

On the *Results* tab, all measurement results for the selected Subject are displayed by a Measurement profile.

To open the Results tab, click the Results button in the Results window:



The Results tab is used for:

- creating a Multiscan Analysis report (chapter 3.6.3);
- creating graphs (chapter 3.6.5);
- viewing acceleration signals (chapter 3.6.6);
- creating a Comparison report (chapter 3.6.4);
- creating Estimation graphs (chapter 3.6.7);
- export of the measurement results (chapter 3.7.2).

Functions of the Pop-up window (click mouse right button) on the Results tab:

- **Select all** –selects all rows that are displayed on the *Results* tab;
- Clear Selection deselects all the selected rows;
- Export filtered results exports selected rows that can be opened with MS Excel;
- Copy selection copies the selected rows;
- Field chooser opens the window columns where the columns to be displayed can be selected.

Additional functions on the Results tab:

- **Measurement profile filter** shows the measurement results of the selected Measurement profile;
- **Comparison** shows the Difference % of two measurement results and allows composing a comparison report. The difference up to 5% is shown in green, 5-10% in yellow and above 10% in red:
- Detailed view all single measurements of the series are displayed in the Results tab.

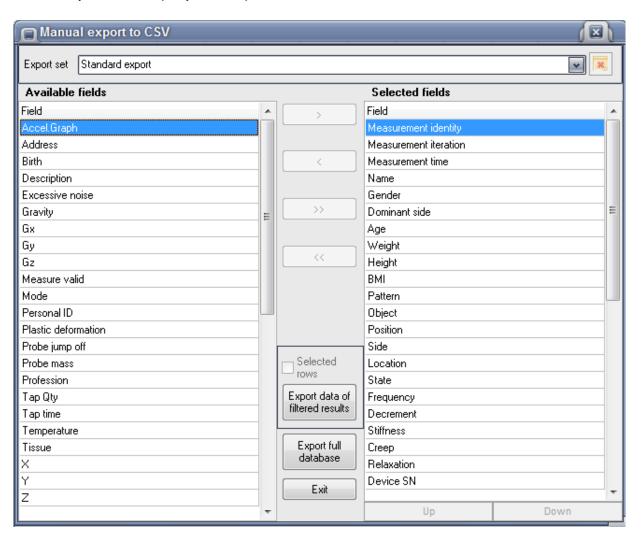




Only two rows of measurement results can be activated if the *Comparison field* is activated. To activate more rows, deactivate the *Comparison field*.

4.2.4 Manual export to CSV

Manual export window (chapter 3.7.2):



To open the *Manual export to CSV* window, click the *Manual export* icon on the main toolbar (chapter 3.7.2, point 3).

The Manual export window contains the following buttons and functions:

- Arrow right > sends selected data field from the section Available fields to the section Selected
 fields to be exported;
- Arrow left < sends the selected field from the section Selected fields back to the section Available fields;



- **Double arrow right >>** sends all the data fields from the section *Available fields* to the section *Selected fields* to be exported;
- **Double arrow left** << sends all the data fields from the section *Selected fields* back to the section *Available fields*;
- Export data of filtered results exports filtered Measurement results from the Results tab;
- **Selected rows** if checked, then only the selected results in the *Results* tab will be exported by clicking the button *Export data of filtered results*;
- **Export full database** exports the full database of the Measurements results of Selected data fields:
- Up moves the selected data field upwards;
- **Down** moves the selected data field downwards.

4.2.5 Device settings window

The Device settings can be changed in the Device settings window of the Settings menu:



To open the Device settings, click the following button in the Settings menu:





To apply the Device power settings, switch the Device ON and connect to the computer via USB. After changing the settings, click *Apply*.

Functions of the *Port configuration* section:

- USB port no determines the port for the Device and Software communication;
- **Synchronize time** synchronises the computer's Date & Time setting with the Device.

Functions of the Power settings section:

- Shut down [min] determines the automatic shut-down of the Device after the last action;
- Get settings from device shows the Power setting for the connected Devices;
- Load defaults loads the default value into the Power settings cells.



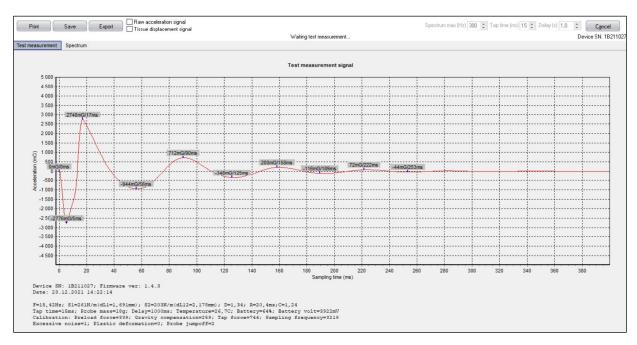
The functions of the *Data backup* section:

- Download entire measurement history downloads the entire measurement history from the connected Device;
- Delete entire measurement history deletes the entire measurement history from the connected
 Device.

4.2.6 Test measuring window

Test mode enables to display measurement results, raw acceleration signal³² and the signal spectrum of the test measurement (chapter 3.3.2).

The acceleration signal can be displayed in the *Test measuring* window:



To open the Test measuring window, click the following button in the Settings menu:



The acceleration signal and the signal spectrum are displayed in the following tabs:

- **1.** Test Measurement,
- 2. Spectrum.

The functions of the *Test measuring* window:

• **Print** – prints the Test measuring protocol;

³² The evaluation criteria for the acceleration signal are provided in chapter 2.3.



- Save saves the Test measuring protocol in the JPG format;
- Export exports the acceleration signal into the CSV format;
- Raw acceleration signal displays the raw acceleration signal along with the filtered signal;
- Tissue displacement signal displays the displacement signal along with the acceleration signal;
- Spectrum max [Hz] changes the upper limit value for the Y-axis in the Spectrum tab;
- Tap time changes the measurement impulse time;
- Delay changes the time delay preceding the measurement impulse.
- **Test/Cancel** starts or cancels the Test measurement.

4.2.7 *Locations* window

Locations of the Software files are shown in the Locations window of the Settings menu:



To open the Locations window, click the following button in the Settings menu:



- **Database** name and location of the connected database.
- MS Excel file shows the name and location of the XLSM file for the automatic export.
- Help file shows the location of the User Manual.
 Given address: http://www.myoton.com/UserFiles/Updates/MyotonPRO_User_Manual.pdf provides access to the latest User Manual.
- Application name and location of the Software functioning log file;
- Data access name and location of the log file for the events related to the manipulation of the Software data;
- Data read name and location of the log file of the events related to the reading of data;



• **Device communication** — name and location of the log file for the events related to the communication with the *Device*.

COMMENT

The default database file of the Software is *MyotonDB.sdf* (stored in the directory: C:\Program Files (x86)\MyotonPRO\Myoton_DB.sdf).

NB! Many database files can be created and used in the Software (chapter 3.8.3).

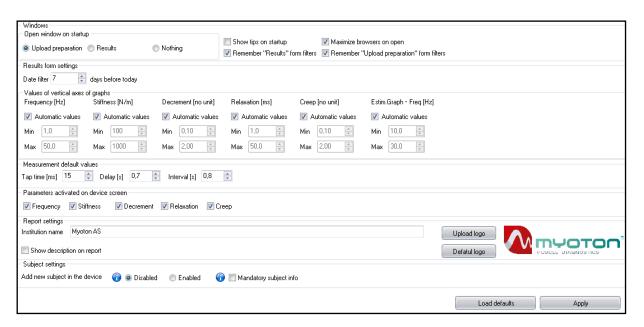


To save and apply the changes of application settings, click Apply.

If the location of log files is incorrect, the functioning of the Software can be affected.

4.2.8 Preferences window

The configuration of the Software can be performed in the *Preferences* window of the menu *Settings* window:



To open Preferences, click the following button in the Settings menu:





To save and apply the changes of application settings, click Apply.



COMMENT To apply the default settings of the Software, click the *Load defaults* button.

Windows section:

- Open window on start-up determines which window opens automatically on start-up.
- Show tips on start-up shows Tips and Suggestions on start-up of the Software.
- Maximize browsers on open maximises the Upload preparation and Results windows.
- Remember "Results" form filters remembers applied filters in the Results window after shutting down the Software.
- Remember "Upload preparation" form filters remembers applied filters in the Upload preparation window after shutting down the Software.

Settings of the Results form:

Date filter - days before today – determines the start date in the Date filter.

Values for charts vertical axis:

- **Automatic values** the default upper and lower limits of the vertical axis. The automatic option provides ± 10% from max and min values plotted on the chart.
- Min Max To change the limits, uncheck the checkbox, type a new Min Max value and click Apply.

Measuring default values:

- Tap time [ms] the default Tap time (15ms) in the Pattern composer.
- **Delay [s]** the default time delay **(0.7s)** of the measurement series.
- Interval [s] the default interval (0.8s) of the measurement series in the Pattern composer.

Parameters displayed on Device screen:

• **F, S, D, R, C** – determines which parameters of the measurement results will be displayed on the Device screen. NB! All parameters are always calculated regardless of which ones are displayed.

Report settings:

- *Institution name* the name of the user organisation that will be displayed on the reports of the measurement results (e.g. on *Multiscan analysis* report).
- **Show description on the report** before generating the reports, the *Description window* opens to enter a comment for the reports.
- **Upload logo** enables to upload a logo that will be displayed on the reports of the measurement results.
- **Default logo** the default logo that will be displayed on the reports of the measurement results.

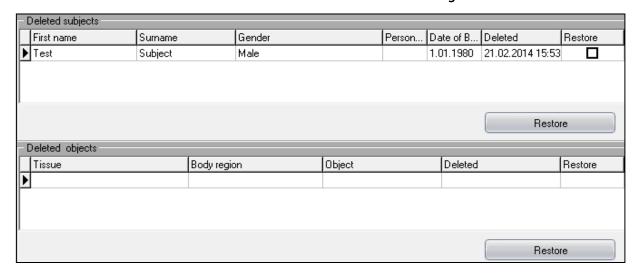
Subject settings:

- Add new subject in the device Enables/Disables the function "add new subject in the Device" without Myoton Desktop Software. This function should be activated if the computer for upload is not available!
- **Mandatory subject info** Uncheck of the checkbox enables to add subjects in the Software with the first name only. All other subject info data fields remain optional.



4.2.9 Deleted items window

Deleted data can be restored under *Deleted items* window in the *Settings* menu:



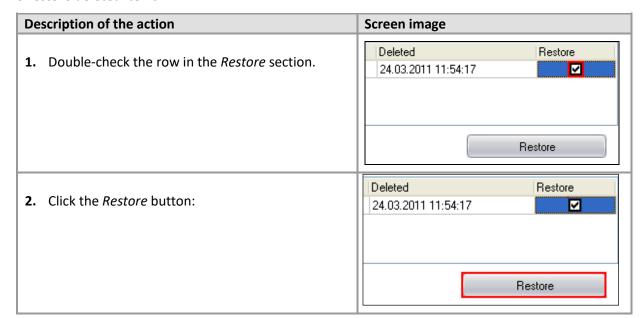
To open *Deleted items*, click the following button in the *Settings* menu:



Following deleted items can be restored in the *Deleted items* window:

- Deleted subjects,
- Deleted objects,
- Deleted patterns,
- Deleted measurements.

To restore deleted items:





Appendixes

Appendix 1 – Definitions of parameters

STATE OF TENSION

F – Oscillation Frequency [Hz]

Characterizes the intrinsic tension of biological soft tissues on the cellular level.

Oscillation Frequency characterizes the tone of superficial skeletal muscles in their passive or resting state without voluntary contraction (EMG signal silent).

The Oscillation Frequency of a muscle in its contracted state characterizes state of tension.

BIOMECHANICAL PROPERTIES

S – Dynamic Stiffness [N/m]

Characterizes the resistance of biological soft tissues to a force of deformation.

The term Dynamic Stiffness originates from the dynamic measurement method applied in Myoton technology. The inverse of stiffness is compliance.

D - Logarithmic Decrement

Characterizes the dampening of tissue oscillation.

The faster the tissue oscillation fades, the higher the dissipation of mechanical energy induced by the measurement impulse. The decrement of tissues' natural oscillation inversely describes elasticity. Elasticity is the biomechanical property of soft tissues that characterizes the ability to recover its initial shape from being deformed.

The higher the decrement, the lower the elasticity. In theory, a decrement of zero (0) represents absolute elasticity (absence of dampening). The inverse of elasticity is plasticity.

VISCO-ELASTIC PROPERTIES

R – Mechanical Stress Relaxation Time [ms]

Characterizes tissue's recovery time from displacement.

The higher a tissue's tension or stiffness, the faster a tissue recovers its shape, meaning the lower the R value.

C – Ratio of Relaxation and Deformation time

Characterizes creep, the gradual elongation of tissue over time when placed under constant tensile stress.

The higher a tissue's tension, structural integrity or stiffness, the higher its resistance to creep, meaning the lower the C value.

Y. C. Fung Biomehanics "Mechanical Properties of Living Tissues", p 41; N. Özkaya, M. Nordin "Fundamentals of Biomechanics, Equilibrium, Motion, and Deformation" 2nd edition, p 3; K. A. Athanasiou and R. Natoli "Introduction to Continuum Biomechanics", p 139.



Appendix 2 – The formulas and Legend of the Acceleration Signal

Frequency [Hz]:

F = f_{max} (signal spectrum computed by Fast Fourier transform - FFT)

Mechanical Stress Relaxation time [ms]:

 $R=t_R-t_1$

Dynamic Stiffness [N/m]:

 $S = a_{max} \cdot m_{probe} / \Delta I$

The ratio of the Relaxation and Deformation time:

 $C = R / (t_1 - t_T)$

Logarithmic Decrement:

 $D = In (a_1 / a_3)$

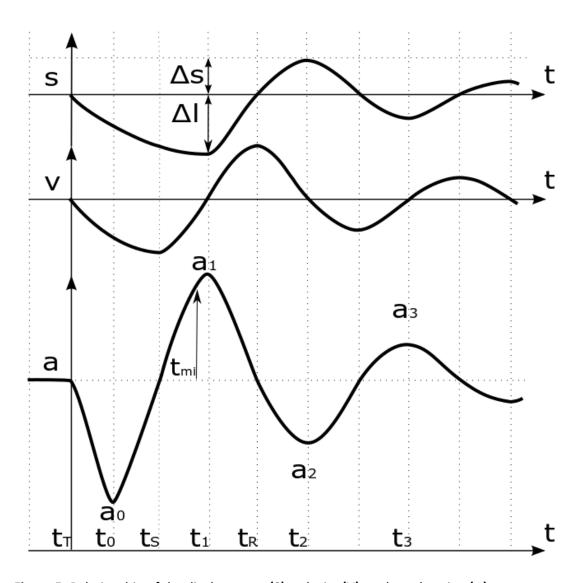


Figure 5: Relationship of the displacement (S), velocity (V), and acceleration (a).

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After a quick-released measurement impulse, the tissue being measured responds immediately in the form of a damped co-oscillation.

The co-oscillation includes:

- a) a tissue being measured,
- b) the pre-compressed subcutaneous tissue layers above a tissue structure being measured,
- c) the Device probe and measurement system.

Oscillation of a soft biological tissue is registered in the form of an acceleration signal (a).

The legend of the figure:

Symbol	Description
а	Acceleration of the damped oscillation – unit: milli G [mG]
a ₀	Maximum acceleration
a ₁	Maximum displacement i.e. maximum tissue resistance measured in milli g [mG]
a ₂	Maximum opposite displacement due to the residual inertia of the tissue oscillation
a ₃	Maximum displacement of the second oscillation period
ΔS	Pre-compression of subcutaneous tissues above a tissue structure being measured
ΔΙ	Maximum displacement of a tissue
m_{probe}	Mass of the measurement mechanism
S	Displacement : mm
t	Time in milli seconds [ms]
t _{mi}	End of the mechanical impulse
t ₀	The timepoint of maximum acceleration
t⊤	Start of the mechanical impulse
t _r	The timepoint of a tissue recovery from being deformed
ts	The timepoint of maximum velocity and acceleration shift to deceleration
$t_t - t_0$	The time between zero to maximum acceleration
$t_0 - t_s$	The time between maximum acceleration to zero acceleration
t _s – t ₁	The time from maximum velocity to complete stop
$t_1 - t_r$	The time between maximum displacement and full recovery.
t _r – t ₂	The time between recovered initial shape and opposite maximum displacement
t ₁	The timepoint of maximum displacement (deformation)
t ₂	The timepoint of opposite maximum displacement (deformation)
t ₃	The timepoint of maximum displacement of the second oscillation period
t ₂ – t ₃	The time of two consecutive displacements
V	Oscillation velocity: m/s



Appendix 3 – Technical Specification

DEVICE TYPE AND MEAS	UREMENT METHOD
Classification Category	 For Research Use Only Monitoring device for non-vital physiological parameters
Device	 Digital palpation device for in vivo non-invasive measurement of soft biological tissues
Measurement method	Mechanical Dynamic Response method
Measurable parameters	 State of tension: Natural Oscillation Frequency [Hz] - characterizes Tone or Sate of Tension
	 Biomechanical properties: Dynamic Stiffness [N/m] Logarithmic Decrement of the oscillation [relative arbitrary unit] characterizes Elasticity and dissipation of mechanical energy
	 Viscoelastic properties: Mechanical Stress Relaxation time [ms] Ratio of Relaxation and Deformation time [relative arbitrary unit] characterizes Creep
Measurement range Min – Max (limited to)	 Natural oscillation frequency - 6 - 80 Hz (110 Hz) Dynamic Stiffness - 70 - 2000 N/m (3000 N/m) Logarithmic Decrement - 0.20 - 3.50 Mechanical Stress Relaxation time - 3.50 - 50 ms Creep - 0.30 - 2.80
Parameter's Coefficient of Variation	 Natural Oscillation Frequency - 0.6% Dynamic Stiffness - 1.7% Logarithmic Decrement - 2.0% Mechanical Stress Relaxation time - 1.2% Creep - 1.5%
Raw signal processing	Proprietary algorithm
MEASUREMENT SYSTEM	
Measurement mechanism	System of frictionless translation motion, driven by solenoid actuator
Measurement sensor	 3-axis Digital Acceleration Sensor, Output resolution 13-bit at ±8 g Sensitivity range due to temp. ±0.01%

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Measurement probe	 PMMA – (Polymethyl methacrylate), Standard diameter D=3 mm Replaceable by user
Probe drive	Shock protected servo mechanism
Probe positions	 Transport position: probe positioned inside the device Replacement position: probe max exertion 14 mm
Pre-load force	0,18 [N] – automatic and independent of the measurement direction
Tap force	0,42 [N] – automatic and independent of the measurement direction
Measurement impulse time duration	 Measurement impulse duration is 15 ms (default value) Automatically reduced impulse times are from 15 to 13, 10, 7 and 6 ms User configurable from 5 to 15 ms
Tissue oscillation recording time	• 400 ms
Measurement position tolerance	±1,5mm in measurement direction
Measurement direction	Any-directional measurements enabled from 0 to 1,3G gravity
Measurement sequence	Automatic, pre-defined by user
Calibration	Pre-calibrated by the manufacturer
Measurement assistance	Probe light, audio and user interface assistance
POWER AND BATTERY	
Battery	 Built-in rechargeable Lithium Polymer Battery 2260mAh, 3.7V, 8.4Wh Replaceable only by the manufacturer
Charger	 AC-DC Adapter, Input: AC 100-240V, 50/60 Hz, 0.3 – 0.15A Output: DC 5V1A, USB type A socket Interchangeable AC plug type: EU, US, AU, GB
Recharge time	Max 5 hours
Recharge cycles	Min 500 cycles
Operational time	 Min 8 hours (in case of normal workload) Min 15 000 continuous measurements in horizontal position

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Power management

- User configurable
- Automatic shut-down in 20 minutes (adjustable)

DISPLAY AND DATA TRANSFER		
Display	 LCD display 2.8" diagonal, Capacitive Touch Panel LED Backlight, High Brightness, Full view angle 	
Data storage	Internal memory available for minimum 500 000 measurements.	
Data transfer cable	USB Type A plug to Type C plug	

DEVICE FIRMWARE		
Operating system	•	Proprietary Linux-based operating system
Content upload	•	Subject and measurement profiles
Content download	•	Measurement results
Date & time	•	Configurable via computer Date & Time settings

ENVIORNMENTAL REQUIREMENTS		
Operating conditions	•	in-door use
Operating temperature	•	-5 to +50° C (23 to 122° F)
Relative air humidity	•	0 – 95 % RH not condensed

DEVICE HOUSING		
Height	•	162 mm
Width	•	67 mm
Depth	•	29 mm
Device	•	240 g
Colour	•	Combination of white, green and grey
Material	•	Polycarbonate UV Stabilized and Elastomer thermoplastic

END OF SPECIFICATION

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Appendix 4 – List of Error Messages

Error Message Severity and Priority

Error messages displayed on the Device screen are written to the error log without being displayed on the screen. For error messages that are displayed, the box title indicates the severity of the message.

WARNING! – indicates that the Device requires attention soon. It does not affect the results of the Subject being measured or the operation of the Device.

ERROR! - requires the operator's attention but does not stop the entire Device from running except in case of Boot errors.

DETECTION MESSAGE! – informs the operator, corrective action may be needed.

BOOT ERROR! – requires the operator to contact support if the problem persists.

SEVERE ERROR! - may stop the Device and requires the operator's immediate attention.

The Device does not contain error messages which may cause danger to an operator or the Subject. Device temperatures given in Warning or Error messages are in Celsius.

Too high temperature above 60 degrees Celsius may damage the battery inside the Device.

Error message from 26 to 36 may occur when the Device hardware errors cause the Device firmware communication issues. If the message persists, please contact support!



In case the Device does not start or the firmware freezes, press the RESET button (chapter 1.4.2 p. 17) on the reverse side of the Device by using any rod (e.g. straighten paper-clip) with diameter less than 1,5 mm.

Seq no	Error window title	Error Message
1	Warning!	Battery is empty! Please re-charge the battery! Shutting down!
2	Warning!	Device temperature (X) is high! Please shut down for cooling!
3	Severe Error!	Device temperature (X) exceeds allowed maximum! Shutting down for cooling!
4	Warning!	Device temperature (X) is low! Please regain working temperature!
5	Severe Error!	Device temperature (X) is too low for normal functioning! Regain working temperature! Shutting down!
6	Error!	Unable to read the device settings. If the problem persists, please contact support.
7	Error!	Please remove any obstacle blocking the probe from being exerted. If the problem persists, please contact support.
8	Error!	Please remove any obstacle blocking the probe from being retracted. If the problem persists, please contact support.
9	Warning!	The probe was pushed in. Do not use excessive force when replacing the probe!
10	Error!	Please upload a Measurement set to perform measurements!



11	Error!	Subject database full. To add a new Subject on the Device, please upload a new
		Measurement set with less than 50 Subjects!
12	Error!	Database error occurred while adding a new Subject.
		If the problem persists, please contact support.
13	Error!	Unable to retrieve information from the database.
		If the problem persists, please contact support.
14	Error!	Unable to read measurements from the database.
		If the problem persists, please contact support.
15	Error!	Unable to process measurement data. If the problem persists, please contact
		support.
16	Error!	Unable to read the required information from the database.
		If the problem persists, please contact support.
17	Error!	No measurement profiles defined in the patterns.
		Please upload valid pattern.
18	Error!	Unable to store measurements to database.
		If the problem persists, please contact support.
19	Error!	This device is not calibrated. Performing measurements with an un-calibrated
		device is not possible. Please contact support.
20	Error!	Unable to initialize a measurement subsystem. If the problem persists, please
		contact support.
21	Error!	Myoton device failed to perform measurement.
22	Detection	Optimizing impulse
	message!	* chapter 2.3.2
23	Detection	Probe jump-off detected!
	message!	* chapter 2.3.3
24	Detection	Excessive noise detected!
	message!	* chapter 2.3.4
25	Error!	Measurement data invalid! * Obtained acceleration signal is not suitable for
		parameters computation.
26	Error!	Unable to initialize a measurement subsystem.
27	Boot error!	Unable to start up the power management. Shutting down!
28	Boot error!	Unable to start up the system monitor. Shutting down!
29	Boot error!	Unable to initialize databases. Shutting down!
30	Boot error!	Unable to initialize user interface. Shutting down!
31	Boot error!	Unable to initialize the device hardware. Shutting down!
32	Boot error!	Unable to initialize the LED driver. Shutting down!
33	Boot error!	Unable to initialize the real time clock. Shutting down!
34	Boot error!	Unable to initialize the sound driver. Shutting down!
35	Boot error!	Unable to initialize USB communication. Shutting down!
36	Boot error!	Unable to open the battery log. Shutting down!
37	System status!	This device is disabled! Please contact support!



Appendix 5 – Environmental Conditions



After the transportation of the Device in a temperature lower than -5°C (23°F), warm up the Device to the room temperature before switch on.

Maximum Permitted Operational Temperature and Humidity	Temperature range: -5 to 50°C (23 to 122°F) Humidity range: 0 to 95%RH (not condensed) No atmospheric pressure limits.
Recommended Operational Temperature and Humidity	Temperature range: +15 to 30°C (59 to 86°F) Humidity range: 10 to 75%RH No atmospheric pressure limits.
Transportation	Temperature range: -10 to 50°C (14 to 122°F) Humidity range: 10 to 95%RH (not condensed) No atmospheric pressure limits.
Transportation package	See handling symbols outside of the package. Temperature range: -10 to 50°C (14 to 122°F) Humidity range: 10 to 95%RH (not condensed) No atmospheric pressure limits.
Storage	Preferably store device in a room temperature. Temperature range: +15 to 30°C (59 to 86°F) Humidity range: 10 to 75%RH No atmospheric pressure limits.

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Important information regarding Electro Magnetic Compatibility (EMC)

With the increased number of electronic devices such as computers and mobile (cellular) telephones, and other electronic devices in use may be susceptible to electromagnetic interference from other devices. Electromagnetic interference may result in incorrect operation of the device and create alterations of measurement results.

In order to regulate the requirements for EMC (Electro Magnetic Compatibility) with the aim to prevent unsafe product situations, the EN60601-1-2:2007 standard has been implemented. This standard defines the levels of immunity to electromagnetic interferences as well as maximum levels of electromagnetic emissions. This device manufactured by Myoton AS conforms to this EN60601-1-2:2007 standard for both immunity and emissions.

Nevertheless, special precautions need to be observed:

NB! Do not use devices, which generate strong electromagnetic fields near the device. This may result in incorrect operation of the unit. The recommendation is to keep a minimum distance of 2 meters. Verify the correct operation of the device in case the distance is shorter.

The MyotonPRO device EMC test report is available at request.

Mechanical and electrical safety

Accordance with mechanical and electrical safety test program MyotonPRO is fully compliant with IEC 60601 1:2005 + Corr. 1:2006 + 2:2007 + AM1:2012; Cl. 7, 8, 9, 15.

The MyotonPRO palpation device does not compromise the safety of the Subject, device operator nor other electonic equipment.

The MyotonPRO device mechanical and electrical safety test report is available at request.

Correct Disposal Electrical & Electronic Equipment



This marking shown on the Device or its documentation indicates that it should not be disposed with other household wastes at the end of its working life. To prevent possible harm to the environment or human health from uncontrolled waste disposal, please separate this product from other types of wastes and recycle it responsibly to promote the sustainable reuse of material resources. This product should not be mixed with other commercial wastes for disposal. This product does not contain any hazardous substances.