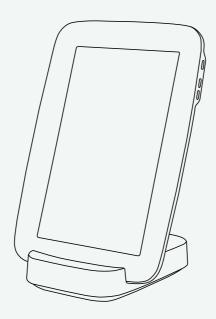


Instructions for Use

# **MESI mTABLET**

Wireless Medical Tablet System



CE1304 SI OLIGINA OLIG



DISTRIBUTOR INFORMATION		
DISTRIBUTOR INFORMATION		

# **CONTACT INFORMATION**

Address MESI, development of medical devices, Ltd

Leskoškova cesta 11a SI-1000 Ljubljana

Slovenia, European Union

Telephone +386 (0)1 620 34 87
E-mail info@mesimedical.com
Website www.mesimedical.com

Instructions for Use

# **MESI mTABLET**

Wireless Medical Tablet System

#### CONTENT

1 SAFETY AND LEGAL RECOMMENDATIONS	7
441 FCAL INFORMATION	7
1.1 LEGAL INFORMATION 1.2 SAFETY INFORMATION	
1.2 SAFETT INFORMATION	/
2 MESI mTABLET & MESI mRECORDS	8
2.1 MESI mTABLET	8
2.2 MESI mRECORDS	9
	40
3 PRODUCT DESCRIPTION	10
3.1 INTENDED USE	10
3.2 WHAT IS IN THE PACKAGE	
3.2.1 Accesssories	
4 TECHNICAL SPECIFICATIONS	14
4.1 MESI mTABLET	
4.1.1 Dimensions	14
4.1.2 Power & battery	14
4.1.3 Classification	
4.1.4 LED indications MTABDSW	
4.1.5 MTABMD specifications	
4.1.6 Connectivity 4.1.7 Operating conditions	
4.1.7 Operating conditions  4.1.8 Transport & storage conditions	
4.1.0 Hansport & storage conditions	19
5 GETTING STARTED	16
5.1 MESI mTABLET UNBOXING	
5.2 SET UP	
5.3 PAIRING A DIAGNOSTIC MODULE	22
6 PERFORMING YOUR FIRST MEASUREMENT	24
OTERIORIMINO TOOK TIKOT MEASOREMENT	.2-т
7 USER PROFILE	27
7.1 LOG IN AND REGISTRATION	27
7.2 ARCHIVE	28
7.3 SHARED RESULTS	29
7.4 SETTINGS	30

8 PATIENT	31
8.1 PATIENT SELECTION  8.1.1 Adding the patient  8.1.2 Selecting the patient  8.1.3 Import existing patient list  8.2 PATIENT PROFILE  8.3 PATIENT ARCHIVE  8.4 PATIENT CHARTS	31 32 32 33 34
9 MANAGING USERS	36
9.1 ADDING & REMOVING USERS 9.2 PATIENT DATA SHARING PRIVILEGES	
10 MESI mTABLET MAINTENANCE	36
10.1 CHARGING THE BATTERY AND STORING  10.2 CLEANING INSTRUCTIONS  10.3 PRODUCT LIFE AND STORAGE	36 36
11 GENERAL WARNINGS	37
11.1 MAINTENANCE	
12 WARRANTY INFORMATION	40
12.1 EXTENDED WARRANTY AND OTHER MESIcare SERVICES	40
13 STANDARD COMPLIANCE	41
44 IMPORTANT LARGE C	42



NOTE: Before using the device for the first time, read the user manual carefully and follow the recommendations and suggestions. See General warnings on pages 16 - 17. For detailed descriptions of individual processes of the device, refer to www.mesimedical.com/mtablet/help. Please keep for future reference.

#### 1.1 LEGAL INFORMATION

All rights reserved. This publication may not be reproduced, copied or stored on a memory device. Furthermore, this publication may not be used for any purpose other than as the instructions for the use of the MESI mTABLET. This publication may not be translated into other languages or converted into other formats in any way without the prior written permission of MESI ltd.

The contents of the instructions for use may be altered without notice. The latest version of the instructions for use is available at www.mesimedical.com.

SAFETY AND LEGAL RECOMMENDATIONS

#### 1.2 SAFETY INFORMATION

To avoid personal injury and/or damaging the device or accessories, follow the safety recommendations given below.

The device must be set up by authorized personnel with adequate professional training and experience who are aware of all the dangers in relation to the setup of the device and its use and who will take adequate risk prevention measures for themselves, users, other personnel and devices.

Only authorized persons may be given access.

Local safety requirements are to be complied with, if so required by regulations. In addition to local safety regulations, the safety instructions in this document are also to be complied with. Should there be any conflict between the safety recommendations in this document and the recommendations stipulated by local regulations, the local regulations take precedence.

MESI mTABLET & MESI mRECORDS

# 2.1 MESI mTABLET

MESI mTABLET is the heart of the MESI system of diagnostic tools. It enables medical personnel to manage all the different diagnostic modules with one device - from running measurements to storing their results. Measurements are saved and linked directly to the patient record, which reduces the loss of data and provides medical personnel with a better overview of patient medical history.

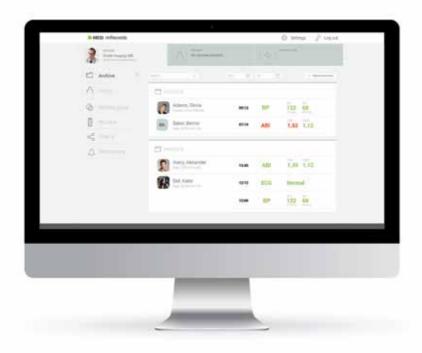
With the MESI mTABLET, the user is also given access to web-based application MESI mRECORDS, where additional diagnostic tools and patient management is possible.



### 2.2 MESI mRECORDS

MESI mRECORDS can be accessed with the same user login data as MESI mTABLET at **https://mrecords.mesimedical.com**. Since MESI mRECORDS is a web app this gives you access from anywhere and anytime. All measurements and patient data is synced between the MESI mTABLET and MESI mRECORDS, thus giving the medical expert access to recorded measurement instantly.

For more information and tutorials please log-in or register your account on **https://mrecords.mesimedical.com**.





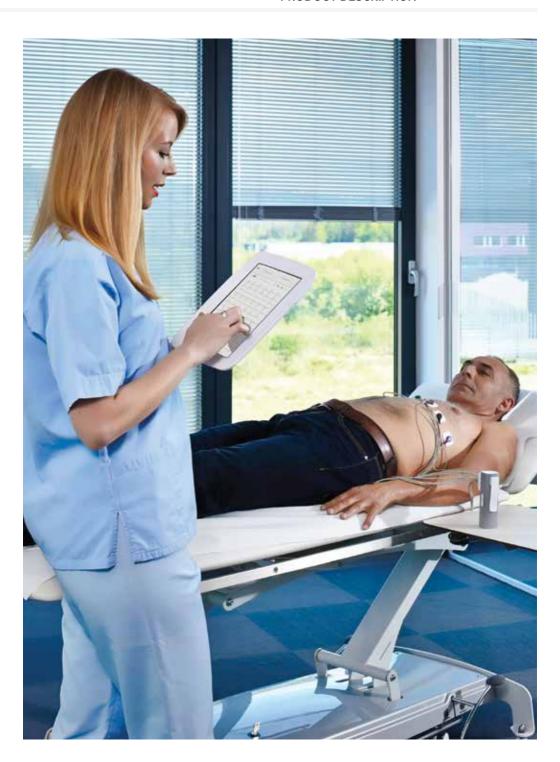
### 3.1 INTENDED USE

The MESI mTABLET is a handheld medical grade tablet unit and a MESI mTABLET docking station with access point. It is a mobile computing platform intended to be used solely in a professional clinical environment by trained healthcare personnel. MESI mTABLET is designed to connect patients, measurements, medical applications and medical personnel within one ecosystem.

MESI mTABLET UNIT is intended to be used either as a standalone solution with a variety of different software or with diagnostic modules.

It is intended to be used by medical personnel in a clinical environment. The expected user can use and knows how to operate smart phones or tablet computers.

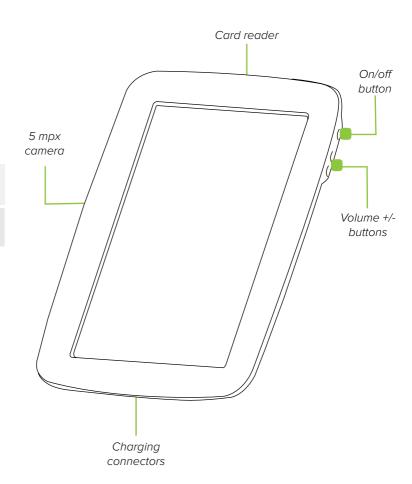
The device can be recharged through AC/DC power supply.



#### 3.2 WHAT IS IN THE PACKAGE

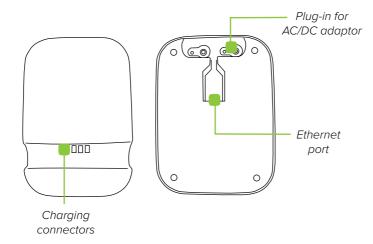
Your package includes the following equipment:

- MESI mTABLET UNIT (MTABMD)
- MESI mTABLET WI-FI DOCKING UNIT (MTABDSW)
- Power adapter
- Network cable
- User manual



Medical Grade Tablet Unit

**Model** MTABMD

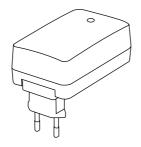


MESI mTABLET docking station with access point for Wi-Fi

**Model** MTABDSW



Ethernet cable to connect docking station to LAN.



AC/DC Power supply for MTABDSW

Please contact your local distributor for more information about MESI mTABLET accessories; such as carry bags, trolleys etc.

3.2.1
ACCESSORIES



Following are the technical information regarding MESI mTABLET, its operating system and accessories provided within the package.

#### 4.1 MFSI mTABI FT

#### **DIMENSIONS**

Width	199 mm
Depth	35 mm
Height	278 mm
Weight	800 g

#### 4.1.2

# POWER & BATTERY

AC/DC adaptor	FW8030M/05
Input	100-240V AC / 50-60 Hz / 600 - 300 mA
Output	5 V DC / 5.0 A
Battery type	Rechargeable Lithium-Polymer battery
Capacity	8800 mAh
Battery operation	More than 8 hours

#### 4.1.3

# CLASSIFICATION

Protection against electric shock	
Medical device classification	
Software safety classification	

Class II equipment

Class IIa

Class A

# 4.1.4

# LED INDICATIONS MTABDSW

Green LED Orange LED

Displays connection state (fixed light)

Represents LAN activity

OS	MESI OS 1.0 (based on Android OS)	4.1.5 MTABMD
Processor	CPU Quad ARM Cortex A53 @ up to 1.2GHz per core	SPECIFICATIONS
Barcode reader	1D/2D barcode imager	
Screen	1280 x 800 px IPS	
Memory	8 GB	
RAM	1 GB	
Connectivity	Wi-Fi 802.11b/g/n and 2.4 GHz single band Bluetooth 4.1	
Camera	5 MP	
Environment	IP20, 90 cm drop resistant	
Audio	Mono speaker	
Security	2 step authentication - User password or PIN, SMS verification code HTTPS transmission protocol	
Bluetooth 2.1 + EDR	Between MTABMD and diagnostic modules	4.1.6 CONNECTIVITY
Wi-Fi 802.11b/g/n	Between MTABMD and MTABDSW	
10/100 Mbps Ethernet connection	Between MTABDSW and LAN	
Temperature, operating	10° to 40° C	4.1.7 OPERATING
Relative humidity	25 to 85 % (no condensation)	CONDITIONS
Pressure during operation	700 to 1060 hPa	
Temperature	15° to 50°C (<1 month) -15° to 40°C (<3 month) -15° to 25°C (<12 month)	4.1.8 TRANSPORT & STORAGE
Relative humidity	25 to 85 % (no condensation)	CONDITIONS
Air pressure	700 to 1060 hPa	

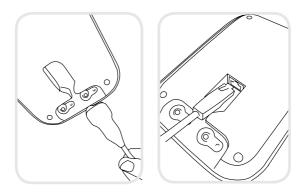


#### 5.1 MESI mTABLET UNBOXING

Before you start, you will need to set up all the components in your practice.

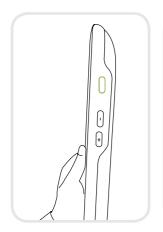
## Step 1

Connect your charging station to the mains and to the local area network with the network cable and power adapter provided.



Step 2

Turn on your MESI mTABLET UNIT with the power button and set it on the charging dock to fully charge it.







After all the components are set the MESI mTABLET will connect automatically to the MTABDSW Wi-Fi and is ready to use.

### 5.2 SET UP

The first time you use the MESI mTABLET you will need to go through a setup process, which establishes the system according to your preferences. The guided process begins when you start your device for the first time and shouldn't take more than 10 minutes.

The first part is the technical set up, which is only done by the first user. This includes setting up additional WI-FI connections and deciding on language use.

The second part is establishing your user account, which will be used to access your patient's data on the MESI mTABLET UNIT or MESI mRECORDS.

## Step 1 - Languages

Since the MESI mTABLET UNIT offers several languages, select the language you wish to use from the drop-down menu. This setting can be changed later in user settings.



#### Step 2 - Wi-Fi

The MESI mTABLET WI-FI DOCKING UNIT for the MESI mTABLET UNIT comes with a built-in Wi-Fi access point to which the MESI mTABLET UNIT will connect automatically on first use.

If another wireless network is desired, please select it from the list and enter security information.

Wi-Fi is not required for the essential functions of the MESI mTABLET, but it is necessary for measurements to be synced to the MESI mRECORDS web application.



### Step 3 - Register

Each user accessing the MESI mTABLET needs to register an account, which will also enable them to access data securely on other devices (personal computer, tablet, phone if needed).

To secure your account, we provide a two-step verification process - meaning you need to confirm the account with your e-mail account, as well as with your mobile phone.



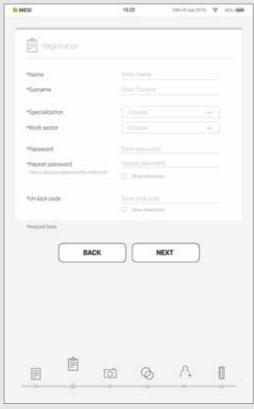
#### Step 4 - Licence Agreement

Before you start using the device, you will need to agree to the terms and conditions. This includes privacy policies and how we handle your data. You can always review it in the MESI mRECORDS web app. The account is not created until you have read and agreed with the terms and conditions.

## Step 5 - Registration

Registration is the part where you insert your personal information like Name, Surname, Specialisation and where you choose all your passwords and lock code for fast tablet access.





#### Step 6 - Choose avatar

For faster identification of your profile, you can choose your avatar from a set that is provided at this step. Profile image can be changed later on under user settings either on MESI mTABLET UNIT or in MESI mRECORDS



# **User types**

Registered users are set into working groups which, depending on their user profile have different rights.

Users are separated into two groups "doctor" and "nurse". A doctor can create and is a working group owner, giving him the option to invite other doctors or nurses into his working group. A "nurse" profile, on the other hand, can only access the MESI mTABLET UNIT in cases where the doctor has invited her into his/her working group. This access can be revoked at any time by the working group owner.

#### Step 7 - Practice info

Like a real practice, the MESI mTABLET system connects medical personnel in a working group environment. They are created to enable patient data sharing between practice staff and at the same time protect it.

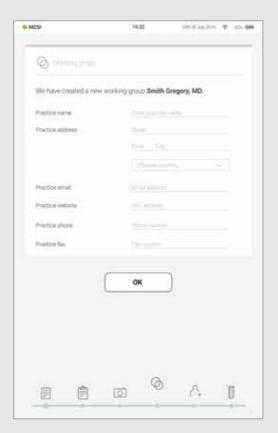
Adding users to your working group helps you share patient data with your coworkers.

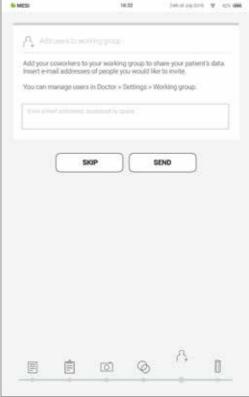
The first time you use the tablet, enter the e-mails of your co-workers. If they already have an account registered, they will become a part of your working group and if not, they will get an invitation in their e-mail inbox to register online.

Adding users into your working group is optional at this point. If you want to add users at another time, go to **Doctor** > **Settings** > **Working groups**.

## Step 8 - Working groups

Each doctor can be the owner of only one working group but can be invited into multiple working groups. At the same time, he can add multiple nurses or doctors into his/her working group. Nurses, on the other hand, can be part of many working groups, but they can't create one or add more people to it. This system enables greater oversight of patient data access.





NOTE: the 1st user that registers becomes the MESI mTABLET UNIT owner which has the highest level of authority on the MESI mTABLET UNIT. This user has the privilege to remove unnecessary accounts and paired modules from the MESI mTABLET UNIT.

# 5.3 PAIRING A DIAGNOSTIC MODULE

Before any recordings can be performed, the appropriate module needs to be paired to your MESI mTABLET UNIT. Please take the MESI mTABLET UNIT and open user tab (for more information about user accounts please see the chapter **9 Managing users**).

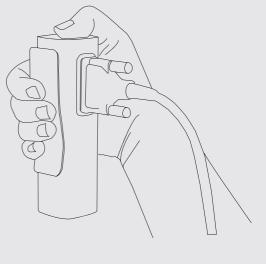
Step 1

Go to User profile > Settings > Modules > +Add module

### Step 2

Press button on top of the appropriate module.





Go to **Settings** > **Modules** and tap +**Add new module** on the hand side. The application will guide you through the next steps.

#### NOTE

If you are operating only with one MESI mTABLET UNIT, then performing this operation is required only once. In case of more MESI mTABLET UNIT this process will have to be repeated on each MESI mTABLET UNIT.

#### Step 3

When the MESI mTABLET UNIT establishes a connection with the module, the light on top of the module will change. Confirm the pairing process by pressing the button on top of the module again.



# Step 4

Final screen indicates successful connection between the MESI mTABLET UNIT and the wireless module. You can access all technical information about the connected modules in **User profile** > **Settings** > **Modules**.





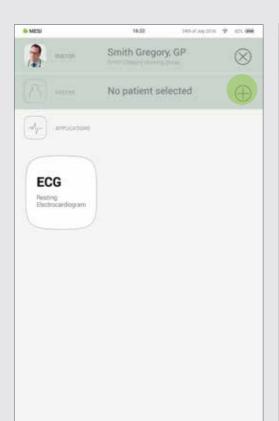
Performing your first measurement is a straightforward task. As you are already signed in to your account, you will need to follow the steps below.

# Step 1 - Add first patient

On your home screen, press the  $\bigoplus$  button in the Patient tab.

### Step 2 - Fill out patient's data

Fill out required fields (Name, Surname, Date of Birth and Gender) and any additional information regarding the patient. Save the patient by pressing the (v) button.





#### NOTE

There are also ways to import patients from your EHR to MESI mRECORDS, which will then sync with MTABMD. Please contact your local MESI representative.

#### NOTE

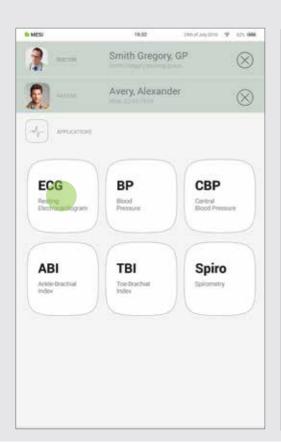
When creating your profile a "Test patient" is added to your working group to help with initial adjusting to MESI mTABLET interface. This patient will be automatically removed after 2 weeks or it can be removed by a user on MESI mRECORDS.

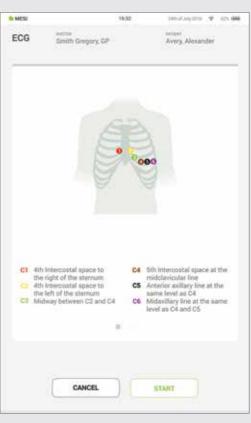
#### Step 3 - Select measurement

Once you have added the patient, tap the Applications tab (lower part of the screen) to bring up the home screen. Each measurement has its own icon and you choose one by tapping it.

#### Step 4 - Prepare diagnostic module

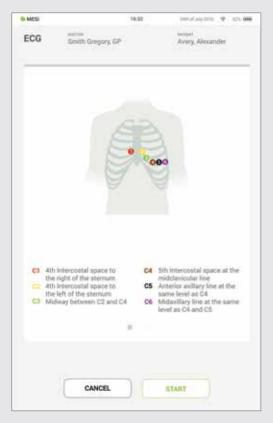
When you access the desired measurement, there will be instructions on screen on how to apply the wireless module in the right way. Swipe left or right to see all instruction steps. When the START button becomes green, you can start the measurement.





## Step 5 - Measurement

The measurement screens depend on the type of measurement being performed. Most measurements will have some graphic representations of measurement in real time (graphs or progress bar) and other parameters specific to the measurement (consult the specific diagnostic module user manual for more details).



#### Step 6 - Results

When the measurement process is completed, the MESI mTABLET UNIT screen displays the result. It consists of five different areas: navigation area, numerical result with interpretations, visual representations, patient's history of measurement and comments on the result.

All the buttons and information placed in the **navigation area** are there to help you find your way around the application. You can toggle between previous results of the patient. If you are not satisfied with the recording for any reason, you can quickly discard it, or in the case of uncertainty you can consult with other doctors by simply entering their e-mail addresses. It also contains the names of both the doctor performing the recording and the patient.

The **numerical result** is a combination of the calculated results and measured values. Tap to show more in-depth interpretations.

**Visual representations** of the measurement depend on the measurement type. For more information please see the instructions for use that came with diagnostic module.

**History** holds an overview of recordings done by the same doctor on the same patient. It shows the trend of the patient's results.

A **comment** can be added to every measurement. It will be stored and always available together with the recording report.

For more information on the specific result form, see the measurement user manual, which you will have received along with the diagnostic module.

#### 71 LOG IN AND REGISTRATION

To freely use the MESI mTABLET UNIT, you need to be listed as a tablet user. This can be done in two ways:

- Registration
- Log in with existing account

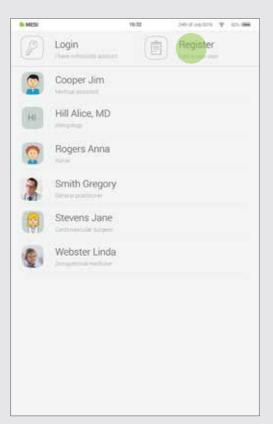
# USER PROFILE

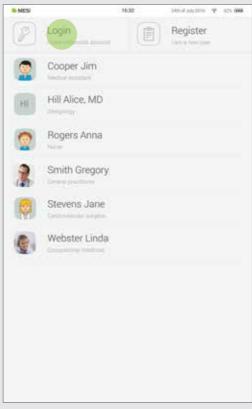
#### Registration

If you want to register as a new user, tap in the right upper corner of the lock screen (Register). It will lead you to the registration form.

## Log in with existing account

If you have registered online, you need to log in with your e-mail and password so the tablet can recognize you. Once you are listed as a tablet user, you will be able to access your data with your 4-digit lock code only.

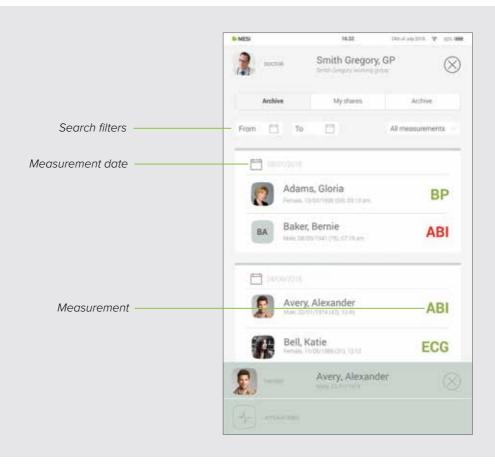




# 7.2 ARCHIVE

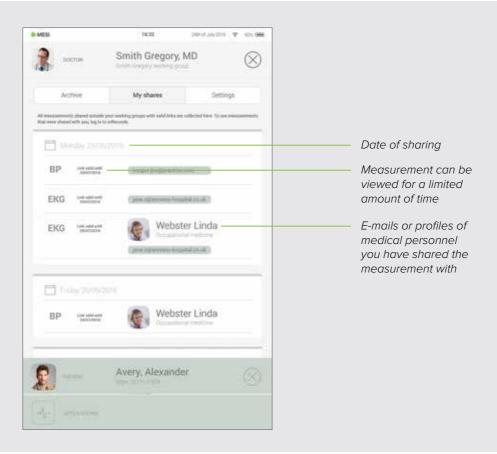
The Archive is the fastest way to reach your previous measurements. All measurements are chronologically sorted from the oldest to the newest.

Every date entry shows patients, time and type of measurement performed. Tapping the tile shows you the result.



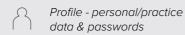
### 7.3 SHARED RESULTS

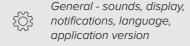
All measurements or recordings shared with specialists outside of your working group will be displayed here. Next to the measurement, you are presented with information such as when the measurement was sent, to whom it was sent and until when the access link is valid.



### 7.4 SETTINGS

Settings is the place for all doctor's/nurse's information, passwords, serial numbers, module pairing, user management etc. Anything that is not directly connected to a measurement is found here.





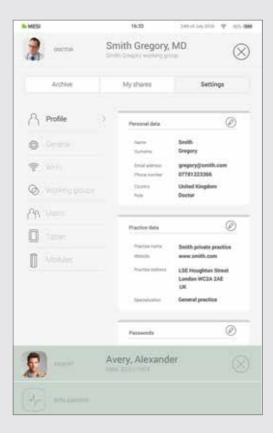




Tablet - information on tablet

Modules - pairing and module information

\*Users - only visible to the main user of the tablet, who has control over who is listed on the tablet



## **8.1 PATIENT SELECTION**

Since MESI mTABLET works as your medical cabinet, there is place to store patient information. Once you put it in, it will be there whenever you need it. You only need to fill out patient data form once. When you add the patient, they will appear on the patient list and you will be able to access their data with one tap.



#### 8.1.1

# ADDING THE PATIENT

#### Step 1

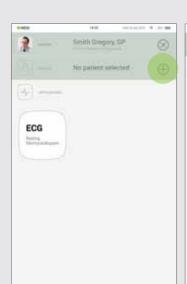
On your home screen, press the  $\bigoplus$  button in the Patient tab.

## Step 2

Fill out required fields (Name, Surname, Date of Birth and Gender) and any additional information regarding the patient.

#### Step 3

Save the patient by pressing the  $\bigcirc$  button.







#### 8.1.2

# SELECTING THE PATIENT

## Step 1

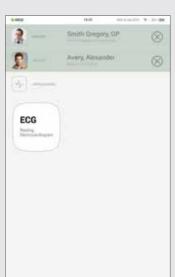
Press Patient tab button on your home screen.

#### Step 2

Use search bar (1) or scroll (2) to the patient who is having the ECG recorded.

## Step 3

Select the patient.







# 8.1.3

# IMPORT EXISTING PATIENT LIST

To import an existing patient list from your EHR please visit MESI mRECORDS (mrecods.mesimedical.com) and log-in to your account. Once logged in access your profile settings and follow the instructions under the category: "Connectivity".

Patients can also be imported directly from patient screen by clicking "Import patients" button.

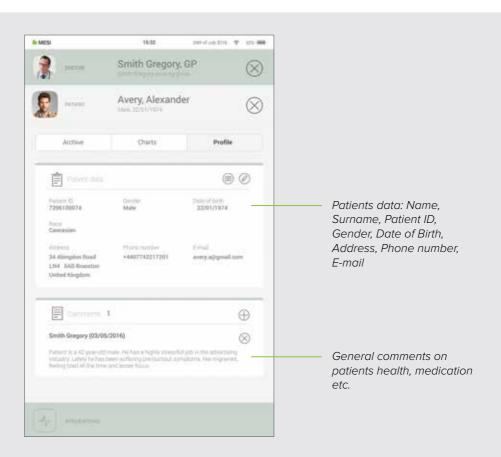
#### 8.2 PATIENT PROFILE

You can edit your patient's data in the Patient's tab by choosing "Profile". Name & surname, insurance ID, date of birth, gender and race – are all required.

If needed, their home address, telephone number and e-mail address can be added to their profile.

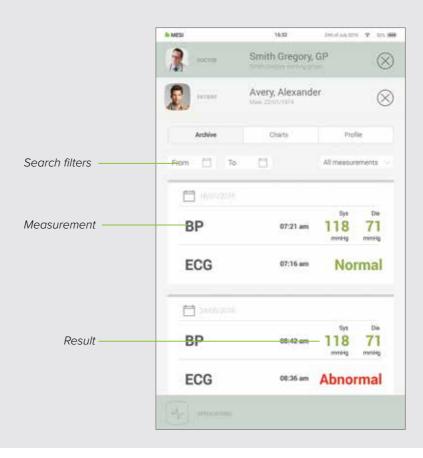
#### NOTE

Deleting a patient is only possible on mrecords.mesimedical.com.



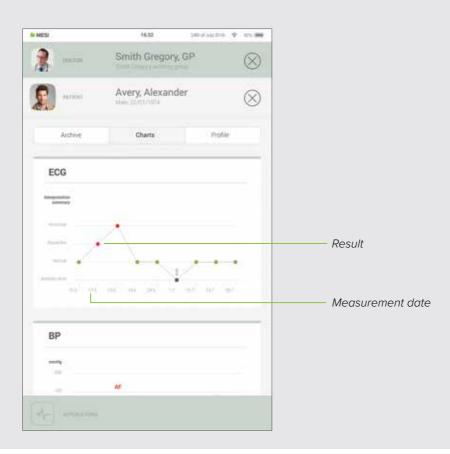
# 8.3 PATIENT ARCHIVE

Similarly to the doctor's, a patient's profile also holds an archive of their measurements, chronologically arranged with the newest measurements at the top.



### **8.4 PATIENT CHARTS**

You can check all of your patient measurements in "Charts". Every measurement is put conveniently into a chart which shows trends in the patients results.



MANAGING USERS

#### 9.1 ADDING & REMOVING USERS

The first account that is registered on the tablet (or the first user) holds the administrative rights. Under administrator profile settings there is another category called "Users", where users can be removed from the MESI mTABLET (accounts are removed but not deleted)

A removed user can still access all his data through MESI mRECORDS and list themselves on the tablet by logging in again on the Lock screen.

#### 9.2 PATIENT DATA SHARING PRIVILEGES

The MESI diagnostic system is built around real-life working relationships. The doctor is the owner of the working group and can share his/her patient data with the nurses added to his/her working group.

If you log in as a nurse, you first need to choose in which working group you want to perform measurements. Every member of a working group has access to the same data - patients, measurements, charts.

10 MESI mTABLET MAINTENANCE

#### 10.1 CHARGING THE BATTERY AND STORING

If you wish to use the device on battery power, you must ensure that the battery is charged regularly. Between use the MESI mTABLET UNIT should be placed on the MESI mTABLET WI-FI DOCKING UNIT to charge its battery.

If the capacity of the battery is significantly decreased after a certain period of intensive use, the battery is most likely worn out and you should contact your dealer or the manufacturer about replacing the battery.

When the device is charging the display on MESI mTABLET UNIT will be displaying charging status.

### 10.2 CLEANING INSTRUCTIONS

Cleaning the device regularly with a soft, dry or slightly damp cloth – is recommended. Do not use aggressive cleaning agents, volatile liquids or excessive force when cleaning the device.

#### 10.3 PRODUCT LIFE AND STORAGE

If correctly used and maintained the device will have a minimum service life of 5 years. The device can be stored under suitable conditions for a maximum of 5 years. When using the device after storage, we recommend that you carry out a thorough maintenance check on the device

Before using the device for the first time, read the user manual carefully and follow the recommendations and suggestions.



MESI mTABLET users must be adequately trained to use the device. Before first use of the device, users must carefully read the entire usage instructions and follow the instructions for use of the connected equipment.



MESI mTABLET complies with EMC regulations for medical products, which gives details about protection against emissions and electrical interference. However, special care must be exercised when the unit is used with high frequency equipment.



Use only accessories and other parts recommended or supplied by MESI. Use of other than recommended or supplied parts may result in injury, inaccurate information and/ or damage to the unit.



This product is not designed for sterile use.



Do not use this unit in areas where there is any danger of explosion or the presence of flammable gases such as anaesthetic agents.



Use only real patient data when creating new profiles, as certain patient data (date of birth, sex, race) impact the performance of different automated interpretive algorithms.

11
GENERAL WARNING

#### 11.1 MAINTENANCE



If the device is used or stored outside the specified temperature and air humidity ranges, the accuracy specified within the technical specifications of the device is not quaranteed.



Before cleaning, disconnect from the mains.



Do not use the device when wet. After cleaning the device with a damp cloth, wait for it to dry. Only use the device when it is completely dry.



Do not, under any circumstances, immerse the unit or cable assemblies in liquid.



Only use non-aggressive cleaning agents to clean the device. The device may be wiped with a damp cloth.



Do not use high temperature sterilization processes (such as autoclaving). Do not use e-beam or gamma radiation sterilization.



Make sure that the device does not come into contact with an electrical current while it is being cleaned.



Do not dispose of the device as unsorted municipal waste. Prepare it for recycling or separate waste collection in accordance with Directive 2002/96/EC on scrap electrical and electronic equipment (WEEE).



To prevent electric shock hazards due to current leakage, only use AC/DC power supplies that are compliant with the technical specifications of the device. The AC/DC power supply must be connected to an easily accessible socket (the AC/DC power supply also serves as galvanic isolation).



The AC/DC power supply must be connected to an easily accessible socket (the AC/DC power supply also serves as galvanic isolation).



To prevent electric shock, do not disassemble the unit. There are no serviceable parts inside. Refer servicing to qualified personnel only.

#### 11.2 FUNCTIONING OF THE DEVICE



The device must only be operated using battery power if the earth connection is suspect or if the mains lead is damaged or suspected of being damaged.



Protect the device from moisture and liquids and extremely high/low temperatures. Also, protect the device from mechanical stress and do not expose it to direct sunlight, as this may cause the device to not function properly.



Never carry out repairs of any kind yourself. Do not open the device. The device does not contain any parts which can be replaced by the user. Do not alter or adapt the device. If a defect occurs, consult your dealer or distributor.



Important information on electromagnetic compatibility (EMC). As the number of electronic devices such as computers and mobile phones in the room increases, medical devices can become sensitive to the electromagnetic influences of other devices. Electromagnetic interference can cause medical devices to malfunction, which can potentially lead to dangerous situations. Furthermore, medical devices must not interfere with other devices. The IEC/EN 60601-1-2 standard was introduced due to the necessity to establish electromagnetic compatibility (EMC) requirements for the prevention of dangerous situations in the use of medical devices. The standard defines the level of resistance to electromagnetic interference for medical devices. This medical device is compliant with the IEC/EN 60601-1-2 standard in terms of resistance to electromagnetic interference and electromagnetic emissions. Nevertheless, do not use mobile phones and similar devices which create strong electromagnetic fields in the vicinity of the device. This can cause the device to malfunction, which can potentially cause a dangerous situation.



Portable RF communications equipment including peripherals such as antenna cables and external antennas should be used no closer than 30 cm (12 inches) to any part of the device including cables specified by the manufacturer. Otherwise degradation of the performance of this equipment could result.



Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment should be observed to verify that they are operating normally.

12
WARRANTY INFORMATION

A warranty period applies to the device, starting from the date of purchase (delivery date shown on the invoice). Warranty claims will only be valid if accompanied by the purchase receipt.

More details about the warranty can be found in the warranty booklet attached to the instructions for use provided.

# 12.1 EXTENDED WARRANTY AND OTHER MESIcare SERVICES

MESIcare is a service which ensures the flawless operation of the device and all of its accessories (patient cables, AC/DC power supply, stand) for the duration of the warranty period. In addition to flawless operation, the service also includes annual calibrations, the immediate replacement of damaged or destroyed components and software upgrades.

# MESIcare services

Extension of the basic warranty for an agreed period.

immediate replacement of damaged or destroyed components which are not included in the basic warranty.

Annual calibrations for an agreed period.

Software upgrades.

Contact your dealer or the manufacturer for more information

The provisions of the Council Directive 93/42/EEC concerning medical devices were complied with. The standards in the table below were complied with.

Reference number	Description
EN 60601-1:2006/ A1:2013	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
EN 60601-1-2:2015	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
EN 60601-1-6:2010/ A1:2015	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
EN 62304:2006/ A1:2015	Medical device software - Software life-cycle processes
EN 62366:2008	Medical devices - Application of usability engineering to medical devices
EN 980:2008	Symbols for use in the labelling of medical devices
EN 303 446-1:2017	Electromagnetic Compatibility (EMC) standard for combined and/or integrated radio and non-radio equipment; Part 1: Specific conditions for equipment in residential locations.
EN ISO 14971:2012	Medical devices – Application of risk management to medical devices
EN ISO 13485:2012/ AC:2012	Medical devices – Quality management systems – Requirements for regulatory purposes

13
STANDARD
COMPLIANCE



The symbols on the labels on the bottom of the device, the packaging and the instructions provide important information about the device. The symbols are described below.



Separate collection of electrical and electronic equipment, do not dispose with domestic waste.



Observe the Operating Manual.



Manufacturer: MESI, development of medical devices, Ltd Leskoškova cesta 11a 1000 Ljubljana, Slovenia

**€ 1304** CE mark



Indication of equipment that include RF transmitters.