BioPot3 Device

Instructions For Use

Sensomedical Labs LTD

Manufacturer:

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Contents

1. BIOPOT3 Kit 5
1.1 BIOPOT VERSIONS, PRODUCT FAMILY DESCRIPTION 5
1.2 KIT 5
1.3 BIOPOT: 6
1.3 Charging 6
1.4 Powering 7
1.5 Reference and ground switch 7
1.6 BIOPOT CAP 8
1.7 BIOPOT Name Description 8
1.8 BIOPOT LEDs mode 9
2. Android Application 9
2.1 Features or functional requirements 9
2.2 Installation 9
2.3 Launch application & set permissions 11
2.4 Patient, Session & user details 12
2.5 Connect to BIOPOT 17
2.6 Main screen 19
2.6.1. BIOPOT information: 20
2.6.2. Tool bar: 20
2.6.3. EEG/EMG channels: 22
2.6.4. Accelerometer channels 23
2.6.5. Recording files 23
2.7 Channels Zoom & Montage 23
2.8 Impedance measurement 26
2.9 Additional settings, filters and device readout 26
2.10 Recording data 28
2.10.1. Recording data types 30
2.12.1. Connection to BIOPOT was lost 35
3. BLE Protocol 36
4.1 Characteristics 1 - [Read & Write] 36
4.2 Characteristics 2 - [Read & Write] 38
4.3 Characteristics 3 - [Read & Write] 38
4.4 Characteristics 4 [Notify] 39
4.5 Characteristics 5 [Read & Write] 40

4.6 Characteristics 6 [Notify] 41
4. Requirements 42
5.1. Temperature and Humidity: 42
5.2. The BIOPOT3 V2 shall withstand during operation the following conditions: Temp: 0°C – 40°C and Humidity: 20 -90 % 42
5.3. The BIOPOT3 V2 shall withstand during storage the following conditions: Temp: -10°C – 50°C and Humidity: 20 -90 % 42
5.4. Atmospheric Pressure (kPa) 42
5.5. 42
5.6. Materials in contact with the patient or operator: 42
All substances in contact with the skin are typical medical grade plastics and other biocompatible materials which are commonly used in adhesive electrode systems. 42
5.7. Cleaning and disinfection: 42
5.8. Waste product 42
6. Instructions for use 43
6.1. The device may be used by a researcher/professional in a specialized lab for data acquisition. It can also be used by a home user together with a mobile device or PC for data acquisition. 43
6.2. The device is used by a researcher/professional in a specialized clinical lab for data acquisition. It can also be used by a home user together with a mobile device or PC for data acquisition. 43
6.3. The primary user may need to collect biopotential data, bioimpedance data, accelerometer data, or some combination of all. Data collection requirements may scale up over time (i.e. start basic with increased functionality with project progress) 43
6.4. The primary user may be working on their own software, or they may require just a basic application for data collection only with no software development required. BOTH potential requirements must be covered: easy software for data collection without development, SDK for customized software development. 43
6.5. The primary user likely requires flexibility in the sensor part of the project, and may need to use a basic off-the-shelf option, or may be working on their own sensors. Multiple options may be required in a single customer/project. 43
6.6. The secondary user is a student that requires an easy platform for simple data collection for basic research purposes. This does not require programming. 43
6.7. The secondary user requires basic software and hardware interfacing and may be encouraged to do their own software development. SDK with examples would be useful, compatibility with MatLab or Labview, and or Python required. 43
6.8. In order to start using the device, the operator need to attach the electrode sticker to the device (as described in section 1.6). To attach the electrode to the patient, see "Electrode patch user manual". After the preparation you can start recording data (as described in section 2.10). 43
6.9. Hazards related to use of the medical device 43
6.10. General: 44

6.11. Technical Description: 45
7. General information 45
7.1. Manufacturer: Senso Medical LTD 45
7.2. Costumer: Senso Medical Labs Ltd. 45
7.3. Costumer's Address: 45
7.4. Equipment Model No.: BP-30-08-00061 45
7.5. Equipment Serial No.: 61 45
7.6. For labels explanation look into Biopot labels file. 45
8. List of accessories, detachable parts, and materials 45
9. Declaration – electromagnetic emissions 46
10. Declaration – electromagnetic immunity 46
11. Recommended separation distances between portable and mobile RF communications equipment and the BioPot SYSTEM 48
12. Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment 48

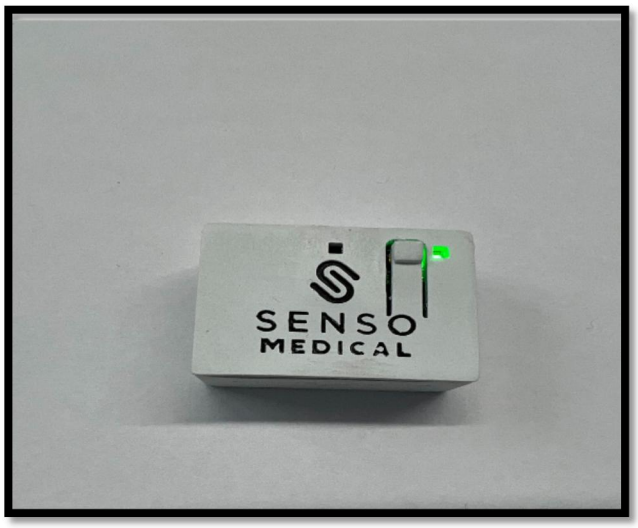
1. BIOPOT3 Kit

1.1 BIOPOT VERSIONS, PRODUCT FAMILY DESCRIPTION

1.2 KIT

KIT includes BIOPOT3 device, docking charging station, and USB-C charging cable:

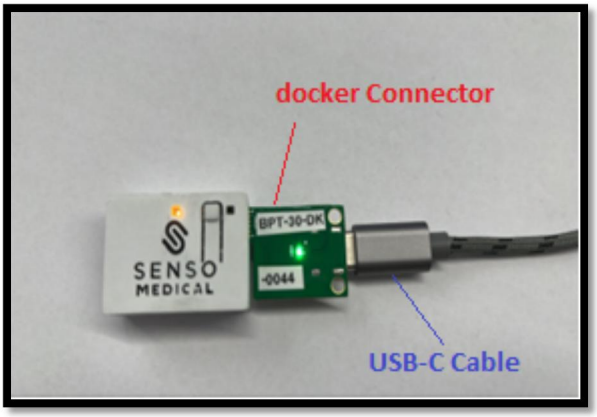
1.3 BIOPOT:



1.3 Charging

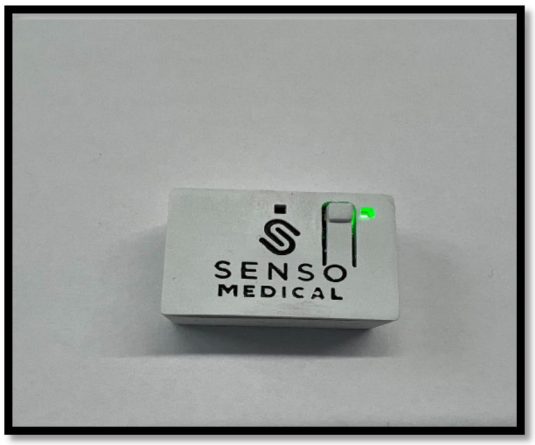
You need to enter the docking station as picture bellow connected to USB cable:

When power cable is connected the yellow LED should turn on and docking station green LED on:



1.4 Powering

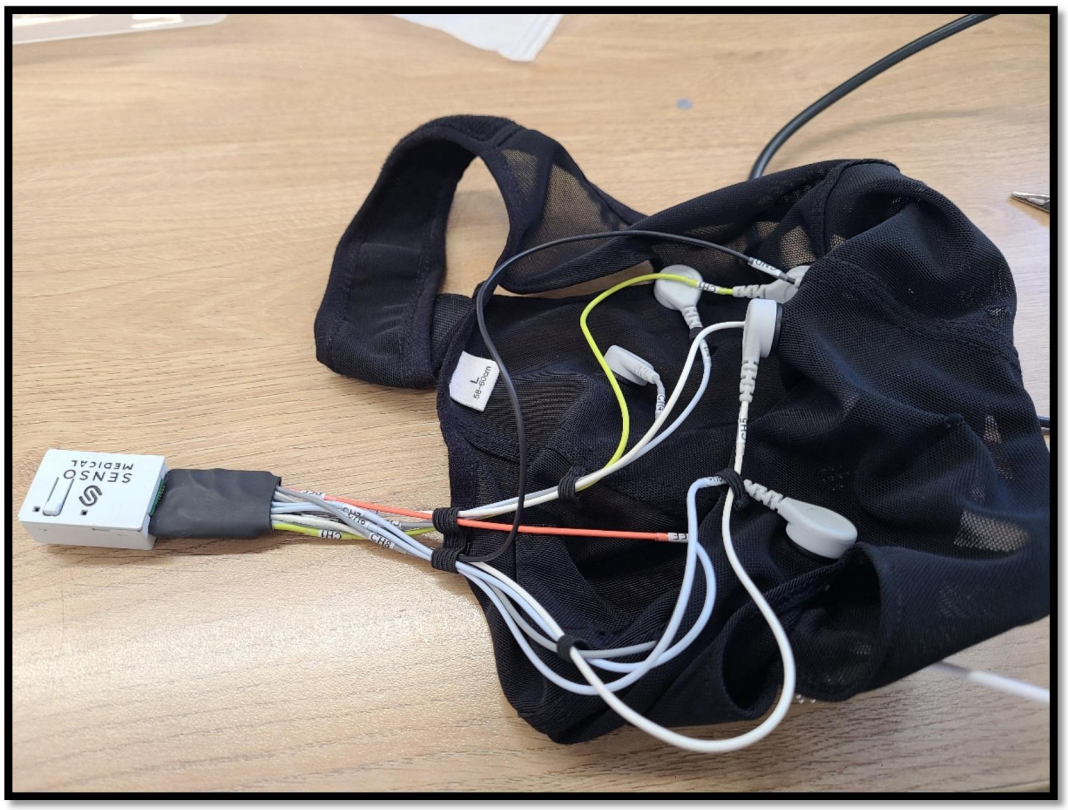
- Short press on power button turns BIOPOT ON, BIOPOT green LED should start blinking.
- Long press on power button turns BIOPOT OFF (close to 1.5 seconds).



1.5 Reference and ground switch

- If switch to the right side that means reference and ground are shorted.
- If switch to the left side that means reference and ground are NOT shorted.

1.6 BIOPOT CAP



1.7 BIOPOT Name Description

Index	Description	Values
2-9	"SML BIO" [8 chars]	Unchangeable
10-11	Channels number [2 chars]	08/16/19
12	Accelerometer [1 char]	X- without accelerometer A-with accelerometer
13	Bio-impedance [1 char]	X- without bioimpedance I-with bioimpedance
14-19	Serial number [4 chars]	Serial number. Value from 0 to 65535

Example: SML BIO 08AX00005: This means, that the EEG device is having 8channels with accelerometer and no Bio-impedance function with serial number "00005"

1.8 BIOPOT LEDs mode

		Green	Blue	Red	Time On [mSec]	Time Off [mSec]
Advertising	Not connected to Bluetooth.	Flashing	Off	Off	100	1500
Idle	while BIOPOT3 connected to Bluetooth and there is no data acquisition.	Off	Flashing	Off	100	100
Data acquisition	while BIOPOT3 acquiring data (also connected to Bluetooth).	Off	Flashing	Off	100	500
impedance	In impedance measurement	Flashing	Flashing	Off	100	500
Low Battery	Low battery while Idle or Acquiring data	Off	Off	Flashing	Same as data acquisition or Idle	

2. Android Application

2.1 Features or functional requirements

Android device:

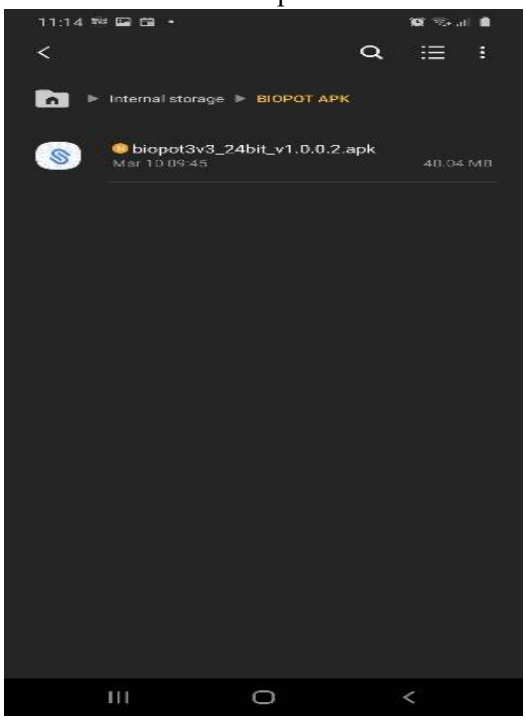
- Android device OS version 6.1 and above.
- Android device Bluetooth version 4.2 and above.

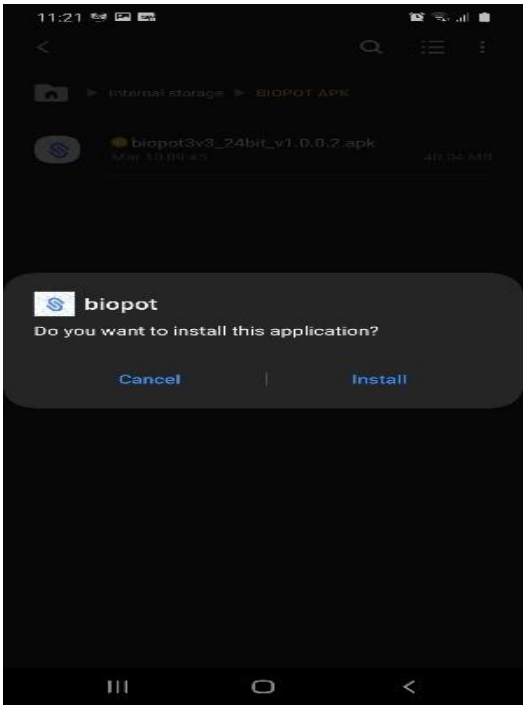
2.2 Installation

In order to install android application, follow these steps:

- Download APK file that you get from SensoMedical Labs.
- If you already have BIOPOT3 application on your device, you need to uninstall it.
- Move APK file to your phone or tablet.

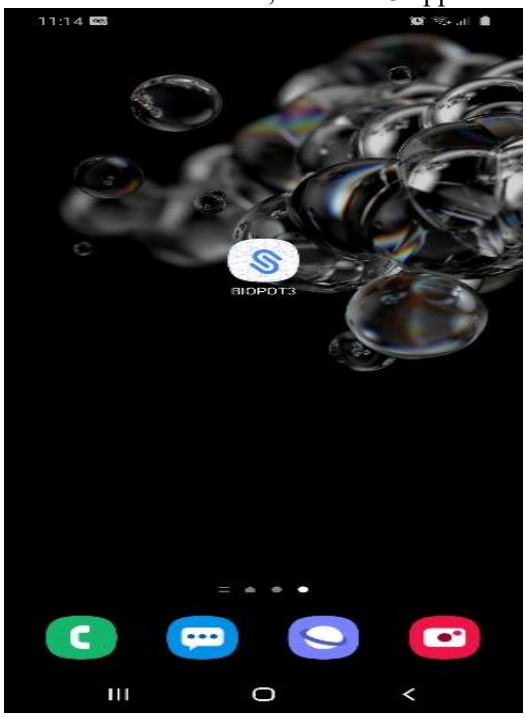
- Location APK file and press on it





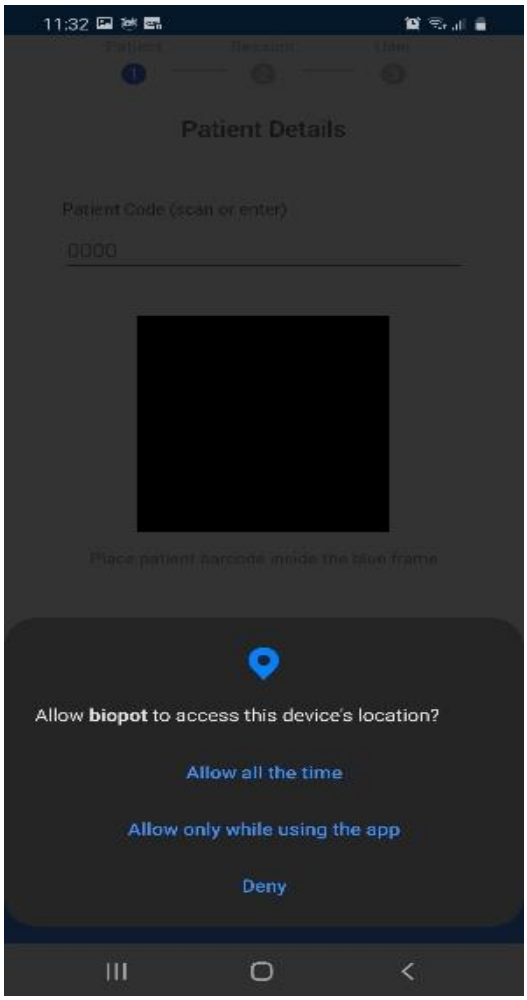
press “install” and follow installation process till installation done.

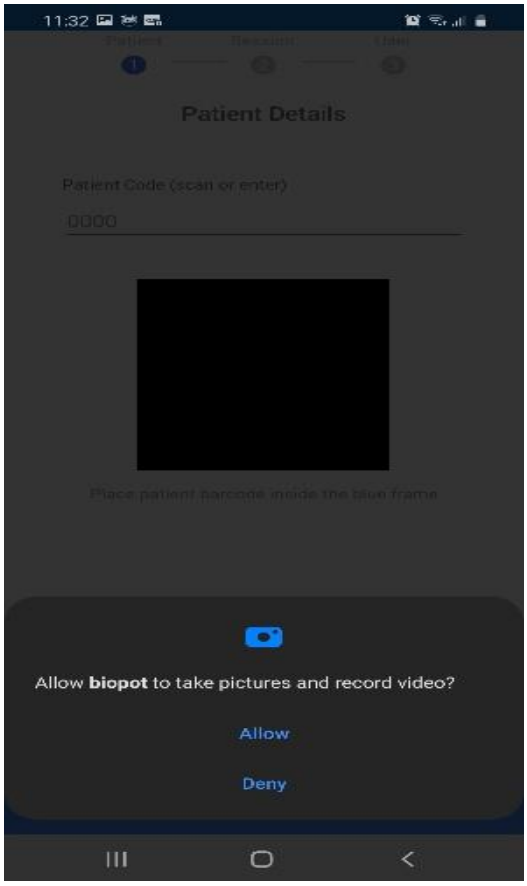
- After installation done, BIOPOT3 application should appear on your home screen:

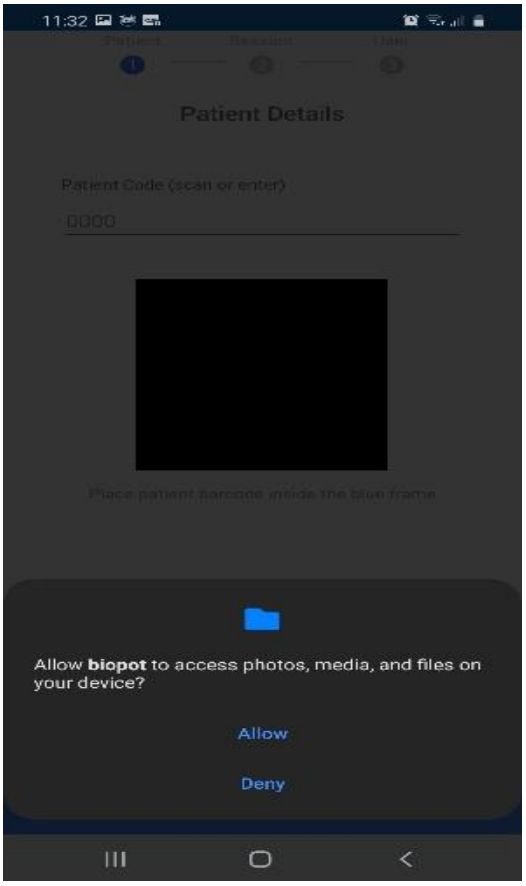


2.3 Launch application & set permissions

Press on BIOPOT3 icon to open application, on first application launch you need to allow android permission in order:





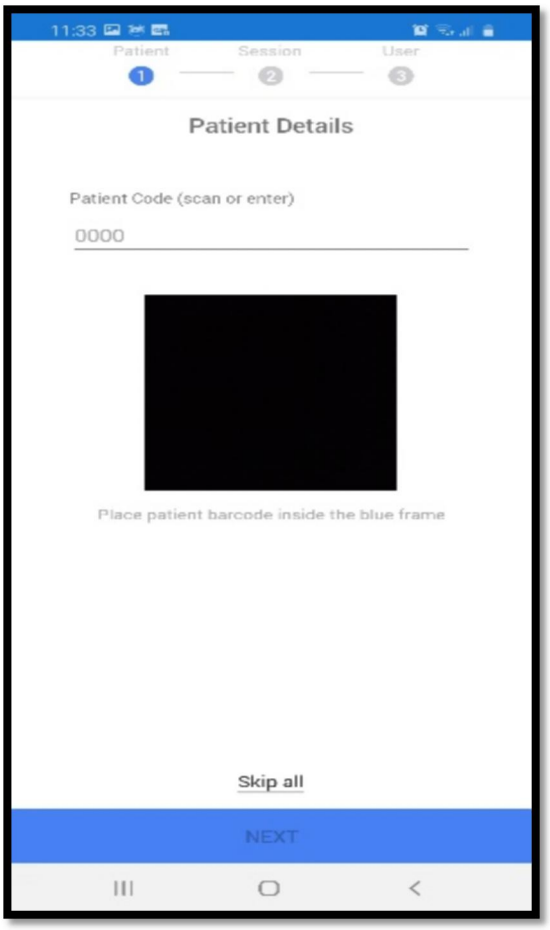


NOTE: make sure that location is Enabled on your android device.

2.4 Patient, Session & user details

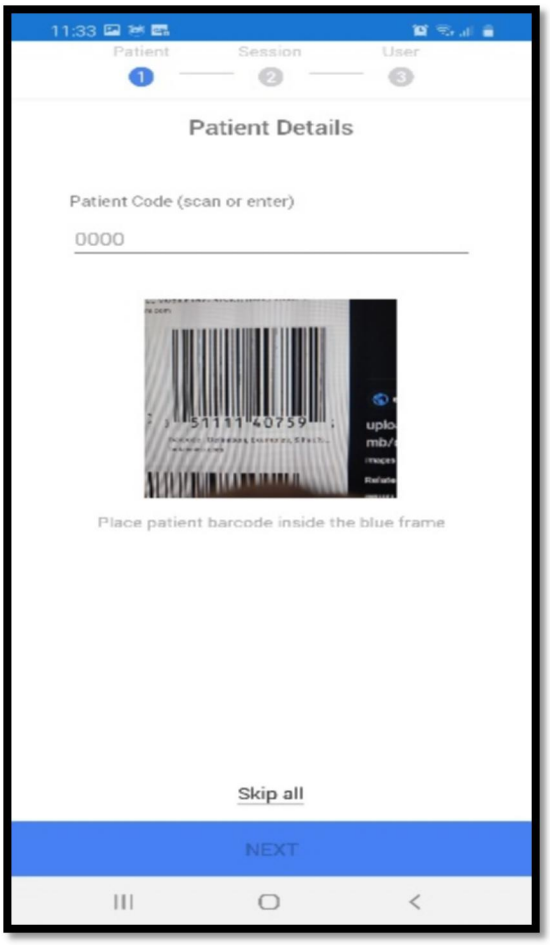
Note: this part can be skipped, press “Skip all” and default parameters will be set (as shown below).

This is Patient Details screen:

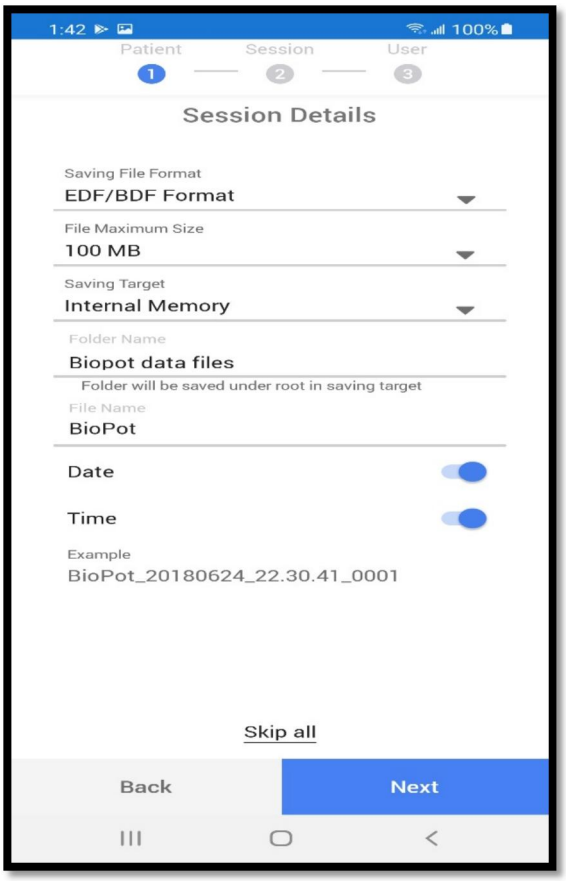


you can Scan patient barcode or enter patient code:

Note: Next button will be disabled if patient code not filled.



Press “Next” to set Session details:



Here you can set BIOPOT recording file location and files name.
Based on example above, recording application files will be on:
phone internal storage >> Biopot data files.
Files name start with BioPot followed by time, date and number of file same as shown in Example.

NOTE: these parameters decide the location of stored files and files names.

Press “Next” to set User Details:

Here you can set user details: Name, ID, Role and Email.

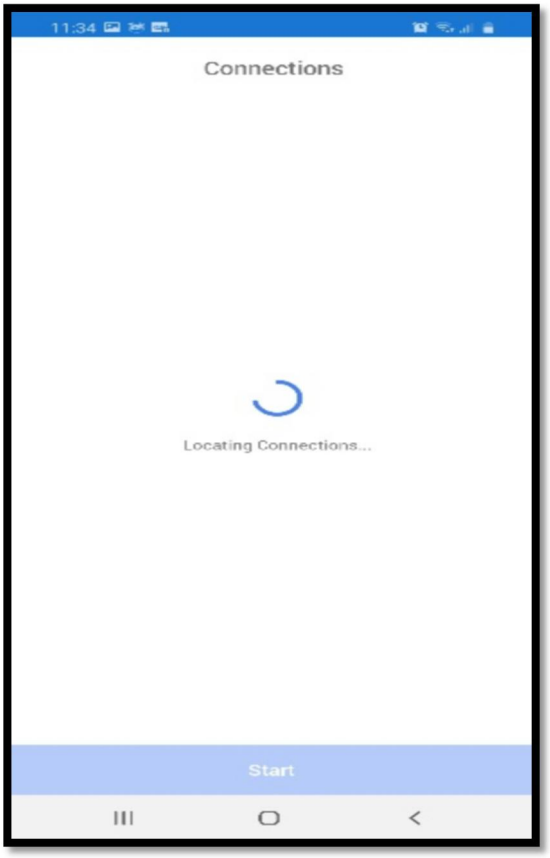
This information will be shown on recording files.

NOTE: this information will be saved on recording text files only.

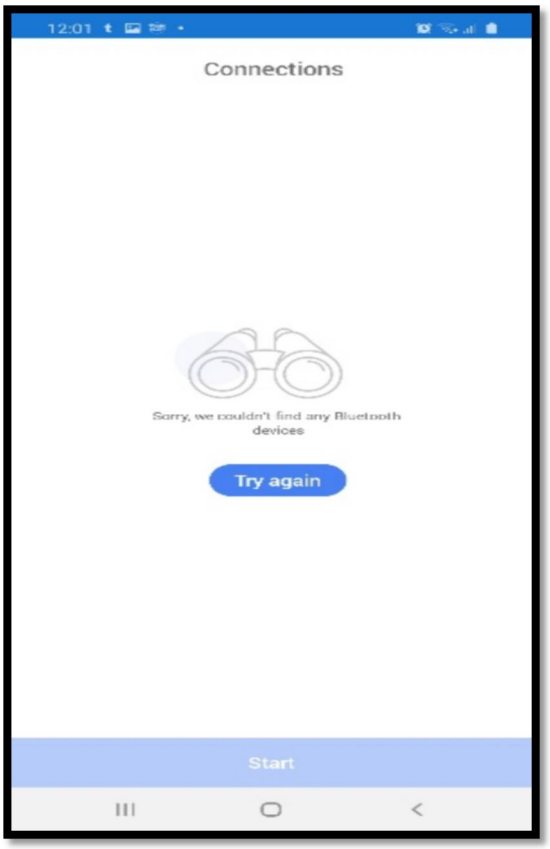
Press “Done” to “Connect to BIOPOT”.

2.5 Connect to BIOPOT

Application locating BIOPOT devices:



If application couldn’t find BIOPOT devices, you shall see this screen:

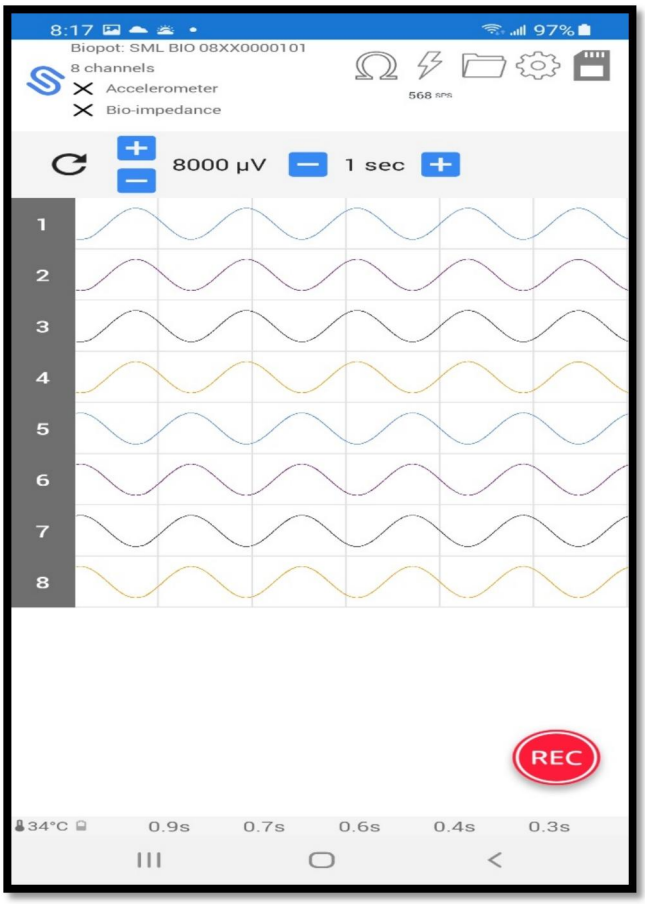


You need to press “Try again” to start location BIOPOT devices again, till you find your BIOPOT device:

If you have more than one device, select the BIOPOT needed to connect and press “Start” Button.

2.6 Main screen

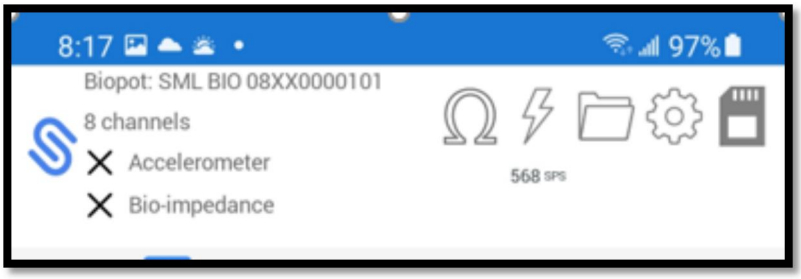
If application succeeds to connect to BIOPOT you should see channels main screen:



Main screen divided to several sections:

2.6.1. BIOPOT information:

BIOPOT information located on the top left on main screen:

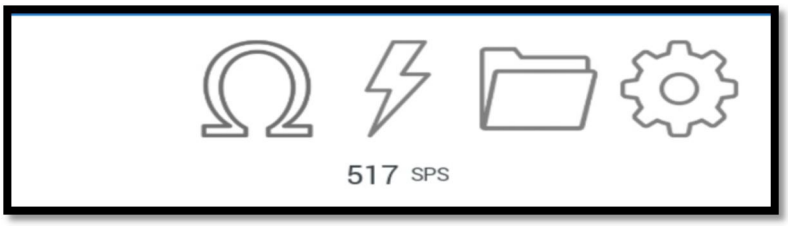


Here you can find the BIOPOT name, EEG/EMG channels number, accelerometer status and Bio-impedance status.

If you press on icon, application navigate to connection screen.

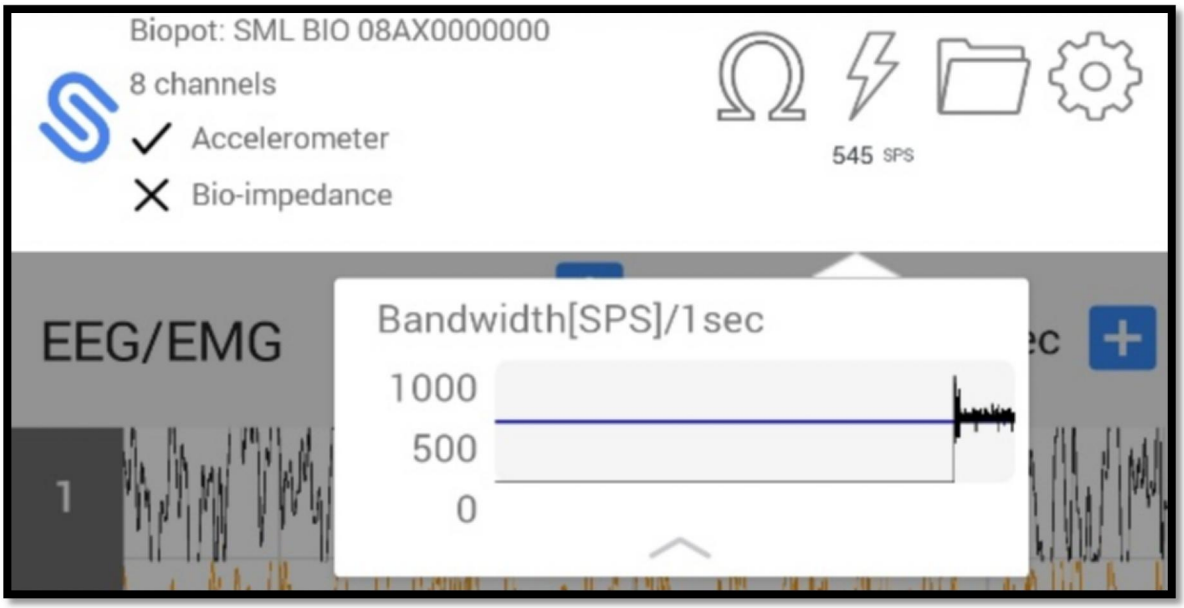
2.6.2. Tool bar:

BIOPOT tool bar location on to right on main screen:



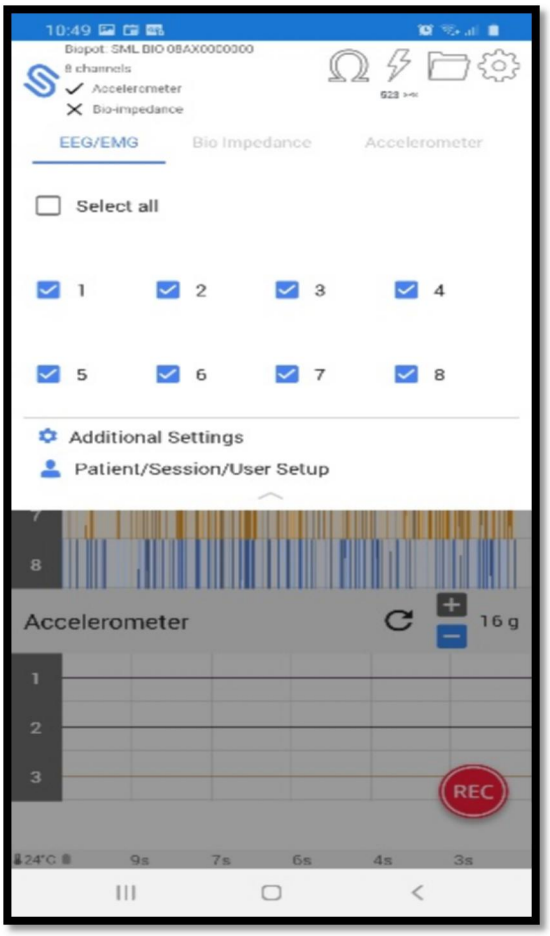
Omega icon navigate to impedance measurement screen.

Flash icon navigates to samples per second's graph:



Folder icon navigates to saved recording files.

Setting icon navigate to:



Here you can set the number of channels you need to see on main screen on each channels types: EEG/EMG, Bio-impedance or Accelerometer.

Additional setting label

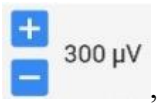
navigates to additional setting screen.

This label

navigate to Patient, Session & user details screen that set before.

2.6.3. EEG/EMG channels:

In EEG/EMG section you should see BIOPOT channels, depends on BIOPOT channels number.

Using 

, you can change charts amplitude values.

Using

, you can change charts period value.

Pressing will reset amplitude to default value 300 micro volt / 10 seconds.

2.6.4. Accelerometer channels

On Accelerometer section you should see BIOPOT accelerometer X, Y, and Z accelerometer axis's if the accelerometer enabled in BIOPOT device.

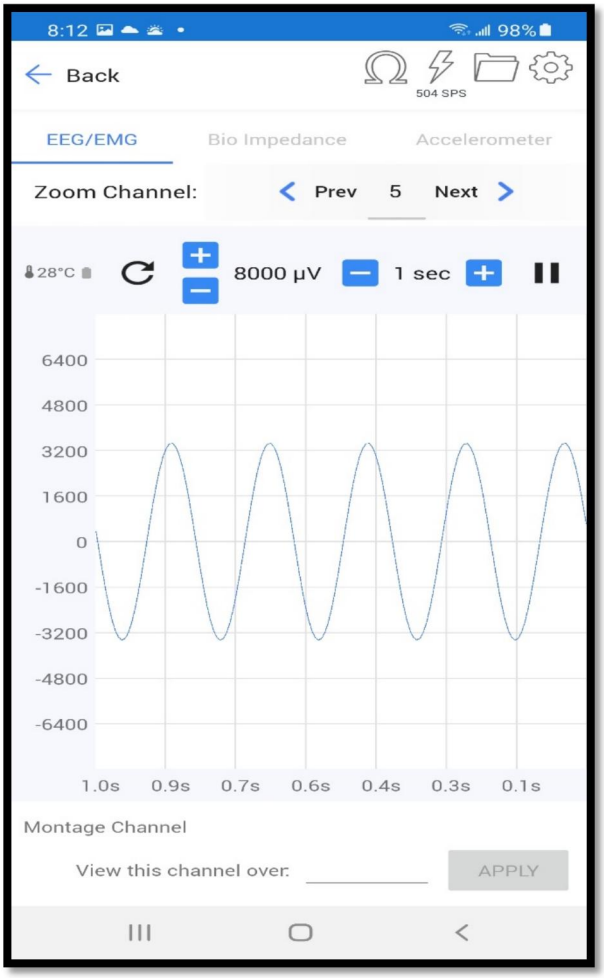
2.6.5. Recording files

Recording button

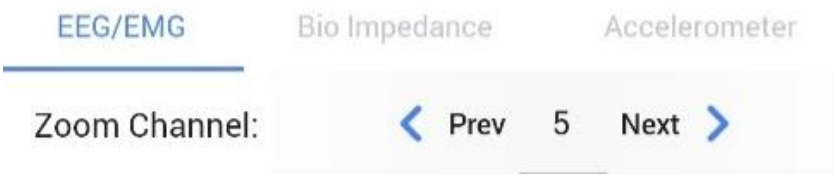
start data recording.

2.7 Channels Zoom & Montage

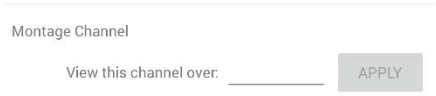
By pressing on channel chart, you will be navigating to chosen "Zoom channel" channel screen:



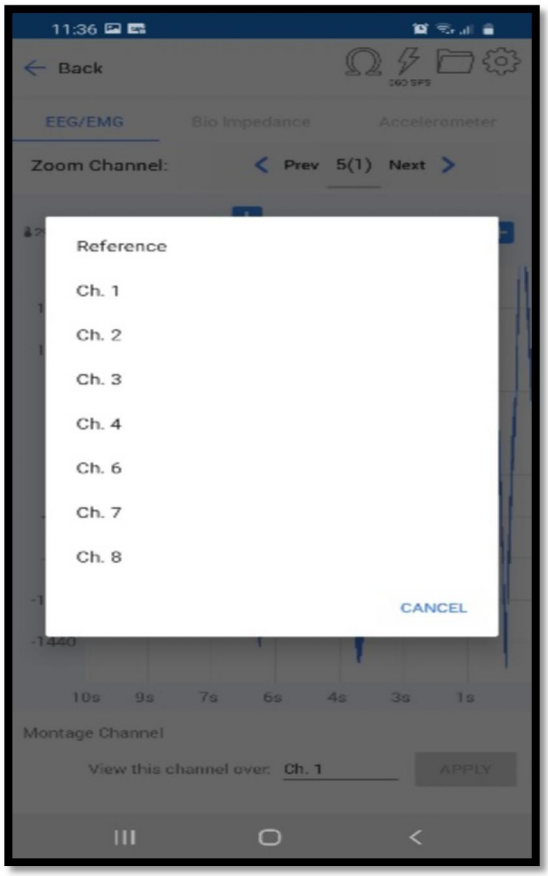
You can switch between channels using “Next” and “Prev” buttons and channels types:

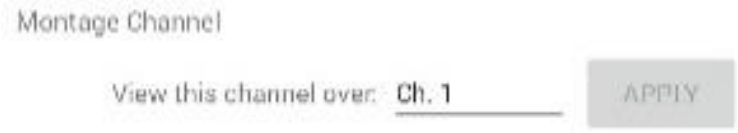


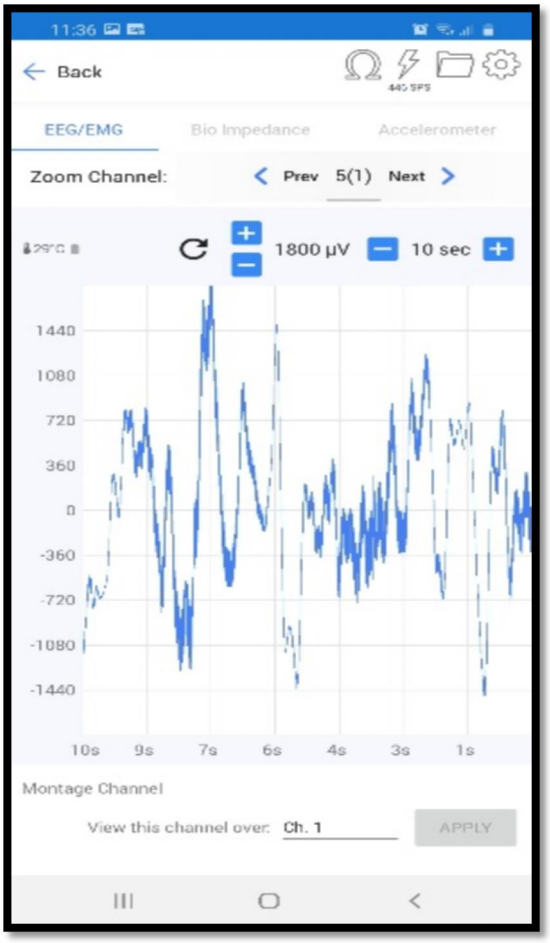
All channels referenced to same referrance/ground, in order to montage channels you need to change referance to wanted channel on the buttom of the zoom channel screen:



After choosing wanted montage channel press “Apply” button to save changes:

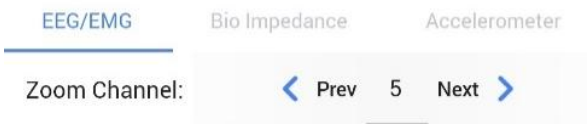




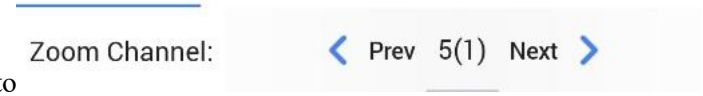


When choosing “montage channel”, channel label will change based to chosen montage channel:

From



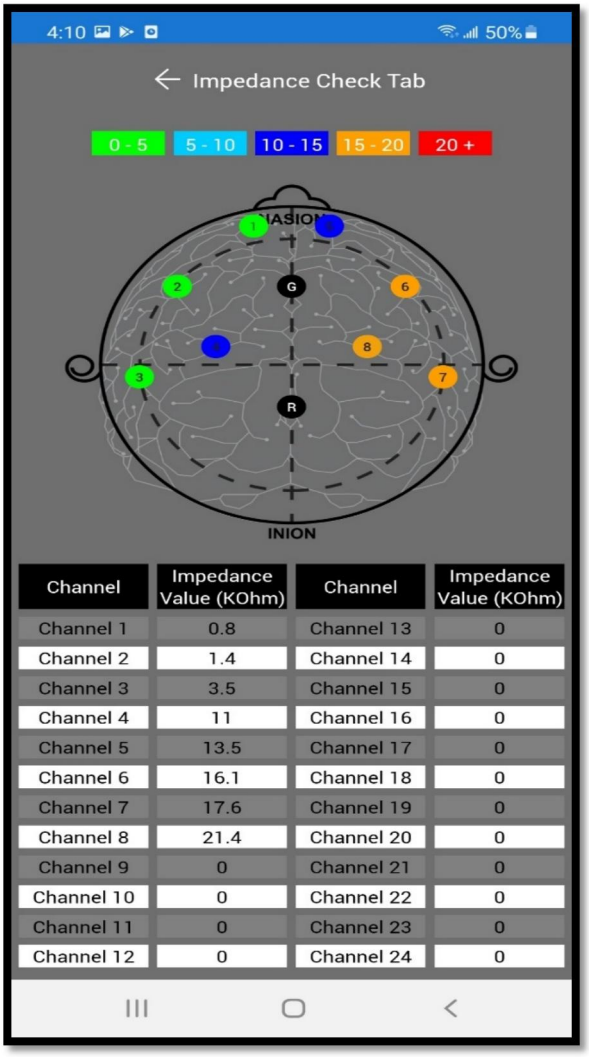
to



that’s mean that 5 is montaged by channel 1.

2.8 Impedance measurement

From main screen, omega icon navigate to impedance screen:



Channel	Impedance Value (KOhm)	Channel	Impedance Value (KOhm)
Channel 1	0.8	Channel 13	0
Channel 2	1.4	Channel 14	0
Channel 3	3.5	Channel 15	0
Channel 4	11	Channel 16	0
Channel 5	13.5	Channel 17	0
Channel 6	16.1	Channel 18	0
Channel 7	17.6	Channel 19	0
Channel 8	21.4	Channel 20	0
Channel 9	0	Channel 21	0
Channel 10	0	Channel 22	0
Channel 11	0	Channel 23	0
Channel 12	0	Channel 24	0

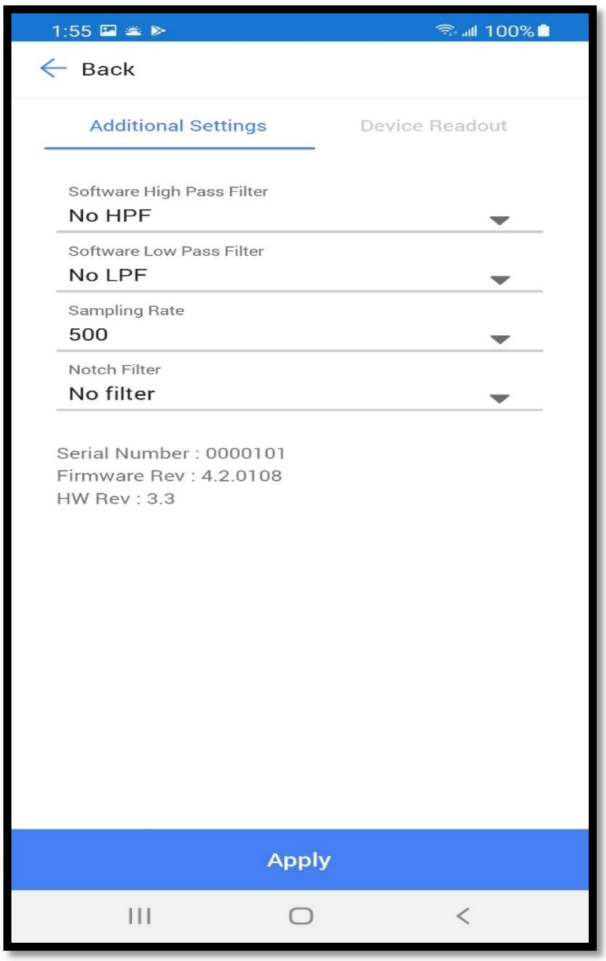
Based on impedance colors and “impedance” you can tell the impedance value/interval.

Based on “channels mapping” you can recognize channel number of impedance measurement.

2.9 Additional settings, filters and device readout

To enter “Additional setting” press on from main screen ,then

Additional Settings on the bottom of screen appears:



Here you can set/change the BIOPOT parameters.

Hardware low pass filter, hardware high pass filter and sampling rate parameters for A2D chip.

Software low pass filter – this filter process after the A2D HW LPF and HPF.

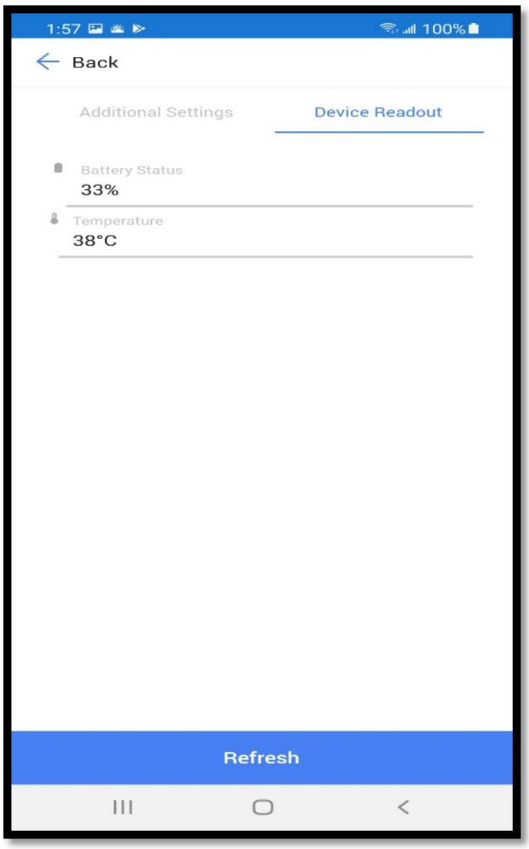
Notch filter – this filter process for removing noise on application channel and not applied on recording data.

Note: recording data filtered by hardware and software filter, notch filter not changed saved data.

After changing additional setting, press “Apply” button to set changes or press back button on the left top “back” button to go to main screen.

“Device Readout” next to “Additional Setting” tab

navigate to “Device Readout screen:



Here you can see BIOPOT battery percentage and BIOPOT temperature

2.10 Recording data

To start recording data, press on from main screen, recording button should change and timer for recording period should appears next to it .

If you need to stop recording, press on button.

You can see recording files from application by pressing Folder icon on main screen:

Extract saved recording files from android device based on “session details” (by default, files saved on: internal Storage >Biopot data files) to:

2.10.1. Recording data types

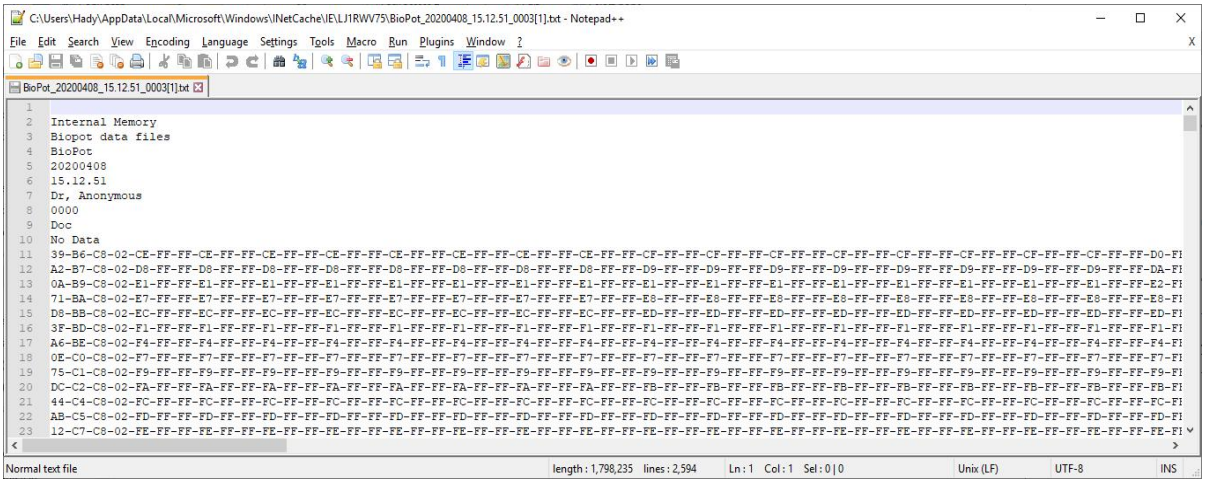
2.10.1.1. EDF/BDF files

Based on BIOPOT version, data recording files type changes, BIOPOTs 16bits in EDF and BIOPOTs 24bits in BDF format.

EDF and BDF files can be opened on any EEDF and BDF readers like EEEGLAB and BDF

2.10.1.2. Text files

On the header of the text file you can find user and patient and session details followed by blocks of data:



2.10.1.2.1. Data format

There 7 types of characteristics 4 buffer data, which depends on the number of channels, number of samples per channels, accelerometer and bio impedance, explained in the table below:

Type	BioPot	Data size [bits]	Channel numbers	Samples per channel	Accelerometer	Bio-impedance	Buffer bytes description	Buffer length
1	8	16	8	15	-	-	4 [TS] + 8*15*2	244
2	8	16	8	14	Activated	-	4 [TS] + 8*14*2 + 12[acc]	240
3	8	16	4	28	Activated	Activated on 4 channels	4 [TS] + 4*28*2 + 4[bio] + 12[acc]	244
4	16	16	16	7	-	-	4 [TS] + 16*7*2	228
5	16	16	16	7	Activated	-	4 [TS] + 16*7*2+ 12[acc]	240
6	16	16	12	9	Activated	Activated on 4 channels	4 [TS] + 12*9*2+ 4[bio] +	236

							12[acc]	
7	19	16	19	6	-	-	4 [TS] + 19*6*2	232
8	19	16	19	6	Activated	-	4 [TS] + 19*6*2+ 12[acc]	244
9	19	16	15	7	Activated	Activated on 4 channels	4 [TS] + 15*7*2+ 12[acc]+ 4[bio]	230
10	8	24	8	10	-	-	4 [TS] + 8*10*3	244
11	8	24	8	9	Activated	-	4 [TS] + 8*9*3+ 12[acc]	232

Example of type 5 from table above:

	Start index	**End index**	**index**			**Low/high**
Timestamps	0	3	0	TS0		low
			1	TS1		
			2	TS2		
			3	TS3		high
Sample 1 of 12 channels	4	27	4	S1	CH1	low
			5			high
			6		CH2	low
			7			high
			8		CH3	low
			9			high
			10		CH4	low
			11			high
			12		CH5	low
			13			high
			14		CH6	low
			15			high
			..		…	…
Sample 2 of 12 channels	28	51	same	S2	…	…
….	…	…		…		
Sample 9 of 12 channels	196	219		S9		
Bio-Impedance	220	223	220-221	S1	…	…
			222-223	S2		
Accelerometer	224	225	224	X1	Point 1	low
			225			high
	226	227	226	Y1		low
			227			high
	228	229	228	Z1		low
			229			high

	230	231	230	X2	Point 2	low
			231			high
	232	233	232	Y2		low
			233			high
	234	235	234	Z2		low
			235			high

Example of type 7 from table above:

Timestamps	0	3	0	TS0		low
			1	TS1		
			2	TS2		
			3	TS3		high
Sample 1 of 19 channels	4	41	4	S1	CH1	low
			5			high
			6		CH2	low
			7			high
			8		CH3	low
			9			high
			10		CH4	low
			11			high
			12		CH5	low
			13			high
			14		CH6	low
			15			high
					…	
			40		CH19	low
			41			high
Sample 2 of 19 channels	42	67	same	S2	…	same
Sample 3 of 19 channels	80	79		S3		
Sample 4 of 19channels	118	117		S4		
Sample 5 of 19 channels	156	155		S5		
Sample 6 of 19 channels	194	231		S6		
Accelerometer	232	233	232	X1	Point 1	low
			233			high
	196	235	234	Y1		low
			235			high
	23	237	236	Z1		low
			237			high
	238	239	238	X2	Point 2	low
			239			high
	240	241	240	Y2		low
			241			high
	242	243	242	Z2		low

			243			high

Example of type 11 from table above:

	Start index	**End index**	**index**			**Low/high**
Timestamps	0	3	0	TS0		low
			1	TS1		
			2	TS2		
			3	TS3		high
Sample 1 of 9 channels	4	27	4	S1	CH1	low
			5			
			6			high
			7		CH2	low
			8			
			9			high
			10		CH3	low
			11			
			12			high
			13		CH4	low
			14			
			15			high
			16		CH5	low
			17			
			18			high
			19		CH6	low
			20			
			21			high
			22		CH7	low
			23			
			24			high
			25		CH8	low
			26			
			27			high
Sample 2 of 9 channels	28	51	Same	S2	…	…
….				…		
Sample 9 of 9 channels	196	219		S9		
Accelerometer	220	221	220	X1	Point 1	low
			221			high
	222	223	222	Y1		low
			223			high
	224	225	224	Z1		low
			225			high
	226	227	230	X2	Point 2	low
			231			high
	228	229	232	Y2		low
			233			high
	230	231	234	Z2		low
			235			high

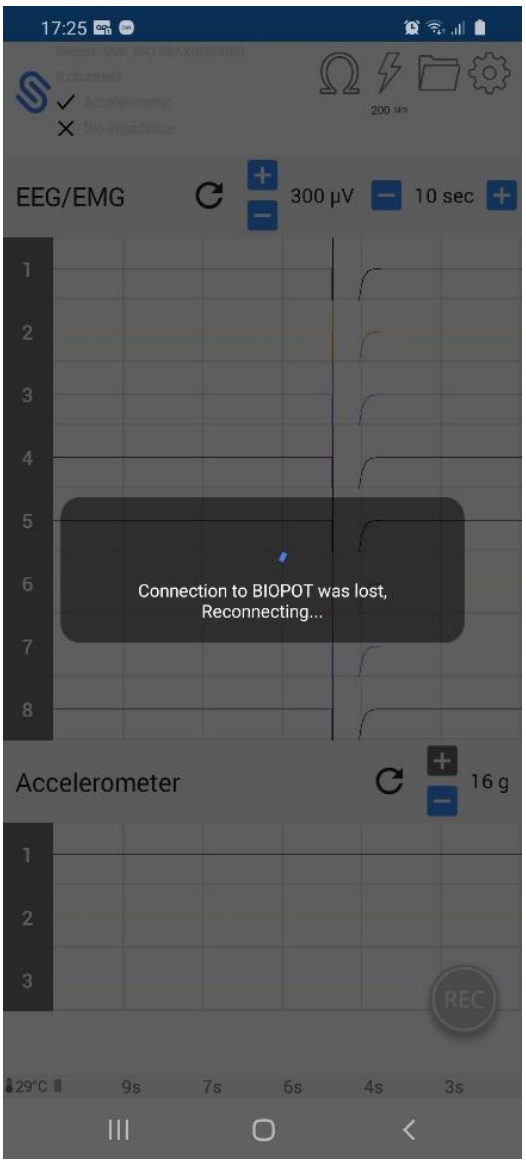
General format:

Data start with 4 bytes of timestamps followed by A2d data sample by sample for all channels based on number of samples followed by accelerometer data if accelerometer is enable.

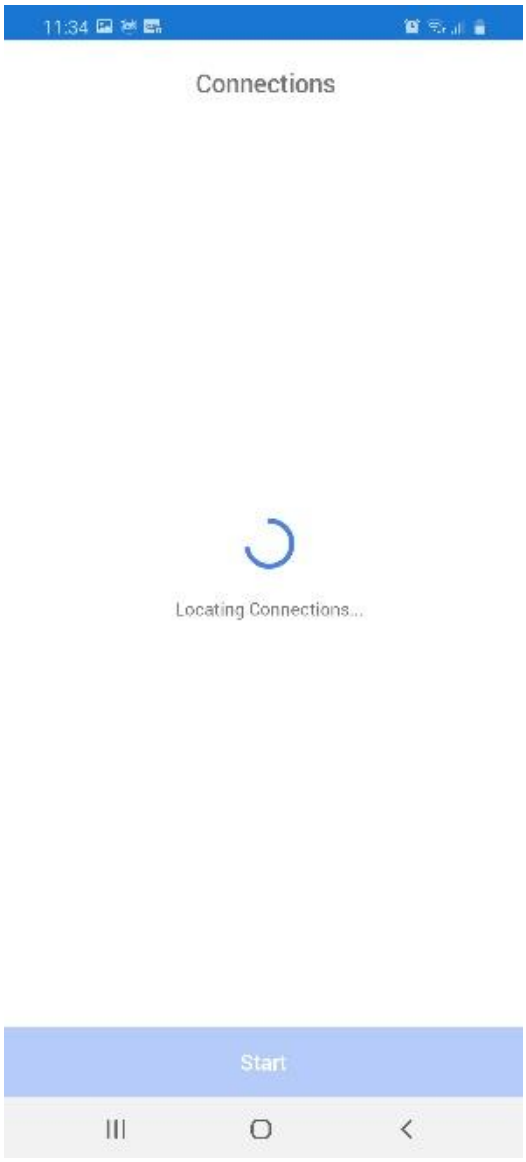
NOTES:

- all data saved in little endian format (low to high).
- Sample size is 2 bytes (BIOPOT 16bits) OR 3 bytes (BIOPOT 24bits).
- Number of samples calculated based on BIOPOT sample size and if accelerometer enabled/disabled.
- See BLE Protocol characteristic 1.

2.12.1. Connection to BIOPOT was lost



This message appears when BIOPOT disconnected, application stuck in “locating connection” screen in order to locate same BIOPOT and automatically connect it.



In order to exit this screen, press the back button on the left/right bottom device bar.

3. BLE Protocol

BLE data protocol:

4.1 Characteristics 1 - [Read & Write]

Byte Index		
0-4	Registers - Reserved	Reserved
5	Channels number	8

6	Accelerometer mode/status	0 – Accelerometer off 1 – 2g dynamically selectable 2 – 4g dynamically selectable 3 – 8g dynamically selectable 4 – 16g dynamically selectable
7	Bio impedance mode/status	0- off 1- on
8	External memory mode/status	0- off 1- on
9	Number of samples per channels	This value changed based on bytes 5,6 and 7, which equal to:
	$\#samples_{channel} = \frac{244 - 4[ts] - 4 * hasBioImp - 12 * hasAccelerometer}{\#channels * SampleDataSize_{InBytes}}$	
10	BIOPOT data size	0x18 – 24 bits Else -16 bits
11	Sync Enable Not implemented	1 – Sync Enabled (in the test device when this byte is written as 1 a sync simulation will start after 3 seconds) 0 – Sync disabled
12	Serial number	BIOPOT3 serial number
13		
14		
15		

4.2 Characteristics 2 - [Read & Write]

Index		
0	BIOPOT data acquisition	0 – Turn data acquisition off 1 - Turn data acquisition on 2- Read external Memory 3- Erase External Memory

4.3 Characteristics 3 - [Read & Write]

Index		
0	Impedance measurement	0.off 1.On 2.Offset Calibration 3.Impedance Calibration
1	Reserved: Bioimpedance	0 – off 1 – on
2	Reserved	Reserved
3-22	Impedance values	20 impedance values in 100Ω resolution. Byte for each channel.

4.4 Characteristics 4 [Notify]

There 7 types of characteristics 4 buffer data, which depends on the number of channels, number of samples per channels, accelerometer and bio impedance, explained in the table below:

Type	BioPot	Data size [bits]	Channel numbers	Samples per channel	Accelerometer	Bio-impedance	Buffer bytes description	Buffer length
1	8	16	8	15	-	-	4 [TS] + 8*15*2	244
2	8	16	8	14	Activated	-	4 [TS] + 8*14*2 + 12[acc]	240
3	8	16	4	28	Activated	Activated on 4 channels	4 [TS] + 4*28*2 + 4[bio] + 12[acc]	244
4	16	16	16	7	-	-	4 [TS] + 16*7*2	228
5	16	16	16	7	Activated	-	4 [TS] + 16*7*2+ 12[acc]	240
6	16	16	12	9	Activated	Activated on 4 channels	4 [TS] + 12*9*2+ 4[bio] + 12[acc]	236
7	19	16	19	6	-	-	4 [TS] + 19*6*2	232
8	19	16	19	6	Activated	-	4 [TS] + 19*6*2+ 12[acc]	244
9	19	16	15	7	Activated	Activated on 4 channels	4 [TS] + 15*7*2+ 12[acc]+ 4[bio]	230
10	8	24	8	10	-	-	4 [TS] + 8*10*3	244
11	8	24	8	9	Activated	-	4 [TS] + 8*9*3+ 12[acc]	232

4.5 Characteristics 5 [Read & Write]

<table>
<tr><td>Index</td><td></td><td></td></tr>
<tr><td>0</td><td rowspan="4">16bits:
Channels off/on.
24bits
Not used</td><td>Bit [32,31, 30…...25]</td></tr>
<tr><td>1</td><td>Bit [24,23, 22…...17]</td></tr>
<tr><td>2</td><td>Bit [16,15, 14…...9]</td></tr>
<tr><td>3</td><td>Bit [8,7,6,5, 4...…1]</td></tr>
<tr><td>4</td><td>Not used</td><td></td></tr>
<tr><td>5</td><td>24bits: SW High pass filter</td><td>
<table>
<tr><th>Index.</th><th>Cutoff [Hz]</th><th>Index.</th><th>Cutoff [Hz]</th></tr>
<tr><td>0</td><td>No HPF</td><td>12</td><td>15</td></tr>
<tr><td>1</td><td>0.1</td><td>13</td><td>20</td></tr>
<tr><td>2</td><td>0.25</td><td>14</td><td>25</td></tr>
<tr><td>3</td><td>0.3</td><td>15</td><td>30</td></tr>
<tr><td>4</td><td>0.5</td><td>16</td><td>50</td></tr>
<tr><td>5</td><td>1</td><td>17</td><td>75</td></tr>
<tr><td>6</td><td>2</td><td>18</td><td>100</td></tr>
<tr><td>7</td><td>2.5</td><td>19</td><td>150</td></tr>
<tr><td>8</td><td>3</td><td>20</td><td>200</td></tr>
<tr><td>9</td><td>5</td><td>21</td><td>250</td></tr>
<tr><td>10</td><td>7.5</td><td>22</td><td>300</td></tr>
<tr><td>11</td><td>10</td><td>23</td><td>500</td></tr>
</table>
</td></tr>
<tr><td>6</td><td rowspan="2">sampling rate</td><td rowspan="2">500[default]/1000/2000</td></tr>
<tr><td>7</td></tr>
<tr><td>8</td><td rowspan="2">Not used</td><td></td></tr>
<tr><td>9</td><td></td></tr>
<tr><td>10</td><td>SW Low pass filter</td><td>
<table>
<tr><th>Index.</th><th>Cutoff</th><th>Index.</th><th>Cutoff</th></tr>
<tr><td>0</td><td>No LPF</td><td></td><td></td></tr>
<tr><td>1</td><td>5hz</td><td>11</td><td>55hz</td></tr>
<tr><td>2</td><td>10hz</td><td>12</td><td>60hz</td></tr>
<tr><td>3</td><td>15hz</td><td>13</td><td>65hz</td></tr>
<tr><td>4</td><td>20hz [Default]</td><td>14</td><td>70hz</td></tr>
<tr><td>5</td><td>25hz</td><td>15</td><td>75hz</td></tr>
<tr><td>6</td><td>30hz</td><td>16</td><td>80hz</td></tr>
<tr><td>7</td><td>35hz</td><td>17</td><td>85hz</td></tr>
<tr><td>8</td><td>40hz</td><td>18</td><td>90hz</td></tr>
<tr><td>9</td><td>45hz</td><td>19</td><td>95hz</td></tr>
<tr><td>10</td><td>50hz</td><td>20</td><td>100hz</td></tr>
</table>
</td></tr>
</table>

4.6 Characteristics 6 [Notify]

0	Reserved	Reserved
1	Reserved	Reserved
2	Reserved	Reserved
3	Read Percentage	0-100
4	Read Finished	0/1
5	Sector Number being erased	0-2048
6		
7	Read Page Number	0-32768
8		
9	Write Page Number	0-32768
10		
11	Reserved	Reserved
12	Battery level value	0-100
13	Temperature value	Current Device temperature
14	Battery charging	0. Battery is charging 1. Battery not charging

4. Requirements

5.1. Temperature and Humidity:

5.2. The BIOPOT3 V2 shall withstand during operation the following conditions: Temp: 0°C – 40°C and Humidity: 20 -90 %

5.3. The BIOPOT3 V2 shall withstand during storage the following conditions: Temp: -10°C – 50°C and Humidity: 20 -90 %

5.4. Atmospheric Pressure (kPa)

5.5.

5.6. Materials in contact with the patient or operator:

All substances in contact with the skin are typical medical grade plastics and other biocompatible materials which are commonly used in adhesive electrode systems.

5.7. Cleaning and disinfection:

The reusable electronic component shall routinely be cleaned and disinfected immediately after they have been used, the cleaning procedure is according to the standard OR cleaning procedure.
The electrode sticker is for one time use so no need for cleaning.

5.8. Waste product

5.8.1. The electrode sticker is for single use, after using it you can throw it to a regular trash can.

5.8.2. The electrical Biopot device and the charger must be taken to an approved household hazardous waste site or battery-recycling center.

6. Instructions for use

6.1. The device may be used by a researcher/professional in a specialized lab for data acquisition. It can also be used by a home user together with a mobile device or PC for data acquisition.

6.2. The device is used by a researcher/professional in a specialized clinical lab for data acquisition. It can also be used by a home user together with a mobile device or PC for data acquisition.

6.3. The primary user may need to collect biopotential data, bioimpedance data, accelerometer data, or some combination of all. Data collection requirements may scale up over time (i.e. start basic with increased functionality with project progress)

6.4. The primary user may be working on their own software, or they may require just a basic application for data collection only with no software development required. BOTH potential requirements must be covered: easy software for data collection without development, SDK for customized software development.

6.5. The primary user likely requires flexibility in the sensor part of the project, and may need to use a basic off-the-shelf option, or may be working on their own sensors. Multiple options may be required in a single customer/project.

6.6. The secondary user is a student that requires an easy platform for simple data collection for basic research purposes. This does not require programming.

6.7. The secondary user requires basic software and hardware interfacing and may be encouraged to do their own software development. SDK with examples would be useful, compatibility with MatLab or Labview, and or Python required.

6.8. In order to start using the device, the operator need to attach the electrode sticker to the device (as described in section 1.6). To attach the electrode to the patient, see "Electrode patch user manual". After the preparation you can start recording data (as described in section 2.10).

6.9. Hazards related to use of the medical device

6.9.1. Inadequate operating instructions, such as:

6.9.1.1. Inadequate specification of accessories to be used with the medical device may lead to device malfunction.

6.9.1.2. Inadequate specification of pre use checks may cause inability to perform data recording resulting with inconvenience to the patient and staff or physical harm to patient resulting from heating up of the electrodes

6.9.1.3. Inadequate specifications of service and maintenance may lead to device

6.9.2. Use by unskilled/untrained personnel may lead to wrong usage and wrong results that may pose a risk to the patient's life or Harm to the device.
6.9.3. Inadequate warning of hazards likely with re-use of single use medical devices. Like the electrode sticker.
6.9.4. Incorrect measurement and other metrological aspects may cause delay in treatment or unnecessary treatment due to hardware failure.
6.9.5. When using the device be aware of Sharp edges or points that may cause to operator or patient injury.
6.9.6. Replacement of the components is forbidden.
6.9.7. To prevent electrical shocks or burns that may happen as a result of mains or other high voltage from other device finds a current return path through BPT V1 SFC's test should be done.
6.9.8. For electromagnetic interference risks look into RMF.
6.9.9. Power supplied from an external DC power source, have hazardous situation. HW damage, may result in patient injury (burns)
6.9.9.1. Non continuous Connection may lead to Device misuse, interfering of other devices, Device not in range and RF noise
6.9.10. Lithium batteries:
6.9.10.1. are classified as Class 9 hazardous material UN3480, a power source with high energy density and dangerous materials in a closed metal case!
6.9.10.2. Lithium batteries must be handled only by qualified and trained personnel.
6.9.10.3. Don't replace the lithium battery.
6.9.10.4. Instruction for fire extinguishing:
• Extinguish with water, if possible, cover battery completely in water
• Extinguishing with water will produce fluoride, phosphate, fluoride-oxide and carbon-oxide.
• Alternatively extinguish with a CO2 extinguisher

6.10. General:

6.10.1. Do not stack and locate the system close to other equipment
6.10.2. Other cables and accessories may negatively affect EMC performance
6.10.3. Portable RF communications equipment including antennas, can affect medical electrical equipment. Any equipment should not be used closer than 30 cm (12 inches) to any part of the BioPot system, including cables specified by manufacturer"
6.10.4. For BioPot system that are classified as class A according to CISPR 11, the instructions for use include the following note: "The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment."

6.11. Technical Description:

6.11.1. The technical description describes precautions to be taken to prevent adverse events to the patient and Operator due to electromagnetic disturbances.

6.11.2. Compliance for each emissions and immunity standard or test specified by this collateral standard, e.g. emissions class and group and immunity test level

6.11.3. Any deviations from this collateral standard and allowances used

6.11.4. All necessary instructions for maintaining basic safety and essential performance with regard to electromagnetic disturbances for the expected service life.

7. General information

7.1. Manufacturer: Senso Medical LTD

7.2. Costumer: Senso Medical Labs Ltd.

7.3. Costumer's Address:

P.O. Box:	2653
Industrial Park Building, Mount precipice.	St.\ Industrial Zone
Nazareth Galilee	, City
Postal Code:	1612102
Israel	
Fax No.:	046800668
Tel No.:	046800668

7.4. Equipment Model No.: BP-30-08-00061

7.5. Equipment Serial No.: 61

7.6. For labels explanation look into Biopot labels file.

8. List of accessories, detachable parts, and materials

1. Biopot device
2. Electrode sticker
3. Charger (Docking + USB to Type C cable)
4. Box includes all the above parts

9. Declaration – electromagnetic emissions

Declaration – electromagnetic emissions		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group1 Class A	The BioPot SYSTEM uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
Harmonic emissions IEC 61000-3-2	Class A	The BioPot SYSTEM is suitable for use in all establishments other than domestic, and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided the following warning is heeded: Warning: This equipment/system is intended for use by healthcare professionals only. This equipment/ system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the BioPot SYSTEM or shielding the location.
Voltage Fluctuations And Flicker IEC 61000-3-3:2013	Complies	

10. Declaration – electromagnetic immunity

Declaration – electromagnetic immunity			
IMMUNITY test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	8 kV contact 2, 4, 8, 15kV air	8 kV contact 2, 4, 8, 15kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	2 kV for power supply lines 1 kV for input/output lines	2 kV for power supply lines N/A	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	1 kV line(s) to line(s) 2 kV line(s) to earth 2 kV Signal input/output) to earth	1 kV line(s) to line(s) 2 kV line(s) to earth N/A	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% UT; 0.5cycle at 0°, 45°, 90°, 135°,180°, 225°, 270° and 315° 0% UT; 1cycle and 70% UT; 25/30 cycles Single phase at 0° 0% UT; 250/300 cycle	0% UT; 0.5cycle at 0°, 45°, 90°, 135°,180°, 225°, 270° and 315° 0% UT; 1cycle and 70% UT; 25/30 cycles Single phase at	Mains power quality should be that of a typical commercial or hospital environment. If the user of the BioPot SYSTEM requires continued operation during power mains interruptions, it is recommended that the BioPot SYSTEM be powered from an uninterruptible power supply or a battery.

		0° 0% UT; 250/300 cycle	
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 (A/m)	30 (A/m)	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE UT is the a.c. mains voltage prior to application of the test level.			
Conducted RF IEC 61000-4-6	3V, 6V	3Vrms, 6V	Portable and mobile RF communications equipment should be used no closer to any part of the BioPot SYSTEM, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = [\frac{3,5}{V_1}]\sqrt{P}$
Radiated RF IEC 61000-4-3	3V/m	3V/m	$d = [\frac{12}{V_2}]\sqrt{P}$ $d = [\frac{12}{E_1}]\sqrt{P}$ 80 MHz to 800 MHz
	3V from 0.15 to 80MHz; 6V from 0.15 to 80MHz and 80% AM at 1kHz	3V from 0.15 to 80MHz; 6V from 0.15 to 80MHz and 80% AM at 1kHz	$d = [\frac{23}{E_1}]\sqrt{P}$ 800 MHz to 2,5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. D Interference may occur in the vicinity of equipment marked with the following symbol:
	3V/m from 80MHz to 2.7GHz	3V/m from 80MHz to 2.7GHz	

11. Recommended separation distances between portable and mobile RF communications equipment and the BioPot SYSTEM

Recommended separation distances between portable and mobile RF communications equipment and the BioPot SYSTEM				
Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter** m			
	150 kHz to 80 MHz outside ISM bands $d = [\frac{3,5}{V_1}]\sqrt{P}$	**150 kHz to 80 MHz in ISM bands** $d = [\frac{12}{V_2}]\sqrt{P}$	**80 MHz to 800 MHz** $d = [\frac{12}{E_1}]\sqrt{P}$	**800 MHz to 2,5 GHz** $d = [\frac{23}{E_1}]\sqrt{P}$
0.01	0.12	0.2	0.4	1
0.1	0.37	0.64	1.3	2.6
1	1.17	2	4	8
10	3.7	6.4	13	26
100	11.7	20	40	80

12. Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment

Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment							
Test frequency (MHz)	Band [a] (MHz)	Service [a]	Modulation [b]	Maximum power (W)	Distance (m)	IMMUNITY TEST LEVEL (V/m)	Compliance level (V/m)
385	380 – 390	TETRA 400	Pulse modulation [b] 18 Hz	1.8	0.3	27	27
450	430 – 470	GMRS 460, FRS 460	FM [c] ± 5 kHz deviation 1 kHz sine	2	0.3	28	28
710	704 – 787	LTE Band 13, 17	Pulse modulation [b] 217 Hz	0.2	0.3	9	9
745							
780							
810	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation [b] 18 Hz	2	0.3	28	28
870							
930							

1720 1845 1970	1 700 – 1 990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation[b)] 217 Hz	2	0.3	28	28
2450	2 400 – 2 570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation[b)] 217 Hz	2	0.3	28	28
5240 5500 5785	5 100 – 5 800	WLAN 802.11 a/n	Pulse modulation[b)] 217 Hz	0.2	0.3	9	9

FCC Warning

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

Any changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

NOTE: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses And can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications.

However, there is no guarantee that interference will not occur in a particular installation.

If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

-- Reorient or relocate the receiving antenna.

-- Increase the separation between the equipment and receiver.

-- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.

-- Consult the dealer or an experienced radio/TV technician for help.

The device has been evaluated to meet general RF exposure requirement.

The device can be used in portable exposure condition without restriction.