DANFLOW 5000

1. Device Description

DanFlow 5000 is a uroflowmetric device for a non-invasive measuring of the urine flow rate by recording the increments of the weight during urination. These records may then be processed and evaluated in another device (smartphone, tablet, or PC).

The slim, disc-shaped body houses electronics with weight sensors, a processor, a memory storage for recorded data, a wirelessly charged accumulator and a Bluetooth module.
A container with a maximum bottom diameter of 100 mm is placed on the disc; due to automatic calibration a wide spectrum of containers can be used.

The device has no connectors; there's only a single power-on push-button on the bottom side of the device. The recorded data is transferred wirelessly using the Bluetooth technology.

2. Principle of Operation

2.1 The device measures and records the weight of urine excreted and retains this information until the data is transferred wirelessly to the evaluation unit.

2.2 Operating is reduced to pressing the push-button on the bottom side of the device. Before recording, the device must be placed on a horizontal surface (e.g. the toilet seat lid) and a container must be put on its top side. The preparation must be completed within 10 seconds from pressing the push-button, before the device beeps; this beep signals the start of recording.

2.3 The flow rate is measured indirectly; it is calculated from the increase in the weight. These increments, as well as their respective times, are recorded.

2.4 The recorded data is kept in the memory until it is wirelessly transferred to the evaluation device. After finishing the transfer, the memory content is automatically cleared.

2.5 The records are evaluated by a physician; the patient only collects data at recommended intervals. Urination should take place under conditions that are as close to the physiological conditions as possible: In privacy, without any particular stress, having a normal urge to urinate initiated by the bladder being full.

2.6 The built-in lithium accumulator will suffice for approximately one week of normal operation when fully charged. The accumulator may be recharged using a standard wireless mobile phone charger.

2.7 The evaluation unit (smartphone, tablet, or PC) must be equipped with a radio module for communication compliant with Bluetooth 4. In compliant units, standard – usually preinstalled – software is used to connect to the DanFlow 5000 device via Bluetooth.

2.8 The records are further processed in the application software: The maximum weight is converted to the urinated volume, and the flow rate is calculated as the derivation of the increase in the weight with respect to time. The records are then displayed graphically in the form of uroflowmetric curves. The software is intended for specialists – physicians – and may be downloaded in the Apple Store.

3. Operating the Device

	**Warning!** The information in this User Guide applies to all colour variants of the device irrespective of the colour of the device in the accompanying photographs. The same applies to the charger supplied for the device.

3.1 Powering On

To power on the device, press the button on the bottom side of the device (the side with the label). A green LED lights up next to the push-button. If a red LED lights up instead, the device signals low battery charge – the device must be recharged.

3.2 Charging

To charge the device, place the bottom side of the device (the side with the push-button) onto the top side of the charging pad (the side with the charging symbol).

Charging in progress is indicated by the blue LED. Full charge is signalled by both blue and red LEDs lighting up.

If only the red LED is flashing, the charger doesn't support this device. Please make sure you are using the correct charger.

If no LED lights up, the charger may be applied to the wrong side of the device, or the device is fully charged and needs no recharging.

3.3 Measuring and Recording Data

In order to ensure accurate results, the device must be placed on a horizontal surface. Once turned on, the device should be placed on a flat surface, with the top side of the device facing upwards. The container, into which the patient urinates, must be put onto the device 10 seconds. After that, the device signals with a short acoustic signal (a beep) that the recording is about to start and that the patient may start urinating. (At the same time, the device also performs auto-calibration to zero, with the container taken into account. The calibration constants are recorded in the marker of the measurement concerned.)

After a pre-set time (one minute most often), the device beeps again to indicate the end of the recording and switches to transfer mode. In this mode, the device waits for a data connection – if no connection is established within two minutes, the device is turned off automatically.

3.4 Powering Off

The device is turned off automatically two minutes after the end of measuring or after the end of communication. It is also turned off when data is successfully downloaded to another system.

3.5 Disinfecting

Before the measuring – and thus the urination – starts, the device should be placed in a thin plastic protective bag. The device may be disinfected using a disinfectant spray (Desident) or by cleaning it with a cloth dampened with a disinfectant solution. The device may not be immersed!

3.6 Transferring Data

After the initial recording period is over (usually 1 minute), the evaluation unit may connect to the device via Bluetooth and download the data for further analysis. For more information, please see Annex D - User Guide for Apple iOS.

	**Warning!** If it is not possible to put the device into operation or operate it following the instructions in the manual, please contact the service centre or the doctor or medical staff member who has given you the device. Do not attempt to interfere with the device yourself!

4. Warning

DanFlow 5000 is equipped with sensitive weight sensors and must be therefore protected against shocks, falls and loads of more than 2,000 g.

The device is not waterproof and cannot be immersed in any liquid. It can be disinfected using a spray or by wiping with a cloth with a disinfectant solution.

The most suitable protection is placing it into a polypropylene bag which is readily available.

While the auto-calibration and zero setting of the sensor are in progress and during the measuring process, do not touch any part of the sensor; the shocks caused could bring undesirable influences into the measured data or influence the calculation of the total urinated volume.

If there is a problem with the transfer of recorded data (weak signal, radio interference, or evaluation unit failure), the device keeps the data in its internal memory and the user can try to transfer the data again. The data is deleted from the internal memory only after it is successfully transferred.

5. Technical Specification

5.1 Description

DanFlow 5000 is a medical device for urinary tract diagnostics using standard measuring methods set by the ICS (uroflowmetry). The device is suitable for screening examinations.

The device is basically a battery-powered weight sensor that measures and stores uroflowmetric data. After the measuring is finished, the data may be transferred into the evaluation unit and further analysed using a dedicated software. Reports are saved in the form of PDF files which may be archived or, if need be, sent to the attending physician by e-mail.

DanFlow 5000 is intended for automatic operation with minimum operation required.

Connectivity is provided by a built-in Bluetooth 4 module.

The device works in the free 2.4 GHz band according to the Bluetooth specification, in accordance with the general authorization VO-R/10/03.2007-4.

The device can be used to examine patients aged 5 years and over. For younger patients (children), who cannot be expected to be able to handle the device and its accessories independently and responsibly, the assistance of the physician, a parent, or a legal representative is necessary. They must be instructed by the physician or medical staff on how to handle the device as responsibly as if they themselves were the users of the device.

Patients suffering from inflammation of the urinary tract should not be examined, as the results of the measuring might be distorted due to the irritation of the urinary bladder.

The device may only be prepared for operation and data may only be evaluated by a properly trained medical staff that has the qualifications meeting the requirements according to the valid regulations.

The patient will be instructed by the medical staff on borrowing the DanFlow 5000 device. They will also evaluate the intellectual capacity of the patient and lend the device only if they are confident that the patient is able to operate the device.

DanFlow 5000 is not a waterproof device. It is designed to be used in ordinary conditions.

The device neither contains nor produces any harmful substances, which allows the safe disposal of the device after the end of its life cycle.

DanFlow 5000 is classified as a medical electrical device. Portable and mobile radio frequency communication devices and other electrical devices emitting radio frequency energy may have an adverse effect on the device.

DanFlow 5000 should not be used adjacent to or stacked with other equipment.

If adjacent or stacked use is necessary, the device should be observed to verify normal operation in the configuration in which it is to be used.

5.2 Warning

Service

The device may only be serviced by a person trained by the manufacturer.

It is forbidden to remove any covers and to tamper, repair and modify in any way inside the device.

Replacing fuses

The DanFlow 5000 has no fuses which could be replaced by the user. The system is protected by the internal automatic cut-out.

Replacing the power supply cell

The DanFlow 5000 is supplied by a lithium secondary cell, which cannot be replaced by the user.

The type used is EEMB LP562438, 3.7 V, 500 mAh.

The built-in power supply cell suffices to supply the device for at least 1 year, typically for 3 and more years depending on the intensity of use of the device.

Calibrating the sensor

The device is factory set in the testing laboratory of the manufacturer. A regular inspection of the settings is performed once a year within the regular annual service inspection. If data is repeatedly apparently incorrect, it is necessary to contact the manufacturer and have a service calibration performed.

5.3 Technical data for DanFlow 5000

Power supply	3.0 to 3.7 V DC
Current consumption	PowerOff mode (Off): 0 A Active mode (measuring): 15 mA typ.
IP 42	IP 4x – the level of protection against hazardous contact with a tool > 1 mm and against the ingress of very small foreign objects; IP x2 – the level of protection against ingress of water – protected against dripping water, 3 + 0.5 mm per minute
Size	Diameter 100 mm x 170 mm
Weight	131 g
Operating temperature	+5 to +40 °C
Operating humidity	15-93 % non-condensing
Storage temperature	–25 to +70 °C
Storage humidity	0-93 % non-condensing
Storage and operating pressure	No special requirements (700-1,060 hPa)
The device has no attachments.	
Volume and flow rate measurement	
Input	Integrated weight sensor
Volume range	500 ml ± 1 % (max. 1,000 ml ± 2 % depending on the collection container used)
Flow rate range	0–500 ml/sec ± 2 %
Radio communication	
Working frequency	Band: 2,402 MHz – 2,480 MHz, depending on the Bluetooth specification
Output power (transmission)	12 dBm
Modulation type	FHSS: GFSK (1 Mbps), modulation index 0.5
Communication rate	57,600 bps
Band width	2 MHz
Power supply	
Power supply	Lithium secondary cell, 3.7 V, 500 mAh
Overcharging protection	Disconnecting the device electronics completely during power supply. The integrated charger sensor monitoring the temperature (charging is not started if the limits are exceeded) and the characteristic of the charging cycle. Limiting the maximum input voltage. Detecting the charged battery according to the achieved voltage level. Time limitation of a charging cycle.
Means of battery short-circuit protection	Internal protection. Disconnecting the battery immediately by the built-in electronic protection after a short circuit (with no voltage on the battery terminals).

6. Troubleshooting

Problem	Possible Cause	Solution
The device does not react when a container is put on the measuring surface.	The device is off.	Turn on the device by the pressing the push-button on the bottom side of the device.
	The power supply cell in the device is empty.	Put the device on the charger.
	The power supply cell in the device is empty and does not charge when applied to the charger.	Please contact the service centre.
The device does not measure.	The sensor is incorrectly calibrated.	Please contact the service centre.
	The sensor is defective.	Please contact the service centre.
The measurement results are not satisfactory.	The sensor is incorrectly calibrated.	Please contact the service centre.
	A methodical error in the measuring procedure.	When measuring, follow precisely the instructions.
Unexpected behaviour of the device not described in the instructions.	A device failure.	Please contact the service centre.

7. Repairs and Guarantee

DanFlow 5000 has a 12-month guarantee according to the Warranty Card, starting from the date of installation.

Repairs and calibration are performed by the service centre. The customer receives the address during installation of the device.

It is forbidden to remove any covers by the customer and to perform any repairs and tamper with the device. The device may only be repaired by the manufacturer and/or by the repair shop specified by the supplier.

<table>
<tr><td rowspan="2">  </td><td>Warning!

If the guarantee seal is damaged, the guarantee becomes void!</td></tr>
<tr><td>Warning!

Lead-free technologies according to DIRECTIVE 2011/65/EU – Restriction of the use of Hazardous Substances (RoHS) are used in the device.

For this reason, the materials used are much more sensitive to ambient influences and even if handled properly, a failure may occur due to the fragility of lead-free solder.

Protect the device against mechanical shocks, especially while in operation, and against increased humidity and thermal overloading.</td></tr>
</table>

8. Preventive Inspections and Periodical Maintenance

The manufacturer of DanFlow 5000 recommends performing an annual preventive inspection of the device.

Warning!

A preventive inspection of the device may only be performed by the manufacturer of the device or by a person authorized and trained by the manufacturer.

A preventive inspection includes the following activities:

- Checking the built-in power supply cell and replacing it if necessary.
- Checking the calibration of the sensor and recalibrating it if necessary.
- Overall cleaning of the device.

The inspection is summed up in the *Preventive Inspection Report*.

If the device is used according to the instructions, the expected service life is at least 5 years. Regular preventive inspections will help to maximize the service life of the device.

9. Disinfection and Maintenance

9.1 Disposable Material

The device is delivered with plastic container for urine collection. These are consumables which are not intended to be reused.

9.2 Disinfecting the Parts Which May Come into Contact with the Patient

Disinfect the device by wiping it with a cloth dampened with a disinfecting agent. The type of the disinfecting agent is to be determined by the Health Officer of the institute.

9.3 Maintenance of the Instrument

The device itself does not come into contact with the patient's body at all; nevertheless, it must be kept scrupulously clean.

It is recommended to disinfect the device by wiping it with an agent with virucidal effects only if it gets contaminated by biological material, especially by blood. The types of these agents are to be determined by local practices and the regulations of the Health Officer of the institute.

For example, an agent based on 2% glutaraldehyde (the agent has no cleaning effects!) may be used as a disinfecting agent. Glutaraldehyde can be supplied by various manufacturers, under protected names such as “Cidex” (manufactured by Johnson and Johnson).

Use only the agents approved by the Health Officer of the institute.

Repeated cleaning of the device and its parts using disinfecting agents containing pigments may cause a change in the colour of the surfaces disinfected. Do not use detergents containing abrasives because they could permanently damage the functional parts or the surface finish of the device.

10. Consumables

A disposable plastic urine collection container is supplied with the device.

11. Risks When Handling Infectious Materials

Uroflowmetry is based on the measuring of the flow rate and volume of the patient's urine. Although the urine of most patients is sterile – and those with inflammation of the urinary tract should not be examined, as the measuring would be distorted by the irritation of the bladder – it is still possible that some patients' urine contains bacteria.

Warning!

Both the patient and the staff must treat the urine in the container and the stained uroflowmeter parts as infectious material to avoid the hazard of becoming infected!

Depending on the type of the infection (in the overwhelming majority of cases, this is gram-negative Escherichia coli), an ascending urinary tract infection might occur. In the case that the skin is injured, purulent infections might occur. In exceptional situations, it is possible to become infected with tuberculosis or infectious hepatitis A.

Recommended procedures for preparing the DanFlow 5000 device:

- Wear personal protective equipment when handling urine (rubber gloves and mask).
- Observe the rules of personal hygiene (washing hands and no eating and drinking in the examination room).
- Pour the urine from the container only when wearing gloves.
- It is recommended that staff are vaccinated against hepatitis A and B.

12. Parts of Supply

The supply of the DanFlow 5000 device includes the uroflowmeter and several collection containers.

The supply also includes thus User Guide in English, a simplified User Guide for medical staff, and a simplified User Guide for patients. Both simplified guides are sealed in a plastic film.

The user guide for medical staff (named “Simple Guide for Doctors and Medical Staff”) is Annex B to this guide.

The user guide for patients (named “Simple User Guide for Patients”) is Annex C to this guide. The patient is the intended operator for operations listed in this annex.

13. Instructions for Handling Waste

The instructions for handling waste produced during the life cycle of the medical device (within the intention of Sec. 10 par. 3 of Act No. 185/2001 Coll., on waste).

Type of Waste	Code[1)]	Category[2)]	Method of Handling
Paper and cardboard packaging	15 01 01	O	Other waste – utilizable waste – must be handed over to a person authorized to handle waste through sorted waste collection in municipalities.
Wood packing	15 01 03	O	Other waste – must be collected and handed over to a waste incineration plant for disposal.
Plastic packaging – PE film	15 01 02	O	
Scrapped electrical and electronic equipment	20 01 35	H	Hazardous waste – it contains batteries and accumulators. When worn out, the complete device must be handed over (free of charge) to a collection point intended for this purpose or returned to the manufacturer. It must not be treated as municipal waste.[3) 4)]
Waste electrical and electronic equipment – scrapped equipment	16 02 14	O	Other waste – utilizable waste – after sorting, it must be handed over to an authorized person purchasing waste or scrap material.
Other scrapped equipment – metallic parts (without residues of oil)	17 04 07	O	
Other scrapped equipment – non-metallic parts	16 02 16	O	Other waste – must be collected and handed over to the operator of a waste site.[3)]
Other scrapped equipment – rubber parts	16 02 16	O	Other waste – must be collected and handed over to a waste incineration plant for disposal.
Small plastic parts[3)]	16 02 16	O	
Other batteries and accumulators – lithium batteries	16 06 05	H	Hazardous waste – must be collected and handed over for disposal to a person authorized to do so.
Consumables which come into direct contact with the patient – potentially infectious material	18 01 03	H	Put consumables used into an infectious material container and dispose of them in the prescribed way.

[1)] Regulation No. 381/2001 Coll., which publishes the Waste Catalogue.

[2)] O – means other waste; H – means hazardous waste.

[3)] WARNING – Due to the toxicity of its combustion products, polytetrafluoroethylene (PTFE, Teflon) must not be incinerated in any other place than a waste incineration plant.

[4)] The ecological disposal of this equipment is ensured within the ASEKOL collective system within the requirement of Act No. 185/2001 Coll., on waste, as amended.

For electrical waste collection points, please see the internet page www.asekol.cz.

14. Contact Addresses

Manufacturer and sales representative:

MEDKONSULT, s. r. o.

Balcarkova 8

779 00 Olomouc, Czech Republic

Telephone: +420 585 414 511

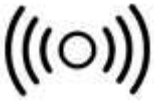
Fax: +420 585 416 045

E-mail: medkonsult@medkonsult.cz

Web: http://www.medkonsult.cz, http://www.uromic.eu

15. List of Symbols

The list of symbols used on the device and in the operating instructions.

	CE symbol		Manufacturer
	Product composed of materials which can be recycled		Read the operating instructions
	Non-ionizing electromagnetic emission		Warning
	Wireless charging		

Annex A – Information about EMC

Warning!

This device has shown compliance with the EMC standards under the conditions which included the use of compatible accessories supplied along with the device.

This device must be installed and commissioned in compliance with the information given in the operating instructions.

Warning!

The DanFlow 5000 device is a radio transmitter and receiver in the 2.4 GHz band according to the Bluetooth specification.

It can cause interference to a radio signal or nearby electronic equipment working in the same frequency band or it can be interfered by such equipment.

Guidance and Manufacturer's Declaration – Electromagnetic Emissions		
The DanFlow 5000 device is intended for use in an electromagnetic environment specified below. The customer or the user of the DanFlow 5000 device should ensure that it is used in such an environment.		
Emission Test	**Compliance**	**Electromagnetic Environment – Guidance**
Radio frequency emissions CISPR 11	Group 1	DanFlow 5000 has a low level of radio frequency emissions and they are not likely to cause any interference in nearby electronic equipment.
Radio frequency emissions CISPR 11	Class B	DanFlow 5000 is suitable for use in all institutions and households.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Not applicable	

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The DanFlow 5000 device is intended for use in an electromagnetic environment specified below. The customer or the user of the DanFlow 5000 device should ensure that it is used in such an environment.			
Immunity Test	**Test Level according to IEC 60601**	**Compliance Level**	**Electromagnetic Environment – Guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV for contact ± 8 kV for air	± 2, 4 and 6 kV ± 2, 4 and 8 kV by air	
Electrical fast transient / burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	Not applicable Not applicable	The DanFlow 5000 device is supplied from the internal electric power supply (battery).
Surge IEC 61000-4-5	± 1 kV line to line ± 2 kV line (to line) to ground	Not applicable Not applicable	The DanFlow 5000 device is supplied from the internal electric power supply (battery).
Voltage dips, short interruptions and voltage variations on power supply input line IEC 61000-4-11	< 5 % U_T (> 95 % dip in U_T) for 0.5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30% dip in U_T) for 25 cycles < 5 % U_T (> 95 % dip in U_T) for 5 sec	Not applicable Not applicable Not applicable Not applicable	The DanFlow 5000 device is supplied from the internal electric power supply (battery).
(50/60Hz) network frequency magnetic field IEC 61000-4-8	3 A/m	3 A/m	The network frequency magnetic fields should be at the levels of a characteristic location in a typical environment.
NOTE: U_T is the AC NETWORK VOLTAGE before the application of the test level.			

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The DanFlow 5000 device is intended for use in an electromagnetic environment specified below. The customer or the user of DanFlow 5000 should ensure that it is used in such an environment.			
Immunity Test	**Test Level according to IEC 60601**	**Compliance Level**	**Electromagnetic Environment – Guidance**
Conducted radio frequency IEC 61000-4-6 Radiated radio frequency IEC 61000-4-3	3 V_{rms} 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3 V_{rms} 3 V/m	Portable and mobile radio frequency communication equipment should be used no closer to any part of the DanFlow 5000 device than the recommended separation distance calculated from the equation suitable for the transmitter frequency. **Recommended separation distance** $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz Where *P* is the maximum output power rating of the transmitter in watts (W) according to the manufacturer of the transmitter and *d* is the recommended separation distance in metres (m). Field strengths from fixed radio frequency transmitters, as determined by a survey of the electromagnetic characteristics of the location concerned [a], should be less than the compliance level in each frequency range [b]. Interference may occur in the vicinity of the equipment marked with the following symbol:
Note 1	At 80 MHz and 800 MHz, the higher frequency range applies.		
Note 2	These guidelines may not apply in all situations. Electromagnetic propagation is influenced by absorption and reflection from structures, objects and people.		

a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile and amateur radio stations, for AM and FM radio broadcast and TV broadcast, cannot be predicted theoretically with accuracy. To assess the electromagnetic environment for fixed radio frequency transmitters, a survey of the electromagnetic characteristics in the location should be taken into consideration. If the measured field strength in the location in which the DanFlow 5000 device is used exceeds the applicable radio frequency compliance level above, the DanFlow 5000 device should be observed to verify the normal operation of the device. If abnormal performance is observed, additional measures such as reorienting or relocating the DanFlow 5000 device may be required.

b The field stress in the entire frequency range of 150 kHz to 80 MHz should be less than 3 V/m.

Recommended Separation Distances between Portable and Mobile Radio Frequency Communication Equipment and the DanFlow 5000 Instrument

The DanFlow 5000 device is intended for use in an electromagnetic environment in which radiated radio frequency interference is controlled. The customer or the user of the device can help to prevent electromagnetic interference by keeping a minimum distance between portable and mobile radio frequency communication equipment (transmitters) and the device as recommended below according to the maximum output power of the communication equipment.

Determined Maximum Output Power of the Transmitter W	**Separation Distance according to the Transmitter Frequency** m		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters where the determined maximum output power is not stated above, the recommended separation distance *d* in metres (m) can be estimated using the equation suitable for the transmitter frequency, where *P* is the maximum output power rating of the transmitter in watts (W) according to the manufacturer of the transmitter.

Note 1 At 80 MHz and 800 MHz, the higher frequency range applies.

Note 2 These guidelines may not apply in all situations. Electromagnetic propagation is influenced by absorption and reflection from structures, objects and people.

Annex B – Simple User Guide for Doctors and Medical Staff

DanFlow 5000 is an ambulatory measuring device designed for urologic specialists as a replacement of the miction calendar, which – when recorded by the patient – is often filled in inaccurately and incompletely.

The device is charged wirelessly. The wireless charger is part of the delivery package.

The delivery package:

- Transport case
- Uroflowmeter DanFlow 5000
- Wireless charger with a power supply
- User guide for doctors and medical staff
- User guide for patients
- Plastic (polypropylene) protective bag with a zip fastener.

1) Charging the device: Place the bottom side of the disc (the side with the push-button) onto the top side of the charging pad (the side with the charging symbol). The blue LED will light up. Full charge is signalized by both blue and red LEDs lighting up. Data cannot be measured or recorded during charging. The battery capacity is sufficient for a week of standard use.

2) Insert charged device into a polypropylene bag. Before handing the device to the patient, give them clear instructions about how to use the device. Additionally, give the patient the *Simple User Guide for Patients*.

3) After getting the device back from the patient, clean it with a cloth dampened with disinfectant. Do not immerse the device!

4) Download recorded data into the evaluating unit using Bluetooth connectivity and dedicated software application: Start by turning the device on by pressing the push-button on the bottom side of the disc, then pair the device with the unit as instructed by the application. After the device signals the end of the recording period with a beep, use the aplication's controls (usually a button labeled "Download") to download the records. The time limit for pairing the device is 3 minutes; after that period, the device turns off automatically and needs to be started again. After connecting, the device remains turned on as long as the data is being downloaded. After all the data is successfully downloaded, the device turns off.

5) As the evaluation unit, a standard PC, a smartphone, or a tablet may be used, as long as applications able to process CSV files are installed. How to use the software, is described in Appendix D of the User Guide.

In the case of any unexpected behaviour of the device please contact the service centre. Do not attempt to interfere with the device yourself!

DANFLOW 5000

Annex C – Simple User Guide for Patients

1) You have received the device fully charged, and as such can be used for a week without recharging. The device is recording only when turned on, and it turns off automatically within 2 minutes after the voiding is finished.

2) Insert the disc into plastic bag with a zip fastener and seal it.

3) Press the push-button that is located on the bottom side of the device (the side with the label) and a green LED lights up next to the push-button. If a red LED lights up instead, the device signalizes low battery charge – please bring the device back to the doctor, so that the device may be recharged. If a green LED lights up, place the device on a flat surface with the top side (the side without a label) facing up.

4) After pressing the push-button and placing the device on a flat surface, put a container on the top side of the device. The container must be placed on the device within 10 seconds after pressing push-button.

5) The device indicates start of the recording with an audio signal 10 seconds after pressing the push-button. Voiding into the container may begin. The device will record up to 60 seconds of voiding.

6) The device stops recording after 60 seconds, then waits 2 minutes for a connection with the evaluation unit. If there is no connection, the device turns off automatically. Recorded data stay in the memory of the device until downloaded successfully.

7) You can proceed with recording repeating the same steps: Start by pressing the push-button, place the device on a flat surface, and put a container onto the top side of the device. After the device beeps, the recording starts and the voiding may begin.

8) Unless stained, the protective plastic bag can be used for the whole monitoring period. In case of urine stains, disinfect the bag or replace it.

9) After the monitoring period is over, remove the device from plastic bag. Return the device to the doctor, and dispose of the protective bag after disinfecting it.

	**Warning!** In the case of any unexpected behaviour of the device please contact the service centre or the physician or the medical staff member who gave you the device. Do not attempt to interfere with the device yourself!

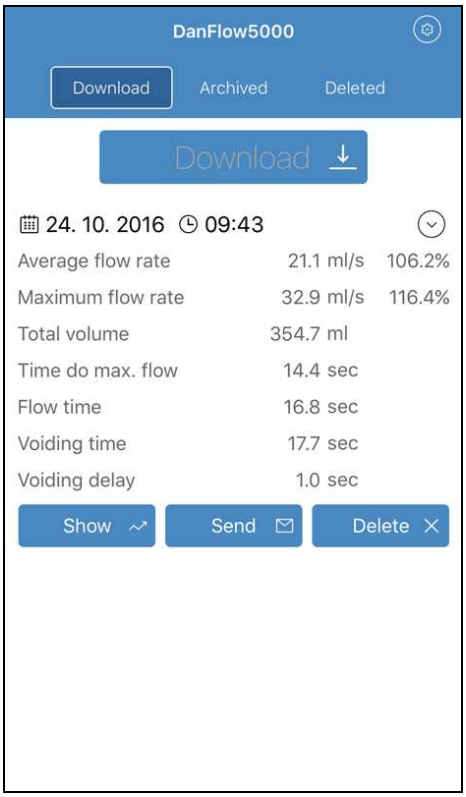
Annex D – User Guide for Apple iOS

The application for transferring data from the DanFlow 5000 uroflowmeter is also available for the Apple devices: iPhone and iPad.

Step 1 – Application homepage

Once the smartphone is connected to the uroflowmeter and the initial recording period is over (usually 1 minute), the user can transfer the recorded data simply by touching the Download button.

To connect the devices, please see Steps 10-13 – Application settings and Connecting the smartphone to the uroflowmeter.



Step 2 – Downloading the data

A table displays all the values that were measured:

- date and time
- total, maximum, and average values

Under the table, there are three buttons:

- Show – displays a graph
- Send – sends the record to user's medical doctor (see Step 15 for further information)
- Delete – deletes the record

After touching any of these buttons, the homepage is cleared, and the record is moved either to Deleted records (Delete button), or Archived records (Show, Send).

Step 3 – Application menu

The top bar offers access to the three main parts of the application simply by touching the corresponding button:

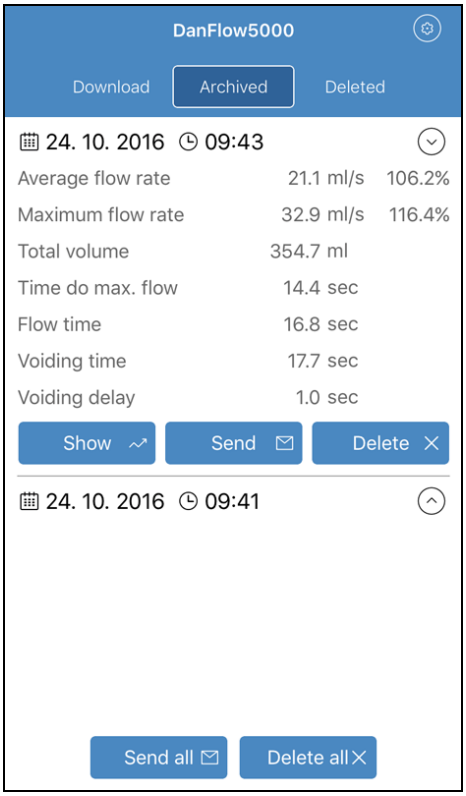
- Download – the starting page of the application
- Archived records – stores all the records that weren't deleted
- Deleted records – stores the deleted records
- Settings (through the Settings icon in the upper right corner) – application settings

Step 4 – Archived records

Archived records are displayed in a chronological order. Under the list of records, there are buttons for a manipulation with multiple records:

- Send all – sends all records to user's medical doctor (see Step 15 for further information)
- Delete all – deleted all records

Touching a single record displays a table with detailed data.



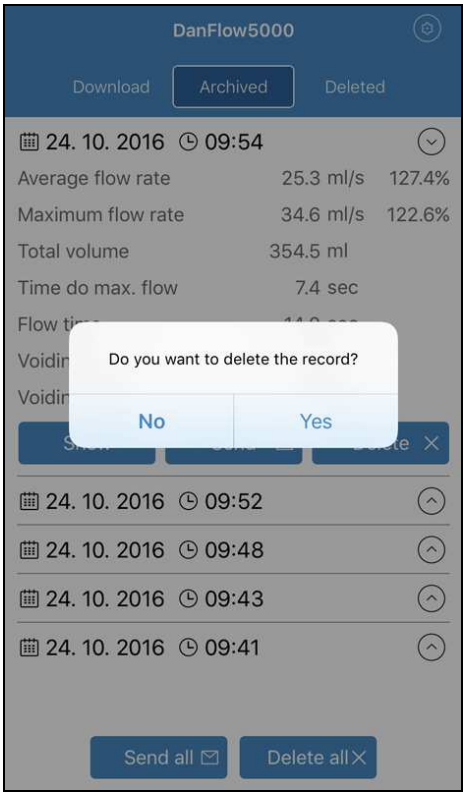
Step 5 – Archived records

A table displays all the values that were measured:

- date and time
- total, maximum, and average values

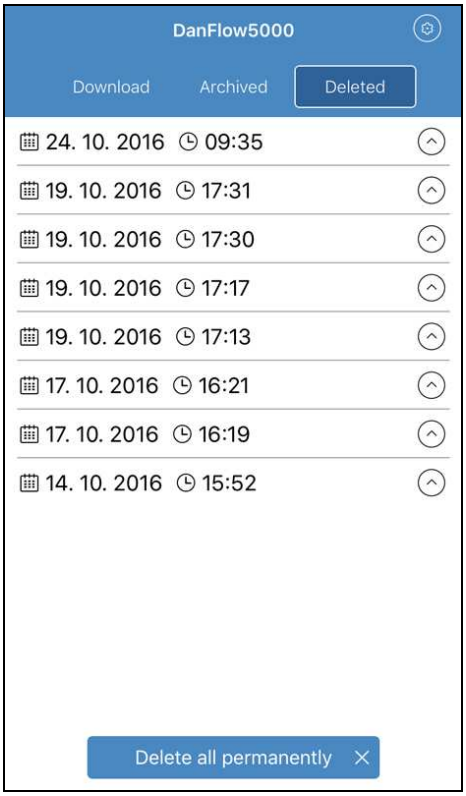
Under the table, there are three buttons:

- Show – displays a graph
- Send – sends the record to user's medical doctor (see Step 15 for further information)
- Delete – deletes the record



Step 6 – Archived records

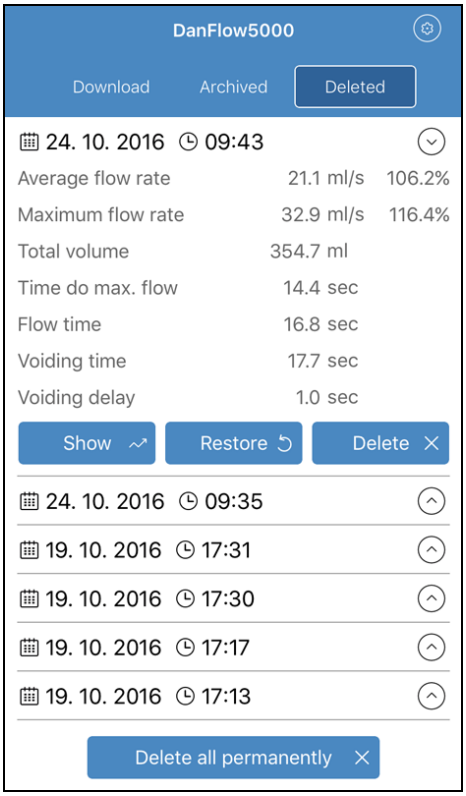
Before deleting the record, the application asks for a confirmation.



Step 7 – Deleted records

Deleted records are displayed in a chronological order. Under the list of records, there's a button for a permanent removal of all previously deleted records.

Touching a single record displays a table with detailed data.



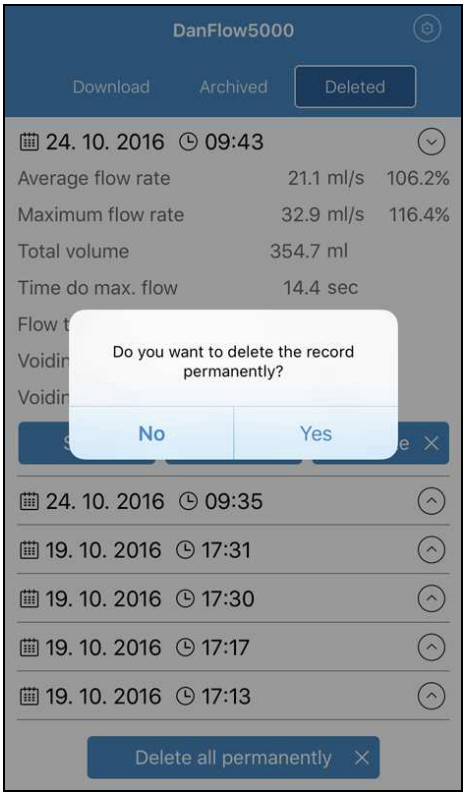
Step 8 – Deleted records

A table displays all the values that were measured:

- date and time
- total, maximum, and average values

Under the table, there are three buttons:

- Show – displays a graph
- Restore – moves the record to Archived records
- Delete – permanently deletes the record



Step 9 – Deleted records

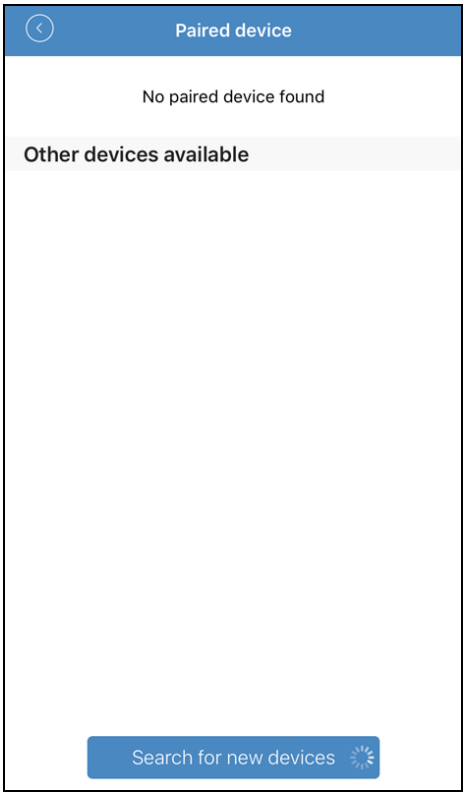
Before deleting the record, the application asks for a confirmation.

Caution: A record that was permanently deleted cannot be restored!

Step 10 – Application settings

The following parameters may be set:

- selection of connected uroflowmeter
- name of the patient (see Step 14 for further information)
- e-mail address of medical doctor, to whom the records will be send (see Step 15 for further information)



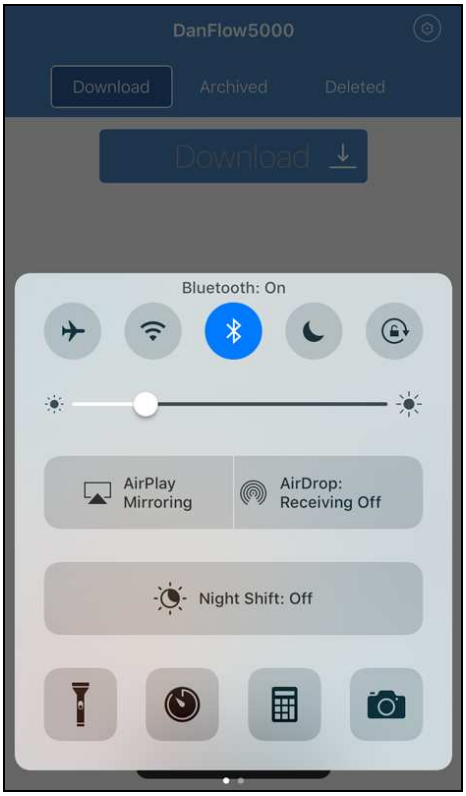
Step 11 – Connecting the smartphone to the uroflowmeter

If not connected to the uroflowmeter, the application will inform the user and offer the option of searching for new Bluetooth devices.

Step 12 – Connecting the smartphone to the uroflowmeter

If the uroflowmeter is turned on, the application will establish communication and display the list of devices that are available.

If only a single uroflowmeter is available, the application will try to pair with the device automatically.



Step 13 – Connecting the smartphone to the uroflowmeter

To be able to connect the uroflowmeter, make sure that Bluetooth is turned on.

Step 14 – Entering or changing patient's name

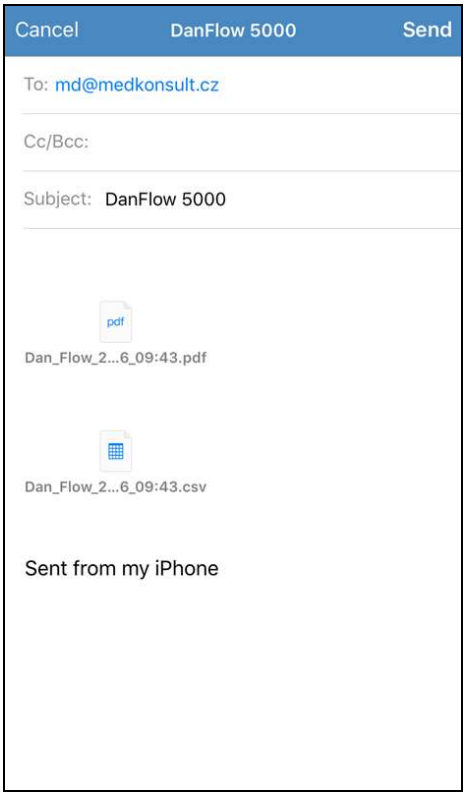
Touching the "Patient's name" entry displays a dialog box which can be used for entering a new name or changing the current name.

Touching the OK button saves all changes, while touching the Cancel button cancels them and keeps the previous information.

Step 15 – Entering or changing medical doctor's e-mail

Touching the "Medical doctor's e-mail" entry displays a dialog box which can be used for entering a new e-mail address or changing the current address.

Touching the OK button saves all changes, while touching the Cancel button cancels them and keeps the previous information.



Step 16 – Sending the records to medical doctor

The application fills in the subject (DanFlow 5000), attaches selected records and sends the e-mail to the address entered in Step 15.

All the user has to do now, is sending the e-mail...

Caution: Please note that the e-mail client may differ from what is in the picture. This depends on manufacturer and custom settings of your smartphone, as well as on the version of the operating system.

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