Sleep signals recorder "ApnOx"

Illustrated catalogue

- **"ApnOx-04"**
  model
  for respiratory screening
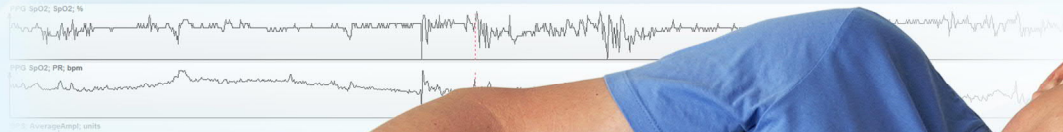 *(apnea screening)*

  Type IV AASM*

- **"ApnOx-10"**
  model
  for apnea screening
  and cardiorespiratory
  monitoring

  Type III AASM*

- **Home sleep testing (HST)**
  or sleep testing in a hospital ward

*AASM - American Academy of Sleep Medicine

Sleep signals recorder "ApnOx"

Designed for the diagnosis of cardiorespiratory disorders in sleep in models:

	"ApnOx-04" model	"ApnOx-10" model
Basic module "ApnOx"	It provides recording of physiological signals and parameters – data on the patient's body position, total movement activity, nasal breathing airflow, frequency and conditional amplitude of breathing, snoring from nasal cannula, pulse rate, blood oxygen saturation values (SpO2), perfusion index. Provides data collection from wireless Poly-4 modules and wireless legs movement activity sensors to record on a memory card in autonomous mode, and transfer of data to PC signals analysis stations in telemetric mode in the **"ApnOx-10" model.**	
Wireless Module "Poly-4"	Not available	Four polygraphic channels of Poly-4 module ensure record of electrocardio signals, thoracic and abdominal respiratory effort, respiratory airflow using a thermistor sensor, the motor activity of the limbs with the help of EMG electrodes and/or accelerometric sensors, signal from snoring sensor and signal of electrodermal activity. The use of an additional (second) module Poly-4 allows you to expand the number of simultaneously recorded signals or provide registration of up to 4 signals in the DC-channel mode.
Wireless legs movement sensors (2 pcs)	If required	Limbs movement registration.
Operative control ay offline record	Using the monitor of operational control of the recorder via Bluetooth, you can control signal recording, setting and changing the parameters of the autonomous study.	
Data storage	After the study, the data from the memory card of the basic "ApnOx" module are transmitted to the signal analysis station or to the station of processing and archival data storage, where the analysis results are formed as a medical report, and reporting forms are prepared for printing out, provides long-term storage of the received records. Export data to form a protocol in Word format by templates, edit templates if necessary. Export signals to the common formats: ASCII, EDF, EDF+.	
Analysis and processing of stored data	Generated statistical reports on identified sleep events - apnea, hypopnea, desaturation, tachycardia, bradycardia, snoring, autonomous activation of the autonomic nervous system and signs of Cheyne-Stokes breathing, and the connection of these events to the body position during sleep. It provides the calculation of numeric values, indicators and trends, as well as the performance of cardio-cyclic dynamics of parameters.	
Additional features of the analysis and processing of the stored data	Not available	Additionally, reports are formed on the presence and severity of events of central, obstructive and mixed apnea, single and periodic limb movements, as well as tachycardia, bradycardia and asystole based on the analysis of electrocardiosignal. Provides an indirect estimate of the dynamics of blood pressure according to heart rate and pulse transit time. The analysis of change dynamics of GSR is provided.

- **The recorder can include a video equipment kit**, which allows you to save the video image of a sleeping patient together with data on their physiological signals for subsequent synchronous viewing and visual analysis of various motor manifestations of sleep disorders.

- **When using the recorder together with the CPAP-apparatus, it** additionally ensures the check of overpressure in the mask of CPAP-apparatus.

- **The recorder does not contain physiological hazard warning systems** and cannot be used as a monitor for vital functions.

- Class of potential risk of recorders is 2A, type code in the nomenclature classification of medical devices – 274140 (Polysomnograph) according to the Annexes to the order of the Ministry of health of the Russian Federation d.d. 6.06.2012 № 4n.
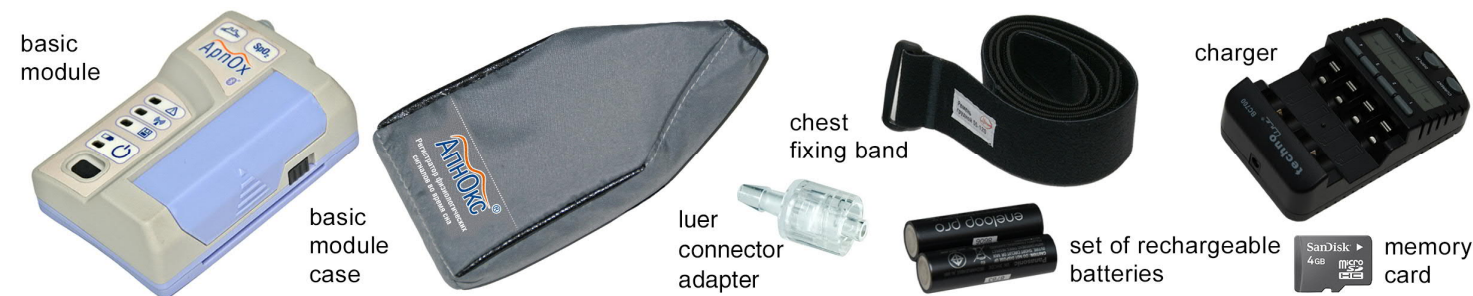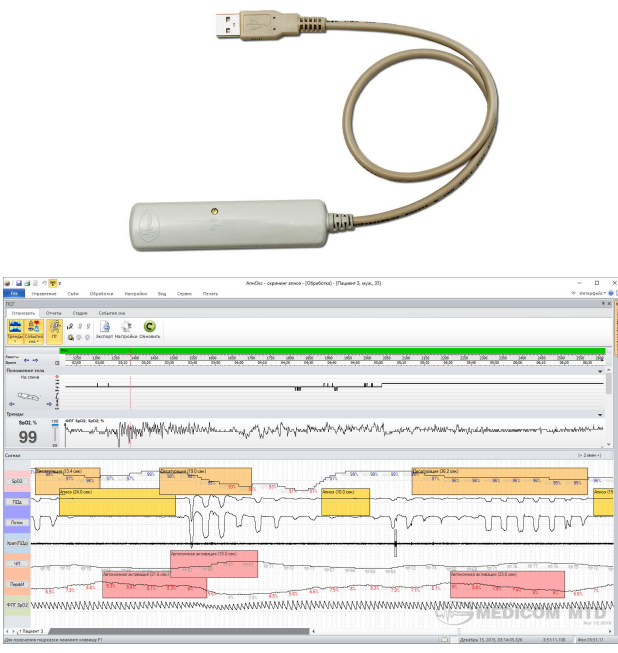
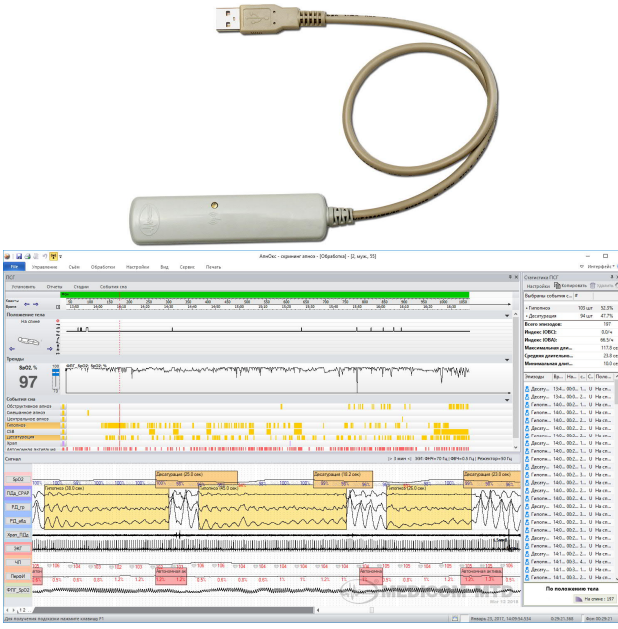# Contents of an illustrated* catalogue

* The appearance of the product samples is given as an example and may have some differences during delivery, not affecting the functional purpose.

№ item	Ref-number	Name and picture	Comments

Sleep signals recorder "ApnOx"

To form the sales package, it is necessary to select from this table the main and additional recorder sets, other equipment, electrodes and sensors

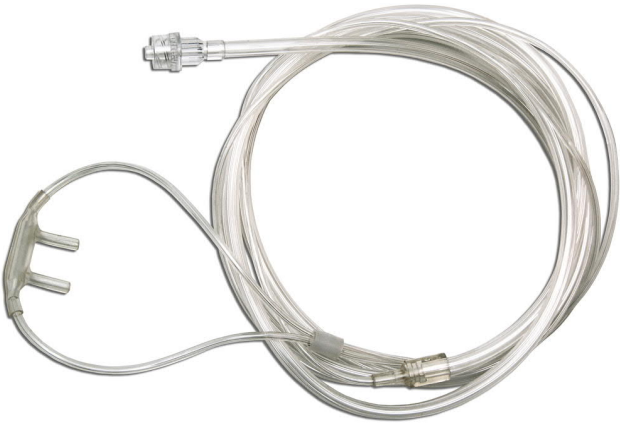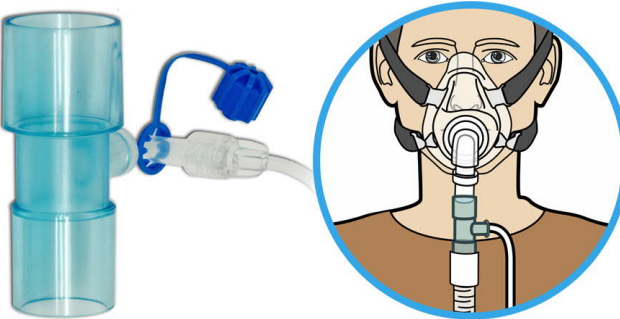| **1.**		**Main sets of Sleep signals recorder "ApnOx"**	

| 1.1 | A_6853 | **The main set of "ApnOx-04" model** | **Required are:** |

- Basic module (A_6653);
- Chest fixing band (A_7983);
- Basic module case (A_8252);
- Charger for Ni-MH batteries (A_2894);
- Rechargeable batteries Ni-MH AA (A_2334) – 2 pcs;
- Luer connector adapter (A_4574) – 5 pcs;
- Operational documentation: operation manual, user manual for SW "ApnOx" (A_8051);
- Memory card (A_2143, MicroSDHC, 4GB).

Required are:
- SpO$_2$ sensors;
- nasal cannulas.

Optional:
- computing machinery;
- video equipment kit;
- transport bag (A_6492).

basic module · basic module case · luer connector adapter · chest fixing band · set of rechargeable batteries · charger · memory card

| 1.2 | A_6858 | **The main set of "ApnOx-10" model** | **Required are:** |

- Basic module (A_6653);
- Chest fixing band (A_7983);
- Basic module case (A_8252);
- Charger for Ni-MH batteries (A_2894);
- Rechargeable batteries Ni-MH AA (A_2334) – 4 pcs;
- Wireless module "Poly-4" (A_5359);
- Wireless module case (A_6296);
- Luer connector adapter (A_4574) – 5 pcs.;
- Operational documentation: operation manual, user manual for SW "ApnOx" (A_8051);
- Memory card (A_2143, MicroSDHC, 4GB).

Required are:
- SpO$_2$ sensors;
- nasal cannulas.
- Sensors for Poly-4 module.

Optional:
- computing machinery;
- video equipment kit;
- transport bag (A_6492).

basic module · chest fixing band · wireless module "Poly-4" · memory card · wireless module case · basic module case · charger · set of rechargeable batteries · luer connector adapter

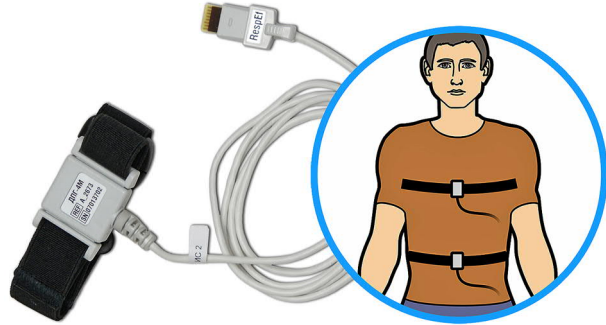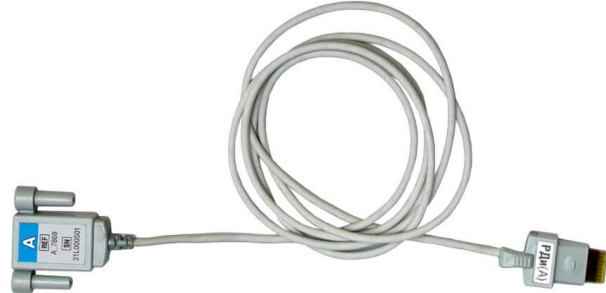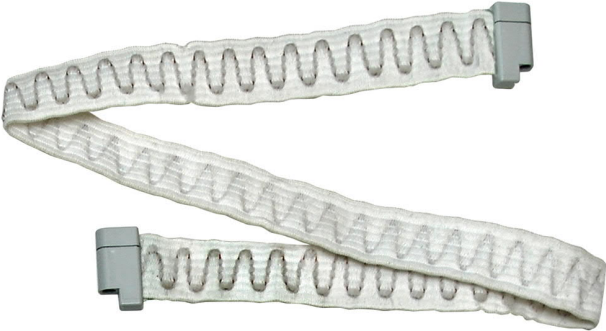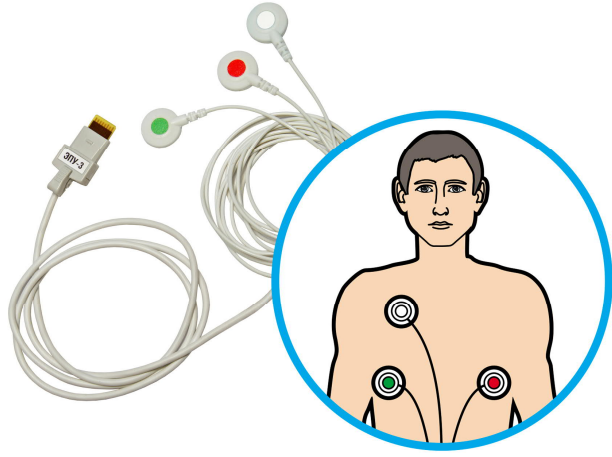| 2.		Software and wireless PC adapter to PC of "ApnOx" recorders		

2.1	A_6896	**"ApnOx-04" model**
		
		Contains:
		
		• **Wireless PC Adapter "IB-4"** (A_0294);
		• **Installation CD with software "ApnOx"** (A_6205-2):
		
		    o provides a record of physiological signals and parameters onto the memory card – data about the patient body position, total movement activity, heart rate, values of blood oxygen saturation (SpO_2), perfusion index, nasal airflow, frequency and nominal respiratory amplitude, the snoring via the nasal cannula, as well as the magnitude of the overpressure (generated by the CPAP machine);
		
		    o generates statistical reports on identified sleep events – apnea, hypopnea, desaturation, tachycardia, bradycardia, snoring, Autonomous activation of the autonomic nervous system and signs of Cheyne-Stokes breathing, and the relationship of these events to the body position during sleep. Calculates numerical values of indicators and trends, and also provides a representation of the cardio-cyclic dynamics of the estimated parameters;
		
		    o After the study, the data from the memory card of the basic "ApnOx" module are transmitted to the signal analysis station or to the station of processing and archival data storage, where the analysis results are formed as a medical report, and reporting forms are prepared for printing out, provides long-term storage of the received records. Export data to form a protocol in Word format by templates, edit templates if necessary. Export signals to the common formats: ASCII, EDF, EDF+.
				Set provides:
				
				• conducting autonomous studies in telemetric mode with one recorder;
				
				• work with additionally purchased basic sets of recorders "ApnOx-04" when used in autonomous, outpatient (Home Sleep Testing) mode, as well as processing and saving data received from these recorders.

2.2	A_6897	**"ApnOx-10" model**
		
		Contains:
		
		• **Wireless PC Adapter "IB-4"** (A_0294);
		• **Installation CD with software "ApnOx"** (A_6205-2):
		
		    Additionally to software of "ApnOx-04":
		
		    o registration via four polygraphic channels of the Poly-4 – electrocardiosignal, chest and abdominal breathing recursion signals, respiratory aiflow by means of a thermistor sensor, limbs movement activity by means of electromyographic electrodes and / or accelerometric sensors, as well as a signal from a snoring sensor and an EDA signal, as well as expansion of the number of simultaneously recorded signals from the additional (second) Poly-4 module, including registration of up to 4 signals in the DC-channel mode is provided;
		
		    o ensures the registration of limbs movements from the wireless sensors of legs movement activity, and also provides registration and analysis of the dynamics of GSR;
		
		    o reports are generated on the presence and severity of events central, obstructive and mixed apnea, single and periodic limb movements, as well as tachycardia, bradycardia and asystole based on the analysis of electrocardiosignal. Provides an indirect estimate of the dynamics of blood pressure according to heart rate and the pulse transit time (PTT)
				Set provides:
				
				• conducting autonomous studies in telemetric mode with one recorder;
				
				• work with additionally purchased basic sets of recorders "ApnOx-04" when used in autonomous, outpatient (Home Sleep Testing) mode, as well as processing and saving data received from these recorders.

3.		Video equipment kit		

3.1	A_3682	**Network video equipment kit**
		
		The kit is used for long-term synchronized video monitoring in the network version (Ethernet) with the signal analysis station or with the station of processing and archival data storage.
		
		Kit includes:
		
		• digital HD video camera, built-in IR backlight and patient's microphone;
		
		• power injector for the camcorder with a set of cables;
		
		• Software for epileptologycal studies with videomonitoring "Encephalan-Video".
		
		    A*dapted SW "Encephalan-Video" provides long - term synchronized recording of PSG and video data, their analysis and archiving, as well as the ability to create a short video (AVI format).*
		
		    Specialized program "Viewer" provides viewing on the doctor's computer recorded on CD/DVD, flash drives card or other media fragments of PSG and video data using the basic functions of visual analysis.
		
		• a clip for camera fixation - fixed on suitable objects of the surroundings
				The manufacturer may replace the video cameras with similar ones with the same characteristics without prior notice.
				
				• Sensitivity – 0.07 lx @ F1.2;
				
				• day-night mode – a mechanical IR-cut filter;
				
				• resolution 1920x1080, 1280x720, 704x576;
				
				• frame rate – 25 fps;
				
				• built-in IR illumination;
				
				• powering – 220 V (via injector);
				
				• a built-in microphone.

3.2	A_3682-1	**Autonomous video equipment kit**
		
		The kit is used for long-term offline synchronized video monitoring for PSG studies in offline mode (Home Sleep Testing)
		
		Kit includes:
		
		• A fixed digital HD video camera, built-in IR backlight and patient's microphone, recirder unit with memory card for recording video data offline; power injector for the camcorder with a set of cables;
		
		• Software for epileptologycal studies with videomonitoring "Encephalan-Video".
		
		    A*dapted SW "Encephalan-Video" provides long - term synchronized recording of PSG and video data, their analysis and archiving, as well as the ability to create a short video (AVI format).*
		
		    Specialized program "Viewer" provides viewing on the doctor's computer recorded on CD/DVD, flash drives card or other media fragments of PSG and video data using the basic functions of visual analysis.
		
		• a clip for camera fixation – fixed on suitable objects of the surroundings
				The manufacturer may replace the video cameras with similar ones with the same characteristics without prior notice.
				
				• Sensitivity – 0.07 lx @ F1.2;
				
				• day-night mode – a mechanical IR-cut filter;
				
				• resolution 1920x1080, 1280x720, 704x576;
				
				• frame rate – 25 fps;
				
				• built-in IR illumination;
				
				• powering – 220 V (via injector);
				
				• a built-in microphone.

3.3		Options to the video equipment kit	
3.3.1	A_6396	IR-lamp for quality video recording in darkness	Provides soft IR light reflected from walls and ceiling for quality record.
3.3.2	A_2811	Portable stand for camera	Optional In addition to a table mount for positioning in any convenient place of the room.
3.3.3	A_3237	Transport bag for video equipment kit	

4.		Modules, sensors, electrodes and accessories to the main "ApnOx" sets	
4.1		Reusable Pulse Oximetry sensors for basic module "ApnOx"	Optional
4.1.1	A_4085-07	**Reusable Pulse Oximetry sensor Y-3227** finger, Y Sensor		Produced by EnviteC-Wismar GmbH, Germany
4.1.2	A_4085-04	**Reusable Pulse Oximetry sensor R-3227** finger, SoftTip®, large		Produced by EnviteC-Wismar GmbH, Germany
4.1.3	A_4085-03	**Reusable Pulse Oximetry sensor RM-3227** finger, SoftTip®, medium		Produced by EnviteC-Wismar GmbH, Germany
4.1.4	A_4085-05	**Reusable Pulse Oximetry sensor RS-3227** finger, SoftTip®, small		Produced by EnviteC-Wismar GmbH, Germany

4.2	Nasal and oro-nasal cannulas for basic module "ApnOx"			Optional
4.2.1	**Nasal cannula (plastic airtube)**			Produced by Embla Systems
4.2.1.1	**A_4007-11**	**Nasal Cannula for adults**		
4.2.1.2	**A_4007-10**	**Nasal Cannula for children**		
4.2.2	**A_4581**	**CPAP connection adapter**		If required Produced by Braebon Medical Coproration
4.2.3	**A_4574**	**Luer connector adapter**		If required Produced by Braebon Medical Coproration
4.2.4	**A_5770**	**P-Flow plug-probe**		If required

4.3		**Sensors for respiratory effort, airflow. ECG, EEM, EDA, snore, movement activity for wireless module "Poly-4" of "ApnOx-10" model**		
4.3.1	**A_2673-2**	**Respiratory Effort Sensor (piezoresistive)** Thoracic **The set includes** belts for children and adults.		Required purchasing 2 sensors – to register thoracic and abdominal respiratory effort.
4.3.2	**A_2673-1**	**Respiratory Effort Sensor (piezoresistive)** Abdominal **The set includes** belts for children and adults.		
4.3.3	**A_7869-3**	**Respiratory Effort Sensor (inductive, A)** Abdominal		
4.3.4	**A_7869-4**	**Respiratory Effort Sensor (inductive, T)** Thoracic		
4.3.5	**A_8891-4**	**Set of Respiratory Effort Sensor belts** Sizes **S** (410-530 mm), **SM** (530-680 mm), **M** (680-900 mm), **LM** (900-1150 mm)		

4.3.6	A_8302	**ECG-Cable ("ECG")** bipolar derivation with neutral electrode 3 snaps for disposable electrodes.		
4.3.7	A_5257	**N Electrode snap connector Wire** Included into the sales package of wireless module "Poly-4"		**Required for:** • Bipolar cable (A_4194); • Skin conductance sensor (A_5119). **Warning!** Used if there is no ECG cable (A_8302) in the montage for PSG studies.
4.3.8	A_4194	**Bipolar cable (EMG, for disposable electrodes)** 2 registering electrodes with a snap connector. To register legs movement activity		**Requires** N Electrode snap connector Wire (A_5257)

4.3.9	A_5361	**Movement sensor** (Move) wired To register legs movement activity		
4.3.10	A_5119	**Skin Conductance Sensor** (EDA-ElectroDermal Activity)		**Requires** N Electrode snap connector Wire (A_5257)
4.3.11	A_2326-4	**Oro-Nasal Airflow Sensor** (Thermistor "T-Flow") **Adult** For evaluation of parameters of oro-nasal respiration (breathing rate and amplitude, duration of in- and exhalation phases) and detection of breathing disorders. Can be used with respiratory airflow sensor cannula.		
4.3.12	A_2326-5	**Oro-Nasal Airflow Sensor** (Thermistor "T-Flow") **Children** For evaluation of parameters of oro-nasal respiration (breathing rate and amplitude, duration of in- and exhalation phases) and detection of breathing disorders. Can be used with respiratory airflow sensor cannula.		
4.3.13	A_1869	**Snore Sensor** ("Snore") For detection and quantitative evaluation of snoring during sleep.		

4.3.14	A_2714	**Disposable snap ECG Electrode** 50 pcs. in 1 pack		Produced by Covidien LLC, USA
4.4		**Additional wireless module "Poly-4" and accessories**		Optional
4.4.1	A_5359	**Wireless module "Poly-4"** • **Can be used for simultaneous registration of physiological signals** by 4 polygraphic channels of the additional module "Poly-4" for PSG studies performed by "ApnOx-10" model (8 channels simultaneously). • **Can be used for simultaneous recording of additional signals in the mode of measuring DC potential** (DC inputs) from a third-party medical equipment or non-medical sensors (CPAP, BPAP, CO2) via 4 polygraphic channels of the module "Poly-4" in "ApnOx-04" and "ApnOx-10" models. **Warning!** In this application, the module Poly-4 is **forbidden** to use for registration of physiological signals and indicators for reasons of electrical safety of the patient.		**Requires** (depending on application): • respiratory effort, breathing airflow, ECG, EMG, EDA, snore, movement activity sensors and N-electrode cable for Poly-4 module (optional); • rechargeable batteries type – AA, 2 pcs.; • DC-input adapter (as many as required).
4.4.1.1	A_1647	**Wireless module "Poly-4" case with a fixing belt**		

4.4.1.2	**A_4731**	**Simulator** Meant for Poly-4 wireless module		Used to check operational condition of Poly-4.
4.4.1.3	**A_8071**	**Bipolar adapter**		For the use of cables (connector – touchproof) with ECG and/or EMG electrodes by the third-party manufacturers at the discretion of the doctor.
4.4.1.4	**A_8328**	**DC-input adapter**		Can be connected to the Poly-4 module's polygraphic channel for simultaneous recording of additional analog signals from third-party medical equipment or sensors. **Warning!** In this case, the Poly-4 module cannot be used for registration of physiological signals and indicators.

4.5	**Other sensors and accessories**		Optional
4.5.1	**A_2732**	**Wireless Movement Sensor** **Includes** battery type – AAA.	**Requires purchasing 2 pcs.**
4.5.2	**A_6297**	**Wireless Movement Sensor Case** with fixing belt for patient's leg.	**Requires purchasing 2 pcs.**
4.5.3	**A_2645**	**USB Cable**	It is used to read data from the memory card of the basic module "ApnOx" into the memory of the PC of the Signals analysis station or PC of the Station of processing and archival data storage via USB-port.
4.5.4	**A_6492**	**Transport bag for "ApnOx" recorder**	
4.5.5	**A_2334**	**Rechargeable batteries Ni-MH AA for basic module "ApnOx" or wireless module "Poly-4"**	

5.		**Equipment for control, analysis and processing of recorded data**	
5.1	A_3681	**Signals analysis station with pre-installed software "ApnOx"** Designed to conduct studies in telemetric mode with a single recorder, as well as for the optional basic sets of recorders "ApnOx" when used in the autonomous mode. The station can be used for processing and storage of data obtained from recorder "ApnOx".	

5.1.1		**Laptop computer (PC)**
		
		Contains:
		
		• a purchased additional set (from section 2):
		
		  o an additional set of "ApnOx-04" model, including wireless PC adapter IB-4 (A_0294) and installation CD with software «ApnOx-04» (A_6205-2) for PC installation
		
		  or
		
		  o an additional set of "ApnOx-10" model, including wireless PC adapter IB-4 (A_0294) and installation CD with software «ApnOx-10» (A_6205-1) for PC installation.
			Minimal requirements:
			
			• Intel Core i5;
			• RAM 4 GB;
			• HDD 500 GB;
			• resolution 1920×1080;
			• OS Windows 10.
			
			Should be included into the sales package (from 3.3.1.1):
			• Additional monitor;
			• SW MS Office
			• antivirus software.

5.2	A_3683	**Station of processing and archival data storage with pre-installed software "ApnOx"** Designed for processing and storage of data obtained from the Signals analysis station or recorder "ApnOx".	

5.2.1		**System unit**
		
		Contains:
		
		• a keyboard;
		• a mouse;
		• a monitor.
		• Preinstalled software "ApnOx-04" (A_6205-2) or "ApnOs-10" (A_6205-2) from additional set of "ApnOx-04" or "ApnOx-10" model for the Signals analysis station. **Warning!** To use the software you need to purchase an SW-key (USB) (A_2329).
		
		Warning! In the case of using the Station of processing and archival data storage as the Signals analysis station (signals analysis station is not supplied), **purchase** the option of section 2:
		
		  o an additional set of "ApnOx-04" model, including wireless PC adapter IB-4 (A_0294);
		  installation CD with software «ApnOx-04» (A_6205-2) for PC installation
		
		  or
		
		  o an additional set of "ApnOx-10" model, including wireless PC adapter IB-4 (A_0294);
		  installation CD with software "ApnOx-10" (A_6205-1) for PC installation.
			Minimal requirements:
			
			• Intel Core i5;
			• RAM 4GB;
			• HDD 500 GB;
			• monitor – Full HD, minimum 23", 16:9;
			• OS Windows 10.
			
			Should be included into the sales package (from 3.3.1.1):
			• Additional monitor;
			• Uninterruptible power supply;
			• SW MS Office
			• antivirus software.
			
			Also from 3.3.3
			SW-key (USB) (A_2329).

5.3	**Additional software and accessories** to the Laptop computer of the Signals analysis station (**3.1.1**) and system unit of the Station of processing and archival data storage (**3.2.1**)		
5.3.1	**A_6843**	**Mobile data storage HDD minimum 1000 GB**	
5.3.2	**A_5109**	**Antivirus software «Kaspersky Internet Security»** Recommended to protect PC from viruses	
5.3.3	**A_4319**	**MS Office** **Mandatory for PC.** Required are Word and Excel	
5.3.4	**A_4299**	**Uninterruptible power supply**	
5.3.5		**Bag for the Laptop computer of the Signals analysis station**	
5.3.6	**A_0687**	**Additional monitor**		**Monitor features:** • diagonal – minimum 23"; • resolution 1920x1080; • aspect ratio 16x9.
5.4	**A_4087**	**Laser printer** to the Laptop computer of the Signals analysis station (3.1.1) and system unit of the Station of processing and archival data storage (3.2.1) • Monochromic; • format – A4		Other printer type should be agreed with manufacturer
5.5	**A_2329**	**SW-key (USB)**		Provides the ability to work with the software on the Station of processing data or on a third-party computer of the user, including the network version with the Signals analysis station.