



BlueNight[®] Trainer

User manual

BlueNight (Android) Version 4.0.0



Sleepinnov Technology 340 rue de l'Eygala 38430 Moirans – France 2023-05-24

BlueNight Acor+ Version 3.0.0



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SGS Belgium NV





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1. Introduction

1.1. BlueNight® Trainer Solution

BlueNight[®] Trainer is a diagnostic device and must not be used for continuous monitoring or for monitoring of vital signs. It collects, visualises, calculates and presents data on:

- 6-minute walk tests, the aim of which is to assess the impact of patients' chronic respiratory disease on their physical condition. This is useful to monitor a patient's state of health and the therapeutic benefits of treatment. Fingertip measurements of SpO2 and heart rate, and total distance walked during the walk test, provide information about the patient's physical condition.
- Stroll tests, the aim of which is to measure the patient's oxygen saturation and heart rate in an everyday context, without aiming to maximise distance.

Tests are carried out under medical supervision in a hospital environment or in a doctor's clinic.

It consists of the following items:

- The **BlueNight[®] mobile application**, installed on an Android tablet.
- PC software called *BlueNight* [®] Acor+.

The first is used to carry out tests. The PC software is used to store and consult results, and is used to generate and print reports.

1.2. <u>Mobile Application: *BlueNight*® (Android)</u>

This application measures the patient's blood oxygen saturation (SpO2) and heart rate. These values are transferred to a tablet using Bluetooth.

This user manual refers to version **4.0.0** of the *BlueNight*^{*} application (Android). The application version number can be seen by clicking on "**About**" in the application menu. Only the first three digits are relevant.

.*					91% 🗎
BlueNight	ABOUT				
Home		Г			
Stored tests	Versio	n	4.0.0		
New walk test	Techn	ical Support		sleepinnov.com	
New stroll test			🕿 + 33 4 76	o 37 05 79	
Settings					
About		Sieepinnov Technology 340 rue de l'Eygala 38430 Moirans - France 24/05/2023			
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1.3. PC software: BlueNight® Acor+

This user manual refers to version **3.0.0** of the *BlueNight[®] Acor+* application. The software version number is shown on the bottom right of the software's home page. Only the first three digits are relevant.

- BlueNight Acor+			
¢ [¢]	sleepinnov		
Download	Patients		
Android tablet or smartphone	Detect Restart ALLFRED Poinson (TAOMEDTEST) ALLX Pénélope ALLEGRE Germaine (GA0088) ALLEMAND Régis AMIOT Rachel (RA0055) ANGOT André AQUITAINE Berlin AQUITAINE Berlin AQUITAINE Monta (MA0051) ARNOULT Augustin (AA0136) AUBERT Gustave (GA0039) AUBIN Jacqueline AUDOUIN Lucienne (LA0053) AUMONT Gilberte (GA0138) AYMARD Patrick BACH Sylvie BAILLARD Christophe (bai) BAILLEUL Fernand BAILLEUT Thomas (TB0147) 		
	3.0.0		



2. <u>Symbol definitions</u>

The table below explains the symbols seen on the Nonin WristOx2 3150 oximeter, which is recommended for use with this solution.

<u>۲</u>	BF type applied part (protection of the patient from electric shocks)
CUL US	UL standard label for Canada and the United States relating to electrical discharge, fire and mechanical risks, in compliance with UL 2601-1 and CAN/CSA C22.2 no. 601.1.
CE ₁₆₃₉	CE mark, indicating that this device complies with directive 93/42/CEE on medical devices. 1639 is the number of the notified organisation.
	Medical device manufacturer symbol
SN	Serial number
SpO2	Remote alarms – Device not designed for continuous monitoring
	Electronic waste is not household waste! Consumers have a legal obligation to dispose of all devices containing electronic components, batteries and accumulators either in a collection point in their local area or at a distributor, regardless of whether the waste contains toxic substances, so that they can be disposed of in a way that protects the environment. Only take discharged batteries and accumulators to collection points!



3. <u>Precautions for use</u>

READ THE WHOLE CHAPTER ON PRECAUTIONS FOR USE CAREFULLY BEFORE USING THE BLUENIGHT* ACOR+.

3.1. <u>Use</u>

BlueNight^{*} Trainer must only be used by qualified personnel. Read all instructions, precautions and technical specifications before use.

BlueNight[®] Trainer is a diagnostic device and must not be used for continuous monitoring or for monitoring of vital signs.

BlueNight[®] Trainer functions only with Nonin WristOx2 3150, Nonin WristOx2 3150 BLE oximeters. Before use, read chapters 5, 6, 7 and 8 of this manual carefully.

Sleepinnov Technology is a distributor of Nonin oximeters. For more information about how to use oximeters, please refer to the manual provided by the manufacturer, Nonin.

The oximeter has only an auxiliary role in evaluating a patient's condition. It must be used in conjunction with other methods of evaluating clinical signs and symptoms.

Only PureLight[™] sensors, manufactured by NONIN, must be used. These sensors are designed to comply with the precision criteria of NONIN pulse oximeters. Use of other brands of sensor may cause the device to function improperly.

When using the BlueNight[®] Trainer product, the user may collect personal data, in which case the user is responsible for adhering to regulation 2016/679.

3.2. <u>Risk of explosion</u>

Do not use the oximeter in an explosive atmosphere or in the presence of anaesthetics or inflammable gases.

3.3. Installation

As for any medical device, take care with cables and connections in order to reduce the risk of tangling or strangulation.

Do not pull on the sensor, except when disconnecting it from the oximeter.

Loss of measurement is possible if any object impedes pulse measurement. Ensure that nothing can limit blood circulation (in particular a blood pressure monitor armband) and then compromise pulse readings.

The oximeter may incorrectly interpret movement as a good-quality pulsatile signal. Take care to minimise as much as possible any movement of the finger to which the sensor is attached.

Do not tighten the oximeter band too much around the patient's wrist, otherwise readings might not be precise.



The pulse oximetry system aims to determine the percentage blood saturation of functional haemoglobin. If there are significant quantities of non-functional haemoglobin such as methaemoglobin, this can reduce the precision of readings.

Correct placing of the sensor is critical is to function properly. The following factors can affect the device's effectiveness: badly attached sensor, wrong type of sensor, humidity in the sensor, poor quality pulse, venous pulse measurements, anaemia or low haemoglobin level, vascular dye, nail varnish, excessive ambient light levels, arterial catheters, blood pressure cuffs, perfusion tubes.

3.4. <u>Maintenance</u>

Do not immerse the sensor or oximeter in water, solvents or cleaning fluids. Sensors and connectors are not waterproof. Do not sterilise oximetry sensors by any method. Refer to the cleaning instructions given in **chapter 12 – Maintenance and Repairs**.

Do not use a device that is damaged or which does not function properly. Stop using the device until the problem has been corrected by a qualified person. Refer to the instructions given in **chapter 12 – Maintenance and Repairs**.

Follow local regulations and advice relating to recycling and/or disposal of batteries. Remove the batteries if the system is not used for 30 days.

Matter that comes out of a liquid crystal screen is toxic when ingested. Be careful when handling a PDA with a broken screen.

3.5. <u>Communication and interference</u>

To ensure optimal communication, it is necessary to maintain a maximum distance of approximately 9 metres between the oximeter and PDA during recording, and to ensure, as far as possible, that there are no obstacles (walls, furniture) between the two devices, which could affect radio communication.

Do not use this product in a magnetic resonance imaging (MRI) environment.

This device conforms to international standard EN 60601-1-2:2015 relating to electromagnetic medical device and/or system compatibility. This standard aims to provide reasonable protection against harmful interference in a typical medical facility. However, given the proliferation of devices that transmit radio waves and other sources of interference in healthcare and other environments, it is possible that high levels of interference caused by close proximity or the strength of these sources could disturb this product's operation.



4. Minimum system configuration

4.1. BlueNight[®] Acor+ software

The BlueNight[®] Acor+ software can be installed only on PCs with Windows 7 or later version (8, 10) installed. The minimum specification is given below.

Architecture	32-bit
Processor	Pentium 4 3GHz
RAM	1 GB
Available hard disk space	2.5 GB
USB ports	1

4.2. <u>BlueNight® software</u>

Tablets are delivered with the BlueNight[®] Android software installed. The minimum specification is given below:

OS	Android
OS Version	4.3
Screen size (required)	7 or 8 inches
Bluetooth	Yes
USB ports	1

5. <u>Installation</u>

All the items below are on the installation CD provided with your order. Download links are also given for PCs that do not have CD drives.

Your tablet is delivered with the *BlueNight*[®] software pre-installed. If an oximeter was also provided, it is already loaded onto the device. Otherwise, refer to §9.1 of this manual for instructions for loading it.

In all cases, follow the instructions in §5.1 and §5.2 to install the solution on your computer.

5.1. Installing the BlueNight ® Acor+ software

Using the installation CD:

- 1. Insert the BlueNight CD into your PC's CD drive.
- 2. The installation program should start automatically. Allow it to run, and follow all the installation instructions.
- 3. A "BlueNight Acor+" icon will be added to the desktop. Double-click this to start the application. A series of configuration windows will be displayed when you first start the application. This is completely normal.

From the Internet:



- Download the installation program from the following address: <u>http://www.sleepinnov.com/download/bluenight_acor/en/Setup.msi</u>
- 2. Once the file has downloaded, run it and follow all the installation instructions.
- 3. A "BlueNight Acor+" icon will be added to the desktop. Double-click this to start the application. A series of configuration windows will be displayed when you first start the application. This is completely normal.

5.2. Installation of drivers for tablet

Installation instructions are given below for all tablets currently on the market. **Please only follow the steps for your device.**

5.2.1. Acer tablets

Using the installation CD:

- 1. In "Workstation", browse the contents of the CD.
- 2. Open the "**Drivers**" folder, then the "**Acer**" folder.
- Follow the instructions in the document "Acer B1 A71 Installation guide.pdf". The installation program is the file "Acer - B1 A71 - Setup.exe"

From the Internet:

- 1. Download the installation program from the following address: <u>http://www.sleepinnov.com/download/support/acer/USB_Acer_2.0_B1-A71.exe</u>
- Follow the procedure described in the document available from the following address: <u>http://www.sleepinnov.com/download/support/acer/Acer_Iconia_B1-A71_-</u> <u>Installation_guide_-_EN.pdf</u>

5.2.2. Huawei tablets

Using the installation CD:

- 1. In "Workstation", browse the contents of the CD.
- 2. Open the "**Drivers**" folder, then the "**Huawei**" folder.
- 3. Run the file "Huawei HiSuite 1.8.10.2606 Setup.exe" (while the tablet is not connected to the PC)
- 4. Complete the installation process and then follow the procedure shown below (a).

From the Internet:

- 1. Download the file: http://www.sleepinnov.com/download/support/huawei/HiSuiteSetup_v1.8.10.2606.exe
- 2. Run the downloaded file (while the tablet is not connected to the PC)
- 3. Complete the installation process and then follow the procedure shown below (a).

Then, regardless of the procedure used:

- a) Connect the tablet to the computer
- b) Run the BlueNight Acor+ software
- c) Once the tablet is correctly detected by BlueNight Acor+, the *HiSuite* software can be uninstalled from the computer. This prevents this application from running every time the tablet is connected to the PC.

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5.2.3. Samsung tablets

Using the installation CD:

- 1. In "Workstation", browse the contents of the CD.
- 2. Open the "Drivers" folder, then the "Samsung" folder.
- 3. Run the file "Samsung Setup.exe" (while the tablet is not connected to the PC)
- 4. Once this has finished, follow the procedure shown below (a).

From the Internet:

- Download the file: <u>http://www.sleepinnov.com/download/support/samsung/SAMSUNG_USB_Driver_for_Mobil</u> <u>e_Phones.exe</u>
- 2. Run the downloaded file (while the tablet is not connected to the PC)
- 3. Once this has finished, follow the procedure shown below (a).

Then, regardless of the procedure used:

- a) Restart the computer
- b) Connect the tablet to the computer
- c) Run the BlueNight Acor+ software

During steps b) and c), watch the screen of the tablet and authorise connection to the computer when asked to do so. This takes the form of the message shown below (example taken from 2 different tablets). **Tick the small box "Always authorise this PC", then click "OK".** If the message does not appear, disconnect the tablet and start again from step b).

		* ¥ \$	98% 🖲 09:12
	НОМЕ		
Home			
Stored tests			
New walk test	Allow USB debugging?		
New stroll test	The computer's RSA key fingerprint is:		
Settings	C0:A9:03:3A:C5:4B:A6:D3:01:48:6D:9C:68:D1:F4:0D		
About	Always allow from this computer		
	CANCEL OK		



5.2.4. Lenovo tablets

Using the installation CD:

- 1. In "Workstation", browse the contents of the CD.
- 2. Open the "Drivers" folder, then the "Lenovo" folder.
- 3. Run the file **"LenovoUsbDriver_autorun_1.1.57_user.exe**" (while the tablet is not connected to the PC)
- 4. Once this has finished, follow the procedure shown below (a).

From the Internet:

- 1. Download the file: <u>https://www.sleepinnov.com/download/support/lenovo/LenovoUsbDriver_autorun_1.1.57_user.exe</u>
- 2. Run the downloaded file (while the tablet is not connected to the PC)
- 3. Once this has finished, follow the procedure shown below (a).

Then, regardless of the procedure used:

- a) Restart the computer
- b) Connect the tablet to the computer
- c) Run the BlueNight Acor+ software

During steps b) and c), watch the screen of the tablet and authorise connection to the computer when asked to do so. This takes the form of the message shown below (example taken from 2 different tablets). **Tick the small box "Always authorise this PC", then click "OK".** If the message does not appear, disconnect the tablet and start again from step b).

		*	98% 🖲 09:12
	НОМЕ		
Home			
Stored tests			
New walk test	Allow USB debugging?		
New stroll test	The computer's RSA key fingerprint is:		
Settings	C0:A9:03:3A:C5:4B:A6:D3:01:48:6D:9C:68:D1:F4:0D		
About	✓ Always allow from this computer		
	CANCEL OK		



6. <u>Carrying out a test</u>

6.1. Carrying out a walk test

This paragraph describes the steps involved in carrying out a walk test on an Android tablet.

6.1.1. Test configuration

On the software home screen, click on " New walk test ".	Home Stored tests New walk test New stroll test Settings About	номе sleep	200. 11:42
If the message opposite appears, this means that the oximeter registration process, as described in the FAQ, has not been performed. Please refer to this section to carry out the registration process.	Home Home Stored tests New walk test New stroll test Settings About	WALK TEST Patient Surname Meter patient information later Walking frame No oximeter paired Oximeters must be paired in the applicat Settings menu Cancel Comment Cancel Cancel Cancel	8 96% III.33 Settings Rest duration Test duration 6 min 1 min 30 metres 0K
The window opposite will appear. If the patient is on assisted respiration, tick the 'oxygen' box and adjust the flow rate using the arrows. If the patient walks using a walking frame, tick the relevant box. The " Settings " field gives times for rest, testing, recovery and distance units used for the walk test. If you would like to change the duration, distance units or dyspnoea test (VAS or Borg) used for the walk test, press on the drop-down list in the lower right corner of the value in question.	Extract tests New walk test New stroll test Settings About	WALK TEST Patient Sumame Value Va	Settings Rest duration 30 sec Test duration 6 min Recov. duration 1 min Unit Distance 30 Dyspnoea test VAS Operator



Patient information can be entered on the mobile device.

The option "**Enter later...**" enables you to postpone patient data entry until you synchronise with the computer.

Click on the "**Start**" button to confirm the information entered and move on to dyspnoea measurement.

6.1.2. Dyspnoea measurement

	79% 🖹 11:47
Buckeye VAS	
Shortness of breath	
min	max
Cancel	ок
	79% 🗎 11:48
Borg	
0	Nothing at all
0.5	Very, very slight
Shortness of breath	Very slight Slight
3	Moderate
4	Somewhat severe
5	Severe
	Very severe
8	,
Cancel OK 9	Very, very severe
10	Maximal
	Shortness of breath min Cance

Confirming the level of dyspnoea at rest causes the recording to start immediately. Before confirming, please ensure that the oximeter is correctly installed and switched on.



6.1.3. Recording the test

	* 96% 0 11:45 walk TEST
 The first step is to look for an oximeter. When the oximeter is detected, a connection is established. 	Image: Starting Image: Starting
2 During recording, a stopwatch is displayed, along with values for the parameters being measured.	Walk TEST Walk 00:05 Measuring
An initialisation phase, and then a rest phase, are displayed before starting the test. During these two phases it is essential that the patient remains calm and does not exert him/herself. At the end of the test, a recovery phase is recorded.	Connected HR 78 bpm +30 m ♥ SAT 98 % ●
 3. During recording, you can indicate if the patient takes breaks. Click on the or button on the right of the screen to start or restart after a pause. Pauses are recorded and shown on signal traces as a grey area. When the patient walks, pressing the button opposite allows the chosen distance units to be added to the distance walked. This button is not activated during pauses. 	+ 30 m



4. Once recording is finished, you will need to enter the distance walked as illustrated opposite.	
The distance walked is pre-filled, depending on the pre-set distance unit. This distance is only an estimate of the distance walked. It will naturally be slightly lower than the actual distance. You can change this distance using the keyboard.	BlueNight Please enter distance walked to validate walk test 122 123 124 0K 0K 0K
5. Once the distance walked has been validated, the final results are displayed as illustrated opposite.	Wanty RESULTS Results Graphs Walk test - Oxygen yes Walking frame no Distance walked 308 metres Mean velocity 1.15 m/sec Dyspnoea test VAS Dyspnoea at rest 1.5 Dyspnoea at end of test 7.0



6.2. <u>Carrying out a stroll test</u>

This paragraph describes the steps involved in carrying out a stroll test on an Android tablet.

6.2.1. Test configuration

		80% 🗰 11:42	
	ou h ■ 11.42. Buotigne HOME		
	Home		
	Stored tests	-	
On the software home screen, click on "New stroll	New walk test		
test".	New stroll test	-	
	Settings	slaaning	
	About	sleepinnov	
		★ 96% 1 11:04	
	BhueNight	STROLL TEST	
	Home	Patient Settings	
If the message opposite appears, this means that	Stored tests	Surname - Dyspnoea test VAS	
	New walk test	Enter patient information later Walking frame	
the oximeter registration process, as described in	New stroll test		
the FAQ, has not been performed.		No oximeter paired	
	Settings	Oximeters must be paired in the application in the Settings menu	
Discourse from the their sections the second section	About	Cancel OK	
Please refer to this section to carry out the			
registration process.		Comment	
		Cancel	
The window opposite will appear.			
The window opposite win appeal.			
If the mations is an excitated membration still the			
If the patient is on assisted respiration, tick the			
'oxygen' box and adjust the flow rate using the			
arrows.			
If the patient walks using a walking frame, tick the			
If the patient waiks using a waiking frame, tick the		≱ 80% 🗎 11:45	
	BlueNight	¥ 80%∎11:45 STROLL TEST	
relevant box.	DiveNight Home		
relevant box.	Home Stored tests	STROLL TEST Patient Surname - Dyspncea test VAS	
		STROLL TEST Patient Patient Sumame Upspnoea test VAS Waking frame	
The dyspnoea test (VAS or Borg) used for the test	Stored tests	StrolL TEST Patient Settings Sumame Dyspnoea test VAS Inter patient information later Walking frame Image: Walking frame Image: Walking frame Image: Oxygen Image: Extractor (pulsed)	
	Stored tests New walk test	STROLL TEST Patient Patient Sumame Uyspncea test VAS Walking frame	
The dyspnoea test (VAS or Borg) used for the test can be changed in " Settings "	Stored tests New walk test New stroll test	STROLL TEST Patient Patient Patient information later Walking frame Orgon Extractor (pulsed)	
The dyspnoea test (VAS or Borg) used for the test	Stored tests New walk test New stroll test Settings	Settings Patient Settings Sumame Dyspnoea test VAS Image: Colspan="2">Organization later Image: Walking frame Dyspnoea test VAS Image: Walking frame Image: Colspan="2">Operator Image: Walking frame Image: Colspan="2">Operator Image: Position 0 Image: Colspan="2">Operator Position 0 Image: Colspan="2">Operator	
The dyspnoea test (VAS or Borg) used for the test can be changed in " Settings "	Stored tests New walk test New stroll test Settings	Patient Settings Surname Dyspnoea test VAS ✓ Enter patient information later Uvalking frame VAS ✓ Oxygen ✓ Extractor (pulsed) Device Activox 3Pro Position 0 0 0	
The dyspnoea test (VAS or Borg) used for the test can be changed in " Settings " Patient information can be entered on the mobile	Stored tests New walk test New stroll test Settings	Settings Settings Valking frame Dyspnoea test VAS Walking frame Device Activox 3Pro Position 0 Device Requested by Operator	
The dyspnoea test (VAS or Borg) used for the test can be changed in " Settings " Patient information can be entered on the mobile device.	Stored tests New walk test New stroll test Settings	Settings Patient Settings Surname Dyspnoea test VAS ✓ Enter patient information later Dyspnoea test VAS ✓ Oxygen ✓ Extractor (pulsed) Device Activox 3Pro Position 0 Requested by Operator Comment	
The dyspnoea test (VAS or Borg) used for the test can be changed in " Settings " Patient information can be entered on the mobile device. The option " Enter later " enables you to postpone	Stored tests New walk test New stroll test Settings	Settings Patient Settings Surname Dyspnoea test VAS ✓ Enter patient information later Dyspnoea test VAS ✓ Oxygen ✓ Extractor (pulsed) Device Activox 3Pro Position 0 Requested by Operator Comment	
The dyspnoea test (VAS or Borg) used for the test can be changed in " Settings " Patient information can be entered on the mobile device.	Stored tests New walk test New stroll test Settings	Settings Patient Settings Surname Dyspnoea test VAS ✓ Enter patient information later Dyspnoea test VAS ✓ Oxygen ✓ Extractor (pulsed) Device Activox 3Pro Position 0 Requested by Operator Comment	
The dyspnoea test (VAS or Borg) used for the test can be changed in "Settings" Patient information can be entered on the mobile device. The option "Enter later" enables you to postpone patient data entry until you synchronise with the	Stored tests New walk test New stroll test Settings	Settings Patient Settings Surname Dyspnoea test VAS Image: Comparison of the structor (pulsed) Device Activox 3Pro Position 0 Position Operator Comment	
The dyspnoea test (VAS or Borg) used for the test can be changed in " Settings " Patient information can be entered on the mobile device. The option " Enter later " enables you to postpone	Stored tests New walk test New stroll test Settings	Settings Patient Settings Surname Dyspnoea test VAS Image: Comparison of the set of the se	
The dyspnoea test (VAS or Borg) used for the test can be changed in " Settings " Patient information can be entered on the mobile device. The option " Enter later " enables you to postpone patient data entry until you synchronise with the computer.	Stored tests New walk test New stroll test Settings	Settings Patient Settings Surname Dyspnoea test VAS Image: Comparison of the set of the se	
The dyspnoea test (VAS or Borg) used for the test can be changed in " Settings " Patient information can be entered on the mobile device. The option " Enter later " enables you to postpone patient data entry until you synchronise with the computer.	Stored tests New walk test New stroll test Settings	Settings Patient Settings Surname Dyspnoea test VAS ✓ Enter patient information later Dyspnoea test VAS ✓ Oxygen ✓ Extractor (pulsed) Device Activox 3Pro Position 0 Requested by Operator Comment	
The dyspnoea test (VAS or Borg) used for the test can be changed in " Settings " Patient information can be entered on the mobile device. The option " Enter later " enables you to postpone patient data entry until you synchronise with the computer.	Stored tests New walk test New stroll test Settings	Settings Patient Settings Surname Dyspnoea test VAS Image: Comparison of the structor (pulsed) Device Activox 3Pro Position 0 Position Operator Comment	
The dyspnoea test (VAS or Borg) used for the test can be changed in "Settings" Patient information can be entered on the mobile device. The option "Enter later" enables you to postpone patient data entry until you synchronise with the computer. Click on the "Start" button to confirm the information entered and move on to dyspnoea	Stored tests New walk test New stroll test Settings	Settings Patient Settings Surname Dyspnoea test VAS Image: Comparison of the set of the se	
The dyspnoea test (VAS or Borg) used for the test can be changed in "Settings" Patient information can be entered on the mobile device. The option "Enter later" enables you to postpone patient data entry until you synchronise with the computer.	Stored tests New walk test New stroll test Settings	Settings Patient Settings Surname Dyspnoea test VAS ✓ Enter patient information later Dyspnoea test VAS ✓ Oxygen ✓ Extractor (pulsed) Device Activox 3Pro Position 0 Requested by Operator Comment	



6.2.2. Dyspnoea measurement

The test (VAS or Borg) will be selected when	
choosing settings.	
VAS:	
	- 79% #11:47 Montes
The window opposite is displayed at the start and	All and a second
end of recording, in order to calculate dyspnoea	Shortness of breath
	Shormess of breath
at rest and after effort.	
Ask the patient to place the red cursor to show	min max
how out of breath he/she is.	
now out of breath neysne is.	
	Cancel OK
Press " OK " to start recording.	
Press "Cancel" to cancel recording and go back to	
the application's main menu.	
BORG:	
Bona:	
	·
The window opposite is displayed at the start and	Bundlet Borg
end of recording, in order to determine dyspnoea	0 Nothing at all
at rest and after effort.	0.5 Very, very slight
	Shortness of breath 2 Slight
	3 Moderate
After you have selected the level of dyspnoea,	4 Somewhat severe 5 Severe
click on " OK " to start recording.	6
-	7 Very severe
	Cancel OK 2
	9 Very, very severe 10 Maximal

Confirming the level of dyspnoea at rest causes the recording to start immediately. Before confirming, please ensure that the oximeter is correctly installed and switched on.

6.2.3. Recording the test

	BlueNight	STROLL TEST	≉ 96% 211:46
1. The first step is to look for an oximeter.	*	00:00 Starting	Stop Oxygen : Position 0
When the oximeter is detected, a connection is established.	Connected	HR - bpm	Ť
		SAT - %	E Comment



2 During recording, a stopwatch is displayed, along with values for the parameters being measured.	Troll OO : O7 End stroll Oxygen : Position 0 Oxygen : Position 0
An initialisation phase, and then a rest phase, are displayed before starting the test. During these two phases it is essential that the patient remains calm and does not exert him/herself. At the end of the test, a recovery phase is recorded.	Connected HR 76 bpm ✓
3. During recording, you can indicate if the patient takes breaks.	
Click on the contract or contract of the screen to start or restart after a pause. Pauses are recorded and shown on signal traces as a grey area.	
 4. When the recording is finished, you can state the distance walked and type of effort the patient used, as illustrated opposite. These 2 values are optional. 	Tree 12:02 Image: STROLL TEST Image: Stroke test <tr< td=""></tr<>
5. Once the previous window has been validated, the final results are displayed as illustrated opposite.	Image: RESULTS RESULTS GRAPHS Stroll test - Type of activity - Oxygen yes Walking frame no Dyspnea at rest Borg Dyspnea at rest 1 Dyspnea at rest 98 % Mean HR at rest 74 bpm



7. Loading a test onto the computer

Once the installation procedure described above is complete, it is very simple to download a test:

- 1. Open the *BlueNight* application [®] on the tablet.
- 2. Connect the tablet to the PC.
- 3. Open the *BlueNight* [®] *Acor+* software on the computer.
- 4. In the "**Download**" zone, the tablet should appear, and tests saved to its memory should appear under the title "**Walk test**" and/or "**Stroll test**".
- 5. Double-click on the test to download it (it is identified by date and time).
- 6. A window will appear. Enter or confirm the patient's data, then click on 💙
- 7. A second window appears. You can provide information about the test. Click on V when you have finished.
- 8. The new test now appears under the patient name in the "Patients" zone of *BlueNight* [®] Acor+.

To configure automatic deletion of tests from your tablet after they are downloaded, click on the

icon that is displayed at the top left of the *BlueNight* [®] *Acor+* home screen.

8. <u>Generating a test report</u>

- 1. Open the *BlueNight* [®] *Acor+* software on the computer.
- 2. In the "Patients" zone, double-click on the patient name to show the patient's tests.
- 3. Double-click on the date and time of the test for which you wish to see the results.
- 4. The test results window is then displayed. It opens on a preview of the test report, which can be printed directly or saved in Word or PDF format. Other tabs are available on the left of the screen, to access more details about the saved results.
- 5. Click on the ficon at the top left of the home screen to go back to the application's home screen.



9. Frequently asked questions (FAQ): tablet software

9.1. [Oximeter] How can I pair an oximeter with the tablet?

The procedure depends on your device:

• Nonin WristOx2 3150 BLE: Turn your device over. On the white label on the back, the "SN" field consists of 9 digits and ends in "BLE". If your device looks like this, you will not be asked for a PIN code.

Otherwise your device is a **Nonin WristOx2 3150** (not the BLE model). Use the following instructions to find out your PIN code before starting.

• Nonin WristOx2 3150: a PIN code will be requested when pairing. This is a 6-digit number which is on the side or back of the oximeter (see picture below). Note it on a piece of paper before starting.



When your device is identified and after you have identified any PIN code:

- 1. Open the *BlueNight*[®] application on the tablet.
- 2. In the application menu, press "Settings".
- 3. If an oximeter is already paired, its settings are displayed on the screen. Press "Search", then "Unpair the device".

If no oximeter is paired, just press "Search".

4. Press the small grey button on the top of the wrist unit (shown by green arrow) until the oximeter starts and the Bluetooth logo appears, then put the sensor on your finger.





- 5. On the tablet's screen, press on the oximeter model to pair.
- 6. A dialogue box may then appear on the screen. This asks for authorisation to activate Bluetooth. Press "**Yes**".
- 7. A list of discovered devices appears. After a few seconds, the name of your oximeter appears in the following format:
 - a. "Nonin_Medical_Inc._XXXXXX" (where "XXXXXX" is the PIN code you noted previously) for Nonin 3150 devices.
 - b. "Nonin3150_XXXXXXXXX" (where XXXXXXXX is the serial number) for Nonin 3150 BLE.
- 8. Click on your device's name.

If it does not appear, press "Refresh" to start the search again.

- 9. For **WristOx2 3150** oximeters (not the BLE model): a dialogue box then asks you to enter the device's PIN code. Enter it and then press OK.
- 10. Close the confirmation messages, then press the "**Previous**" button to go back to the application menu. The device is now unpaired.

9.2. [Saving] What are the buttons shown during a walk test for?

Button	Description
Stop	During: o Connection of sensor: cancels the test o Rest: triggers the start of the walk phase. o Walk: triggers the start of the recovery phase. o Recovery: ends the test.
Oxygen: XXX	Optional. This button is only shown if the "Oxygen" setting was selected before the test. XXX is the current oxygen setting. It can be changed by pressing the button.
×	Shows that the patient is currently moving. Pressing this button shows that the patient has stopped walking and is having a rest. This button can only be pressed during the walk phase.
Ť	Shows that the patient has stopped. Pressing this button shows that the patient has started walking again. This button can only be pressed during the walk phase.
+ XX m	XX is the distance of travel configured before the test. Pressing this button shows that the patient has gone beyond this distance and started a new lap. XX metres are added to the distance travelled by the patient since the start of the walk. This button can only be pressed during the walk phase.
Comments	Add a comment during the test.



9.3. [Saving] What are the buttons shown during a stroll test for?

Button	Description
Stop	Stops the test
Start stroll	Stops the rest phase and triggers the start of the stroll phase.
End stroll	Ends the stroll phase and triggers the start of the recovery phase.
Oxygen: XXX	<i>Optional. Only shown if the "Oxygen" setting was selected before the test.</i> XXX is the current oxygen setting. It can be changed by pressing the button.
-×	Shows that the patient is currently moving. Pressing this button shows that the patient has stopped walking and is having a rest. This button can only be pressed during the walk phase.
Ť	Shows that the patient has stopped. Pressing this button shows that the patient has started walking again. This button can only be pressed during the walk phase.
Comments	Add a comment during the test.

9.4. [Password] I have forgotten the tablet's password, what should I do?

The default password is "a". If this has been changed and you have forgotten the new one, it can be changed in the *BlueNight® Acor+* software. In order to do this:

- 1. Open the *BlueNight*[®] application on the tablet.
- 2. Connect the tablet to the PC.
- 3. Open the *BlueNight* [®] *Acor+* software on the computer.
- 4. In the "Download" zone, press on the line "Android tablet or smartphone"
- 5. In the ribbon on the right, click on the * icon
- 6. In the window that appears, click on the "Change password" button.
- 7. Enter the new password into the two text boxes, then click on \checkmark

The button to confirm the new password can only be clicked if the two passwords entered are identical. If it is greyed out, delete the contents of the text boxes and start again.

9.5. [Logo] Can I use a custom logo on the tablet?

Yes, a logo can be configured to be displayed alongside the "Sleepinnov Technology" logo on the application's home screen. To do this:

- 1. Open the *BlueNight*[®] application on the tablet.
- 2. Connect the tablet to the PC.
- 3. Open the *BlueNight* [®] *Acor+* software on the computer.
- 4. In the "Download" zone, press on the line "Android tablet or smartphone"
- 5. In the ribbon on the right, click on the * icon
- 6. In the window that appears, click on the "Set a new logo" button.
- 7. Select the image file for your logo and click OK.



10. Frequently asked questions (FAQ): PC software

10.1. [Installation] My computer does not meet the minimum specifications described in chapter 4

- 1. Open the *BlueNight*[®] application on the tablet.
- 2. Click on "About" in the menu on the left
- 3. If the version shown is **3.2.0** or higher, the *BlueNight® Acor+* software cannot be installed on this PC.

Otherwise, version **1.3.0** of *BlueNight[®] Acor+* is the most recent version of the software that is compatible with all computers running Windows XP or later versions. It can be downloaded from the following address:

http://www.sleepinnov.com/download/bluenight_acor/1.3.0/Setup_EN.msi

10.2. [Installation] The software requires version 4.6 or later of the .NET Framework

To install the correct version of the Framework, download and run the install file which is linked to in the warning message. This is given below for information: <u>https://www.microsoft.com/en-us/download/confirmation.aspx?id=49982</u>

10.3. [Installation] Does the application require special access rights?

All users of the application must have read, write and save access to the following folders:

- C:\ProgramData\SleepInnov Technology\BlueNight Acor+
- Content of the application's data folders (see §10.12)

If this is not the case, a warning message should be displayed when the application starts.

10.4. [Save] Which files and folders need to be saved regularly?

In order not to lose data if your computer crashes, you are recommended to save the following 2 locations regularly:

- C:\ProgramData\SleepInnov Technology\BlueNight Acor+
- Content of the application's data folders (see §10.12)

10.5. [Download] The tablet is connected but the software doesn't find it, what should I do?

♥ To refresh the list of connected devices and the tests stored on them, click on the ♥♥ icon in the "Download" zone of the home screen.

There are several causes of this problem, but the following will resolve the problem in most cases:

- Has the software just been installed? If yes, have the drivers been installed? See **§5.2** for what to do next. If this step has not been carried out, the tablet and the tests on it cannot be used by the *BlueNight*[®] *Acor+* software.
- Is the *BlueNight*[®] software shown on the tablet screen? If not, run it and start again.
- If it still does not work, try to connect the device to a different USB port.



- If the tablet is still not detected, restart it, restart the computer, connect it again, and then open the *BlueNight*^{*} *Acor+* software.
- If the problem persists, contact us.

10.6. [Download] The tablet is connected but the software does not list the tests, what should I do?

Follow the instructions given in §10.5.

10.7. [Patients] Is it possible to search for a patient from the list?

Yes, this is the purpose of the text box displayed at the top of the patient list.

- 1. Open the *BlueNight[®] Acor+* software
- 2. On the home screen, just under the "Patients" title, click on the text box on the right labelled "Search".
- Start typing the surname, first name or identifier of the patient you wish to find.
 As soon as you have typed 3 characters, the patient list will be updated to contain only the patients whose surname, first name or identifier contain the characters you have entered.
- 4. Continue typing to further narrow down the displayed results.

The text you enter can be from any part of the surname, first name or identifier. "Pont" will find any patient with the surname "Pontarlier", and any patient with the surname "Dupont" or "Dupontel".

Click on the "Restart" button or delete the content of the text box to go back to displaying all patients.

10.8. [Patients] Can saved data for a patient be changed?

Patient identity information can be changed at any time.

- 1. Open the *BlueNight* [®] *Acor+* software on the computer.
- 2. In the "Patients" zone, click on the patient name.
- 3. In the ribbon on the right, the 🖃 icon appears. Click on this icon.
- The following data can be changed and will be immediately propagated to all tests relating to this patient: surname, first name, identifier, date of birth and sex.
 Height and weight can also be changed, but will only be used in subsequent tests.





10.9. [Reports] How can I configure the graphs used in test reports?

Only reports from walk and stroll tests can be configured. There must be at least one patient with this type of test in the database in order to do this.

- 1. Open the *BlueNight[®] Acor+* software
- 2. In the home screen, in the "Patients" zone, double-click on the name of a patient with at least one test whose report you wish to configure.
- 3. Under the patient name, click on the "Walk test" or "Stroll test" title.



he *** icon appears on the right of the "Patients" zone.

- 4. Click on this icon. The window for configuring walk test (or stroll test) reports appears.
- 5. Make the changes you wish to make, then click on \checkmark to save the changes.

All walk test reports (or stroll test reports, depending on what you clicked in step 3) will now adhere to the settings you have just chosen.

10.10. [Reports] How can I create a report that compares several walk tests?

It is possible to generate a report that compares the results of several walk tests for one patient. To do this:

- 1. Open the *BlueNight[®] Acor+* software
- 2. In the home screen, search for the patient in the "Patients" zone.
- Double-click on the name to show that patient's tests.
 If this patient has at least 2 walk tests, continue. If not, it will not be possible to generate a comparative report.
- 4. Double-click on the "**Walk test**" title under the name.

(You can also just click on this item and then click on the *first* icon that appears in the "Patients" zone).

5. In the window that is displayed, select the tests for which you wish to generate a report, then

click on ✓. The report is then displayed on the screen.

The button to display the report can only be clicked if 2-4 tests have been selected. If it is greyed out, tick or untick tests until either 2, 3 or 4 tests are selected.

BlueNight[®] Trainer User manual (ref. 24-05-2023)



10.11. [Reports] Can I add a logo to the test reports?

Yes, a logo can be configured to appear to the right of the walk and stroll test results title. Use the following procedure to set a logo:

- 1. Open the *BlueNight[®] Acor+* software
- 2. Click on the ****** icon at the top left of the home screen, and the "Application Configuration" window will appear.
- 3. Under the line "Set a logo" in the "Reports" zone, click on the "Browse..." button.
- 4. Select the image file to be added to your reports, then click on \checkmark to close the window.

The image you have set will be added to all walk and stroll test reports automatically from now on.

10.12. [Data] Where does the application store data?

Patient data are stored in two different locations:

- Patient information are saved in the application's database.
- Measurements taken during tests are saved in the tests folder.

In version **2.0.0** or later, these locations can be configured by the user when first launching the application. To view configured locations:

- 1. Open the *BlueNight[®] Acor+* software
- 2. Click on the ****** icon at the top left of the home screen.
- 3. The two folders are shown in the "Data location" area, under the names: "Database" and "Tests".

10.13. [Data] Can the path for saving patient data be changed?

Yes, but this is an advanced operation. The procedure is given below for information.

- Using a text editor, open the file config.xml, which is in the following folder: C:\ProgramData\SleepInnov Technology\BlueNight Acor+
- 2. Change the path on the line that starts with cpatients> and ends with /patients> and replace it with the full path of the directory you would like to configure.
- 3. Save the file.

If you have saved tests, you will also need to perform the following tasks:

- 4. Move the contents of the directory that was configured in the previous step to the new location.
- 5. Restart the software, check that you still have access to patient data.



10.14. [Data] Can the database path be changed?

Yes, but this is an advanced operation. The procedure is given below for information.

<u>Caution:</u> If you have several databases, only one may be used. It is not possible to merge existing databases.

- Using a text editor, open the file config.xml, which is in the following folder: C:\ProgramData\SleepInnov Technology\BlueNight Acor+
- 2. Change the path on the line that starts with <database> and ends with </database> and replace it with the full path of the directory you would like to configure.
- 3. Save the file.
- 4. Next, move the database from the old location to the new folder. It is advisable to make a copy first.
- 5. Restart the software and check that you still have access to patient data.

10.15. [Data] Can automatic database saving be deactivated?

By default, the database is automatically saved once a week, in a folder named "Backups" which is created in the same directory as the database (see **10.12**).

This automatic saving can be deactivated, but this is an advanced operation. The procedure is given below for information.

Using a text editor, open the file config.xml, which is in the following folder: C:\ProgramData\SleepInnov Technology\BlueNight Acor+

- 1. Find the line that starts with <auto_database_backup> and ends with </auto_database_backup>.
- 2. Between these two tags, replace true with false.
- 3. Save the file.
- 4. Restart the software and check that it starts without errors.

11. Frequently Asked Questions (FAQ): other

11.1. [Oximeter] How do I prepare the Nonin WristOx2 3150/3150 BLE oximeter?

Remove packaging and inspect the NONIN oximeter to ensure that it is intact.

Open the battery compartment by sliding the door on the back of the device, and insert two new AAA alkaline batteries.



Slide the door back into place.

The illustrations below show you how to attach the bracelet that keeps the oximeter on the patient's wrist.

BlueNight[®] Trainer User manual (ref. 24-05-2023)







Usual procedure for switching oximeter on



The oximeter turns on automatically when the patient puts the sensor on their finger. For walk tests, the oximeter starts after the sensor is connected, as shown in the image opposite. The device turns off automatically.

Fitting the oximeter to the patient





Information displayed on the oximeter



188 ***	%SpO2 display (percentage of blood oxygen saturation). The range is 0 - 100%.
888	Pulse rate in beats per minute (bpm). The range is 18 - 321 bpm.
	Activation switch. When this switch is pressed, the Bluetooth radio activates for 3 minutes. It also turns the device on when it is on standby.
P	Sensor fault indicator (if sensor is disconnected, poorly aligned or incompatible with the device). It also appears if the finger is removed from the sensor.



v))))))))	Pulse signal intensity indicator. The heart is always visible, the number of curved lines appearing on the screen depends on the intensity of the pulse as determined by the oximeter (maximum of 9).
\otimes	Weak pulse indicator. The signal is insufficient or the device is not registering a pulse. This can also appear if the sensor location moves excessively.
	Battery indicator This indicator shows whether the batteries are full, half full, low or almost empty.
*	Bluetooth [®] indicator This indicator appears when the Bluetooth [®] radio is on. It takes the form of the Bluetooth [®] logo, or the same logo with animated bars. If the device is connected to a master device, the indicator appears with animated bars. If the Bluetooth [®] radio is on while the device is entering Standby mode or is connected via the USB interface, the Bluetooth [®] indicator remains displayed for a maximum of 10 seconds and then the Bluetooth [®] radio turns off.

11.2. [Updates] How can I be notified of updates?

When you order from us, your email address is automatically added to our distribution list. This is used to tell our customers when a new version of the PC and/or tablet software becomes available. If you want to be certain of finding out about updates, please send an email to <u>contact@sleepinnov.com</u> and ask to be added to the *BlueNight*^{*} *Trainer* updates distribution list.

If you no longer wish to be notified of updates to *BlueNight[®] Trainer*, send us an email to the same address, asking for your address to be removed from the distribution list.

11.3. <u>I have noticed an error or I have a functionality suggestion</u> Tell us by emailing <u>support@sleepinnov.com</u>.

11.4. <u>I have a question and have not found the answer in this manual</u> Contact us at <u>support@sleepinnov.com</u> or using the details given on the last page of this manual.



12. Maintenance and Repair

The BlueNight[®] Acor+ does not require calibration.

12.1. Cleaning

Clean the NONIN oximeter with a soft cloth dampened with isopropyl alcohol. Do not pour or evaporate any fluid on the device and do not let any fluid enter the device via any orifice. Allow to dry completely before using the device after cleaning.

IMPORTANT! Do not immerse the device in any fluid, and do not apply any caustic or abrasive cleaning agent.

Clean the oximeter separately from its sensors. For instructions about sensor cleaning, consult the user guide provided by Nonin.

12.2. Repairs and return of device

Any repairs and maintenance must be sent to SleepInnov Technology or one of its authorised representatives.

Before sending any device, you must obtain detailed mailing instructions by contacting your retailer:



Please clean the defective device before sending it back to your retailer. Ensure that it is completely dry before packing it. Pack the device safely in its original packaging.

Enclose the following:

- A letter describing the problem as precisely as possible
- Address and invoice details for sending back the oximeter and the bill incurred for this repair.
- Contact details of a person if any questions about the repair.



13. Specifications

The specifications below are provided by Nonin, the company that manufactures the oximeter included in the BlueNight[®] Acor+.

Oxygen saturation range	0 - 100% (%SpO ₂)	
Pulse range	18 - 321 beats per minute	
Precision		
Oxygen saturation	70 - 100% ± 2 units for adults	
No movement	± 2 units	
Low irrigation	2 units	
Movement	± 3 units	
Pulse ± 3%		
Connection indicators Bluetooth [®] icon		
Power measurement wavelength		
Red	660 nanometers at 0.8 mW (rated value)	
Infrared	910 nanometers at 1.2 mW (rated value)	
Internal power source		
Batteries	2 AAA 1.5V batteries	
Battery life	44 hours of use with new batteries	
Storage	9 months	
Weight	71 g with sensor and bracelet	
Temperature		
Operation	-5°C to +40°C	
Storage / Transport	-40°C à +70°C	
Relative humidity		
Operation	10 to 95% (with no condensation)	
Storage / Transport	10 to 95% (with no condensation)	
*If the device is moved from an enviror	ment which does not conform to operating temperat	

*If the device is moved from an environment which does not conform to operating temperature and/or humidity, allow at least one hour for the device to adapt before use.



BlueNight[®] Trainer

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