

# NOX-RIPDLEAF-0113 REV4

140,00 mm ± 2 mm

## Nox Disposable RIP Belts

- Instructions for Use

### Introduction

The disposable RIP belts come in five different sizes: Pediatric (P), Small (S), Medium (M), Large (L) and Extra Large (XL).

### Intended Use

The Nox RIP Belts are intended for measuring of respiratory effort signals. They function as accessories for sleep/polysomnography (PSG) systems.

The Nox RIP Belts are indicated for use on patients greater than 2 years of age.

The intended environments are hospitals, institutions, sleep centers, sleep clinics, or other test environments, including the patient's home.

### Scope

This leaflet is designed to instruct users on how to use the Nox Disposable RIP Belts.

### Warnings and Cautions

- Only connect the RIP belts to Medical Electrical Equipment/Medical Electrical Systems complying with the collateral standard IEC 60601-1-1 or the general standard IEC 60601-1 3rd edition. Any person that connects the belts to an electrical device has formed a new electrical system and is responsible for the patient safety of the system. If in doubt, contact a qualified medical technician or your local representative.
- The RIP belts should fit the patient snugly without being uncomfortably tight.
- Re-using the disposable RIP belts may affect the quality of the signal recorded.
- The use of the same disposable RIP belts on more than one patient poses a risk of cross-infection. The Nox Disposable RIP belts are single patient use.
- Do not use damaged equipment, sensors or accessories.
- As with all medical equipment, carefully route cables and connections to reduce the possibility of entanglement or strangulation.
- The device is NOT CERTIFIED TO BE USED FOR CONTINUOUS MONITORING where failure to operate can cause injuries or death of the patient.
- Do not use the RIP belts and cables in an MRI (Magnetic Resonance Imaging) environment.
- Do not use the RIP belts and cables during radiography/X-ray studies.
- Warning: No modification of this equipment is allowed.
- Caution: U.S. federal law restricts this device to sale by or on the order of a licensed medical practitioner.

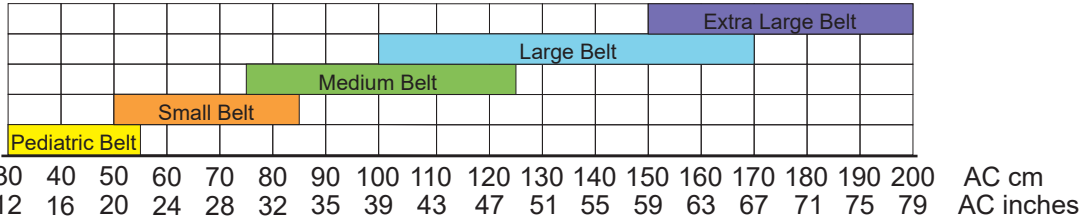
170,00 mm ± 2 mm

**Instructions for use**

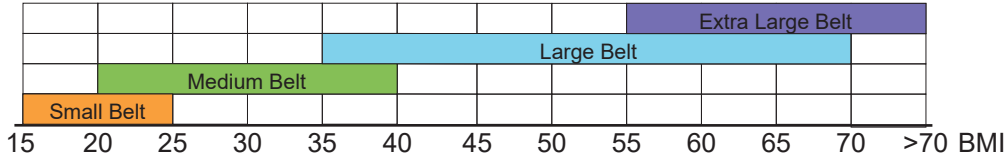
**Belt Size Selection**

For most patients the Respiratory Inductance Plethysmography (RIP) belts do not need to be adjusted if the correct size is chosen based on the patient's abdomen circumference as listed in Chart 1 below. If the abdomen circumference is not known the patient's body mass index can be used for reference, refer to Chart 2 below.

**Chart 1: Abdomen Circumference (AC)**



**Chart 2: Body Mass Index (BMI)\***



\*The BMI reference is only valid for patients 18 years of age or older.

**Available RIP Belts Sizes**

Description	Reference Number
Nox RIP Belts Disposable, Pediatric 20 sets	55 10 10
Nox RIP Belts Disposable, Small 20 sets	55 10 20
Nox RIP Belts Disposable, Medium 20 sets	55 10 30
Nox RIP Belts Disposable, Large 20 sets	55 10 40
Nox RIP Belts Disposable, Extra-large 14 sets	55 10 50

140,00 mm ± 2 mm

170,00 mm ± 2 mm

# Back

## Copyright Notice

No part of this publication may be reproduced, transmitted, transcribed, stored in a retrieval system, or translated into any language or computer language, in any form, or by any means: electronic, mechanical, magnetic, optical, chemical, manual, or otherwise, without the prior written authorization from Nox Medical.

## Disclaimer

This document may contain typographical errors or technical inaccuracies. Nox Medical does not accept any liability for the use or misuse whether direct or indirect of the products, or for damages arising out of the use of or inability to use the products. Users must accept all responsibility for any results obtained by or concluded from data obtained by the products including software from Nox Medical. All clinical conclusions and decisions that are based on the use of this product are the responsibility of the user.

**Nox RIP Belts are a patented design.**

**Covered by Patents: US 9,059,532 and EP 2584962**

For distributor information go to: [www.noxmedical.com](http://www.noxmedical.com)

Manufactured for:  
Nox Medical ehf  
Katrínartúni 2  
IS-105 Reykjavík  
Iceland  
[www.noxmedical.com](http://www.noxmedical.com)

NOX-RIPDLEAF-0113-REV4  
Last issued: April 2017  
Copyright ©2017 Nox Medical - All rights reserved

140,00 mm

170,00 mm











## Disposal

Follow local governing ordinances and recycling instructions regarding disposal or recycling of this product.

## Material Information

The RIP Belts are made out of polyester/dorlastan, tin plated copper wire and ABS plastic.

## Descriptions of Symbols and Labels

- |  |  |                    |   |
|--|--|--------------------|---|
|    | ▶ Operating instructions / Consult instructions for use  | (01)1569431111XXXX | ▶ Unique Device Identifier (UDI): Application Identifier (01) represents the device identifier (DI) ("1569431111XXXX"), the Application Identifier (11) the production date/date of manufacture ("YYMMDD", with "YY" the last two digits of the production year, "MM" the production month and "DD" the production day), and the Application Identifier (10) the lot number of the device ("ZZZZZZ") if applicable. |
|    | ▶ Manufacturer Information   | (11)YYDDMM         |   |
|    | ▶ Date of manufacture  | (10)ZZZZZZ         |   |
|    | ▶ Batch code / Lot number  |                    |   |
|    | ▶ Catalog number / Reference number  |                    |   |
|   | ▶ CE marking indicating conformance to EC directives 93/42/EEC and 2007/47/EC concerning medical devices |                    |   |
|  | ▶ Temperature limitation   |                    |   |
|  | ▶ Humidity limitation  |                    |   |
|  | ▶ Atmospheric pressure limitation  |                    |   |
|  | ▶ Do not re-use  |                    |   |

140,00 mm

170,00 mm

**Hook Up**

For hook up, snap the belts on the snaps located on the cable and/or device to secure the belts around the patient's abdomen and thorax as shown in the figures 1 and 2 to the right.

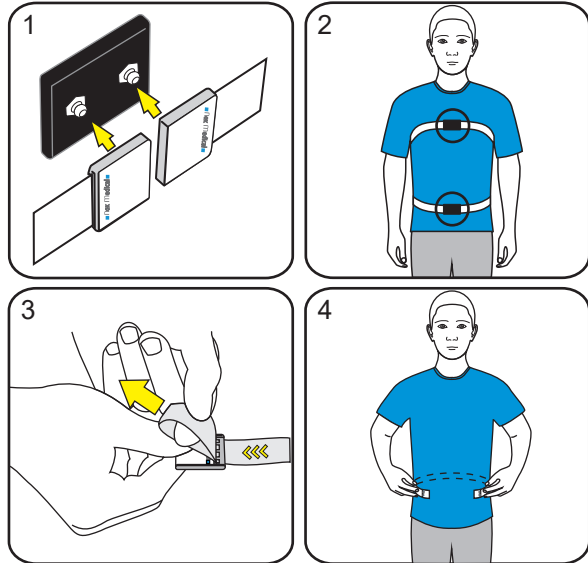
For good signal quality, the belts should fit snugly without being uncomfortably tight.

If needed, it is possible to shorten the length of the belts by pulling the loop on each end as shown in figure 3. For best results the un-stretched belt should cover two thirds of the patient's circumference as shown in figure 4.

The RIP belts are intended to be worn over clothing.

The disposable RIP belts are single use.

The RIP belts have been validated for use with Nox Sleep Recording Systems and Nox RIP Cables.



Patented design

**Compatible Devices and RIP Cables**

Description	Reference Number
Nox T3® System Kit	51 10 10 / 51 11 10
Nox A1® System Kit	51 30 10 / 51 31 10*
QDC-PRO Sensor Unit	51 40 11
Nox Abdomen Cable	56 20 10
QDC-PRO Abdomen Cable	56 20 60
Nox RIP Cable Kit E	56 20 50
Nox RIP Abdomen Cable E	56 20 51
Nox RIP Thorax Cable E	56 20 52

**Environmental Conditions**

- Temperature** - Operation: +5°C to +50°C (+41°F to +122°F).  
 - Transport and storage: -25°C to +70°C (-13°F to +158°F).
- Rel. Humidity** - Operation: 15-95% (non-condensing)  
 - Transport and storage: 10-95% (non-condensing)
- Pressure** - Withstands atmospheric pressures from 700 hPa to 1060 hPa.

\* Not distributed in the USA

140,00 mm

170,00 mm

Front

**nox medical**

# Nox RIP Belts - Disposable

Instructions for Use

140,00 mm

170,00 mm