Dyna-Vision© Unit

Instructions for Use

RS TechMedic BV
Broeker Werf 6
1721 PC Broek op Langedijk
The Netherlands
Version: 4.66

CE 0344 FDA

CONTENTS

INTRODUCTION

Following the Dyna-Vision© is a Class IIb medical device to be used for recording and/or (simultaneous) transmission of ECG and SpO2 signals and/or other sensor signals that might be connected to a Dyna-Vision© unit.

In this manual you will learn how to use the Dyna-Vision© device and how to connect it to a patient.

To use the device you will need the Dyna-Vision© Monitor software. Instructions on how to use this software are supplied with the software.

Please follow the instructions in this manual as they will assist you in getting the best possible results with the product. May you have further questions or in the case you need more assistance, please contact the manufacturer or your local representative.

Manufacturer contact details:

RS TechMedic BV
Broeker Werf 6
1721 PC Broek op Langedijk
The Netherlands
Tel: +31-226-342044
Fax: +31-226-341446
E: info@rstechmedic.com
I: www.rstechmedic.com

INTENDED USE

Dyna-Vision© is intended for general hospital , clinical, outdoor and home-use applications by medical professionals whenever it is required to assess a patient's long-term, continuous, ambulatory electrocardiogram (ECG) and/or SpO2. This product allows a trained physician, or other health care professional, to record, store and/or remotely transfer the Electrocardiogram (ECG) and/or Oxygen Saturation (SpO2) non-invasively in mobile patients. The available data transfer methods are Bluetooth, USB and GSM. All transfer methods are integrated in the device.

WARNINGS AND CAUTIONS

- Healthcare providers, responsible for using Dyna-Vision©, must be trained in the system and be aware of the inherent risks of misinterpretation of the collected and displayed parameters.
- Use of Dyna-Vision© is restricted to medically trained staff, such as a physician and / or registered nurse.
- Safe and effective use of this device requires proper set-up and operation by trained personnel.
- Never use Dyna-Vision© on a patient when connected to the mains or the power adaptor. Serious injury to the patient or the caregiver can occur.

PRECAUTIONS AND LIMITATIONS:

- Do not connect other machines, devices, sensors or cables to Dyna-Vision© or its accessories because damage to Dyna-Vision©, the machines, devices or cables may occur.
- Risk of electrical shock; do not attempt to service electrical components; refer servicing to qualified personnel.
- Do not use if any of Dyna-Vision© components is visibly opened or damaged.
- Do not flood Dyna-Vision© components with excessive amounts of fluids.
- If liquids enter the equipment, turn off the power supply from a safe electrical panel immediately. Do not operate the equipment until trained personnel have inspected the interior.
- Check all external parts of Dyna-Vision© prior to use.
- When connecting auxiliary equipment approved by RS TechMedic BV, ensure that the summed leakage current does not exceed local standards.
- Do not open the cover or back of the system. Doing so may void equipment warranties.
- The final decision regarding the treatment of patients lies with the prescribing physician.
- There are no user serviceable components inside the system.
- Authorized service personnel should do all internal troubleshooting and repair or replacement using only parts and accessories approved by RS TechMedic BV.
- Periodically check all connector cables and power receptacles for damage. Do not operate the equipment if the integrity of these items is questionable.

LIABILITY NOTICE

Failure to follow the conditions set forth in this document shall absolve RS TechMedic BV from any responsibility for the safety, reliability, and performance of the equipment. Each operator must read this manual in full before using the system. Only authorized personnel may carry out assembly, modification, or repairs of the system. Electrical wiring must comply with local standards. Equipment must be used in accordance with its intended use.

TERMS OF WARRANTY

RS TechMedic BV ("TECHMEDIC") warrants that its products are free from defects in material and workmanship. Subject to the conditions and limitations set forth below, TECHMEDIC will, at its option, either repair or replace any part of its product(s) that prove defective by reason of improper workmanship or materials. Repaired or replacement parts/products will be provided by TECHMEDIC on an exchange basis. This warranty does not cover any damage to this product that results from accident, abuse, misuse, natural or personal disaster, or any unauthorized disassembly, repair, or modification.

Dyna-Vision© units sold by TECHMEDIC are warranted for 24 months. All accessories, supplies, and disposables are warranted for ninety days. This warranty covers only repair or replacement of defective TECHMEDIC products, as provided above. TECHMEDIC is not liable for, and does not cover under warranty, any costs associated with patient care, servicing, and/or the installation of TECHMEDIC products. TECHMEDIC will not discontinue support of its products, nor obsolete its products, as long as there are component materials and products available in the marketplace and reasonable customer demand for the products.

THE FOREGOING IS THE COMPLETE WARRANTY FOR TECHMEDIC PRODUCTS AND SUPERSEDES ALL OTHER WARRANTIES AND REPRESENTATIONS, WHETHER ORAL OR WRITTEN. EXCEPT AS EXPRESSLY SET FORTH ABOVE, NO OTHER WARRANTIES ARE MADE WITH RESPECT TO TECHMEDIC PRODUCTS AND TECHMEDIC EXPRESSLY DISCLAIMS ALL WARRANTIES NOT STATED HEREIN, INCLUDING, TO THE EXTENT PERMITTED BY APPLICABLE LAW, ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. IN NO EVENT WILL TECHMEDIC BE LIABLE TO THE PURCHASER OR TO THE USER OF A TECHMEDIC PRODUCT FOR ANY DAMAGES, EXPENSES, LOST REVENUES, LOST SAVINGS, LOST PROFITS, OR ANY OTHER INCIDENTAL OR CONSEQUENTIAL DAMAGES ARISING FROM THE PURCHASE, USE OR INABILITY TO USE THE TECHMEDIC PRODUCT, EVEN IF TECHMEDIC HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES.

COPYRIGHT

RS TechMedic BV
Broeker Werf 6
1721 PC Broek op Langedijk
The Netherlands
T: +31-226-342044
F: +31-226-341446
www.rstechmedic.com

GETTING HELP

To get help with either technical or user issues:

1. Call RS TechMedic Help Desk at +31-226-342044 Monday - Friday 8AM - 5PM CET, or

2. You local representative / supplier.

DYNA-VISION SPECIFICATIONS

DEVICE

Dimensions:	115 x 59 x 26 mm
Weight:	190 gram
Power:	Internal battery (3.7 V)
Operation time:	15-68 hours (depending on the selected mode)
Memory:	1 Gb. embedded micro SD card
Controls:	Ruggedized Foil with integrated buttons
Power consumption:	100 mWatt
Charger:	Auto switching 110 - 230 VAC (external adaptor)
Event button:	Yes
External modem:	No, not required

ECG

Leads:	3, 6 or 12 (3, 5 or 10 lead wires)
ECG cable:	Special with Active Noise Reduction
Sample rate:	1.0 kHz
R-peak analysis:	Yes, automatically
RR intervals:	Yes, automatically

SPO2

Range (SpO2):	0 to 100%
Rate Range:	18 to 321 beats per minute (BPM)
Type:	Infrared 910 nanometers @ 1.2 mW maximum average
SpO2 Accuracy:	70-100% (Adults/Pediatrics Neonates (No Motion))
Pulse Rate Accuracy:	18-300 BPM (Adults/Pediatrics Neonates (No Motion))
Peak detection:	Automatic peak detection on plethysmogram

BLUETOOTH

Operating freq. range:	2400 ... 2483,5 MHz ISM Band
Compliance:	Bluetooth specification, version 2.0 + EDR
Class:	Class 1 (50 meters)

GSM/GPRS

Operation frequency:	GSM 850, E-GSM 900, DCS 1800 and PCS 1900
SIM card:	Local SIM card to be installed by manufacturer

USB

Type: 2.0

Note: the accuracy of the QRS heart beat detection was validated against the MIT database, AHA database and the NST database. The average accuracy of the beat detection is found to be 99,2 %.

Note: the device is not classified as waterproof. Do not use the device in wet environment such as rain, bathrooms, showers and other areas where water could reach the device.

END OF LIFE STATEMENT

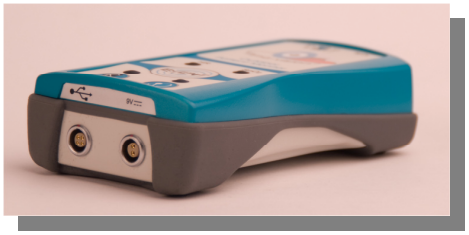
The life expectancy of the Dyna-Vision unit has been determined to be five (5) years.

PARTS

In this section you will find all the parts that come with you package.

DYNA-VISION© UNIT

The Dyna-Vision© unit is a small, portable, battery powered and light weight device which can be worn on a belt. It is attached to the patient by cables and skin electrodes.

	
Device image	**Backside Sticker**

THERE ARE 4 ARTICLE CODES POSSIBLE:

- DVM-012: Dyna-Vision unit with ECG and Bluetooth
- DVM-012G: Dyna-Vision unit with ECG, Bluetooth and GPRS
- DVM-012S: Dyna-Vision unit with ECG, SpO2 and Bluetooth
- DVM-012SG: Dyna-Vision unit with ECG, SpO2, Bluetooth and GPRS

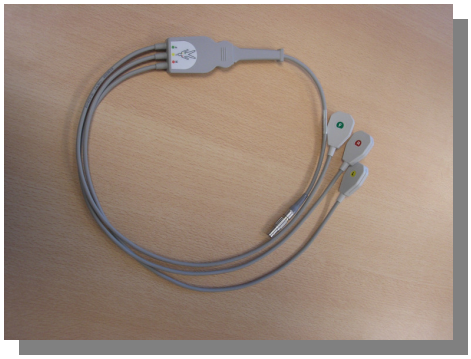
SERIAL NUMBER

(1) DV
(2) Xx Y
(3) Xx B
(4) xxxx

The serial number indicates the type of device (1), the manufacturing year (2), the batch number (3) and the device number manufactured in that batch (4).

ECG CABLE

The ECG cable is a special cable with active noise reduction. The device does not work with other cables.

	
3 lead wire ECG cable	**Snaps with integrated electronics**

ECG ELECTRODES

Dyna-Vision© works with standard ECG electrodes. However, we do recommend you to use high quality electrodes as they greatly determine the quality of your measurement. If the skin contact is corrupted or of low quality, you will not be receive acceptable signal quality.

SPO2 CABLE

Dyna-Vision© Advanced is capable of monitoring the oxygen saturation and works with the following Nonin brand sensors:

- 8000 SS
- 8000 SM
- 8000 SL
- 8000 SS-WO
- 8000 SM-WO
- 8000 SL-WO
- 6000 A
- 6000 P
- 6000 I
- 6000 N

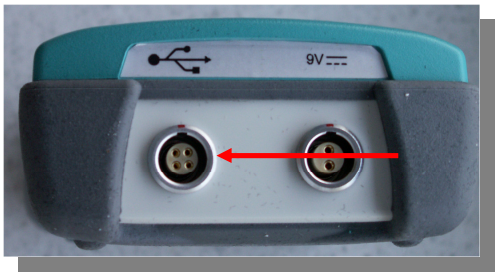
The sensors can't be connected directly to Dyna-Vision©. We supply the sensor from Nonin with a LEMO connection that is suitable for use with Dyna-Vision©. This is done to make sure that the user can not make any mistakes with connecting a SpO2 sensor to the device which is not suitable.

Example of compatible sensor

USB CABLE

Use the USB cable to download the recordings from the device to a PC.

DV-USB



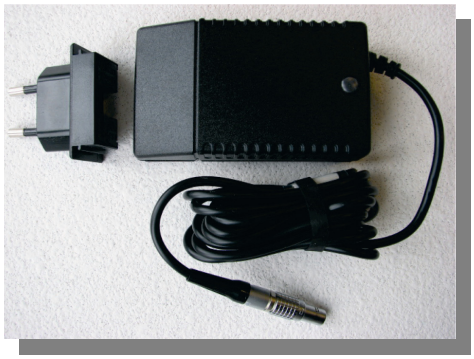
Connection port for USB cable

POWER SUPPLY UNIT

The Dyna-Vision© unit has an integrated rechargeable lithium-polymer battery. It can be recharged with the supplied Power Supply Unit.

Note: do not use other chargers to recharge the internal battery as serious damage to the device, the patient or the user may occur.

Note: using other parts than the ones supplied with the product waives the manufacturer from any warranty claims.



ACCESSORIES

Please check with your supplier for more details about available accessories.

CONNECTING THE ECG CABLE AND SENSORS

Dyna-Vision© works with the supplied ECG cable only! The cable has built in electronics to reduce artefacts and noise by movement of the cable parts. The electronics are built in the snap of the cable.

Note: Do not use other cables as this could damage the device or cause injury to the patient or the user of the product.

Note: Do not misuse the cable and the snaps as damage to the cable might occur. This will influence the ECG signal quality.

CONNECTING THE CABLE TO THE PATIENT

The quality of the ECG signal highly depends on the contact with the skin. To optimize results, prepare the skin before you place the ECG electrodes. The proper technique is to remove hair from the place where the electrodes have to be placed. Avoid skin lesion in the case you have to shave the area. Clean the area with alcohol and make sure that the skin is completely dry before placing the ECG electrodes. Then attach the ECG electrodes to the snaps of the ECG cable.

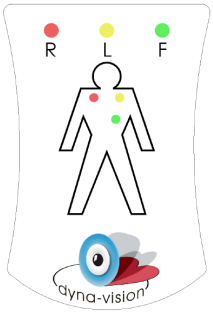
Attach the coloured snaps of the cable to the sticker electrodes. Remove the back foil of the electrodes and attach them to the skin. Placement of the electrodes depends on the lead configuration. You can choose between 3, 5 and 12 lead ECG. Normal configurations are shown in the pictures below.

Note: placement of the electrodes other than normal makes that the morphology of the ECG signal changes.

Recommendation: we recommend you to place the electrodes over bone structures. Avoid placement of the electrodes over large muscles or fatty tissue because these will cause artefacts and noise in the ECG signal.

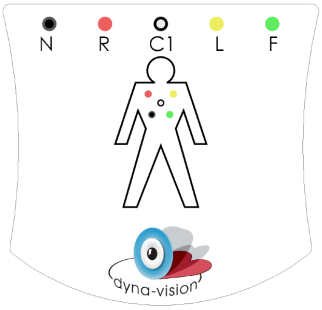
Recommendation: always tape the snap and the electrode to the skin to avoid movement of the ECG snap, leads and trunk cable as this creates noise on the ECG signal.

3-LEAD CONFIGURATION



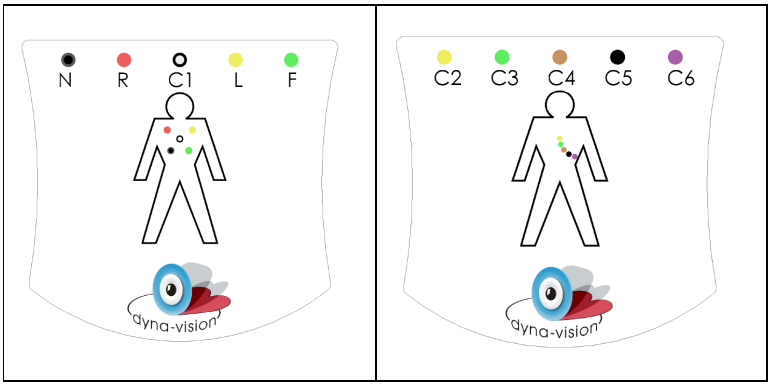
This cable is used for 3-lead ECG recording (R, L, F).

5-LEAD CONFIGURATION



This cable is used for 5-lead ECG recording (N, R, C, L, F)

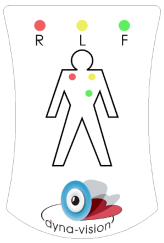
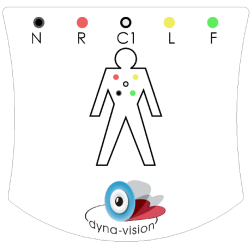
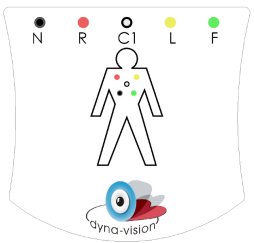
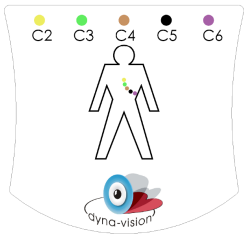
12-LEAD CONFIGURATION

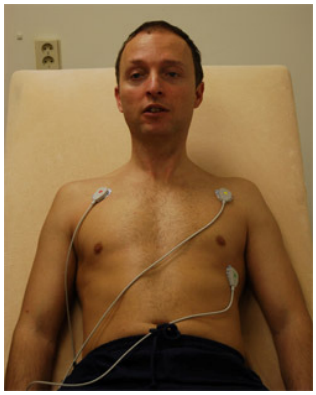


To make a 12-lead ECG recording you will need a 5-lead ECG cable (N, R, C, L, F) and a second cable to extend to 12-leads (C2, C3, C4, C5, C6).

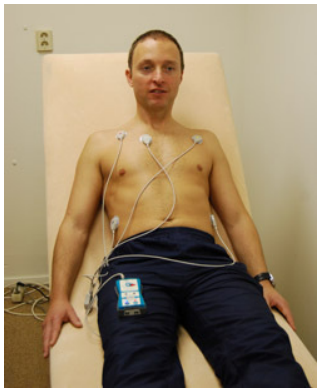
PLACEMENT OF THE ELECTRODES

In order to make good diagnosis based on the ECG signals recorded with Dyna-Vision© it is important to place the ECG electrodes and the ECG cable the correct way. Otherwise a physician will not be able interpret the collected signals. Proper placement for the 3 available cables is shown in the images below. Note that placement over bone structures results in the best possible signal quality:

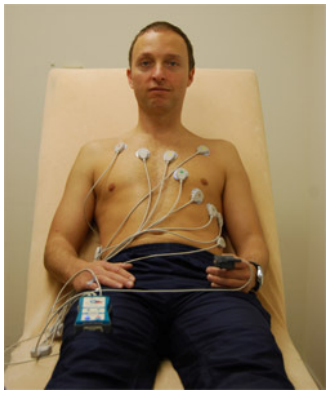
3-lead connections	5-lead connections	12-lead connections
		 
R = Right front side of the shoulder L = Left front side of the shoulder F = Left hip	R = Right front side of the shoulder L = Left front side of the shoulder N = Right hip F = Left hip C1= Right of the sternum	R = Right front side of the shoulder L = Left front side of the shoulder N = Right hip F = Left hip C1= Right of the sternum C2 = Left of the sternum C3 = Between C2 and C4 C4 = Under left nipple C5 = Between C4 and C6 C6 = Left side of thorax in line with axe



3-lead



5-lead



12-lead

OTHER CONFIGURATIONS

Other configurations are possible and should be based on the indication for using the device.

CONNECTING THE CABLE TO THE DEVICE

The cable has a metal plug. Insert the plug in the port at the top side of Dyna-Vision©. On the front side of the device you will find the indicators for the correct port.

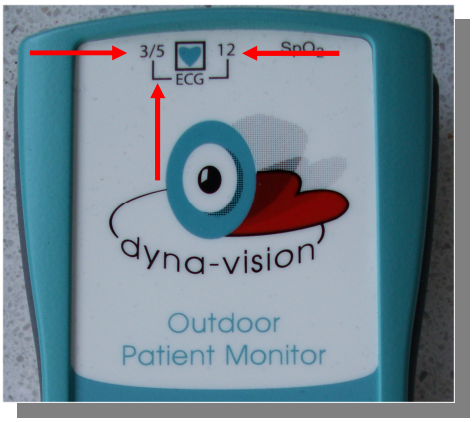
There is a red dot indicator on the plug that corresponds with a red dot on the connector in the device. The plug only fits in one direction. If inserting the plug does not go smoothly.

Inserted ECG cable

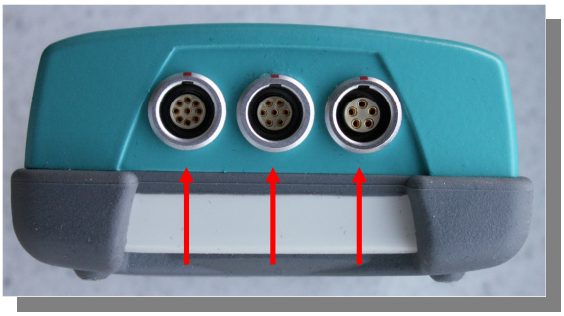
Note: do not force (!) the plug into the connector. Damage to the plug and/or the device may occur.

3, 5 OR 12 LEAD CONNECTION PORTS

Dyna-Vision© can be used for 3, 5 or 12-lead ECG recording. The next pictures show the correct usage of the connections.



3/5 or 12-lead configuration



The plug fits in one port only

- Port 1: 3 or 5-lead ECG cable (R, L, F or N, R, C, L, F).
- Port 2: extension for the 12-lead cable (C2, C3, C4, C5, C6).
- Port 3: Spo2 cable

CONNECTION OF THE SPO2

PLACING THE SENSOR ON THE PATIENT

The choice for the type of sensor depends on the application for use. For normal SpO2 testing at home or in the hospital we recommend to use a re-usable sensor. For the long-term SpO2 monitoring or sleep study we recommend to use disposable sticker sensors to avoid the sensor to lose contact with the skin.

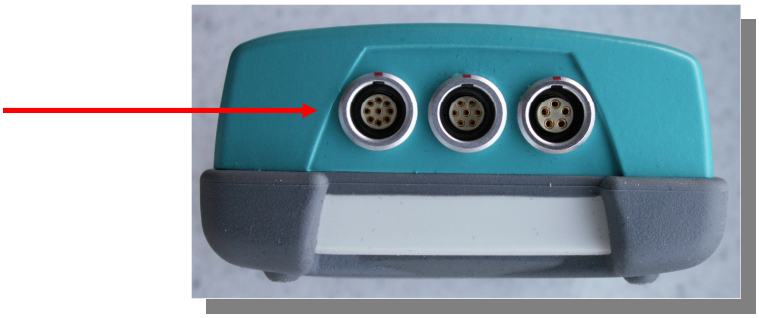
We recommend the placement of the finger tip sensor as depicted below.

CONNECTING THE CABLE TO THE DEVICE

The SpO2 cable can be connected to the Dyna-Vision© unit with the plug at the end of the cable. On the front side of the device you can find the port for the SpO2 cable.

There is a red dot indicator on the plug that corresponds with a red dot on the connector in the device. The plug only fits in one direction.

Note: if inserting the plug does not go smoothly, never force the plug… damage to the plug and/or the device may occur.



- Port 1: 3 or 5-lead ECG cable (R, L, F or N, R, C, L, F).
- Port 2: extension for the 12-lead cable (C2, C3, C4, C5, C6).
- Port 3: Spo2 cable

Note: Connect the SpO2 cable to the designated connection port at the top side of the Dyna-Vision© unit only!

Note: Dyna-Vision© is compatible with the Nonin product line. Please do not use other sensor brands as this could damage the device.

Note: SpO2 sensors can be purchased at RS Techmedic BV or at your local Dyna-Vision© representative. It is also possible to directly purchase the sensors at Nonin or their representatives.

USING THE DEVICE

SWITCH-ON THE UNIT

You that the patient is connected to the device, switch it on by pressing the On/Off button. The LED indicators on the device will flash one time to indicate start-up. The LED on top of the On/Off button will be lit continuously when the device is on.

Off

On

CHECK PROPER FUNCTIONING OF THE BUTTONS

Press the Bluetooth button to check if the button is working. The blue LED should go off when the button is working. Press the button again to switch the Bluetooth back on.

Press and hold down the event button for 2 seconds to create an event. When the event is registered all the LED's will flash 3 times to confirm.

Note: when one or more buttons are not working, do not use the device and contact RS TechMedic or the supplier.

CHECK SIGNAL QUALITY

When the unit is connected it will continuously monitor the signal quality of the sensors. If the signal quality is good, the green LED with the "HR" will flash.

If the signal quality is not good, the green LED will not be lit. If this is the case, repeat the steps for connecting the sensors to the patient. If the problem remains, please contact the supplier of the device for further assistance.

RECORDING AN EVENT

There are 2 ways that the device is able to create an event:

MANUAL EVENTS

When you experience symptoms for which you received Dyna-Vision©, press and hold the Event button for 3 seconds to start a recording. The start of the recording is indicated by 3 times rapid flashing of the 4 LED's on the front panel of the device. During transmission of an event by the internal GPRS connection, all 4 LED's are continuously illuminated.

Event button

4 LED's flash 3 times

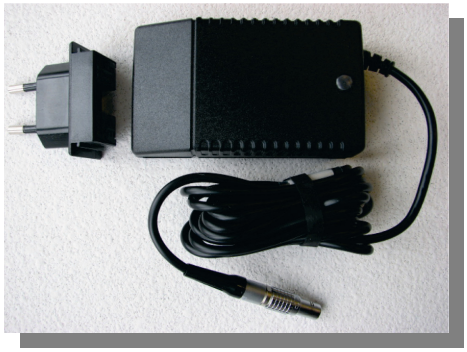
AUTOMATIC EVENTS

Dyna-Vision© can create events automatically. The thresholds that determine the event detection can be set-up in the Dyna-Vision© Monitoring software. Please refer to the Dyna-Vision© Monitoring User Manual for further details about this feature.

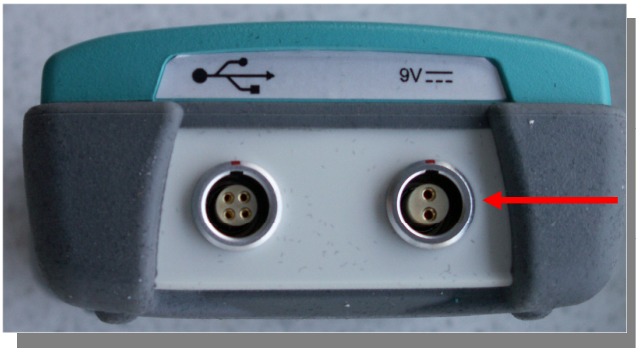
RECHARGING THE BATTERY

When the LED with the On/Off button starts flashing, the battery is almost exhausted. Please recharge the internal battery by connecting the Power Supply Unit.

Note: do not use other chargers because damage to your device or injury to the patient or the user will occur.



Charger



Connector for charger

Connect the charger to the mains. Insert the plug on the other side into the port which is marked with “9V” on the bottom of the unit. The plug fits one port only! During charging of the unit, the LED with the On/Off switch is flashing every second. When the charging process is finished, the LED will flash every two seconds.

Note: when the device is OFF during charging, there will be no LED indication of the charging status but the device does charge while it is connected to the charger.

Note: when charging is completed, you can leave the charger connected until you will use it on a patient. In that way you are always sure that the battery is completely charged before use.

Note: charge the unit after each use. We recommend to keep the unit connected to the charging unit until next use to make sure that the battery is fully charged when used with the next patient.

CLEANING

Please make sure that you clean the device and the cables after each use on a patient and before using it on a new patient. Avoiding cross contamination has to be taken seriously. The device and the cables can be cleaned using a mild detergent solution. Do not submerge or rinse the product or parts. Use a clean cloth and wipe the product and parts dry after cleaning.

WARRANTY

Your Dyna-Vision© unit comes with a 12 months warranty period. The sensors have a 90 days warranty. For warranty claims contact the manufacturer or your local representative for further instructions.

Please note that only cleaned and disinfected parts will be services or repaired. Make sure that you only ship products and parts that are properly cleaned.

SERVICE AND SUPPORT

Your Dyna-Vision© unit does not need calibration. We recommend you to replace the internal battery every two years as the battery power and operation time decreases after this period. Contact RS TechMedic or your supplier for changing out the battery.

Note: do not open the device or replace parts yourself as damage to the device could occur.

FCC STATEMENT

Dyna-Vision© and all variants are approved by the Federal Communications Commission (FCC). The label at the back side of the product has the FCC logo and label to indicate the approval and compliance.

For the Dyna-Vision© product, the indication is shown below:

	X5J-RSTM-DVM
FCC logo	FCC registration number

For the Telesentry© product, the indication is shown below:

	X5J-RSTM-TSY
FCC logo	FCC registration number

For the WOBI© product, the indication is shown below:

	FCC-RSTM-WOB
FCC logo	FCC registration number

REGULATORY INFORMATION

FCC INFORMATION TO USER

This product does not contain any user serviceable components and is to be used with approved antennas only. Any product changes or modifications will invalidate all applicable regulatory certifications and approvals.

FCC RF EXPOSURE INFORMATION

This device meets the U.S. Government's requirements for exposure to radio frequency electromagnetic fields. This device contains a radio transmitter and receiver. This device is designed and manufactured not to exceed the emission limits for exposure to radio frequency (RF) energy as set by the FCC of the U.S. Government.

This device has been tested for body worn operation and meets the FCC RF exposure guidelines.

FCC ELECTRONIC EMISSION NOTICES

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions:

1. This device may not cause harmful interference
2. This device must accept any interference received, including interference that may cause undesired operation.

FCC RADIO FREQUENCY INTERFERENCE STATEMENT

This equipment complies with FCC RF radiation exposure limits set forth for an "uncontrolled environment". SAR has been evaluated for body-worn application. This equipment has been tested and found to comply with the limits for a class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. Operation of this equipment in a residential area may cause harmful interference, in which case the user will be required to correct the interference at his own expense. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna
- Increase the separation between the equipment and receiver

- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected
- Consult the dealer or an experienced radio/TV technician for help