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INSTRUCTIONS FOR USE

RECTOSCOPE / ANOSCOPE (VIDEO version)
BOB R-OM TYPE
MODELS

BOB R - OM 100x1
BOB R - OM 100x2
BOB R - OM 150x1
BOB R - OM 150x2

CE

First edition of 20/03/2014

NOTE

The instructions of BOB Technika Światłowodowa have been prepared to provide the user with all essential knowledge on safe use of devices and of their accessories.

In case of further questions on the manner of use, safety of devices or other documents of the company, please contact a local representative of the company or go to the website.

Before you begin to use the product, the instructions are to be carefully read.
You should observe all recommendations from the instructions.

Lack of understanding of all recommendations may cause:

- death or serious patient injury,
- serious user injury;
- serious injury of third persons,
- device damage.

The instructions contain technical data, information on maintenance of the equipment and on problem solving which may help to provide safe and effective operation of the device.

The instructions are to be kept in safe, easily accessible place.

TABLE OF CONTENTS

1. INTENDED USE AND MARKINGS

Endoscopic examination with the use of devices by BOB Technika Światłowodowa company enables not only to produce a proper diagnosis of the disease but to assess its advancement and to assess the efficiency of the treatment of premalignant and neoplastic lesions.

Using our equipment we receive the good quality picture of the inside of an alimentary canal. This picture, together with the microscopic examination, constitutes the basis for recognising a disease among majority of patients with lesions.

Esophagogastroduodenoscopy (oesophagus, stomach and duodenum examination - EGD) enables to make inflammatory lesions visible and to conduct biopsy of the upper section of the alimentary canal for microscopic examinations. Rectoscopy (anus, rectum), sigmoidoscopy (sigmoid colon) and ileocolonoscopy (colon and the final section of the small intestine) enable the above in the lower section of the alimentary canal.

The range of the endoscope ends slightly outside the lower fold of the duodenum (gastroscopy) or slightly behind Bauhin's valve (colonoscopy).

Endoscopic examination allows to detect typical inflammatory lesions located in the oesophagus, stomach or duodenum.

In case of colonoscopy, it is possible to reach the final section of the small intestine in more than 60% of cases. It allows to observe lesions not only in the area of the large intestine but also in ileum terminale (the final section of the small intestine) in which inflammatory lesions in chL-C are most frequently located.

The anoscope equipped in the video camera enables the monitoring and computer registration of the alimentary canal.

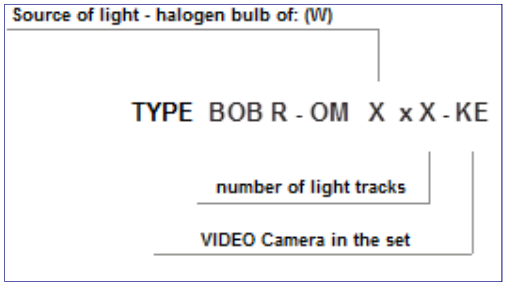
Graphic images used in the documentation of the product in accordance with PN-EN 60601-1:2006 norm.

1	B type application part	
2	Non-observance of the instructions marked with this symbol carries the danger of serious damage of the equipment and even a threat to health and life.	
3	Triangle, as above, without the yellow background – familiarise with the operation manual (nameplate)	
4	Familiarise with the procedure guideline	
5	Date of production	
6	Manufacturer	
7	serial number of the product	SN

BOB Technika Światłowodowa company is the manufacturer of:

- **BOB R - OM type VIDEO Rectoscope** adapted and intended for diagnostic examination and treatment of anus, rectum and sigmoid colon diseases.
- **BOB R - OM type VIDEO Anoscope** enabling treatment and removal of haemorrhoids of anus.

Designations of the type and models:



Examples of designations:

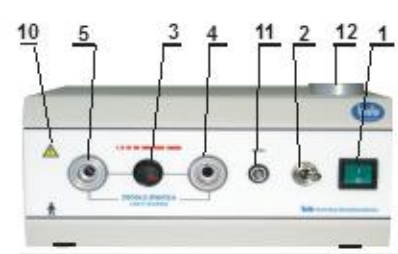
BOM R-OM 150x2-KE VIDEO RECTOSCOPE
Equipped in two light tracks with a power of 150W light bulbs and a video camera

BOM R-OM 150x2 RECTOSCOPE
Equipped in two light tracks with a power of 150W light bulbs

2. TECHNICAL DATA BOB R - OM series of types

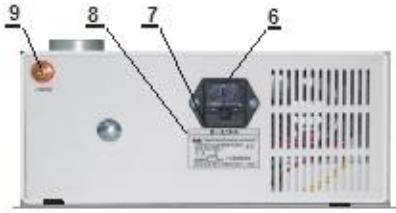
* LIGHT SOURCE	100W 12V halogen bulb OSRAM Catalogue No. 64637 average lifemin. 1500 h
* LIGHT SOURCE	150W 15V halogen bulb OSRAM Catalogue No. 64620 average life min. 1500 h
* COLOUR TEMPERATURE	3200K
* ADJUSTMENT OF LIGHT INTENSITY	0 - 100%
* OPERATING CONDITIONS:	ambient temperature - 0 - +40 □ C relative humidity - 85%
* TYPE OF OPERATING	intermittence 2.5 h of work/ minimum15 min. break
* POSITION OF OPERATING	horizontal
* POWER SUPPLY FOR BOB R-OM 100x1	230V 50Hz power consumption - maximum 110W fuse - T2 1,6 A
* POWER SUPPLY FOR BOB R-OM 150x1	230V 50Hz power consumption - maximum 160W fuse - T2 3,15 A
* CLASS OF PROTECTION AGAINST ELECTRICAL SHOCK	class I
* TYPE OF PROTECTION	B
* CASING PROTECTION DEGREE	IP 20
* DIMENSIONS L x H x D (mm)	235 x 115 x 255
* WEIGHT	3.8 kg

Picture 1



Front plate of the illuminator:

*Power switch - illuminated, green - 1
*Light tracks switch - 2
*Light intensity regulator - 3
*Input to connect optical fibres - 4,5
*NOTE see section (4E) - 10
*Connection of the CCD video camera - 11
*CCD video camera handle - 12



Rear plate:

*Power cord socket - 6
*Fuse socket - 7
*Nameplate - 8
*VIDEO OUT output for a display screen - 9

3. POSSBILE DAMAGE AND MANNERS OF REPAIRING IT

	**Note!** **It is inadmissible to disassemble the illuminator without prior unplugging of the power cord from the mains socket.**

Illuminator cannot be turned on NO ILLUMINATION	Burned out fuse	Replace the fuse
Fan is operating Light switch illuminated NO LIGHT	Burned out light bulb	Replace the light bulb
Fan is not rotating	Damaged fan	Repair, servicing

A. Replacement of the mains fuse

- Unplug the mains power cord from the mains socket.
- Remove the fuse drawer from the socket, picture 7 - back plate.
- Replace the damaged fuse for a new one. for BOB R-OM 100 - T2- 1,6A
- for BOB R-OM 150 - T2- 3,15A

B. Replacement of the halogen bulb

- Unscrew the 4 cover mounting screws and slide down the cover.
- Remove the damaged light bulb from the handle mounting the light bulb.
- Install a new light bulb of the same type and the cover in the reverse order.

4. SAFETY AND OPERATING CONDTIONS

The devices should be:

A. Placed in the manner enabling free air circulation around the illuminator away from materials sensitive to heat

B. You should avoid bending the optical fibre. Unplug the optical fibre from the input jack for transportation purposes.

C. You should avoid looking directly at the source of light through the input jack of the optical fibre and at the emitting end of the optical fibre.

D. You should immediately unplug the device if you observe that:

   a. the cooling fan is not rotating

   b. manipulators are not in the running order

E. The warning symbols on the front plate inform that the plate in the area of the optical fibre input may be hot after long use of the illuminator.

WARNING !!!

To avoid risk of electrical shock, the device must be connected to the mains with PE.

:

You must not modify the device in any manner.

:

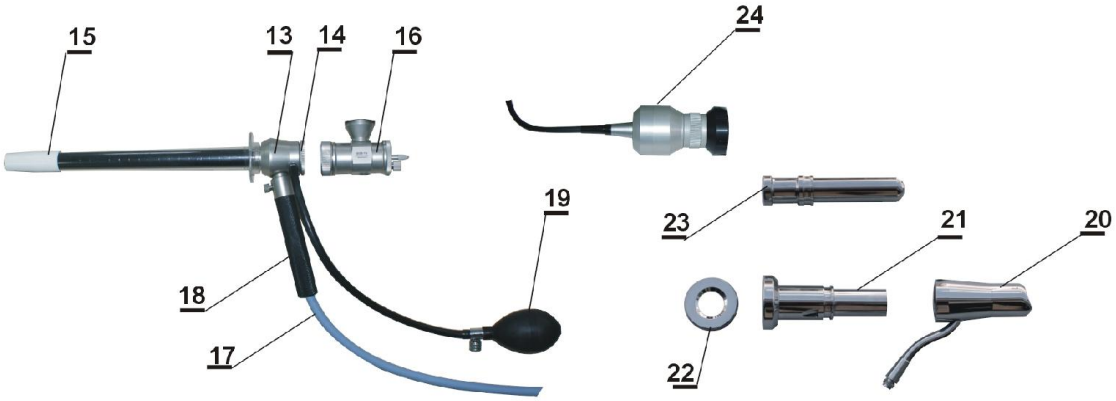
You must not modify the device without the manufacturer's authorisation.

:

If the device has been modified, proper inspections and testing should be performed to provide safe continuous use of the device.

5. STRUCTURE AND OPERATION OF THE RECTOSCOPE AND ANOSCOPE

Picture 2



REKTOSKOP BOB R- OM ANOSKOP BOB R - OM

13. Rectoscope head
14. Magnifying eyepiece
15. Disposable tube
16. Elbow (angle) connector
17. Fiber optic guide
18. Handle
19. Air pump
20. Anoscope head
21. The needle introducing duct (channel)
22. Magnifying eyepiece
23. Obturator

A. Insert the optical fibre into the input jack (see Picture 1, pos. 4).

B. Attach the application end, rectoscope or anoscope to the optical fibre.

RECTOSCOPE

- Insert the other end of the optical fibre through the handle (18) and attach to the connection socket of the rectoscope's head (13).
- Mount the handle (18) on the head's socket using the crank.
- Put the rubber tube of the insufflation pump (19) on the connector of the rectoscope's head.
- Screw the disposable tube (15) onto the joint of the rectoscope's head (13)
- Insert the obturator of the tube through the hole in the rectoscope's head (13) holding the handle (18) of the rectoscope's head all the way
- Hold the obturator with your thumb.
- The rectoscope is ready for application.
- The obturator of the tube is to be removed after the application.
- In the event of using the insufflation pump (19), the ocular lens (14), which seals the rectoscope's head and simultaneously provides 1.5x zoom of the observed area, is to be tightened up at the head (13)
- To use the biopsy pliers with the concurrent monitoring tighten up the elbow connector (16) at the rectoscope's head (13). Description on page 9.

ANOSCOPE

- Attach the other end of the optical fibre to the connection socket of the anoscope's head (20).
- Combine the anoscope's head with the obturator (23).
- Idle the obturator with your thumb.
- The anoscope is ready for application.
- After the application, remove the obturator and in its place insert the rotary working part (21)

with the installed magnifying ocular lens

- Make an injection injecting the needle with the guidewire
  NOTE :do not rotate the working part with a protruding needle.

C. **Additionally as an option, CCD video camera (24) may be installed directly on the magnifying ocular lens.**
D. **In devices equipped with the CCD video camera, plug the video camera to the socket (11) and connect the VIDEO output (9) with a display screen using the attached VIDEO cable.**
E. **Connect the power cord with the illuminator and plug it into the mains socket with an earthing contact.**
F. **Turn on the power switching the power switch (1).**
G. **Set the desired light intensity with the regulator (3).**
H. **In the event when one of the light bulbs burns out, insert the optical fibre into the other socket (5) and switch the track switch (2) in two-track illuminators.**

It is advisable to use disposable tubes which have marketing authorisation

6. STRUCTURE AND OPERATION OF THE ELBOW CONNECTOR

Picture 3

Adapter cooperates with pliers by NOPA company and enables diagnosis and biopsy while observing the procedure through the ocular lens or on a display screen with the use of the CCD video camera.

The manner of assembly

Screw the connector in the place of the rectoscope's ocular lens turning the top (1) all the way. The top is the part of the clutch which enables to set the adapter in any position in relation to the rectoscope's head.
The observation ocular lens with 1.5x zoom is positioned at an angle of 90 degrees in relation to the axis of the rectoscope's head. The CCD video camera may be placed on the ocular lens regarding the position of the indicator on the camera.
The rear part with positioning markers (2), which is loose after you lightly unscrew the screw (3), enables: - to insert the biopsy pliers with the possibility to pump air.

- *to insert another instrument without pumping air*
- *the observation without the inserted biopsy pliers with the possibility to pump air*

Relevant markers on the casing set the proper position of the mobile part of the adapter in relation to the body. Having set the position, tighten the screw (3).

Picture 4

For cleaning, you are to disassemble the connector unscrewing the screws (3), (4) and the sealant of the biopsy pliers (5)

After cleaning, disinfection and possible sterilisation, before the assembly you are to grease the gasket (6) with a layer of vaseline oil. In the event of leakiness, you are to replace the gaskets.

NOTE! Before inserting the biopsy pliers, you are to grease them with a layer of vaselin oil and to regulate the pressure of the sealant (5) to obtain tightness !!!

7. CONDITIONS OF STERILISATION AND MAINTENANCE OF THE RECTOSCOPE AND ANOSCOPE

Cleaning

Clean immediately after using to prevent drying of the residue.
It is advisable to wash with a soft brush using soapy or pure water.
The rectoscope's tube is to be disposed of.

If it is washed in a machine for washing or with chemicals,
follow the recommendations of the chemicals' manufacturer.
Clean the polished outlets of the optical fibre bundles very carefully.

Do not clean with ultrasounds!
After washing, rinse thoroughly with demineralised water and dry in max. 90 degrees C.

Disinfection

We advise soaking in a disinfectant or a thermochemical disinfection in max. 65 degrees C in a water steriliser.
Strictly follow the disinfectant manufacturer's recommendations!
Failure to follow the disinfectant manufacturer's recommendations may result in damaging of the endoscope.

After disinfection, rinse with sterile demineralised water and dry thoroughly with a sterile gauze.

Sterilisation

Sterilisation of the endoscope is not required if used for diagnostic purposes. After the aforementioned washing, the endoscope may be sterilised with ethylene oxide in the temperature up to 65 degrees C.

Sterilisation in B or S type autoclaves may be made when the conditions introduced by the manufacturer are satisfied.

We do not recommend rapid sterilisation in an autoclave or dry heat sterilisation.

Cleaning of the elbow connector

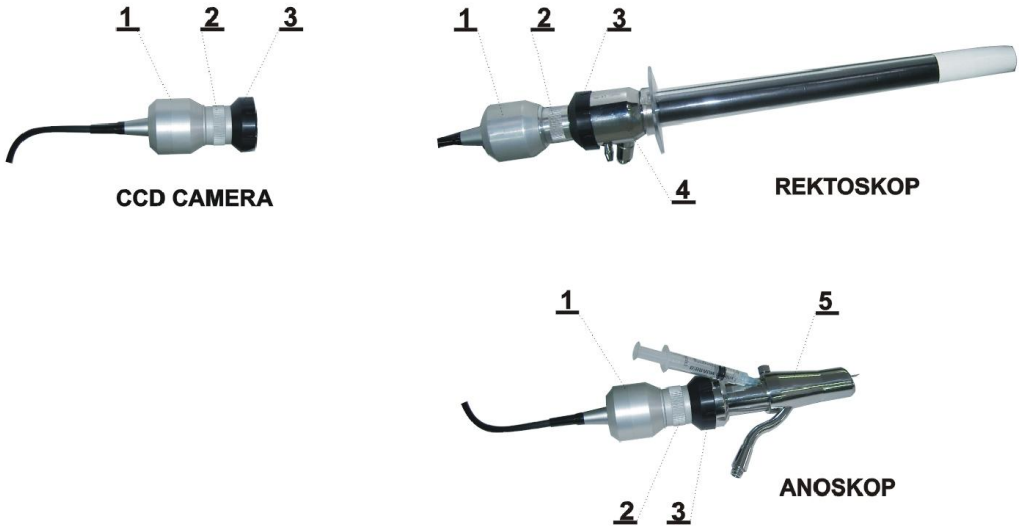
Clean immediately after using to prevent drying of the residue.
It is advisable to wash with a soft brush using soapy water. If it is cleaned in a machine for washing or with chemicals, follow the recommendations of the chemicals' manufacturer.

Do not clean with ultrasounds!

After washing, rinse thoroughly with demineralised water and dry in the temperature of max. 90 degrees C.

8. BOB KE Video Camera

Picture 5



CCD 1/4”
470 lines
1.0lux/F 1.2
Intensification - AUTO
White balance I- programmed
Weight: 200 g with a cable
VIDEO output - composite
Length of the video camera: 100 mm
Diameter of the video camera: 40 mm

The video camera (1) is attached onto the rectoscope's (4) or anoscope's head (5) with the connector (3) by placing it directly onto the ocular lens.

The adjustment ring (2) is used for adjusting sharpness of an observed picture on any display screen with VIDEO output.

The video camera is connected with a cable terminated with LEMO type plug for the socket on the front plate of BOB R-OM illuminator (11) page 5.

The display screen is to be connected with a signal cable attached to the set with the VIDEO OUT socket which is at the rear of the BOB OM illuminator (9) page 5.

NOTE

The ocular lens and the protective lens of the video camera is to be wiped with a liquid preventing evaporation.

The video camera is to be kept clean first by wiping it with a damp cloth and subsequently by wiping it until dry. Do not soak or sterilise it in an autoclave.

If not used, place it in the handle (12) page 5.

9. OPTICAL FIBRES

Medical optical fibres are the high class optical devices and they may be irretrievably damaged if used improperly.

We ask you to carefully read the following instructions before using the optical fibre.

1. Source of the cold light cooperating with the optical fibre is to be plugged into the mains socket equipped in an earthing contact.
2. Contact of the optical fibre with any items with sharp edges, which may irretrievably damage the cover of the optical fibre, is to be avoided.
3. The end of the optical fibre is not to be unplugged from the socket of the source of cold light by pulling the flexible cover.
4. The emitting end of the optical fibre is not to be left near flammable materials. The light of high intensity may cause ignition of these materials.
5. Under no circumstances can you look directly at the emitting end of the optical fibre, it may harm your eye.
6. The unused optical fibre ought to be kept in a dry and clean room.
7. Use a possible, gentle optical fibre bending radius.

If needed, it is advisable to wash by hand using a gentle detergent or soap and to rinse in lukewarm water.

Dry with a cotton cloth or in a gentle stream of air.

Do not dry with hot air above 80 degrees C.

From time to time clean the front of the optical fibre by wiping it with a cotton pad moistened with 70% isopropyl or ethyl alcohol solution

Final remarks

It is inadmissible to use mechanical and ultrasonic washers.

Gas sterilisation in formaldehyde or ethylene oxide steams is advisable.

You should take into consideration the necessity to air the optical fibre after sterilisation

Do not tightly roll the optical fibre during the sterilisation. It may result in breaking of the fibres inside the cover.

Do not put any instruments or other optical fibres on the optical fibre during disinfections or sterilisations.

From time to time assess the optical fibre beam by directing one end of the optical fibre at daylight and observing the other end.

Broken optical fibres of the device are visible as dark points.

The optical fibre should be repaired or replaced for a new one if the comfort of observation is reduced (30% of fibres are being damaged).

NON-COMPLIANCE WITH THE INSTRUCTIONS
MAY RESULT IN THE LOSS OF WARRANTY

Picture 6

10. CLEANING, DISINFECTION AND STERILISATION OF ACCESORIES

Sterilisation is to be performed in accordance with the requirements of 'Sterilization of medical devices' ISO 17664 norm. In principle, the accessories may be cleaned manually or automatically, obtaining satisfactory results. Methods of manual cleaning cause risk of infecting personnel responsible for decontamination. Automatic methods reduce this risk and are more beneficial in view of standardised, repetitive procedures and ones subjected to validation. Therefore, fundamentally, BOB company advises to use the methods of automatic cleaning. After using immediately treat the accessories as it has been described in these instructions.

Treat the new accessories as if they have been used. New accessories are to be decontaminated using the complete decontamination cycle.

Procedures and agents for decontamination by BOB company may not be compatible with some methods of decontamination.

BOB company distinguishes two degrees of compatibility:
- compatibility subjected to validation in the scope of microbiological effectiveness
- compatibility verified in the scope of material compatibility.

Validation in the scope of microbiological effectiveness

Submission to validation in the scope of microbiological effectiveness means that the effectiveness of the procedure or the agent has been submitted to validation in the scope of decontamination of accessories, as it has been described in the instructions of a given product and in this document.

Verification in the scope of material compatibility

Verification in the scope of material compatibility means that - in accordance with the current state of knowledge - the procedure or the agent used for decontamination will not affect materials or the instrument's functionality negatively. Verification in the scope of material compatibility does not mean that the microbiological effectiveness can be guaranteed.

Selection of a decontamination method

The decontamination method selected by an institution should be defined by national and local

guidelines and also by the hospital infection control committee.

Selection of an agent for decontamination

The selected by the institution agent for cleaning and disinfection ought to be defined by national and local guidelines and also by the hospital infection control committee.

Monitoring

Monitor and submit to validation all disinfection and sterilisation processes.

Although there are no biological indicators for verification of disinfection processes, there are available test strips enabling to monitor the concentration of the disinfection agent. Monitor the concentration in accordance with the instructions of the agent's manufacturer to provide that the solution has not been diluted below the effective concentration

Patient tissue residues and agents for decontamination are hazardous.

Wear personal protection clothing to be protected from hazardous chemicals and materials which may be potentially infectious. During cleaning, disinfection and sterilisation put on proper personal protection clothing, such as eyes protection, face mask, moisture-resistant clothing and chemical resistant gloves which exactly fit and are sufficiently long so that no skin surface is uncovered.

Always remove the contaminated protection clothing before leaving the area of decontamination.

A room for disinfection/sterilisation must be properly ventilated.

The surface of the illuminator may not be sterilised.

The surface of the device is to be cleaned and disinfected.

Before cleaning:

- Switch off the power switch.
- Unplug the power cord.
- Wait until the device cools down to room temperature.

Remove dust and contamination using a proper, lint-free cloth which is to be moistened if needed.

To disinfect the device, wipe it with a cloth moistened in a disinfectant.

Disinfectants are to be selected in accordance with its scope of applications.

The disinfectant must be approved by the manufacturer for disinfection of specific (surfaces of) medical devices.

Follow the technical data, provided by the manufacturer, on temperature, contact time and concentration.

To avoid the risk of ignition and explosion, leave the device to cool down to room temperature.

Never immerse devices in liquid!

Preparation of the device for decontamination in a place of use

Reusable accessories are to be prepared for subsequent contamination directly in an operating room after use.

To avoid blood and protein deposits, the whole equipment is to be decontaminated directly after

use. If the above does not take place, take special measures to pre-clean the equipment.

Reusable accessories

Remove contamination from accessories wiping them with a proper, lint-free disposable cloth. Disassemble the accessories. Do not use excessive force because it will damage the accessories. If needed, the accessories may be immersed in an abstergent or disinfectant solution directly after use.

Transportation of reusable products

Transport the reusable products from the place of use to the decontamination area. Fundamentally, a wet, dry or immersed in liquid instrument may be transported. Exceptions are introduced in the instructions of individual products.

For the time of transportation the reusable products are to be packed to avoid possible contamination of environment or people.

If dry instruments are packed, do not allow for considerable contamination to dry.

Begin the below cleaning procedure directly after use.

If this period is exceeded, the user must take necessary measures to obtain proper cleaning results. If you are packing instruments immersed in liquid, begin the below procedure within 1 hour of the use.

Do not use saline solution for immersing.

Before cleaning

Endoscopic accessories are to be thoroughly cleaned before disinfection. Thorough cleaning removes microorganisms and organic material. The ineffective removal of organic material reduces the effectiveness of disinfection.

High level disinfection

To obtain information on effectiveness of germicides in each solution, familiarise with instructions for the solution or contact the manufacturer of the solution.

A chemical used for disinfection ought to kill/neutralise:

- bacillus,
- vegetative bacteria,
- viruses (hepatitis, HIV, BPV etc.)
- fungi,
- some bacterial spores.

Disinfection procedure

- Prepare a disinfectant solution in accordance with instructions attached by the manufacturer of this disinfectant.
- Fill a container, sink or a tank for disinfection with the disinfectant solution.
- Open shut-off valves.

If instruments remain dry for a longer period, impurities on them may dry and cause formation of deposits which may be difficult to remove.

If accessories remain immersed in liquids for a longer period, they may get damaged and the gaskets may also get damaged or may stop functioning properly. Decontaminate the accessories directly after use. Do not exceed the aforementioned time limits of transportation. Do not leave any instruments for the night before decontamination.

BOB company advises, if possible, to use fractional, pre vacuum steam sterilisation.

Pre vacuum steam sterilisation has been subjected to validation in respect of the effectiveness of a germicide with majority of endoscopes. Information on the compatibility with the steam sterilisation process may be found in instructions of the specific products.

11. INSPECTIONS

The manufacturer has established the lifetime of the medical illuminators to be 12 years. There is a possibility to extend the lifetime for 3 years as a result of the positive inspection.

The obligation to perform inspections is defined by the Act on Medical Devices of

May 20, 2010 (Dz.U. [Journal of Laws] No.107, item 679, Art. 90, point 4)

The manner and the principles have been established by the norm: PN-EN 62353 'Medical electrical equipment - Periodic inspection and testing after repair of medical electrical equipment'.

The following tests are compulsory:

1. **Before putting into operation.....At the expense of the manufacturer**
2. **After the warranty service repair.....At the expense of the manufacturer**
3. **After the post-warranty service repair.....At the expense of the user**
4. **Once in 36 months .....At the expense of the user**

We draw users' attention to the issue that operating a device without the valid periodic inspections constitutes the violation of the Act on Medical Devices and of the 'Medical Incident' Ordinance of the Polish Ministry of Health (Dz. U. [Journal of Laws] 2011, No. 33, item 167 of 2 February 2011).

NOTE!

The testing may be exclusively performed by the person authorised by Polish Electricians Association (*Stowarzyszenie Elektryków Polskich - SEP)* to conduct electrical measurements above 1KV using the equipment with current calibration status.

12. ENVIRONMENT PROTECTION - RECYCLING

In accordance with the Act on Waste (Dz.U. [Journal of Laws], 2001 No. 62, item 628) and 91/689/EEC Directive of the European Union, it is prohibited to dispose of electrical equipment in the trash.

A client undertakes to transfer the used equipment to a specialist company recycling electronic waste, according to the manufacturer's instructions or the client's discretion.

13. CONDITIONS OF CONDUCTING REPAIRS

THE MANUFACTURER PROVIDES A 60 MONTH WARRANTY CALCULATED ON GENERAL PRINCIPLES FROM THE DATE OF THE PURCHASE

The compulsory paid inspection of the device after 36 months is the condition to receive the 5 year warranty.

The warranty does not include:

- Halogen bulbs
- mechanical damage of the casing
- mechanical damage of the optical fibre
- damage resulting from the inconsistent with the instructions use of the illuminator

AFTER THE WARRANTY PERIOD HAS EXPIRED, THE MANUFACTURER PROVIDES THE PAID SERVICE.

Manufacture and Service BOB - Technika Światłowodowa
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tel. 48.22.4982666; e-mail: bobts@bobts.pl ; www.bobts.pl

Serial No. of the illuminator _____

Serial No. of the video camera _____

Date _____ **Signature**_____