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# **Instrument trolley GRACIE** UN-PACKING MANUAL

INSTRUCTION MANUAL



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Instrument trolley GRACIE

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## Content

Introduction	5
1 Un-packing manual	8
2 Basic versions overview	8
<b>3 General instructions</b> 3.1 General safety 3.2 Related standards 3.3 Electrical safety and EMC:	11 12
<ul> <li>4 Usage</li> <li>4.1 Adjusting the instrument trolley</li> <li>4.2 Individual parts of the instrument trolley</li> <li>4.2.1 Upper utensil</li> <li>4.2.2 Warming-up controller</li> <li>4.2.3 Waste bins</li> <li>4.2.4 Racks and doses for instruments and materials</li> <li>4.2.5 Back container for used speculums</li> <li>4.3 Jam spots</li> </ul>	13 13 15 16 16 17
5 Mandatory selection of accessories 5.1 GKB-067.12.03 Plastic slippage 5.2 GKB-067.46 Metal slippage	20
6 Optional accessories 6.1 GKB-067.48 Wire basket, stainless steel 6.2 GKB-067.51 Wide-neck flask with stopper 6.3 GKB-067.44 Stainless container for speculums 6.4 Instrument shelf (GKB-067.52 Left/ GKB-067.53 Right)	21 21 21
<ul> <li>7 Maintenance</li></ul>	23 24 25 26
8 Enviroment protection 8.1.Disposal 8.1.1 Within Europe	28 28

# Introduction

Please carefully read the whole operating instructions created so that you become acquainted with proper usage and relevant parameters of the instrument trolley of a doctor – gynaecologist (hereinafter only "instrument trolley") prototype. Please behave always according to the instructions mentioned in this manual and use the device solely in accordance with the instructions.

Keep these operating instructions close to the product for the whole time of its operation. These instructions must be read and familiar to each person operating the product.

Especially important information is labelled with the following symbols in this manual:

Logo	Meaning		
CE	EU legislation compliant product		
UK CA	UK CONFORMITY ASSESSED (UKCA) marking (product normatively harmonized for great britain economic area)		
UK REP	Authorized representative in Great Britain		
CH REP	Authorized representative in Switzerland		
	Quality management systems certification authority marking		
CESKA KVALITA	Quality management systems certification authority marking		

Pictogram	Meaning	
	WARNING	
	WARNING:	
<u>_7</u>	Dangerous electric voltage	
	This symbol introduces any information, that may help you to avoid operative problems	
SN	Production number	
REF	Reference Number (Product type depending on configuration)	
EAC	EAC marking	
int x/y	Marking of intermittent operation, i.e. if the product has been continuously operated for time period "x", then it must rest idle for time period "y". For example int 10 / 20 means that after 10 minutes of continuous use /positioning the product must be out of use/not positioned for 20 minutes	
IP X #	Constructional protection against water leakage, dangerous touch contact and intrusion of foreign objects	
$\frac{\Delta}{\Delta} = kg$	Safe operational load	
	Safe patient load	
	Producer	
$\sim$	Date of production	
	Follow the instructions manual.	
$\checkmark$	Equipotentiality	



Ť	Packaging material: "Keep dry"	
Ţ	Packaging material: "Fragile!"	
<u>††</u>	Packaging material: "This side up"	
X	Temperature limitation	
) N	Transportation marking: "Relative air humidity".	
\$	Transportation marking: "Air pressure".	
	Marking according to the directive EC 2002/96/EC (Directive about the disposal of old electric and electronic appliances). Symbol for: "Do not dispose of the product into communal waste. Use special collection points for old electronic appliances."	

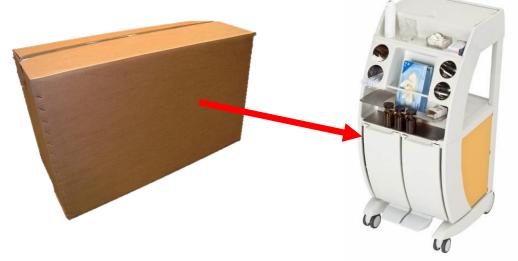
Abbreviation	Meaning	
REF	Catalogue number	
LED	Light emitting diodes	
VA	Power intake units	
VGA	Computer standard for computer imaging technology	
USB	Universal serial bus	
LCD	Liquid crystal display	
IT	Information technology	
PC	Personal computer	
dB	Sound intensity unit	
hPa	Pressure unit	
ČSN	Protected marking of the Czech technical norms	
Hz	Frequency unit in the SI system	
EMC	Electromagnetic compatibility	
VF	High frequency	
ME	Medical equipment	
CISPR	International Special Committee on Radio Interference	

Please consult possible questions directly with the producer, company LINET spol. s r.o.



# 1 Un-packing manual

Remove Instrument trolley from the box. Then dispose of the carton in compliance with your local regulations concerning waste disposal.



From container for used speculums remove the electric cable (only in GKB-167 version). There you can find also a box with flacons (accessories GKB-067.51) (Fig. 1) and stainless steel holder (Fig. 2), which you insert into marked grooves.

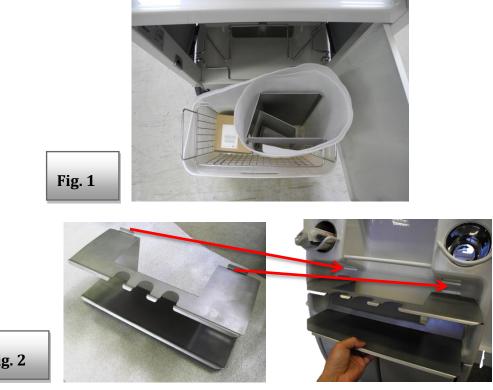


Fig. 2

# 2 Basic versions overview

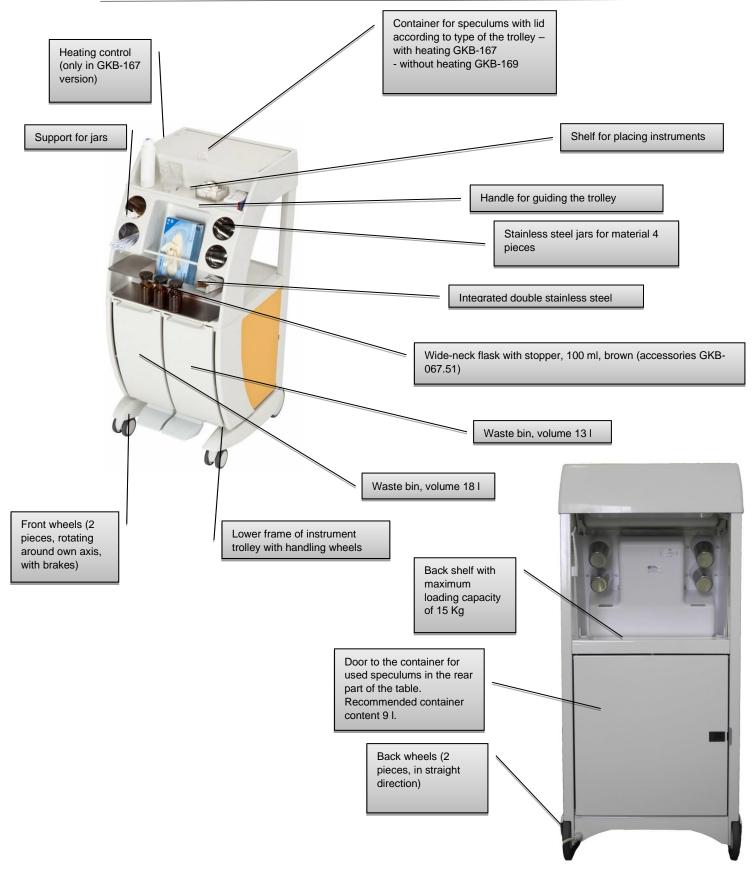
Instrument trolley with heating (GKB-167.X)	Instrument trolley without heating (GKB-169.X)
Container with warming of gynaecological speculums (1piece)	Container without warming of metal gynaecological speculums (1piece)
Waste bins (2pieces)	Waste bins (2pieces)
Container for used speculums (1piece)	Container for used speculums (1piece)
Stainless steel jars (4 pieces)	Stainless steel jars (4 pieces)
Stainless steel holder forbottles (1piece)	Stainless steel holder for bottles (1piece)
Handle (1piece)	Handle (1piece)
Handling wheels (4 pieces)	Handling wheels (4 pieces)
Electrical equipment - universal transformer 100V, 120V, 230V	

## **Color versions**

Substituted by the letter "X".

A - violet	M - yellow
B - blue	P - orange
F - green	





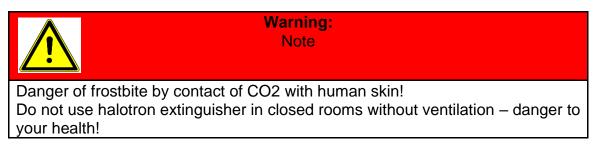
# **3** General instructions

Instrument trolley can be operated only on places that fulfil the conditions of valid standards for electric mains on places for medical purposes.

### 3.1 General safety

- Be very particular of proper fastening the accessories (tightening the handles etc.).
- Do not dismantle or do not make unqualified repair of any part of the product.
- Design changes reserved!
- Objects, which could get into collision with the trolley, may not be placed in immediate proximity of the chair.
- Never use other than original accessories. All original accessories are marked with original label containing the name and brand of the manufacturer, serial number or batch ID and date of manufacture.

### Fire Extinguishing Information



The medical product is categorised as energised electric installation, hence, fire can be extinguished by the following types of extinguishers.

Use	Do not use
Powder extinguisher	Foam extinguisher
CO2 extinguisher	Water extinguisher
Halotron extinguisher	





### 3.2 Related standards

This product complies with the relevant harmonization regulations of the European Union. Since the device is powered from the mains, it may cause interference with sensitive equipment due to generation of electromagnetic field. To prevent the occurrence of these problems the trolley must be used in compliance with this manual.



3.3 Electrical safety and EMC:

- The trolley is intended only for use by medical professionals.
- The trolley may cause radio interference, which can have effects on the operation of nearby equipment. It may be necessary to take measures to reduce these effects, such as redirection, relocation or shielding of the device.
- The trolley must be installed and put into operation in compliance with information related to EMC provided in the accompanying documentation. Portable and mobile HF communication devices may influence the electrical medical device.

Manual and declaration of the manufacturer - electromagnetic radiation		
The trolley is intended for use in electromagnetic environment specified below. The customer or user of the trolley must ensure that the bed is used in such environment.		
High frequency radiation CISPR 11	Group 1	Trolley uses high frequency energy only for its internal functioning. Therefore, its high frequency radiation is very low and is not likely to cause any interference with nearby electronic equipment.
High frequency radiation CISPR 11	Class A	Trolley is intended for use in all facilities <b>other</b> than households and
Harmonic emissions IEC 61000-3-2	Not applicable	buildings which are directly connected to a public low-voltage power supply network that supplies buildings used for residential purposes.
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	

## 4 Usage



The essential function is an additional equipment of a gynaecological examination room.

The instrument trolley integrates instrument trolley, waste bins, mirror utensil and utensil for used speculums.

### 4.1 Adjusting the instrument trolley



The instrument trolley is intended primarily for travelling within the consulting room. Passaging raised places (doorsills etc.) is not recommended.

Rear castors are fixed in forward direction and unbraked.

Adjust the trolley by means of four castors, two (front) of which are rotary around their axis for better handling. After adjusting the instrument trolley fix it by means of brakes on each front castor.

## 4.2 Individual parts of the instrument trolley

### 4.2.1 Upper utensil

It is used for plastic / metal gynaecological speculums. The utensil can be closed using the upper cover.

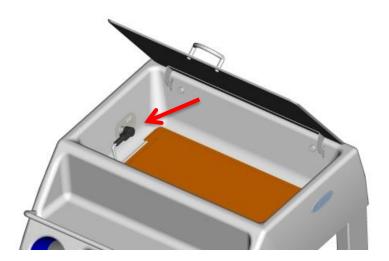




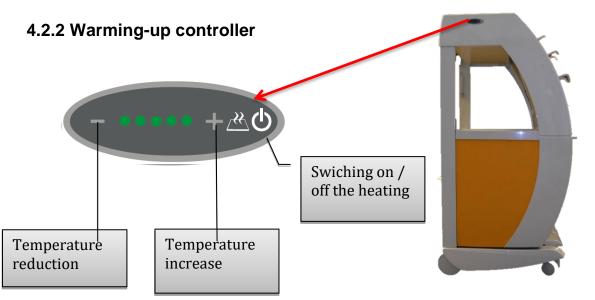
The reflective foil makes a standard part of the cover from the inside and it enables a doctor being in a sitting position to have a more accurate view over the prepared gynaecological speculums and other instruments in the container. The upper container has three hinges facilitating a smooth adjustment of the cover into any fixed position needed.



In GKB-167 model optional equipment is a removable heated cushion of the upper utensil being instrumental to pre-heating metal gynaecological speculums, is a component part. The pad can be taken out of the container after connector is disconnected.







#### **Error messages**

Problem description	Probable cause	Action by qualified service personnel
Flashing 4LED	Defective or disconnected electric blanket	Connect or replace



Heating temperature of the mat is only for guidance. The temperature can be influenced by ambient conditions, mode of use and quantity of installed tools. The temperature of installed tools can also be influenced by opening or closing of the mirror table door. The intensity of thermal impact on the tools depends on the distance to the heat source, however, it should not exceed 42° C. This only applies to version GKB-167.



### 4.2.3 Waste bins



# Waste bins are not designed for liquids. For this purpose, you can use rear utensil

Can be opened manually catching by upper handrail of the bin, or by foot depressing the pedal for opening the bin. Volume of the left bin, from doctor's view, is 18I and volume of the right bin, from doctor's view, is 13I.

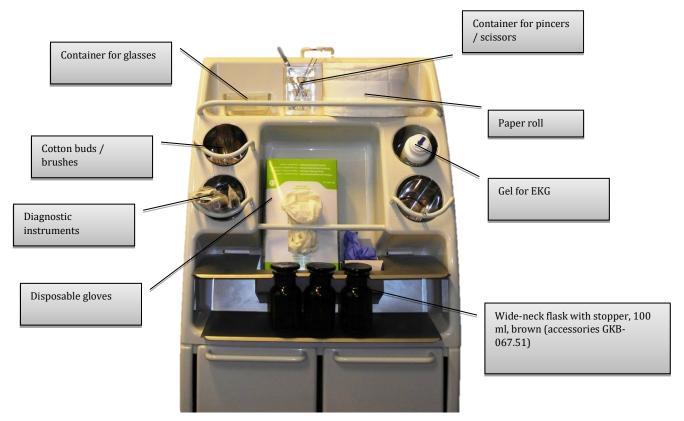


### 4.2.4 Racks and doses for instruments and materials

The removable stainless steel doses facilitate organizing verricules and brushes.



In the area between the jars there is a space for situating for instance a box with gloves. The integrated rack can be used as a flacons holder (GKB-067.51). The upper rack is instrumental to putting of instruments and materials.



### 4.2.5 Back container for used speculums

Inside the utensil, there is a wire basket (accessories GKB-067.25) for easy removal of the used speculums. Before using, pour in disinfecting solution into the utensil, maximum to a scale line illustrating maximum level of solution in the utensil. There is a hole for throwing metal speculums in above the right (from doctor's view) smaller bin (GKB-067.12.03 Plastic slippage / GKB-067.46 Metal slippage).





#### Removal of the whole container

To open the rear door of the tooling table, push the black button in the direction of the arrow. Hold the container by its grip holes and pull it out of the rear part of the tooling table, in the direction of the arrow (towards yourself). If you hold it anywhere else, you may pinch your hands and spill the disinfection solution out of the container.



#### Mirror dripping

The wire basket design allows it to be hanged on the plastic container for as long as needed to let the solution liquid drip off the used speculums. Use the ears to hang the wire basket on the container, as shown in the next picture.

### Restoration of the whole container

Hold the container by its grip holes and then push it into the rear part of the tooling container, in the direction of the arrow (away from yourself). If you hold it anywhere else, you may pinch your hands and the disinfection solution may spill out of the container. Fit the container in so it does not protrude out of the rear part of the table and so the door is not obstructed. Then close the door of the tooling table.



### 4.3 Jam spots



In the course of working (examining), it is important to take care that the instrument trolley is not in collision with other subjects in its surroundings. In particular, it is necessary to take care that it is not situated under a lifted foot support of the gynaecological chair which could deform it irrevocably moving down.



# **5** Mandatory selection of accessories

5.1 GKB-067.12.03 Plastic slippage

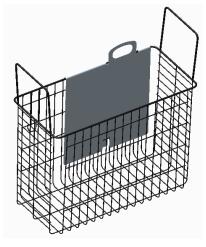


5.2 GKB-067.46 Metal slippage



# 6 Optional accessories

6.1 GKB-067.48 Wire basket, stainless steel



6.2 GKB-067.51 Wide-neck flask with stopper

100 ml, brown



## 6.3 GKB-067.44 Stainless container for speculums

It serves for storing sterile metal speculums in the container for gynaecological speculums. The container is warmed up on a switched on heating blanket and keeps the speculums for a patient in an optimum examination temperature.





## 6.4 Instrument shelf (GKB-067.52 Left/ GKB-067.53 Right)

Serves as a shelf for examination instruments, e.g. instruments for hysteroscopy, for the preparation of vaginal speculums, intrauterine device, etc.

The instrument shelf is safely protected against accidental releasing from the inactive position.

Instrument shelf itself can be ordered under GKB-067.52.07.

- If the shelf is not being used, it is recommended to lift it to the inactive position and to place the tray to the rear of the instrument trolley.
- Maximum permitted loading of the shelf is 10 kg.
- When working with instruments placed on the shelf, work carefully to prevent the instruments from falling on the ground!



# 7 Maintenance

The manufacturer recommends a regular annual revision of the product.

## 7.1 Basic technical data

Width	520 mm
Depth	600 mm
Height	1125 mm
Weight	47 kg
Volume of front bin – right	13
Volume of front bin – left	18
Volume of the rear basket	18 I
Recommended volume of liquid in the back bin	91
Loading capacity of the middle shelf	15 kg
Loading capacity of the shelf for storing speculums	3 kg
Max temperature of heating electrical blanket may reach (only in GKB-167 type)	about 38°C + 10%
Time of warming the space for speculums - Ambient temperature: 24°C - Number of metal speculums in the area: 5 - Measured place: 10mm under upper lid - final temperature: 38°C	c. 40 min
Nominal value of the fuse in the control unit (100V-240 V)	1 AT
Protection class	l
Protection level	IPX4
Frequency (100 V-240 V)	50/60 Hz



## 7.2 Production label with UDI

The serial label contains information about Address of Manufacturer, Manufacturing Date (Year-Month-Day), Product Reference Number, Product Serial Number, Global Trade Item Number (GTIN), Unique Device Identification (UDI), symbols, weight specifications and electrical specifications.



Please address any potential queries to the authorized representative or directly to the producer L I N E T spol. s r.o.

## 7.3 Cleaning and disinfection



### CAUTION!

Risk of injury due to accidental trolley movement!

### WARNING!

Risk of damage to property due to incorrect cleaning / disinfection!

- Do not use washing machines.
- Do not use pressure or steam cleaners.
- Follow the instructions and the dosage recommended by the manufacturer.
- Make sure that disinfectants are selected and used exclusively by qualified hygiene professionals.
- When cleaning and disinfecting, pay attention to the materials used! See the following table for information.

Trolley components	Materials used
Frame construction, surface, trash can, etc.	Powder coated steel (powder is epoxy - polyester)
Chassis covers, trolley top, other plastic surfaces etc.	ABS

#### For safe and gentle cleaning:

- Do not use any strong acids or bases (optimal pH range is 6 8).
- Use only cleaning agents that are suitable for cleaning medical equipment.
- Do not use abrasive powders, steel wool or other materials and cleaning agents.
- Never use any corrosive or vitriolic cleaning agents.
- Never use cleaning agents that cause calcium carbonate to settle.
- Never use cleaning agents with solvents that could affect the structure and consistency of plastics (benzene, toluene, acetone, etc.).
- Carefully clean the electrical components and allow them to dry completely.
- Never immerse SCU in water or clean it with steam.
- Follow local guidelines for infection control.
- Do not use open flames when working with cleaning and disinfecting agents!
- Make sure that all cleaning agents used are approved





Recommended disinfection (disinfectants for wiping)		
RTU- Ready-to-use non-diluted products – spray or foam		
Active substance	How to use	Example of disinfectant
Amine, Alcohol up to 30%	Spray and wipe	Incidin foam
Hydrogen Peroxide	Spray and wipe	Incidin OxyFoam S
Disinfection wipes		
QAS	Wipe	Sani cloth active
Hydrogen Peroxide	Wipe	Incidin OxyWipe S
Amine, Alcohol up to 30%	Wipe	Bacillol 30 tissues
Concentrated disinfectants, to be diluted		
Active substance	Concentration of the prepared solution of the disinfectant	Example of disinfectant
Amine, QAS	0,5-1%	Terralin protect
Oxygen, QAS	1%	Desam OX
Oxygen, QAS	1%	Incidin Oxydes
Amine, QAS	0,5%	Incidin pro
Amine, QAS	0,5%	Surfanios premium
Oxygen	0,5%	Anios Oxy Floor
Oxygen	1%	Incidin Active
Oxygen	1%	Perform

*Warning!* Do not use disinfectants with active substance: alcohol over 30%, active chlorine, iodine, aldehydes.

## 7.4 Transport, Operation and Storage conditions

#### Storage and transport conditions:

10°C - 40°C, 30% - 75%, 795 hPa - 1060 hPa

#### **Operation conditions:**

-10°C – 50°C, 20% – 90% (non-condensing), 795 hPa – 1060 hPa



After unpacking and adjusting the instrument trolley on the place of usage let the product acclimatize for a period of 2 hours.

## 7.5 Service and Repairs

The product is provided with a 2-year warranty under conditions of regular annual revisions.

For all medical equipment produced by the LINET spol. s r.o.. company, the operator must ensure regular technical safety inspections according to the producer's recommendation. The inspections must take place at least 1x per year or after the carrying out of any repair of the medical equipment or after any malfunction of the electrical system of the medical equipment. The details about the scope, parameters and procedures of the technical safety inspection are specified in the service manual of the medical equipment.

If any other discrepancies occur, please contact (preferably in English language) directly the manufacturer at the following address:

### Manufacturer address:

L I N E T spol. s r.o.. Želevčice 5 274 01 Slaný Česká republika

Tel.: +420 312 576 111 Fax: +420 312 522 668 E-mail: <u>info@linet.cz</u>

http://www.linet.com Service department: service@linetgroup.com

When repairs are undertaken, exclusively use L I N E T spol. s r.o.. original parts and take advantage of the skilled service technicians with authorization to repair this product type. Unskilled repairs will be considered as an essential violation of the warranty conditions and at the same time, the manufacturer renounces its responsibility for further possible damages to this product resulting from an unskilled action.

- All revisions, service inspections, or technical inspection must be done by technician trained by LINET spol. s r.o..
- Diagrams, parts lists, descriptions or other information to aid service personnel in the repair of product parts, repairable by service personnel in opinion of the manufacturer, are available on request at the manufacturer.



### 8 Enviroment protection

The company L I N E T spol. s r.o. is aware of the importance of environmental protection for future generations. Within this company the environmental management system is applied in accordance with the internationally agreed standard ISO 14001.

The compliance with this standard is annually tested by the external audit executed by an authorised company.

Materials used in this product are not environmentally hazardous L I N E T spol. s r.o. products meet valid requirements of national and European legislation in the areas of **RoHS** and **REACH**, so they do not contain any prohibited substances in excess quantities.

None of the wooden parts is made of tropical wood (such as mahogany, rosewood, ebony, teak etc.) or made of timber from the Amazon region or from similar rainforests. Product noise (sound pressure level) meets requirements of the regulations for the protection of public health against undesirable effects of noise and vibration in protected interior spaces of buildings (according to standard IEC 60601-2-52). Used packaging materials are in accordance with requirements of the Packaging Act.

For disposal of packaging materials after installation of products contact your sales representative or manufacturer's customer service about the possibility of a free take-back of packaging through an authorized company (more details on <u>www.linet.cz</u>).

### 8.1.Disposal

### 8.1.1 Within Europe

#### To dispose of the equipment:

- The equipment must not be disposed of as household waste.
- Dispose of this equipment at designated collection points or take-back points.

L I N E T spol. s r.o. participates in a collective system with take-back company REMA System (see **www.remasystem.cz/sberna-mista/**).

By bringing electric and electronic equipment to a take-back point, you participate in recycling and you save primary raw material resources while protecting your environment from effects of unprofessional disposal.

## 8.1.2 Outside Europe

- Dispose of the product or its components in accordance with local laws and regulations!
- Hire an approved waste disposal company for disposal!

