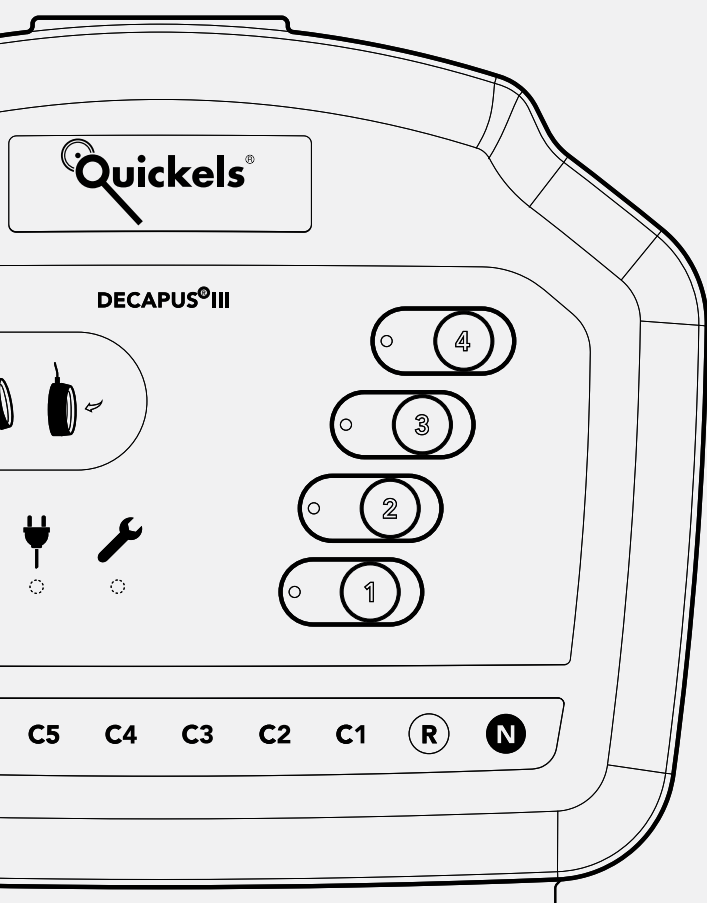


USER MANUAL

Decapus® III



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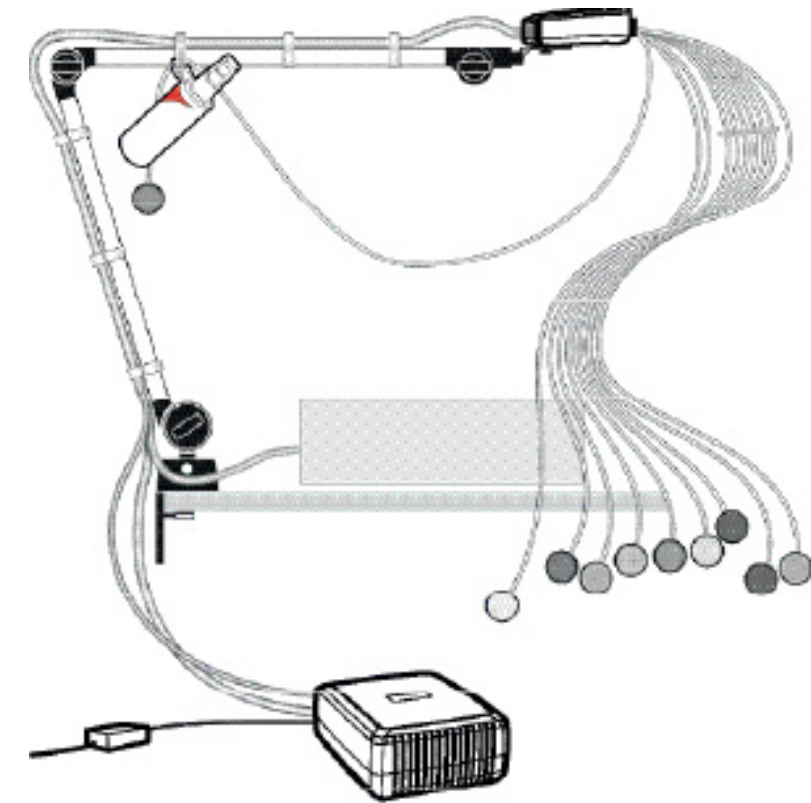
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ver.15.9.3

This is Decapus® III



Decapus® III is hygienic, easy to use and time saving. The system has all the advantages that are normally associated with vacuum application, but lacks the disadvantages.

Vacuum-ECG with flow compensated negative pressure prevents the negative pressure from significantly exceeding the level selected on the patient module. Double filters efficiently prevent fluid-borne contaminants from being sucked into the system and causing an obstruction.

The easily exchangeable Quickels electrodes can be replaced as necessary, which means that from a hygienic point of view Decapus® III is comparable to adhesive electrodes. In special situations, the signal modules can easily be replaced with adhesive electrodes.

UNIQUE SIGNAL MODULE AND FILTER

What makes Decapus® III unique are the patented signal modules and Quickels electrodes. Quickels electrodes are easy to attach to the patient's skin. Decapus® III automatically maintain the chosen negative pressure level, even if leakage occurs and air gets in. This means that Quickels electrodes stay fastened and give a good contact, with little risk of the patient feeling uncomfortable or getting suction

marks. The primary filter in Quickels electrodes is a super absorbent and can absorb up to 1 ml of fluid.

The secondary filter, which is in the signal module, provides further protection and never needs changing.

Quickels Systems AB's innovations in the Quickels electrodes and signal modules make Decapus® III a hygienic and reliable system that seldom needs to be shut off to clean blocked signal modules or patient cables. The reinforced patient cables with high tensile strength to ensure good signal quality over long periods. The system is defibrillation protected.

BATTERY OPERATION MEANS FREEDOM

Decapus® III has a battery operation with built-in charger as an optional extra, which makes it completely mobile. The battery is a lithium-ion type giving a long operating period (3.5 hours) and a fast charging cycle (2 hours).



Important safety information



SAFETY CLASSIFICATION

Decapus® III complies with the safety requirements of the International Electrotechnical Commission, publication IEC 60 601-1: Safety of Medical Electrical Equipment, Safety Classification Group I, type CF with defibrillation protection and Classification Group IIa in accordance with the Medical Device Directive 93/42/EEC.

WARNING OF POWERFUL ARM SPRING

Check that the friction screw in the middle of the arm is tight when the arm is unpacked, otherwise the arm may spring up. In the interests of safety, hold the arm together with a firm grip when the tape is removed. The arm is locked with a friction screw.

CONNECTION TO AN EARTHED ELECTRICAL SOCKET

The safety classification states that Decapus® III may only be connected to an earthed socket. Note! Connection must not be via a multi-socket extension to which other electrical equipment that does not have the same safety classification as specified above is connected.

IMPORTANT INFORMATION ABOUT RADIO TRANSMISSION EQUIPMENT ETC.

Decapus® III complies with the EMC requirements of IEC 60 601-1-2. Radio transmission equipment etc. must not be used in the vicinity of the apparatus, since this could affect its function. Special care must be taken when using powerful interference sources such as for diathermy and similar, and also ensure that diathermy cables etc. are not located on or near the Decapus® III. In case of doubt, please consult responsible personnel, or the supplier.

CONNECTION TO ECG PRINTERS AND MONITORS

The Decapus® III printer cable may only be connected to:

- ECG printers and monitors that comply with Medical Device Directive 93/42/EEG and are defibrillation protected, type CF, according to IEC 60 601-1.
- Decapus® III must not be connected to ECG apparatus of Safety Classification B, according to IEC 60 601-1.

SYSTEM CONSTRUCTION

Decapus® III is a system made up of modules. What is stated in this User manual about safe use assumes that Decapus® III is used in its entirety, i.e. that no part of Decapus® III is replaced with other equipment. The same applies to all the system's cables.



Decapus® III is marked with this symbol. This is the international warning symbol to indicate that use of the equipment may be dangerous. It is therefore important that you read this user manual carefully.

Before any equipment is used, the operator must ensure that there is no sign of damage. Take any necessary action if:

- Fluid has been spilled onto the system.
- The cover or casing is split, damaged or missing.
- Cables or connectors show signs of damage.
- The system has suffered possible mechanical damage, e.g. fallen on the floor.

Safety precautions should be taken when ECG measurements are to be taken from patients fitted with a pacemaker or other electric stimulator.



Important safety information contd.

Decapus® III must only be used as a vacuum applicator for ECG electrodes in the way described in this user manual. Quickels Systems AB will not guarantee the equipment's function if it is exposed to higher levels of electromagnetic interference than it has been tested for. Quickels electrodes must be replaced at least once per day, and at least after every tenth patient, to maintain the system's function and lifetime. When Decapus® III is equipped with a lithium-ion (li-ion) battery, this must not be thrown away when reached the end of their useful life but sent for recycling.

DEFIBRILLATION PROTECTION

The symbol on the back of the patient module means that Decapus® III has built-in protection against defibrillation voltages and that the system has been tested and approved for use in connection with defibrillation. The system has been designed so that it cannot be damaged, even if the defibrillator electrodes come into contact with the Quickels electrodes. During defibrillation: never touch the patient or any other conductive item that is in contact with the patient.

EXPLOSION RISK

Decapus® III is not designed for use in locations where there is an explosion risk.

FIRE AND EXPLOSION HAZARD

Decapus® III contains a li-ion-battery as an option. Only replace the battery with the type specified.

WARNING!

You must read the user manual before using the system.

Conductive parts of patient cables, Quickels electrodes and signal modules, including the neutral leads and the electrode, must not come into contact with other conductive parts, including earth protection.

The USB input must only be connected when Decapus® III is being serviced, i.e. never when the system is near or connected to a patient.

CURRENT LEAKAGE

The patient module cables are galvanically insulated from the pump module and from earth, guaranteeing that electric current through the patient is kept at a safe level. If a Quickels electrode, the ECG connector or the patient cables come into contact with other conductors, there is a risk of patient shock. This applies whether the object is earthed or not. No equipment not approved by Quickels Systems AB may be connected, or there is a danger of current



Important safety information contd.

leakage occurring. If other electrical equipment, which is not classified according to the above, is used in the same premises or in the vicinity of the patient, appropriate precautions must be taken.

CLEANING

Cleaning should be made daily.

- Cleaning should be carried out only with a damp cloth and mild detergent (soap solution or washing-up liquid). Wipe dry afterwards.
- If necessary, disinfect with a cloth soaked with 70% alcohol or surface disinfectant. Wipe dry afterwards.
- None of the equipment should ever be immersed into fluids of any kind. Nor should liquid be sucked through the system.
- No part of the system should ever be hot-sterilised with water, steam or hot air. Nor should ether be used.

If it is decided to use the same Quickels electrodes on more than one patient, clean and disinfect by wiping with a cloth dampened with 70% alcohol.

PREVENTIVE MAINTENANCE

For safe and trouble-free use of Decapus® III, preventive maintenance is required at least once a year as follows:

- Inspection for visible damage.
- Inspection of the arm.
- Inspection of cables.
- Check on power supply and functional earthing.
- Check for current leakage.
- Checking the pump module’s vacuum functions.
- Checking the signal modules’ valve and filter functions.
- If the system is equipped with a battery: Check battery and charger.

Rectify any faults. If in any doubt, consult authorised service personnel.

For more information please see the Service manual Decapus® III.

SERVICE

Repairs to Decapus® III or service measures if Decapus® III is not working must be performed by Quickels Systems AB or our appointed and authorised agents (see www.quickels.com). If any parts are replaced, original spares must be used. Measures carried out must be



Important safety information contd.

documented showing what has been done, when, where and by whom (company and signature).

WASTE HANDLING

At the end of their useful lifetime, the product and any replaced parts must be treated as electronic waste (WEEE) in accordance with the local system for recycling. Other materials such as paper and plastic are recycled as such. Contact your local authority or the supplier for more information.

Key to symbols



CE label



Recycling



Follow the manufacturer's instructions



Protection for defibrillation voltage



Caution



Warning



Off/on



Service needed



Connected to the mains



Battery status, 4 levels



Serial number



Batch code



Non-sterile



Dispose of as electronic waste



Keep dry



Catalogue number

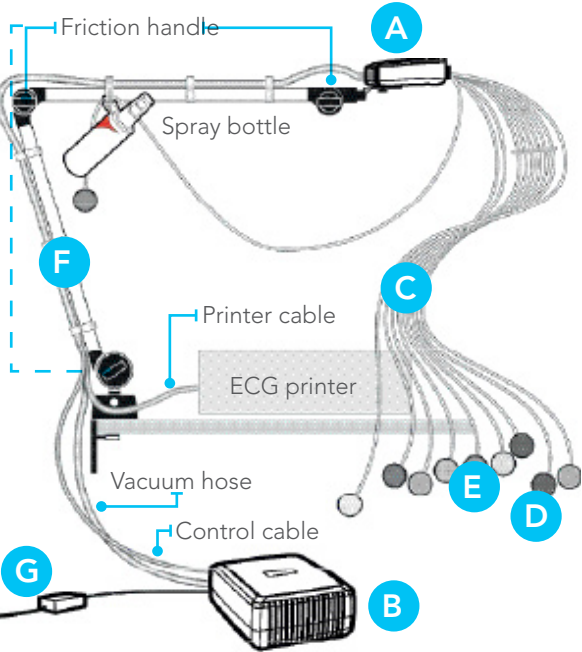


Date of manufacture



Manufacturer

Decapus® III system design



PATIENT MODULE A

Decapus® III is controlled from the control panel on the patient module. The control cable and vacuum hose connect the patient module with the pump module (B). The recorder cable connects to an ECG printer.

PUMP MODULE B

The pump module includes vacuum pump, silencer, vacuum and pulsation dampers, control electronics and (as an option) a rechargeable battery.

PATIENT CABLES C

The ten shielded, interference-free patient cables are low-friction type and are highly flexible. Like the signal modules they are clearly marked with identification complying with IEC standards. A connector, 4 mm in diameter, allows adhesive electrodes to be used.



The recorder cable must only be connected to MDD 93/42/EEG approved ECG printers of type CF according to IEC 60 601-1.

Decapus® III consists of pump module, patient module, power supply, control cable, vacuum hose, recorder cable, patient cables, signal modules, Quickels electrodes, table fixation and arm.

SIGNAL MODULE D

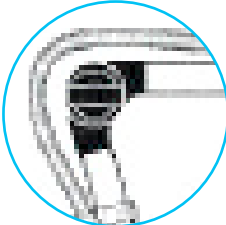
Signal module with filter that absorbs 1.5 ml of fluid.

QUICKELS ELECTRODES E

The easily replaceable Quickels electrodes contain a primary filter that can absorb 1 ml of fluid and prevents fluid-borne contamination from entering the system. The electrode itself is coated with silver/silver chloride for high signal quality.

ARM F

The easily adjustable arm supports the patient module and simplifies patient movement from rest to stress position. Arm movements are adjusted using the three friction screws.



POWER SUPPLY G

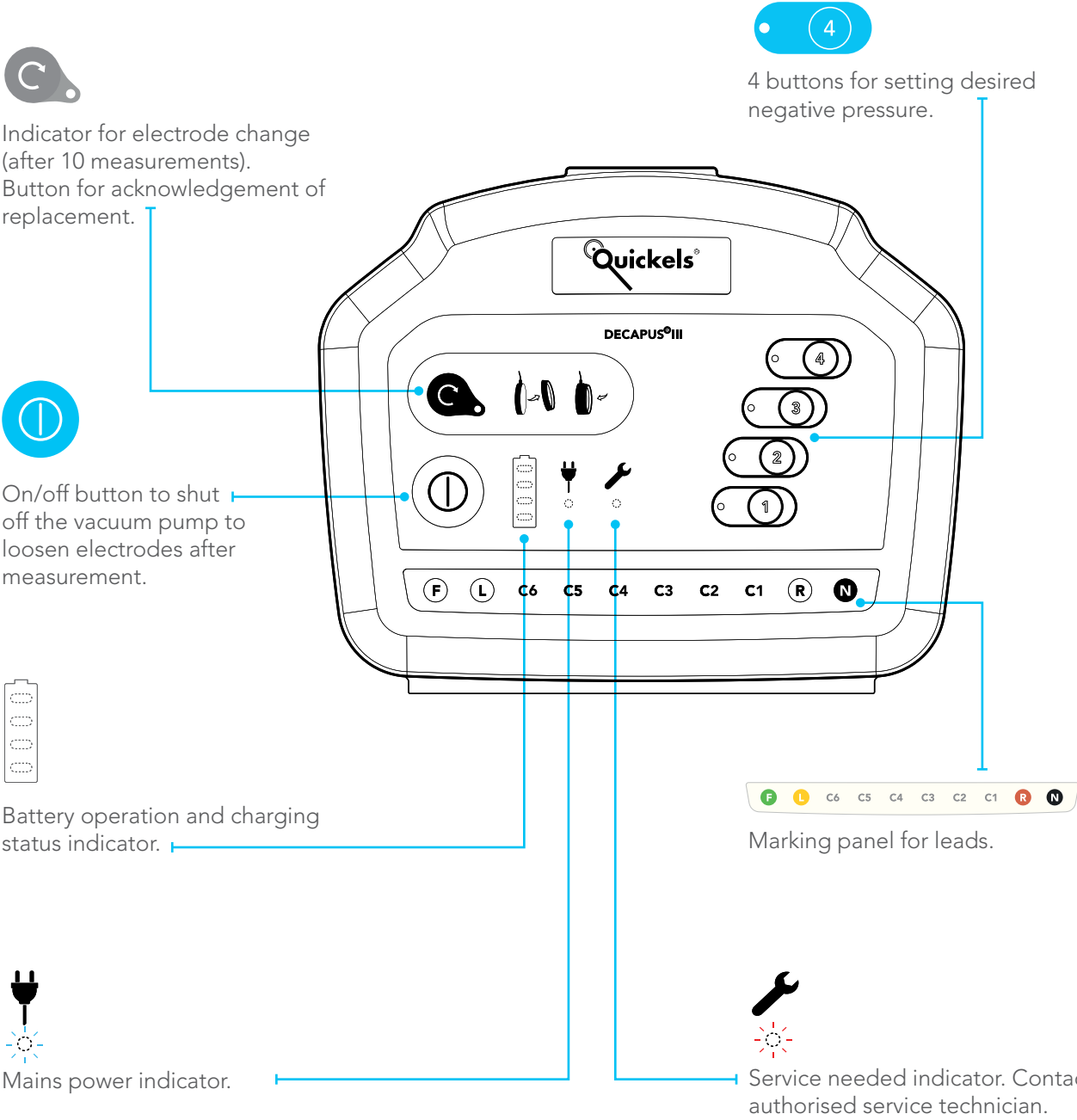
Connects to an earthed mains supply.

Pump fastening, other arm fastenings and ECG-adapters for ECG printers are available as accessories.

Patient module

The parts

The patient module consists of a control panel, control electronics and a defibrillation protector. The control panel has touch buttons and is easy to use and clean.



Indicator for electrode change (after 10 measurements). Button for acknowledgement of replacement.



On/off button to shut off the vacuum pump to loosen electrodes after measurement.



Battery operation and charging status indicator.



Mains power indicator.



4 buttons for setting desired negative pressure.



Marking panel for leads.

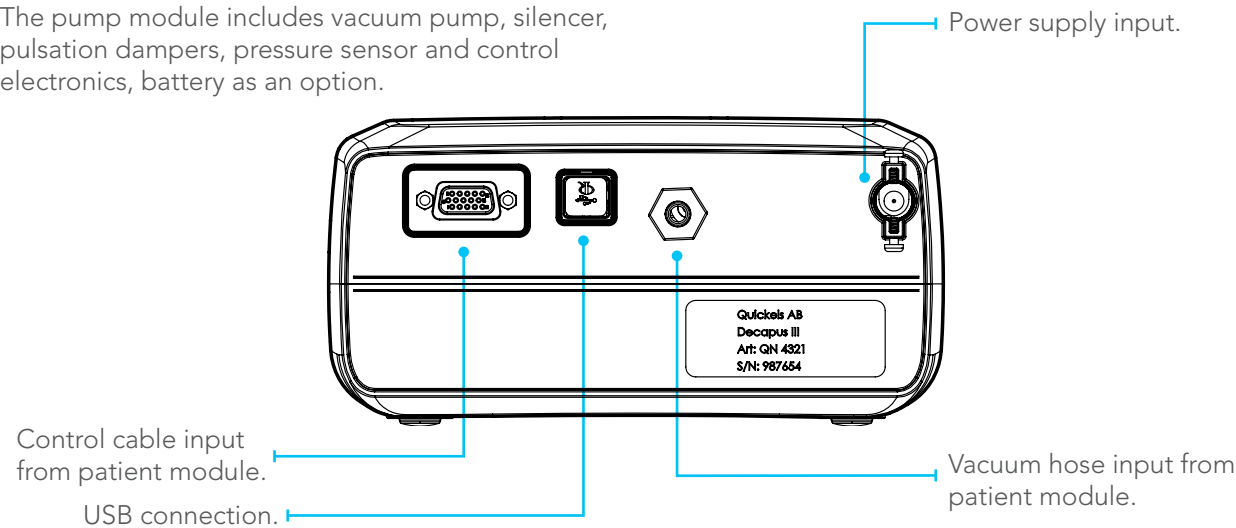


Service needed indicator. Contact authorised service technician.

Pump module

The parts

The pump module includes vacuum pump, silencer, pulsation dampers, pressure sensor and control electronics, battery as an option.



⚠ Never connect to anything other than the intended power supply!

⚠ Only connect with Decapus® III patient module!

⚠ The USB input must only be connected when Decapus® III is being serviced, i.e. never when the system is near or adhered to a patient.

⚠ **Li-ion battery. Fire and explosion hazard!**
Never use any other kind of battery!

The battery may only be replaced by a qualified service technician.

Battery operation

Battery operation (option) means that Decapus® III can function as a completely mobile system. Battery charging occurs automatically when the system is connected to the mains and the vacuum function is off. The life time is around 400 charging cycles. The battery charging time is about 2 hours and the runtime is about 3.5 hours, which corresponds approximately to:

- 50 resting ECGs (5 min per round).
- 10 ECG stress tests (20 min per round).

Battery status is indicated by four levels on the control panel:

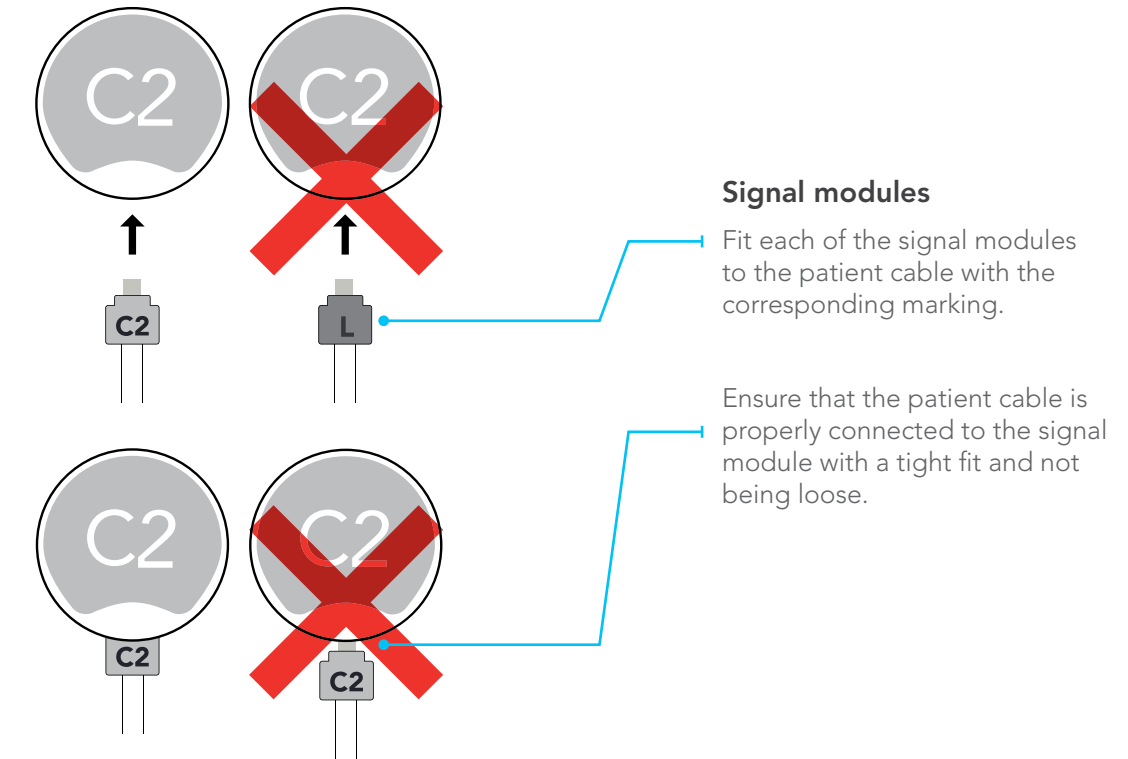
- Steady green lights in fields 1-4 indicate the charge level of the battery.
- A blinking orange light in the lowest field indicates low battery level. After use, the system should be connected to an earthed mains socket to recharge the battery.
- When battery capacity reaches the minimum level, the system shuts off and shows only a blinking orange light if the operator presses any button on the control panel.
- A green blinking light indicates that the battery is charging. During charging the steady lights show the battery's level of charge.

During operation on battery without mains connection, the vacuum pump starts when the vacuum level is selected with buttons 1-4 on the control panel. If the vacuum pump is left turned on during battery operation, it will shut down automatically after one hour.

In the event of battery failure, the service light on the patient module lights up: contact an authorised service technician.

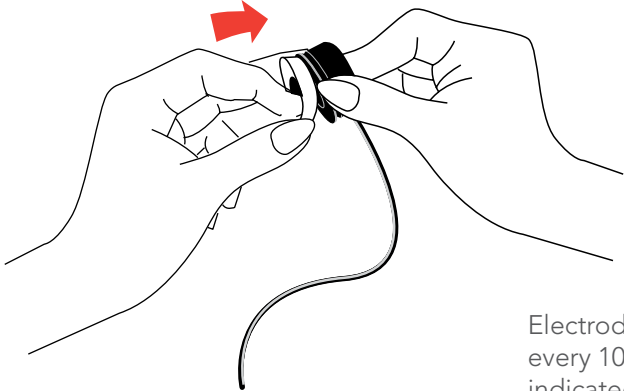


Signal module and electrodes



Signal modules
Fit each of the signal modules to the patient cable with the corresponding marking.

Ensure that the patient cable is properly connected to the signal module with a tight fit and not being loose.



Electrodes should be replaced after every 10 measurements, which is indicated by a diode on the front of the patient module.

All 10 electrodes in the system must be changed at the same time. The acknowledgement button on the control panel of the patient module should then be pressed in.

⚠ **All 10 electrodes are replaced at the same time.**

The system's 10 Quickels electrodes must be replaced at the same time; then press the acknowledgement button after changing them.



How to use Decapus® III

1

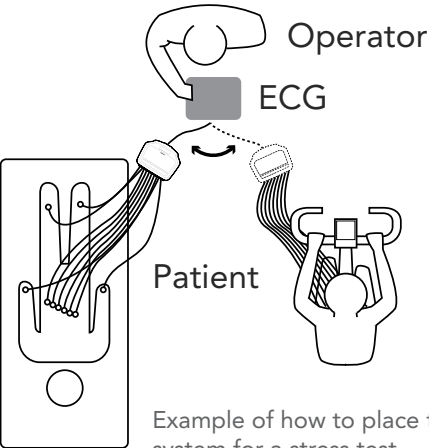
PERFORMING SAFETY CHECKS

Check that there is no visible sign of damage on the system. Ensure that the safety requirements in the section *Important safety information* have been complied with.

Ensure that the system is connected to ECG equipment according to the section *Important safety information*.



Decapus® III must not be used for ECG recordings for longer than 40 minutes at a time.

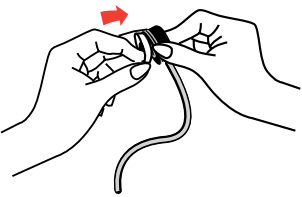


Example of how to place the system for a stress test.

2

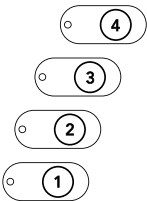
PREPARING THE SYSTEM

Check that there are Quickels electrodes on all signal modules.



Adjust the position of the arm so that the patient module comes close to the patient.

The vacuum pump starts when you select the appropriate vacuum level with buttons 1-4 on the patient module.

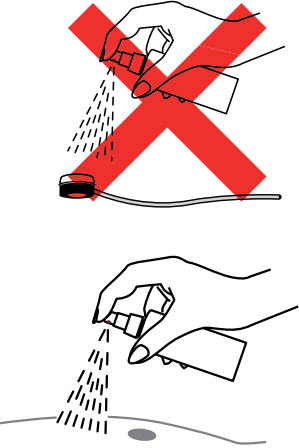


For good ECG recording, the patient must be able to lie completely relaxed. Arms and legs must not touch any other objects in the room. Reduce the antenna effect by gathering the cables together.

3

PERFORMING MEASUREMENTS

Moisten the area thoroughly where the electrodes are to be attached, using a dressing with salt solution, or spray on a salt solution. Never spray the Quickels electrodes or signal modules directly. The filter would become full of fluid and salt bridges would be created.



Fasten the Quickels electrodes to the patient by gently pressing the top of the signal module (this opens the valve in the signal module, creating negative pressure).



If necessary, adjust the pressure level to reduce the risk of suction marks.



How to use Decapus® III contd.

4

AFTER MEASUREMENT



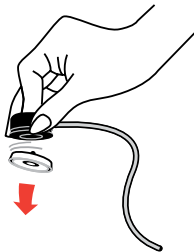
Press the on/off button on the control panel to release the Quickels electrodes from the patient. If no button on the patient module is pressed for an hour, the vacuum pumps shuts off automatically.

If the system is equipped with a battery, it must always be connected to the mains when not in use, to recharge the battery.



When the electrode change lamp lights, replace the Quickels electrodes and acknowledge this by pressing the button.

If you choose to use Quickels electrodes for more than one patient, wipe them off with a cloth moistened with 70% alcohol between uses. Replace the Quickels electrodes at least once per day to maintain signal quality.



If needed, disinfect the signal modules with 70% alcohol or surface disinfectant. Wipe dry with a cloth afterwards.



Only salt solution should be used.

Otherwise there is a risk of skin damage.



Change electrodes regularly.

To ensure the apparatus is not damaged, the Quickels electrodes must be changed when the filter is full or after every 10 patients.



Do not pull the cables.

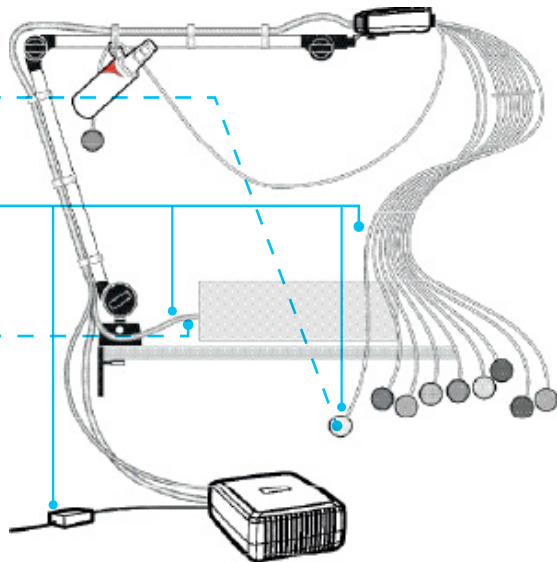
They may break.

Service and maintenance

DAILY PREVENTIVE MAINTENANCE

Inspect the condition of the equipment daily and check:

- Check that the Quickels electrodes have been changed and the filters are not full.
- Check signal modules, patient cables, recorder cable and power supply for visible damage (e.g. worn insulation, defective contacts etc.).
- Replace cables if needed.
- Check that the recorder cable is properly connected to the ECG printer.
- Check that the arm and table fixation are properly fixed.
- Check for any cracks or defects that might make it possible to get into the internal electronics areas unintentionally.



CLEANING

Cleaning should be done as needed or in accordance with a schedule.

Disconnect the system from the mains supply by withdrawing the plug from the mains socket.

- Clean the plastic casings of the system and the patient cables with a cloth moistened with a solution of mild detergent and water.
- Thoroughly wipe the unit dry after cleaning with a clean soft cloth or paper towel.
- If needed, disinfect with a cloth moistened with surface disinfectant (disinfecting agent with ethanol (70% - 80%), propanol (70% - 80%) or aldehyde (2% - 4%)).
- Wipe dry afterwards.



Authorisation to perform service and maintenance

Servicing may only be performed by qualified personnel.



Caution

Decapus® III must not be sterilised or immersed in fluids. Neither should fluids be allowed to be sucked through the system.



Annual maintenance

If the hospital or institution does not have an acceptable schedule for cleaning and inspection of this apparatus, this may result in failure of the apparatus and health risks. Annual maintenance must be performed by qualified personnel.

EU Declaration of Conformity

We,

QUICKELS SYSTEMS AB

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SE-114 19 STOCKHOLM
SWEDEN

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declare that the product below conform to applicable requirements in the Swedish Medical Products Agency's regulations on technical medical products (LVFS 2003:11). The products thereby also conform to the requirements of Directive 93/42/EEC, MDD (Medical Device Directive) and conform to the standards for electromedical equipment safety: IEC 60 601-1:1988 and A1 + A2, IEC 60 601-2-25:1993 and A1. Also with Biocompatibility: In vitro cytotoxicity ISO 10993-5, Skin irritation ISO 10993-10, Allergy ISO 10993-10.

The product also fulfil the applicable requirements of the European Parliament and Council's Directives 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHSII), and 2012/19/EU on waste comprising or containing electrical or electronic products (WEEE).

Type	Vacuum application of ECG-electrodes
Product class	MDD Class IIa
GMDN	36369
Name	Decapus® III (Catalogue number QN D3)

Stockholm, February 2nd 2015
Quickels Systems AB

Krister Sjöberg
Managing Director

Statement

Manufacturer's liability

Quickels Systems AB is only liable for safety and performance if:

- Assembly, additions, adjustments, changes or repairs are only performed by persons who are authorised by Quickels Systems AB.
- The Decapus® III apparatus is used in accordance with the instructions.

The customer's liability

The user of this product is responsible for ensuring that acceptable maintenance routines are introduced. Failure to do this may lead to unnecessary faults and potential health risks.

Apparatus identification

Equipment from Quickels Systems AB is identified with an item and serial number on the back of the apparatus. Care should be taken not to damage the serial number labels.

Copyright and brand information

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Guarantee

Your guarantee from Quickels Systems AB

Quickels Systems AB (hereinafter called “Quickels”) hereby guarantees Quickels products (hereinafter called "products") from defects in materials and manufacture with normal use, service and maintenance during the guarantee period for such products from Quickels or authorised dealers of Quickels representatives. Normal use, service and maintenance means operation and care in accordance with the respective instructions and/or directions. This guarantee does not cover damage to products caused by one or more of the following circumstances:

- a. Damage during carriage.
- b. Parts and/or accessories for the products that do not come from or are not approved by Quickels.
- c. Incorrect handling, incorrect use, carelessness and failure to follow instructions and/or directions.
- d. Accident, a disaster that affects the products.
- e. Changes or modifications to products without the consent of Quickels.
- f. Other circumstances that reasonable lie outside Quickels' control or that do not arise during normal operation.

COMPENSATION UNDER THIS GUARANTEE IS LIMITED TO:
1. REPAIR OR REPLACEMENT WITHOUT CHARGE FOR WORK OR MATERIALS,
2. PRODUCTS THAT ARE CONFIRMED TO BE DEFECTIVE AFTER INSPECTION BY QUICKELS.

This compensation applies on the condition that Quickels is notified of the stated defects during the guarantee period and as soon as these have been discovered. Quickels' obligations under this guarantee are also on condition that the buyer of the products accepts (i) all costs of return carriage to Quickels' main premises or another place specifically designated by Quickels or an authorised dealer of representative of Quickels and (ii) the entire risk of loss during transport. It is expressly agreed that Quickels' liability is limited and that Quickels does not act as an insurer. In accepting and purchasing a product, the buyer confirms and agrees that Quickels is not responsible for loss or damage directly or indirectly caused by any event or consequence of this with regard to the products. If Quickels should become liable to anyone under any rule of law (other than the express guarantee stated here) for loss or damage, Quickels' liability is limited to the lower of the actual loss or damage or the original purchase price of the product when sold.



Technical data

GENERAL	Safety	MDD Classification Class IIa IEC 60 601-1 class I, type CF, with defibrillation protection.
ENVIRONMEN- TAL REQUIREMENTS	Ambient temperature	In operation: +10 to + 40°C. In storage -10 to +40°C
	Relative humidity	25-95%, no condensation
	Air pressure	700-1060 mbar
PUMP MODULE	Power consumption Negative pressure Airflow Measurement Weight	Max 35 W 0-600 mbar 7.5 litres/min at the patient end H 100 mm, L 240 mm, W 180 mm 1.1 kg
PATIENT MODULE	Defibrillation protection Rapid negative pressure selection Measurement Weight	10 kOhm with surge protection 140 V 120, 200, 240, 280 mbar H 30 mm, L 110 mm, W 135 mm 1.1 kg
POWER SUPPLY	Model Mains voltage and frequency Current rating AC input Classification	XP Power Model: AFM 45US15 100-240 V, 50 or 60 Hz Max 1.1 A IEC-320-C14 Class I, according to IEC 60 601-1
CABLES	Printer cable Control cable Vacuum hose	2.7 m, DA-15 plug/socket 2.8 m, DE-9 plug/socket 2.8 m
PATIENT CABLE	Length Tensile resistance	Extremities: 1.2 m. Chest: 1.0 m Minimum 50 N
QUICKELS ELECTRODE	Material	Ag/AgCl sensor, fulfils recommendations of AAMI. Biocompatibility and toxicology studies in accordance with biocompatibility: In vitro cytotoxicity ISO 10993-5, Skin irritation ISO 10993-10 and Allergy ISO 10993-10.
BATTERY	Battery pack (option) Manufacturer Lifetime Charging	Rechargeable Li-ion-battery 11.1 V, capacity 2.6 Ah Quickels Systems AB, Catalogue number: QN D103 Approximately 400 charging cycles Charging time approximately 2 hours
SIGNAL IN/OUT PUMP MODULE	Control cable input USB input DC input	DE-9 socket/plug USB B socket/plug DC plug
STAND	Length of folding arm Table fixation	570/650 mm Clamp measurement 10-130 mm
SERVICE APPLICATION	Software	Compatible with Windows XP, 7 and 8

Changes may occur without prior notice.



Technical data contd.

OPERATOR PROFILE	Clinics with ECG training, health centre workers, hospitals or private care centres. Must understand the language used in the user manual.
INTENDED USE	Record ECG signals from the patient and transfer these to an ECG printer, for the purpose of discovering/checking various types of deviant heart rhythms. The system is intended for recording rest and stress ECG, although not for longer than 40 minutes.
NORMAL USE	Normal use means about 25 resting ECGs per day (5 min per round).
PATIENT GROUP	From 5 years. Not intended for patients with open wounds or other major skin damage in the regions where Quickels electrodes are applied.
SYSTEM LIFETIME	10 years.
OTHER	Materials in the Quickels electrodes and signal modules do not contain latex. The material in the patient module and pump module covers is made of ABS/PC plastic.

Changes may occur without prior notice.