

Operating manual

InnuPure C16 *touch*

Extraction System



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1 Basic information

1.1 User manual notes

Contents

The InnuPure C16 *touch* is intended for operation by qualified specialist personnel observing this user manual.

The user manual informs about the design and operation of the InnuPure C16 *touch* and provides the personnel familiar with the isolation and purification of nucleic acid with the necessary expertise for the safe handling of the equipment and its components. The user manual further includes notes on the maintenance and service of the equipment and potential causes and remedies of any faults.

Conventions

Instructions for actions, which occur in chronological order, are numbered and combined in action units.

Warnings are indicated by warning triangles and a signal words. The type and source of the danger are stated together with notes on preventing the danger. The meaning of the signal words used is explained in the following.

The elements of the control program are indicated as follows:

- Small caps indicate program terms (e.g. menu FILE).
- Arrows separate menu items (e.g. PROJECT ▶ OPEN).

Symbols and signal words

The user manual uses the following symbols and signal words to indicate hazards or instructions. The warnings are always placed before an action.



WARNING

Indicates a potentially hazardous situation, which might cause death or very serious injuries (deformities).



CAUTION

Indicates a potentially hazardous situation, which might cause light or minor injuries.



ATTENTION

Provides information on potential material or environmental damage.

1.2 Intended use

The InnuPure C16 *touch* is a flexible and efficient extraction system for the fully automated isolation and purification of nucleic acid in chemical and biological laboratories. The device is intended for general laboratory use.

The InnuPure C16 *touch* including its original accessories must only be used for the applications described in this instruction manual. The manufacturer does not accept liability for any other use, including that of any individual modules or components.

1.3 Warranty and liability

The warranty duration and liability comply with the legal requirements and the provisions in the general terms and conditions of Analytik Jena.

Deviations from the intended use described in this user manual result in limitations of warranty and liability in the event of a damage. Damage to wearing parts is not included in the warranty.

Warranty and liability claims are excluded for personal injury and property damage due to one or several of the following causes:

- use of the InnuPure C16 *touch* other than intended
- improper commissioning, operation and service of the InnuPure C16 *touch*
- modifications of the equipment without prior consultation with Analytik Jena
- operation of the device with faulty safety equipment or improperly fitted safety and protection equipment
- inadequate monitoring of the equipment components subject to wear
- use of other than original spare parts, wearing parts or consumables
- improper repairs
- faults due to the non-observance of this user manual

2 Safety instructions

2.1 General notes

For your own safety and to ensure error-free operation of the InnuPure C16 touch, please read this chapter carefully before using the appliance.

Observe all safety notes listed in this user manual and all messages and notes displayed by the IPExtract control program on the screen.

You must also comply with the safety instructions on the labels as well as the information on handling, storage and disposal of the kits. Only use consumables and accessories recommended for use with the InnuPure C16 touch and corresponding kits.

Besides the safety instructions in this user manual and the local safety regulations that apply to the operation of the device, the general applicable regulations regarding accident prevention, occupational health and safety and environmental protection have to be observed and complied with.

References to potential dangers do not replace the work protection regulations that must be observed.

2.2 Safety markings and notice signs on the InnuPure C16 touch

There are safety and notice symbols attached to the InnuPure C16 touch whose content must always be observed.

Damaged or missing safety and notice symbols can cause incorrect actions leading to personal injury or material damage! Symbol labels must not be removed or wetted with methanol! Damaged symbol labels must be replaced immediately!



Fig. 1 Warnings and notice symbols at the front and rear side

Number	Warning / notice symbol	Meaning
1		Biohazard
2		Observe the operating manual
3		Reaching inside the device prohibited during operation Danger due to crushing by moving parts
4		Warning against electric voltage Before opening disconnect the mains plug
5		Before opening the device always disconnect the mains plug
6		China only: The device contains substances subject to regulation. Analytik Jena guarantees that the substances will not leak within the next 25 years and, therefore, will not cause any environmental danger or health risk within this period if the device is used as intended.

2.3 Technical condition

The InnuPure C16 touch corresponds in its design and construction with the current state-of-the-art technology. Unauthorized modifications or changes, especially such that affect the safety of the staff and the environment, are generally not allowed.

Please observe the following:

- The operator must only operate the device in a sound and operationally safe condition. The technical condition must always comply with the legal requirements and regulations.
- Prior to every use, the device must be checked for damage and sound condition.
- Any changes in the device affecting its safety must be reported by the operating personnel to the operator without delay.

2.4 Requirements for the operating personnel

The InnuPure C16 touch must only be commissioned, operated and serviced by trained personnel instructed in technical safety.

The instruction also includes imparting the contents of this user manual. Furthermore, the user manual must be accessible to the operating and service personnel at any time!

2.5 Safety instructions, transport and installation

Only transport the device in its original packaging! Ensure that all transport protections have been fitted and the device is completely empty, cleaned and decontaminated.

The InnuPure C16 touch may only be installed by the service personnel of Analytik Jena or by persons authorized by Analytik Jena.

To prevent health damage the following must be observed when moving the device in the laboratory (lifting and carrying):

- For reasons of safety 2 persons are required to transport the device and must position themselves on both sides of the equipment.
- Since the device does not have handles, grip the device firmly with both hands at the lower end, lifting it simultaneously. Make sure the door is closed. Do not hold onto the door area or the plexiglas front.
- The guide values and statutory limits for lifting and carrying loads without auxiliary equipment must be observed and adhered to.

2.6 Safety instructions - operation

2.6.1 General

- The device may only be operated if all protective equipment (front doors) are in place, properly installed and fully operational.
- Free access to the device switch on the back of the enclosure must be ensured during operation.
- During operation and after aborting an extraction protocol, the operator must not reach with his hands into the device chamber. There is a risk of crushing due to the motor-driven carriage.
- Careless handling during preparation of the sample tray may lead to crushing of fingers when the clamps for locking of the reagent plates and strips are pushed down.
- The ventilation equipment on the device must be in good working condition. Covered ventilation grilles or slits etc. may cause the device to break down or may cause damage to it.
- Do not introduce any objects into the device and prevent liquids from entering the device through openings or gaps.
- The operating system of the tablet and the IPExtract program form a closed system. There is no active antivirus protection. The user is responsible for data safety of inserted USB Memory Sticks.

2.6.2 Safety instructions relating to ambient conditions

- Working with explosive substances in this device or operating the device in an explosive environment is prohibited.
- Smoking or open flames in the operating room of the InnuPure C16 touch are prohibited! Observe the flammable ingredients (ethanol-containing buffers) of the kits.
- Keep all combustible materials away from the device.

2.6.3 Safety instructions - electrical equipment

- Work on the electrical components of the InnuPure C16 touch may only be performed by a qualified electrical technician according to applicable electro-technical regulations. Lethal voltages may occur in the device! Contact with live components may cause death, serious injury or painful electrical shock.
- The mains plug must be connected to a proper CEE power socket to ensure that the device meets protection class I (ground connector). The device may only be connected to power sources whose nominal voltage is the same as that on the rating plate of the equipment. The protective effect must not be invalidated by the use of an extension line without protective conductor.
- Before opening the device, it must be switched off at the device switch and the mains connector must be disconnected from the mains outlet! Any work on the electronics (behind the device enclosure) may only be carried out by the customer service of Analytik Jena and specially authorized technicians.
- Do not short circuit the device fuses and only use fuses in accordance with the specifications in the technical data.

2.6.4 Handling hazardous substances

Even with intended use, there is a risk of health damage when handling hazardous substances. The operator is solely responsible for the compliance with all safety requirements to protect individuals and property when handling radioactive, infectious, toxic, caustic, flammable and other hazardous substances.

- Control the handling of hazardous substances in accordance with the safety category of the lab, the details in the manufacturer safety data sheets and additional national and international regulations (WHO, "Laboratory Biosafety Manual").
- Wear personal protective equipment when working on the device.
- Avoid overfilling of consumables or escaping of residue liquids. Biochemical substances may contaminate the device or the environment of the device and, subsequently, infect the user.
- Observe all notices on cleaning and decontamination of the device (→ Cleaning the InnuPure C16 touch p. 55). Before using a cleaning or decontamination procedure other than that described, the user is required to check with Analytik Jena that the intended procedure will not damage the device.

2.6.5 Chemical resistance of the device

Aggressive substances may damage the device. Although the materials used are resistant to most of the commonly used substances, material damage from aggressive substances cannot be precluded.

- Before using any aggressive substances (e.g. acids, bases, organic solutions), check whether the materials in direct contact with the substances are resistant to them.
- Only use substances compatible with the materials listed.
- If in doubt contact Analytik Jena.

Overview 1 Components and materials in direct contact with the sample

Components	Material
Filter tips	PP
Piston seal	Aluminum, stainless steel, PTFE, rubber (NBR 70). The pistons are not contaminated with sample if the filter tips are used.
Reagent cups	PP or PTFE

The above-mentioned components are not resistant to the following substances:

- hydrogen fluoride
(HF/hydrofluoric acid)
- highly concentrated acids
- cleaning powder
- paint thinner
- naphtha
- gasoline
- acetone
- cleaning spray
- ozone
- salt-containing detergents
(NaOCl/sodium hypochlorite)

2.7 Behavior during emergencies

If there is no immediate danger of injury, immediately switch the device switch of the InnuPure C16 touch to the "0" position in the event of dangerous situations or accidents and/or disconnect the mains plug from the mains outlet!

2.8 Safety instructions: service and repair

The customer service department of Analytik Jena or its authorized and trained specialist personnel usually service the InnuPure C16 touch.

Independent servicing can maladjust or damage the device. The operator may generally only carry out the tasks listed in chapter "Maintenance and care" p. 55 ff.

3 Function and setup

3.1 Principle of operation

The InnuPure C16 *touch* is a flexible and efficient extraction system for the fully automated isolation and purification of nucleic acid. The system, developed and produced in Germany, has been designed for low sample throughput. A large selection of different source materials can be used. The system combines a unique liquid handling technology with an extremely fast walk-away principle.

The InnuPure C16 *touch* is equipped with pre-installed extraction protocols to prevent time-consuming programming. The high degree of flexibility offered by the InnuPure C16 *touch* enables the parallel isolation of DNA and RNA from up to 16 samples. The work-intensive process of sample lysis, which so far mostly had to be performed separately, is now part of the automatic extraction process (dependent on the source material).

The nucleic acids to be isolated adsorb at surface-functionalized magnetic or paramagnetic particles. The necessary extraction chemicals are added manually as necessary and enable the purification of ultra-pure nucleic acids with excellent yields.

The ready-to-use extraction kits simplify the day-to-day laboratory work routine. All kits come in two variants: with reagent strips for individual extractions and with reagent plates for up to 8 samples. Preparation of the InnuPure C16 *touch* is done in one step: populating the sample tray. This reduces the number of preparatory steps.

The extraction principle effectively prevents cross contamination, a problem often occurring in vacuum-based extraction methods. The isolated nucleic acids can then be used immediately for further downstream applications.

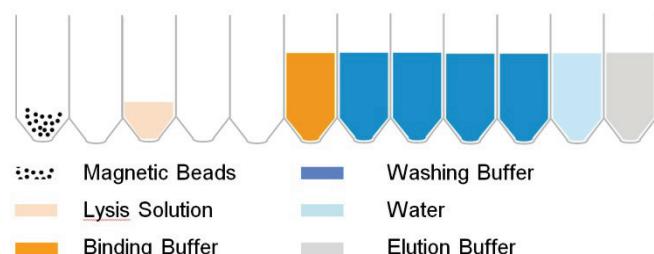
The following specially optimized extraction kits are available for the InnuPure C16 *touch*:

- isolation of genomic DNA
- viral or bacterial nucleic acids
- processing of forensic samples
- processing of food samples
- processing of plant samples
- PME extraction of cell-free DNA

Depending on the application, the extractions take between 21 and 100 minutes.

3.2 Isolation and purification of nucleic acids with magnetic beads kits

Pre-filled reagent structure



Reagent structure

The reagent strips or reagent plates are completely pre-filled and contain, in addition to the magnetic particles, all reagents necessary for the extraction process for the binding, washing and elution of nucleic acids.

After an extraction protocol has started, the InnuPure C16 touch takes the tips provided in the corresponding row in the tip block of the sample tray.

External lysis



Lysis

Depending on the type of source material, the lysis is processed either inside the device (internal) or must be performed manually outside the device (external).

Internal lysis



The lysis step for the corresponding source material is described in detail in the manual for the respective extraction kit.

Mixing lysate and magnetic particles



Binding

With the aid of the binding buffer, the nucleic acids are bound to the magnetic particles (MAG suspension).

Transferring the binding buffer to the sample



Depending on the protocol sequence with external or internal lysis, the binding of the nucleic acids takes place in different positions of the reagent structure.

Mixing binding buffer and sample



In case of external lysis, the mix of lysed sample and MAG suspension is first homogenized by pipetting on and off. The binding buffer is then transferred to the sample.

Collecting magnetic particles and transferring the supernatant



During the next step, the magnetic unit is moved to the floor of the work cavity. The magnetic particles with the bound nucleic acids are held by the magnetic field on the floor of the work cavity.

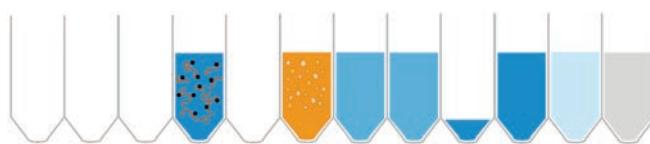
Depending on the selected protocol, the supernatant binding buffer is transferred by pipetting to the initial holding position and/or to cavity 2.

Transferring the washing buffer**Washing****Collecting magnetic particles and transferring the supernatant****Washing of the nucleic acids**

The magnetic particles remain in the work cavity. The washing buffers are transferred there. By pipetting different washing buffers on and off the nucleic acids are washed.

The number of washing steps and the volume and type of washing buffers depend on the type of the source material used. In addition, the buffers differ in the case of DNA or RNA extraction.

Between each washing step, the magnetic particles are collected with the bound nucleic acids from the cavity floor. The corresponding washing buffer supernatant is pipetted off and returned to their original holding position.

Aspirate washing solution from the 1st work cavity**Dispense the work solution in the 4th work cavity****Washing the tips**

To prevent the carry-over of washing solution residue, the tips used are flushed between specific washing steps.

Change of the work cavity

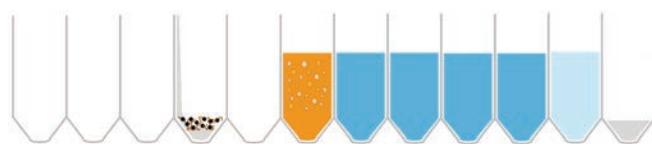
Prior to the last washing step, the entire washing solution is aspirated from the 1st work cavity and transferred to the 4th work cavity.

The quality of the already washed nucleic acids is significantly improved by the transfer into a clean work cavity. Any lysis residue at the walls is retained in the "dirty" cavity and only the already washed nucleic acids bound to the magnetic particles are transferred on.

Ethanol removal

The removal of ethanol residue at the magnetic particles and within the cavity takes place via a drying step. In this step, a heating is activated at the cavity floor, causing ethanol residues to evaporate.

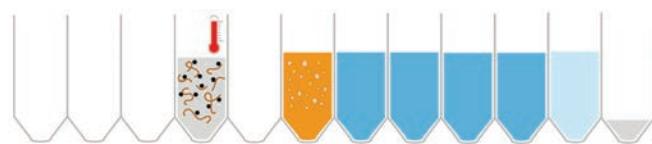
Transferring elution buffer in the work cavity



Elution

The elution volume can be adjusted in the range of 20 – 500 µl, depending on the extraction protocol, and is defined at the start of the protocol.

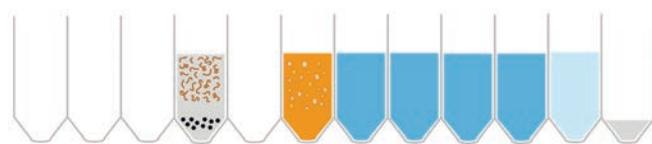
Warming the elution buffer



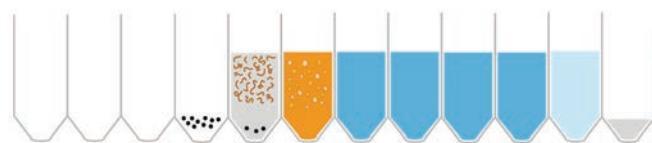
The correspondingly selected volume is aspirated from the holding position and transferred to the magnetic particles in the work cavity.

The elution process represents the separating of the nucleic acids from the magnetic particles. This is improved by heating the elution buffer and mixing well through pipetting on and off.

Elution and collection of the magnetic particles

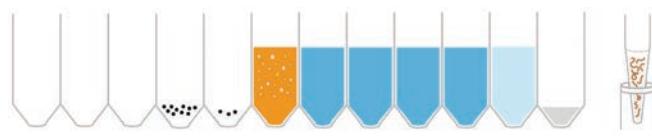


Changing the work cavity



To be able to transfer the eluates free from magnetic particles into the elution tubes, the eluate is transferred once again into a new work cavity. There, the remaining magnetic particles are finally collected at the cavity floor.

Transferring the eluate



Eluate transfer

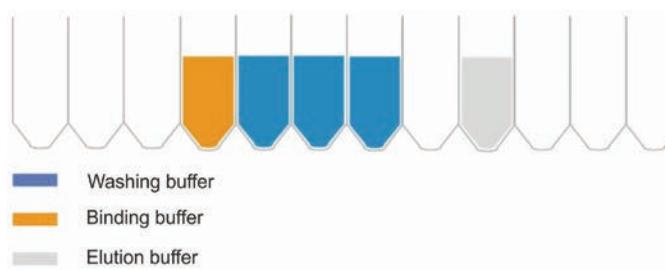
The nucleic acids are now *extracted*, are transferred into the elution tube and are available for further downstream applications.

Note:

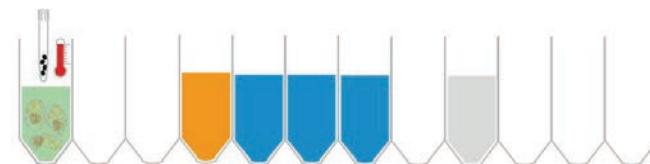
Filling levels and filling colors are only shown for illustration and do not match the actual filling levels and colors of the kit reagents.

3.3 Isolation and purification of nucleic acids with SmartExtraction kits

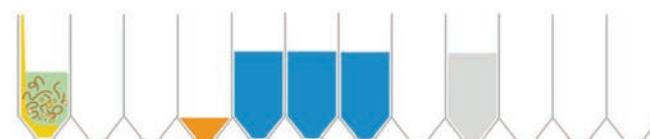
SmartExtraction completely changes the process for isolation and purification of nucleic acids by eliminating the need for a number of work steps, extra materials and specialized equipment. SmartExtraction kits combine the patented extraction chemistry (DC technology) by Analytik Jena with an intelligent pipette tip. The uniquely modified "Smart Modified Surface" inside the 1 mL filter tip selectively binds the desired nucleic acids, which are then efficiently eluted. In addition to a variety of different starting materials, SmartExtraction is particularly suited to samples with high starting volumes or high application quantities. All SmartExtraction Kits use special 1 mL filter tips and corresponding SmartExtraction protocols in the InnuPure C16 touch.

Pre-filled reagent structure**Reagent structure**

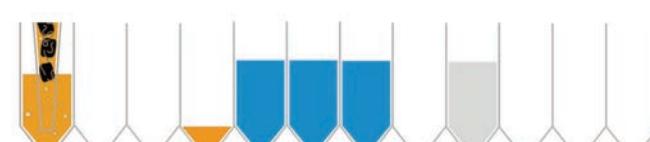
The reagent strips or reagent plates of the SmartExtraction kits are completely pre-filled and contain all reagents necessary for the extraction process for the binding, washing and elution of nucleic acids.

Lysis**Lysis**

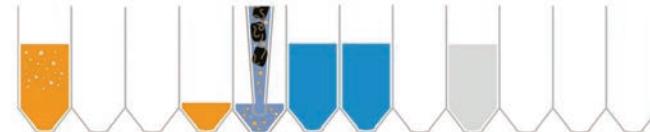
Depending on the type of source material, the lysis is processed either inside the device (internal) or must be performed manually outside the device (external). The nucleic acids are released from the cells during lysis.

Transferring the binding buffer to the sample**Transfer of the binding buffer**

After lysis, the binding buffer is transferred to the lysed samples.

Binding

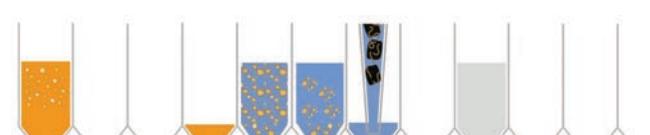
The binding buffer binds the nucleic acids to the modified surfaces inside the pipette tip.

Washing I**Washing of the nucleic acids**

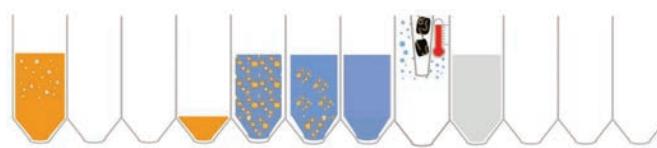
The nucleic acids bound in the pipette tip are now transferred to the respective washing buffers by changing the working position.

Washing II

By pipetting different washing buffers on and off the nucleic acids are washed.

Washing III

The number of washing steps and volume and type of washing buffer depend on the type of the source material used.

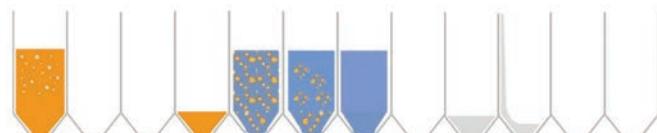


Ethanol removal

The removal of ethanol residues from the samples in the pipette tip is realized via a drying step. In this step, a heating is activated at the cavity floor, causing ethanol residues to evaporate.

As an alternative the ethanol is dissolved in the rinsing liquid by a short mixing step and is so removed.

Transferring elution buffer in the work cavity

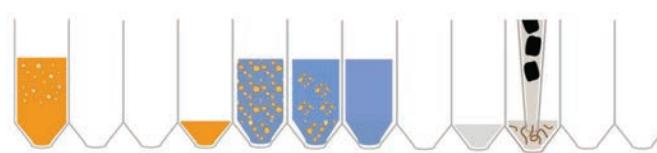


Elution

The elution volume can be adjusted in the range of 150 – 500 µl, depending on the extraction protocol, and is defined at the start of the protocol.

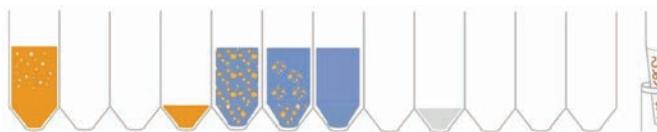
The correspondingly selected volume is removed from the holding position and transferred to the elution position.

Elution



During the elution process the nucleic acids are separated from the modified surfaces inside the pipette tip. This is improved by heating the elution buffer and mixing well through pipetting on and off.

Transferring the eluate



Eluate transfer

The nucleic acids are now *extracted*, are transferred into the elution tube and are available for further downstream applications.



Elution buffer with extracted nucleic acids

Note:

Filling levels and filling colors are only shown for illustration and do not match the actual filling levels and colors of the kit reagents.

3.4 Design of the InnuPure C16 touch

The InnuPure C16 *touch* is a stand-alone device. The device is equipped with a combined magnet/heating unit. This allows for the nucleic acids that bind to magnetic and paramagnetic particles to be effectively collected at the cavity floor while the washing solution, for example, evaporates at temperatures of up to 70 °C. The device is operated and controlled via a 10" tablet attached to the front and the IPExtract program. Sample processing follows pre-installed protocols tailored to the extraction kits. The kits include all reagents necessary for extraction, permitting extraction to run fully automated.



Fig. 2 Front view of the InnuPure C16 touch

- | | |
|---|--|
| 1 Tablet with IPExtract control program | 3 Upper front door, manual opening for cleaning |
| 2 LED status indication | 4 Lower front door, automatic opening for insertion of the sample tray |

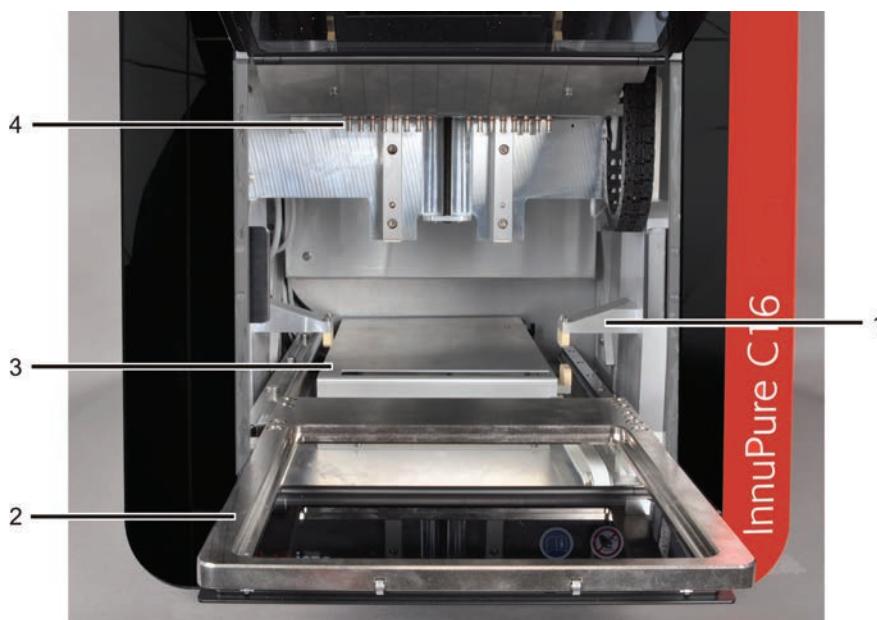


Fig. 3 Device view with open front door

- | | |
|------------------------------|---|
| 1 Sample tray counter-holder | 3 Protection cover of the combined magnet/heating element |
| 2 Drawer | 4 Cones tip attachment |

During operation, the front door of the InnuPure C16 touch is closed. The device is equipped with an LED for status control. Depending on the operating status, the LED illuminates green or red.

All pre-manufactured reagent packs, the filter tips and the elution tubes required for the extraction process are placed onto the sample tray. Depending on the number of samples, reagent plates (deep well plates) with eight sample positions or reagent strips for individual samples will be used. Thus, within a single extraction protocol, individual samples in reagent strips or up to 16 samples in two reagent plates can be processed. The optionally available adapter is required to accept the reagent strips. Reagent plates are placed directly onto the sample tray. For populating the sample tray with plates and strips, the tray must be placed into the priming station supplied.

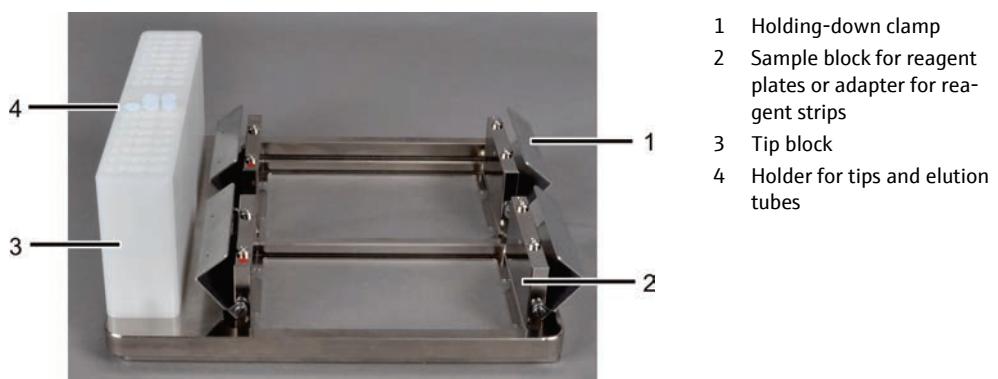


Fig. 4 Sample tray



Fig. 5 Priming station

The loaded sample tray is placed on the drawer and moved by the software to the correct position inside the InnuPure C16 touch. The prefilled and sealed kits must be pierced manually. During the extraction process, used tips are automatically deposited in different positions of the strips or plates.

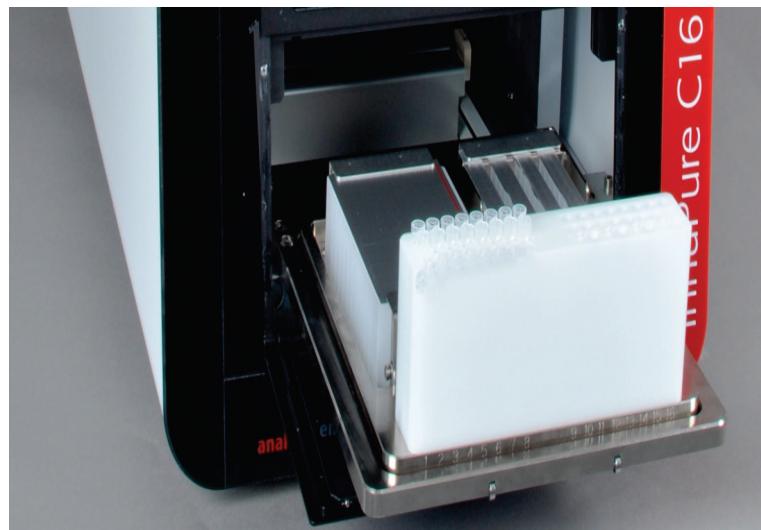


Fig. 6 Front view with inserted sample tray

The InnuPure C16 touch is controlled via a large 10" touchscreen and the IPextract program. The integrated computer based on Windows 8.1 enables the use of typical Windows functions with a clearly structured menu interface. Thus, the entire system becomes a stand-alone device.

IPextract contains pre-installed extraction and decontamination protocols. Thus, the desired elution volume is automatically held ready and the eluate is afterwards automatically transferred into the elution tubes. Video sequences and the remaining time are displayed to monitor the ongoing extraction. The user can thus follow every routine clearly and continually. Data exchange with an external computer is possible via a USB Memory Stick. For processing of large sample quantities, the system allows for USB connection of a barcode reader to read sample information. Prepared sample layouts can be imported and exported via the USB interface.

4 Installation and commissioning

4.1 Installation conditions

Ambient conditions	For requirements with regard to the ambient conditions at the installation location, refer to "Technical data" p. 66. If required, make sure that the room is temperature-controlled.
Requirements with regard to the installation location	<p>The installation location of the InnuPure C16 touch must meet the following requirements:</p> <ul style="list-style-type: none">■ Free from caustic vapors in close proximity of the device Connections and assemblies of the device may corrode.■ Free from draft, do not install the device close to windows or doors■ Away from electromagnetic sources of interference■ No direct sunlight and away from radiant heaters■ The front door and air vents must not be obstructed by other equipment or furnishings■ Keep a safety distance of at least 5 cm from the rear of the device to other equipment or walls

4.1.1 Energy supply



WARNING

The InnuPure C16 touch must only be connected to a properly grounded mains outlet in accordance with the voltage specifications on the rating plate!

The InnuPure C16 touch is operated on single-phase alternating current grid. The installation of the electrical equipment of the laboratory must comply with the standard DIN VDE 0100. At the connection point an electrical current in accordance with the standard IEC 60038 edition 6.2 2002 (EN 60038:2011) must be available.

Only use the supplied power cord with protective conductor to connect the InnuPure C16 touch to the power supply. The protective effect must not be invalidated by the use of an extension line without protective conductor.

4.1.2 Space requirement

The space requirement results from the device dimensions:

Closed device (W x D x H)	400 mm x 560 mm x 600 mm
Device with open front door (W x D x H)	400 mm x 661 mm x 600 mm
Device with ejected tray holder (W x D x H)	400 mm x 728 mm x 600 mm
Sample tray (W x D x H)	204 mm x 210 x 91 mm
Priming station (W x D x H)	214 mm x 260 x 174 mm

For insertion of the sample tray, the lower front door opens automatically and software-controlled. The drawer is ejected at the front of the device. The device door must also be opened for cleaning and maintenance purposes and must therefore be added to the dimensions.

The ventilation slits at the rear of the device must remain unobstructed to ensure air circulation.

4.2 Connections and control elements

The mains connection, the fuse holder and the mains switch are located at the rear side of the InnuPure C16 touch.

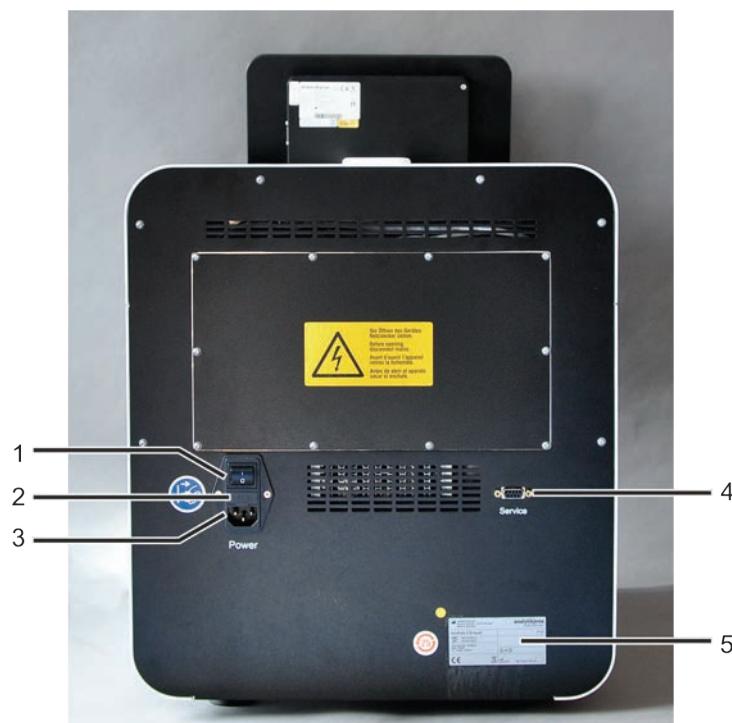


Fig. 7 Rear connections and switches on the InnuPure C16 touch

- | | |
|--------------------|-----------------------------------|
| 1 Mains switch | 4 RS 232 interface (service only) |
| 2 Fuse holder | 5 Rating plate |
| 3 Mains connection | |

The rating plate is also attached to the rear of the device. The rating plate shows among other information the serial number of the device and the electrical connection data:

- Manufacturer (with address)
- Device type and model
- Order number
- Serial number
- Electrical connection
- Waste disposal symbol
- Protection class of the housing

- Safety symbols
- Year of manufacture
- Device number

The 10" tablet with touchscreen is located at the front of the device. It is used to control the InnuPure C16 touch. The tablet is attached via a support bracket to the basic device and can be easily mounted and dismounted. The tablet features an interface with the basic device and two USB ports for data transfer via USB stick or barcode reader.

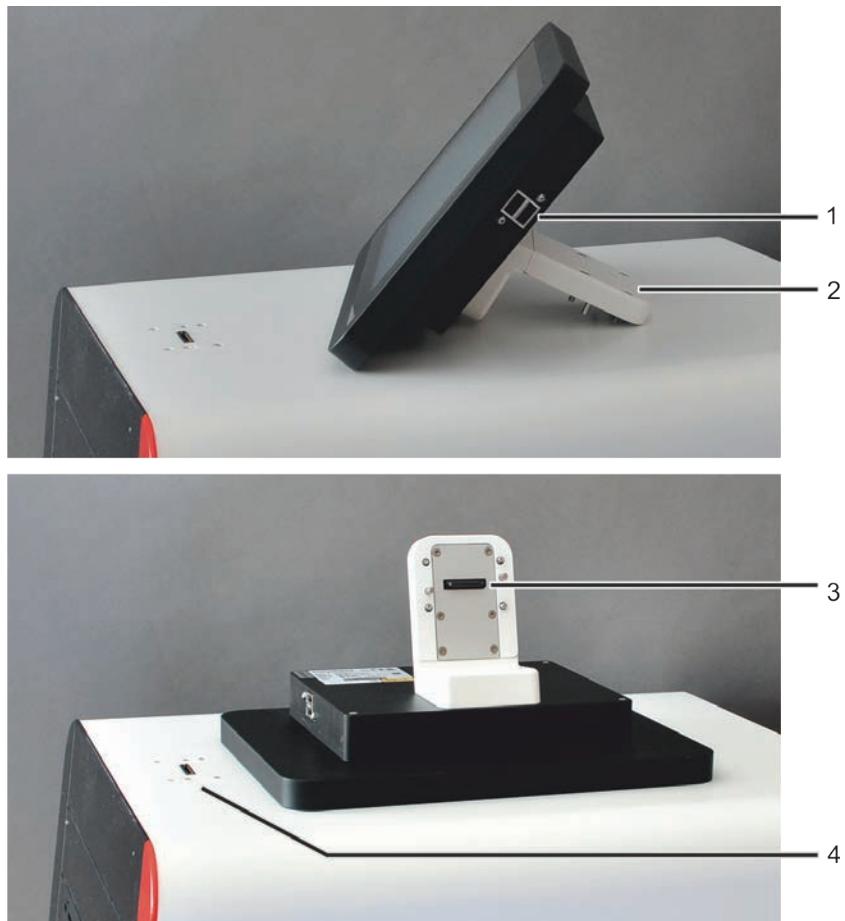


Fig. 8 Tablet with connections and operating elements

- | | |
|-------------------|-------------------------------|
| 1 USB ports | 3 Interface (on tablet) |
| 2 Support bracket | 4 Interface (on basic device) |

4.3 Connecting the InnuPure C16 touch and switching it on/off



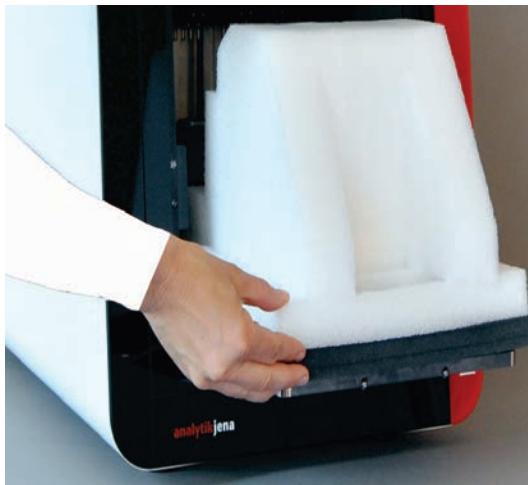
ATTENTION

Retain the transport packaging! Return transport for service must be in the original packaging. This alone prevents transport damage.

Connecting the device

1. Remove the InnuPure C16 touch from the packaging.

2. Check the device for completeness and soundness.



3. Open the front doors manually and pull out the drawer. Remove the transport lock from the device.
Store the transport lock for later use.

4. Slide back the drawer and close the front doors.



5. Using the support bracket, mount the tablet to the top of the InnuPure C16 touch.

- Before that, remove the protective cap from the interface on the device and store for later use.
- Place the tablet with support bracket on top of the device, inserting the two guide pins (see markings) into the round holes in the casing. Push the support bracket towards the device until it is flush with the casing.

6. Fasten the tablet using the four hexagon socket screws.

- ✓ The interface between tablet and basic device is now connected.

7. Connect the mains cable on the rear side of the device.

- ✓ The InnuPure C16 touch is now ready for operation.

Switching the device on

- Switch on the InnuPure C16 touch using the mains switch on the back of the device.
✓ The tablet and IPextract program start up automatically. The InnuPure C16 touch is now ready for operation. The status LED lights up green.

Status LED

The status LED is located on the front of the device above the front door (Fig. 2 p. 18).

LED signal	Device Status
Flashing green light	Ongoing initialization
Steady green light	The device is operational
Flashing green light	Ongoing application (tool or extraction)
Steady red light	A device error occurred
Flashing red light	The door was opened during operation.

Turning the device off

Do not switch off the InnuPure C16 touch during an extraction. Wait until all processes of the current extraction protocol have been completed.

1. If there is a loaded sample tray inside the device (after a recently completed extraction) confirm the message to eject the tray or eject the tray via the  button. Wait until the drawer with the sample tray is completely ejected.
2. Remove the sample tray. Remove used reagent structures and elution tubes. Clean the sample tray if required.
3. Put the empty sample tray back onto the tray holder of the InnuPure C16 touch or close the door automatically by confirming the corresponding message without inserting the sample tray.
4. Shut down the tablet via IPExtract: Tap on  on the HOME page. Confirm the prompt to shut down the system.
 - ✓ IPExtract is shut down. The operating system is shut down.
5. Switch off the InnuPure C16 touch using the mains switch on the back of the device.
 - ✓ The InnuPure C16 touch is now completely switched off.

**ATTENTION**

Risk of data loss! The tablet does not have its own battery. When you turn off the basic device using the mains switch, you switch off the tablet at the same time.

5 Sample preparation

5.1 Preparing buffers and solutions

All buffers and solutions are provided in pre-filled and sealed reaction tubes (reagent plates or strips) depending on the extraction routine and source material. The preparation of the sample tray is described in detail in each kit manual and in the sections "Preparing the sample tray for kits with magnetic beads" p. 26 and "Preparing the sample tray for SmartExtraction" p. 29.

In addition to the pre-filled and sealed reaction tubes, additional kits are available which must first be filled with the reagents according to the descriptions in the corresponding kit manuals. Follow the instructions described in the preparatory steps within the kit components of the kit manual.

5.2 Preparing the sample tray for kits with magnetic beads



CAUTION

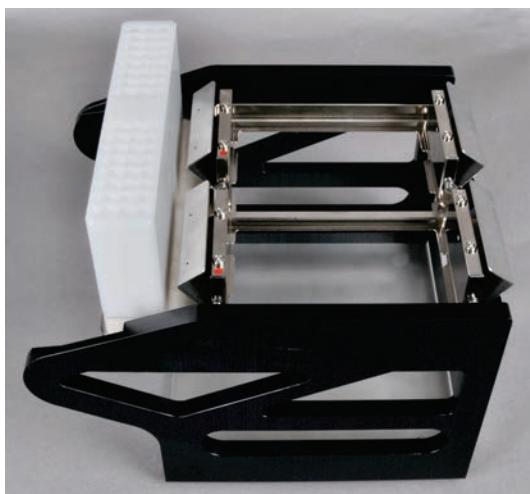
Nickel allergy! The sample tray is coated with nickel.



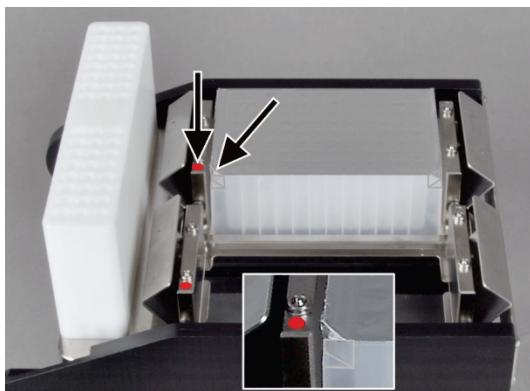
ATTENTION

Use the priming station to populate the sample tray. The filter tips are longer than the tip block and would impact against the tabletop!

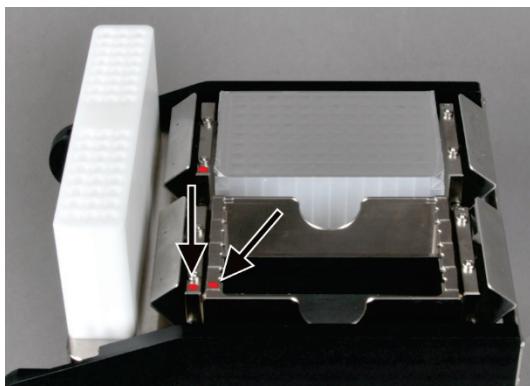
Prior to extraction, the sample tray must be loaded with the reagent plates and/or reagent strips of the kit used. In the example the sample tray is populated with a reagent plate and four reagent strips. When inserting the plates and strips always ensure the correct orientation!



1. Slide the sample tray into the priming station. Fold the holding-down clamps on the sample tray up.



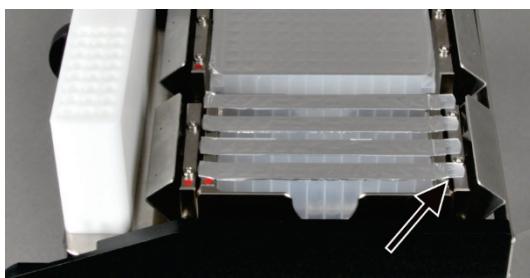
2. Insert the reagent plate into the sample block of the sample tray. The chamfered corners must point to the red dot on the holder.



3. Place the adapter for the reagent strips into the sample block. Here, too, the red marking on the adapter must point to the red point on the sample block.

Attention:

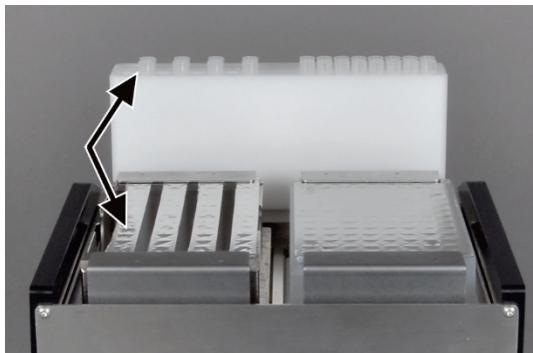
Load both sample blocks of the sample tray evenly (see below)!



4. Insert a maximum of 4 strips into the adapter. The long tab marked with the label "AJ" must point to the side opposite of the tip block.



5. Fold down the holding-down clamps to prevent the plates and strips from being pulled out of the sample block during the extraction process.



6. Place the filter tips into the two rows with the smaller drill holes. Place the elution tubes into the wider drill holes at the edge of the tip block.

Empty sample positions shall not be filled. With the strips, make sure that for every strip the tips and the elution tube are in the corresponding positions in the tip block (arrows in figure on the left)!

7. Attention

The elution tubes are selected depending on the eluate volume. Observe the description of the kit!

8. Open all cavities of the strips and plates with the piercing tools for 1 or 8 cavities.

Press the piercing tool down as far as it will go to make the tips pierce through the sealing film and create large openings.

9. Make sure that all cavities are opened completely (at least 7 mm diameter).



After extraction: Close the elution tubes using lids.



Notes on sample tray loading

For an extraction run, it is necessary to **always** populate both sample blocks of the sample tray to ensure that the tray is balanced and to allow for optimum movement of the tray inside the device to the necessary positions:

- If only extracting one sample, insert an adapter with an empty strip or an empty deep well plate into the second sample block of the sample tray.
- If processing more than one reagent strip during the extraction protocol, insert two adapters into the tray if possible and distribute the strips evenly between them.
- If processing all samples in one reagent plate, populate the second sample block with an empty deep well plate, available at Analytik Jena.

5.3 Preparing the sample tray for SmartExtraction



CAUTION

Nickel allergy! The sample tray is coated with nickel.



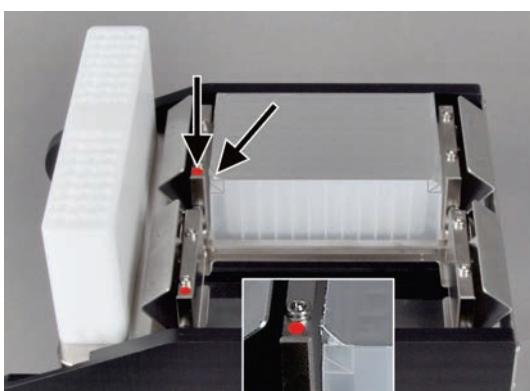
ATTENTION

Use the priming station to populate the sample tray. The filter tips are longer than the tip block and would impact against the tabletop!

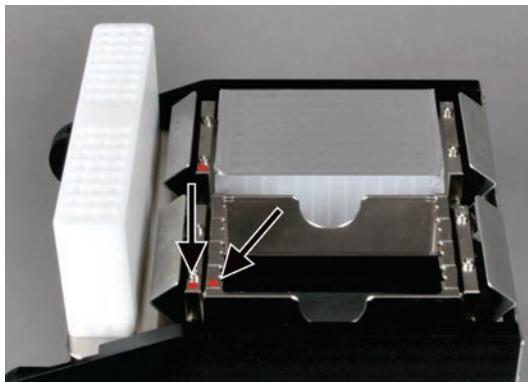
Prior to extraction, the sample tray must be loaded with the reagent plates and/or reagent strips of the kit used. In the example the sample tray is populated with a reagent plate and four reagent strips. When inserting the plates and strips always ensure the correct orientation!



1. Slide the sample tray into the priming station. Fold the holding-down clamps on the sample tray up.



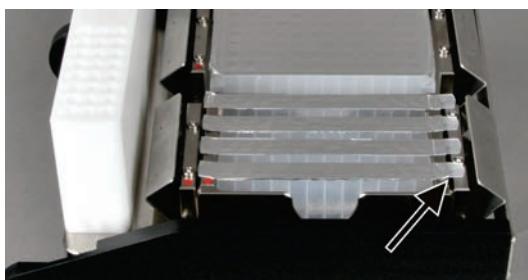
2. Insert the reagent plate into the sample block of the sample tray. The chamfered corners must point to the red dot on the sample block.



3. Place the adapter for the reagent strips into the sample block. The red marking on the adapter must point to the red point on the sample block.

Attention:

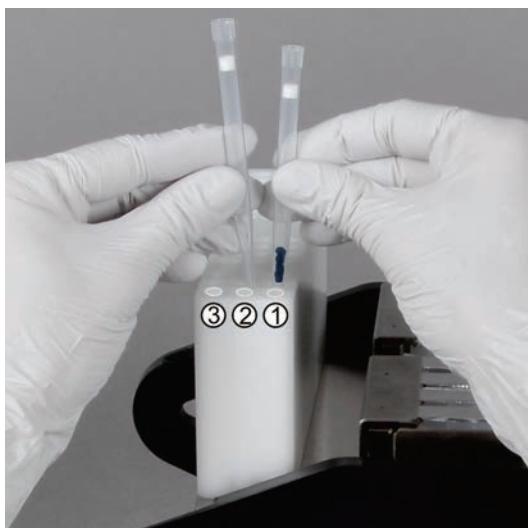
Load both blocks of the sample tray evenly (see below)!



4. Insert a maximum of 4 strips into the adapter. The long tab marked with the label "AJ" must point to the side opposite of the tip block.



5. Fold down the holding-down clamps to prevent the plates and strips from being pulled out of the sample blocks during the extraction process.

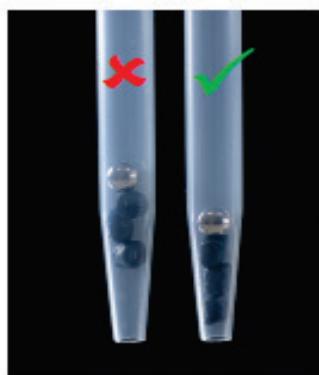


6. Insert the filter tips and the elution tubes into the tip block:

- Insert the SmartExtraction filter tips with granulate in the first drill hole (1).
- Insert the longer filter tips without granulate in the center drill hole of the tip block (2).
- Place the elution tubes into the wider drill hole at the edge of the tip block (3).

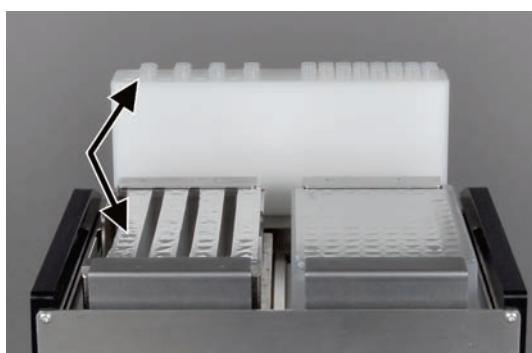
Attention

Place the filter tips correctly! If long tips are placed in position 1, they will reach the bottom of the elution tubes during extraction and cannot be ejected anymore. The device aborts the extraction process.



7. Check the SmartExtraction filter tips. Make sure that the granulate for adsorption of the bacterial DNA is distributed evenly and without gaps and sits close to the tip outlet.

Tap the tip with your finger or shake the tip to dislodge the granulate.



Empty sample positions shall not be filled. With the strips, make sure that for every strip the tips and the elution tube are in the corresponding positions in the tip block (arrows in figure on the left)!



8. Open all cavities of the strips and plates with the piercing tools for 1 or 8 cavities.

Press the piercing tool down as far as it will go to make the tips pierce through the sealing film and create large openings.

Make sure that all cavities are opened completely (at least 7 mm diameter).



9. After extraction: Close the elution tubes using lids.

Notes on sample tray loading

For an extraction run, it is necessary to **always** populate both sample blocks of the sample tray to ensure that the tray is balanced and to allow for optimum movement of the tray inside the device to the necessary positions:

- If only extracting one sample, insert an adapter with an empty strip or an empty deep well plate into the second sample block of the sample tray.
- If processing more than one reagent strip during the extraction protocol, insert two adapters into the tray if possible and distribute the strips evenly between them.
- If processing all samples in one reagent plate, populate the second sample block with an empty deep well plate, available at Analytik Jena.

6 Operation with IPextract

6.1 Overview of IPextract

HOME start page

All IPextract program functions can be accessed via the HOME page.

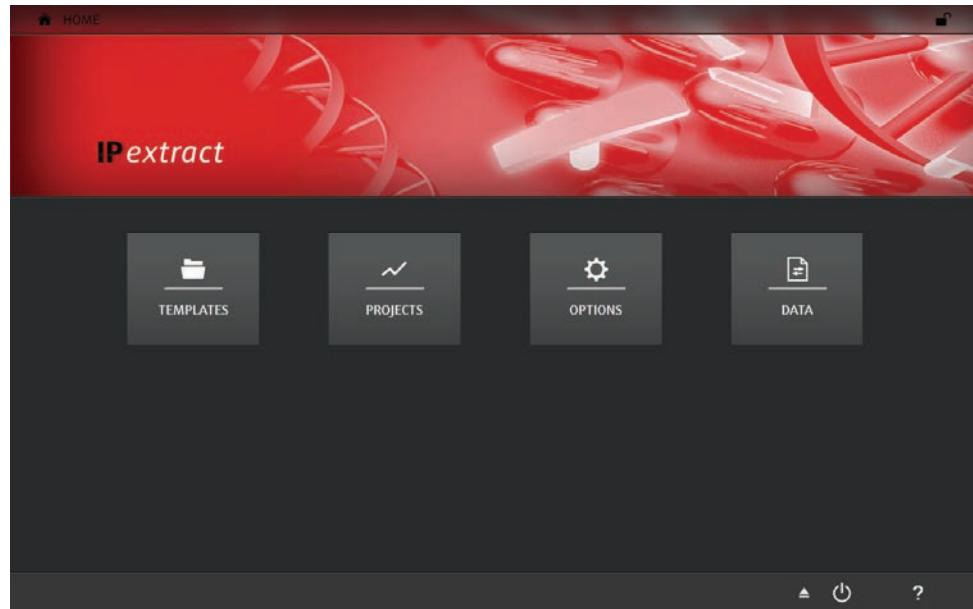


Fig. 9 HOME page

The HOME page appears after starting IPextract. Via the menus displayed on this page, all basic functions of IPextract can be accessed:

MENU	Functions
TEMPLATES	Creating a new extraction template Activating a stored template for an extraction Starting extraction and saving the process (log file) in the project
PROJECTS	Opening a stored project of a completed extraction run
OPTIONS	Checking and executing individual device functions with special tools Selecting the language of the program Selecting the extraction protocols to be displayed in the template Updating the program Sample type management Setting/adjusting the time zone
DATA	Following files can be managed: projects, templates, sample layout, print reports and log files of the heating test Exchanging files between the tablet PC and another PC via USB Memory Stick Copying, moving and deleting files and folders

Frequently used icons

The following icons/functions are frequently used in the program:

Icon	Function
	Call up help.
	Confirm change/input/selection.
	Cancel change/input/selection.
	Start TRAY OUT tool. The sample tray holder is ejected and retracted for loading and unloading (→ "Checking and executing individual device functions with tools" p. 48).
	Shut the tablet down. The button is on the HOME page.
	Return to the HOME page.
	Lock the touch function of the touchscreen. Ongoing processes continue while the touchscreen is locked.

Activating a function

Program functions are activated by tapping.

In case of input errors, an alphanumeric keyboard is opened in the computer design. Inputs into fields must be confirmed with ENTER to be applied. The keyboard window is closed with .

Switching the tablet off

The tablet has to be shut down with software support.

1. Tap on on the HOME page.
2. Confirm the prompt to shut down the system.
 - ✓ The IPExtract program is shut down and the tablet is switched off.

**ATTENTION**

Risk of data loss! The tablet does not have its own battery. When you turn off the basic device using the mains switch, you switch off the tablet at the same time.

Exiting IPExtract

The tablet is not intended for any other purpose than operating the InnuPure C 16 touch. The operating system of the tablet is password protected and shall only be accessed for service purposes.

1. Select the menu item OPTIONS ▶ GENERAL from the HOME page.
2. Tap on and enter the service password
 - ✓ The IPExtract program is shut down and the operating system of the tablet appears.

Templates and Projects

A template contains all information relative to running an extraction protocol. A template can be either created directly before starting an extraction protocol, loaded or extracted from an existing project.

Templates are stored with the file extension *.ipt (IPExtract Template File).

After completion of an extraction protocol, the information contained in the template and the information on the extraction process can be stored together in a project.

Projects are stored with the file extension *.ipp (IPExtract Project File).

6.2 Creating and loading templates

Creating a new template

1. Open the HOME start page.
2. Select the menu item TEMPLATES ► NEW TEMPLATE ► KIT-BASED.
 - ✓ The Template window for entering the extraction parameters appears (→ Editing and saving extraction parameters p. 35).

Loading a template

1. Open the HOME start page.
 2. Select the menu item TEMPLATES ► OPEN TEMPLATE.
 3. Select the storage medium: TABLET PC or USB MEMORY STICK.
 4. Highlight the template.
 5. Tap on .
- ✓ The TEMPLATE window appears with the prepared extraction parameters.

Note:

A template can be *extracted* from a saved project also.

Loading the latest used templates

The latest templates used are displayed separately:

1. Open the HOME start page.
 2. Select the menu item TEMPLATES ► LAST TEMPLATES.
 3. Select the template in the menu.
- ✓ The template is loaded.

6.3 Editing and saving extraction parameters

The window TEMPLATE contains all information about the execution of an extraction protocol:

Page	Contents
GENERAL	Description of the experiment
KIT INFORMATION	Data of the used kit
EXTRACTION	Selection of the extraction protocol
SAMPLE LAYOUT	Overview about the samples
MONITORING	Summary of the extraction parameters Start of the extraction protocol Saving the extraction parameters in a template Exporting the template as PDF for a print report

Templates are stored with the file extension *.ipt (IPExtract Template File).

Overview of TEMPLATE window

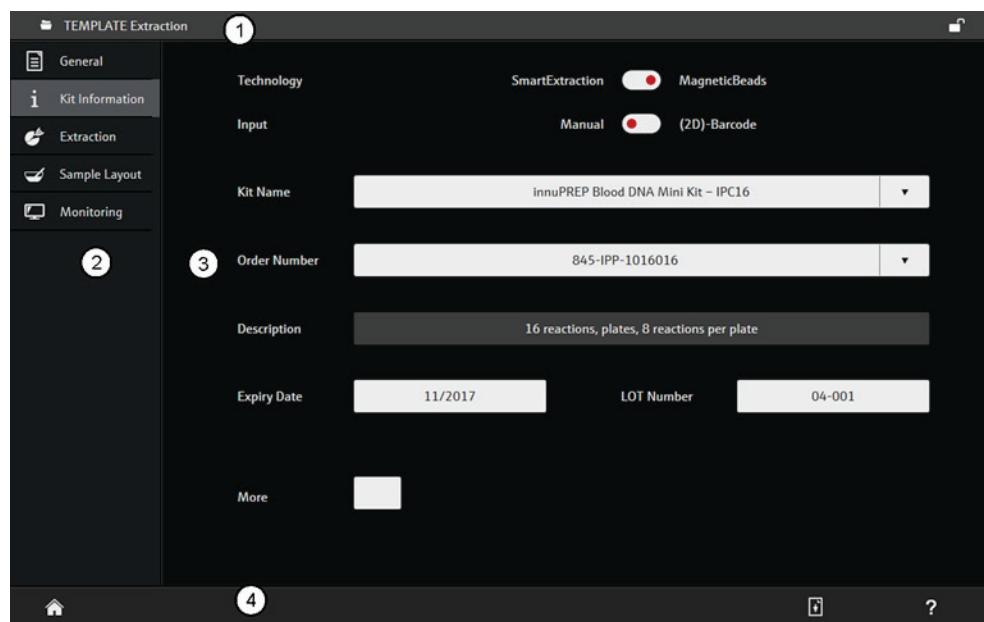


Fig. 10 Overview of template screen

No.	Element	Description
1	Headline	Information on the name of the template or project file and the button to locking the <i>touch</i> function of the screen
2	Screen selection	Selection of the template page
3	Template screen	Display of the selected page
4	Icon bar	The functions and icons vary depending on the contents of the selected screen.

6.3.1 The General page – entering general extraction run options

The GENERAL page contains general information on the extraction. All details entered on this page are optional.

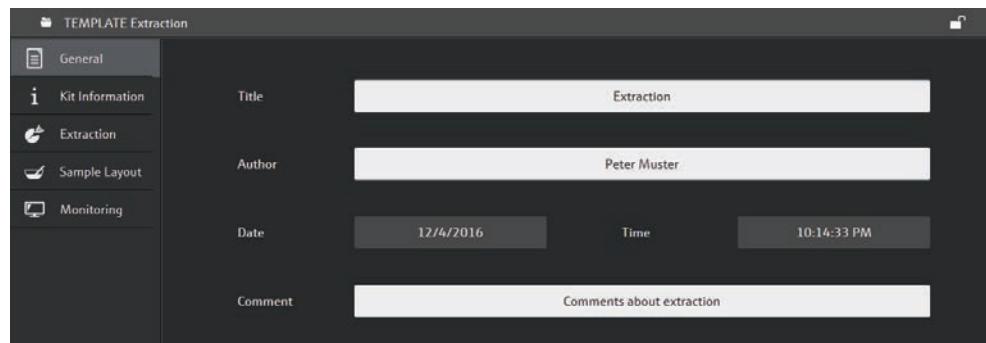


Fig. 11 Template page GENERAL

Enter the following optional data:

Field	Description
TITLE	Title of the extraction run
AUTHOR	Name of the author

Field	Description
DATE/TIME	Shows date and time of the creation of the template This data is automatically adopted from the operating system of the tablet.
COMMENTS	Additional information on the extraction run

6.3.2 The Kit Information page - Entering kit data

Enter the kit data on the KIT INFORMATION page. You find the required data on the packaging of the kits.

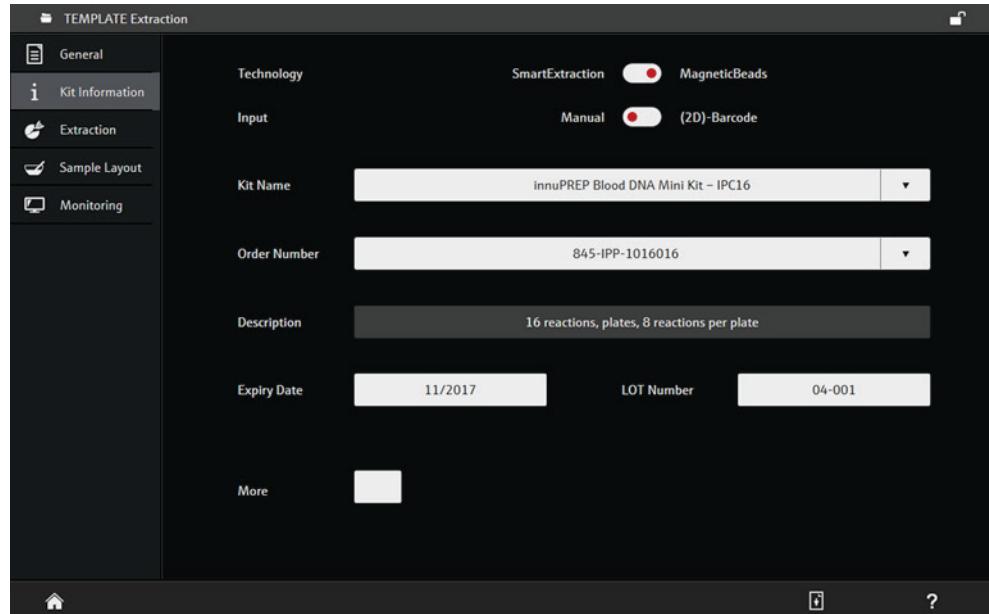


Fig. 12 KIT INFORMATION page

Enter the following data:

Element	Description
TECHNOLOGY	Select the extraction method SMARTEXTRACTION or MAGNETICBEADS and the corresponding kit information. To switch between these two options, tap on the options button. The dot is on the side of the method that has been selected. The selected method determines which kits are contained in the KIT NAME list.
INPUT	Select either MANUAL or (2D)-BARCODE. MANUAL manual input of kit data (2D)-BARCODE read kit data with barcode scanner A connected barcode scanner is automatically recognized by the program. When the option (2D) -BARCODE is activated, no more entries are possible in the input fields on this template page. All fields are filled when scanning the kit barcode. The More option is still available.
KIT NAME	Select the kit name.
ORDER NUMBER	Order number Note: After manual input of the order number, the kit name is entered automatically.

Element	Description
DESCRIPTION	The description of the selected kit is displayed.
EXPIRY DATE	Enter the expiry date of the kit (see packaging of the kit) using the date format MM/YYYY, e.g. 12/2017. This entry is mandatory. It is checked whether the expiry date has been exceeded. After confirming a corresponding message, it is also possible to start an extraction with a kit past its expiry date.
LOT NUMBER	LOT number of the kit
MORE	Run an extraction with several kits simultaneously (see below).

Extraction with several kits

This procedure is recommended for experienced users only. It is possible to use several kits in one extraction run if these kits use the same extraction protocol. The protocol of the first kit is used for the extraction run. Details on the other kits is stored as information in the project.

1. Activate the MORE option after entering the data of the first kit.
2. Enter the number of kits used in the field or set it via the slider (max. 8).
 - ✓ A column of dots (arrow in Fig. 13) appears next to the DESCRIPTION field. The dots symbolize the order of the kits starting with the uppermost. The active kit is displayed in red.
3. Swipe over the column of the dots from the bottom to the top to switch to the next kit.
4. Enter the data of the next kit in the input mask.
5. Repeat the steps (3 – 4) until all kits are entered.

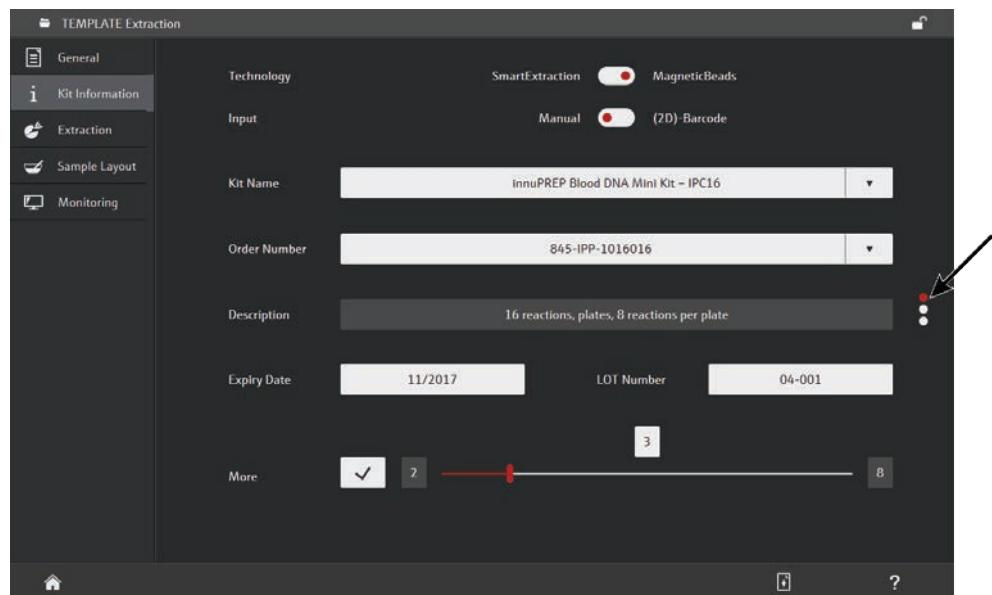


Fig. 13 KIT INFORMATION page with 3 different kits

6.3.3 The Extraction page – selecting the extraction protocol

The extraction page serves to select the lysis type and the extraction protocol used. Please refer to the kit manual for information on the suitable protocol and the lysis.

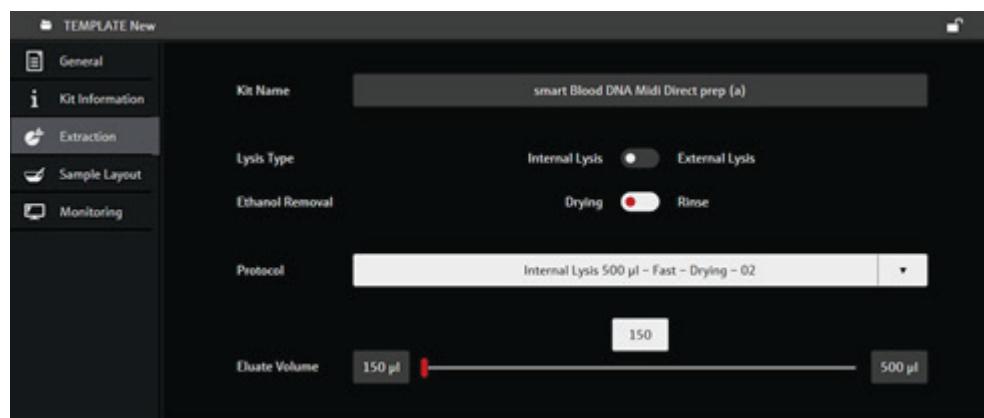


Fig. 14 EXTRACTION page for SmartExtraction kits

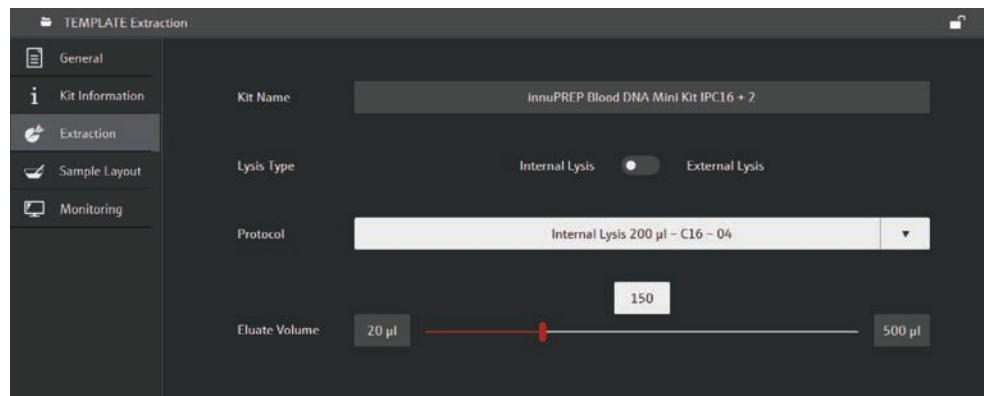


Fig. 15 EXTRACTION page for kits with magnetic beads

Enter the following data:

Element	Description
KIT NAME	Name of the kit, adopted from the KIT INFORMATION page
LYSIS TYPE	Select lysis type depending on the source material: INTERNAL LYSIS Lysis is processed inside the device EXTERNAL LYSIS Lysis is performed manually outside the device
ETHANOL REMOVAL	For SmartExtraction only Select the procedure of ethanol removal DRYING Evaporate ethanol by heating the bottom of the cavity RINSING Dissolve ethanol in the rinse solution during a mixing step
PROTOCOL	Select the extraction protocol (→"Creating and loading templates" p. 35).
ELUATE VOLUME	Enter the eluate volume or setting it via the slider.

6.3.4 Sample Layout page – entering the sample information

The sample information is entered on the SAMPLE LAYOUT page. Inputs on this page are optional.

Sample information can be edited in either the graphical or the spreadsheet view.

Editing sample information in the diagram

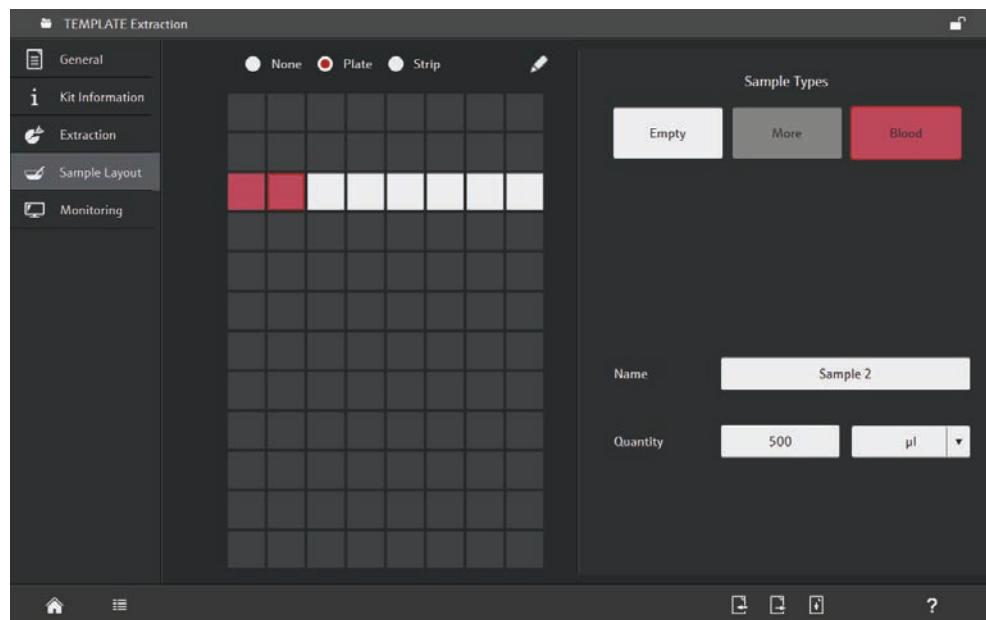


Fig. 16 SAMPLE LAYOUT page with input of sample ID for the left sample block with one reagent plate

The graphical overview of the SAMPLE LAYOUT page shows the sample tray loaded with reagent plates/strips in the same orientation as the sample tray when moved into the InnuPure C16 touch. White sample positions in the sample layout are empty. Occupied sample positions are marked in color depending on the selected sample types.

1. Select the loading of the sample tray side: PLATE (reagent plate) or STRIP (reagent strip).
2. Tap on a white sample position field.
 - ✓ The field is highlighted and marked with a red frame.
3. Tap on .
 - ✓ The input of the sample information for the highlighted sample appears.

Note: Swipe with your finger horizontally over the fields if you want to highlight several adjacent sample positions.

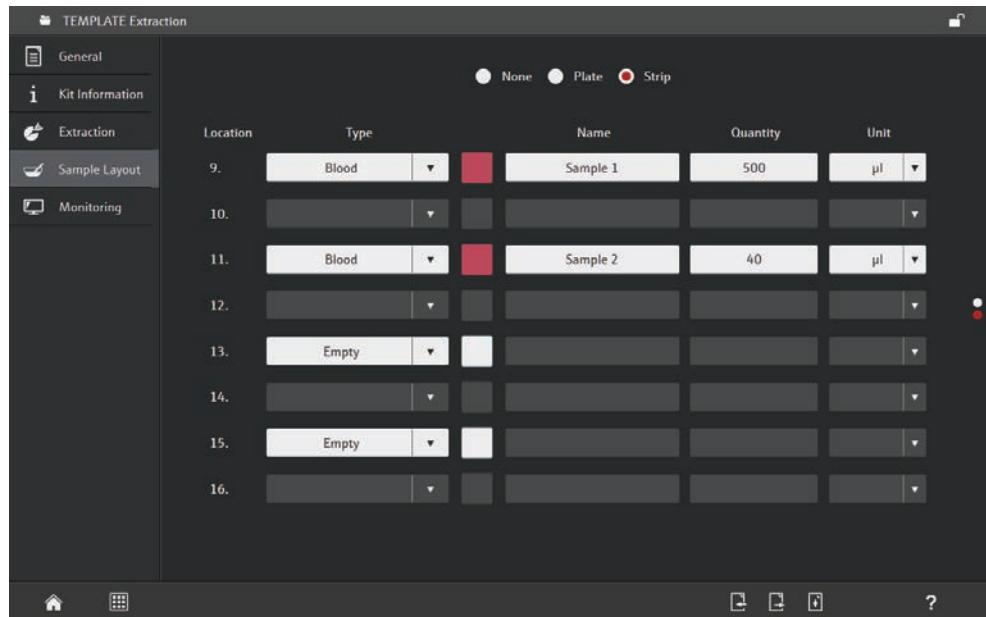
4. Select the sample material via SAMPLE TYPES:

Sample type	Description
EMPTY	This place on the sample tray is empty.
Colored buttons	Sample type (sample material) contained in the kit description
MORE	Use a custom sample type A list of user-defined sample types opens. An expression can be selected from the list or a new expression can be entered directly into the input line. The user-defined sample types are managed centrally (→ Managing user-defined sample types p. 51).

5. Enter the sample name in the NAME field or scan it with the barcode reader.
6. Enter the sample quantity in the QUANTITY field and select the measurement unit from the list.
7. Tap on the next sample displayed in the sample layout and repeat the steps from step (3) until data input is completed.
 - ✓ Data input in the sample layout is completed.

Editing sample information in the table

You can switch to the spreadsheet view after having entered the sample information in the graphical view. To do so, tap on  in the icon bar.



	Location	Type	Name	Quantity	Unit
9.	Blood		Sample 1	500	µl
10.					
11.	Blood		Sample 2	40	µl
12.					
13.	Empty				
14.					
15.	Empty				
16.					

Fig. 17 Spreadsheet view of the SAMPLE LAYOUT

The table shows the assignment of one sample block at a time. You can switch between the two blocks using the column of dots on the right-hand side of the table. The upper dot represents the left block of the sample tray; the lower dot represents the right block. One table row is assigned to each location in the sample block.

1. Swipe vertically over the column of dots on the right-hand side of the table to select the desired sample holder.
 - ✓ The currently displayed holder is marked with a red dot.
2. Select the loading of the sample tray side: PLATE (reagent plate) or STRIP (reagent strip).
3. Tap on the arrow in the TYPE field and select the sample material from the list.
Opening the sample materials list activates the input field. Alternatively, the sample material can be entered manually in this field.
4. Enter the sample name in the NAME field or scan the name with the barcode reader.
5. Enter the sample quantity in the QUANTITY field and select the measurement unit via the UNIT field.
 - ✓ Data input for one sample is completed.

Notes on data entry:

- When confirming an entry with ENTER, the cursor moves to the next active (occupied) field below. In the last line the cursor remains in the field, the entered value is accepted.
- If a barcode scanner is connected, the sample name can be read with the scanner.

Exporting a sample layout

The layout can be exported or imported in a csv-file (*.csv). If you want to create your own layout in Excel, first export a layout as template.

1. Tap on  on the SAMPLE LAYOUT page.
 2. Select the storage location: TABLET PC or USB Memory Stick.
 3. Enter the file name in the SAVE AS field.
 4. Tap on .
- ✓ The layout data is now exported and can be edited in Excel.

Importing a sample layout

1. Tap on  on the SAMPLE LAYOUT template page.
 2. Select the storage location: Tablet PC or USB Memory Stick.
 3. Select the file and tap on .
- ✓ The layout data is imported.

6.3.5 The Monitoring page – parameter overview / saving templates / starting an extraction protocol

The MONITORING page contains following functions:

- Overview of the most important extraction parameters
- Saving parameters as a template
- Exporting the template as PDF
- Starting an extraction protocol (→ Executing an extraction protocol p. 43).
- Storing the extraction run in a project (→ Storing log data of the extraction run in a project p. 45)

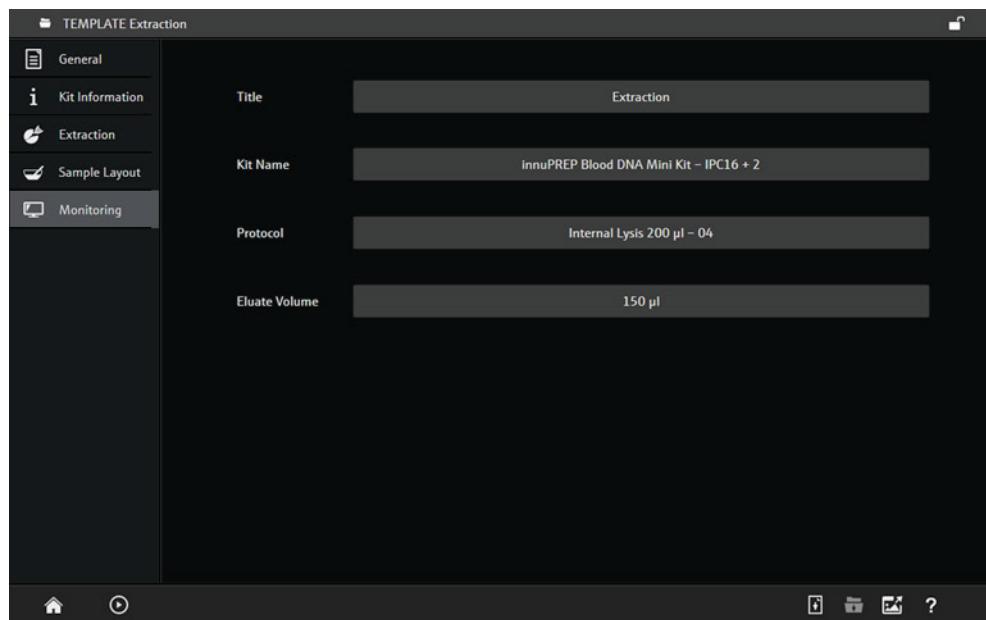


Fig. 18 MONITORING page

Saving a template

1. Tap on after entering all parameters on the TEMPLATE window.
 2. Select the storage medium: TABLET PC or USB MEMORY STICK.
 3. Enter the file name in the SAVE AS field.
 4. Tap on .
- ✓ The template is stored and is now available via the TEMPLATES ▶ OPEN TEMPLATE function.

Note:

On the tablet, all data is saved on the local user folder. In this folder, you can create as many subfolders as you want using the DATA function.

Exporting a template as PDF

1. Tap on after having entered all parameters on the TEMPLATE page.
 2. Select the storage medium: TABLET PC or USB MEMORY STICK.
 3. Enter the file name in the SAVE AS field.
 4. Tap on .
- ✓ The template information will be exported in a PDF document.

6.4 Executing an extraction protocol



CAUTION

Risk of burns!

Do not reach inside the device after abortion of an extraction protocol and after having removed the sample tray. Wait for at least 5 min to let the device cool down to less than 70°C to avoid burns!

6.4.1 Starting the extraction protocol

Starting prerequisites

A template containing the following information is required to start an extraction run:

- Data of the used kit (→ The Kit Information page - Entering kit data p. 37)
- Selection of the extraction protocol and the eluate volume (→ The Extraction page – selecting the extraction protocol p. 39)

General information given on the GENERAL page and the sample information entered on the SAMPLE LAYOUT page are optional information.

Starting the extraction run

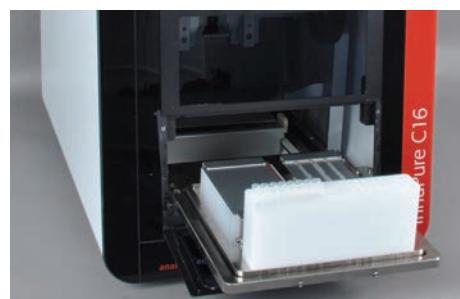
1. Open or create the template for the extraction run.

2. Prepare the sample tray.

3. Go to the MONITORING page.

4. Tap on .

- ✓ The extraction run starts by ejecting the sample tray drawer.



5. Place the sample tray onto the drawer. The tip block points to the user.

6. Confirm the message to retract the sample tray with .

 **CAUTION**

Risk of crushing while the loaded sample tray is retracted. Do not *touch* the tray. Do not reach inside the Innupure C16 touch.

- ✓ The extraction starts. During the run, the currently performed steps are shown in a video sequence. In addition, the following time-related information is displayed:

REMAINING TIME – remaining time of the overall protocol

CURRENT STEP TIME – remaining time of the currently performed step

This displayed remaining times are only round values. The real values depend from the device and the room temperature.

7. Confirm the message to eject the sample tray with  after completion of the extraction run.

8. Close the elution tubes.

- ✓ The extraction process is completed and by confirming again the holder is retracted and the front door is closed automatically.

Note: It is recommended to lock the touchscreen during an ongoing process to avoid accidental changes. Ongoing processes continue while the touchscreen is locked (→ "Locking the touchscreen" p. 45).

Interrupting an extraction

An extraction process can be interrupted and continued later:

1. Tap on  on the MONITORING page.

- ✓ The currently performed step of the extraction process is interrupted.
2. Tap again on .
- ✓ The extraction process is continued.
- Stopping the extraction
1. Tap on  on the MONITORING page.
 - ✓ The extraction process is stopped and cannot be continued later.
2. If required, use software tools to empty and eject tips and to eject the sample tray (→ "Checking and executing individual device functions with tools" p. 48).

6.4.2 Locking the touchscreen

The *touch* function of the touchscreen can be locked at any time. Ongoing processes continue while the touchscreen is locked. This helps for example to avoid interruption of an ongoing extraction process due to accidental *touchscreen* operation.

1. Tap on the padlock item  in the upper right corner of the *touchscreen*.
 - ✓ The touchscreen is locked. A padlock item appears in the middle of the touchscreen.
2. To unlock the screen, tap on the padlock icon in the upper right corner.
 - ✓ The touchscreen is unlocked for further entries.

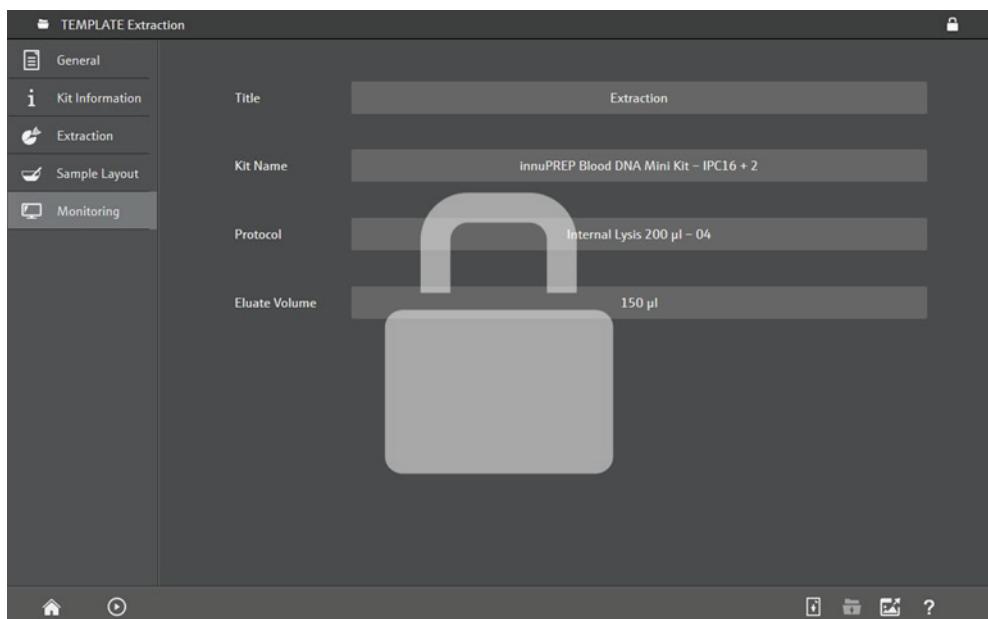


Fig. 19 Locked touchscreen

6.4.3 Storing log data of the extraction run in a project

After completion of the extraction, the log data and the template entries can be stored in a project. Saving the project, the work with the actual template is finished.

1. Tap on  on the MONITORING page.
2. Select the storage medium: TABLET PC or USB MEMORY STICK.

3. Select the file name in the SAVE AS field.

4. Tap on .

✓ The project is stored.

For the next extraction protocol, a new template has to be created or loaded. In addition, it is possible to *extract* a template from the project (→ Opening a project p. 46).

Note: After an extraction run, a new one can be started with the same template, if the project is not saved. The log data will be overwritten.

6.5 Opening a project

After the run of the extraction protocol, the log data and the template information can be saved (→ Storing log data of the extraction run in a project p. 45). If the project is loaded, the extraction parameters are shown on the pages of the PROJECT window. The page MONITORING contains the log data of the extraction run.

Opening projects

1. Open the HOME page.
 2. Select the menu item PROJECTS▶ OPEN PROJECT.
 3. Select the storage medium: TABLET PC or USB MEMORY STICK.
 4. Select the project.
 5. Tap on .
- ✓ The project is loaded and the log data of the extraction run are displayed on the MONITORING screen.

Latest projects used

The latest projects used are displayed separately:

1. Open the HOME page.
 2. Select the menu item PROJECTS▶ LAST PROJECTS.
 3. Select the project in the menu.
- ✓ The project is loaded.

General	Time	Type	Name	Description
Kit Information	4/11/2017 8:30:01 AM	Info	Software Version	1.0.3.2 Beta
Extraction	4/11/2017 8:30:17 AM	Information	Protocol Start	The Demo_C16_04 protocol is started.
Sample Layout	4/11/2017 8:30:17 AM	Info	Serial Number	3223A-0102
Monitoring	4/11/2017 8:31:23 AM	Start	Step 001 finished ("Protocol Starting")	Initialization - Please wait...
	4/11/2017 8:31:32 AM	Tip Handling	Step 002 finished ("Taking Tips")	The tips are taken from tip row 1.
	4/11/2017 8:31:49 AM	Piercing	Step 003 finished ("Opening Cavities")	The cavities 2, 6, 7 and 11 are opened.
	4/11/2017 8:32:10 AM	Mixing	Step 004 finished ("Mixing")	The Magnetic Beads are mixed in cavity 1.
	4/11/2017 8:32:35 AM	Mixing	Step 005 finished ("Collecting")	The Magnetic Beads are collected on the bottom of cavity 1.
	4/11/2017 8:32:59 AM	Transferring	Step 006 finished ("Transfer: Supernatant")	The supernatant of the collecting step is transferred to cavity 11.
	4/11/2017 8:33:21 AM	Transferring	Step 007 finished ("Transfer: Lysate")	The lysed sample is transferred to the Magnetic Beads in the cavity 1.
	4/11/2017 8:33:35 AM	Mixing	Step 008 finished ("Mixing")	The lysed sample and the Magnetic Beads are mixed by vibration up and down in cavity 1.

Fig. 20 Loaded project with log data on the MONITORING page

Exporting the project as PDF

Like the template, a project can also be exported on the MONITORING page as a PDF. The export can take place immediately after running of an extraction protocol or after opening a saved project.

1. Tap on on the MONITORING page.
 2. Select the storage medium: TABLET PC or USB MEMORY STICK.
 3. Enter the file name in the SAVE AS field.
 4. Tap on .
- ✓ The template information will be exported in a PDF document.

Creating a template on the basis of a project

A project is closed after completion of the extraction run. In order to use the parameters of the protocol for another experiment, it is possible to create a template based on the project.

1. Open the project (see above).
 2. Tap on .
 3. Select the storage medium: TABLET PC or USB MEMORY STICK.
 4. Select the file name in the SAVE AS field.
 5. Tap on .
- ✓ The project parameters are stored as template and can be selected with the menu item TEMPLATES ▶ OPEN TEMPLATE.

6.6 Checking and executing individual device functions with tools

Individual device functions can be executed and checked using special programs (tools). These tools allow, for example, for the filter tips to be emptied and ejected after abortion of an extraction protocol.

Integrated tools

The following tools have been integrated into the program:

Icon	Tool	Function
	TAKE TIPS	Take filter tips from the tip block.
	EMPTY TIPS	Emergency emptying of strips and plates after protocol abortion into any cavity to discharge fluid from the tips in a controlled manner. The sample tray must be populated with corresponding strips and plates.
	HEATING TEST	Test of the heating function In this test, a defined temperature is set and held for a period. The setting of the temperature and the temperature constant during the holding time are documented. The log file of the test will be saved in the local user folder of the tablet.
	INITIALIZATION	Initialization of the InnuPure C16 touch after protocol abortion or after an error occurred
	REMOVE TIPS	Ejection of the filter tips into the 3rd cavity after a protocol abortion. The sample tray must be populated with corresponding strips and plates.
	MAGNET TEST	Check positioning of the magnet unit
	TRAY OUT	Ejection of the sample tray from the device
	DECONTAMINATION	With installed decontamination light only: Carry out decontamination with UV light
	LIGHT	Switching the interior light on/off separately

Using the tools

1. Select the menu item OPTIONS ▶ TOOLS from the HOME page.
2. Tap on the tool button.
3. Follow further instructions on the tablet.

6.7 General Settings in IPextract

Select the menu item OPTIONS ▶ GENERAL on the start page HOME for general settings in IPextract.

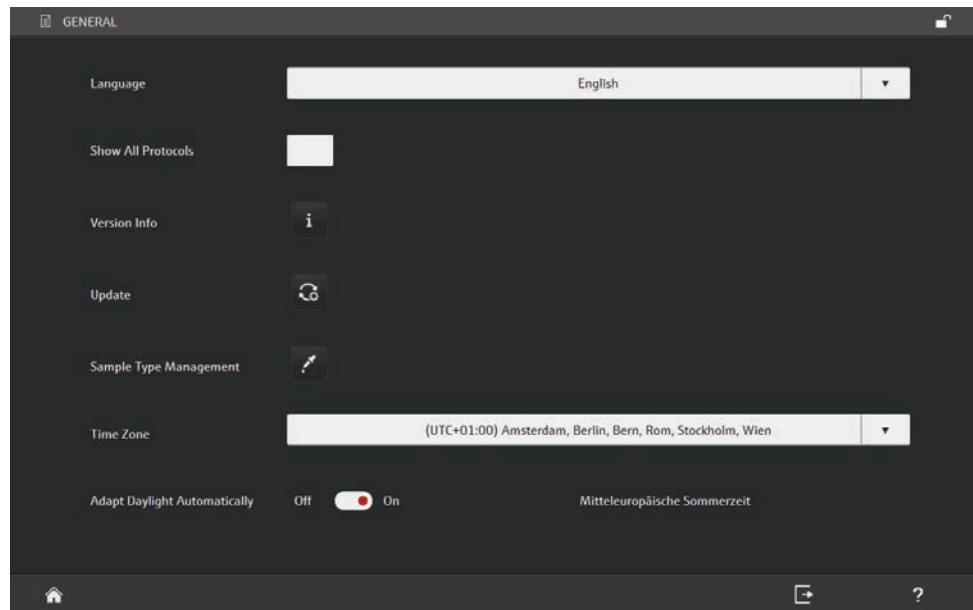


Fig. 21 GENERAL page with general settings

The page GENERAL includes following functions:

- Language selection for the program display (Currently, English is the only language available.)
- Selection of display of extraction protocols
- Display of the program version
- Software update
- Managing user-defined sample tips
- Setting/adjusting the time zone

6.7.1 Selecting the language

The language is selected on the GENERAL page. Currently, English is the only language available.

1. Select the menu item OPTIONS ▶ GENERAL from the HOME page.
2. Select the language in the LANGUAGE list to set the language.

6.7.2 Selecting the display of available extraction protocols

In the default settings, only the Kits with the same lysis type (internal or external) are available for the multi kit use (option MORE on the KIT INFORMATION type). Experienced users also can choose other protocols.

1. Select the menu item OPTIONS ▶ GENERAL from the HOME page.
2. Activate the option SHOW ALL PROTOCOLS to display a larger selection of kits for the option MORE on the KIT INFORMATION page.
 - ✓ All kits with internal and external lysis are offered regardless of the lysis type of the first kit.

6.7.3 Displaying the device information

Following device information will be displayed:

- Serial number of the device
- Firmware version
- Composer version
- Service addresses

1. Select the menu item OPTIONS ▶ GENERAL from the HOME page.
2. Tap on  beside VERSION INFO.
 - ✓ The version number of the actual IPExtract version is displayed.

6.7.4 Updating IPExtract

The update of IPExtract can be started on page GENERAL.

1. Select the menu item OPTIONS ▶ GENERAL on the start page HOME
2. Tap on  beside UPDATE.
3. Insert the USB memory stick on the tablet, if following message appears "Do you want to update the software? Please insert a USB Memory Stick with the setup."
4. Tap on .
5. Confirm the security query for the start of the setup with YES ("Do you want to allow the following program from an unknown publisher to make changes to this computer?").
 - ✓ The update starts. Follow the messages on the display.

Error messages

Error messages	Error removal
USB memory stick not found.	Insert the USB memory stick to the tablet. Start the update again.
Could not find the setup. Please insert a USB Memory Stick with the setup in a directory Setup (including setup.exe file) on the USB Memory Stick.	There was no setup on the USB memory stick.

6.7.5 Managing user-defined sample types

User-defined sample types are managed in this tool. In the template, entered sample types also appear in the sample type management.

1. Select the menu item OPTIONS ▶ GENERAL on the start page HOME.
2. Tap on  near SAMPLE TYPE MANAGEMENT.
 - ✓ The SAMPLE TYPE MANAGEMENT page appears with the user-defined sample types.

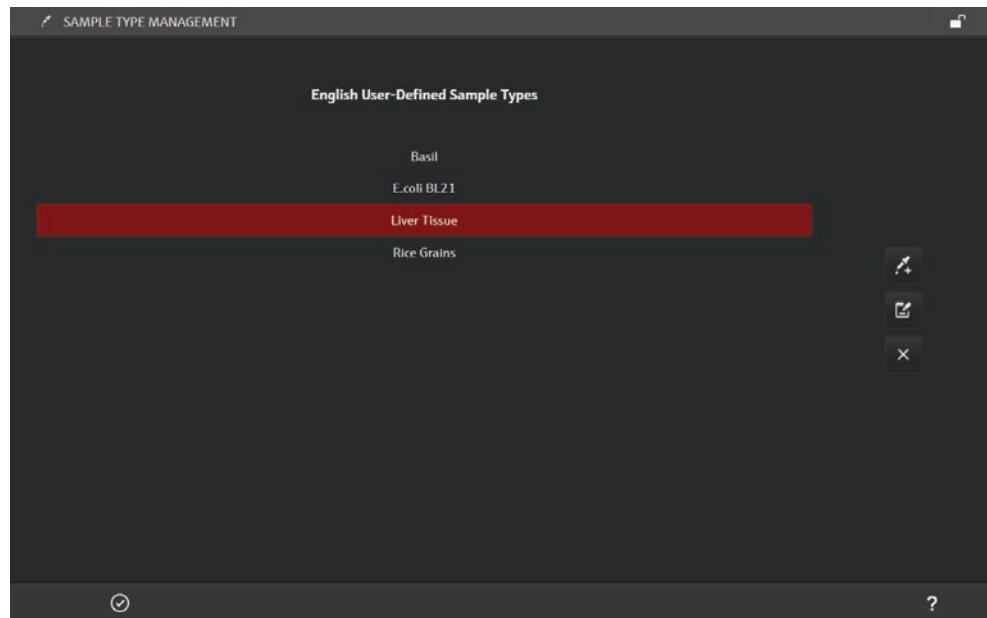


Fig. 22 SAMPLE TYPE MANAGEMENT window

Following functions are available in the SAMPLE TYPE MANAGEMENT window:

Icon	Function
	Entering a new sample type: <ul style="list-style-type: none">■ Tap on .■ Enter a new expression in the input field.
	Editing a sample type: <ul style="list-style-type: none">■ Select the sample type in the list.■ Tap on .■ Edit the expression in the field.
	Delete sample types: <ul style="list-style-type: none">■ Select the sample types in the list.■ Tap on  and confirm the message.

6.7.6 Selecting the time zone / adapting daylight

You can select the system time according to the local time zone. The time zone is selected on the GENERAL page.

1. Select the menu item OPTIONS ▶ GENERAL from the HOME page.
2. Select the current time zone in the TIME ZONE list.
 - ✓ The time zone has been updated.

For automatic adjustment of the daylight saving time, activate the option ADAPT DAYLIGHT AUTOMATICALLY on the GENERAL page. Note: This option is not available for all time zones.

6.8 Managing data



Notice

The operating system of the tablet with IPextract is a closed system. The tablet has no active antivirus protection. The user is responsible for the safety of the USB Memory Stick!

The IPextract program features a data management that supports the exchange of data between the tablet and a USB Memory Stick.

Data formats

The following data formats are available in IPextract:

Extension	File type
*.ipt	Extraction run template
*.ipp	Project file with information contained in the template used for the extraction run and the log data.
*.csv	Files with sample layouts
*.pdf	Print reports of templates and projects
*.txt	Log data of the heating test

Note

On the tablet, all data are saved on the local user folder. In this folder, you can create as many subfolders as you want using the Data function.

Opening the data management

- Tap on DATA on the HOME page.
 - ✓ The DATA MANAGEMENT page appears.

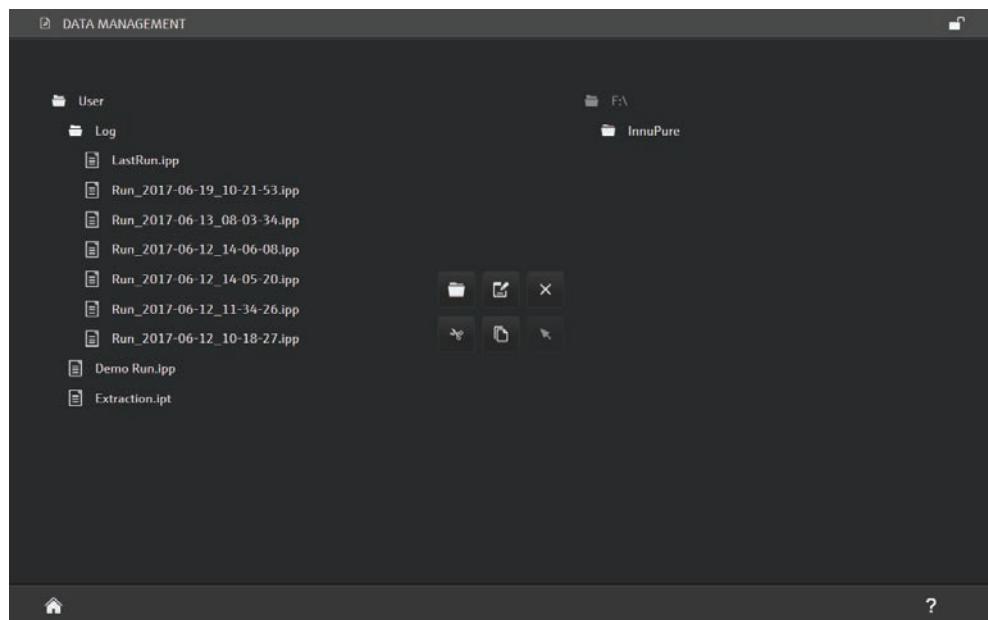


Fig. 23 DATA MANAGEMENT page

Icons

Icon	Function
	Create a new folder
	Rename a folder/file
	Delete a folder/file
	Cut a folder/file The folder/file is copied to the clipboard and removed from its original storage location.
	Copy a folder/file to the clipboard
	Paste a folder/file from the clipboard in a selected folder

Exchange a folder/file between the tablet and a USB Memory Stick

Files are exchanged between a folder and the USB Memory Stick as follows:

1. Tap on the file to be exchanged.
 - ✓ The highlighted file is marked with a red bar.
2. Copy it to the clipboard with or cut it with .
3. Tap on the target folder.
4. Paste the file into the target folder with .
 - ✓ The file is now transferred. Folders are transferred in the same way.

Creating a new folder

1. Tap on the folder list of the tablet or USB Memory Stick to select the folder to which you want to add a subfolder.
2. Tap on .
3. Enter the name of the folder.
4. Tap on .
 - ✓ The new folder is added to the folder structure.

Renaming files/folders

1. Tap on the folder or file.
 2. Tap on .
 3. Enter the new name.
 4. Tap on .
- ✓ The folder or file is now displayed with the new name.

Deleting a folder/file

1. Tap on the folder or file.
 2. Tap on .
 3. Confirm the prompt about deleting the folder file with .
- ✓ The folder or file is deleted.

7 Maintenance and care

The InnuPure C16 *touch* is mainly maintenance-free. Care and maintenance are limited to cleaning the device, changing the fuses and installing software updates.



WARNING

Danger of electric shock!

The device cover must only be opened by the technical customer service of Analytik Jena or its authorized agency. Before opening the device, disconnect the mains plug!

7.1 Cleaning the InnuPure C16 touch



WARNING

Danger of electric shock!

Prior to cleaning the device with disinfection agents, switch off the InnuPure C16 *touch* and the tablet and disconnect the mains plug from the mains outlet at the rear of the device!

The InnuPure C16 *touch* must only be recommissioned once it is completely dry!

CAUTION

Risk of burns!

Wait for at least 10 minutes after switching the device off prior to start cleaning the interior of the InnuPure C16 *touch*. After this cooling-down period, the temperature directly below the heating strip is less than 50 °C.

- Avoid contamination by handling sample substances carefully.
- Wipe spilled samples or reagents immediately with an absorbent cloth or piece of paper. To do so, open the lower front door via the software or open the upper front door manually (see Fig. 24).
- If the InnuPure C16 *touch* is used for the analysis of infectious material, great care must be taken because the InnuPure C16 *touch* cannot be decontaminated as a whole device.
- Visible contamination must be removed immediately using suitable detergents, making sure that no solvent enters the inside of the device.
- The adapters for accepting the reagent strips can be autoclaved and are also suitable for dip and spray disinfection.
- The sample tray is also suitable for dip and spray disinfection.
- We recommend the following disinfection agents for the device interior

Decosept AF

by Dr Schuhmacher GmbH

Meliseptol HBV cloths

by B. Braun

These are only to be used for wiping disinfection. If using a spray head, first apply the disinfection agent on suitable cloths.

- We recommend the following disinfection agent for the front screen made of acrylic glass and for the

Decosept Special by Dr Schuhmacher GmbH

This is only to be used for wiping disinfection. If using a spray head, first apply the disinfection agent on suitable cloths.

- Only the use of ethanol or isopropanol-containing disinfection agents are approved for wiping disinfection. The use of disinfection agents with ingredients or concentrations that differ from the recommended disinfection agents invalidates all warranty claims regarding damage to the device or effectiveness.
- If an InnuPure C16 touch has to be sent to Analytik Jena for service, a prior decontamination must be carried out and documented.



Fig. 24 Wiping disinfection with open front doors

7.2 Exchanging fuses



WARNING

Danger of electric shock!

Disconnect the mains plug from the mains connection at the rear prior to exchanging fuses!

1. Disconnect the mains plug from the connection at the rear of the device.
2. Carefully open the fuse holder using a screwdriver.
3. Replace the defective mains fuses. Use 2 x 4A / 250 V fuses only.
4. Close the fuse holder again.
5. Connect the InnuPure C16 touch to the power supply.
6. Switch the device and the tablet back on.



Fig. 25 Fuse holder at the rear of the device

8 Fault removal



Attention

If faults cannot be remedied by the customer, the Analytik Jena service department or agency must always be informed. This also applies for the repeated occurrence of individual faults.

In case of an error message, perform the following steps:

- Confirm the error message with [OK].
- Switch the InnuPure C16 touch off and back on.
- If required, remove any sample residue and filter tips left behind with the tools EMPTY TIPS and DROP TIPS.

If this does not fix the error or if the problem reoccurs, take a picture of the display showing the error message or note the error message down and notify the service department of Analytik Jena.

General information and tips for preventing problems

Observe the following notes to prevent errors during the daily routine:

1. After switching on the InnuPure C16 touch wait until the tablet is booted up AND the IPextract user interface is fully loaded. Only start operating the device once the HOME page appears on the device. Otherwise, program faults may result.
2. If tips (with or without liquid) are still attached to the cones after a protocol abortion or power failure, the tips are ejected via a safety function starting automatically the next time a protocol or tool is started. In this case, the customer can freely choose one cavity into which the liquid is dispensed and one into which the tips are ejected. Please also observe the context-specific messages and notes on the screen! The safety function offers the option to remove consumables /reload the tray with consumables. If the dispensing system is in start position after protocol abortion, or if the customer confirms that there is no residual liquid in the pipette tips, the customer can only select a cavity for tip ejection.
3. Before starting a tool, make sure that no consumables from previous processes have remained in the tray. If consumables remained in the tray, remove these consumables using the tool [TRAY OUT] in the TOOLS menu.
4. Wait for at least 10 minutes after switching off the device before cleaning the interior of the device. After this cooling-down period, the temperature on the heating strip is less than 50°C.

9 Transport and storage

9.1 Transport

9.1.1 Preparing the device for transport



WARNING

Risk of damage to health due to improper decontamination!

Perform a professional and documented decontamination of the device before returning it to Analytik Jena. The decontamination protocol is provided by the service when the return is registered. Analytik Jena must refuse acceptance of contaminated devices. The sender may be liable for any damage caused by inadequate decontamination of the device.



CAUTION

When packaging the InnuPure C16 touch, two persons are required to lift the device by holding onto the bottom of the device.



ATTENTION

Use the transport packaging recommended by AJ for packaging. Only this provides optimum protection of the InnuPure C16 touch against transport damage.

Assembly of the transport box



The individual parts are connected using clamping brackets that are inserted in the recesses at the edges of the side parts.

The brackets have a long and a short end and can be installed in only one way.



The tool required to remove the brackets is bolted on the transport box.

Unscrew the tool to disassemble the box. Screw the tool back on the box after assembly of the box.



To remove the brackets, slide the tool under the up curved side of the bracket and carefully lift the bracket. While doing so, hold the bracket with one hand!

⚠ CAUTION!

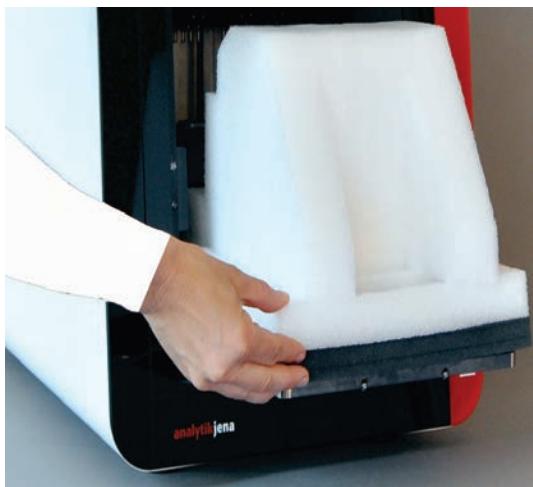
Risk of injury! If you do not hold the bracket, it may jump away and cause injuries!



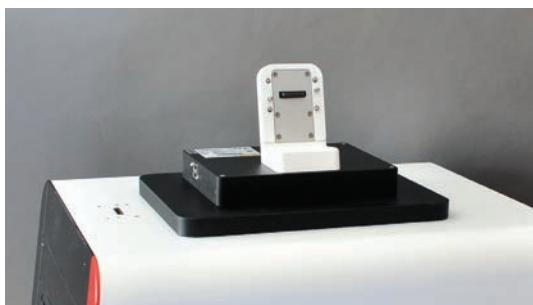
Assemble the side panels with the arrows of the printed symbols pointing upwards.

Packaging instructions

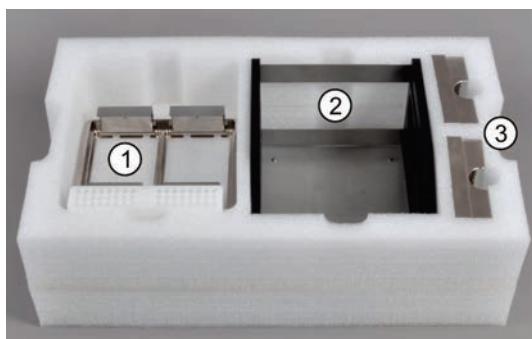
When packaging the device, insert a transport lock in the sample chamber.



1. Remove remaining consumables from the InnuPure C16 touch.
2. Move the dispensing unit with the wiper in the top position.
3. Shut down the tablet and switch off the basic device. Disconnect the mains cable.
4. Insert the transport lock in the InnuPure C16 touch:
 - Open the front doors manually and pull out the drawer.
 - Place the transport lock on the drawer.
 - Slide back the drawer manually. Close the front doors.



5. Dismount the tablet.
 - To do so, undo the four hexagon socket screws.
 - Pull off the tablet and support bracket upwards.
 - Screw on the protective cap to cover the tablet port on the basic device.



6. Insert the sample tray (1), the priming station (2) and the adapters for reagent strips (3) (optional) into the spaces in the accessory box provided.

If there are no adapters (3), fill the empty spaces with the suitable foam parts.



7. Place the foam cover on the sample tray and place the insert in the priming station.

8. Place the power cable in the insert.



9. Mount two side panels on the pallet.

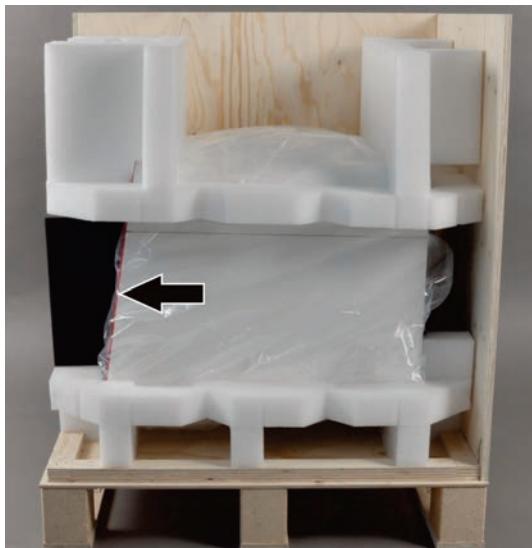
10. Place the foam frame for the device base onto the pallet.



11. Wrap the InnuPure C16 touch in the plastic bag to protect it against scratches and place it into the packaging box.

⚠ CAUTION!

For reasons of safety, 2 persons are required to lift the device who must position themselves on both sides of the equipment. Firmly hold onto the bottom of the device with two hands and lift it simultaneously.



12. Slide the second foam frame for the device top onto the InnuPure C16 touch.

13. Place the black foam wedge in front of the plexiglas front screen to protect it against scratches (see arrow).



14. Wrap the tablet in foil and slide it in the compartment in the upper foam frame.

15. Place the accessory box between the struts of the foam frame.

16. Cover the accessory box with foam foil.



17. Place the cardboard cover on the foam frame.

18. Place the folder with the device documentation between the struts of the lid.

Note:

If returning the Innupure C16 touch to Analytik Jena, complete the decontamination description and place it together with an error description into the transport box.



19. Mount the two missing side panels.

20. Close the transport box with the lid.

21. Screw the tool required to remove the brackets on the transport box.

9.1.2 Transport notes

Observe the safety instructions in chapter "Safety instructions, transport and installation" p. 9. Avoid the following during transport:

- Impacts and vibrations
Risk of damage due to shock, impacts or vibrations!
- Major temperature fluctuations
Risk of condensate build-up!

9.1.3 Moving the device in the laboratory



CAUTION

Unintentionally dropping the device poses a risk of injury and damage to the device!

Move the InnuPure C16 touch with great care! Two persons are required to lift and carry the device!

When moving the InnuPure C16 touch in the laboratory observe the following:

1. Switch off the tablet and the InnuPure C16 touch. Remove the tablet from the device.
2. To prevent health damage the following must be observed when moving the device in the laboratory (lifting and carrying):
 - For reasons of safety, 2 persons are required to transport the device and must position themselves on both sides of the equipment.
 - Because the device does not have carrying handles, grip the device firmly with both hands at the lower device end, but not in the door area. Make sure the doors are closed before lifting the device simultaneously.
 - Observe the guide values and adhere to the legally mandated limits for lifting and carrying without auxiliary means!
3. For installation at the new location, observe the notes in section "Installation conditions" p. 21.

9.2 Storage



Attention

Environmental influences and condensate formation can destroy individual components of the device!

The device must only be stored in air-conditioned rooms. The atmosphere must be low in dust and free from aggressive vapors.

If the device is not installed immediately after delivery or not required for prolonged periods, it should be stored in its original packaging. A suitable desiccant should be added to the equipment to prevent damage from moisture.

Ambient conditions

For requirements with regard to the ambient conditions at the storage location, refer to "Technical data" p. 66.

10 Disposal

At the end of its service life the InnuPure C16 *touch* and all its electronic components must be disposed of in accordance with the applicable regulations as electronic waste.

11 Specification

11.1 Technical data

System parameters	
Extraction principle	Based on surface-functionalized magnetic or paramagnetic particles or based on the Smart extraction principle
Extraction duration	< 45 min (without lysis) < 100 min (with lysis)
MAG kits yield	Depending on the sample type and quantity <ul style="list-style-type: none"> ▪ Tissue (20 mg): up to 50 µg ▪ Whole blood (200 µl): up to 10 µg ▪ Plant (100 mg): up to 60 µg
SE kits yield	Depending on the sample type and quantity <ul style="list-style-type: none"> ▪ Tissue (5-20 mg): between 15 and 150 µg ▪ Whole blood (0.5-3 ml): between 5 and 90 µg
Drive	Low-noise long-life stepper and servomotors (noise emission max. 65 dB)
Device operation	Stand-alone via IPExtract with 10" touchscreen (color)
Maintenance	Maintenance-free through the use of non-wearing stainless steel pistons
Cleaning	System components are easily accessible through large, split front door
Temperature control	Heating up to 90 °C
Application parameters	
Consumables	Completely contained in the required kit Sealed, pre-filled reagent strips or plates
Lysis step	Automated in the device (dependent on the source material)
Extraction routines	Pre-installed protocols (optimized for the most varied source materials)
Cross contamination	Completely excluded through sealed reagent strips and plates
Tips	Max. 32 per preparation each with a capacity of 1000 µl, equipped with aerosol filter
Samples	
Sample capacity	Up to 16 preparations in parallel, incl. handling of individual samples Processing of different source materials possible with identical pipetting protocols
Sample preparation	Insertion of the pipette tips, samples and elution tubes into the sample tray Insertion of pre-filled reagent strips/plates into the sample tray
Sample volume	Up to 10 ml or up to 180 mg

Elution	Separate storage tubes with lid
Elution volume	Depending on the protocol from 20-500 µl adjustable in 10 µl steps
Accessories and kits	
Sample tray	Carrier for the pre-insertion of all consumables and samples
Priming station	Rack for easy preparation of the sample tray
Kits	DNA extraction and RNA extraction from different source materials
Piercing tool	Tool set with piercing tool for manual opening of individual positions or of 8 positions in parallel on the strips or plates
Adapter for reagent strips (optional)	Adapter for accepting a maximum of 4 reagent strips
Barcode reader (optional)	Sample name detection via barcode reading
UV light (optional)	Decontamination with 254 nm UV light between 2 extraction runs
Other technical data	
Weight	Approx. 30 kg
Dimensions (W x H x D)	400 mm x 560 mm x 600 mm
Electrical variables	
Power supply	100-240 V AC, 50/60 Hz
Fuses	2 x 4AT / 250V
Max power consumption	250 VA
PC interface	USB
Environmental conditions	
Temperature during operation	5-35 °C
Humidity during operation	Max. 80 % at +30 °C
Temperature during storage	-10-55 °C
Humidity during storage	Max. 80 % (use desiccant)

11.2 Guidelines and standards

Protection class and type of protection	The InnuPure C16 <i>touch</i> is protection class I. The casing is rated IP 20.
Device safety	<p>The InnuPure C16 <i>touch</i> complies with the safety standards</p> <ul style="list-style-type: none">■ DIN EN 61010-1■ DIN EN 61010-2-081
EMC compatibility	<p>InnuPure C16 <i>touch</i> has been tested for radio interference resistance and radio interference emissions in accordance with DIN EN 61326-1:2013 and meets the requirements according to:</p> <ul style="list-style-type: none">■ Interference immunity according to table 1 (normal environment) with tablet control■ Interference immunity according to table 2 (industrial environment) with external PC control■ Interference emission according to class B for all operating variants
EC directives	<p>The InnuPure C16 <i>touch</i> is designed and tested in accordance with standards meeting the requirements of EC directives 2014/35/EU and 2014/30/EU. The device leaves the manufacturer in a pristine and technically safe state. To maintain this condition and to ensure safe operation, the operator must strictly observe the safety and operating instructions contained in this manual. For accessories which have also been supplied, and system components from other manufacturers, their operating instructions should be referred to.</p>
Guidelines for China	<p>The device contains substances subject to regulation (according to regulation "Management Methods for the Restriction of the Use of Hazardous Substances in Electrical and Electronic Products"). Analytik Jena guarantees that the substances will not leak within the next 25 years and, therefore, will not cause any environmental danger or health risk within this period of time if the device is used as intended.</p>

EG-Konformitätserklärung

EC Declaration of Conformity

Analytik Jena AG • Konrad-Zuse-Straße 1 • 07745 Jena

Wir erklären hiermit in alleiniger Verantwortung die Übereinstimmung der (des) genannten Produkte(s) mit der EG-Richtlinie 2014/30/EU über die elektromagnetische Verträglichkeit, der Niederspannungsrichtlinie 2014/35/EU für die Gerätesicherheit und der RoHS-Richtlinie 2011/65/EU zur Beschränkung einzelner gefährlicher Stoffe

Bei Änderungen am Produkt, die nicht von uns autorisiert wurden, verliert diese Erklärung ihre Gültigkeit.

We declare under sole responsibility the compliance of the mentioned product(s) with the requirements of the Electromagnetic Compatibility Directive 2014/30/EU, the Low Voltage Directive 2014/35/EU for device security and the RoHS Directive for Restriction of certain Hazardous Substances

Any modification to the product, not authorized by us, will invalidate this declaration.

Gerätebezeichnung / Device name

InnuPure® C16 touch

Normen / Standards & Sicherheitsziele / Safety Goals

EN 61326-1 :2013 (Tabelle 1)

EN 61010-1:2010

EN 61010-2-081:2015

EN 50581:2012

Konformitätsbewertungsverfahren / assessment procedure

Konformitätsbewertungsverfahren InnuPure_C16_touch

Das Gerät ist gekennzeichnet mit / The device is marked with:

CE



Ulrich Krauss
Vorstandsvorsitzender
CEO

Jena, den 16.12.2016



Dr. Jürgen Otte
Leiter Qualitätsmanagement
Head of Quality Management