Instructions for use

NICCI Technology

IFU NICCI-01-R02 / 2021-03 EN

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1 NICCI components

NICCI components		Component variants	Article numbers
	**NICCI Module**** Connected to the host monitor PulsioFlex PC4000	NICCI Module	PC6500
	**NICCI Mouse*** Connected to the NICCI Module	NICCI Mouse	PC6510
	**NICCI Upper Arm Cuff*** Connected to the NICCI Module	NICCI Upper Arm Cuff, S NICCI Upper Arm Cuff, M NICCI Upper Arm Cuff, L NICCI Upper Arm Cuff, XL	PC6531 PC6532 PC6533 PC6534
	NICCI Upper Arm Cuff Tube* Connected to the NICCI Upper Arm Cuff	NICCI Upper Arm Cuff Tube	PC6530
	**NICCI Sensor*** Connected to the NICCI Mouse	NICCI Sensor S, single use NICCI Sensor M, single use NICCI Sensor L, single use	PV6550 PV6551 PV6552

Tab. 1: NICCI components

*Not made with Natural Rubber Latex (**the NICCI Module is not in contact with patient skin)

NICCI compatibility:
PulsioFlex PC4000 equipped with the software version 6.0 or higher.

2 About this manual

This manual is an extension to the **PulsioFlex operator's manual** (PC406*) that specifically describes the NICCI technology integrated into the PulsioFlex monitor PC4000. Both manuals need to be considered.

* plus two digit language code according to ISO 639-1

WARNING!

This icon in connection with the signal word WARNING indicates a hazardous situation that, if not avoided, could result in death or serious injury. It may also describe potential serious adverse reactions and safety hazards.

CAUTION!

This icon in connection with the signal word CAUTION indicates a hazardous situation that, if not avoided, could result in minor or moderate injury.

NOTICE

This icon indicates information considered important, but not hazard-related. The icon indicates items of information for which careful attention must be paid in order to avoid damage to the equipment or inaccurate data as well as operational errors. Additionaly, the NOTICE is generally used as the signal word.

► This icon indicates helpful user information.

All figures contained in this manual are examples and are subjects to change without further notice. Some localization rules in the figures may be omitted.

3 Frequently used functions

Function	Refer to section
NICCI setup	NICCI Setup & Start [⏩ Page 24]
Entering patient data	Entering patient data [⏩ Page 27]
Start measurement	Measurement via PulsioFlex [⏩ Page 30] Measurement via NICCI Module [⏩ Page 31]
NICCI-controlled blood pressure calibration with internal NIBP	NICCI NIBP [⏩ Page 32]
CO calibration	CO/CI calibration subscreen [⏩ Page 43]
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Stop measurement	Measurement via PulsioFlex [⏩ Page 30] Measurement via NICCI Module [⏩ Page 31]
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Cleaning and disinfection	Cleaning & disinfection [⏩ Page 54]

Tab. 2: Frequently used functions

4 General information

4.1 Intended Use

NICCI is intended to be used as an accessory for continuous non-invasive blood pressure and pulse rate measurement, and other derived parameters.

4.2 Indications for Use

NICCI is indicated in patients where the monitoring of continuous non-invasive blood pressure and derived parameters is useful.
NICCI is indicated for the monitoring of the following physiological processes:

- Monitoring the impact of a medical procedure on blood pressure.
- Blood pressure monitoring of ill or circulatory unstable patients.
- Monitoring of the blood pressure before, during and after a medical procedure or treatment of a patient.

4.2.1 Intended Patient Population

NICCI is intended for patients with suitable finger sizes.
NICCI is not intended for neonates and infants up to the age of three years.

4.2.2 Intended Body Parts (Interacted With)

NICCI is intended to interact with a combination of either the index and middle finger, or middle and ring fingers of either the left or right hand.

In the case where an automatic Non-Invasive Blood Pressure calibration is applied, NICCI is intended to interact with either the left or right upper arm of the patient.

NICCI is intended to interact with intact skin for an application time up to 72h.

4.2.3 Intended User Profile

NICCI is intended to be used by trained health care professionals.

4.2.4 Intended Use Environment

NICCI shall be operated in surgical, medical, and other hospital units.

4.3 Contraindications

NICCI has no absolute contraindications.

4.4 Warnings

WARNING!

Defibrillator protection requires use of manufacturer specified applied parts, patient cables, lead wires, transducers and accessories.

WARNING!

Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in the improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

WARNING!

Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

WARNING!

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the specified equipment including cables. Otherwise, degradation of the performance of this equipment could result.

WARNING!

The blood flow interference can be affected and result in harmful injury to the patient caused by continuous NICCI Upper Arm Cuff pressure due to connection tubing kinking.

WARNING!

Too frequent NICCI Upper Arm Cuff measurements can cause injury to the patient due to the blood flow interference.

WARNING!

The application of the NICCI Upper Arm Cuff over a wound can cause further injury.

WARNING!

The application of the NICCI Upper Arm Cuff and its pressurization on any limb where intravascular access or therapy, or an arterio-venous (A-V) shunt, can cause the temporary interference to blood flow and could result in injury to the patient.

WARNING!

The NICCI Upper Arm Cuff and its pressurization shall not be applied on the arm on the side of a mastectomy.

WARNING!

The pressurization of the NICCI Upper Arm Cuff can temporarily cause loss of function of simultaneously used monitoring medical equipment on the same limb.

WARNING!

Check that operation of the NICCI Upper Arm Cuff does not result in prolonged impairment of patient blood circulation.

WARNING!

Improper selection of the NICCI Sensor could lead to an inaccurate measurement.

WARNING!

Improper selection of the NICCI Upper Arm Cuff size could lead to an inaccurate calibration of the NICCI system.

WARNING!

Make sure that the patients' fingers are inserted completely so that the proximal end is within the NICCI Sensor cuffs. Correct finger placement ensures that the measurement can be conducted properly and does not lead to inaccurate values.

WARNING!

Do not root the NICCI Mouse cable in the area of the patient's carpal tunnel. A wrong placement with applied pressure may lead to the damage of the nerve.

WARNING!

Do not cover the NICCI Mouse with cloth or heating blanket.

WARNING!

Be aware that the NICCI Module starts with delivering of the pressure signal to the bedside patient monitor only after confirmation of zero calibration.

WARNING!

Changes in the position of the NICCI Sensor regarding heart level (e.g. re-positioning of the patient and/or patient's arm) and/or repositioning of the fingers inside the NICCI Finger Sensor may have an immediate influence on the absolute blood pressure values. To assure accurate blood pressure measurement, check the setup and repeat the NIBP calibration after repositioning.

WARNING!

Ensure proper fit and positioning of the NICCI NIBP Cuff and NICCI Finger Sensor and make sure that the measurement is not impaired by movement artefacts especially before, during, and initially after NIBP measurement. In case the displayed parameters are not plausible, check the setup and repeat NIBP calibration.

WARNING!

Make sure that the NICCI Mouse cable is guided in a way to avoid compression or tension of the cable.

WARNING!

Remove all objects (e.g. rings) from the patient's fingers before applying the NICCI Sensor.

WARNING!

Do not apply the NICCI Sensor over a wound.

WARNING!

After zeroing of the pressure input channel, check values and curve on the bedside monitor for plausibility.

WARNING!

Ensure that the system parts (sensor and arm cuff) do not induce pressure points on the patient's body/tissue. In case of possible pressure points, apply adequate countermeasures (e.g. reposition the patient's arm or hand); introduce additional material in the setup to protect any affected body parts.

WARNING!

To prevent prolonged impairment of peripheral blood circulation during the continuous blood pressure measuring process, an inspection of the pertinent extremities must be performed frequently. In case of inadequate perfusion, discontinue the continuous blood pressure measurement immediately and disconnect the sensor connector cable.

4.5 Safety instructions

CAUTION!

Use of the upper arm cuffs other than the one supplied are not validated and might result in measurement errors.

CAUTION!

Before using the device, check if NICCI is properly assembled.

4.6 Notes

NOTICE

The use of the equipment is restricted to one patient at a time.

NOTICE

The medical electrical equipment does not have special means of protection against burns when used with HF Surgical Equipment. To reduce hazards of burns in the event of a defect in the neutral electrode connection please inform yourself about the system setup (e.g. location of electrodes) in advance in the accompanying documentation of the operated HF device and strictly follow the instructions.

NOTICE

The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication.

NOTICE

Any reading taken by NICCI Upper Arm Cuff can be affected by the measurement site, the position of the patient, exercise, or the patient's physiologic condition.

	NOTICE **The performance of the automated NICCI Upper Arm Cuff can be affected by extremes of temperature, humidity and altitude.**
	NOTICE **Avoid compression or restriction of the connection tubing of the NICCI Upper Arm Cuff.**
	NOTICE **The NICCI Mouse should be protected against unauthorized use.**
	NOTICE **Make sure that the NICCI Upper Arm Cuff is positioned on the designated limb over the artery.**
	NOTICE **To avoid interference with the NICCI measurement, preferably attach the upper arm cuff to the contralateral arm than the NICCI Sensor.**
	NOTICE **When used, adjust the bedside patient monitor pressure channel label to avoid confusion with the pressure input source of an invasive technology.**
	NOTICE **Before removing the patient's hand from the NICCI Sensor, ensure that the measurement is stopped.**

4.7 Additional use

The NICCI can be used for pregnant women including pre-eclampsia patients.

5 NICCI technology

5.1 Technology principle

For continuous non-invasive measurement of the patient's blood pressure, NICCI uses state-of-the-art technology, also defined as the enhanced vascular unloading principle. Infrared light, emitted from a light emitting diode, is sent through the finger. The light is partly absorbed by arterial blood, which changes according to the heart activity (pulse). A light detector receives the non-absorbed light on the other side of the finger and produces a continuous pulse signal.

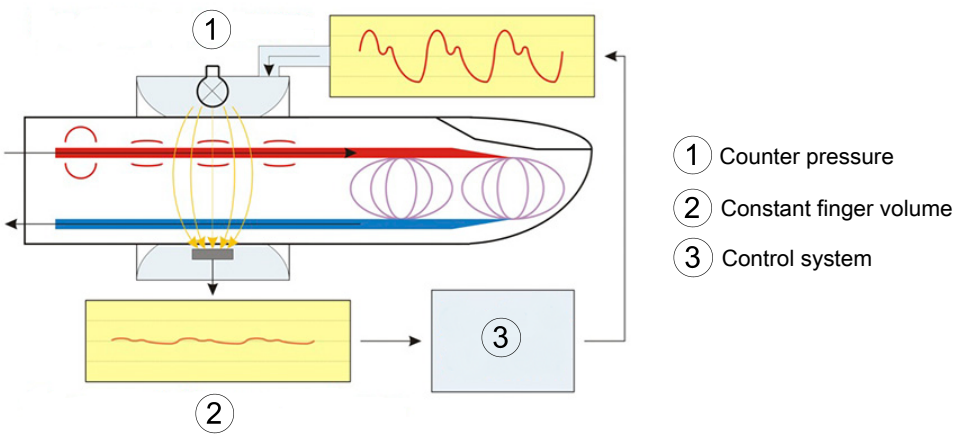


Fig. 1: Mechanism of action of NICCI Mouse with NICCI Sensor

Counter pressure is exerted from the outside in such a way that the arterial wall is totally unloaded. This continuously-changing outside pressure keeps the arterial blood volume constant at all times and directly corresponds to the arterial pressure. The intra-arterial pressure is therefore measured indirectly.
To calibrate the continuous pulse-contour curve with the correct absolute blood pressure values, an automatic non-invasive blood pressure (NIBP) measurement is either performed on the patient's upper arm or provided by the user or a bedside monitor.

5.2 Technology components

Application of the NICCI Module requires the PulsioFlex host monitor, which serves as power supply and user-interface for NICCI.
Further essential technology configurations consist of the following components:

- NICCI monitoring units (NICCI Mouse and NICCI Sensor)
- NICCI Upper Arm Cuff

The PULSION PulsioFlex patient monitor must be equipped with software version 6.0 or higher.

► Details of currently installed software version can be found in the "Info" screen. If further information about this screen is needed, please refer to PulsioFlex operator's manual.

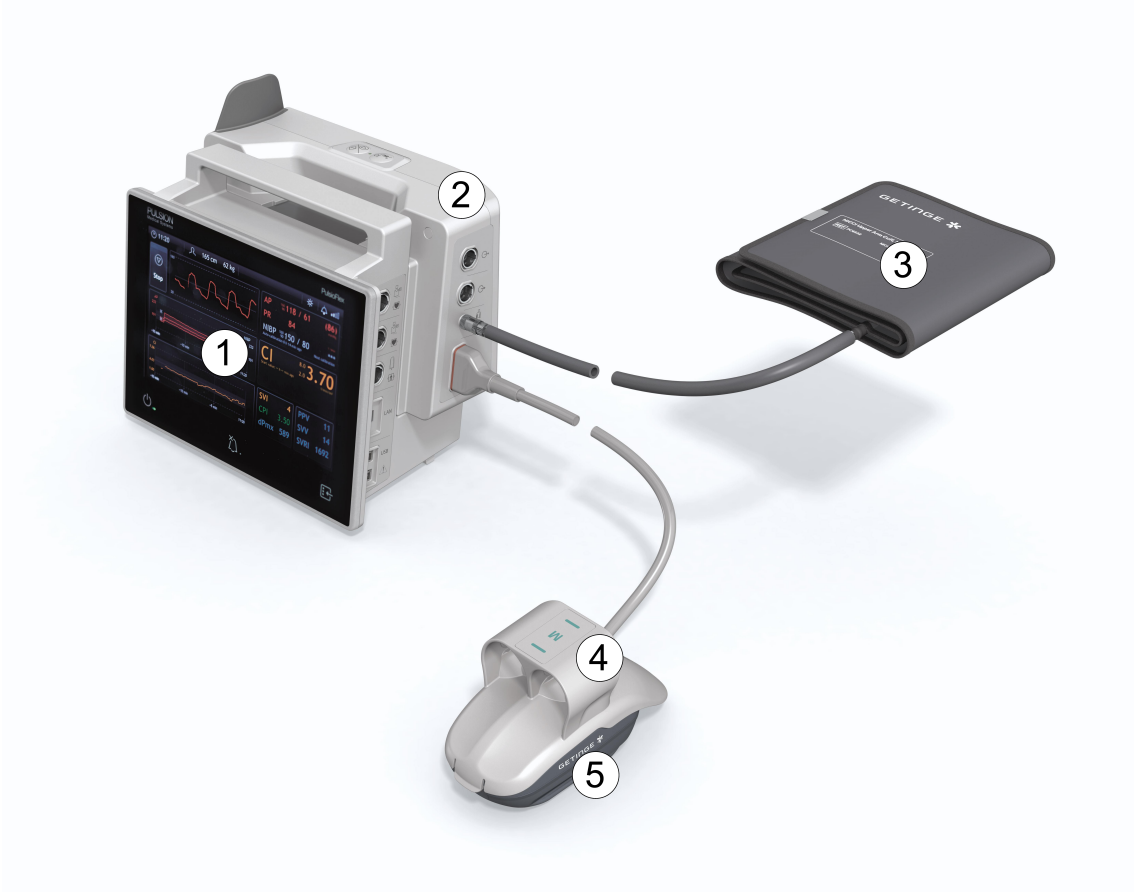


Fig. 2: Technology components

1 PulsioFlex
1 NICCI Module
3 NICCI Upper Arm Cuff
4 NICCI Sensor
5 NICCI Mouse

5.2.1 NICCI Module

Fig. 3: NICCI Module connectors

1, 2	Extension ports (currently not used)
3	AUX Connection for AUX adapter for continuous pressure transmission to the bedside monitor
4	NICCI Upper Arm Cuff Connection for the tube of the NICCI Upper Arm Cuff
5	NICCI Mouse Connection for the NICCI Mouse
6	PulsioFlex host monitor Connection for the PulsioFlex host monitor

► Do not touch the accessible contacts of connectors of the NICCI Module and the patient simultaneously.

Fig. 4: NICCI Module elements

1	Button to start/stop NIBP measurement
2	LED
3	Button to start/stop NICCI measurement
4	NICCI Mouse storage possibility

5.2.2 NICCI monitoring units

NICCI Sensor

The NICCI Sensor is mounted on the NICCI Mouse and applies counter pressure to the fingers via pneumatic bladders. The NICCI Sensor also contains an NFC chip (round tag located on the bottom side of the sensor) recording data from the finger sensor. This data can only be read by the NICCI Mouse. The NICCI Sensor comes in three sizes to accommodate 3 different finger circumferences, each size is clearly marked by differently colored labels.

Fig. 5: NICCI Sensors

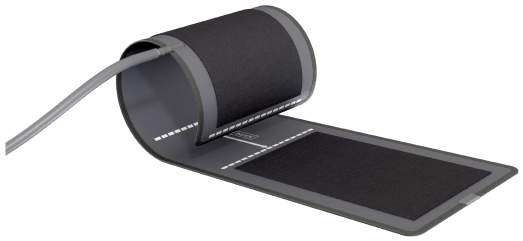
Size	Finger diameter
S	13 - 17 mm
M	16 - 22 mm
L	21 - 28 mm

NICCI Mouse

The NICCI Mouse holds the NICCI Sensor and is connected to the NICCI Module. It controls the bladder pressure, emits infrared light, measures the signals from the NICCI Sensor and relays the resulting parameters. The NICCI Mouse also contains an NFC antenna to read the NICCI Sensor data.

Fig. 6: NICCI Mouse

5.2.3 NICCI Upper Arm Cuff



The NICCI Upper Arm Cuff is used to calibrate the blood pressure signal on a pre-defined basis. It comes in four different sizes.

Fig. 7: NICCI Upper Arm Cuff

Size	Arm circumference
S	17-26 cm
M	24-32 cm
L	32-42 cm
XL	38-46 cm

5.3 Parameters and ranges of normal values

NICCI uses the normal ranges for the parameters that are based upon clinical experience and can vary from patient to patient. The stated normal ranges are therefore given without guarantee.

Basic parameters

Abbreviation	Parameter	Normal range	Min. – max. range	Unit
APsys	Systolic Arterial Pressure	90-140	40-250	mmHg
APdia	Diastolic Arterial Pressure	60-90	30-210	mmHg
MAP	Mean Arterial Pressure	70-105	35-230	mmHg
PR	Pulse Rate	60-100	30-200	bpm

NIBP parameters

Abbreviation	Parameter	Normal range	Min. – max. range	Unit
NIBPsys	Systolic Non-Invasive Blood Pressure	90-140	40-250	mmHg
NIBPdia	Diastolic Non-Invasive Blood Pressure	60-90	20-210	mmHg
NIBPm	Mean Non-Invasive Blood Pressure	70-105	35-230	mmHg

Derived parameters

Abbreviation	Parameter	Normal range	Min. – max. range	Unit
SV	Stroke Volume	-	0-300	ml
SVI	Stroke Volume Index	40 - 60	0 - 150	ml/m²
SVV	Stroke Volume Variation	0 - 10	0 - 40	%
$CO_{Trend/Cal}$	Continuous Cardiac Output	-	0 - 20	l/min
$CI_{Trend/Cal}$	Continuous Cardiac Index	3.0 – 5.0	0 - 10	l/min/m²
SVR	Systemic Vascular Resistance	-	0 - 5000	$dyn*s*cm^{-5}$
SVRI	Systemic Vascular Resistance Index	1700 – 2400	0 - 5000	$dyn*s*cm^{-5}*m^2$
PPV	Pulse Pressure Variation	0 - 10	0-40	%
CPO	Cardiac Power Output	-	0.01 - 9.99	W
CPI	Cardiac Power Index	0.5 – 0.7	0.01 - 9.99	W/m²
dPmx	Index of Left Ventricular Contractility	-	200 - 5000	mmHg/s

Input parameters

Abbreviation	Parameter	Normal range	Min. – max. range	Unit
CVP	Central Venous Pressure	-	-40 - 40	mmHg

Tab. 3: NICCI parameters and ranges of normal values

6 NICCI Setup & Start

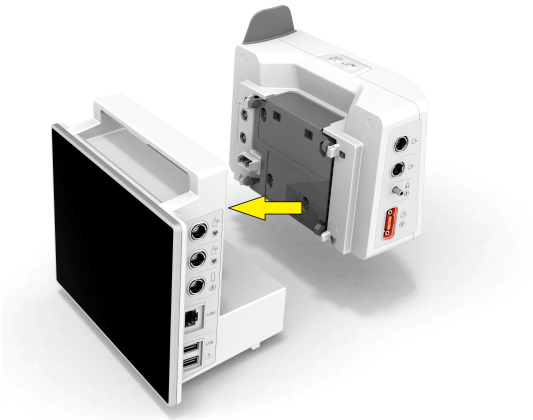
When the NICCI Module is attached to the PulsioFlex, it automatically switches on when the PulsioFlex is switched on.

► When the NICCI Module is connected, the button can be seen in the Root menu screen. If further information about this screen is needed, please refer to **PulsioFlex operator's manual**.

6.1 Attachment of the NICCI Module to the PulsioFlex Monitor

1. Turn the interface plug protection on the rear of the PulsioFlex device away from the plug.

2. Move the module in horizontal direction until it locks in place.

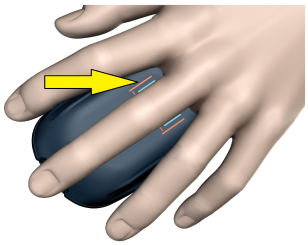
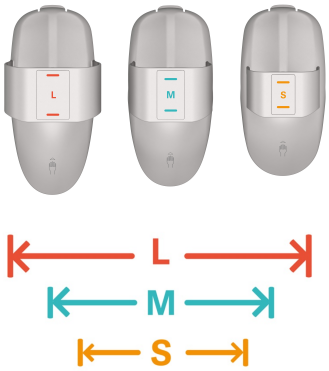


Tab. 4: Attachment of the NICCI Module to the PulsioFlex monitor

6.2 Attachment of NICCI monitoring units

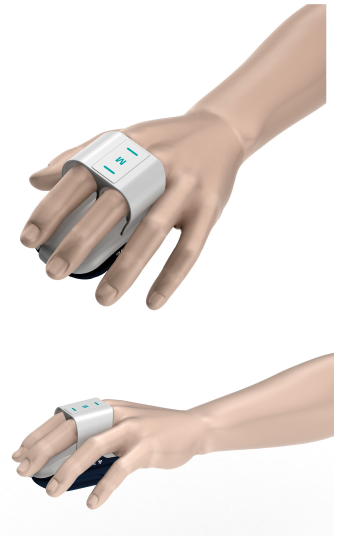
6.2.1 Selection of the NICCI Sensor

In order to guarantee a correct measurement, select the appropriate finger sensor size by placing the patient finger on the printed scale under the NICCI Mouse.

1. Use the bottom part of the NICCI Mouse.	2. It is important to measure the proximal end of the largest finger. The visible lines indicate the size needed.	3. Select the appropriate size of the NICCI Sensor. The lines on the sensor can be also used to measure the finger and indicate the width of the fitting finger.
		

Tab. 5: Selection of the NICCI Sensor

6.2.2 Attachment of the NICCI Sensor

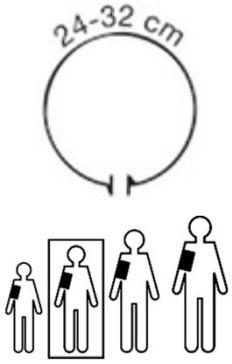
1. Place the NICCI Sensor on the NICCI Mouse from the cable side of the NICCI module. Press/Flip the Sensor forward and down until a click is heard and felt on the NICCI Mouse.	2. Insert the patient hand in the direction indicated on the NICCI Sensor. Assure that the patients fingers are fully inserted. The NICCI Finger Sensor can be applied to index or middle finger or the middle and index finger of either left or right hand. Correct finger placement ensures that the measurement can be conducted properly.	3. Make sure that the cable is guided in a way that the patient is not impaired. Connect the assembled hardware to the appropriate NICCI Module connector (see chapter NICCI Module [⏩ Page 19]).
		

Tab. 6: Attachment of the NICCI Sensor

6.3 Selection and attachment of the NICCI Upper Arm Cuff

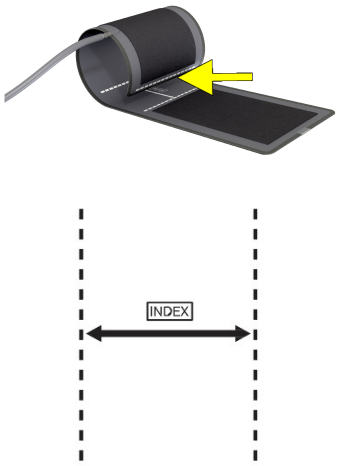
In order to guarantee a correct measurement, select the appropriate NICCI Upper Arm Cuff size:

1. Select the correct size of the NICCI Upper Arm Cuff for your patient according to the indicated arm circumference and marked patient category.

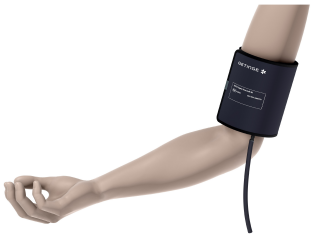


The cuff end with the dotted white line must be located within the indexed area when the cuff is closed to assure correct size selection.

2. Situate the end of the cuff within the range identified by the Index label.



3. Place the cuff on the patient's arm above the elbow at heart level, the cuff tubing pointing up toward the patient's elbow. The cuff side labeled with Patient is facing the skin.



4. When the NICCI Upper Arm Cuff is applied, this arrow ⬇ must be located over the brachial artery.

5. Make sure that the tube is guided in a way that the patient is not impaired. Connect the upper arm cuff tube to the NICCI Module (see chapter NICCI Module [⏩ Page 19]).

Tab. 7: Selection and attachment of the NICCI Upper Arm Cuff

7 NICCI Measurement

WARNING!

To prevent prolonged impairment of peripheral blood circulation during the continuous blood pressure measuring process, an inspection of the pertinent extremities must be performed frequently. In case of inadequate perfusion, discontinue the continuous blood pressure measurement immediately and disconnect the sensor connector cable.

7.1 Patient data

7.1.1 Entering patient data

► The patient management data screen is automatically displayed after switching the PulsioFlex monitor on. If further information about this screen needed, please refer to **PulsioFlex operators manual**.

When the NICCI Module is connected to the PulsioFlex, the following patient settings are available in the **Patient settings screen**:

Entry item	Description	Settings	Entry type
Patient name, patient ID, bed number	Input of information about patient.	**n/a**	optional
Gender	Input of patient gender.	**Male / Female**	mandatory
Date of birth	Input of date of birth of patient.	**0 – 99 years**	mandatory
Height	Input of actual height.	**100 – 220 cm**	mandatory
Weight	Input of actual weight. Any patients with short-term increase in body weight due to illness (e.g. edema) should still have weight input to the initial measurement. Obese patients should have their weight entered.	**20 – 200 kg**	mandatory

7.1.2 NICCI Sensor functions

► The NICCI Finger Sensor properties allow storing and exchanging the patient data. However, patient identifying information is not stored if HIPAA functionality is activated in the service settings. For further information about this function, please refer to **PulsioFlex operator‘s manual**.

When the NICCI Sensor is connected to the NICCI Mouse, the following buttons are available in the **Patient settings screen**:

Activate Sensor	Button to activate the NICCI Sensor (for further information refer to chapter New NICCI Sensor [⏩ Page 28]). ► This button is only visible when a new NICCI Sensor is connected.
Sensor	Button to open the NICCI Sensor settings screen (for further information refer to chapter NICCI BP Settings subscreen [⏩ Page 41]). ► This button is only visible when an activated NICCI Sensor is connected.

7.2 NICCI Sensor activation

► To perform NICCI measurement, the NICCI Mouse establishes communication to NICCI Sensor via NFC technology. The communication is established automatically as soon as the NICCI Sensor is attached to the NICCI Mouse. If further information about this function is needed, please refer to Appendix - Technical specifications - Near Field Communication [⏩ Page 64].

7.2.1 New NICCI Sensor

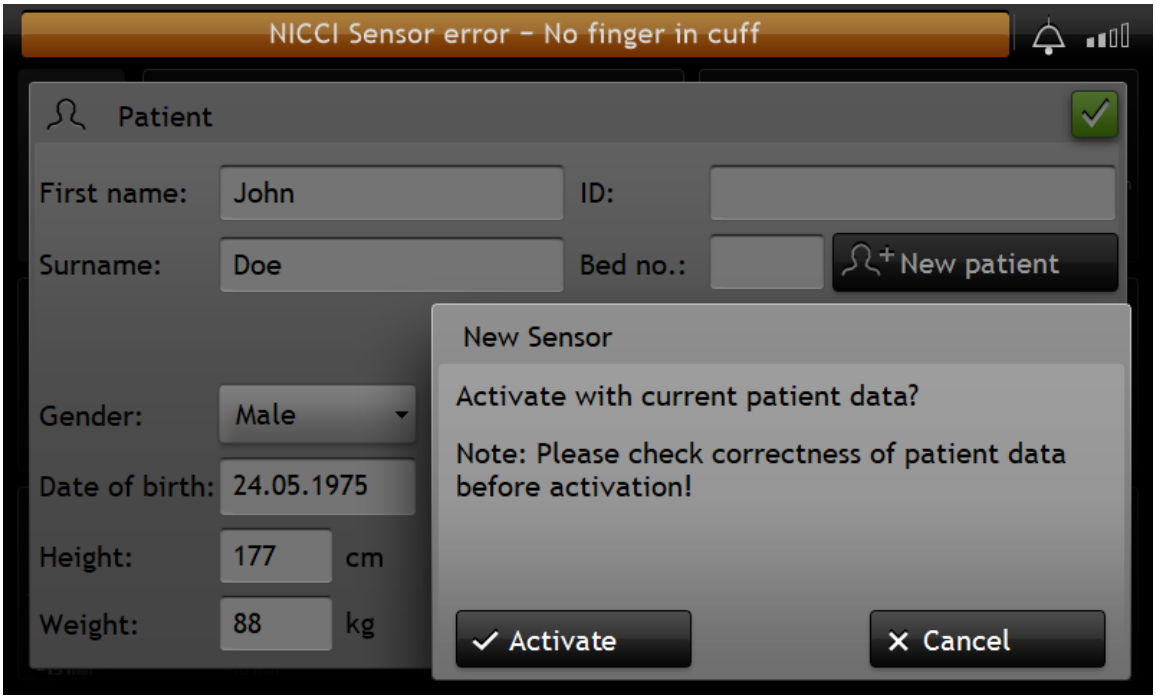


Fig. 8: New sensor pop-up

This pop-up opens automatically when a NICCI Sensor is connected to the NICCI Mouse. To activate the sensor at least following patient data has to be entered in the Patient settings screen:

- Gender
- Date of birth
- Height
  Weight

These inputs are mandatory for the calculation of the NICCI parameters.

The following options are available on this screen:

✓ Activate	Button to activate the connected NICCI Sensor. Activation enables the pressure measurement and starts the timer for the allowed application time.
✕ Cancel	Button to leave the pop-up without sensor activation.

When the pop-up is closed, the button Activate Sensor is displayed in the patient screen. Use this button to reopen the New sensor pop-up.

7.2.2 Activated NICCI Sensor

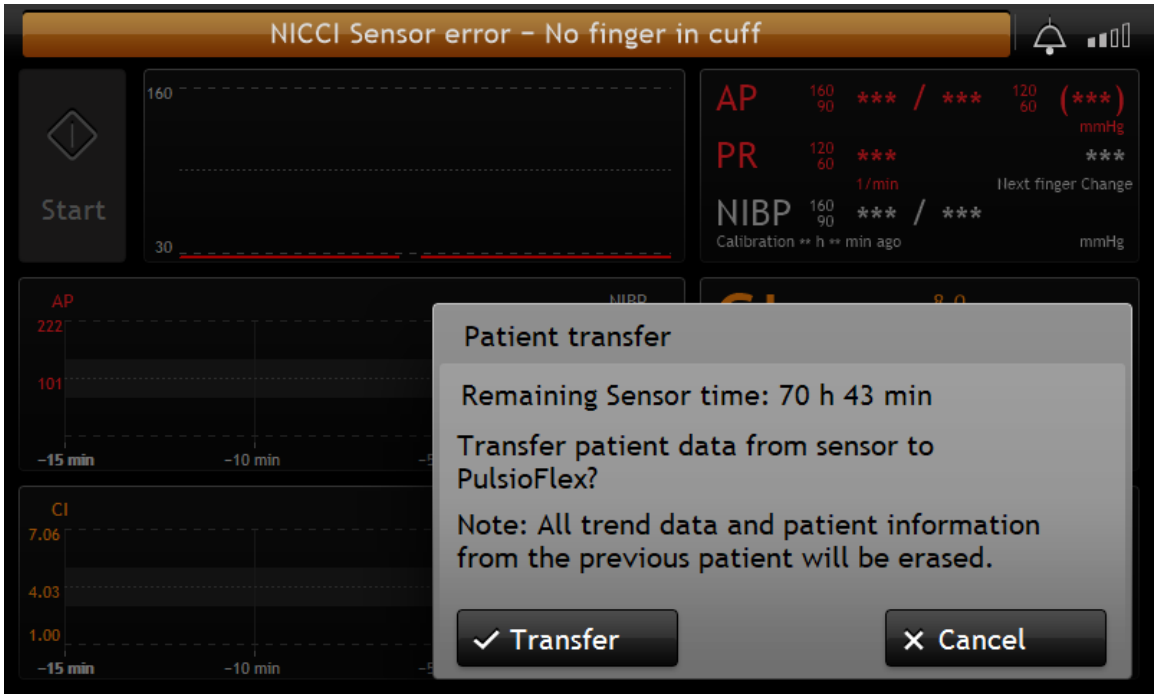


Fig. 9: Patient transfer pop-up

This screen is displayed automatically when an activated NICCI Sensor is connected and the stored patient data on the sensor is different from patient data stored on the PulsioFlex.

The following options are available on this screen:

✓ Transfer	Button to activate the patient data transfer from the connected NICCI Sensor to the PulsioFlex monitor. ► Patient data transfer is still possible when the NICCI Sensor is expired or allowed application time was exceeded.
✕ Cancel	Button to leave the pop-up without data transfer.

When the pop-up is closed, the Sensor button is displayed in the patient screen. Use this button to open the NICCI BP Settings to display information about the connected sensor (see chapter NICCI BP Settings subscreen [⏩ Page 41]).

7.3 Measurement via PulsioFlex

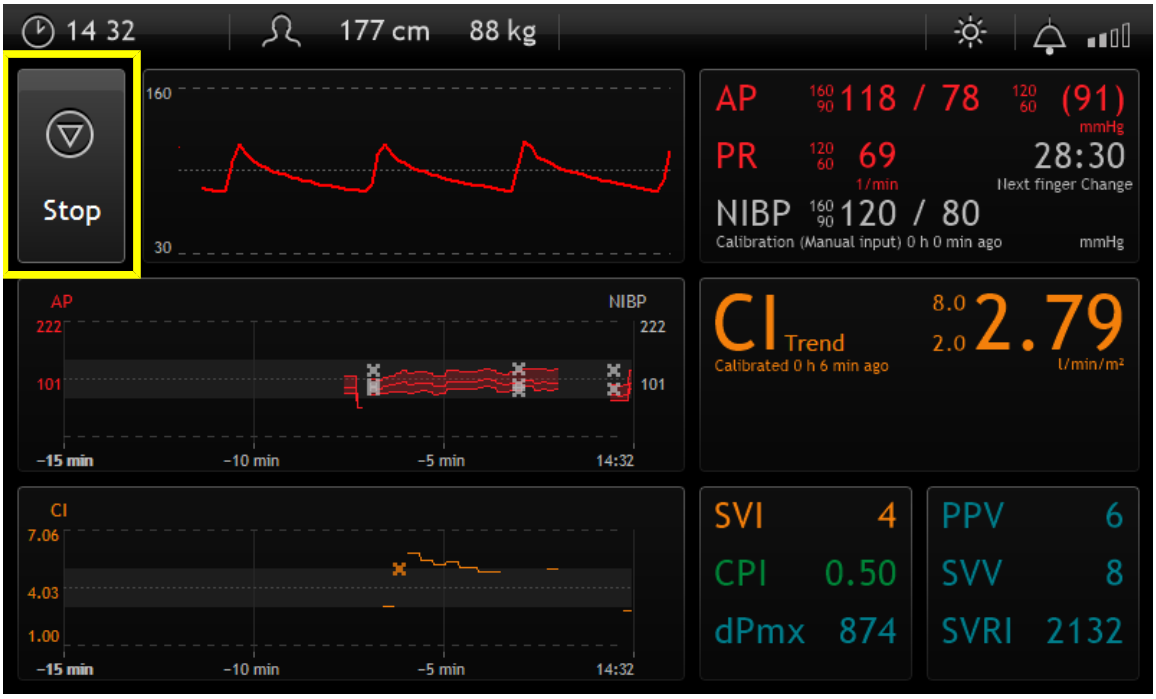


Fig. 10: NICCI measurement via PulsioFlex interface

The measurement is conducted according to the following workflow:

1. Press this button on the upper left side of the screen to start the NICCI measurement. The button will toggle states when pressed.

2. NICCI triggers a calibration phase in which the measured arterial pressure values are calibrated with the available NIBP reference values. For further information refer to chapter NIBP modes for continuous NICCI measurement [⏩ Page 32].
► AP values, that are not calibrated to NIBP reference values, are shown in grey bars.

3. Press the button on the upper left side of the screen to stop an ongoing NICCI measurement.

7.4 Measurement via NICCI Module

Fig. 11: NICCI measurement via NICCI Module buttons

The measurement is conducted according to the following workflow:

 1. Press this button at the top of the NICCI Module to start the NICCI measurement.	2. NICCI triggers a calibration phase in which the measured arterial pressure values are calibrated with the available NIBP reference values. For further information refer to chapter NIBP modes for continuous NICCI measurement [⏩ Page 32].	 3. Press this button at the top of the NICCI Module to stop the ongoing NICCI measurement.

The buttons on the GUI and the NICCI Module can be used interchangeably.

8 NIBP measurement modes

One of the following NIBP modes (NICCI BP Settings subscreen [⏩ Page 41]) can be used to measure the blood pressure:

- NICCI NIBP (default mode)
- Manual input
- NIBP only (e.g. in case the NICCI Sensor is defective)

If applicable, for routine BP measurement in case of condition hypertension, please consider the following:

- adjust the pressure reduction rate;
- patient position: the patient is comfortably seated, the feet are flat on the floor, the legs not crossed, back and arm supported;
- the middle of the cuff is at the same level as the right atrium of the heart;

  during the measurement the patient should try to relax and avoid speaking and other body movement;

  prior to the first measurement a resting phase of at least 5 minutes is recommended;

  take the comfortable position to conduct the measurement.

WARNING!

Ensure proper fit and positioning of the NICCI NIBP Cuff and NICCI Finger Sensor and make sure that the measurement is not impaired by movement artefacts especially before, during, and initially after NIBP measurement. In case the displayed parameters are not plausible, check the setup and repeat NIBP calibration.

8.1 NIBP modes for continuous NICCI measurement

The following NIBP modes determine the source for the required NIBP reference value to conduct the NICCI measurement via NICCI Sensor:

- NICCI NIBP (default mode)
- Manual input

► Every finger change triggers a NIBP reference value measurement. System-controlled measurements are triggered based on the set time intervals. Extension of the recalibration interval might affect measurement results.

8.1.1 NICCI NIBP

In the NIBP mode ‘NICCI NIBP’ the non-invasive blood pressure is measured from the patient’s upper arm through the NICCI Upper Arm Cuff. The NICCI NIBP measurement is either controlled automatically by the system or it can be triggered manually. In both cases the NIBP and Finger Change pop-up screen is opened (NIBP and Finger Change screen [⏩ Page 41]).

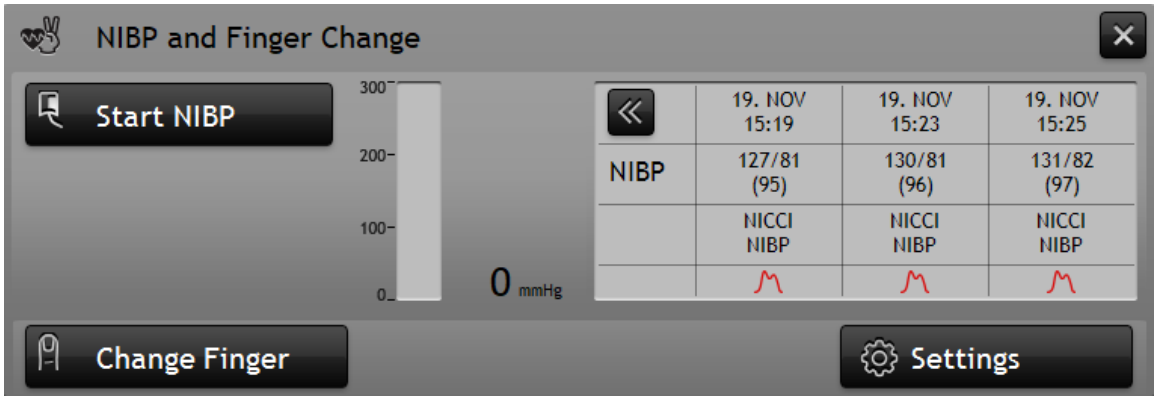


Fig. 12: NIBP and Finger Change - NICCI NIBP

System triggered measurement:

When the patient setup is completed, the system-controlled measurement of the NIBP reference value starts automatically by starting the NICCI measurement.

User triggered measurement:

Alternatively, the NIBP measurement can be triggered manually in two ways:

1. via buttons in the NIBP and Finger Change screen of the PulsioFlex; or
2. via the control button on the top of the NICCI Module.

Start/stop NICCI NIBP measurement:

Start NIBP or  1. Press this button to start the NIBP measurement.	2. The ongoing NIBP measurement is visualized by a cuff pressure bar. After a successful NIBP measurement the NIBP values are shown and the user can confirm or cancel the AP calibration to the measured NIBP reference value (see chapter NICCI NIBP [▸▸ Page 32]). By pressing the Yes button the measured NIBP values are stored as new reference value for the continuous NICCI measurement. By pressing the No button the measured NIBP values are discarded and will not be taken as new reference values.	Stop NIBP or  3. Press this button to stop the ongoing NIBP measurement. The NIBP measurement is stopped immediately. If available, former NIBP values remain valid as reference values for the continuous NICCI measurement.

8.1.2 Manual NIBP input

When the NIBP mode ‘Manual input’ is selected, the NIBP values from external sources, e.g. from a NIBP arm cuff which is not part of the NICCI or from other patient monitors, can be manually entered. The entered NIBP values are stored as reference values for continuous NICCI measurement by pressing the ✓ Calibrate button or can be discarded by pressing the ✕ Cancel button.

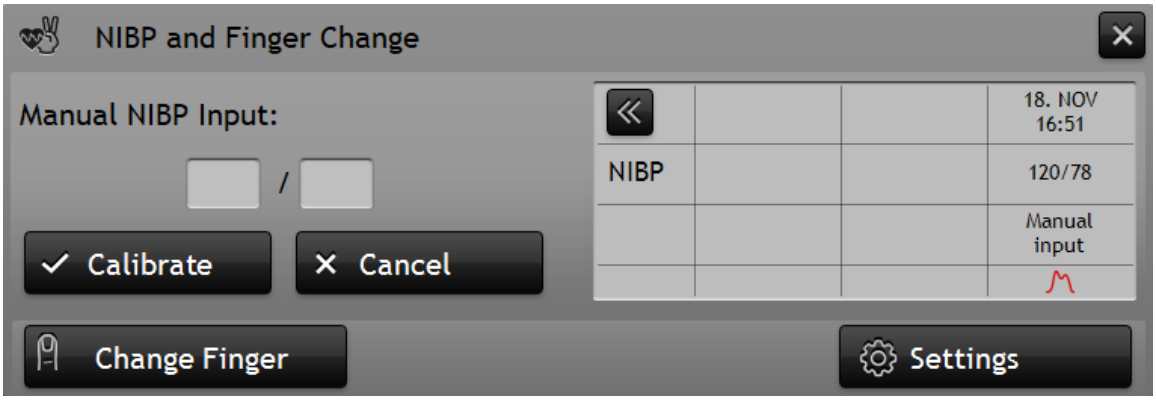


Fig. 13: NIBP and Finger Change - Manual NIBP input

8.2 NIBP only measurement

The ‘NIBP only’ mode is mainly intended for short term interventions in case of emergency situations or disturbed peripheral blood circulation. In this case only NIBP values are measured via NICCI Upper Arm Cuff, the continuous blood pressure measurement with NICCI Sensor is deactivated.
The activation of the ‘NIBP only’ leads to the changes in the interface of PulsioFlex.

Fig. 14: NIBP only measurement - PulsioFlex interface

► To reactivate the NICCI measurement, select ‘NICCI NIBP’ or ‘Manual input’ NIBP mode in the NICCI BP Settings subscreen (see chapter NICCI BP Settings subscreen [⏩ Page 41]).

The NIBP only measurement is either controlled automatically by the system or it can be triggered manually. In both cases the NIBP and Finger Change pop-up screen is opened (NIBP and Finger Change screen [⏩ Page 41]). The ongoing NIBP measurement is visualized by a cuff pressure bar.

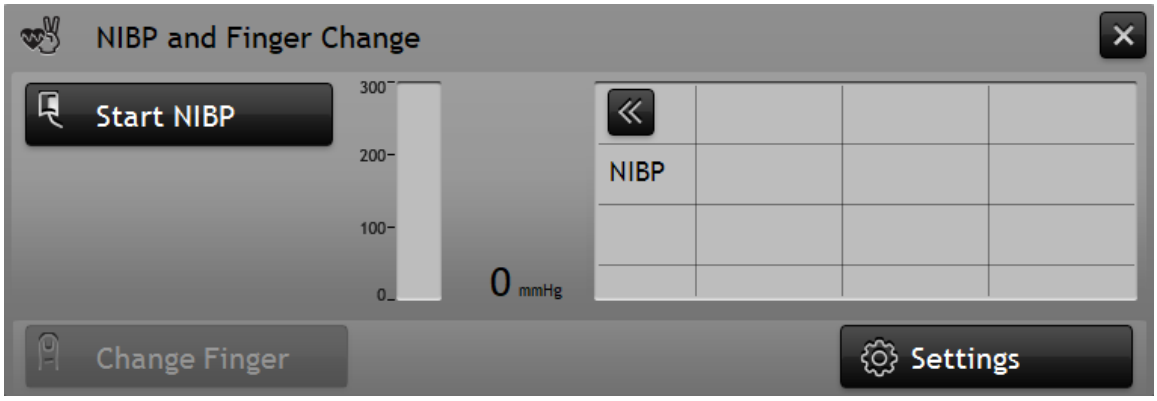


Fig. 15: NIBP and Finger Change - NIBP only

System triggered measurement:

When the NIBP mode ‘NIBP only’ is selected, the measurement via NICCI Upper Arm Cuff starts automatically with the selected NIBP interval (see options in NICCI BP Settings subscreen [⏩ Page 41]).

User triggered measurement:

Alternatively, the NIBP measurement can be triggered manually via the 

button in the NIBP and Finger Change screen or via the hardkey  on the NICCI Module.

9 End of treatment

To dismount NICCI, make sure the ongoing NICCI or NIBP measurement is stopped.

1. Use lever on distal end of the NICCI Mouse, lift the lever and remove the NICCI Sensor by pulling it upwards simultaneously.

2. Remove NICCI Upper Arm Cuff from the patient arm.

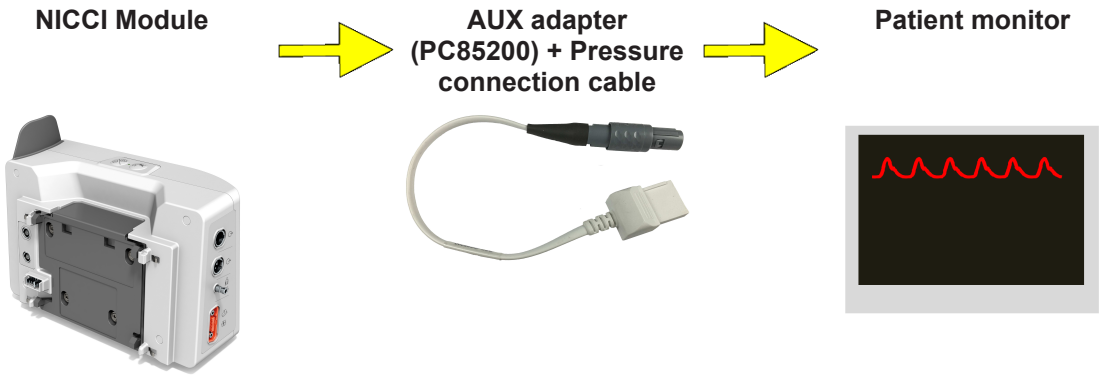
3. To dismount the NICCI Module remove all cables and connectors first.

4. Unlock the NICCI Module from the PulsioFlex by pushing the release button on the top of the module and gently remove the module in a horizontal direction from the monitor. Turn the plug protection back (see chapter Attachment of the NICCI Module to the PulsioFlex Monitor [⏩ Page 24]).

Tab. 8: Detachment of NICCI Sensor

10 NICCI additional configuration: transmission of blood pressure values to patient monitor

The NICCI Module provides the AUX port (see chapter NICCI Module [⏩ Page 19]) to transfer the continuous measured blood pressure values to bedside patient monitors. To prepare the transfer of the measured arterial pressure (AP) the optional AUX adapter (PC85200) is used to connect the AUX port of the NICCI Module to the pressure input channel of a bedside monitor. A pressure connection cable specifically fitting to the respective bedside monitor is required. To start the transfer of the pressure waveform, zeroing of the pressure input channel and adjustment of an appropriate pressure label on the bedside monitor is required. For further details refer to chapter Zero AP Out to Patient Monitor subscreen [⏩ Page 40].



11 NICCI graphical user interface: elements and options

► NICCI can be operated with help of the touch screen buttons or the functional hardware key on the PulsioFlex. If further information about these screen elements or types of visualization is needed, please refer to the **PulsioFlex operator's manual**.

11.1 Real time pressure curve

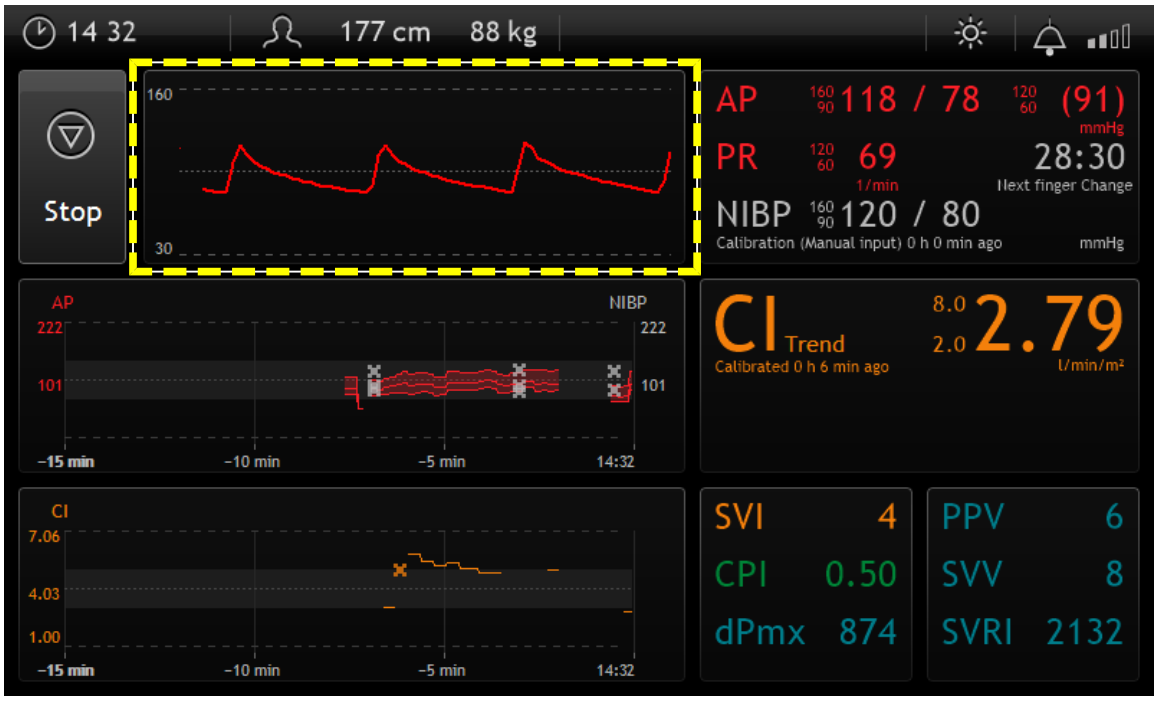


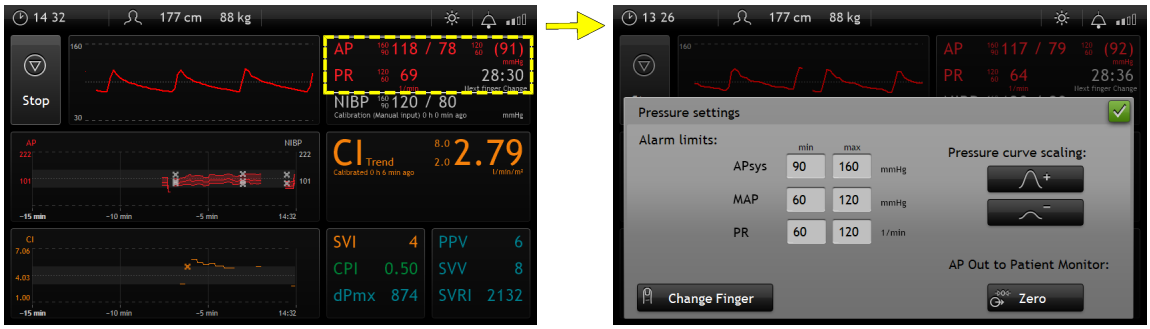
Fig. 16: Real time curve of arterial pressure

Arterial pressure is continuously displayed as a pressure curve. Pressing the curve on the touch screen leads directly to the Pressure settings screen (see chapter Pressure settings screen [⏩ Page 39]).

11.2 Parameter fields

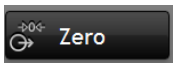
11.2.1 Pressure settings screen

Touching the numeric values field for pulse rate, systolic and diastolic pressure opens the **Pressure settings screen**.

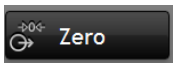


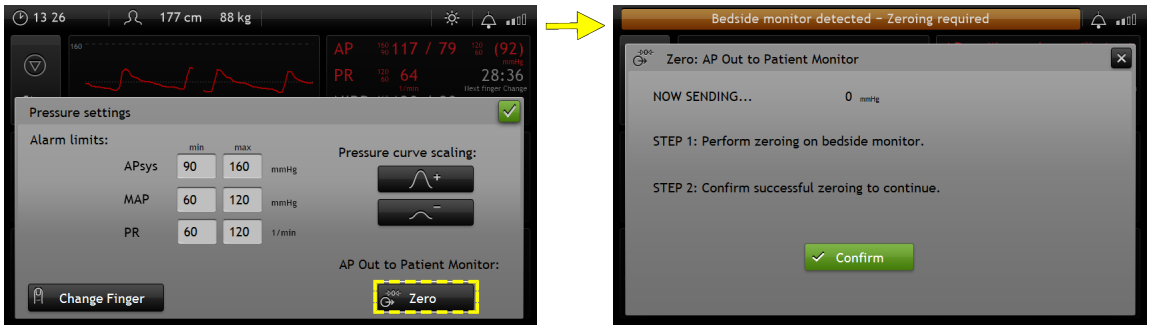
Tab. 9: Selection of pressure settings screen

The following options are available on this screen:

Alarm limits	Pressure curve scaling 	AP Output to patient monitor 	
Fields to set the alarm limits for: ▪ APsys ▪ MAP ▪ PR For further details refer to chapter Parameter alarm limits [⏩ Page 47].	Buttons to scale the AP pressure curve.	Button to open zeroing screen for pressure transfer to a patient bedside monitor. For further details refer to chapter Zero AP Out to Patient Monitor subscreen [⏩ Page 40].	Button to trigger a change between the fingers being measured with the NICCI Sensor.

11.2.1.1 Zero AP Out to Patient Monitor subscreen

The  button opens the **AP Out to patient monitor screen** which provides a stepwise instruction to zero a connected bedside patient monitor.



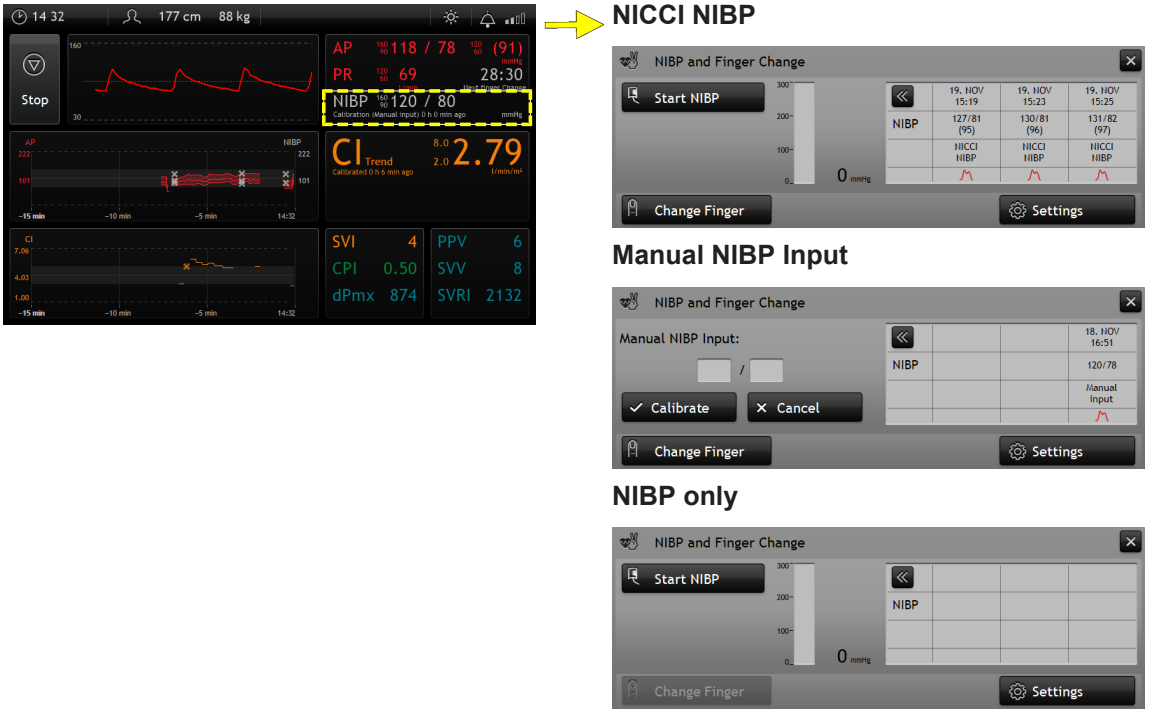
Tab. 10: Zeroing of a patient monitor

The PulsioFlex automatically sends the pressure value of 0mmHg to the patient monitor when the AP Out to bedside patient monitor screen is opened. Please follow the steps on the screen to complete the zeroing. In order to confirm and complete the zeroing, press the  button on the PulsioFlex Monitor.

Make sure to select an appropriate label for the respective pressure input channel of the bedside monitor to avoid wrong interpretation of the non-invasive continuous arterial pressure from NICCI e.g. as an invasive arterial pressure value.

11.2.2 NIBP and Finger Change screen

Touching the NIBP value in the pressure parameter field, opens the **NIBP and Finger Change screen**. This screen adapts its content to the selected NIBP mode, allows to trigger the a NIBP measurement and to review the measured NIBP reference values (see chapter NIBP measurement modes [⏩ Page 32]).



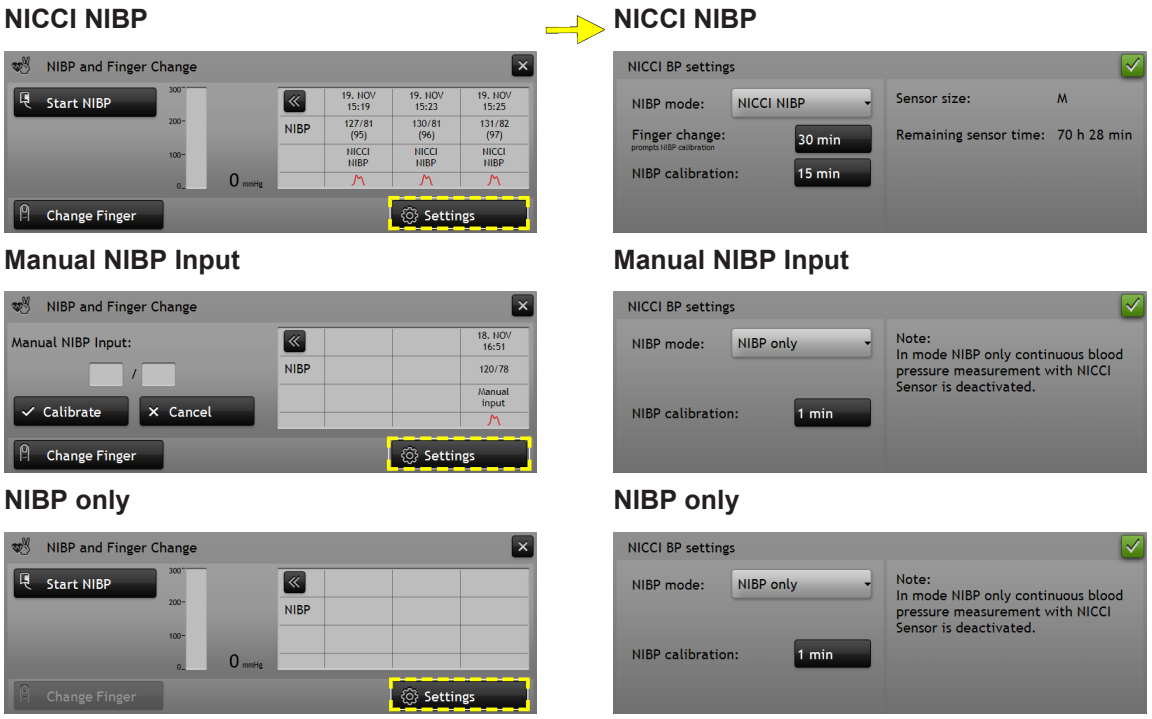
Tab. 11: Selection of NIBP and Finger Change screen

The following options are available in this screen:

Change Finger	Settings	NIBP values
Button to trigger the change between the fingers being measured with the NICCI Sensor.	Button to open the NICCI BP Settings (see chapter NICCI BP Settings subscreen [⏩ Page 41]).	Button to extend the NIBP history. ► The waveform icon in the table is shown if the measured arterial pressure is calibrated with the available NIBP reference values.

11.2.2.1 NICCI BP Settings subscreen

Selecting the Settings button in the **NIBP and Finger Change screen** opens the **NICCI BP Settings**. The settings screen adapts its content to the selected NIBP mode and finger sensor status.



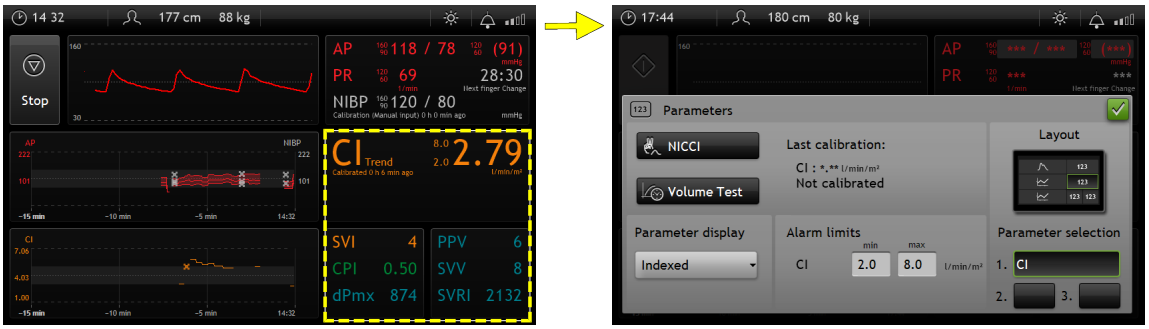
Tab. 12: Selection of NICCI BP Settings

The following options are available on this screen:

NIBP mode:	Drop down menu to switch between available NIBP modes: ▪ NICCI NIBP ▪ Manual input ▪ NIBP only Default setting: NICCI NIBP
Finger change:	Button to switch the time interval for finger changes of the NICCI Sensor: 5 min, 10 min, 15 min, 20 min, 30 min, 60 min Default setting: 30 min
NIBP calibration: (NICCI NIBP)	Button to switch the time interval for automatic NIBP calibration in NICCI NIBP Mode: 5 min, 10 min, 15 min, 20 min, 30 min, 60 min Default setting: 10 min
NIBP calibration: (NIBP only)	Button to switch the time interval for automatic NIBP calibration in NIBP only mode: 1 min, 2 min, 3 min, 4 min Default setting: 1 min
Sensor status:	Information field about the NICCI Sensor status: ▪ Sensor size ▪ Remaining sensor time

11.2.3 Parameters screen

Touching one of the parameter fields opens the **Parameters** screen.



Tab. 13: Selection of parameters screen

The following options are available in this screen:

NICCI	Parameter display	Alarm limits	Layout	Parameter selection	Volume test
Button to open the CO/CI Calibration screen. For further details refer to chapter CO/CI calibration subscreen [⏩ Page 43].	Drop down menu to switch the parameter: ▪ Indexed ▪ Absolute	Fields to set the alarm limits for the selected parameter. ► Available only if the touched parameter field contains the parameter with the alarm limits. For further details refer to chapter Parameter alarm limits [⏩ Page 47].	Button to open the layout selection.	Three buttons to open parameter picklists to select the displayed parameters.	Button to open the volume test selection screen.

► If further information about the volume test is needed, please refer to the **PulsioFlex operator's manual.**

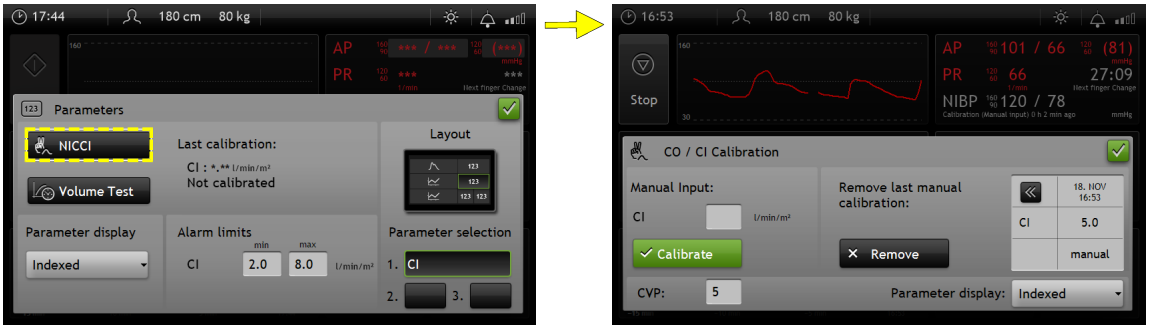
11.2.3.1 CO/CI calibration subscreen

The NICCI uses two approaches to determine the initial start-value for the CO/CI: automatic and manual.

The automatic approach generates a start-value using the arterial blood pressure and patient data. Once the value is calculated, CO/CI_{Trend} is displayed in the parameter field. The automatically-generated value for cardiac output (CO/CI_{Trend}) can only be regarded as an estimate and might not accurately represent the patient's current clinical situation.

The manual CO/CI calibration allows to enter the CO/CI strart-value derived from another hemodynamic monitoring technology. If the calibration is performed manually, CO_{Cal} is displayed in the parameter field. In general calibration of the cardiac output trend is necessary when starting to monitor a patient and when there have been considerable changes to the condition of the patient's or treatment.

Selecting the  button opens the **CO/CI Calibration screen** where the CO/CI calibration can be triggered. The screen also allows to review the calibration reference values used for CO/CI calibrations.



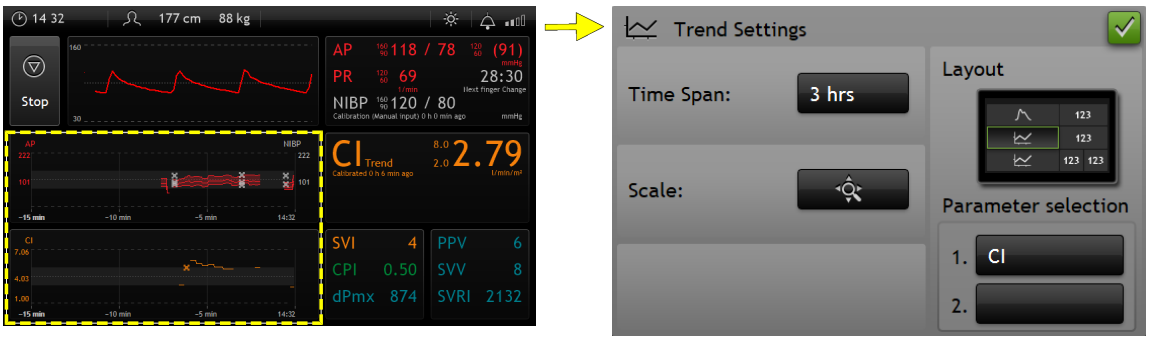
Tab. 14: Selection of CO/CI calibration screen

The following options are available in this screen:

CO/CI input field	✓ Calibrate	✕ Remove	CVP	Parameter display	Calibration results
Input field to enter the CO/CI reference value derived from another haemodynamic monitoring technology.	Button to confirm the calibration value.	Button to remove the last manual calibration.	Input field to enter the CVP reference value. Default setting: 7mmHg	Drop down menu to switch the displayed parameter values: ▪ Indexed ▪ Absolute	Button to expand the calibration history table.

11.3 Trend curves screen

The displayed trend curve can be moved with two fingers. Touching the trend curve opens the Trend screen.



Tab. 15: Selection of Trend Settings screen

The following options are available on this screen:

Time span	Scale	Layout	Parameter selection
Button to select the time span of trend display (15 min/30 min/1 hrs/3 hrs/6 hrs/12 hrs/24 hrs/2 days/3 days/6 days/12 days)	Button to scale the trend curve.	Button to select the layout.	Button to open the parameter picklists to select displayed parameters in the trend screens.

12 NICCI Module markings & functions

12.1 Control buttons

The NICCI Module provides access to the technology's two main functions through buttons (hard keys) located directly on the module.

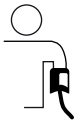
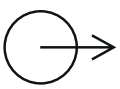
	This button could be used to start/stop the NICCI measurement.	For further information refer to chapter Measurement via NICCI Module [⏩ Page 31]
	This button could be used to manually trigger the NIBP measurement by the NICCI Upper Arm Cuff.	For further information refer to chapter NICCI NIBP [⏩ Page 32]

12.2 LED status lights

The status lights on the NICCI Module could display the following status:

	Flashing green	Power on / start-up
	Constant, but interrupted green	Stand-by / ready for the measurement
	Constant green	Other states (e.g. measurement ongoing)

12.3 Connector markings

	NICCI Mouse connection
	NIBP connection
	AUX port connection to transfer the continuous pressure signal to the bedside monitor

13 Alarms and messages

► This manual describes the messages which can be caused by the NICCI only. The alarm condition types, categorization of priorities, conditions of visual and auditory signals, other information needed to handle alarms and messages on the PulsioFlex is disclosed within the **PulsioFlex operator‘s manual**.

13.1 Parameter alarms

Message on PulsioFlex	Cause / Origin of alarm	Remedy	Category*	Type**
High NIBPm	NIBPm > alarm limit	Active until parameter is in alarm range	1	P
Low NIBPm	NIBPm < alarm limit	Active until parameter is in alarm range	1	P
High NIBPsys	NIBPsys > alarm limit	Active until parameter is in alarm range	1	P
Low NIBPsys	NIBPsys < alarm limit	Active until parameter is in alarm range	1	P
High PR	PR > alarm limit	Active until parameter is in alarm range	1	P
Low PR	PR < alarm limit	Active until parameter is in alarm range	1	P
High CO	CO > alarm limit	Active until parameter is in alarm range	1	P
Low CO	CO < alarm limit	Active until parameter is in alarm range	1	P
High CI	CI > alarm limit	Active until parameter is in alarm range	1	P
Low CI	CI < alarm limit	Active until parameter is in alarm range	1	P

Tab. 16: Parameter alarms

* Alarm category: 1 = high, 2 = medium, 3 = low, 4 = information signal

** Alarm type: G = General, P = Physiological, T = Technical

13.2 Parameter alarm limits

Parameter alarm	Factory default "min"	Factory default "max"
APsys	90	160
MAP	60	120
PR	60	120
CI	2	8
CO	Calculated and if no height and weight BSA = 1.7	Calculated and if no height and weight BSA = 1.7

Parameter alarm	Factory default "min"	Factory default "max"
NIBPsys	No input, value is the same as APsys alarm limit (min)	No input, value is the same as APsys alarm limit (max)
NIBPm	No input, value is the same as MAP alarm limit (min)	No input, value is the same as MAP alarm limit (max)

Tab. 17: Parameter alarm limits

13.3 Technical alarms

Message on PulsioFlex	Cause / Origin of alarm	Remedy	Category*	Type**
AP not calibrated - NIBP required	AP calibration necessary - Perform NIBP measurement	Provide NIBP reference value by measuring or manual input.	1	T
Communication error - Reconnect NICCI Sensor.	Internal communication error	1. Reconnect NICCI Sensor. 2. Replace NICCI Sensor if error persists. 3. Replace NICCI Module if problem persists.	1	T
Connected sensor not compatible with NICCI System	Invalid Finger Cuff	Replace NICCI Sensor.	3	T
Hardware error - Reconnect NICCI Mouse.	Problem with hardware of NICCI Mouse (e.g. power supply low)	1. Reconnect NICCI Mouse. 2. Replace NICCI Mouse if problem persists. 3. Replace NICCI Module if problem persists.	1	T
Insufficient Light Transmission - Check/ Clean NICCI Sensor	Not enough light for measurement	1. Clean light connection surface of NICCI Sensor and NICCI Mouse. 2. Replace NICCI Sensor if problem persists. 3. Replace NICCI Mouse if problem persists.	3	T
Internal communication error - Reconnect NICCI Module.	Internal communication or hardware error	1. Reconnect NICCI Module. 2. Replace NICCI Module if problem persists.	1	T
Internal error - Reconnect NICCI Module	Internal error (e.g. communication or hardware failure)	1. Reconnect NICCI Module. 2. Replace NICCI Module if problem persists.	3	T
Internal error - Reconnect NICCI Mouse.	Internal communication error	1. Reconnect NICCI Mouse. 2. Replace NICCI Mouse if problem persists.	1	T

Message on PulsioFlex	Cause / Origin of alarm	Remedy	Category*	Type**
Low signal in NICCI finger cuff – Check perfusion	1. Low finger perfusion 2. Blood pressure is out of physiological measurement range	1. Check patient for low peripheral blood flow. 2. If possible enhance finger perfusion 3. Check sensor size 4. Check fitting of NICCI sensor cuff 5. Change measurement site (other pair of fingers, other hand)	1	T
Internal error - Reconnect NICCI Sensor.	Problem during self test or NICCI measurement.	1. Remove NICCI Sensor, check pneumatic connection and reconnect. 2. Replace NICCI Sensor if problem persists.	1	T
Internal Error - Update Required. Please contact service.	PulsioFlex configuration needs update	Update PulsioFlex Software.	1	T
Internal NIBP error - Leakage detected	Leakage detected during service test procedure	Check all NIBP components and connections	3	T
Internal NIBP error - Reconnect NICCI Module. If error remains replace NICCI Module.	Internal error with NIBP components	Reconnect NICCI Module. If error remains replace NICCI Module.	1	T
Leakage detected - Replace NICCI Sensor	Leakage detected in one of the finger cuffs	1. Remove sensor, check pneumatic connection and reconnect. 2. Replace sensor if problem persists.	1	T
Measurement stopped due to mains power interruption – Restart measurement	Mains power supply was interrupted	Check cables and mains power connection and restart device	1	T
Module communication error - Reconnect NICCI Module	Internal communication or hardware error	1. Reconnect NICCI Module. 2. Replace NICCI Module if problem persists.	2	T
NIBP communication error	Internal communication failure	Reconnect NICCI Module.	3	T
NIBP error - Check upper arm cuff and repeat measurement.	Problem with NIBP measurement (e.g. too strong movement, pressure range exceeded, air leakage)	Check fit and connection of upper arm cuff and repeat measurement. If error remains, exchange upper arm cuff or enter NIBP values manually.	3	T

Message on PulsioFlex	Cause / Origin of alarm	Remedy	Category*	Type**
NIBP Software - Update required. Please contact service.	Incompatible software version of NIBP component	Request service technician to perform software updates.	2	T
NIBPdia out of measuring range	NIBPdia parameter value out of rated measuring range	Active until parameter value is in rated measuring range	1	T
NIBPm out of measuring range	NIBPm parameter value out of rated measuring range	Active until parameter value is in rated measuring range	1	T
NIBPsys out of measuring range	NIBPsys parameter value out of rated measuring range	Active until parameter value is in rated measuring range	1	T
NICCI Module – Update required. Please contact service.	Software version of NICCI Module is not compatible	Update NICCI Module software	1	T
NICCI Module disconnected - Check and confirm	NICCI Module was disconnected	1. Reconnect NICCI Module. 2. Replace NICCI Module if problem persists.	3	T
NICCI Module Error - Check buttons.	Problem with buttons on NICCI Module	1. Check button in NICCI Module and reconnect module. 2. If no obvious problem exists, replace NICCI Module.	3	T
NICCI Mouse disconnected - Check and confirm	NICCI Mouse was disconnected	1. Reconnect NICCI Mouse. 2. Replace NICCI Mouse if problem persists. 3. Replace NICCI Module if problem persists.	3	T
NICCI Sensor disconnected - Check and confirm	NICCI Sensor disconnected	1. Check NICCI Sensor connection. 2. Replace NICCI Sensor if problem persists.	3	T
NICCI Sensor too large - Change sensor size	NICCI Sensor too large for current patient	1. Remove NICCI Sensor, check fit of finger cuff and reconnect sensor. 2. Replace NICCI Sensor if problem persists.	1	T
NICCI Sensor too small - Change sensor size	NICCI Sensor too small for current patient	1. Remove NICCI Sensor, check fit of finger cuff and reconnect sensor. 2. Replace NICCI Sensor if problem persists.	1	T

Message on PulsioFlex	Cause / Origin of alarm	Remedy	Category*	Type**
NICCI System – Update required. Please contact service.	Incompatible software versions detected	Request service technician to perform software updates.	1	T
Pressure error - Remove patients hand and disconnect NICCI Mouse!	Pressure error (e.g. pressure in finger cuff too high)	1. Remove patients hand from NICCI Sensor. 2. Remove NICCI Sensor and Mouse, check pneumatic connections and reconnect. 3. Replace NICCI Mouse if problem persists.	1	T
Start of NICCI measurement failed - Restart measurement. If error remains reconnect NICCI Mouse.	NICCI measurement could not be started	1. Restart measurement. 2. Reconnect NICCI Mouse if error persists.	3	T
Temperature error - Reconnect NICCI Module.	Overtemperature in NICCI Module detected	1. Disconnect NICCI Module to cool down internal temperature. 2. Replace NICCI Module if problem persists.	1	T
Temperature error - Remove patients hand and disconnect NICCI Mouse!	Temperature error in NICCI Mouse detected	1. Remove patient fingers from NICCI Sensor. 2. Disconnect NICCI Mouse to cool down internal temperature. 3. Replace NICCI Mouse if problem persists.	1	T
Too much ambient light - Check NICCI Sensor fit	Too much ambient light	1. Reduce ambient light 2. Check fitting of NICCI Sensor cuff. 2. Replace sensor if error persists.	3	T
No USB device detected	No USB storage device available for performance data recording	Connect USB storage device	3	T
External data carrier full	Connected USB storage device has not enough space left for performance data recording	Delete data on data carrier or use different storage device	3	T

Tab. 18: Technical alarms

* Alarm category: 1 = high, 2 = medium, 3 = low, 4 = information signal

** Alarm type: G = General, P = Physiological, T = Technical

13.4 Physiological alarms

Message on PulsioFlex	Cause / Origin of alarm	Remedy	Category*	Type**
Finger change failed - Measurement time on one finger exceeds 30min. Check finger perfusion.	Finger change failed; finger measurement on finger exceeded 30min	1. Check finger perfusion 2. depending on 1: Change measurement site (other pair of fingers, other hand)	3	P
Finger change failed - Measurement time on one finger exceeds 60min. Check finger perfusion, change measurement site and resume measurement.	Finger change failed; finger measurement on one finger exceeded 60min	1. Check finger perfusion 2. depending on 1: Change measurement site (other pair of fingers, other hand)	1	P
CO / CI calibration error - Check pressure and retry	CO / CI calibratiion not possible	Check arterial pressure signal and try to calibrate CO/ CI again.	3	P
CO/CI calibration not possible - Perform NIBP calibration	CO/CI calibration requires calibrated pressure values.	Perform NIBP calibration (measurement or manual input).	4	P
NIBP measurement temporarily not available (redo in max. 30sec)	NIBP is temporarely blocked (max. 30 sec.)	Wait for 30 seconds and redo action.	3	P
PR / AP not available - Please check	Pressure and pulse parameters were invalid too long	1. Check fit of finger cuff and restart measurement. 2. Perform NIBP measurement if problem persists. 3. Replace NICCI Sensor if problem persists.	1	P

Tab. 19: Physiological alarms

* Alarm category: 1 = high, 2 = medium, 3 = low, 4 = information signal

** Alarm type: G = General, P = Physiological, T = Technical

13.5 General alarms

Message on PulsioFlex	Cause / Origin of alarm	Remedy	Category*	Type**
Bedside monitor detected - Zeroing required	A bedside monitor was connected to the NICCI Modul, but zeroing was not performed yet.	Perform AUX Zeroing process	3	G
Calibration removed	Manual NIBP calibration was removed.	No action required.	4	G

Message on PulsioFlex	Cause / Origin of alarm	Remedy	Category*	Type**
Calibration successful	CO/CI calibration was successful.	No action required.	4	G
NIBP interval has been adapted automatically	NIBP interval was adapted due to changed Finger Change interval.	No action required.	4	G
NICCI measurement was started 24 hours ago. Change hand on which NICCI is applied after 24 hours.	24 hours application time have passed. After this period change of application site is recommended.	Change application site of NICCI Mouse and Sensor to the other side (hand).	4	G
NICCI Sensor activated	NICCI Sensor was activated	No action required.	4	G
NICCI Sensor already activated - Replace sensor to change patient data.	Change of patient data not allowed when NICCI Sensor was activated	Replace NICCI Sensor or keep current patient data.	3	G
NICCI Sensor connected	NICCI Sensor was connected.	No action required.	4	G
NICCI Sensor error - No finger in cuff	No fingers detected in NICCI Sensor	1. Put patient fingers in NICCI Sensor. 2. Reconnect NICCI Mouse if problem persists. 3. Replace NICCI Mouse if problem persists.	3	G
NICCI Sensor expired - Exchange sensor	Shelf life of NICCI Sensor is exceeded	Replace NICCI Sensor.	3	G
Operating time exceeded - Exchange NICCI Sensor	Allowed operating time of NICCI Sensor is exceeded	Replace NICCI Sensor.	3	G
Patient data transferred	Patient data successfully transferred from NICCI Sensor to PulsioFlex	No action required.	4	G
Remaining sensor time: xx h xx min - Exchange NICCI Sensor in time	Allowed operating time of NICCI Sensor is exceeded	No action required.	4	G
Sensor error - Activate sensor	NICCI measurement only allowed with activated NICCI Sensor	1. Activate NICCI Sensor. 2. Replace NICCI Sensor if problem persists.	4	G

Tab. 20: General alarms

* Alarm category: 1 = high, 2 = medium, 3 = low, 4 = information signal

** Alarm type: G = General, P = Physiological, T = Technical

14 Cleaning & disinfection

Ther following NICCI components are resistant against disinfection and cleaning agents:

- NICCI Module
- NICCI Mouse
- NICCI Upper Arm Cuff

For cleaning and disinfecting the components and its accessories only PULSION approved substances and methods shall be used. PULSION makes no claims regarding the efficacy of the listed chemicals or methods as the means of controlling infection. Please consult your hospital's Infection Control Officer or Epidemiologist.

In order to clean the components and its accessories use a lint-free cloth, moist with warm water (max. 40° C), and soap, diluted non-caustic detergents, tensides or detergents containing ammonia or alcohol. Do not use strong solvents like dimethylketone or trichloroethylene. The devices shall be cleaned before disinfection.

Recommended cleaning and disinfection agents:

- alcohol based;
- aldehydes based.

Do only use recommended cleaning and disinfection agents, any other agents may lead to surface damage of device or accessories.

15 Disposal

The NICCI components (NICCI Module and NICCI Mouse) are subjects of 2012/19/EU Directive, which aims to separate the collection, reuse, recovery and recycling of waste from electrical and electronic equipment at the end of the products' lifecycles. These recommendations do not supersede the local regulations. Dispose the NICCI Sensor and NICCI Upper Arm Cuff at the end of the products' lifecycles in accordance with respective national regulations.

16 Service & maintenance

PULSION recommends to check the NICCI on a daily basis concerning the following:

- check the whole system (components, applicable cables, accessories, connectors, etc.) for any mechanical damages;
- check NFC tag on the NICCI Sensor for any mechanical damages or scratches;
- check all functions necessary for the patient monitoring.

Installation, calibration, safety tests, repairs and modifications:

- shall be performed by PULSION trained personnel or PULSION Technical Service;
- shall be performed every 2 years.

For telephone inquiries relating to service, technical support, accessories or other matters contact PULSION Medical Systems SE or your local sales representative.

17 Appendix - Accessories & detachable components

Related to NICCI component	Accessory or detachable component	Article number
NICCI Module	AUX adapter	PC85200
n/a	PulsioFlex operator’s manual	PC406*

Tab. 21: NICCI accessories & detachable components

* plus two digit language code according to ISO 639-1

18 Appendix - Technical data & essential performance

General	
Mode of operation	Continuous
Equipment class	II b
Recovery time after exposure to defibrillation voltage	The recovery time after defibrillation shall not exceed 10 s after transient electromagnetic phenomena. When the NICCI Module and attachments has been used together with HF surgical equipment it shall return to the previous operating mode within recovery time after exposure without loss of any operator settings or stored data.
Essential performance	Maximum error is less than or equal to ±3 mmHg.

Environmental conditions	
Temperature	Operation: 0° – 35°C Transport & storage: -20° - 60°C (ISTA test for 72 hours)
Relative humidity	Operation: up to 85%, non-condensing Transport & storage: up to 90%, non-condensing (ISTA test for 72 hours)
Atmospheric pressure	Operation: down to 700 hPa Transport & storage: 700 – 1060 hPa (ISTA test for 72 hours)

Tab. 22: Technical data - all NICCI components

NICCI Module	
Size (W x H x D)	218 x 156.2 x 96.5 mm
Weight	912 g
IP class	IP31

Tab. 23: Technical data - NICCI Module

NICCI Mouse & Sensor	
Size Mouse (W x H x D)	~ 65.8 x 102.2 x 41.6 mm
Weight Mouse with cable	~ 280 g
Size Sensor (W x H x D)	Size S: ~ 128 x 69 x 64 mm Size M: ~ 136 x 75 x 63 mm Size L: ~ 142 x 79 x 73 mm
Weight Sensor	Size S: ~ 34 g Size M: ~40 g Size L: ~45 g
Protection against electric shock	Applied part type BF (defibrillation-proof)

NICCI Mouse & Sensor	
IP class	IP31
Range of the cuff pressure	0-280 mmHg

Tab. 24: Technical data - NICCI Mouse & Sensor

NICCI Upper Arm Cuff*	
Size (W x H)	Size S: ~ 410 x 115 mm Size M: ~ 520 x 140 mm Size L: ~ 610 x 170 mm Size XL: ~ 610 x 170 mm
Weight	Size S: 60 g Size M: 80 g Size L: 105 g Size XL: 105 g
Protection against electric shock	Applied part type BF (defibrillation-proof)
Rated measurement range	20-250 mmHg (for min./max. ranges of each parameter see chapter Parameters and ranges of normal values [⏩ Page 21])
Range of the cuff pressure	0-300 mmHg

Tab. 25: Technical data - NICCI Upper Arm Cuff

*Clinically investigated according to the requirements of ISO 81060-2:2013

19 Appendix - Electromagnetic compatibility

According to IEC60601-1-2 the NICCI can be used at “professional healthcare facility environment”. The NICCI is tested for HF surgical equipment compatibility.

Guidance and manufacturer’s declaration – electromagnetic emissions		
The NICCI is intended for use in the electromagnetic environment specified below. The customer or the user of the NICCI should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The NICCI uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The NICCI is suitable for use in all establishments other than domestic and those directly connected to the public low -voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

Tab. 26: Guidance and manufacturer’s declaration - electromagnetic emissions

Guidance and manufacturer's declaration - electromagnetic immunity			
The NICCI is intended for use in the electromagnetic environment specified below. The customer or the user of the NICCI should assure that it is used in such an environment.			
Immunity test	**IEC 60601-1-2 test level for professional healthcare facility environment**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact discharge ± 15 kV air	± 4 kV contact discharge ± 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV 100 kHz repetition frequency ± 1 kV 100 kHz repetition frequency for signal input/output lines	In compliance with the standard	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	Line-to-line: ± 0,5 kV, ±1 kV Line-to-ground: ± 0,5 kV, ±1 kV, ± 2 kV	In compliance with the standard	Mains power quality should be that of a typical commercial or hospital environment.

Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% UT; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315°	In compliance with the standard	Mains power quality should be that of a typical commercial or hospital environment. If the user of the NICCI requires continued operation during power mains interruptions, it is recommended that the NICCI be powered from an uninterruptible power supply or a battery.
	0 % UT; 1 cycle and 70 % UT;25/30 cycles Single phase: at 0°	In compliance with the standard	
	0 % UT 250/300 cycles	In compliance with the standard	
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m 50 Hz or 60 Hz	In compliance with the standard	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE	U_T is the A.C. mains voltage prior to application of the test level.		

Tab. 27: Guidance and manufacturer's declaration - electromagnetic immunity

Guidance and manufacturer's declaration - electromagnetic immunity			
The NICCI is intended for use in the electromagnetic environment specified below. The customer or the user of the NICCI should assure that it is used in such an environment.			
Immunity test	**IEC 60601-1-2 test level for professional healthcare facility environment**	**Compliance level**	**Electromagnetic environment - guidance**
			Portable and mobile RF communications equipment should be used no closer to any part of NICCI, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance:**
Conducted RF IEC 61000-4-6	3 V 0,15 MHz - 80 MHz 6 V in ISM bands between 0,15 MHz and 80 MHz 80 % AM at 2 kHz	In compliance with the standard	d = 1.17 1/V * √P

Radiated RF IEC 61000-4-3	3 V/m 80 MHz - 2,7 GHz 80 % AM at 2 kHz	In compliance with the standard	d = 1.17 m/V * √P for 80 MHz to 800 MHz d = 2,33 m/V * √P for 800 MHz to 2,5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strength from fixed RF transmitters, as determined by an electromagnetic site survey, a should be less than the compliance level in each frequency range b Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE 1	At 80 MHz and 800 MHz, the separation distance for the higher frequency applies.		
NOTE 2	These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection of structures, objects and people.		
	a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the NICCI is used exceeds the applicable RF compliance level above, the NICCI should be observed to verify normal operation. If abnormal performance is observed, 10additional measures may be necessary, such as reorienting or relocating the NICCI.		
	b Over the frequency range 150 kHz to 80 MHz, field strength should be less than 3 V/m.		

Tab. 28: Guidance and manufacturer’s declaration – electromagnetic immunity

Test frequency (MHz)	Band [a] (MHz)	Service [a]	Modulation [b]	Maximum Power (W)	Distance (m)	IMMUNITY TEST LEVEL (V/m)
385	380 - 390	TETRA 400	Pulse Modulation [b] 18 Hz	1,8	0,3	27
450	430 - 470	GMRS 460, FRS 460	FM [c] ±5 kHz Deviation 1 kHz sine	2	0,3	28
710	704 - 787	LTE Band 13, 17	Pulse Modulation [b] 217 Hz	0,2	0,3	9
745						
780						
810	800 - 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse Modulation [b] 18 Hz	2	0,3	28
870						
930						
1720	1700 -1990	GSM 1800, CDMA 1900, GSM 1900, DECT, LTE Band 1, 3, 4, 25, UMTS	Pulse Modulation [b] 217 Hz	2	0,3	28
1845						
1970						
2450	2400 -2570	Bluetooth, WLAN, 802.11b/g/n, RFID 2450, LTE Band 7	Pulse Modulation [b] 217 Hz	2	0,3	28
5240	5100 - 5800	WLAN 802.11 a/n	Pulse Modulation [b] 217 Hz	2	0,3	9
5500						
5785						
NOTE:	If necessary to achieve the IMMUNITY test level, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.					
	[a] For some services, only the uplink frequencies are included. [b] The carrier shall be modulated using 50 % duty cycle square wave signal [c] As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.					

Tab. 29: Test specifications for enclosure port immunity to RF wireless communications equipment

20 Appendix - Technical specifications - Near Field Communication

The NICCI uses Near Field Communication (NFC) technology to enable communication between the NICCI Mouse and NICCI Sensor without having an electrical connection.

This device complies with part 15 of the Federal Communications Commission (FCC) Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

Note: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the NICCI Mouse, which integrates the receiving antenna.
- Increase the separation between the equipment and the NICCI Mouse.
- Consult an experienced technician for help.

Functional description

NFC is an international transmission standard for the wireless exchange of data over the short distances. During operation of NICCI, the following data is exchanged between the NICCI Mouse and the NICCI Sensor:

NICCI Mouse with radio frequency module	**↔communicates with↔**	**NICCI Sensor with NFC tag**
NICCI Mouse reads only:	▪ interface version ▪ sensor type ▪ restricted lifetime (shelf life) ▪ max. time since first use ▪ max. allowed effective measuring time ▪ maximum amount of patients ▪ maximum allowed patient data modifications ▪ manufacturing date ▪ lot number	
NICCI Mouse writes and reads:	▪ patient information: patient ID, bed number, patient surname, patient first name, day of birth ▪ anthropometry data: gender / category, age, height, weight, HD calibration info ▪ NICCI Sensor usage information: measuring time since first use, current number of patients, current patient data modifications, date of first use, current date of use	

Technical description

In general, a radio frequency module is (usually) a small electronic device used to transmit and receive the radio signals between two devices. The radio frequency module is a part of NICCI Mouse printed circuit board. It contains the NFC reader chip with an integrated antenna, which sends and receives the data from a transponder.

When powered on and operating, the radio frequency module has two operating states:

1. The NICCI Sensor with its NFC tag is in the reading distance. The communication between NICCI Mouse and NICCI Sensor is possible.
2. The NICCI Sensor with its NFC tag is not in the reading distance. The communication between NICCI Mouse and NICCI Sensor is not possible.

The user cannot change the wireless communication specification such as operating mode, power level or bandwidth.

Radio frequency module	
NFC reader chip	NXP CLRC663
NFC tag	NXP ICODE DNA (Type V)
Reading / writing mode	supports ISO/IEC 15693
Reading distance	less than 22 mm (measured from the NICCI Mouse surface)
Operating frequency	13.56 MHz
Operating mode	▪ operating ▪ power off (no standby mode)
Power output (max.)	1.5 Watt

Tab. 30: Technical data - Radio frequency module

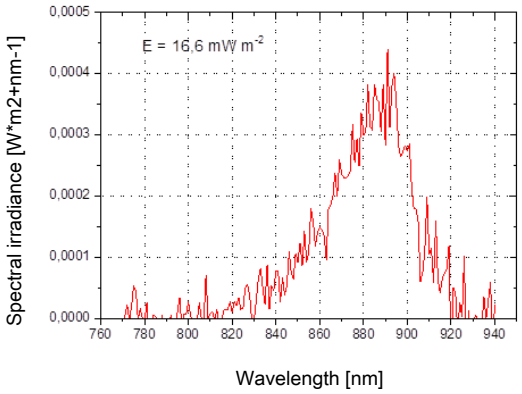
Restriction of data access

The data stored on the NFC tag is separated into different memory areas in order to restrict access to the violent data via third party devices (e.g. mobile phones):

1. NICCI Sensor information is stored on the NFC tag, is read-only and cannot be changed.
2. Patient information is given through the manual input by the user. In order to read or change the patient data, the radio frequency module inside of the NICCI Mouse uses an authentication key to encode the encrypted patient data on the NFC tag.

21 Appendix - Technical specifications - Light source equipment

NICCI Mouse LED	
Output of optical radiation (max.)	890nm
Variation of output	2,13 W/cm2 (peak) 0,34 W/cm2 (average)
Pulse duration	0.18ms
Pulse interval	0.98ms

LED spectral irradiance	Location of light emission aperture
	

Tab. 31: Technical data - NICCI Mouse LED

22 Symbols

	Equipment Type BF, protected against defibrillation
	Separate disposal of electrical and electronic equipment
	Manufacturer
	Date of manufacture
REF	Catalogue number
SN	Serial number
LOT	Batch code
CE 0123	CE mark
	Humidity limitation
	Temperature limit
	Atmospheric pressure limitation
	Follow instructions for use
	MR unsafe
	Do not re-use
	Use-by date
SGS	NRTL (SGS) certification for electrical safety
MD	Medical device
℞ only	Caution: Federal (US) law restricts this device to sale by or on the order of a physician

Tab. 32: Symbols

Notes

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