PURPOSE

This document is the master of instructions for use for NICCI technology.

SCOPE

n/a

REFERENCES

Ref	Doc ID	Version	Document Title
[1]	LAB-000194	04	NICCI System instructions for use set-up and design specification
[2]	SDS-000056	06*[2]	CNAP - Alarms & Messages
[3]	REQ-000036	05	PR00678 Default Parameter
[4]	SDS-000062	01*[1]	UI Integration Manual - User Interaction Specifications

*[1] The IFU contents are according to Polarion baseline 23.07.2019.

*[2] Every message is listed only once in the IFU (despite the different error codes).

CHANGE HISTORY

Version	Edit Date	Description	Issuer	Reference to the project (DCC, DCP)
01	28 May 2019	First release	I. Sichna	VIENNA
02	27 July 2019	1. Update of 'Alarms and messages' according to SDS-000056-05. 2. Changes in the SW description: • Explanation of grey bars in the pressure parameter field; • Addition of the term 'CO calibration' to the index; • Explanation of the curve icon in the NIBP history table. • Format improvements in chapter 'D2 NICCI Sensor activation'. • Changes in the description of 'NIBP only' mode (chapter new 'E2 NIBP only measurement') 3. Minor wording/pictures improvements in the chapter 'Setup&start'. 4. Updates according to LAB-000194-02: • chapter A1-3 (impact of RAC-000498-06). • chapter B3 (impact of REQ-000065-08 and REQ-000036-05) • chapter A4-6: transfer of new/removing/update of warnings/cautions/notes • appendix O (addition of rated range of the sensor cuffs pressure 0-280 mmHg)	I. Sichna	VIENNA

03	13 Aug. 2019	1. Minor wording/pictures improvements in the chapter 'Setup&start'. 2. Appendix O: addition of rated measurement range (20-250mmHg). 3. Update of 'Alarms and messages' according to SDS-000056-06.	I. Sichna	VIENNA
04	5 Sept. 2019	1. Chapter K: update according to LAB-000194-03 (update of cleaning and disinfection agents, impact of REQ-000065-09).	I. Sichna	VIENNA
05	18 Sept. 2019	1. Table 15 (electromagnetic immunity): update of ESD test level and ESD compliance level	I. Sichna	VIENNA
06	17 Dec. 2019	1. Addition of the placeholder for IFU unique identifier on the last page.	I. Sichna	VIENNA
07	27 Jan. 2020	1. Chapter P: update according to LAB-000194-04 (ESD test level and ESD compliance level). 2. Chapter O: update of the weight of the NICCI Upper Arm Cuff.	I. Sichna	DCC-19-062 DCC-19-089

NICCI Technology

Operator's Manual

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NICCI components

Table 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 Sensor*** Connected to the NICCI Mouse	NICCI Sensor S, single use NICCI Sensor M, single use NICCI Sensor L, single use	PV6550 PV6551 PV6552

*Not made with Natural Rubber Latex

NICCI compatibility:

PulsioFlex PC4000 equipped with the software version 6.0 or higher.

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

⚠	This icon 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. Additionaly, the **WARNING** is generally used as the signal word.

⚠	This icon indicates a hazardous situation that, if not avoided, could result in minor or moderate injury. Additionaly, the **CAUTION** is generally used as the signal word.

☞	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 **NOTE** 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.

Contents

Q 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 electrical connection.

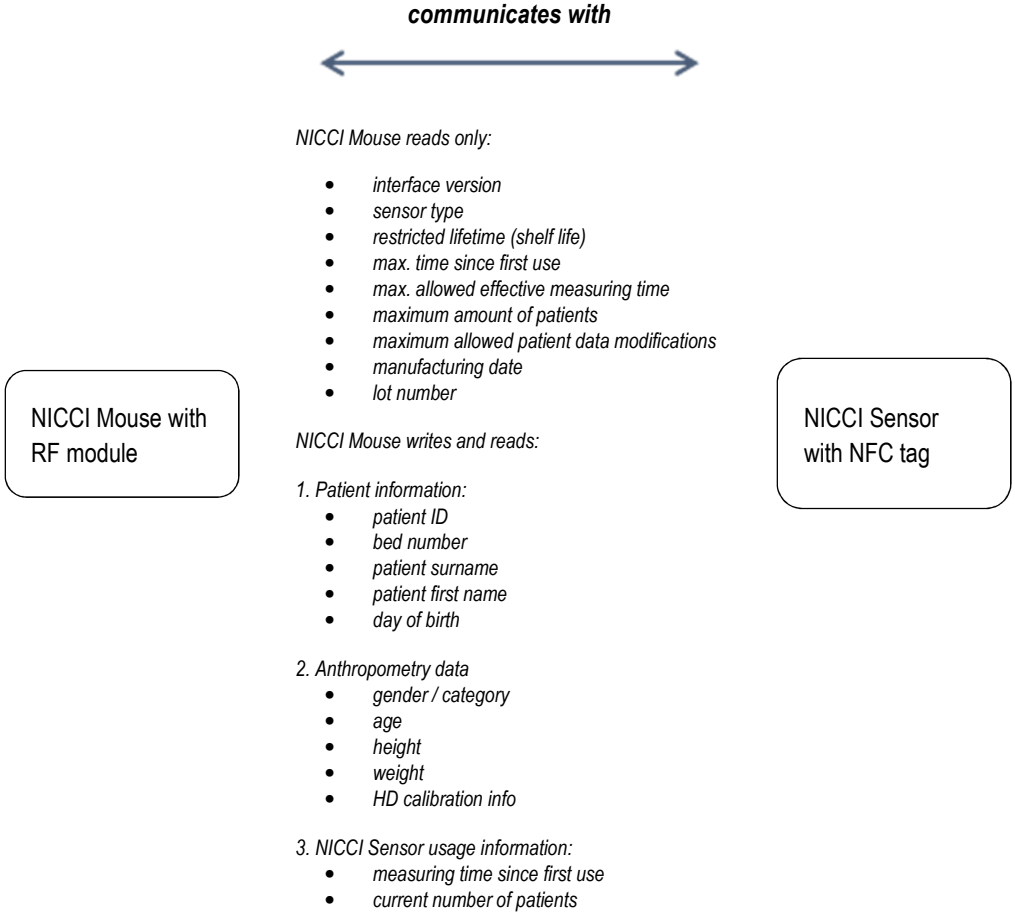
This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation'.

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 the NICCI, the following data is exchanged between the NICCI Mouse and the NICCI Sensor:



- *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 send and receive 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.

Table 18 – Technical data - Radio frequency module

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

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.

R Appendix - Technical specifications - Light source equipment

Table 19 – Technical data - NICCI Mouse LED

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

Information

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