LEYCOM® Inca
User manual V1926.13
Issue date: Juni 2020

The Intra Cardiac Analyser system, Leycom Inca® is manufactured, marketed and supported by:

CD Leycom
Asveldweg 2
7556 BP Hengelo
The Netherlands
Tel : +31 (0) 117 307 388
Email: info@cdleycom.com

DISCLAIMER

CD Leycom makes no warranties with respect to the contents or use of this manual, and specifically disclaims any express or implied warranties of merchantability or fitness for any particular purpose. Furthermore, CD Leycom reserves the right to revise this publication and to make changes to this content, at any time, without obligation to notify any person or entity of such revisions or changes.

TRADEMARKS

LEYCOM® Inca® is a registered trademark of CD Leycom, a registered tradename of CardioDynamics BV.

WARNINGS

The Inca and the Inca PV Loop System cannot be used as vital functions monitor

The Inca accepts 100-240VAC, 50/60Hz as power input.

To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth.

Keep the Inca away from high capacity transformers, electric motors and other devices which may create strong electromagnetic fields.

Data recorded during usage of electro-surgical or defibrillation equipment usage should not be used for diagnostics. The device is defibrillator proof for safety. Measurement recovery is not guaranteed.

Please be advised that this medical equipment complies with the requirements of the applicable EMC-standards. Electronic equipment exceeding the radiation limits defined in the EMC-standards may affect the working of our equipment.

Use of other cables and accessories than specified in this manual may negatively affect EMC performance. Only use cables and accessories as specified in this manual.

Any equipment connected to the Inca must comply with relevant environment safety regulations. The Inca should not be used for safety isolation for other devices.

Only CD Leycom conductance catheters are permitted to be used with the Inca.

All CD Leycom Conductance catheters are for single use and are not to be reused. Before using a catheter, always check the expiration date on the catheter package and the sterilisation mark on the inner pouch.

The Inca PC and all components connected to the PC should always be conform the local restrictions where the system is used.

WARNING: No modification of this equipment is allowed.

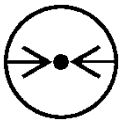
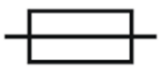
☑ Important

This manual is intended for end-users.
An employee of CD Leycom will perform the initial installation, training and testing of the Inca.
He/she will give you instructions to familiarize you with the Inca.
See installation and testing, chapter 4.1.

Contra-indications

Use of a conductance catheter is contraindicated in the case where the introduction of a catheter would constitute an unacceptable risk to the patient. For full information about contraindications, warnings, and adverse reactions to the conductance catheter, you are strongly recommended to read the manufacturer's instructions for use for catheters.

Symbols on Inca

	Defibrillation-proof type CF applied part complying with IEC 60601-1. Note 1 - C = Cardiac. Note 2 - F = Floating applied part.
	Power symbol. Indicates that a module is powered on.
	LAN or Ethernet symbol. Note 1 - LAN = Local Area Network.
	Pressure measurement symbol. To signify the measurement of pressure.
	Fuse symbol. Indicates the value and number of fuses that are used in the equipment.
	Serial Number Indicates the manufacturer's serial number so that a specific medical device can be identified.

	Warning.
	CE marked device. 0344: Registered Notified Body: DEKRA, The Netherlands
	Follow instructions for use Read the instructions in this operation manual carefully before using the Inca, and read the safety instructions before setting up or using this device.
	Manufacturer symbol. The name and address of the manufacturer are noted near this symbol.
	WEEE symbol: Separate this device from other household-like waste and send it to collection facilities for recovery and recycling.

Table of Contents

1. Introduction

Cardiac performance is mainly determined by five factors: preload, afterload, inotropic state, intra-ventricular dyssynchrony and heart rate. Traditional indices such as ejection fraction (EF) or cardiac output (CO) are, to some extent, dependent on all these factors. Therefore, a change in EF or CO may be due to a change in intrinsic myocardial factors, intra-ventricular dyssynchrony or external factors such as loading conditions. In contrast, analysis of pressure-volume relations provides relative load-independent measures of the contractile state (e.g. the end-systolic pressure-volume relation) enabling accurate quantification of cardiac function. However, intra-ventricular dyssynchrony may independently affect cardiac performance.

The Inca aims to further facilitate the quantitative assessment of cardiac function in the clinical routine setting at the cardiology laboratory, cardiac surgery operating room, cardiology intensive care unit, and cardiac hybrid laboratory. The Inca uses the pressure-volume catheter technique to measure ventricular volume and pressure in real-time. The Inca software greatly facilitates optimal catheter placement and calibration. In addition, the Inca software provides all features required for real-time display, storage and analysis of pressure, volume and intra-ventricular dyssynchrony measures.

1.1 The Volume catheter method

The volume catheter method to determine ventricular volume (both total and segmental volumes) is based on measurement of the electrical conductance of the blood in a ventricular cavity. The method has been evaluated extensively in both heart ventricles, and the following brief description is based on measurements from the left ventricle. Studies to investigate the possibility and accuracy of the conductance catheter method to measure right ventricular and single ventricle volumes have been performed as well. The unique feature of this method is that it provides a continuous, real-time of ventricular volume. Below a brief description of the method is given.

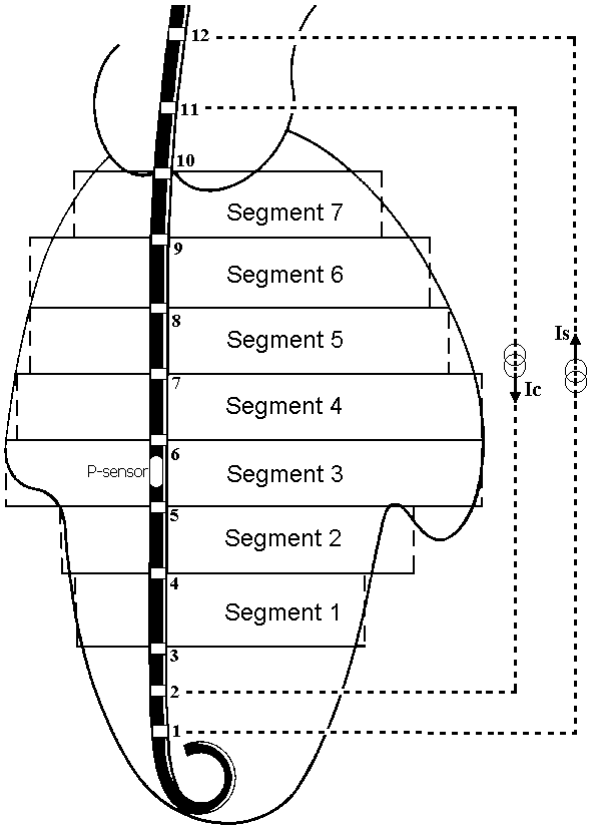


Figure 1.1 Catheter

1.1.1 Principle

To measure left ventricular volume, a 12-electrode volume catheter is introduced into the left ventricle and positioned along the long axis of the ventricle. A small electric field is generated via the two most distal electrodes, positioned in the apex, and two proximal electrodes, close to the aortic valve. Segmental electrical conductivity is measured continuously by the remaining electrodes. The measured conductivity present can be converted to calibrated volume signals by taking into account the inter-electrode spacing, the conductance of structures outside the

cavity (see ejection fraction and 'parallel conductance' below) and a cardiac output calibration factor (see below). The Inca also provides segmental PV loops.

1.1.2 Ejection Fraction and Parallel Conductance

Absolute values of ejection fraction (EF) can be determined by measuring conductance by injecting a bolus of hypertonic saline in the pulmonary artery to induce a transient change in blood conductivity. The Inca software calculates parallel conductance, and consequently absolute EF, from the volume signal registered during the passage of hypertonic saline through the left ventricle, due to the hypertonic saline's increased conductivity than that of blood.

1.1.3 Absolute Cardiac Output

After determining absolute ejection fraction for the correction of parallel conductance, the volume measured by the conductance catheter is directly proportional to actual ventricular volume. However, generally the volume catheter method may underestimate or overestimate true volume by a fixed percentage, which may vary between patients. To correct for this, stroke volume measured by the conductance catheter should be matched to stroke volume by some independent method (e.g. thermodilution, Fick method, Echo, MRI). The accuracy of the reference method determines the accuracy of the final, absolute volumes as measured by the volume catheter.

1.2 Measuring Pressure

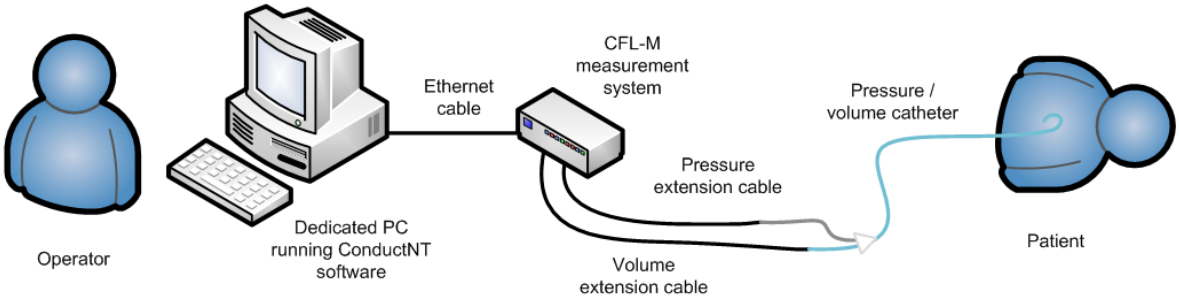
The Inca comprises a dedicated module to measure high-fidelity pressure from the solid-state sensor of the CD Leycom pressure-volume catheter. The pressure signal will be automatically calibrated within 15 seconds after connecting the pressure arm of CD Leycom's pressure-volume catheter with the pressure module of the Inca.

2. Inca Description

2.1 System description

The 'Inca PV Loop System' offers a simple, safe and effective method for the real-time, operator independent acquisition and analysis of pressure and volume data directly from a cardiac ventricle. Inca PV Loop System (IPVLS) consists of:

- CFL-M
- Conductance catheter
- Conduct NT software installed on the dedicated computer



Note: All the equipment used by the Inca PV Loop System will be supplied by CD Leycom.

An intra-ventricular catheter with an array of conductance electrodes and a high fidelity solid-state pressure sensor is placed in the ventricle over a guide wire. The catheter is connected to the CFL-M acquiring real-time pressure and volume data from up to 7 segments (volume slices perpendicular to the long-axis) in the ventricle.

From the data, time varying changes in intra-ventricular pressure and volume can be monitored on-line on a connected PC running specific software (Conduct NT). Common indices of cardiac performance (SV, Ees, PRSW, +dP/dt, -dP/dt, Tau, etc) are shown, as well as indices of ventricular mechanical dyssynchrony derived from the volume slices.

For the operating instructions of the CFL-M and Conduct NT, the user should refer to the respective Instruction for Use.

2.2 Cardiac Function Laboratory - Modular

Currently, three models of CFL-M measuring system are available:

- **Inca**
- Sigma 5 DF Plus
- Sigma M

Only the Inca model will be discussed in the remainder of this document.

The Inca was developed to facilitate the on-line measurement and analysis of ventricular pressure-volume-dyssynchrony in the clinical routine setting. The pressure and volume signals are obtained using intra-cardiac catheters. The Inca allows the user to measure, display and analyze the signals continuously and in real-time. The data is digitized and stored on a hard disk, which can subsequently be retrieved and analysed. The operator controls the Inca through menu-driven software that must be installed on a personal computer, ideally dedicated to the Inca only.

For the acquisition of ventricular volume data, the Inca uses the volume catheter method. The CD Leycom volume catheter method employs a multi-electrode catheter positioned in a cardiac ventricle to measure the intra-ventricular electrical conductance (figure 2.4). These signals are converted to continuous volume signals and displayed on screen. Real-time dyssynchrony values are calculated from the segmental volume signals. Ventricular pressure is measured using a solid-state pressure sensor that is mounted on the same catheter.

The Inca system is comprised of a power source, a volume module, a pressure amplifier module and an analog-in module.

The Inca is not intended to function as a patient's vital functions monitor, though it can be used as a diagnostic or interventional procedure tool in combination with a standard vital functions monitor. The Inca is not intended to provide functionality that could result in unacceptable risk to the patient upon degradation or absence of that functionality (essential performance). Pressure data derived from a vital functions monitor should always be used to verify pressure data provided by the Inca. The volume measurements provided by the Inca are relative volumes which should be calibrated by other techniques. Volume data from ECHO or MRI techniques should always be used to verify volume data delivered by the Inca.

2.2.1 **Intended use**

The CD Leycom "Cardiac Function Laboratory - Modular (CFL-M)" equipment (Inca) is intended to be used as a modular measurement setup for the measurement of parameters used for the quantitative diagnostic assessment of the cardiac function in patients.

2.2.2 **Intended users**

The Inca user and/or operator must be a health care professional with the relevant medical background, skills and training to operate this device. A clinician trained in delivering cardiac

catheters, would be sufficiently able to position the conductance catheter. A technician or a trained nurse under supervision of a clinician can operate the Inca; this would include setting up the system and initializing measurements. Medical knowledge of pressure-volume loops is a prerequisite for clinician to operate Inca to its full capacity.

2.2.3 **Essential performance**

Inca does not have an essential performance as defined by IEC 60601-1 international standard.

2.2.4 **Clinical benefits**

The clear and peer reviewed routine clinical and clinical research capabilities of CD Leycom's intra-ventricular pressure-volume analysis technique outweighs the apparently small chance on a clinical complication by using this analysis technique. The numerous publications showing new insights in cardiac diseases and its therapeutics, which could hardly be achieved by other techniques, testifies of added value of using this technique for the cardiac patients.

2.3 Main Features

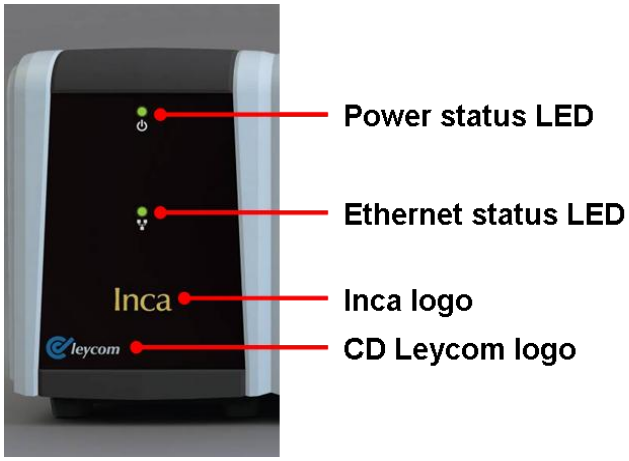
2.3.1 System Configuration

The Inca is a modular system. The picture on page 2-1 shows a system consisting of a Power & Communication module, an Analog-In module, a Volume module and a Pressure module. Depending on the user's needs, the configuration can be extended with multiple modules. The following chapters briefly describe the different module types.

LED's are only an additional help for the operator to view the state of activity of the modules but contain no measurement information. Green LED's indicate an active state of the module concerning the related function.

2.3.2 Power & Communication Module

This module comprises the power source and main Inca processor. It is connected to the PC by an Ethernet-port at the back allowing for fast data transfer. The upper LED indicates power status; when the LED is off the system power is off, a changing colour from yellow to green light indicates warming-up, green light indicates ready for use. A green lower LED indicates an active connection with the Conduct-NT PC. A system can only comprise 1 Power & Communication module.

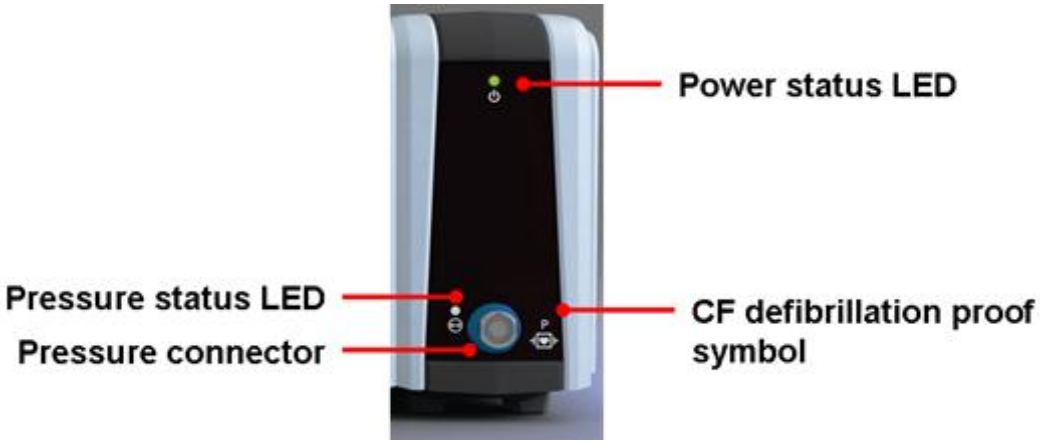


2.3.3 Volume Module

This module interfaces with the volume arm of CD Leycom's pressure-volume catheter by means of a Lemo connector attached to the volume extension cable of the CD Leycom catheter. The upper LED indicates power status; when the LED is off the module is not turned on by the software, when the light is yellow the module is recognized by the software and when green the LED indicates that the module is active in live data. The middle LED indicates single (I) or double (II) electrical field stimulation when the lights are green, lights off indicate no active measurements. The seven numbered LED's indicate the segmental volumes in use when lighted green, lights off indicate no active measurements. In addition to volume measurements, this module also measures the intra-cardiac ECG on one or two of the segments indicated by the yellow light. This module has a

defibrillator-proof cardiac floating input. There can be up to 2 Volume modules in a system. Only certified CD Leycom pressure-volume catheters can be used.

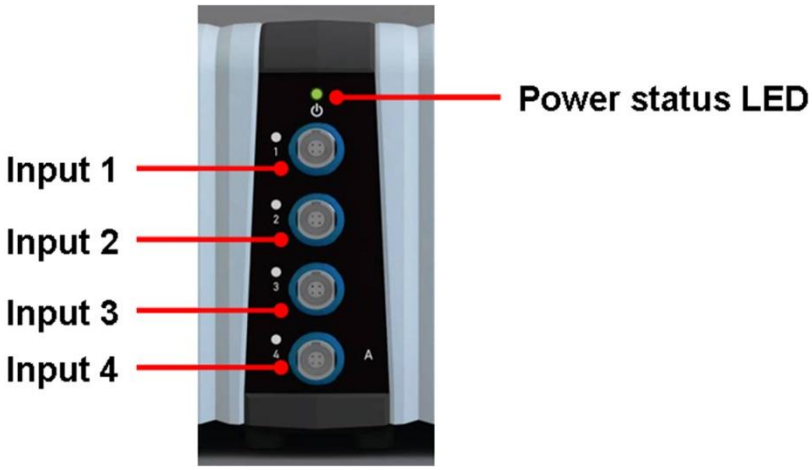
2.3.4 **Pressure Module**



This module interfaces with the pressure sensor on CD Leycom's pressure-volume catheter by a dedicated Lemo connector affixed to the pressure extension cable. The upper LED indicates power status; when the LED is off the module is not turned on by the software, when the light is yellow the module is recognized by the software and when green the LED indicates that the module is active in live data. The left lower LED indicates pressure catheter connection with yellow and a working pressure sensor when the light is green after pressure calibration.

The module has a defibrillator-proof cardiac floating input. A system can contain up to 3 Pressure modules. The pressure signal will be calibrated automatically within approximately 15 seconds after connecting the pressure arm of the catheter with the module. Only certified CD Leycom pressure or pressure-volume catheters can be used.

2.3.5 **Analog-In Module**



This module comprises four connections for auxiliary signals. The upper LED indicates power status; when the LED is off the module is not turned on by the software, when the light is yellow the module is recognized by the software and when green the LED indicates that the module is active in live data mode. The LED's beside the connectors will indicate signal connections when the lights are green after calibration of the indicated signal. A system can contain up to 2 Analog-In modules. Only signals from -10 up to +10 Volt from approved medical devices are permitted to be connected. The software provides automated calibration options for external signal inputs.

3. Setting up the Inca

3.1 Preparing the Inca location

Once unpacked and assembled, the Inca is easy to transport to different locations.

The general requirements for the working environment of the Inca are summarised below.

3.1.1 Environment

The Inca is intended to be used in the professional healthcare facility environment.

Place the Inca in a well-ventilated room, with the following conditions:
- Room temperature 10°C to 30°C. (50°F to 86°F).
- Relative humidity 20% to 80% with no condensation.
- Stable environment, no abrupt temperature or humidity changes.

3.1.2 Installation precautions

Please note the following:
- Do not expose to excessive sunlight, chemicals, or vibration.
- Place the Inca always on a flat clean, stable and dry surface.
- The Inca's anti-slip feet ensure that the Inca stays well on the surface, otherwise use another surface or an optional mounting plate.
- Connect the power cord directly into a grounded wall socket.
- Do not make use of multiple portable socket outlets between the Inca and the grounded wall socket.
- Do not place any heavy objects on the power cords. Damage to a cable may cause electric shock or fire.
- Allow adequate ventilation around the Inca so that heat can properly dissipate.
- Keep the Inca away from high capacity transformers, electric motors and other devices that may create strong magnetic fields.
- Portable or mobile RF communications equipment and other RF equipment may affect the functioning of the Inca.

3.2 Check what you need before you start

Listed here are only those items specifically related to the PV measurements. It is assumed that all normal requirements needed for a cardiac catheterization, are fulfilled.

3.2.1 Power socket

The Inca will be delivered on a trolley with one power cable. You need a power socket within 1.5 meter from the trolley.

3.2.2 Computer with Conduct NT

A PC with Conduct NT installed should be on the trolley. Conduct NT is software that is controlling Inca; all relevant data will be displayed on the PC screen. The minimum requirements to run Conduct NT on a separate computer are:
- Pentium 333 MHz
- 128 MB memory

- Microsoft mouse
- Windows 2000 or higher

3.2.3 Connection cables

Volume cable: Used to connect volume-arm of the catheter to the volume module of the Inca; provided by CD Leycom. Please note that this cable is non-sterile and that you need a sterile sleeve to cover the cable.

Pressure cable: Used to connect pressure-arm of the catheter to the pressure module of the Inca; provided by CD Leycom. Please note that this cable is non-sterile and that you need a sterile sleeve to cover the cable.

Auxiliary cable (optional): Used to connect an extra signal to the analog-in module of the Inca (up to four), provided by CD Leycom. Please note that this cable is non-sterile and that you need a sterile sleeve to cover the cable.

3.2.4 Catheters

CD Leycom pressure-volume catheter (single use clinical combination-catheter) are mandatory for use of the Inca. It is not possible nor permitted to use any other type of catheter for pressure-volume measures. Catheters are available with different sizes and electrode spacing's to meet the user's needs. All catheters have 12 electrodes to measure pressure, volume and ECG. The types available are:

CD Leycom Standard Pressure/Volume Dyssynchrony Catheters				
Model	Size	Spacing	Pressure sensor	Pigtail/ lumen
CA-41063-PN	4 Fr	6 mm	between 5 and 6	Yes / No
CA-41103-PN	4 Fr	10 mm	between 5 and 6	Yes / No
CA-71083-PL	7 Fr	8 mm	between 5 and 6	Yes / Yes
CA-71103-PL	7 Fr	10 mm	between 5 and 6	Yes / Yes
CA-71123-PL	7 Fr	12 mm	between 5 and 6	Yes / Yes

CD Leycom provides two single-channel pressure catheters. These catheters can be used to measure the aorta, venous and arterial pressure.

CD Leycom Standard Pressure/Volume Dyssynchrony Catheters				
Model	Size	Spacing	Pressure sensor	Pigtail/ lumen
CA-61000-PL	6 Fr	n.a.	At distal tip	Yes / Yes
CA-61000-PLB	6 Fr	n.a.	At distal tip	Yes / Yes

Please refer to info sheet 'Select the best catheter'. For more information regarding catheters please visit: www.cdleycom.com

In the absolute volume measurement setup, a thermodilution catheter (pulmonary artery catheter or PA catheter) can be used to calibrate cardiac output (CO) by thermodilution and to inject hypertonic saline in the pulmonary artery to assess ejection fraction. Alternatively, hypertonic saline can also be injected in the central venous compartment, and CO determined by any other reference method.

3.2.5 Hypertonic saline

In most studies 5-10 ml of 5-7.5 % hypertonic saline is used, depending on place of injection, cardiac output and patient weight.

3.2.6 Reference method to measure Cardiac Output

The most frequently used cardiac output reference method is thermodilution. Other options are Echo or MRI.

3.3 Activate Inca

Connect mains of the trolley and switch the panel PC to 'on.' After you enter your default password "conductnt", the software Conduct NT will start automatically.

Select 'Create New Study' or choose 'New study' in the 'Study' menu to create a new study or select an existing study.

3.4 Pressure-volume catheter

Before placement of the CD Leycom catheters, please refer to the manufacturer's instructions for use.

The software Conduct NT will recognize that the pressure arm is connected, and an indication bar will appear denoting the pressure calibration process. A zero-signal will appear on the screen when calibration is complete, and the pressure signal will change in colour from red (uncalibrated) to yellow (calibrated). This colour change indicates that the pressure calibration was successful. The catheter is now ready for insertion preferably using an appropriate introducer sheath.

Use fluoroscopy or Echocardiography to position the PV catheter in the left ventricle. Ideally the catheter is placed straight along the long axis of the ventricle with its tip in the apex. Avoid bending of the catheter during contraction and, if necessary, pull back slightly.

Connect the volume-arm of the catheter to the Inca. Check and optimise the (segmental) volume signals. Fixate the pressure-volume catheter.

Now the setup is ready to acquire hemodynamic measurements.

3.5 Stopping Inca

After you finished your hemodynamic measurements, stop live data acquisition. The LED indicators will switch off. Put the switch on the rear panel of the Inca Power and Communication Module in the 'off' position. The power is shut down from the Inca and it can be safely moved to another location.

4. Service

4.1 Inca training

The Inca will be unpacked and assembled on-site by a CD Leycom representative. The user should not attempt to unpack and assemble the equipment themselves.

When an order for the Inca is placed with CD Leycom, a prospective delivery date for the equipment transmitted to the client in the order for confirmation. As this date approaches, the client is contacted again to set a definite delivery date and to make an appointment for the Installation and Training. At the agreed time the client is visited by a representative of CD Leycom to carry out the installation of the Inca and to instruct the user in the use and maintenance of the equipment.

The training involves the following aspects:

- Unpacking and testing the Inca.
- Correct installation and test.
- Demonstration to the user of the features of the Inca, and Inca real-time display, acquisition and analysis software.
- Instruction in how to measure pressure-volume signals, including proper catheter placement, calibration techniques, data acquisition and basic analysis of pressure-volume data.
- Instruction regarding simple cleaning, storage, and maintenance of the Inca.

A copy of the Conduct NT software program is provided on a USB. CD Leycom pre-installed the program Conduct NT onto a separate dedicated PC.

4.2 Inca service & maintenance

The CD Leycom Inca is designed to function reliably, and it meets or exceeds the specifications at the time of sale. Despite the care exercised during design and manufacture, it is impossible to eliminate malfunction due to ordinary wear and tear and random component failure. Accordingly, CD Leycom agrees that when the product is used and maintained in accordance with accompanying instructions it will replace or repair the unit at no additional cost for 3 years following the date of purchase. Maintenance, repair, modifications and calibration of the Inca can only be performed by CD Leycom.

If the unit fails to operate as described in these instructions, contact CD Leycom:

CD Leycom
Asveldweg 2, 7556 BP Hengelo (Ov) The Netherlands.
Tel. : +31 (0)117 307 388
Email : support@cdleycom.com
Website : www.cdleycom.com

CD Leycom's technical team will assist you in determining the cause of a malfunction and attempt to solve the problem. If the problem cannot be corrected easily, CD Leycom will authorise the return of the unit. The customer will receive guidance for proper shipment of the device.

CD Leycom will incur all transportation charges related to repairs during the warranty period. After this period, transportation costs will be charged to the customer.

It is advisable to have CD Leycom perform yearly maintenance and calibration checks on the Inca to ensure safe and proper functioning of the system. To this end the customer can enter into a service agreement with CD Leycom. Please contact CD Leycom for details. However, preventative maintenance on the Inca is not required.

Should the customer decline the offer of entering into a service level agreement, it is recommended that the user have CD Leycom test the system once every 12 months to ensure proper functioning. This system test is in no way a substitute for a full-service check-up, which also involves safety checks and preventive maintenance carried out by a qualified engineer accredited by CD Leycom.

If the user experiences any problems at all with the functioning of the Inca, CD Leycom should be contacted immediately. Never attempt to open or repair any part of the Inca as this may damage the system and endanger patient safety. Attempts to open or repair the Inca will invalidate the warranty if still applicable.

4.2.1 Daily maintenance

To clean the surface of the Inca, use a lint-free, non-abrasive cloth and a neutral based cleaner, non-abrasive cleaning solution for best results. Advised is the use of Johnson & Johnson Baby wipes and Clorex wipes. For disinfection, use 70% Isopropyl Alcohol buffered by 30% distilled water and take care with amount of fluids for connectors of the Inca. It is recommended to include the Inca in the daily cleaning practice at the location where the Inca is functioning; preferably after each patient operation.

In case of accidental wetting the device, it is recommended to immediately power off the Inca, detach the power cable from wall socket, and suspend the cardiac measurements. Then dry and clean the wetted surface with non-abrasive cloth and contact your local technical support contact (i.e. Biomedical Engineering Group) to check the function of the Inca and electrical safety.

If there is any doubt about the functioning of the Inca, always contact CD Leycom direct.

5. Technical details

5.1 Precautions and warnings

The Inca is not a vital functions monitor; should you wish to connect your vital functions monitoring devices to the Inca's analogue in module, please ensure that the patients vital functions are monitored separately from the Inca and the related software display.

Compare the results of the vital functions monitor (i.e. heart rate, blood pressure) with the results from the Inca to exclude diagnosis based on wrong data. Compare the volume measurements results of ECHO or MRI measurements with the volume data provided by the Inca in case absolute values are necessary for diagnosis.

The Inca was not designed as a vital monitor, consequently Inca does not incorporate meant to protect the patient against burns in case when used with High Frequencey equipment in case of defect or missing neutral electrode (grounding). To prevent any hazardous situation from happening in case of defect HF surgical equipment, it is recommended not to use IPVLS simultaneously with this particular type of surgery.

Avoid direct fluid contacts with the Inca.

Use power cords, cables and catheters provided by CD Leycom. Only devices compliant with UL 60601-1/EN 60601-1 with outputs <10 Volt are permitted to be used as sources for the auxiliary Inca modules.

Inca, PC and interface screen, and other possible connected devices, should not use the same wall socket or multiple socket outlet to avoid excess of the limits of earth leakage currents, which may endanger patient or operator.

Pressure calibration should be performed with care. The wetting of the pressure sensor in saline at room temperature is mandatory. The membrane of the sensor must be saturated with saline for optimal pressure performance. In case of suboptimal wetting, the pressure signal have an offset. A possible offset in pressure can be detected at the end of the measurements, during removal of the catheter from the patient. At the moment that the catheter exits the body, the pressure should be zero; the deviation from zero is the offset. This offset can be corrected for in all recorded files of that pressure sensor. The offset should be determined within 1 second after the pressure sensor exits the body, as pressure signal changes will occur inherently due to temperature changes of the pressure sensor.

Only CD Leycom single use clinical PV catheters can be used in combination with the Inca.

Modification of the Inca can only be carried out by CD Leycom. Means of isolating the Inca from mains supply is by disconnecting the mains input cable or by switching off the main switch on the backside of the Inca.

Data recorded during usage of electro-surgical or defibrillation equipment usage should not be used for diagnostics. The device is defibrillator proof for safety. Measurement recovery is not guaranteed.

After power interruption the Inca switches off. The software running on the panel PC is still working but during power down no signal will appear on the screen. As soon as the Inca is working again, the signal will appear on the screen again.

Be aware: if you need to restart the software, you need to recalibrate the pressure sensor again by removing the catheter from the patient.

NOTICE Any serious incident that has occurred in relation to the Inca PV Loop System should be reported to the manufacturer and the competent authority of the Member State in which the user is established.

5.1.1 EMC and EMI

Although severely tested and being compliant to international standards, strong electromagnetic fields may still interfere with the operation of the Inca. It is recommended to keep any devices that generate strong fields (i.e. mobile phones, microwave ovens or surgical knives) out of the vicinity of the Inca (minimum 30 cm) while performing a measurement. Data acquired during HF surgical equipment usage or defibrillation procedures should be neglected for diagnostic use. The electrical safety of the Inca, regarding EMC and EMI, is guaranteed by design. In there is any doubt about the proper functioning and safety of the Inca, please contact CD Leycom. Refer to chapter 3.3 for more information.

5.1.2 Warranty exclusions

Usage of other catheters than CD Leycom catheters will violate any warranty in place on the usage of the Inca.

Usage of personal computers not compliant with UL 60601-1/EN 60601-1 when placed in the medically used room will violate any warranty in place on the usage of the Inca.

Connection of auxiliary devices not compliant with UL 60601-1/EN 60601-1 or exceeding 10 Volts will violate any warranty in place of the Inca.

Attempts to open or repair the Inca will invalidate any applicable warranty of the Inca.

Usage of the Inca together with PC, interface screen or other connected devices at the same wall socket or multiple portable socket outlet will violate any warranty in place of the Inca.

5.1.3 Troubleshooting: Power module

No LED lit on the power module	Check Power switch on the back of the Inca system. Check Power cord connection between the earthed wall socket and Inca. Check Fuses in the Inca power entrée. Check Power from the earthed wall socket.
Power status LED lit in a different colour than green after 10 sec power up	"Inca start up fault" retry by turning power off and on.
Ethernet status led is off or lit in a different color then green	Check the network cable between the Conduct pc and Inca. Check that the Conduct pc has complete the startup process. Check the windows network setup.

5.1.4 Disposal of Inca

At the end of life, the Inca is considered standard, small electronic waste. The Inca can be disposed using standard disposal rout for electronic appliances (computers, monitors, etc.)

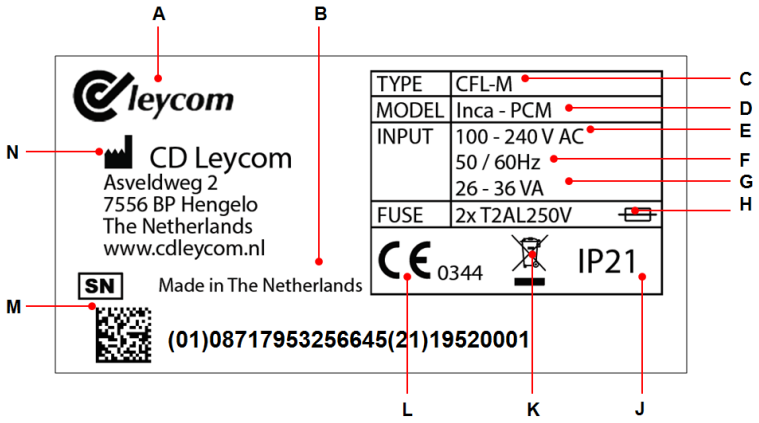
5.2 Standards and safety

The Inca meets the following safety standards:

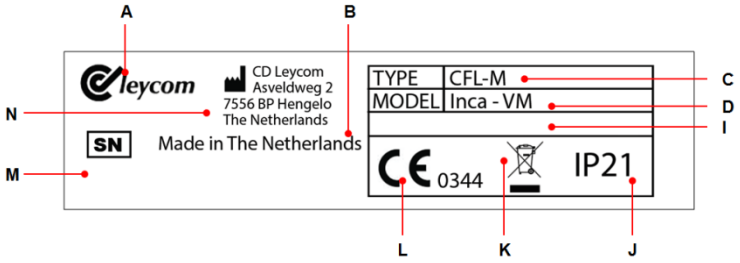
EN 60601-1:2006 / A1:2013 + national deviations for North America and Canada	Medical electrical equipment - Part 1: General requirements for safety
IEC 60601-1-2:2015	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances - Requirements and tests
IEC 60601-1-6:2006	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
EN 62366:2008	Medical devices - Application of usability engineering to medica devices
EN 60601-2-34:2014	Medical electrical equipment - Part 2-34: Particular requiremen for the safety, including essential performance, of invasive bloc pressure monitoring equipment
EN 62304:2006 / AC:2008	Medical device software – Software life cycle processes
EN ISO 14971:2012	Medical devices - Application of risk management to medical devices
EN ISO 14155:2011 / AC:2011	Clinical investigation of medical devices for human subjects - Good clinical practice
EN 1041:2008+A1:2013	Information supplied by the manufacturer of medical devices
EN ISO 15223-1:2016, Cor. 2017-03	Medical devices - Symbols to be used with medical device label labelling and information to be supplied - Part 1: General requirements

5.3 Device labels

Each module contains an identification label is located on the back of the modules.



Type 1: Power & Communication module



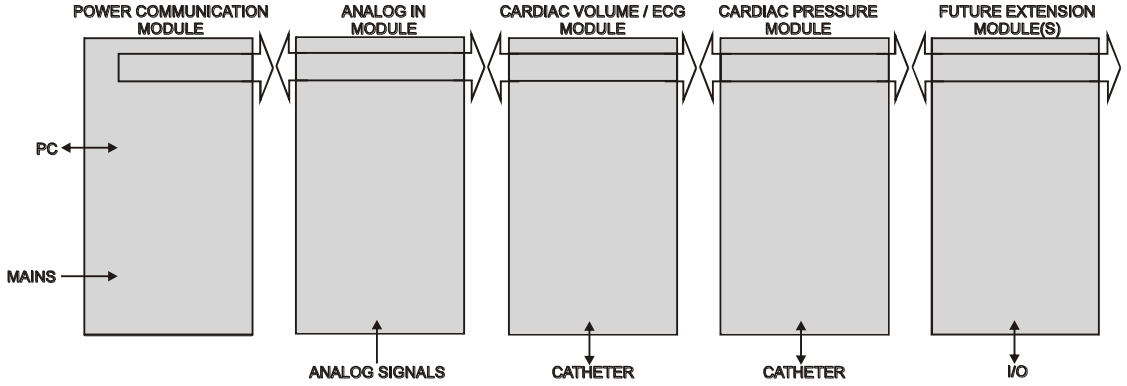
Type 2: Other modules

The labels contain the following information:

A) CD Leycom logo
B) Country of origin
C) Device type: CFL-M
D) Device model: Inca, with module identifier:
   - PCM: Power & Communication module
   - VM: Volume module
   - PM: Pressure module
   - AM: AnalogIn module
E) Required supply voltage
F) Required supply frequency
G) Power consumption range
H) Fuse count and value
I) Reserved space
J) Dust and humidity classification
K) WEEE symbol: separate this device from other household-like waste and send it to collection facilities for recovery and recycling
L) CE marking with Notified Body registration number
M) Serial number with year and week of manufacturing
N) Manufacturer name and address

Appendix A. Specifications

Following figure shows a global block diagram of a typical CFL-M measurement system.



General			
Type	CFL-M		
Models	Medical : Inca Sigma 5 DF Plus Non-medical : Sigma M		
Mains supply	100-240 Vac / 50/60 Hz		
Power range	26-36 VA		
Fuses	2x T2AL (250V)		
Medical safety class	Inca, Sigma 5 DF Plus : Class IIa Sigma M : N/A		
IEC 60601-1 classification	Inca, Sigma 5 DF Plus : Class I Sigma M : N/A		
Applied parts	Catheter : Class CF		
PC communication	Ethernet UDP sockets over max. 20m		
MAC address	02-00-xx-xx-xx-xx, with xx-xx-xx-xx is s/n of Power & Communication Module		
IP address	192.168.201.129		
UDP	47001, 47002		
Setup	Modular configuration		
Size	330 x 155 x 155 mm (typ. setup as shown above)		
Weight	3.3 kg (typ. setup as shown above)		
Protection against the ingress of water, particulate matter	IP21		
Ambient temperature	Operational: 10°C to 30°C Transport / storage: -10°C to 50°C		
Relative humidity	Operational: 20% to 80%, no condensation Transport / storage: 10% to 95%, no condensation		
Module specific	**Volume module**	**Pressure module**	**AnalogIn module**
Max. modules per system	2	3	2
Supply voltage	24 Vdc	24 Vdc	24 Vdc
Max. supply current	140 mA	65 mA	70 mA
Data channels	7x Volume + 1x ECG	1x Pressure 1x Temperature	4x Analog
Amplifiers	Bipolar differential, AC coupled	Unipolar and bipolar differential	Bipolar differential
AD Conversion	16-bit	16-bit	16-bit
Input range	± 20 mVpp	0 - 5,95 V full bridge,	± 10 Vdc

		± 50 mV half bridge	
Module specific (cont.)	**Volume module**	**Pressure module**	**AnalogIn module**
Measurement range		-50 – 300 mmHg	± 10 V
		Accuracy: 3%	
Resolution		0.25 mmHg	
Sample speed	250 - 1000 Sa/s		
CMRR	Volume >130 dB, ECG > 90 dB		
Excitation modi	Single field / dual field		
Excitation frequency	18,5 and 21,5 kHz sine		
Excitation current	12,5 - 100 uA AC	1 mA	
	THD < -32 dB		
	Accuracy: 2%		
Electrical safety	Cardiac Floating Defibrillator proof	Cardiac Floating Defibrillator proof	
Connectors	1x 14-pin keyed	1x 19-pin keyed	4x 4-pin keyed

Emissions and immunity standards and compliance

Standard	Emissions class/group or Immunity test level
CISPR 11	Class: B / Group: 1
CISPR 32	Class: B / Group: 1
IEC 61000-3-2	Class: A
IEC 61000-3-3	
IEC 61000-4-2	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air
IEC 61000-4-3	Radiated RF EM fields: 3 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz RF wireless communications equipment: Frequency: Immunity test level: 385 MHz 27 V/m 450 MHz 28 V/m 710 MHz 9 V/m 745 MHz 9 V/m 780 MHz 9 V/m 810 MHz 28 V/m 870 MHz 28 V/m 930 MHz 28 V/m 1720 MHz 28 V/m 1845 MHz 28 V/m 1970 MHz 28 V/m 2450 MHz 28 V/m 5240 MHz 9 V/m 5500 MHz 9 V/m 5785 MHz 9 V/m
IEC 61000-4-4	AC power: ± 2 kV, 100 kHz repetition frequency Ethernet: ± 1 kV, 100 kHz repetition frequency
IEC 61000-4-5	AC power (line-to-line): ± 0,5 kV, ± 1 kV AC power (line-to-ground): ± 0,5 kV, ± 1 kV, ± 2 kV
IEC 61000-4-6	3 Vrms, 0,15 MHz – 80 MHz 6 Vrms in ISM bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz
IEC 61000-4-8	30 A/m, 50 Hz for 230V mains and 60 Hz for 115V mains
IEC 61000-4-11	0 % UT; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°

Different frequencies and immunity levels are not expected in the intended environment.

Main Accessories

ICBL-RBNC-1.5M	= analog input cable Inca BNC 1.5 M.
ICBL-RBNC-3.0M	= analog input cable Inca BNC 3.0 M.
ICBL-RBD-1.5M	= volume input cable Inca Dual field 1.5 M.
ICBL-RBS-1.5M	= volume input cable Inca Single field 1.5 M.
ICBL-RBD-3.0M	= volume input cable Inca Dual field 3 M.
ICBL-RBS-3.0M	= volume input cable Inca Single field 3 M.
ICBL-RPP-0.5M	= pressure input cable Inca 0.5 M.
ICBL-ETHS-1.5M	= network cable shielded 1.5 M.
ICBL-ETHS-3.0M	= network cable shielded 3.0 M.
INCAPWRCRD-xxx	= power cord

Catheters

Catheters are available in various French sizes.
All CD Leycom catheters are CE marked for clinical use.

See the catheter pricelist to receive a complete overview.