NImedical

USER MANUAL
FOR
NEW NI MEDICAL (2011) LTD's
MODEL

NICaS™ CS

With Software version 3.58

BIOIMPEDANCE CARDIAC MEASURING
and ANALYZING SYSTEM

Caution: Federal Law restricts this device for sale, distribution and use by or on the order of a physician.

CE
0473

Catalogue No. NI5.0001.01

TABLE OF CONTENTS

1. INTRODUCTION

The NICaS (Non-Invasive Cardiac System) is a bioimpedance system focusing on noninvasive assessment and monitoring of cardiovascular, respiratory, and fluid parameters. The system provides real-time data on various parameters of a patient's cardiac vascular functions. The data from any given reading session is displayed on the screen according to the different parameters, patient reports can be issued and saved, trends in the patient's heart condition can be viewed and monitored, and the system also provides historical data and comparative reports.

The NICaS device replaces the CD drive in any laptop computer, transforming it into a medical instrument for non-invasive measuring of various cardiac functions. These measurements include the cardiac output and its derivatives, as well as an assessment of the left ventricular cardiac contractility. The NICaS is also unique in that it is the only method of Impedance Cardiography (ICG) which utilizes dual impedance electrodes, placed on two limbs, preferably one on the wrist and the other on the contra-lateral ankle. This type of electrical surveillance is called Regional ICG, or RIC.

This technology is based on two independent principles:

The first is the fact that the electrical conductance of the blood is higher than that of the surrounding tissue structures. Consequently, with each arterial systolic expansion (pulsation), an increase in the electrical conductance (or reduction in the electrical resistance) of the body is measured. This change in systolic resistance (**impedance**) is marked **ΔR**, and the baseline body resistance is **R (measured in ohms Ω).**

The second principle, which is called the Granov Goor Index (GGI), is based on the systolic time intervals (STI) which, similarly to Left Ventricle Ejection

Fraction (LVEF), can assess cardiac function i.e., as indicated by LVEF measurement, the lower the GGI the graver the condition).

The NICaS is a tetrapolar apparatus which operates by an alternating current of 1.4 mA and 32 kHZ. The analog resistance signals are received by the device, where they are amplified and filtered. These signals are then transmitted to a microprocessor, where they are digitized and analyzed via mathematical algorithms.

ECG resistance and respiratory waveforms as well as numerical patterns are displayed on the screen

The collected data can be easily printed or viewed through several easy to define reports.

2. SAFEGUARDS & STANDARD CLASSIFICATION

2.1. CLASSIFICATION

2.1.1. Equipment Classification according to IEC 601-1

- CLASS II EQUIPMENT according to the type of protection against electrical shock;
- EQUIPMENT not suitable for use in the presence of a FLAMMABLE ANAESTHETIC MIXTURE, with air or with oxygen or with nitrous oxide;
- CONTINUOUS OPERATION according to the mode of operation.

2.1.2. Equipment Classification According to EU Medical Device Directive DEGREE OF PROTECTION against electric shock is type BF.

2.2. SIGNS

 Class II double isolated device

 General warning sign

 BF-type (body-protected floating) symbol

2.3. CAUTION

NOT FOR INTRACARDIAC USE. The instrument does not utilize a protective (earth) ground. The instrument is not protected

INPUT PROTECTION: The device is not protected against defibrillation. Therefore, before the patient undergoes defibrillation, all five electrodes (3 ECG and 2 dual impedance) must be disconnected from the patient. This can be achieved by pulling the two main cable plugs from the NICaS box.

2.4. WARNINGS

DO NOT USE ANY ELECTRODE PASTE, WHICH WILL REDUCE ELECTRICAL CONDUCTION.

DO NOT REMOVE COVERS OR PANELS. REFER TO QUALIFIED SERVICE PERSONNEL.

NO MODIFICATION OF THIS EQUIPMENT IS ALLOWED

3. TECHNICAL SPECIFICATIONS

NICaS Dimensions: (L)12.8 x (W)13.1 x (H)1.3 cm (5.0 x 5.2 x 0.5 inch)
Weight: 150 gm (5 oz)
Power: USB: 5v/15]0mA DC
Temperature: 10C,50F to 32C to 90F for operation and sensor transport and storage

ICG	
Method:	regional impedance
Lead mode:	1 lead (I, V+, V-, I_GND)
Waveform	single channel
Sweep speed	25 mm/s
Impedance range:	200-500 Ω
ΔR Range	to 1Ω
ΔR Signal Bandwidth	0.3Hz to 12 Hz
Accuracy	±5%
Sample Rate	200 Hz
Injection Current	1.35 +/- 0.1mA RMS at 32.5 +/-0.5kHz

ECG	
Lead mode	3 lead (RA,LA,LL)
Waveform:	single channel
Gain	x1,x2,x4
Sweep speed	25mm/s
Heart Rate range	30-240bpm
HR Accuracy	±1bpm

4. TAKING CARE OF YOUR SYSTEM

4.1 ROUTINE CARE

The following rules should be applied in everyday work to allow the NICaS CS extended durability:

- Keep the NICaS CS dry.
- Do not expose the NICaS CS to extreme temperatures.
- Keep the NICaS CS away from dust and any kind of dirt (pay particular attention to the electrode connectors).

4.2 MAINTENANCE

All repairs are to be performed only by New NI Medical (2011) Ltd. service personnel or, alternatively, by authorized distributor personnel.

4.3 CLEANING

ECG and BIP cables and lead wires must be cleaned with soap and water before each application to a new patient.

4.4 ORDERING INFORMATION

See Section 16.

5. COMPONENTS

The package includes the following components (*See Figure 1*):

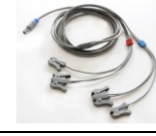
5.1 One NICaS CS device	
5.2 One laptop computer is required for system: (purchase from NI Medical is optional)	
5.3 ICG Cable	
5.4 ECG Cable	
5.5 NICaS CS USB cable	
5.6 NICaS CS Sensor Kit, pack of 20 applications (may be sold separately)	

Figure 1: NICaS Components

Note:

Please inspect the device to verify that no parts are missing, and that no visible damage has occurred during shipment.

6. UNIT SETUP

According to IEC 601-1-1, if the computer (or any other attached device) is connected to an external power source (the power supply should be listed to UL 60950) it must be kept at least 1.5m (60 inches) away from the patient. When the laptop, connected to the NICaS , is operated on a battery, no distance limitations exist. The lifespan of a fully charged battery is approximately one hour.

6.1 CONNECTING TO A POWER OUTLET

Connect the power cord to the NICaS CS back panel and to a laptop USB slot. The AC power connects to a power supply that supplies DC power to the computer, and simultaneously recharges its battery.

6.2 CONNECTING THE LEAD WIRES TO THE CONNECTORS PANEL

Connect the lead wire plugs as shown below in *Figure 2.*

- Plug ECG connector into designated slot (No. 2 in *Fig. 2).*
- Plug Impedance Cardiography (ICG) connector into designated slot (No.1 in *Fig. 2*).
- Connect power/data cable to the laptop USB port (No. 3 in *Fig. 2*).

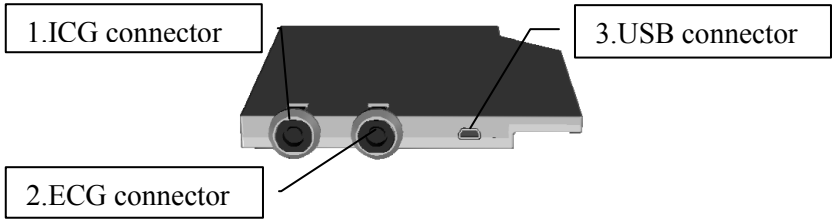


Figure 2: NICas Device Connectors

7. PATIENT HOOKUP

Five sensors connect to the patient: two (2) are paired ICG sensors and three (3) are ECG sensors**.**

7.1. CONNECTING THE ICG SENSORS

ICD Cable is connected by a blue plug to the ICG slot of the NICaS. The ICG Cable is split into two branches labeled 1 (Red) and 2 (Blue), each have 1 double connector and one single connector.

Connect the ICG sensors to the patient as follows (see *Figure 3)*:
1 (Red) branch:

Single connector – left wrist proximal;

Double connector – left wrist distal;

2 (Blue) branch**:**

Single connector – right ankle proximal;
Double connector – right ankle distal;

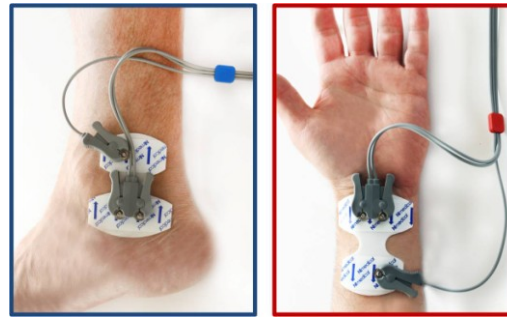


Figure 3: ICG Sensors locations and connection to ICG Cable

7.2. CONNECTING THE ECG SENSORS

Place the ECG sensors onto the patient as described in *Figure 4.*

- The White ECG lead wire is attached to the Right Arm.
- The **Black** ECG lead wire is attached to the Left Arm.
- The **Red** ECG lead wire (ground) is attached to the patient's lower abdomen or leg.

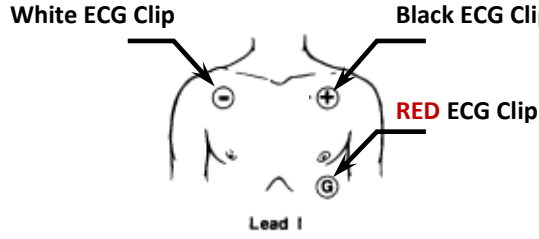


Figure 4: Connecting the ECG sensors

NICaS CS is optimized for the wrist-ankle (WA) connection which allows to estimate the SV based on both upper and lower peripheral flow. In case that pulse can be palpated the signal is strong enough for the NICaS to correctly estimate the SV.

Note: Do not place the connector on a limb with the following abnormalities, and choose a different limb:

- Peripheral Arterial Disease (PAD)
- Significant Edema
- Damaged skin

Note: Do not use any sensor paste, as this will reduce the electrical conduction.

- Make sure the area where sensors are to be placed on patient's arm and leg is clean, free of perfumes/colognes and lotions and the skin is not damaged.
- Patient's limbs should not be cold, and pulse should be palpated.
- Patient's limbs should be placed so that electrodes do not touch each other.
- There should be no metal in the vicinity of patient's limbs.
- Place a new set of disposable electrodes onto patient's skin before each measurement.
- To prevent the sensors from drying out, do not open until immediately before use.

Caution: Do not use sensors after specified shelf life has expired.

8. GETTING STARTED

8.1. TYPICAL OPERATING SEQUENCE NICAS

The following paragraphs describe a typical operating sequence with the NICaS CS monitor

8.1.1. Power Up NICaS CS

Ensure the laptop is on and running and that the NICaS CS is connected to its USB connector. Double-click the NICaS icon. The start-up process might take a few minutes to complete.

8.1.2. Connecting Lead Wires to a Patient

See explanation in section of Patient Hookup.

8.1.3. Measurement Start-Up

To start the monitoring process, select either 'New Patient' or 'Existing Patient'.

8.1.3.1. To begin measurement of a **new patient** **select one of the following 3 options:**

a. Press 'Patient' button and select 'New'

b. Press the first icon on the toolbar 

After selecting one of these two options, a window with all the details relevant to the patient will open. Fill in details and click  . The measurement will

begin.

c. Press the ‘Measurement Start’ button  . The following window will open:

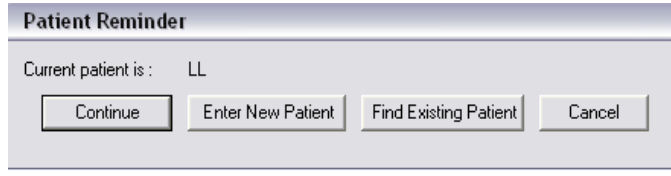


Figure 5: Patient Reminder

Select ‘Enter New Patient' and the window with all the details required for the patient will open.

8.1.3.2. To start the measurement of an **existing patient** select one of the following 2 options:

a. Press 'Patient Button'  and select ‘Find’.

b. Press ‘Measurement Start' button  . The 'Patient Reminder' window opens (see above):

i. If the name in the field following 'current patient' is **correct** - select ‘Continue’.

ii. If the name in the field following 'current patient is' **incorrect** or **blank** - select ‘Find Existing Patient’. A ‘Patient List’ window will open, in which you can seek the relevant patient (see a more detailed explanation in the Functional Description below).

8.2. FUNCTIONALITIES DURING MONITORING

8.2.1. **Alarms** – NICaS has a built-in alarm system that alerts the user of a technical failure. This alarm may sound while monitoring a patient however it indicates a technical failure only. In the event of a technical failure the system sounds an audio notification and the status line at the bottom of the screen will display the cause of the alarm.

Note: See Alarms (*Section 11*) for a more detailed explanation.

8.2.2. **Review Collected Data** – 'Review Mode' enables the review of previously measured data. This mode can be accessed by directly pressing the 'Review' button on the main menu or by pressing  .

8.3. TABLE OF PARAMETERS

Parameter	Abb.	Definition	Normal Range
Heart Rate	HR	Number of heart beats each minute	58 - 86 bpm (beats per minute)
Stroke Volume	SV	Number of heart beats each minute	60 - 130 milliliter
Stroke index	SI	Stroke volume normalized for body surface area	35 - 65 milliliter/beat/m^2
Cardiac Output	CO	Amount of blood pumped by the left ventricle per minute	4.5 – 8.5 liter/min
Cardiac Index	CI	Cardiac Output normalized for body surface area	2.5 - 4.7 liter/min/m^2
Cardiac Power Index	CPI	An indicator of myocardial contractility	0.45 - 1.0 watt/m^2
Granov Goor Index	GGI	An indicator of Left Ventricular Function, which is strongly related to Ejection Fraction	> 10.0 (equals an Ejection Fraction > 55%)
Total Peripheral Resistance	TPR	The resistance to the flow of blood in the arterial system (often referred to as “Afterload”)	770 - 1500 dynes·sec·cm^{-5}
Total Peripheral Resistance Index	TPRI	The resistance to the flow of blood in the arterial system normalized for body surface area	1540 - 3000 dynes·sec·cm^{-5}/ m^2
Total Body Water	TBW	The amount of extracellular fluid in % or kilograms	40.0 – 63.0%
Respiration rate	RR	Number of breaths each minute	8 – 24 breaths / minute

8.4. GGI – Granov Goor Index - is a ratio that assesses Left Ventricular Systolic Function similarly to LVEF. Higher GGI readings indicate a better Left Ventricular Systolic Function. Below is the Correlation graph of GGI vs LVEF (GGI < 10 is associated with LVEF of < 55). The graph represents Blinded comparison of EF and GGI in 60 patients presenting at a cardiology clinic asymptomatic of ischemic heart disease and, selected to undergo echocardiography, and selected in accordance with device exclusion criteria. Data is not from an unselected population.

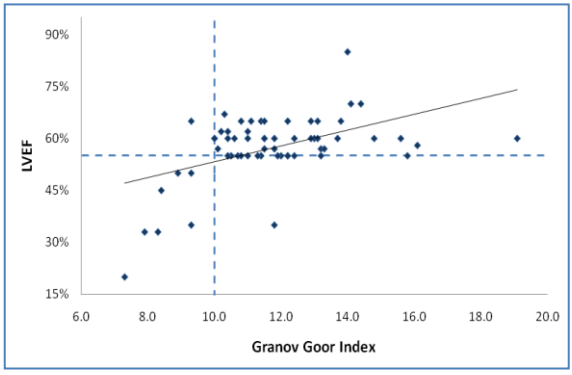


Figure 6: Granov Goor Index

9. FUNCTIONAL DESCRIPTION

9.1. Main Screen

The main screen is used to navigate and operate the system and present the different views of the measurement data (*see Figure 7* below).

Toolbars and menus: At the top of the screen there are 2 navigation toolbars. They are functionally identical – the top one is textual and the bottom one has icon representations.

The screen is divided into 3 main sections as follows:

Left pane display is divided horizontally into three sections. The sections display waveforms representing real time ECG, ΔR and Respiratory rate of the present measurement.

Right pane displays 10 user pre-selected parameters (from a total of 14). The values of the parameters are preprogrammed to be updated at 10, 20 or 30 seconds intervals during a measurement.

Bottom left pane, below the wavelength, displays the trends of three of the parameters selected from the vertical right side readings (HR, SV and CO) during a measurement.

Figure 7: Main Screen

9.2. THE DISPLAY

Left pane screen – waveform display (refer to *Figure 7* above):

I. GREEN waveform represents the ECG.

II. RED waveform represents the bioimpedance ΔR.

III WHITE waveform represents the respiration.

The waveforms progress from left to right along a horizontal axis drawing the vertical values (of the ECG, ICG and respiratory measurements). The Horizontal axis is marked by 1 second interval indicators

Right pane display:

The right pane displays 10 parameters that provide data on the current measurements. These parameters display the real time values of the measurement for the selected parameters. The normal measurement range for each parameter is displayed below the measured value.

The color display is to enhance distinction between the parameters in real-time and does not qualify the measurement in any way.

For parameters glossary of abbreviations see the Table of Parameters in the section Getting Started.

Bottom left pane – Trends display:

This area is divided into 3 graphs. The trends are chosen from a list of 14 parameters in the Options window (see *Figure 12* below), whereas, HR, SV and CO are the default trends displayed. Each point on the screen represents the measured and computed result of a single measurement. The sequence of points displays the TREND for that parameter during the specific measurement at 10, 20 or 30 seconds preset intervals. The latest measurement point is located furthest to the right.

9.3. Toolbar menus

The main screen offers 2 options for navigating through the NICaS system: the top is a text menu and the bottom is a graphic tool bar (*see Figure 8*).

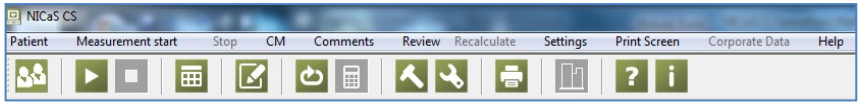


Figure 8: Main screen navigating menu

Patient - Patient Management window

Before entering a new patient you may want to check if he/she is already registered in the system: use this option to add a new patient, find an existing one, or to edit data of an existing patient (*See Figure 9*).

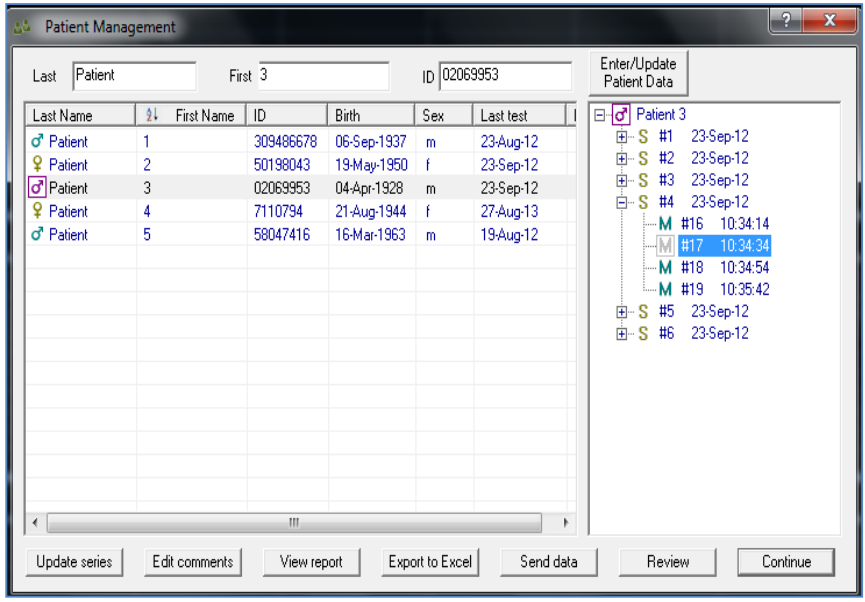
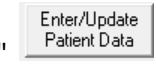


Figure 9: Patient Management

The window displays the list of patients already registered in the system. To enter a new patient or to search for an existing patient, enter the patient's Last Name, First Name or ID in one of the top 3 boxes.

If the patient exists, click on the selected patient in the list of patients. Patient First Name, Last Name and ID will appear in the top 3 boxes.

Clicking the button "Enter/Update patient data" 

on the upper right corner opens 'New Patient' window were patient data need to be filled in. In the event of an existing patient, just update data that were changed from previous measurement (*see Figure 10*).

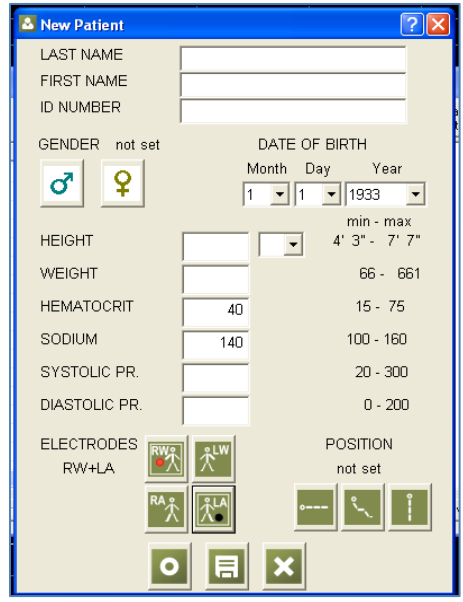


Figure 10: New Patient

The following Patient data menu should be completed in full:

- Type in full name and ID number
- Click on the icon to indicate sex M/F
- Choose from scroll menu date of birth mm/dd/yy
- Enter the data for the Height, Weight, Hematocrit; Sodium; Systolic Blood Pressure, Diastolic Blood Pressure.
    - Note: If no updated data on Hematocrit and Sodium for

- Note: If no updated data on Hematocrit and Sodium for patient the system enters a default measurement.
- The numbers on the right indicate the accepted range for each of the data entered.

- Connecting the sensors: choose 2 options - left and right wrists (RW/LW) and left and right ankles (RA/LA).
  - Clicking on your choice of icons will change the "not set" to indicate the selected placement: i.e. RW+ LA
- Choose one of the three positions of the patient during the measurement: supine, sitting or standing.

- Click  to save and measure
- Click  to save and exit
- Click  to cancel

Patient measurements file display

Click on a selected patient from the left pane list will display his/her measurements file in the right pane. The name of the patient appears at the top of the right pane. Selecting the relevant patient's name displays the measurement data on a 3 level hierarchy.

Example *Figure 9* – left pane Patient 3 is selected; Right pane shows the Patient 3 measurement library. Click on Patient number to open all files.

P – Patient name or number (Patient 3)

were taken (23-Sep-12). Each Series has several measurements.

M – Listed Measurements stating by the measurement number (M #17) and hour 10:34:34).

The Patient Management window has additional 6 function buttons at the bottom of the window for accessing, managing and retrieving patient data and issuing reports.

a. Update series - enable changing the following parameters of existing series: Systolic Blood Pressure, Diastolic Blood Pressure, Sensors Location, Patient Position.

b. Edit comments - Opens a window for entering free text comments relevant to the patient, the specific measurement or other data entered. These comments will appear at the bottom of the series reports (*see Figure 11*). To write a comment, position cursor in the right box, type-in the comment, and press the arrow to transfer the comment into the highlighted series at the left box. The left box shows all the comments that were written for the selected patient, and their dates.
All comments are displayed in the patient report, with the date and time of entry.

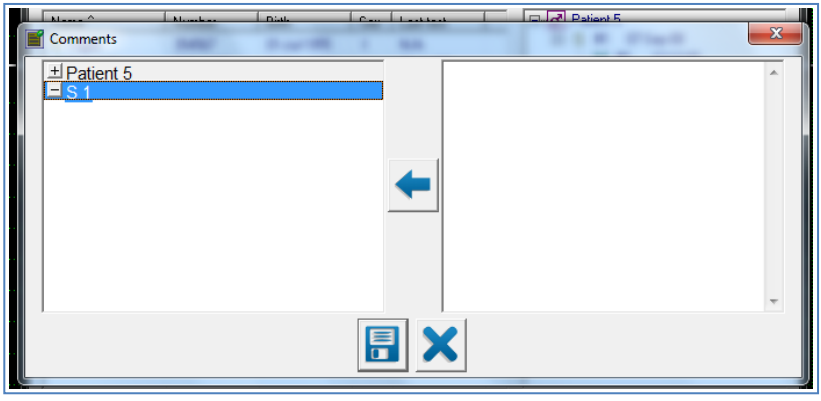


Figure 9: Add Comments

c. View report – Opens a window with the option to view the data through four types of reports: Measurement Report, Series Report, History Report (in ascending order) and Hemodynamic Navigator.

d. Export to Excel - Export data of specific patient or of all data base to Excel.

e. Review - Use this option to review a selected measurement.

f. Continue - Use this option to start an additional measurement of an existing patient. After patient has been selected, clicking 'Continue' will start a measurement.

Measurement Start - Starts the measurement. Clicking this button changes it to 'Measurement Pause'

Patient Reminder – A window that opens when the program is reopened. The window includes the name of the current patient, and 4 options:

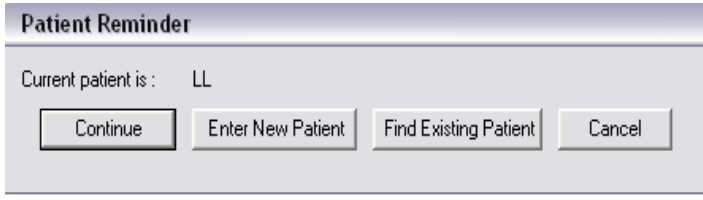


Figure 10: Patient Reminder

- Continue – Choosing this option continues the measurement of the current patient.
- Enter New Patient – Opens a window that includes all the data necessary for a new patient (see above).
- Find Existing Patient – Opens the 'Patient List' window, from which the relevant patient can be selected by marking his/her name in the left screen.
- Cancel – Closes this window.

Measurement Pause  - Stops the measurement. To continue, select 'Measurement Continue'  . The measurement continues the sequence from where it was stopped, without losing the data already accumulated for this series i.e. trends and last results of all parameters.

When Pause is activated, 4 menus can be opened: 1) Report – for a single measurement; 2) Settings – 'options' are available, the number and/or types of trends displayed on the screen can be changed; 3) Comments; and 4) Help.

Stop  - Stops the measurement. When restarting, the measurement continues the sequential numbering from the last measurement (**without** retaining comparative data).

Review - Opens a window with a 4 graphs display: ECG, dR, dR/dt and respiration, and the calculated results of the patient's last measurement. This option is available only when the patient is no longer connected to the NICaS system. In addition, any other measurement can be selected from the 'Patient List' window, and by clicking this 'Review' button in the 'Patient List', the review of the selected measurement will appear. To stop the measurement review, press the 'Stop' button.

Setting/Options - Use this window to select your default or pre-measurement settings. Click on 'Settings' or the icon to open a window menu that displays all the system parameters and check boxes (*see Figure 11*).

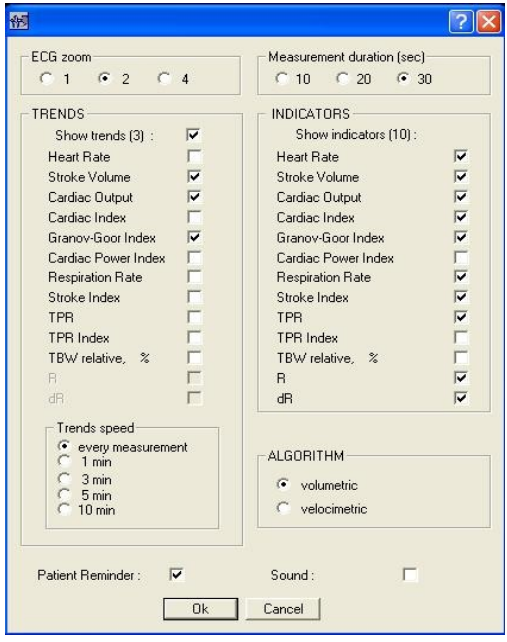


Figure 11: Setting/Options

- **ECG zoom** – Choose one of three amplitude gain options for the ECG: 1, 2 or 4. Gain 2 is default.
- **Measurement duration** – Offers the option to choose the rate of updating the data during the measurement: 10, 20, or 30 seconds intervals (default is 20 seconds).
- **Trends -** Lists the parameters that can be selected to be displayed in the trends charts at the bottom left of the main screen (*see Figure 11*). Choose 3 of the 11 options for display per measurement by ticking the relevant checkbox.
- **Parameters** - Lists the parameters that can be selected to be displayed in the Parameters pane to the right of the main screen (*see Figure 11)*. Choose 10 of the 14 options for display per measurement by ticking the relevant checkbox.
- **Trends Speed** - Determines the rate at which measurement data will be displayed on the chart to create the trend graph. Choose from 1, 3, 5 or 10 minute intervals.

Settings/Techniques  - is available when measurement is paused or stopped. It can be accessed only by authorized personal with validated password. The advance setting enables the Algorithm Selection (*See Figure 12*).

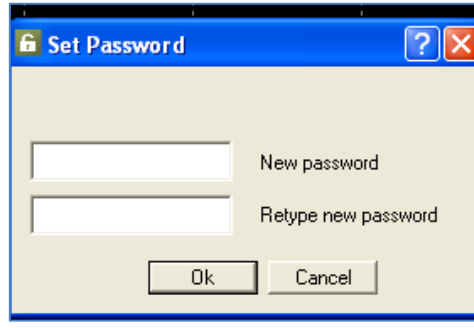


Figure 12: Advance Settings Authorization

Algorithm selection:

The default setting is for volumetric measurement and should be the standard mode of measurement. This option is for use by advance settings and should be changed only by an authorized technician (*see Figure 13*).

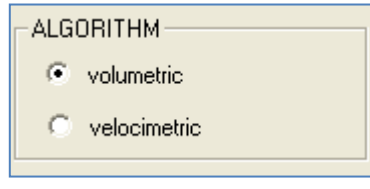


Figure 13: Advance Settings Authorization

There are two options for measuring the CO:

A) The standard Volumetric method, where the SV is calculated by Frinerman's (ΔR) algorithm.

B) The alternative Velocimetric method, where the SV is calculated by the first derivative of ΔR.

The velocimetric option should be used only when the patient's admitting diagnosis is "acute heart failure".

Enclosed is a graph showing correlations with range lines of the results from acute heart failure and another graph for all other patients. The data from which these two graphs were constructed were published in Cotter's paper (Physio Measures 2006; 27:817-27).

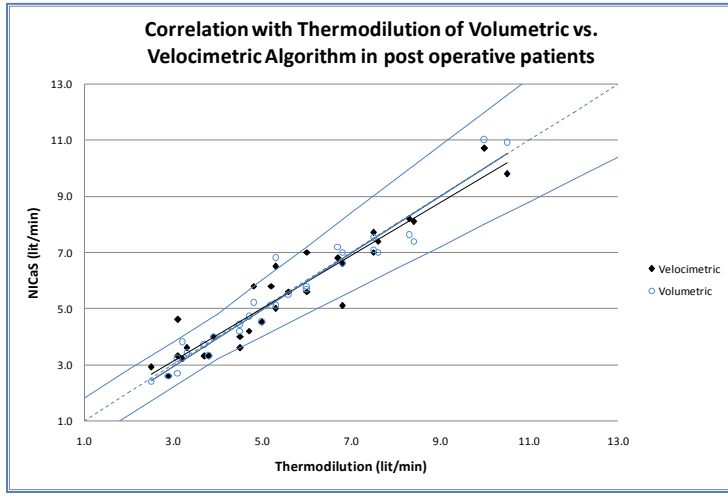


Figure 14: Correlation with TD in P Operative Patients

*Range lines in the plot represent +/- 0.8 L/min for TD CO values <= 4 L/min, +/- 20% for TD CO values > 4 L/min.

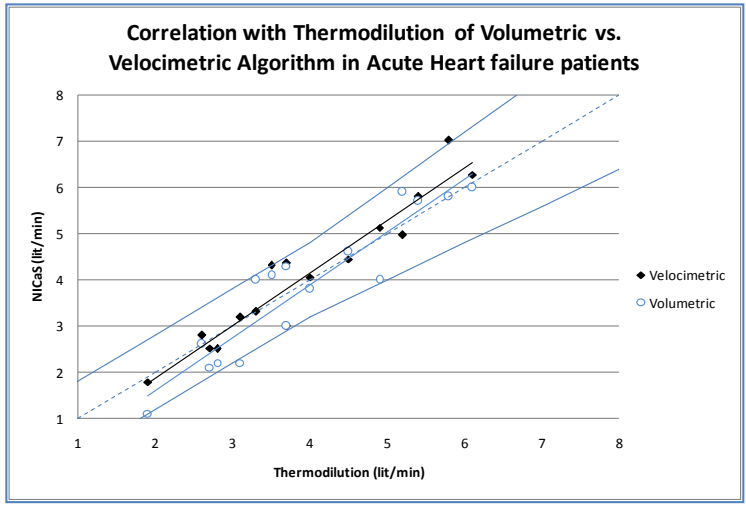


Figure 15: Correlation with TD in Acute Heart Failure Patients

*Range lines in the plot represent +/- 0.8 L/min for TD CO values <= 4 L/min, +/- 20% for TD CO values > 4 L/min.

As one can see in the acute heart failure group, the lower the cardiac output (below 4.0 lit/min) the higher the accuracy of the velocimetric results, and the higher the cardiac output, the better the volumetric results.

Results of an additional group of patients measured with the Volumetric algorithm – (see *Figure 18)* below.

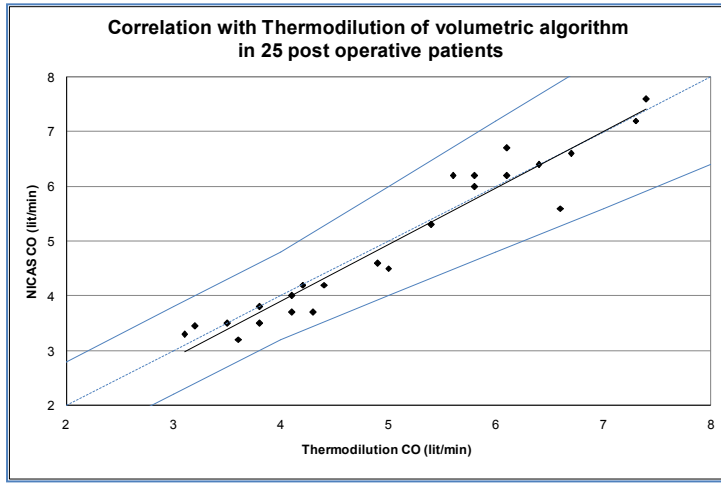


Figure 16: Correlation of Volumetric Algorithm to TD in Post-Operative Patients

*Range lines in the plot represent +/- 0.8 L/min for TD CO values <= 4 L/min, +/- 20% for TD CO values > 4 L/min.

Print Screen - is a function that enables converting the data on the screen into a PDF format and then save or send it to a mail recipient.

Help – Click to access the electronic user guide.

Your NICaS version – provides information regarding the version currently installed.

Exit – To close the program click on the at the top right of the main screen.

Shut Down

Pressing the laptop's Power button will begin the shutting down sequence.

Note: If you wish to continue using your laptop, simply exit the NICaS application by clicking on the X at the top right of the screen

10. COMPARATIVE SCREEN

The NICaS system offers users a shift between the regular measurement (*Figure 7:* Main screen) screen to a comparative screen (*Figure 17:* Comparative Screen). The comparative screen is designed to enable users to perform a set of comparative measurements according to different parameters.

Figure 17: Comparative Screen

Click on  to shift from the regular to the comparative screen.

The top screen display is of the ECG (green) and ΔR (red) waveforms.

Note: Enter the comparative parameters of your choice for each measurement/series in **Parameters 1/Parameter 2**. These parameters can

be customized through the 'Setting/Options' menu.

Click  to open the Comparative Measurement Options and edit Parameters 1 and 2 according to your comparative parameters. Before starting a new measurement the system will open a dialog box reminding the user to change the comparative parameters for that measurement.

The right pane displays the data for each series – in descending sequential order; the current or last measurement appears at the bottom. The numerical data in the right pane columns displays and updates the values per series with reference to the comparative parameters 1 and 2.

The left pane displays 4 trends representing the series graphically and numerically (each dot is a measurement in a series). The numeric data displays current vs. average values. When the measurement is stopped, a click on any of the dots changes the top ECG/ΔR waveforms to that of the specific measurement. Placing the cursor on the dot and right click on the mouse neutralizes it from the average calculation for that trend (displayed numerically at the side).

The bottom right continues the numerical comparison between the current and average values for the other parameters

When opening the Patient Management window from this screen the patient file also displays the date of each of the series.

11. NICAS REPORTING SYSTEM

There are 3 types of reports:

Patient Measurement report – report of 1 measurement obtained by clicking on the required measurement (e.g. M #12 in Figure 20).

Patient Series report – report of average of a few measurements obtained by clicking on the required series (e.g. S #3 in Figure 20).

Patient History report – report of all historical series obtained by clicking on the patient name (e.g. Patient 1 in Figure 20).

After required report has been selected press 'View Report'

View report to generate a PDF report.

Hemodynamic Navigator - provides Cardiovascular and Cardiac Function graphs for on-line drug titration – double mouse click on Patient name.

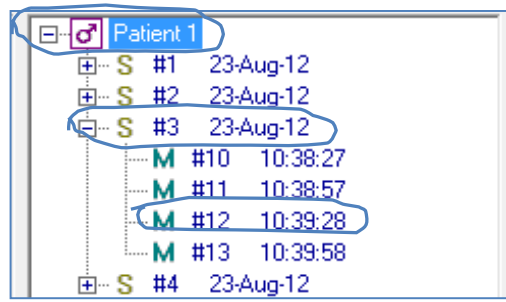


Figure 20: Selecting reports

All reports display the patient's identification data as entered during registration: Name, ID number, sex, date of birth, and height.

All other data and display varies according to the selected event and type of report.

11.1. PATIENT SINGLE MEASUREMENT REPORT

The report heading states the number of the selected measurement for the report (see *Figure 21*: M13). Top of the page shows patient's permanent data and identifies the date and time of the measurement and the recording intervals (20 seconds).

This is followed by a tabular display of all the measurement parameters and their results. The table states the name and abbreviation of each parameter, the measurement unit and the actual reading. The last column displays a scale with the low to high values for each parameter. The measurement reading is indicated on the scale: Green = in norm; Red = out of norm.

The table is followed by 2 graphs representing a sample of ECG and ΔR waveform of the measurement.

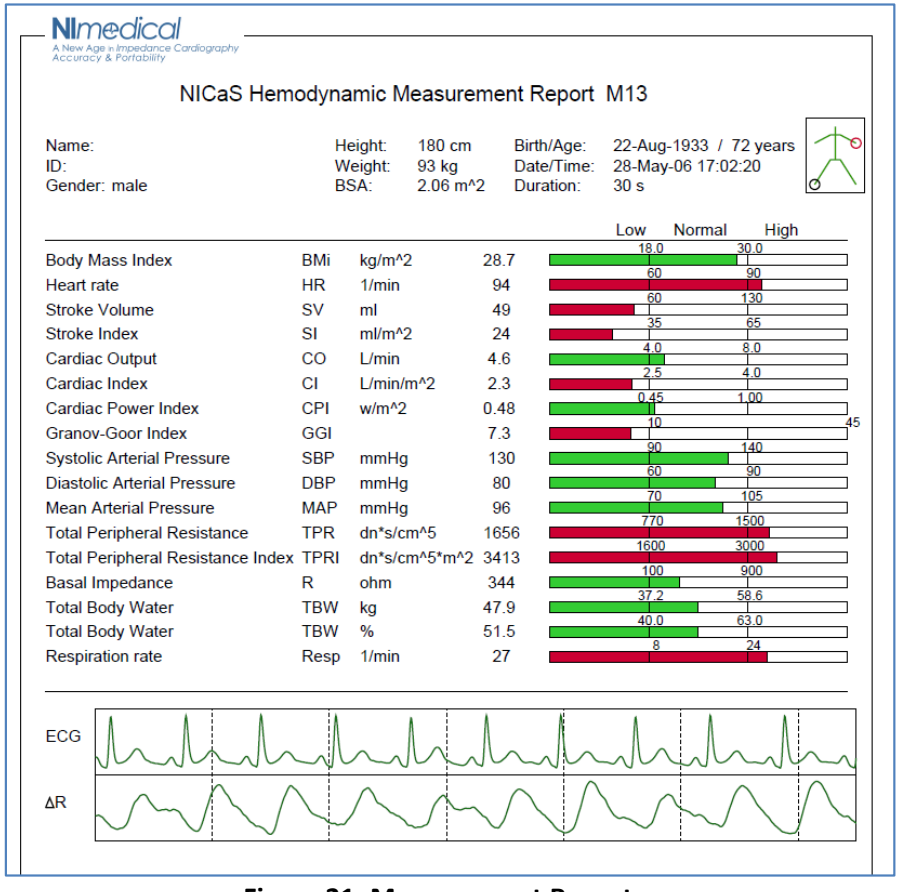


Figure 21: Measurement Report

11.2. PATIENT STATUS REPORT

The Series Report is similar in form to a Measurement Report with certain additional data. The tabular data displays the average of the series' measurements results per parameter.

The scale displays the readings per series within the high/low range for each parameter. The continuous colored section on the scale indicates the values for the current series measurement.

In addition, Patient Series report compares the current series measurements with those of the last series taken on the sequential date prior to the current one (see *Figure 22:* M3). The earlier series is marked with a dot before the date (column heading).

The dot indicating the values of earlier measurement - it can be within the colored range (lower) or out of the colored range (higher) than the current value/reading.

The graphic data displays the ECG and ΔR waveform.

The report displays 3 measurement trends chosen for that series. Each dot on the trend display represents a single measurement.

Example: HR, SV, CO

The bottom of the page displays all the comments entered by the physician.

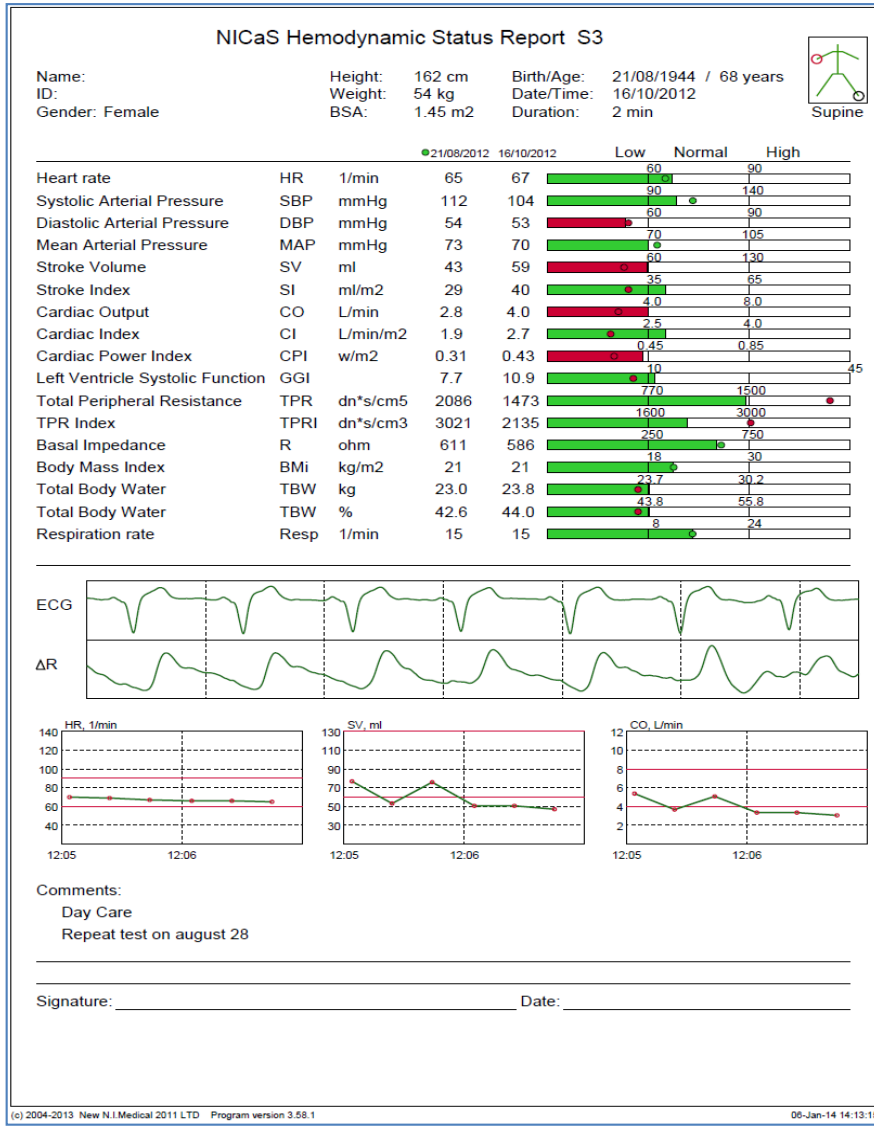


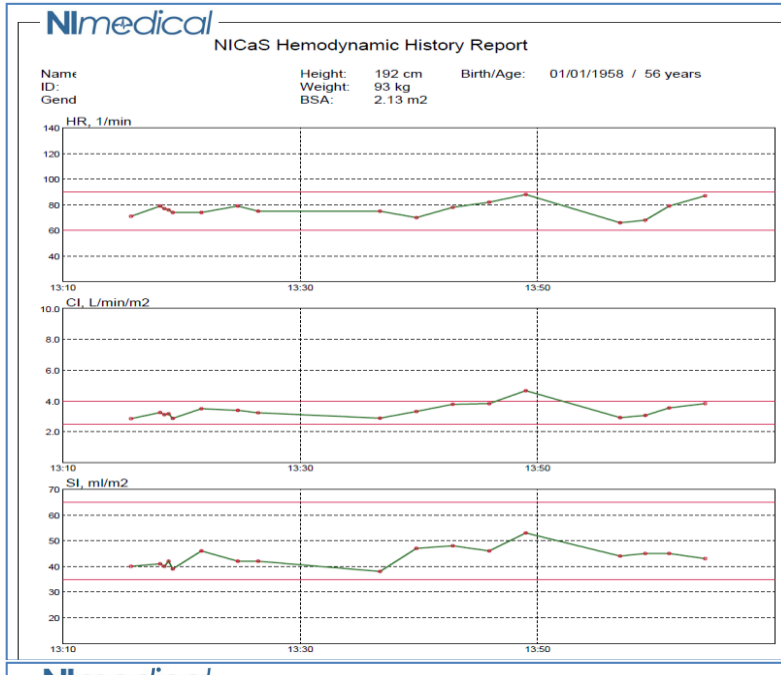
Figure 18: Status Report

11.3. PATIENT HISTORY REPORTS

The top of the page shows patient’s permanent data.

A Hemodynamic Patient Report provides a tabular summary of a patient's previous measurements in ascending order of occurrence. Additionally, the values of three user-selected parameters are plotted to display the trend with relation to its time sequence.

All the physician's comments are displayed at the bottom of the page.



NIMedical

SN	Date/Time	SBP	DBP	MAP	HR	SI	CI	CPI	GGI	TPRI	TBW kg	TBW %	R
017	19/01/14 14:04	151	96	114	87	43	3.8	0.97	12.6	2384	51.5	55.4	358
016	19/01/14 14:01	124	76	92	79	45	3.5	0.72	12.4	2083	51.6	55.5	357
015	19/01/14 13:59	100	68	78	68	45	3.1	0.53	10.6	2039	51.5	55.4	358
014	19/01/14 13:56	149	99	115	66	44	2.9	0.74	10.2	3166	52.0	56.0	354
013	19/01/14 13:49	149	99	115	88	53	4.7	1.19	15.3	1972	52.3	56.2	352
012	19/01/14 13:45	140	83	102	82	46	3.8	0.87	12.9	2131	52.0	56.0	354
011	19/01/14 13:42	128	73	91	78	48	3.8	0.76	13.2	1923	52.0	56.0	354
010	19/01/14 13:39	112	67	82	70	47	3.3	0.60	12.0	1978	52.3	56.2	352
009	19/01/14 13:36	106	68	80	75	38	2.9	0.51	10.6	2235	52.7	56.6	349
008	19/01/14 13:26	120	75	90	75	42	3.2	0.65	11.0	2232	54.2	58.3	337
007	19/01/14 13:24	120	75	90	79	42	3.4	0.68	11.0	2128	54.7	58.8	334
006	19/01/14 13:21	120	75	90	74	46	3.5	0.70	12.2	2059	55.1	59.2	331
005	19/01/14 13:19	120	75	90	74	39	2.9	0.57	8.8	2509	54.4	58.5	336
004	19/01/14 13:18	120	75	90	76	42	3.2	0.63	10.8	2271	54.4	58.5	336
003	19/01/14 13:18	120	75	90	77	40	3.1	0.62	10.3	2315	54.4	58.5	336
002	19/01/14 13:18	120	75	90	79	41	3.3	0.65	10.7	2215	54.4	58.5	336
001	19/01/14 13:15	120	75	90	71	40	2.9	0.57	9.7	2562	54.5	58.7	334

Comments:

Signature: _____ Date: _____

Figure 19: Patient History Report

11.4. NICAS HEMODYNAMIC NAVIGATOR REPORT

Provides Cardiovascular and Cardiac Function graphs for on-line drug titration – double mouse click on Patient name.

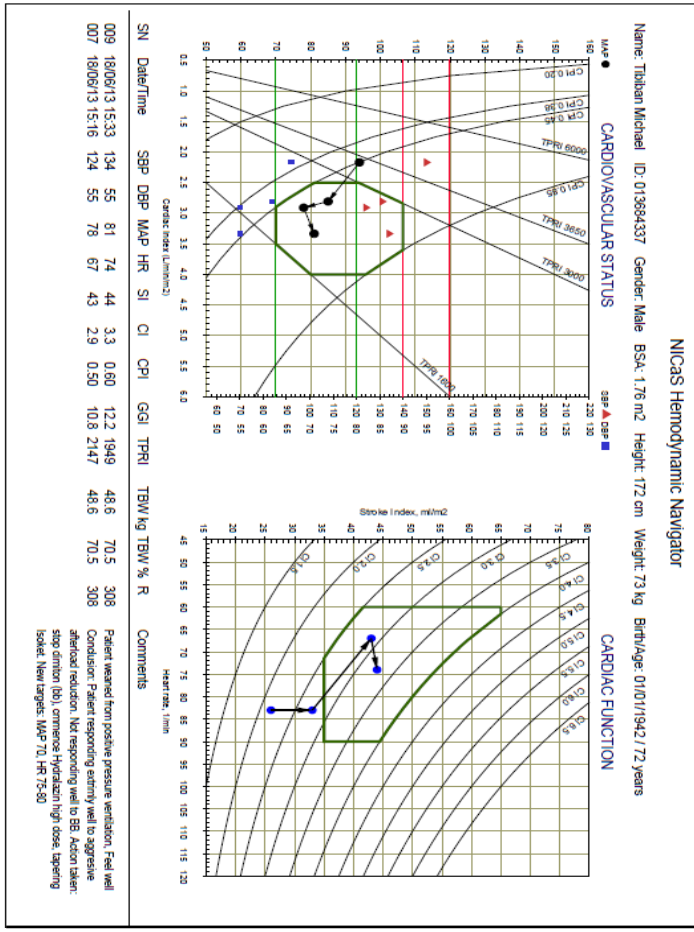


Figure 20: Hemodynamic Navigator

11.4.1. Cardiovascular Status Graph

This graph displays Blood Pressure vs. Cardiac Index and helps understand the vascular status. To the left and right of the graph **are the measurement** scales for MAP, SBP and DBP – each with a graphic representation (MAP – black dot; SBP red triangle; DBP blue square). The normal range is indicated by a green hexagon. Measurement values within the hexagon boundaries are within norm. Below the graph is a tabular display of the values for the two measurements parameters.

11.4.2. Cardiac Function

This graph display of Stroke Index (SI) vs. Heart Rate (HR). Each series is represented by a blue dot on the graph. The arrow indicated the sequence, earlier measurement to later. The Green graphic form indicates the norm. Measurement values within the graphic boundaries are within norm. Below the graph is a tabular display of the values for the two measurements parameters.

11.5. REPORT OPTIONS

11.5.1. Quick Report

Pointing the mouse to a measurement (M) or to a series (S) in the right-hand pane will open a small window with the results of 5 parameters (HR, SV, CO, CI, TPR) either for the specific measurement or the average for the series.

11.5.2. Omitting a measurement/s from a report

Selecting a measurement or several measurements with the right mouse button excludes these measurements from statistics and from calculated averages in reports (see *Figure 25*: M#8).

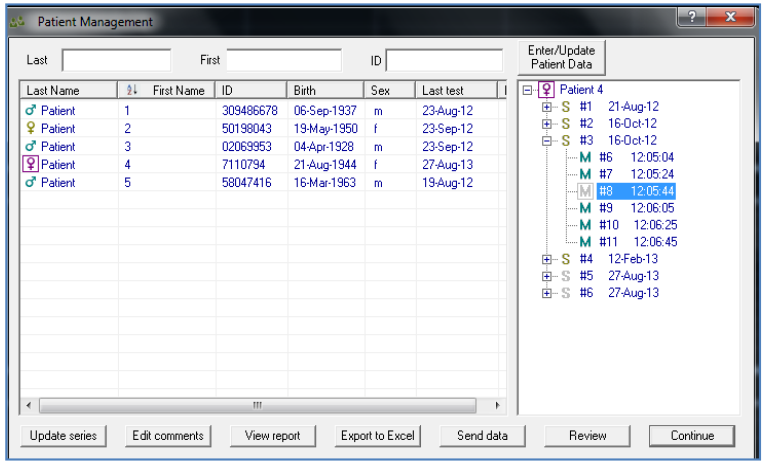


Figure 21: Patient Management Windows

12. ALARMS

As mentioned in the previous section, the system can set-off one type of alarm while monitoring a patient.

Technical Alarm

Technical alarms are activated as a result of a technical or software failure. When a technical alarm sounds, a unique technical-alarm audio notification is heard, and the status line in bottom of the screen displays the cause of the alarm. *Figure 23* demonstrates a technical alarm scenario.

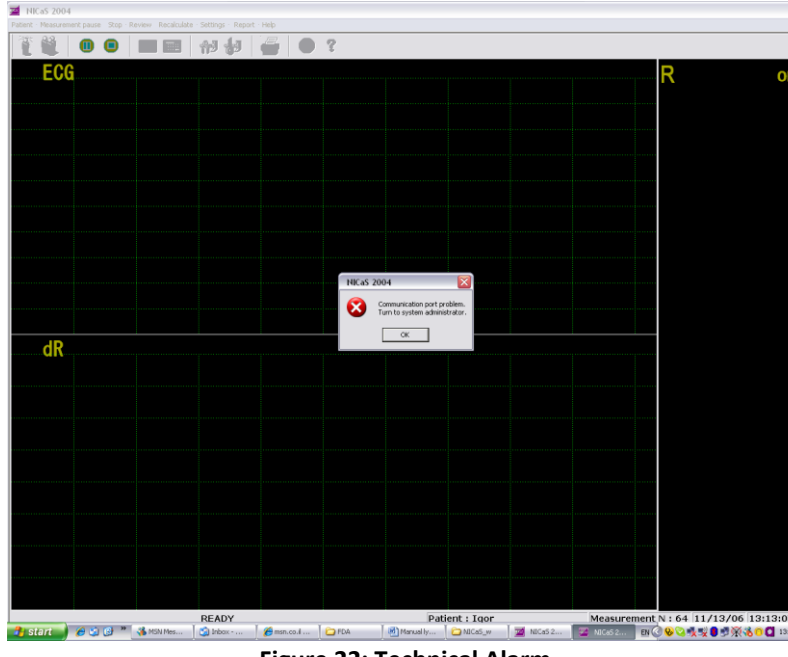


Figure 22: Technical Alarm

Possible Technical Alarms are:

A) Communication port problem- there is no data received from the unit
   Root cause:
   - Communication cable is not properly connected.
   - Hardware defect on the cable, or port of NICaS or PC.

B) Bad electrodes - No data from electrodes.
   Root Cause
   - Electrodes are not attached properly
   - Hardware defect on electrodes

C) Cannot calculate results - Bad data from electrodes
   Root Cause
   - Electrodes are not attached properly
   - Electrodes are dry

13. INTENDED PATIENT POPULATION

The NICaS CS is intended to monitor and display patients hemodynamic parameters (including stroke volume, stroke index, heart rate, cardiac index, cardiac output, total peripheral resistance, and the Granov-Goor Index), in males and females with known or suspected cardiac disorders needing cardiac assessment.

Exclusion Criteria

For proper use of the RIC technology, the following exclusion criteria must be strictly adhered to:

- Aortic valve insufficiency
- Significant aortic valve stenosis
- Severe mitral valve insufficiency
- The following aortic conditions:
  a) aneurysm; b) coarctation; c) obstruction (bifurcation)
- Peripheral vascular disease with feeble or absent peripheral pulses
- Restlessness and/or chaotic breathing
- Congenital cardiac malformations
- Extra-cardiac shunts
- During renal dialysis
- Adiposity – 50% or more than normal
- Height under 1.50 m and above 2.00 m.

Attention: For optimal results, the patient must be motionless except for normal breathing. If the patient cannot be immobile, sedation is recommended.

14. TROUBLESHOOTING

When problems arise, a message will be displayed at the top of the screen referring the user to the following chart:

PROBLEM	ACTION
9.1 MESSAGE: "Check Connectors"	- Check if power connection and the RS232 plug are properly plugged in. - If problem persists, contact manufacturer's local Service Department.
9.2 MESSAGE: "Bad Electrodes"	- Check ECG and impedance electrodes for dirt or broken parts. - Unplug sensors, clean connectors with a clean cloth and 90% alcohol. - If unsuccessful, replace with new set of electrodes.

In case of a general problem, refer to the following chart for further details:

PROBLEM	RESOLUTION

15. SERVICE

Should service be required during or after the warranty period, please contact New NI Medical representative as per list below (please visit our website www.ni-medical.com for an update distributor list) to obtain a Return Authorization Number. Please repackage the device carefully in its original box or in a sturdy carton to prevent damage. Include a note describing the nature of the problem and your return address. We also suggest that you insure the package. Send the medical device to:

Main Office
New NI Medical (2011) Ltd.
3 En Hay St.
Kfar Mallal 4592000, Israel
Tel.: +972 9 7407031
Fax: +972 9 7401030
Email: sales@nimedical.co.il
www.ni-medical.com

EU Official representative
New NI Medical (2011) UK
TEL: +44-(0)758-049-8397
E-mail: sales@nimedical.co.uk
www.ni-medical.com

USA
New NI Medical (2011) USA
500 Market St. Suite205
Chapel Hill, NC 27516 USA
Tel.: +1-800-979-2904
Fax: +1-888-724-2926
E-mail: sales@ni-medical.com
www.ni-medical.com

NI Medical will provide service and support for the product for at least seven years from the day of manufacture.

16. ORDERING INFORMATION

If for any reason you wish to order one of the following items, please write to us or to your supplier, and remember to enter part number and description, as specified below:

Part No.	Description
NI2.0001.01	NICaS CS Module, Integrated ECG
NI2.0005.01	NICaS CS ICG Cable
NI2.0006.01	NICaS CS ECG Cable
NI2.0009.04	NICaS CS Sensor Kit, ICG only, box of 100 applications

APPENDIX A: LIMITED ONE-YEAR WARRANTY

1. Warranty

N.I. Medical Ltd. warrants that for a period of twelve (12) months from installation of equipment at a customer's premises, such equipment (excluding consumable component) will materially conform to its published specifications under normal use and service. New NI Medical Ltd.'s sole obligation and customer's sole remedy, for any failure of an equipment to perform as warranted above, is, the correction or replacement, at New NI Medical Ltd.'s option, of the non-conforming equipment, provided, however, that New NI Medical Ltd. has been notified by customer or New NI Medical Ltd.'s authorized distributor of the non-conformity prior to expiration of the warranty period set forth above; replacement of equipment shall be made by New NI Medical Ltd. only against receipt of the defective equipment unless otherwise agreed between the parties.

2. Warranty Exceptions

The warranty set forth herein will not apply, and, customer will reimburse New NI Medical Ltd. or its authorized distributor, as applicable, for any costs and expenses incurred in connection with goods or services provided in the event:

a) the equipment has been used other than in accordance with this User Manual, its documentation or other written operating instructions or has been subject to negligence or accident by anyone

other than New NI Medical Ltd. or its authorized distributor;

b) use of the equipment in excess of the maximum period determined by New NI Medical Ltd. or its authorized distributor;

c) products or parts identification labels are removed or altered from the equipment;

d) the equipment has been modified, repaired, serviced, maintained or altered by anyone other than New NI Medical Ltd. or its authorized distributor;

e) the equipment has been combined with software, hardware or other equipment not supplied by New NI Medical Ltd. or its authorized distributor;

f) if at any time the power supplied to any part of the equipments exceeds the rated tolerance design parameters or applicable local regulations;

g) the equipment has been installed not in accordance with the written installation instructions provided by New NI Medical Ltd. or by its authorized distributor;

h) the equipment has been damaged by causes beyond the control of New NI Medical Ltd.;

i) the equipment has been modified without New NI Medical Ltd.'s written consent; or

j) if any time the serial number plate is removed or defaced.

Customer will reimburse New NI Medical Ltd. for all expenses and costs involved in New NI Medical Ltd.'s efforts in the event the problem for which service sought is not covered by the above warranty.

3. Limited Warranty.

EXCEPT FROM THE WARRANTY SPECIFIED ABOVE THE EQUIPMENT IS PROVIDED “AS IS” AND THERE ARE NO OTHER WARRANTIES EXPRESSED OR IMPLIED, IN LAW OR IN FACT, INCLUDING THE IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE TO CUSTOMER HEREUNDER. CUSTOMER ACKNOWLEDGES THAT THE EQUIPMENT IS NOT A DIAGNOSTIC OR THERAPEUTIC DEVICE AND MAY BE USED ONLY FOR THE PURPOSES APPROVED BY THE FDA AS SPECIFIED BELOW. CUSTOMER ACKNOWLEDGES THAT EQUIPMENT MAY BE USED ONLY ON PERSONS WHICH ARE INCLUDED IN THE "INTENDED PATIENT POPULATION" SPECIFIED ABOVE AND THAT DO NOT FALL WITHIN ANY OF THE EXCLUSION CRITERIA SPECIFIED THEREIN.

4. Limitation of Liability.

N.I. MEDICAL LTD. IS NOT LIABLE TO CUSTOMER FOR INDIRECT, SPECIAL, INCIDENTAL, OR CONSEQUENTIAL DAMAGES RESULTING FROM ANY BREACH OF WARRANTY OR BREACH OF THIS AGREEMENT OR UNDER ANY OTHER

LEGAL THEORY INCLUDING, BUT NOT LIMITED TO, LOST PROFITS, DOWNTIME, GOODWILL, DAMAGE TO OR REPLACEMENT OF EQUIPMENT AND PROPERTY, AND ANY COSTS OF RECOVERING, REPROGRAMMING, OR REPRODUCING ANY PROGRAM OR DATA STORED IN OR USED WITH AN EQUIPMENT EVEN IF N.I. MEDICAL LTD. HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES OR LOSSES. IN NO EVENT SHALL N.I. MEDICAL LTD. BE LIABLE FOR THE CUSTOMER'S COSTS OF PROCURING SUBSTITUTE PRODUCTS OR COMPONENTS. IN NO EVENT SHALL N.I. MEDICAL LTD. BE LIABLE FOR ANY THIRD PARTY PRODUCTS (SUCH US COMPUTERS) THAT ARE USED TOGETHER WITH THE EQUIPMENT EVEN IF THEY WERE PURCHASED VIA N.I. MEDICAL LTD. OR ITS AUTHORIZED DISTRIBUTORS.

THE AMOUNT OF LIABILITY OF N.I. MEDICAL LTD. FOR ANY CLAIM ARISING UNDER CUSTOMER'S USE OR INABILITY TO USE THE EQUIPMENT, WHETHER BASED ON BREACH OF CONTRACT, BREACH OF WARRANTY, NEGLIGENCE, STRICT LIABILITY OR OTHERWISE WILL NOT EXCEED THE AMOUNT PAID BY CUSTOMER. THESE LIMITATIONS APPLY TO ALL CAUSES OF ACTION IN THE AGGREGATE.

SOME OF THESE LIMITATIONS MAY NOT BE FULLY APPLICABLE IN CERTAIN JURISDICTIONS.