

ICM+ Standard of Procedures



Masimo ROOT monitor

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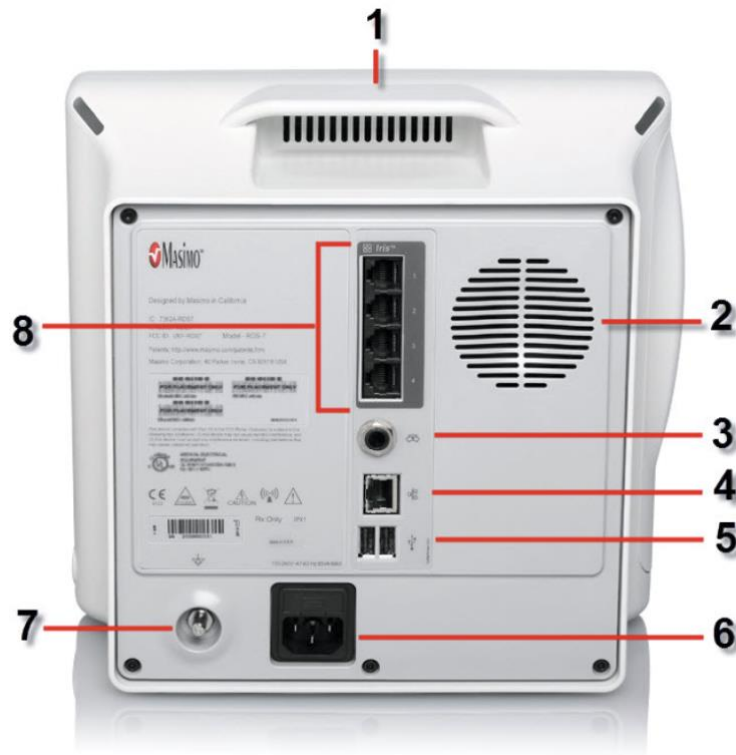
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Prerequisites

1. **A laptop (or a PC) with the latest ICM+** and its Masimo IAP (or ASCII1) module installed
2. **Masimo ROOT monitor**
3. **Appropriate cables** – a null modem USB-USB cable (eg FTDI USB NMC), with drivers installed on the ICM laptop.

Configuring ROOT monitor for data export

In order for the connectivity to work the ROOT monitor needs to be appropriately configured and the baud rate must be then matched by the ICM+ data source configuration. This can be done in the Device Settings: the baud rate can be set in the Access Control option (note that this is protected by a password), and the USB port mode is set in the Device Output option. There are two USB ports (see picture below, item 5) and any one can be configured for streaming data in ASCII1 or IAP format. The baud rate can be any of the supported ones, as long as ICM+ configuration matches it, however the manufacturer's recommendation for Root monitors is to use 115200 rate for ASCII1 format and 921600 for IAP format. IAP format give access to the waveform data as well as numerics. Once configured the monitor needs to be connected with the ICM+ laptop using a USB-USB null modem cable (as shown below). The data collection has been tested with a cable manufactured by FTDI Chip (<http://www.ftdichip.com/Products/Cables/USBtoUSB.htm>)



Locking and unlocking ICM+

ICM+ includes a simple system of user based permissions, which allows it to be used safely in a clinical environment, also by people with minimal training, ensuring that the vital data collection process is not inadvertently interrupted or disturbed.

If your ICM+ is correctly configured when the program is run it will automatically initialize with the default user 'Nurse'. There are three other users already configured in ICM+, the Administrator, the Manager and the Operator. The users have been configured with progressively decreasing operational rights.

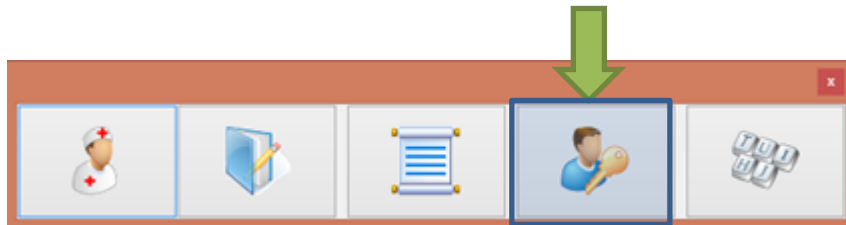
The **Nurse** is the user with the fewest rights in the software, effectively only being able to insert clinical events, browse the charts and starting new sessions, without any possibility to disrupt the data collection procedure. Please refer to the 'How to use the events form' for more details. After 3 minutes of inactivity, ICM+ automatically logs in as a Nurse.

The **Administrator** is the user that will have full access to the full features of the application.

The **Manager** will have the same privileges but will not be able to manage user accounts.

The **Operator** will only be capable of starting new Recording sessions with available profiles, browsing data, inserting clinical information and display configuration.

Login (change users) form is accessible via a button on the tool bar/main menu bar.



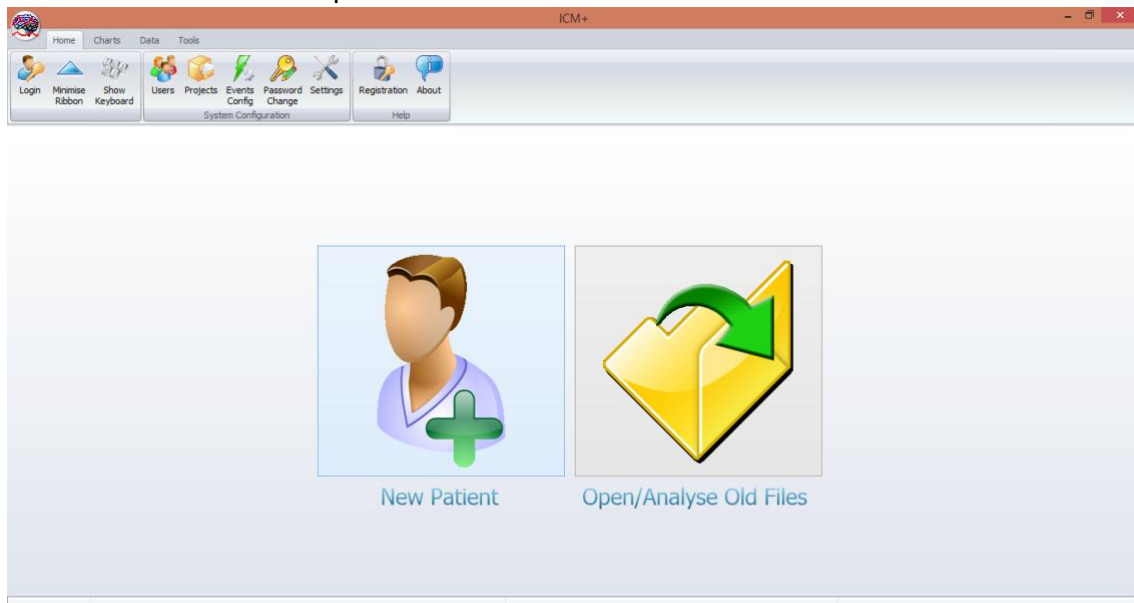
When the Login button is pressed, the User login form will appear.

In this form you will find:

1. A button to the Default user and a button to lock the application so that nothing but the login button is accessible.
2. A key pad to insert the Password for a given use.
3. And a Drop-Down menu to select the user to Login as

Starting a new data collection session

To create a new data acquisition session hit New Patient button.



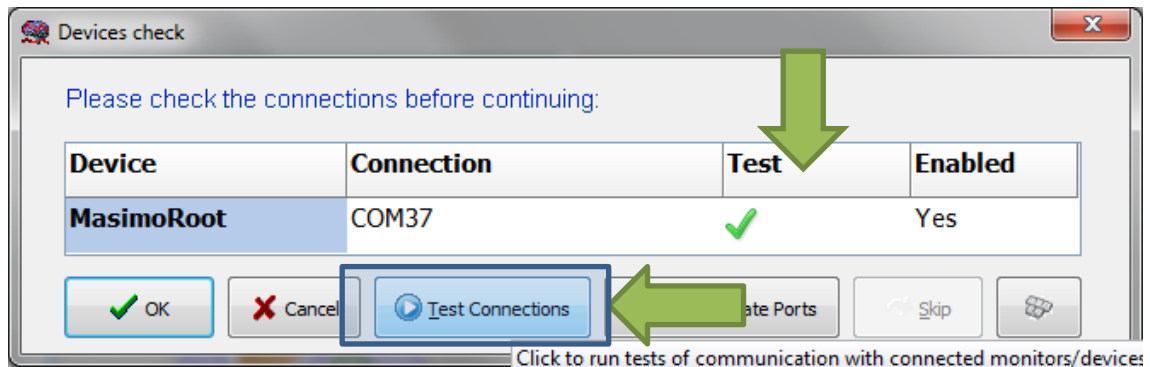
This will bring up a new form, where patient details can be provided:

 The screenshot shows the 'New Data Acquisition Session Form' dialog box. It has a title bar with a close button. The form contains several sections:

- Project:** A dropdown menu set to 'Devel' and a 'New Project' button.
- Data File:** A text field showing the path 'C:\Users\peter\Documents\ICM+Data\Projects\Devel\Devel_CAM_20161222145556_HEX.icmp' and a file selection icon.
- Patient's information:**
 - First Name, Middle Initial, Surname, Hospital ID, Room/Bed No, and Anonymised ID (text input fields).
 - Date Of Birth, Date Of Ictus, and Date Of Admission (date and time pickers, all set to 22/12/2016 00:00).
 - Gender (radio buttons for Male and Female, with Male selected).
- Clinical background:** A large text area.
- Retrieve Demographics From ...:** A button and a dropdown menu.
- Data Acquisition/Analysis Configuration Profile:** A dropdown menu showing 'W:\ICM+\Configs\Other Devices\Masimo Root.icmc'. A green arrow points to this dropdown.
- Customise the profile:** Three buttons: 'Clear All', 'Signals Sources', and 'On Line Analysis'.
- Buttons:** 'OK' (with a green checkmark), 'Cancel' (with a red X), and 'On Screen Keyboard'.

More importantly a data acquisition/analysis profile (configuration) file should be selected, either from the history list box or loaded from the file system. These can then be modified if necessary using Signal Sources editor (describe below), and/or On Line Analysis editor.

After the OK button is clicked, the Devices check dialogue is presented.



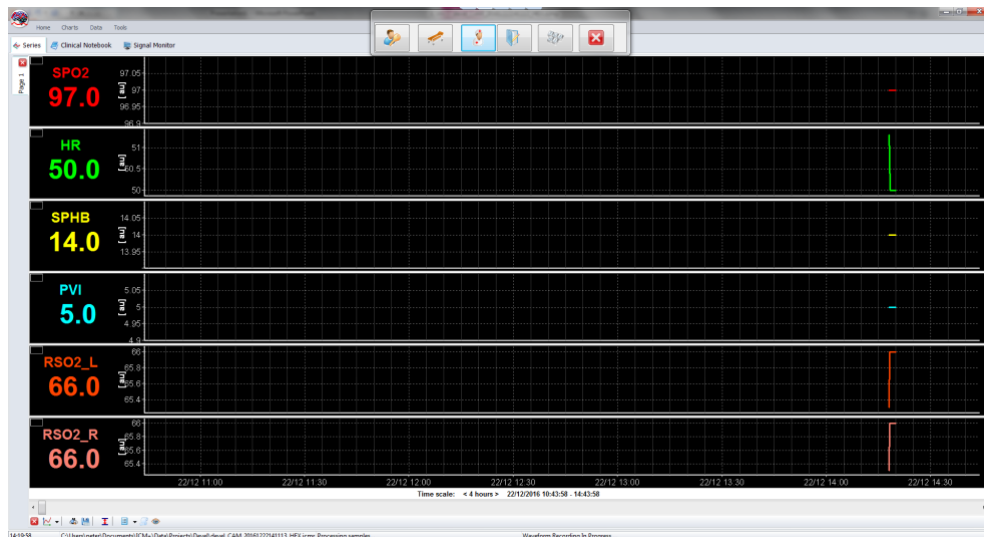
This dialogue is used to test the communication between the ICM+ and the monitor (the 'Test connections' button). If the test is successful the OK button can be pressed.

This form can also be used to modify the connection port (if it is a serial connection) or an IP address (in case of a network interface). For serial connections, the button 'Auto allocate ports' can be used to initiate the process of scanning and testing all the available ports for automatic port allocation.

Just before the session starts, the user is prompted to insert some additional information about the patient, if configured, via the Project Specific data dialogue. This form is also accessible from the Patient Notebook tab but it is highly recommended that it is filled in, as much as possible and practical to do, at the start of the session.

GCS	5
CT Marshall score	IV
Type of TBI	Diffuse brain injury
Polytrauma	Abdominal

After this dialogue, ICM+ main display is presented and the session begins recording automatically, if this behaviour is configured in the used project. Otherwise use Start button to start data acquisition (see below). The charts with configured calculated parameters will get updated with the rate specified in the configuration profile. In order to see the raw data as it comes in from the monitor(s) click on the Signal Monitor tab, or the Monitor button if the tab is not available yet (see below).



Data analysis, main, display (as configured in the loaded profile). The charts can be modified using Charts top menu tools.



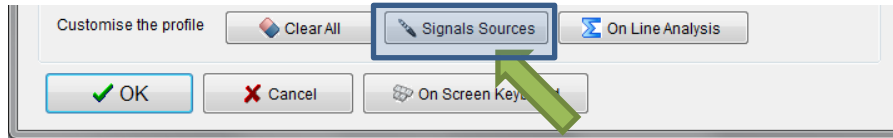
The raw signal monitor, showing all the data as it comes in. Please note that this raw data is stored in a separate file (or files if the one grows too large) with the name shown at the bottom of this panel.

If ICM+ **shuts down during a recording session** the next time it is run, the previous session is automatically restored, but here the user must first verify that all the signals are being received correctly in the Monitor button. After this the Start button must be pressed and the session resumes recording.

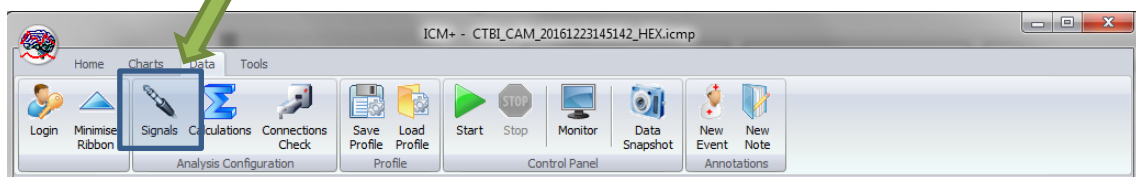


Manually configuring data collection

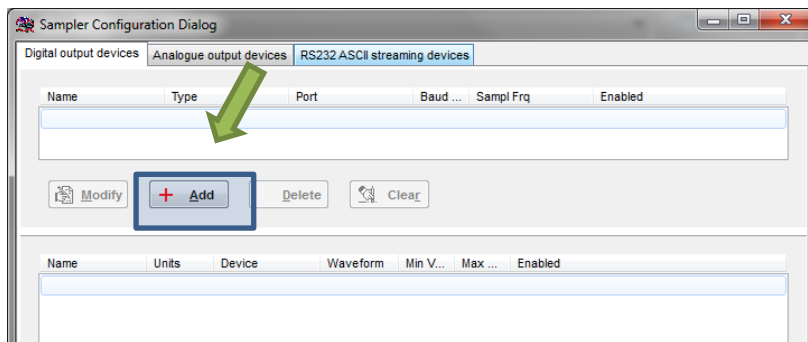
If there is no prepared profile available that includes desired data collection from the Masimo monitor or if there is a need to modify or add parameters downloaded from the monitor Signal Sources option needs to be used. This can be done in the New Data Acquisition Form:



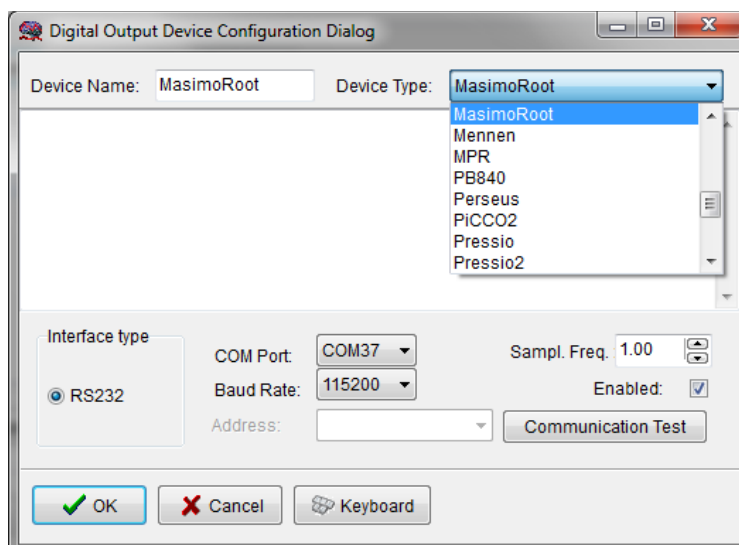
Or using Signals button in the main Menu (Data Section), with the data acquisition in pause mode.



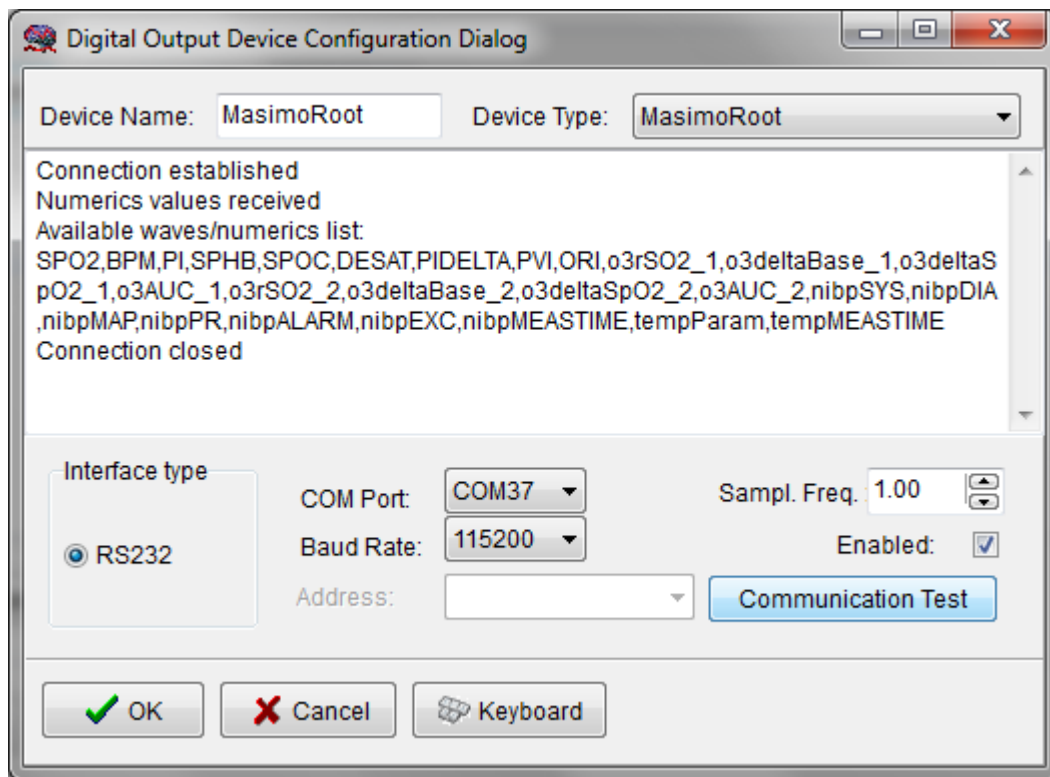
This brings up the Sampler Configuration form:



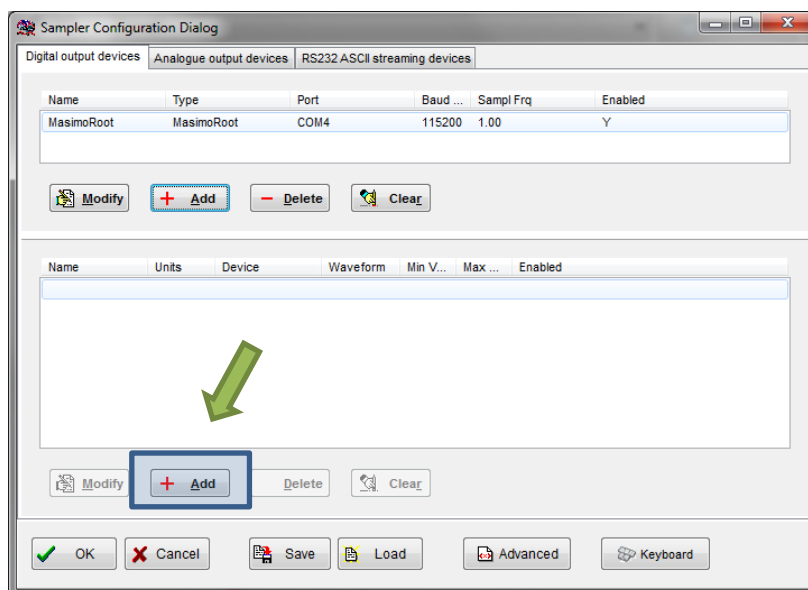
Clicking on Add button in the upper part (Digital Output devices tab) opens a Device Configuration dialog. Here, one can select the monitor module from the list of available (installed) interfaces, as well as specify the serial port (real or virtual, when using USB-RS232 adapter) and its baud rate to match the one configured/offered by the device.



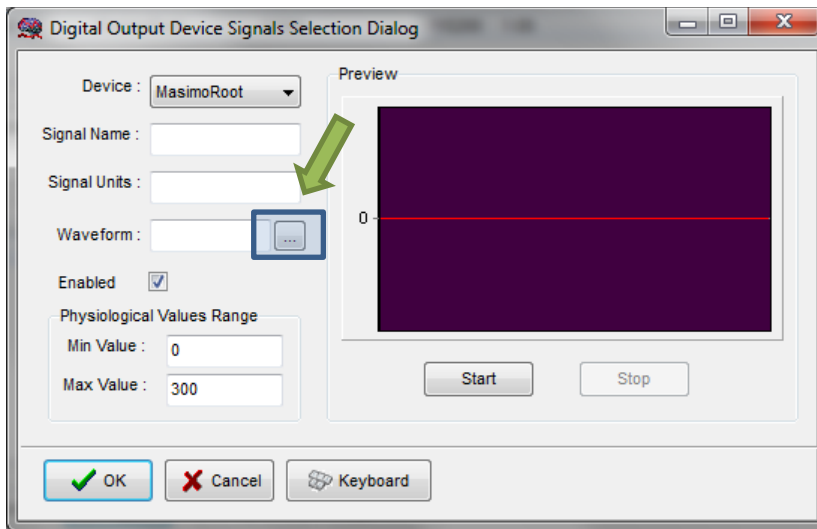
When the correct interface module, the COM port and the baud rate is chosen, clicking on 'Communication Test' will try to establish communication with the monitor and the log of that communication is printed in the memo box, listing also all the parameters that are available to download from the monitor .



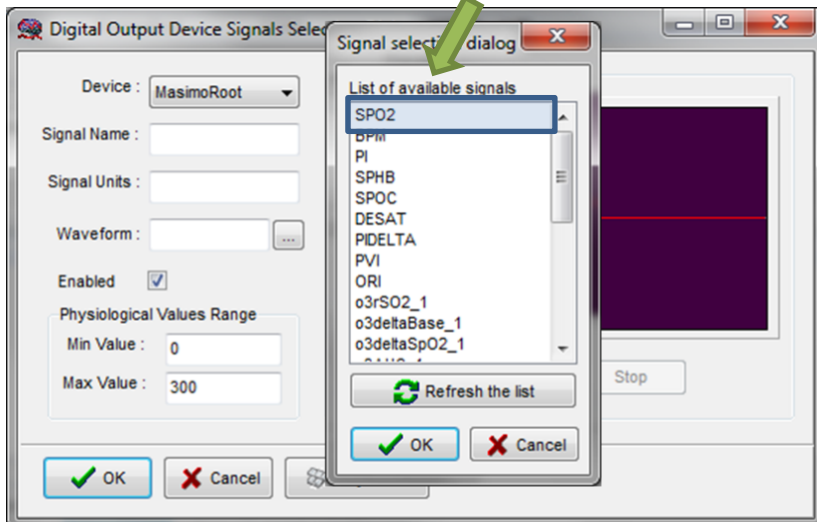
When the connectivity is confirmed the dialog can now be closed, which causes the device to be added to the data collection configuration. What remains to complete the configuration is adding to the configuration all the desired parameters to be downloaded. This can be achieved by using the Add button in the lower part of the Sampler Configuration dialog.



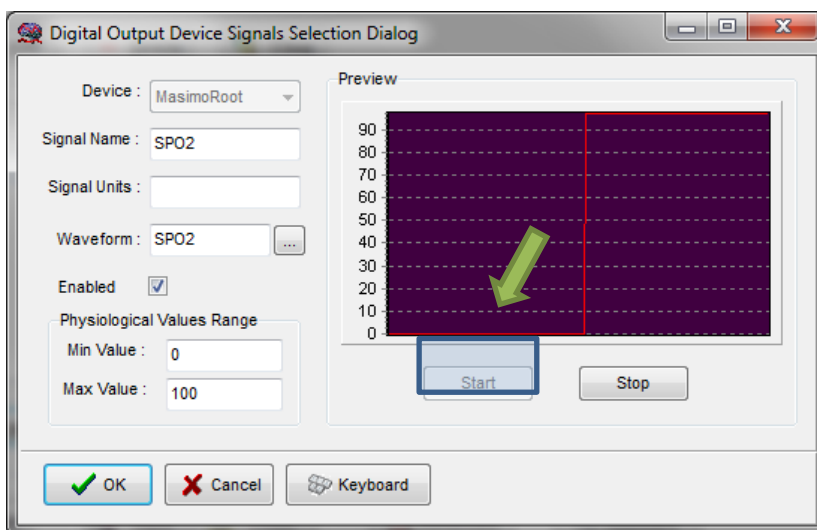
This opens a signal selection dialog:



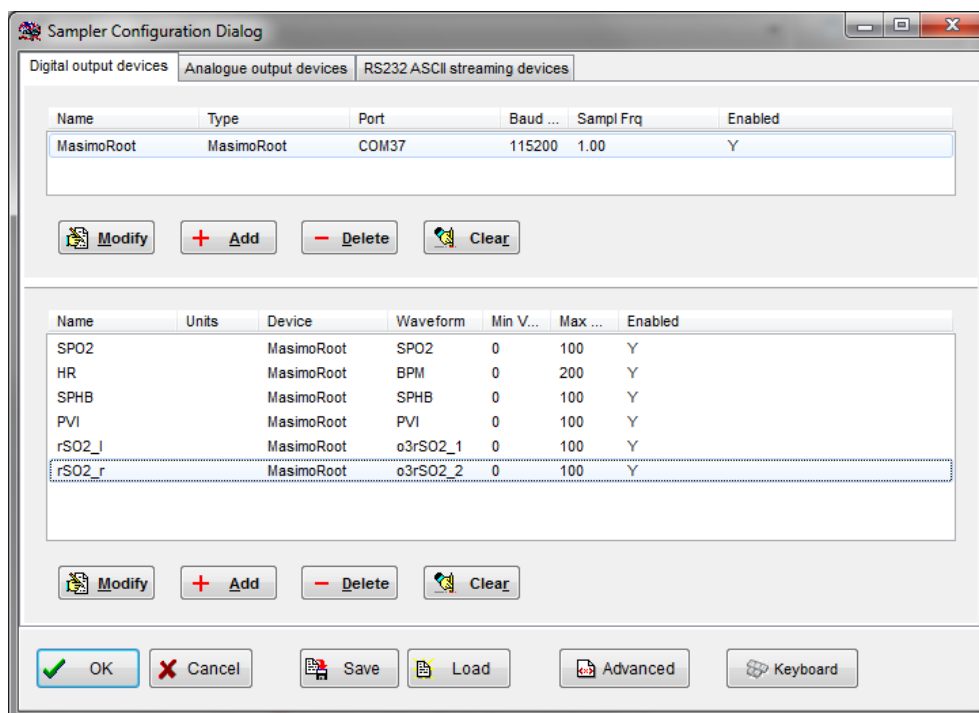
Using the little '...' button one can select available signal, one at a time.



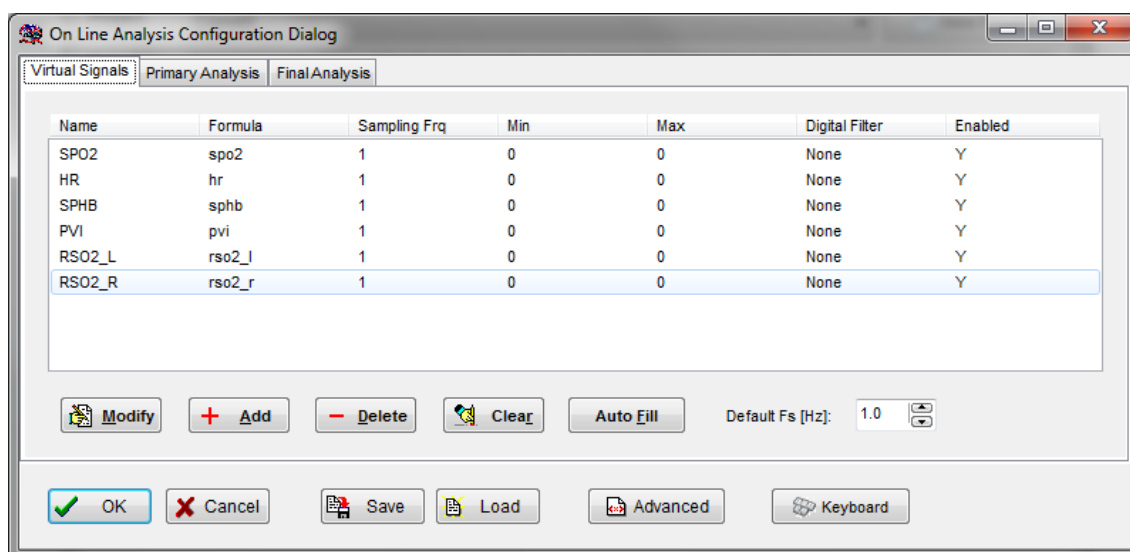
When a parameter is selected one can test if the data is coming in as expected by using the Start button



This process can be repeated as many times as it is needed putting together the complete list of parameters to be collected, which complete the data acquisition configuration procedure.



Please note, that adding parameters/signals to the data collection will make ICM+ show and record the data through the Signal Monitor window but the trends charts will not automatically get configured to show them. This is because the trend charts only show results of calculations, not the raw data. So to display even just a mean trend of a newly added variable collected from the monitor ICM+ this needs to be configured first in the analysis section, as in picture below, and then the new trend added to the charts.



Annotating clinical events

As soon as the acquisition of data starts the main menu tool bar will get minimised and in its place a small, 'data acquisition essentials', tool bar will open, as below.



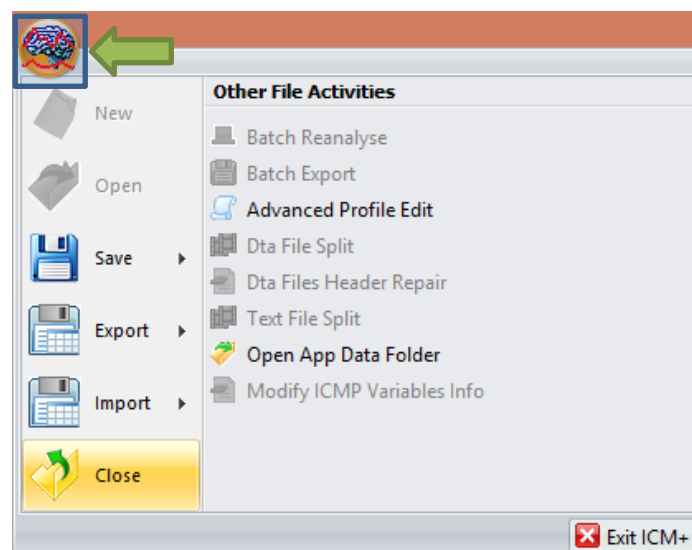
There, from left to right the following functions are accessible:

1. Log-in/Log-off form – to change the user (ie privileges)
2. Event annotation form
3. Free textual annotations form
4. An on-screen keyboard
5. The last button closes this tool bar and unfolds the main men toolbars

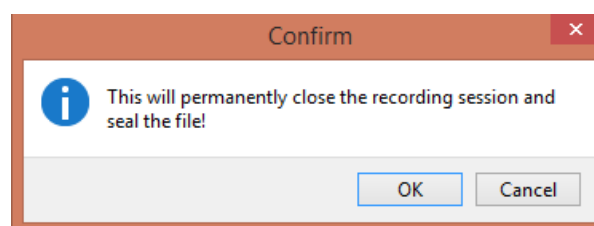
Terminating the data collection session and uploading the data

When the data acquisition process is finished the recording session can be closed using the Close button present in the ICM+ button. This will initialize a cascade of forms that will eventually lead to the sealing of the file and subsequent archiving the data to the file server, if required.

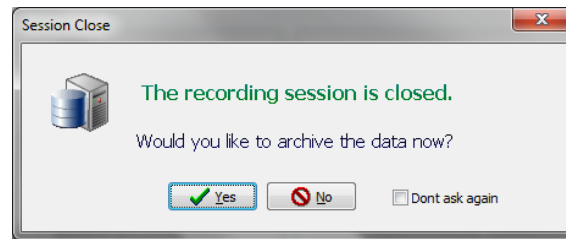
Closing a session is different from closing the program. To close the ICM+ application you need to press the red cross present on the upside corner of the right side of the screen. If ICM+ is closed (Exited) using this button or if the computer shuts down, the next time it is run, the recording session will be resumed with the same configurations it had at the moment of shutdown.



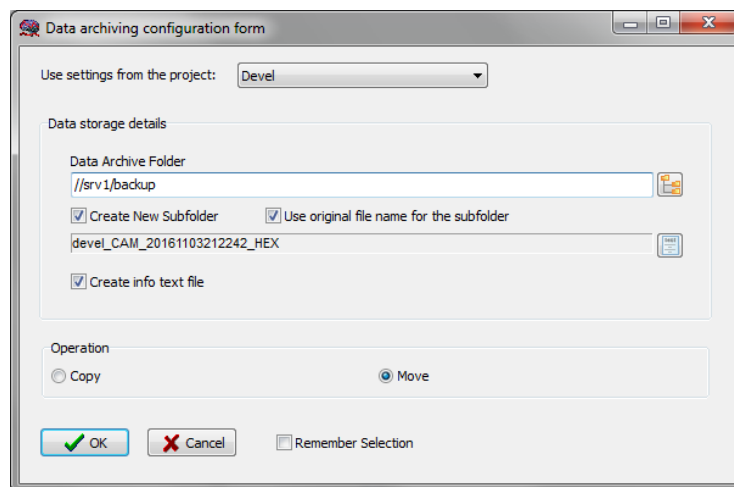
When this button is pressed a dialogue is presented prompting the user to confirm the closure of the recording session:



After confirming the end of the recording session another dialogue is presented prompting the user to archive the data:

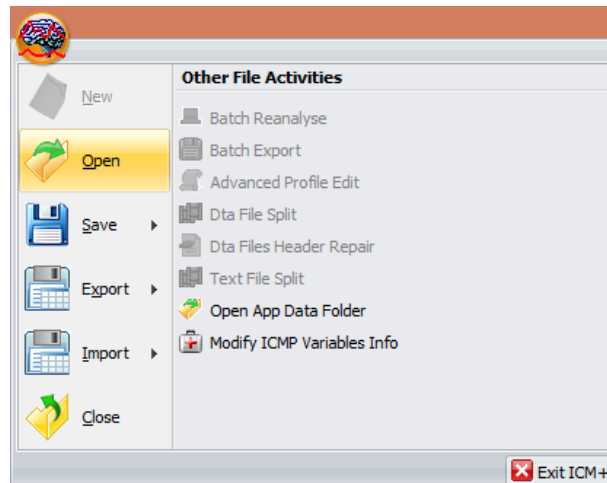


After confirming this dialogue the Data Archiving Form is presented, where the user can specify/confirm the location of the server and its share to use:

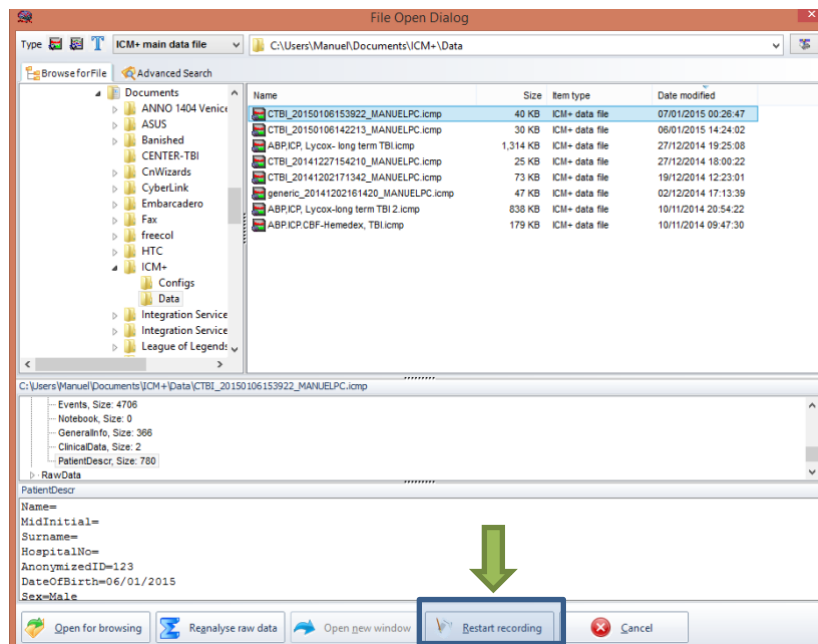


Restoring a closed data collection session

If a session was for some reason closed and a recording needs to be restored again the button open can be pressed.



The dialog that opens can be used to reopen the file in order to upload the data to our servers or to restore the recording session.



To reopen a file for inspection or to upload it is only necessary to double-click the desired file.

To restore the recording session, the highlighted button must be pressed and the recording resumes using the same profile as when it was closed.

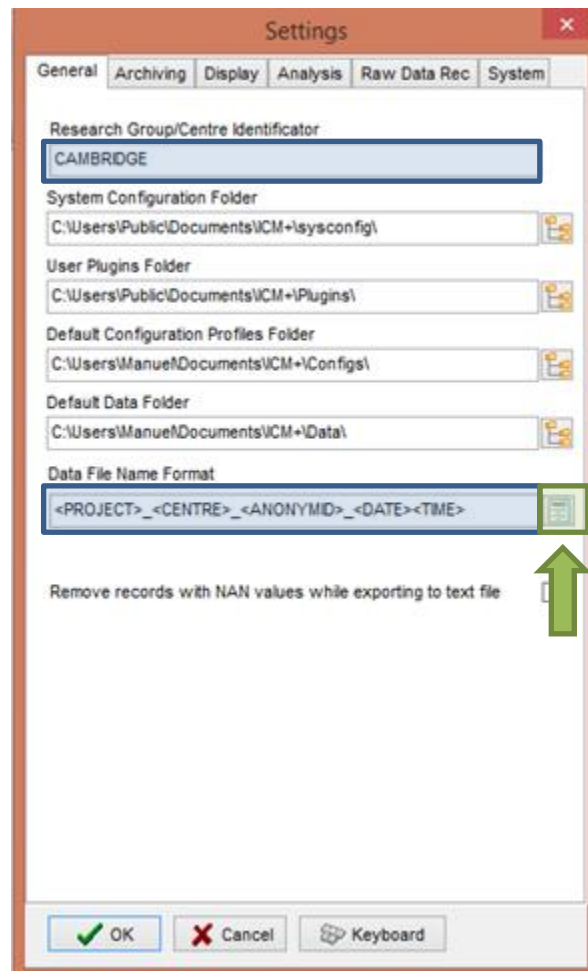
Appendix 1: Configuring ICM+ system options

Most of the programmable behaviours of the software can adjusted via the Settings menu. This menu can be found by clicking the Home tab and the Settings button.



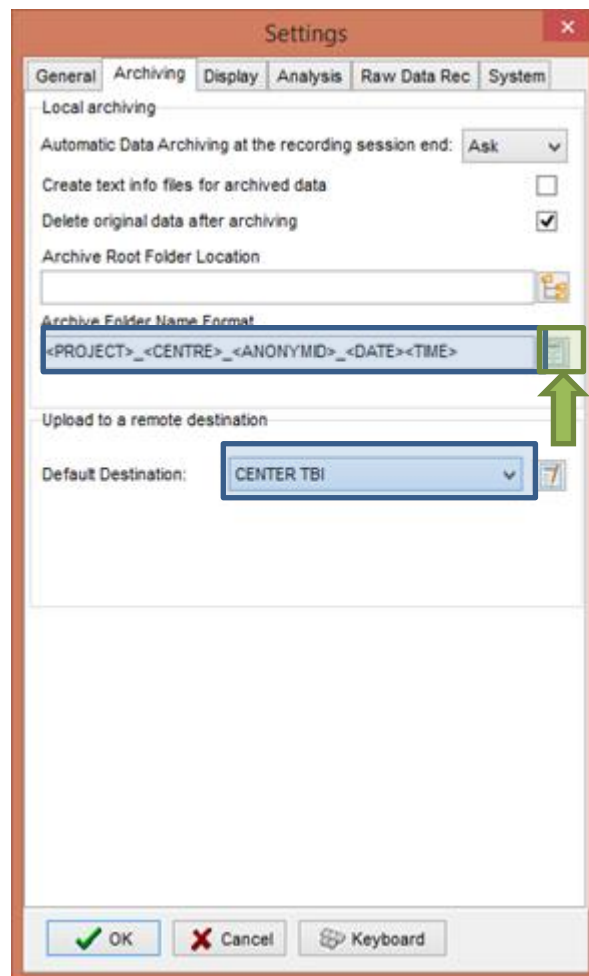
In the Settings menu you will need to configure several things:

- On the General tab:



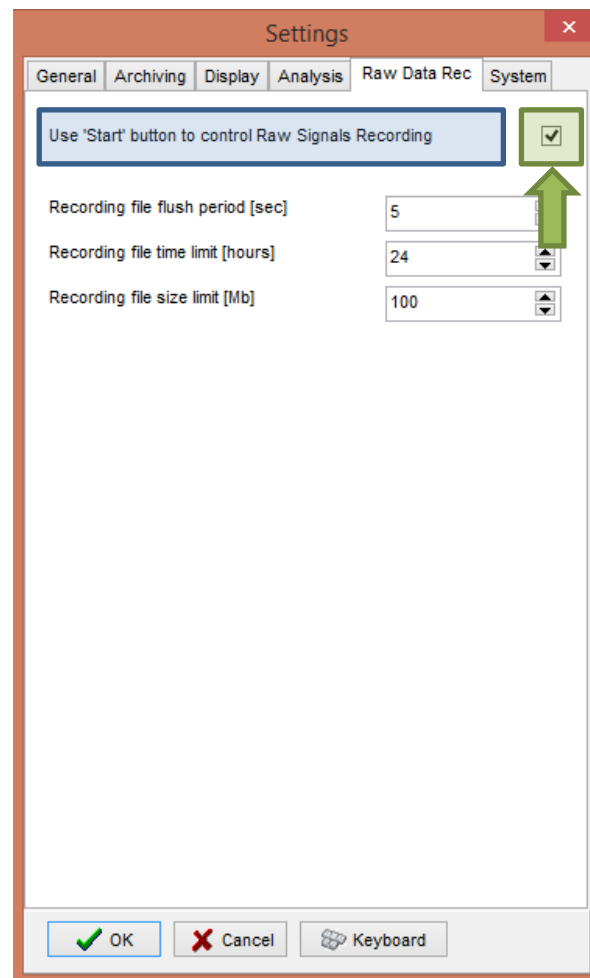
- The Research Group/Centre identification will be a unique name in the project that will identify the centre. This name should be fully inserted in capitals (ex. CAMBRIDGE).

- The **Data File Name Format** will be used to configure the structure to be used on the construction of the name of each data file. As each file generated in the study must have a unique identifier we agreed in using a structure that uses the format highlighted in the picture. A description on how to build this File Name format is presented further down in this appendix.
- On the Archiving tab:



- The Archive Folder Name Format will follow the same structure as the Data File Name Format. This setting is used for organising local archival storage of the data files.
- The remote server Upload (accessible via the upload function) default Destination can be selected here but it is the matching setting in the Project configuration that will ultimately take precedence.

- On the Raw Data Rec tab:



- The Use 'Start' button to control Raw Signals Recording **must be checked if you are using ICM+ to record any data directly from bed side monitors**

- On the System tab:

Settings

General Archiving Display Analysis Raw Data Rec System

Auto restore session in progress on startup Enable

Auto restart recording at program startup Enable

Inactivity time to software auto logout [min] 0

Auto unlock program as user : Nurse

Operating System Policy

Use this program instead of Windows shell Disable

Disable logoff/shutdown Disable

Disable Task Manager Disable

Disable locking the computer Disable

Disable Windows password change Disable

Windows Auto Login

State Disable Password

User Confirm

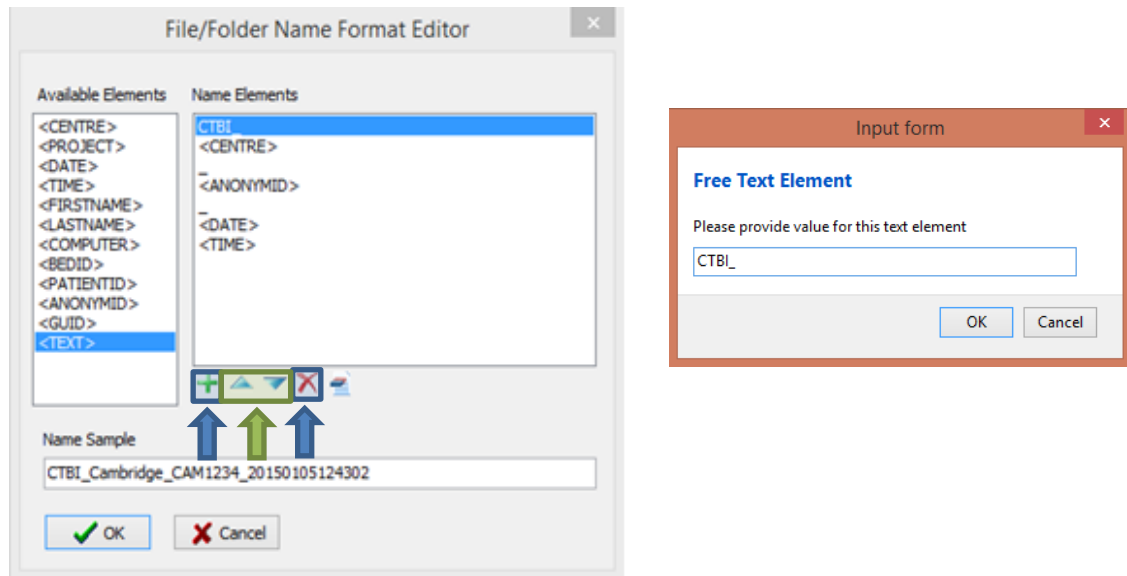
Patient description encryption

Passphrase

OK Cancel Keyboard

- Set the Auto unlock program as user to Nurse. Setting the inactivity time to a value greater than 0, eg 10 min, will cause the software to auto log-in as that default user following a selected period of time without interaction with the software (this will only happen of course if the program was unlocked as another user)

To build the **Data File Name Format** you will need to click the highlighted button and the following form will appear:



In this form it is possible to add/remove any name element present in the Available Elements menu.

The '_' and any additional static text can be inserted by using the element '<text>' and inserting the text to be added manually.

Appendix 2: ICM+ configuration folders and files

ICM+ uses two locations (configurable via the Settings form) to store all its configuration files:

Location 1: C:\Users\<username>\Documents\ICM+.

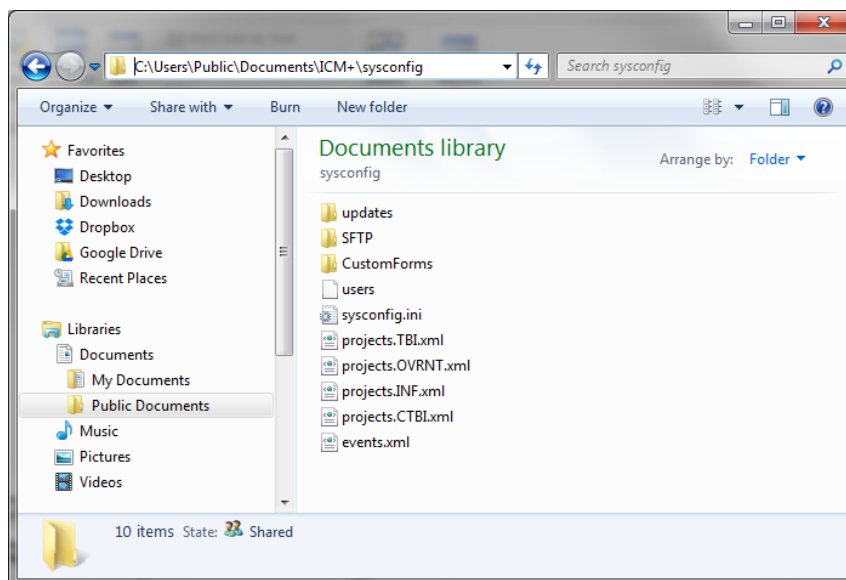
There are two subfolders here:

 ‘**Data**’ folder, where all the data recorded during the acquisition process is stored, and

 ‘**Configs**’ folder, used to store the data collection and analysis configuration ‘profile’ files, as in the figure below.

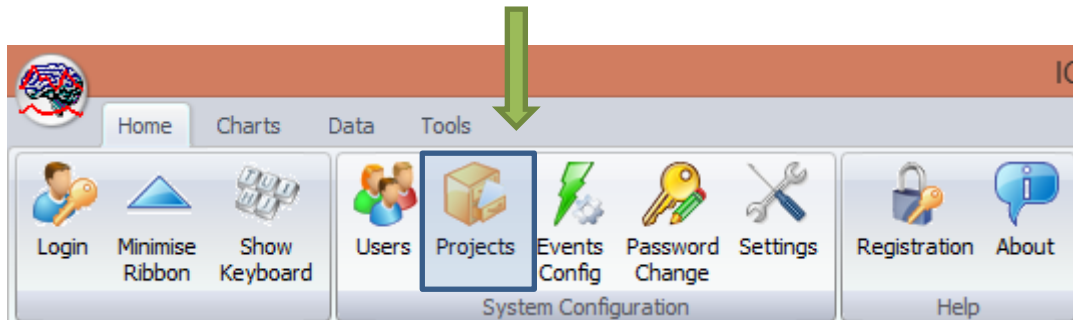
Location 2: C:\Users\Public\Documents\ICM+

Here all the environment configurations/settings are stored. This location contains a folder called **Plugins**, where 3rd party function libraries reside, a folder called **TxtFilters**, containing parsing definitions for different text format data files, and a folder called **sysconfig** containing all the settings of the software, except the data collection and analysis profiles which are store in the Location 1 (as above). Although these files could be edited directly using a text editor ICM+ has specific user interface forms to edit all aspects of the program functionality.

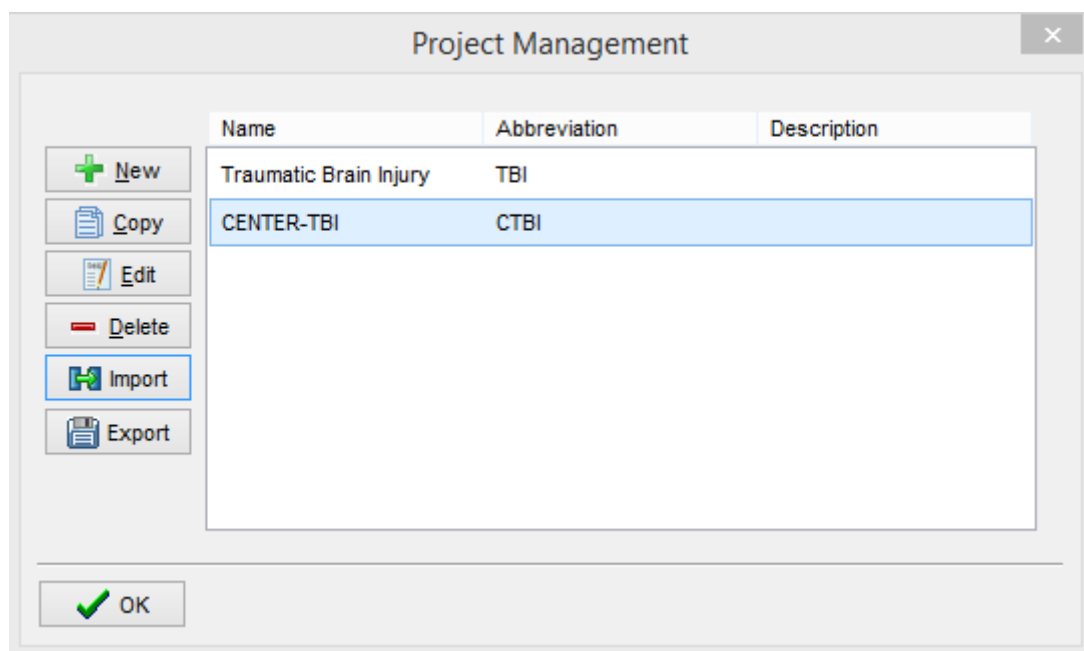


Appendix 3: Editing ICM+ Projects

Projects contain various configurations specific to a particular research project. These can be edited using **Projects** button in the main menu tool bar.



Clicking this button will open the Project Management dialogue, where you create, copy, edit, delete, export/import selected projects to/from a file.



Double clicking on a selected project or clicking on Edit will open a Project Editor where all the custom project settings can be modified.

The following screen shots describe the CENTER-TBI specific settings. These settings would have already been preconfigured for you if you have copied the provided project.ctb.xml file to the ICM+ sysconfig folder, or used the Project Manager to import the settings from that file. Please do not modify those for CENTER-TBI project.

Project Configuration

General | Data Fields | Events | Data Archiving

Project Definition

Name: CENTER-TBI

Abbreviation: CTBI

Description:

Data Folder: C:\Users\peter\Documents\ICM+Data\Projects\CENTER-TBI

Data File Name Format: <PROJECT>_<CENTRE>_<ANONYMID>_<DATE><TIME>

OK Cancel Keyboard

1. The project **abbreviation** will be part of the file name

2. '**Data Folder**' is a local folder where the data collected as part of this project will be stored

3. **Data File Name Format** lists elements that will be used to create automatic file names for each new data acquisition sessions. Please note that elements listed here will have to be filled in (e.g Centre ID, or the anonymous Patient ID) at the New Data Acquisition form stage before continuing.

Project Configuration

General | Data Fields | Events | Data Archiving

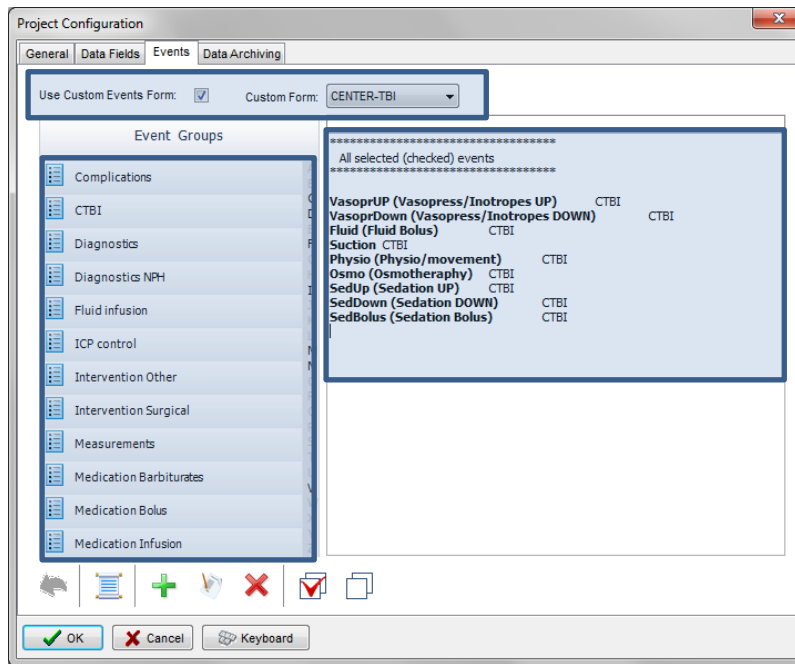
Data Fields Definitions

Name	Caption	Type	Description
GCS	GCS	Category	Glasgow Coma Score at admission
CT	CT Marshall score	Category	CT Marshall score at admission
TypeTBI	Type of TBI	Category	General type of brain trauma
Polytrauma	Polytrauma	Category	Other significant injury

Buttons: Add, Edit, Remove, Move Up, Move Dn

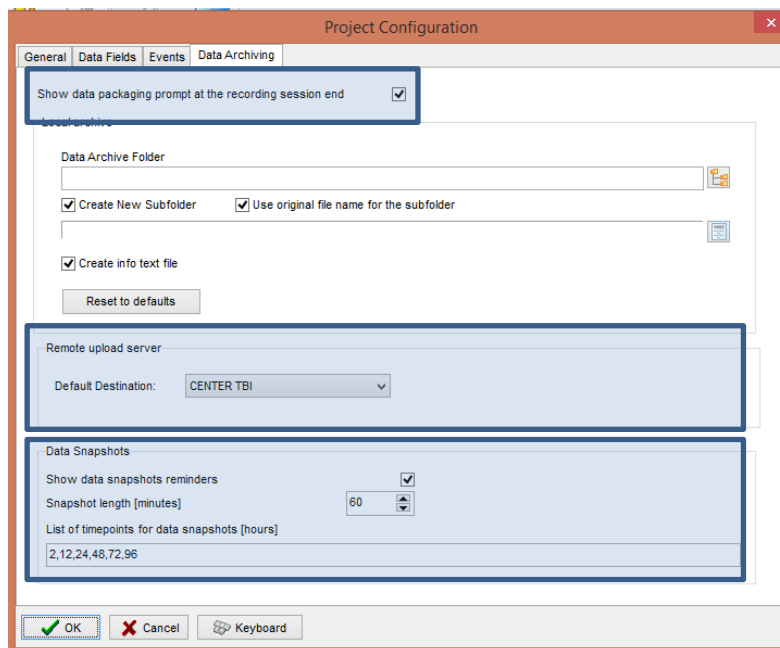
OK Cancel Keyboard

The data fields define placeholders for general clinical descriptors that characterise the patient at the time of admission to the critical care unit, that are useful to be kept together with the monitoring data.



This is where events that are already defined elsewhere (in the Events form), listed in the left panel (1), can be assigned to the particular project (listed in the right panel 2.).

Please note that CENTER-TBI uses a customised event form, selected using the 'Custom Forms' list box (3). It is possible however to add more events to the project but those will only be accessible from within the 'Event List' panel, toggled from the main menu tool bar panel, Charts section.



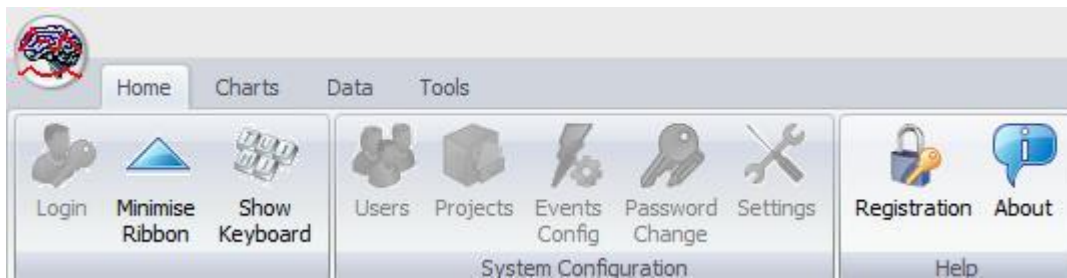
Here one can define the location and format of data archives as well as, essentially for CENTER-TBI:

1. This should be ticked in order for you to be prompted to convert the file to HDF5 at the end of the recording session
2. the destination of the remote server for data uploads,
3. the data snapshot length and the data snapshot reminders

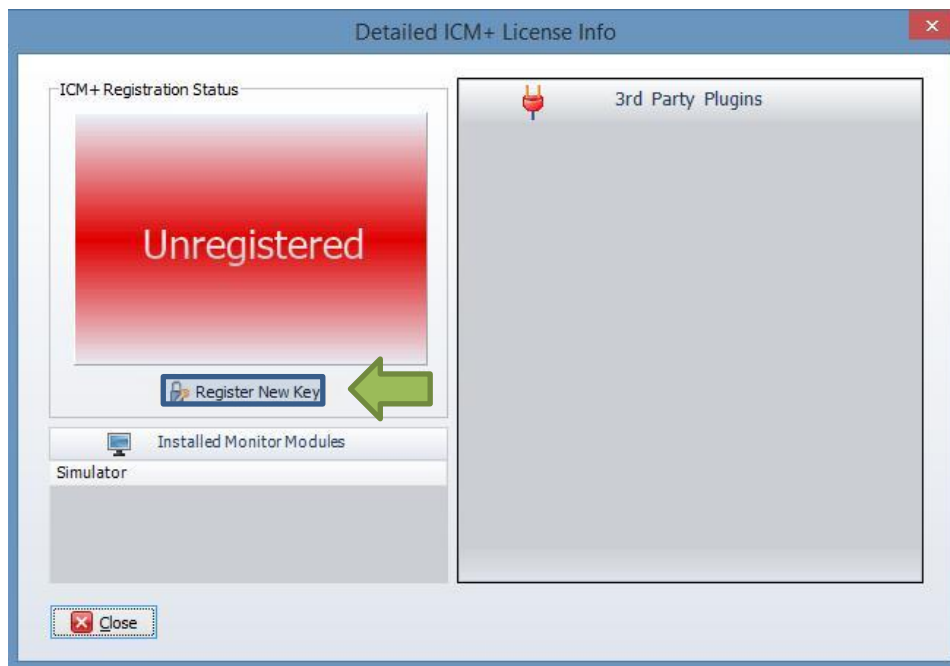
Appendix 4: Registering ICM+

When ICM+ is successfully installed for the first time in a computer it needs to be registered. This will probably already be done for you when you get the laptops, but if any major update needs to be done you will have to register it again.

To register ICM+ you need to press the Registration button on the Home tab.



This will bring up the Detailed ICM+ License Info window where you will need to press the Register New Key button.



This will bring forth the ICM+ Registration Form and here you will have to press the Copy Details.



ICM+ REGISTRATION FORM

Please quote this code for any further assistance
InstallCode: 485ACBC6D289

Username: ICMadmin

Institution: Institution Name

Computer: CTBI-Copenh2

→ **Copy Details** (button) **Email Details** (button)

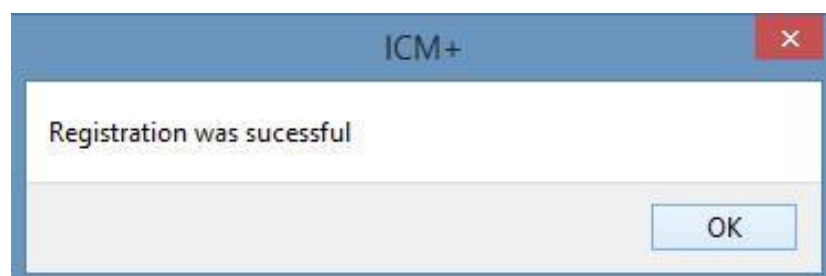
Register Now

Please enter the registration key, then press the [Register] button

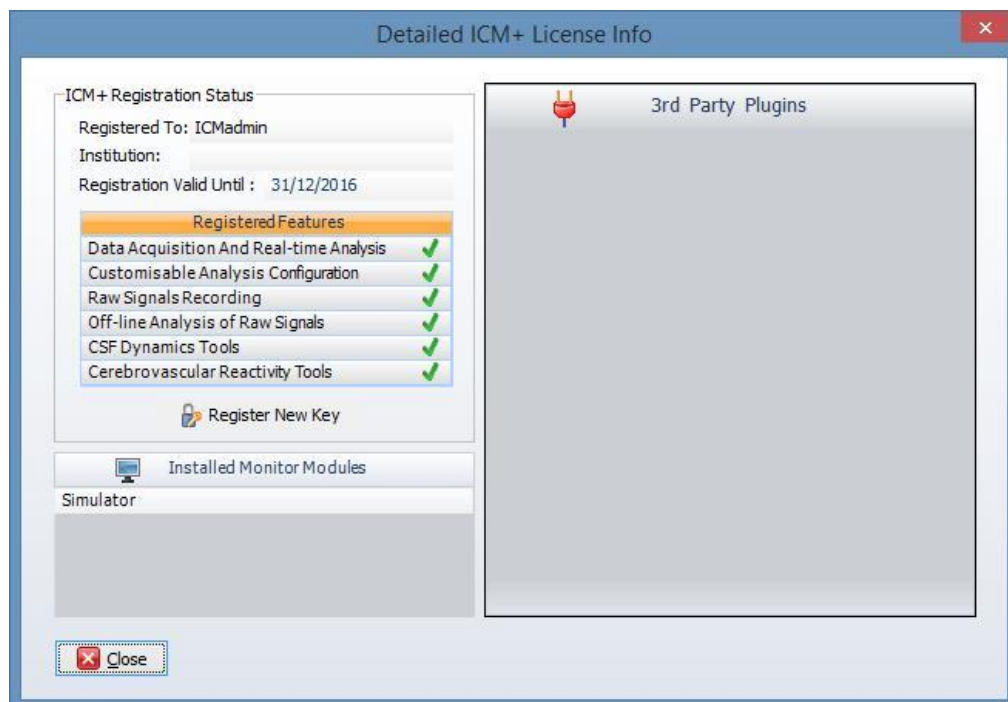
↑ **Register Now** (button) **Cancel** (button) **Keyboard** (button)

This will let you paste the details anywhere you want. You will then have email those details to Dr Peter Smielewski (ps10011@cam.ac.uk) or Manuel Cabeleira (mc916@cam.ac.uk) so that we can generate your product key and send it to you.

You will then have to paste the Key to the highlighted space and click Register now. If you are successful you will see the Registration successful dialogue.



And your Detailed ICM+ License Info window should look like this:



Appendix 5: Preconfigured users and passwords

Administrator – 2718

Manager – 1618

Operator – 3142

Nurse – 1414

The users, their passwords, and their rights are fully configurable in the software, using Users form. The default users have been chosen to fulfil the following roles:

User	Role
Administrator	Complete access to all the software configuration options, the users and passwords
Manager	Access to all the configuration options, except the users and password. This will normally be the user to do the entire configuration needed for data collection.
Operator	Control of the data collection process using preconfigured profiles, and changes to the charts layout and properties.
Nurse	Access to clinical annotations tools only. This should be normally set up as the default user kept logged-in during the data collection process, in order to prevent any inadvertent disruption to data recording but at the same time allowing and encouraging quick access to the clinical annotations.
Guest	This 'user' has no rights, making it impossible to interact with the software in any way.