CENTER-TBI

ICU High Resolution data acquisition

Standard of Procedures (SOP) for ICM+

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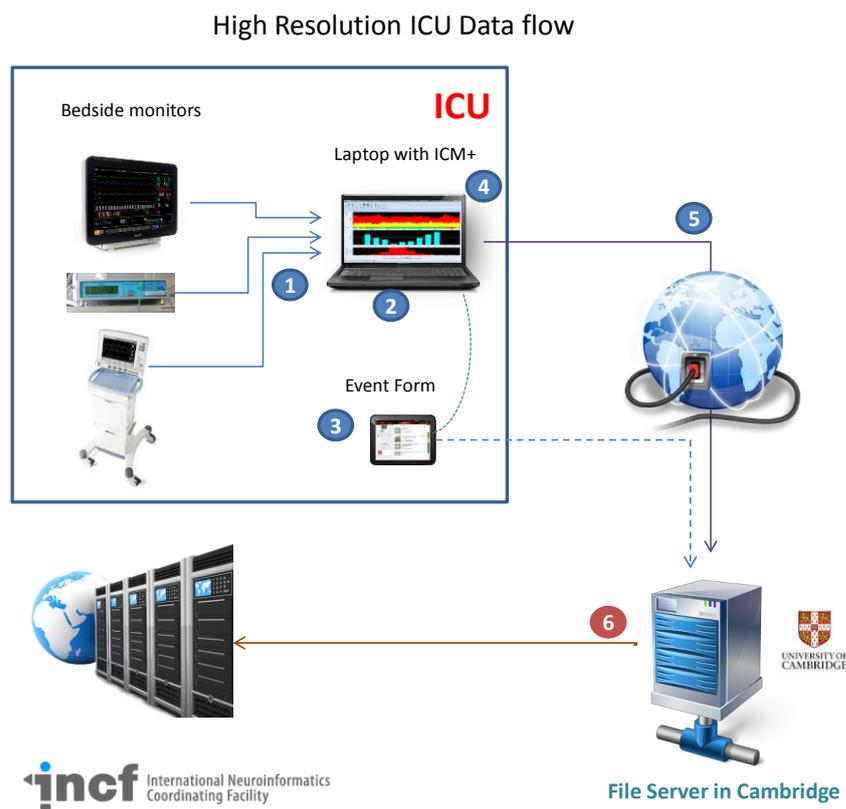Dr Ari Ercole (ae105@cam.ac.uk)

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Table of Contents

Summary of the HR ICU data flow using ICM+ system

Enrol the patient to the study and acquire a temporary Patient Number from the CENTER-TBI web page.

High Resolution ICU Data flow

At admission (to the study)

1.   Connect ICM+ laptop to the medical devices using the appropriate cables. Consult appendix 'Monitors Connectors' for more details about which cables to use for every medical device.
2.   Start ICM+ session Refer to chapter 'Creation of a new session' for more information about how to create a new monitoring session in the CENTER-TBI context.

During the data collection

3.   Ensure that you take note of as many events as possible through the Event Form. Refer to chapter 'Using the events form' for more information about how to use the event form.
4.   At 1-4 hours after the start of the data collection session take a data snapshot in ICM+ and transmit it to Cambridge Refer to chapter 'Creating Data Snapshots' for more information about how to use the snapshot form.

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Repeat the same process at 12 hours and 24 hours.

At the discharge (from the study)

5.   Stop the data analysis on ICM+, package the data and send it to the Cambridge Server. Refer to chapter 'Terminating a monitoring session and uploading the data' for more information about how to terminate the data acquisition.

In due course in Cambridge

6.   The data is checked, cleaned and uploaded/registered with the INCF central data base

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Configuring ICM+ to CENTER-TBI

The first time ICM+ is run, some configurations need to be made before the data acquisition process begins. These configurations are made in the Settings menu. This menu can be found by clicking the Home tab and the Settings button.
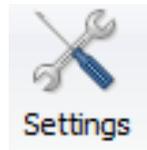
In the Settings menu you will need to configure several things:

- On the General tab:
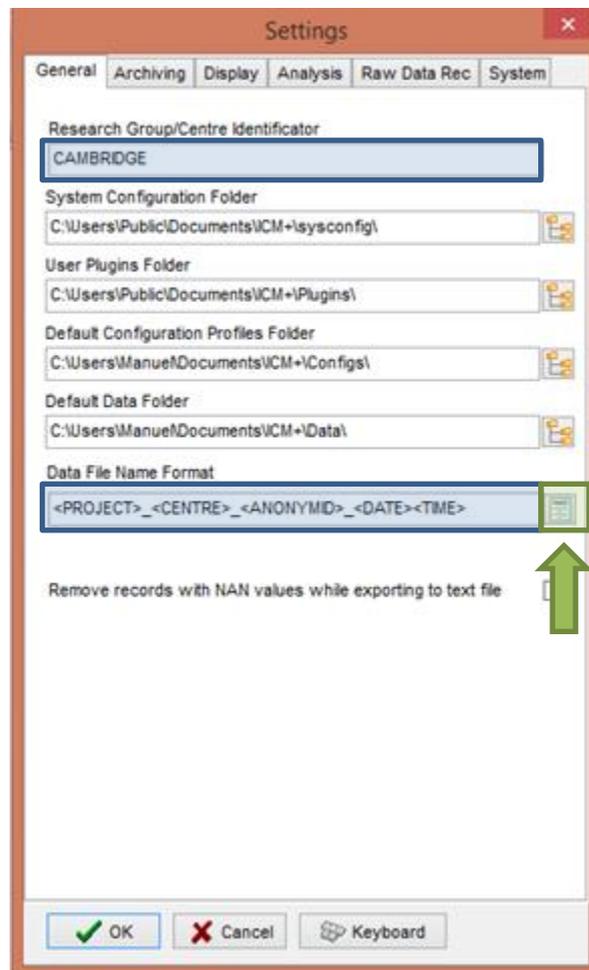
> o   The Research Group/Centre identification will be a unique name in the CENTER-TBI project that will identify the centre. This name should be fully inserted in capitals (ex. CAMBRIDGE).

> o   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 chapter.
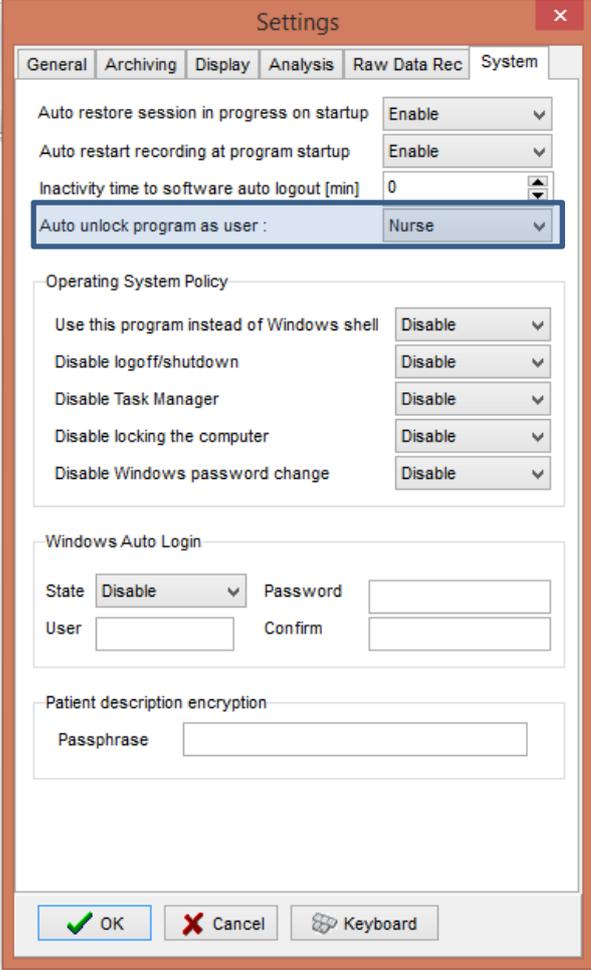
- On the Archiving tab:
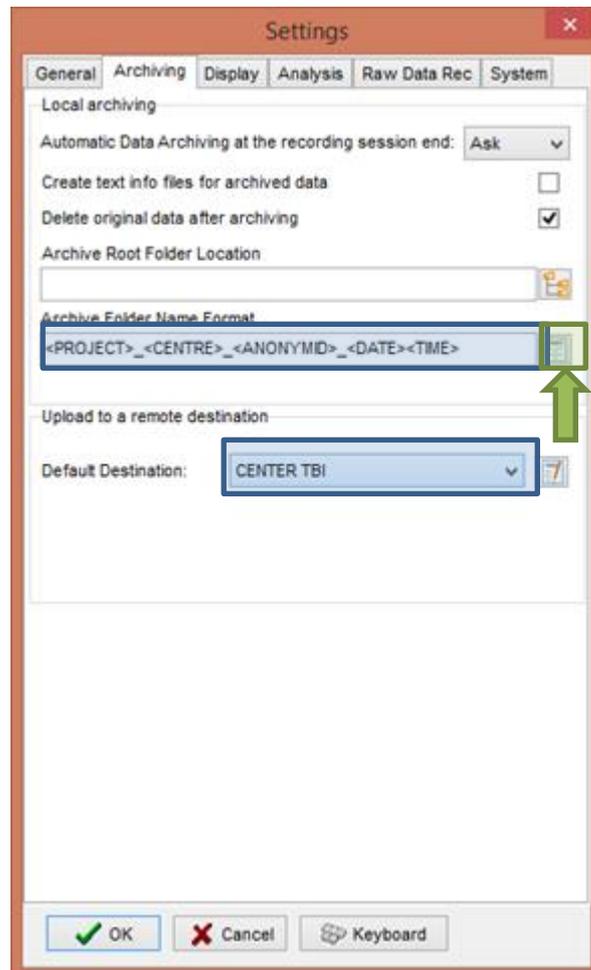
o The Archive Folder Name Format will follow the same structure as the Data File Name Format.

o The default Destination needs to be set to CENTER-TBI

- On the Raw Data Rec tab:
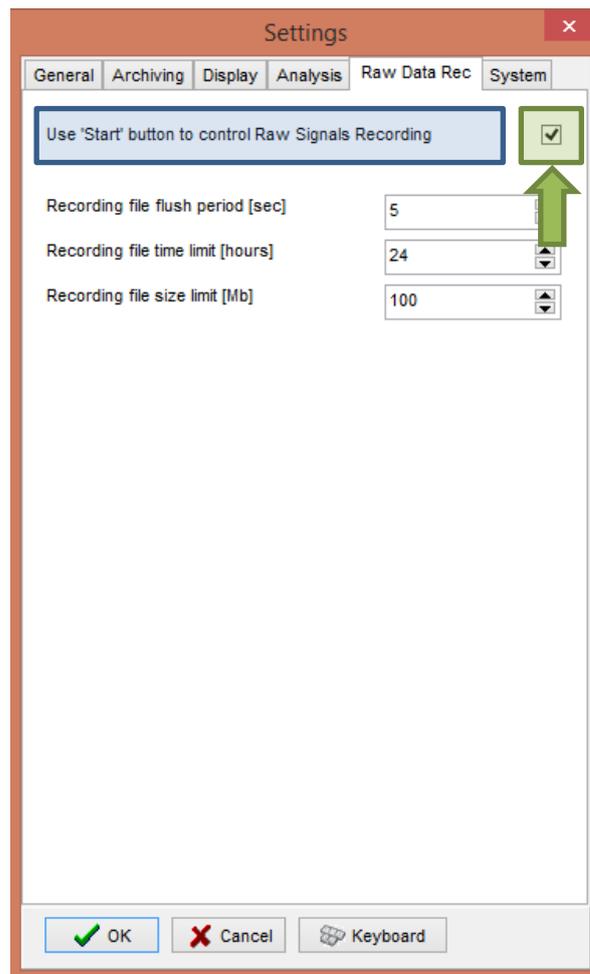
- o The **Use 'Start' button to control Raw Signals Recording** should be **checked** if you are an **ICM+ only user**.
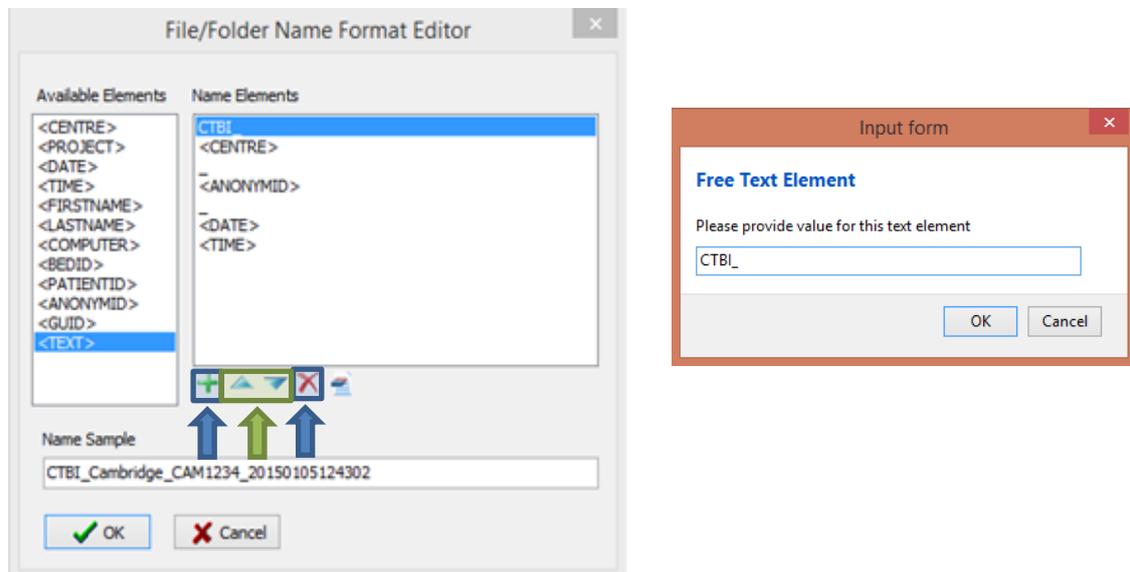
- On the System tab:

  o Set the Auto unlock program as user to Nurse.

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.

Logging in to ICM+

If your ICM+ is correctly configured when the program is run it will automatically initialize with the default user 'Nurse'. There are three ore users already configured in ICM+, the Administrator, the Manager and the Operator.

The **Nurse** is the user that will use the application for longer periods of time and will only have access to a simplified button menu allowing her to efficiently capture relevant events. Refer to the 'How to use the events form' for more details. The default Nurse **Password** is 1414.

In this form you can also find the Login button that you can use to change users. This button is also present in all tabs from the main tool bar.

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.

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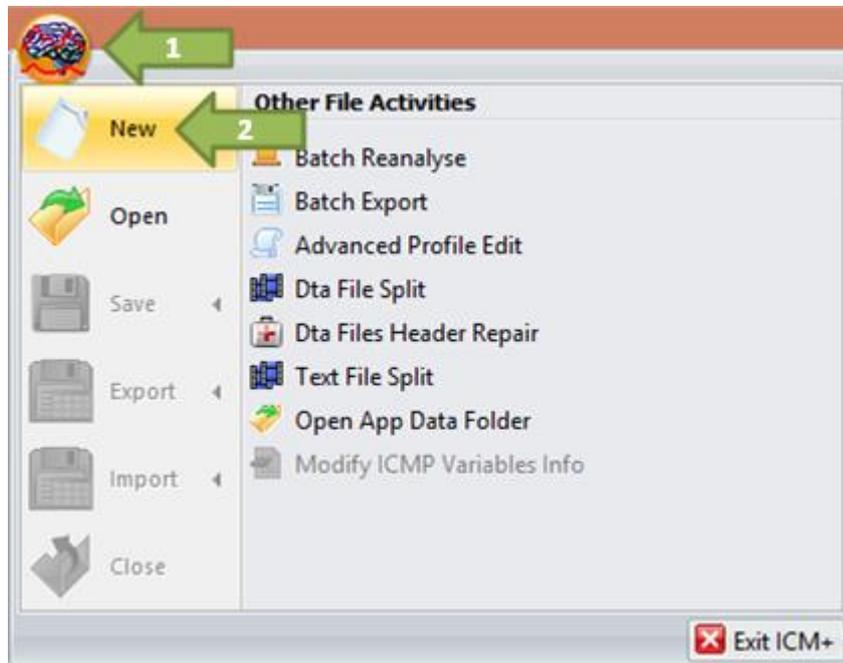

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In this form you will find:

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 user

3. And a Drop-Down menu to select the user to Login as.

Creation of a new session

To create a new data acquisition session hit the ICM+ button and select New.

This will bring up a new form:

SOP-CENTRE-TBI ICU High Resolution Data collection

1. You can insert the Patient information manually by using the fields presented in this form, or if you have already inserted these values on the bed-side monitor you can just import those using the button 'Retrieve Demographics from...' to use this button you will need to have already selected the profile you will be using in this data acquisition session.

2. This is the only field of the Patient Demographics that **you will always have to insert**. This is the anonymised ID that you will get from the CENTER-TBI website. If you don't have the **GUPI** (Global Unique Patient Identifier) use the temporary identifier. Unless you insert this number you will not be able to start a new session.

3. This button will open the folder where you have all the profiles that you can use for this data acquisition session. The pane just beside this button will provide a faster way to select the most used profiles.

4. Before starting a new session please ensure that the project is set to CENTER-TBI.

5. It is very important that you fill in the Date of Birth, Date of Ictus and the Date of Admission (if possible the hour and minutes too) as it will be important in the analysis part of the CENTER-TBI project. This is especially important for paediatric and new-born patients.

If for any chance you need to tweak the profiles, please **don't overwrite** the ones provided. If you don't have experience with creating or altering profiles please contact us and we will be happy to help you. These profiles should only be used for the CENTER-TBI project.

As you are aware there is a minimum set of signals that we will be requiring from every patient on the study:

- ICP at a sampling rate of at least 100 Hz,
- ABP at a sampling rate of at least 100 Hz,
- ECG at a sampling rate of at least 200 Hz,
- Any core temperature at a sampling rate of at least 100 Hz

If you have at your disposition any more sources of signal you can also insert them in the profile (ex. Lycox, Microdialysis, etc.).

This version of ICM+ is compatible with the profiles of the older versions.

Don't be afraid of inserting patient demographics in this section as it will not be transferred to the HDF5 file that you will be uploading to Cambridge and it will be highly encrypted in the ICM+ file.

Using the Events form

As soon as the acquisition of data starts a new form will pop-up and in this chapter we will discuss the function of the first button of this new form.
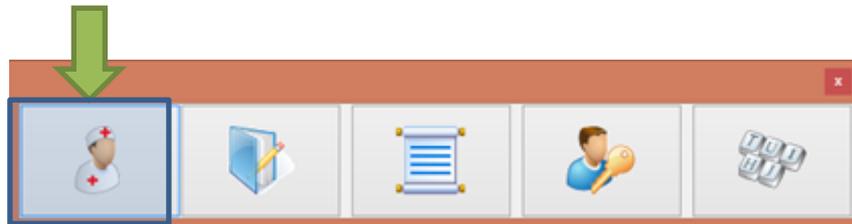
Clicking this button will bring up another form called Event Window.
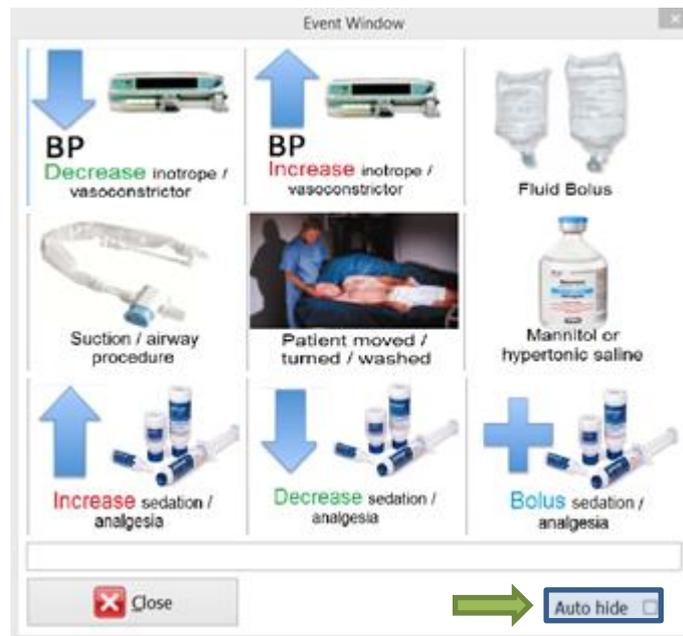
This form is composed by 9 buttons, each representing a different event that can occur during the data acquisition process. This form is meant to be used by the nurses and every time the patient is intervened the nurse should press the button that most resembles the occurrence. By pressing one of these buttons, a new form will come up:

SOP-CENTRE-TBI ICU High Resolution Data collection

This form will present the nurse with a summary of the selected event and if everything is correct the confirm button needs to be pressed in order to send the event to our servers. This from will allow the user to edit the time of the occurrence if something prevented the nurse press the button immediately after the event occurred. It is also possible to add a comment to the event if something relevant should be said about it.

If the event is not confirmed during a given time window it will automatically confirm, but this scenario should be avoided as much as possible.

After the confirmation or cancelation of an event this window will close and the Event Window will pop-up again.

The event window can always be closed if, for example, the doctor needs to browse through the application to look at the signals and calculated indexes. If the auto hide check box is ticked, the Event Window will not reappear automatically. If the box is not ticked, the window will reappear automatically after one minute of inactivity.

Creating Data Snapshots

During the data acquisition process, data snapshots should be taken periodically and uploaded to our servers for confirmation of the validity of the acquired data. These snapshots should be taken after the first hour of acquisition, again after 6 hours and at least once every day afterwards. The Data Snapshot button can be found on the Data tab on the control panel section.

After the button is pressed a new HDF5 file is generated and a window called Packing data into an HDF5 file is presented. This window shows the file creation procedure. Once finished and the button ok is clicked
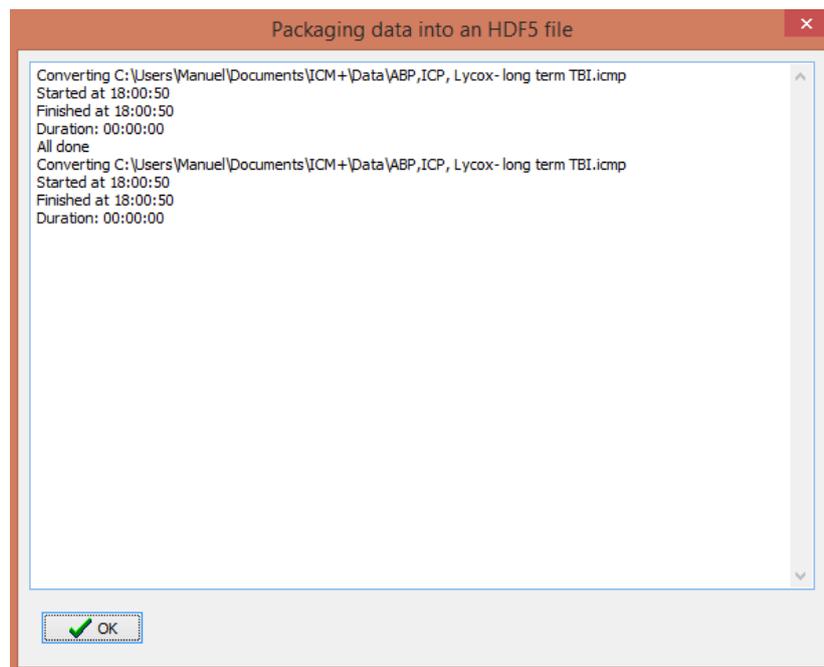
After confirming that the file is to be uploaded a new form is presented:

SOP-CENTRE-TBI ICU High Resolution Data collection
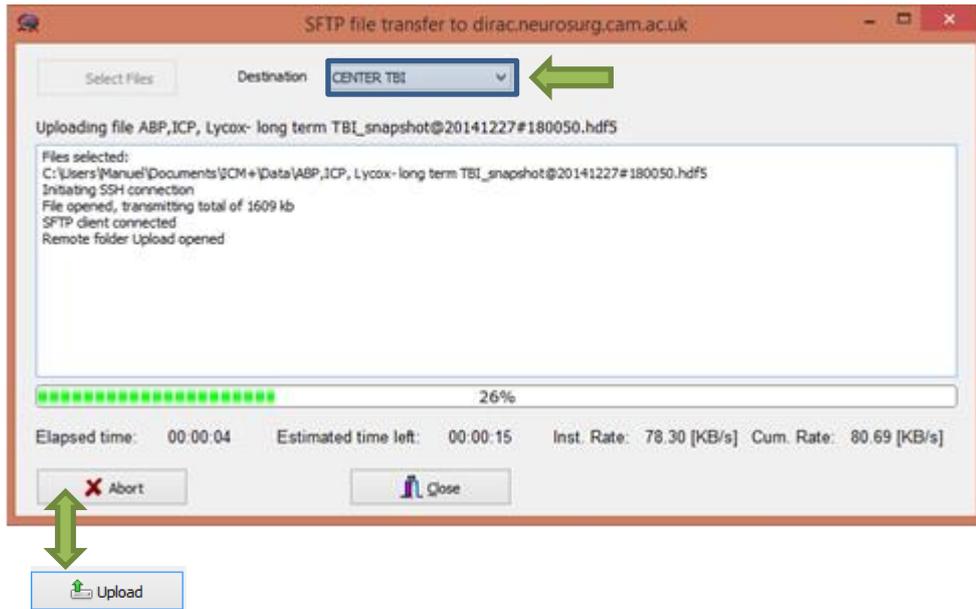
In the dropdown menu called destination, the option CENTER TBI must be selected. After this the button upload can be pressed and the file is uploaded to our servers.

Terminating a monitoring 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 upload of the generated HDF5 file to Cambridge servers.

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 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.
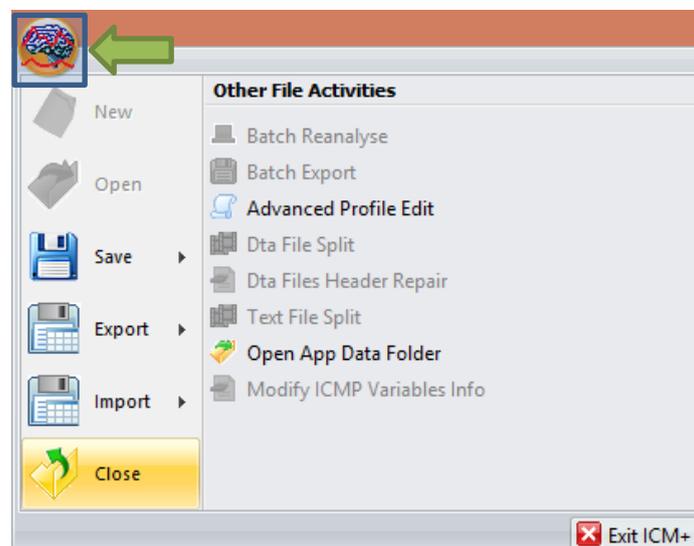

When this button is pressed a dialogue is presented prompting the user to confirm the closure of the recording session:
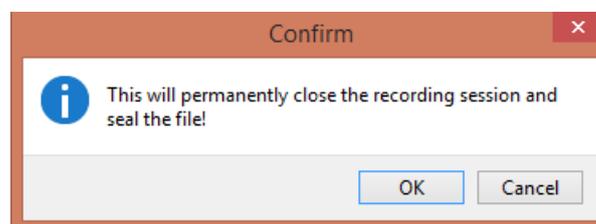

After confirming the end of the recording session another dialogue is presented prompting the user to package the data into a single file:

SOP-CENTRE-TBI ICU High Resolution Data collection
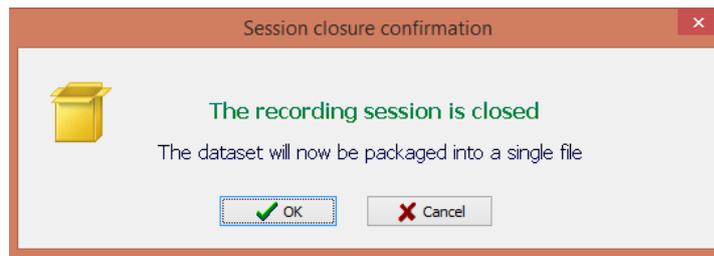
After confirming this dialogue the Data Packaging Form is presented, here the user must confirm the names of the files to be used in the creation of the HDF5 file. The user should confirm the monitor type used in the unit in the highlighted drop-down menu and tick the Unidentify checkbox.
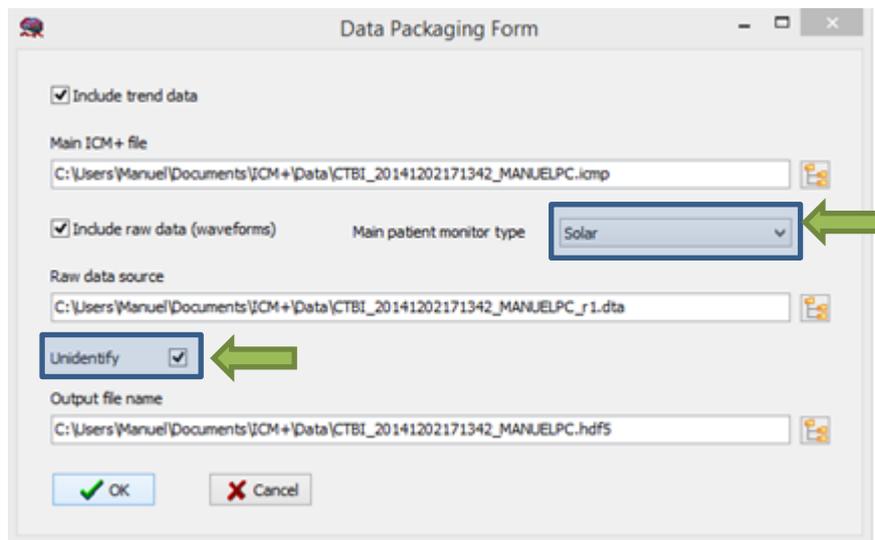

After confirming another window will be presented showing all the steps of the creation of the HDF5 file:

SOP-CENTRE-TBI ICU High Resolution Data collection
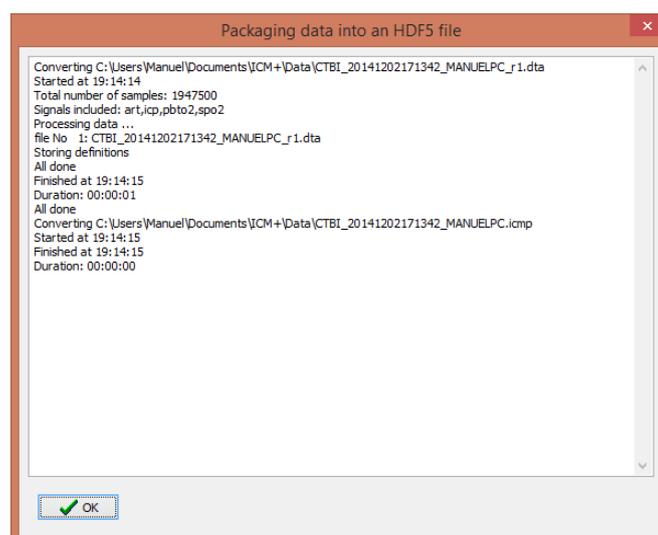
When the file is successfully created another dialogue will show up prompting the user to archive, upload or leave that for later. The user should hit the upload button in order to send the file to the server back in Cambridge to be validated and inserted in the main database. Please ensure that the internet connection the computer running OCM+ is using is capable of uploading files with huge dimensions (ex. 3G Wi-Fi is not a good connection to upload this file due to the amount of traffic it will consume).
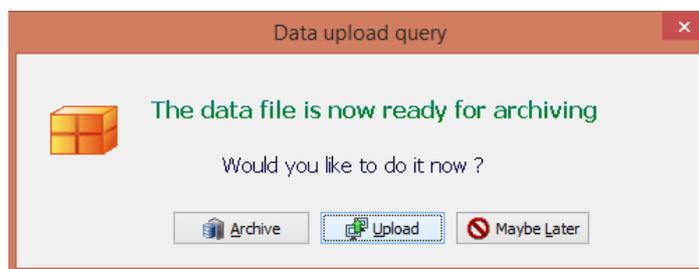

By hitting upload one final form will be presented:
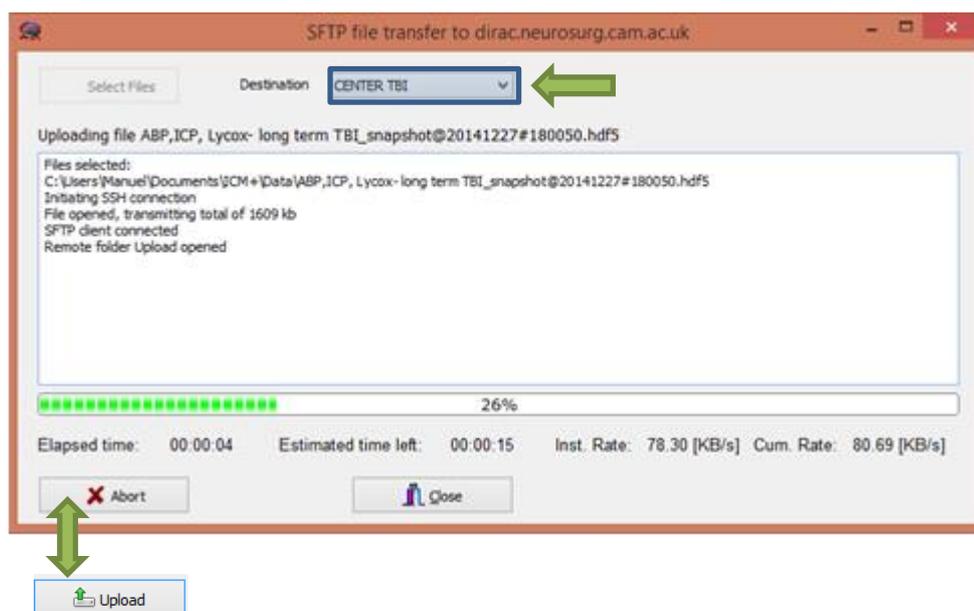
Here the user should ensure that the destination is CENTER TBI and should hit the Upload button.

On the Data Upload Query form, if the internet connection at the moment of the closing of the recording session will not permit the upload, the button Archive can be pressed instead. This will bring forth the following form.
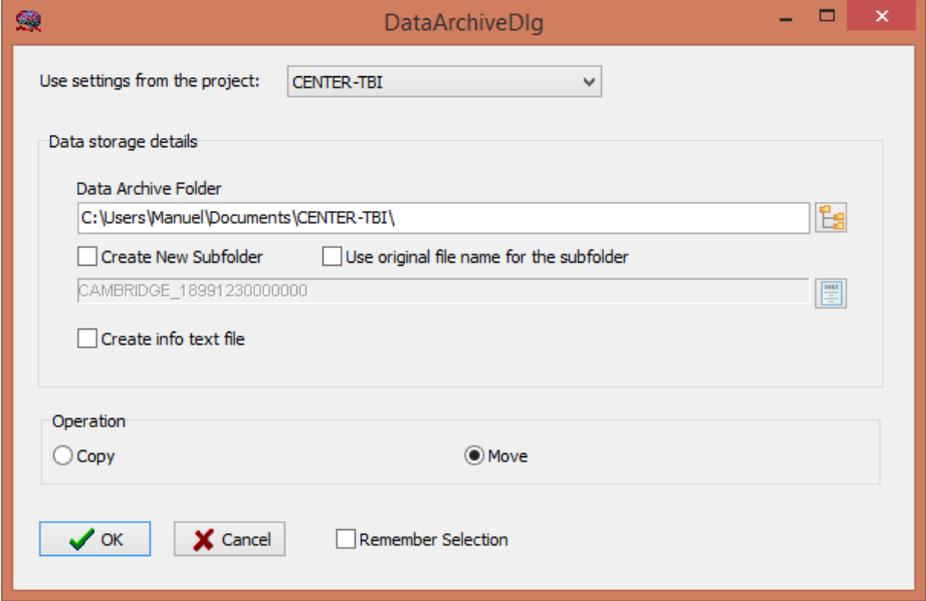
In this form you can move or copy the file to a specified folder to be uploaded later by the application Manager or Administrator.

Appendix – 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.
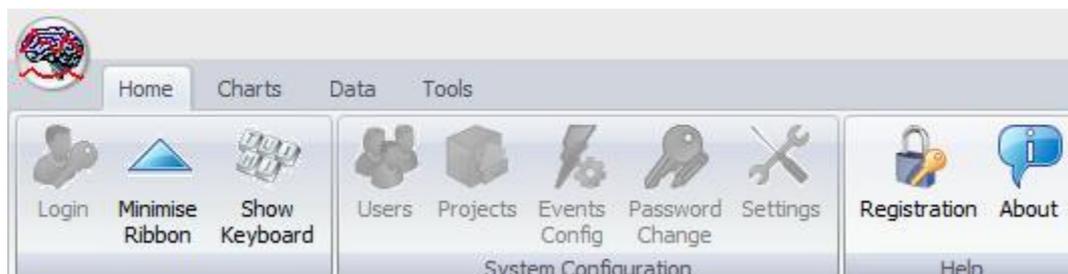
This will bring up the Detailed ICM+ License Info window where you will need to press the Register New Key button.
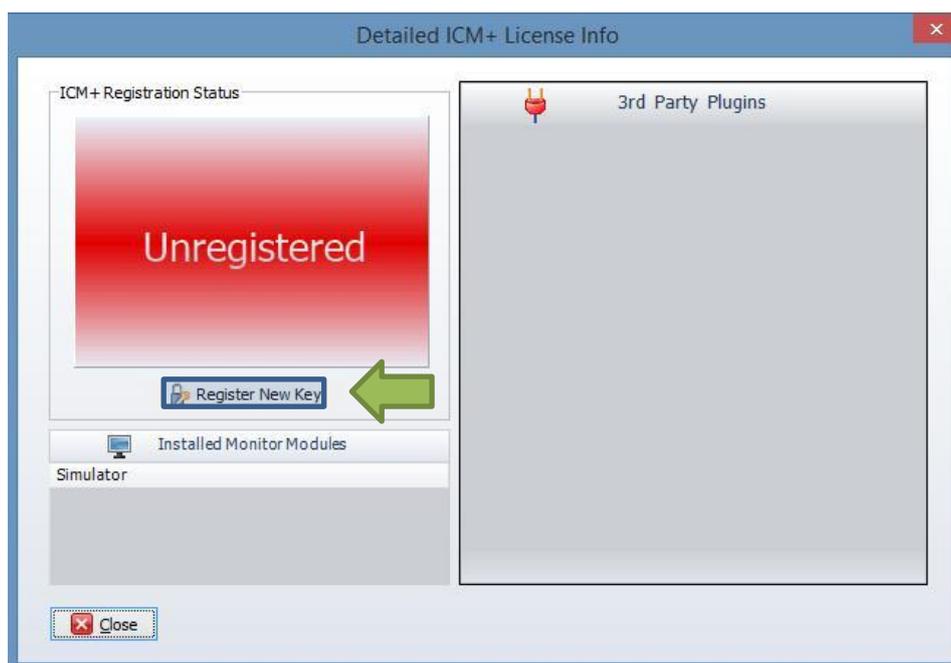
This will bring forth the ICM+ Registration Form and here you will have to press the Copy Details.

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.
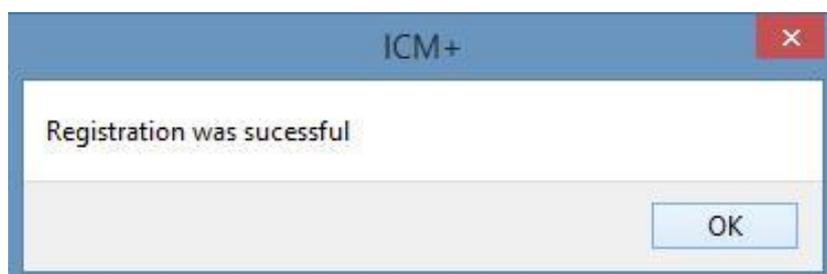
And your Detailed ICM+ License Info window should look like this:
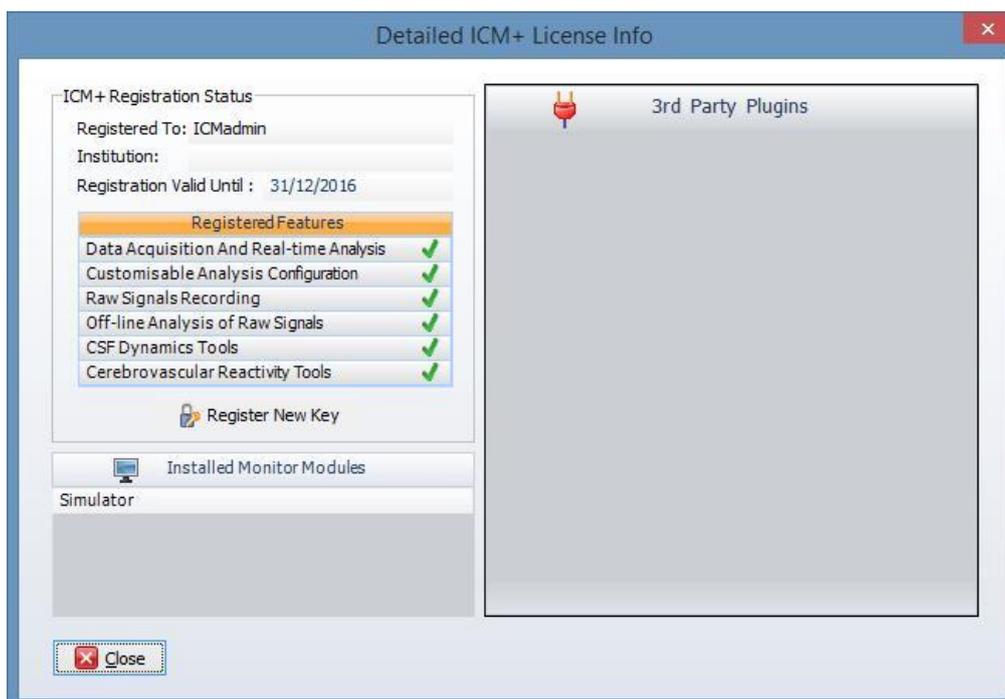
Appendix – The ICM+ Folders

ICM+ will use sets of folders to store files needed for the good functioning of the program.

The first set of folders is present on **C:\Users\CENTER-TBI\Documents\ICM+**. Here, in the **Data** folder is where all the data being generated during the acquisition process is stored. The **Conigs** folder is used to store the files containing the profiles that are selected at the beginning if the Data acquisition.

The other set of folders is located on **C:\Users\Public\Documents\ICM+** and here is where all the environment configurations are stored. Here you will find a folder called **Plugins** where all the equipment drivers are located.

The folder **sysconfig** will contain files that will be read when the application is run and should be left untouched by everybody but the **Administrator**. Inside this folder you will find the **CustomForms** folder that will contain the initialization file for the event form. The **SFTP** will contain the files that indicate to ICM+ where to send the data when uploading. Here you can also find files containing information about available projects in the **projects.xml** file and events in the **events.xml** file. The file **users** stores information about the credentials of ICM+ users.

Appendix – Updating ICM+ Projects

If by the project file needs to be updated the **Administrator** needs to access the button project present on the Home tab of the Main Task-bar.
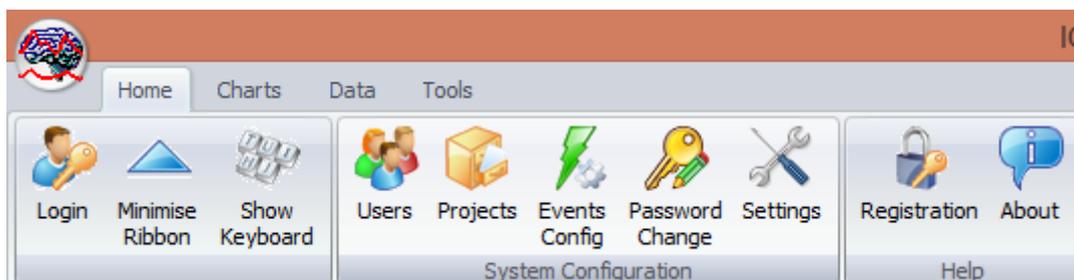
By clicking this button you will open the Project Management dialogue. Here you can press the Import button and select the file provided by us. This will automatically update the project list. Here you can also create, copy, Edit, Delete or Export projects.
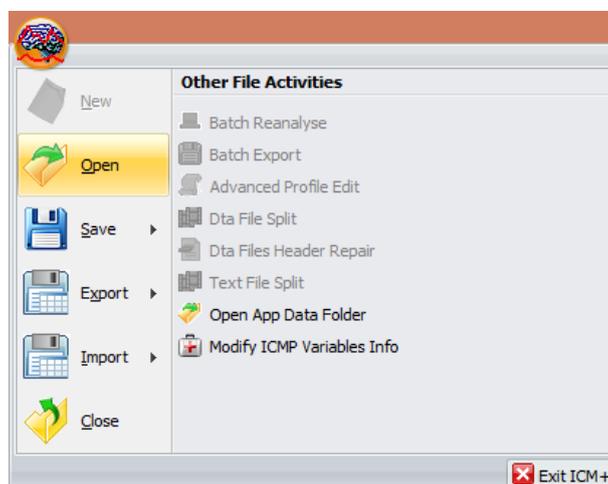

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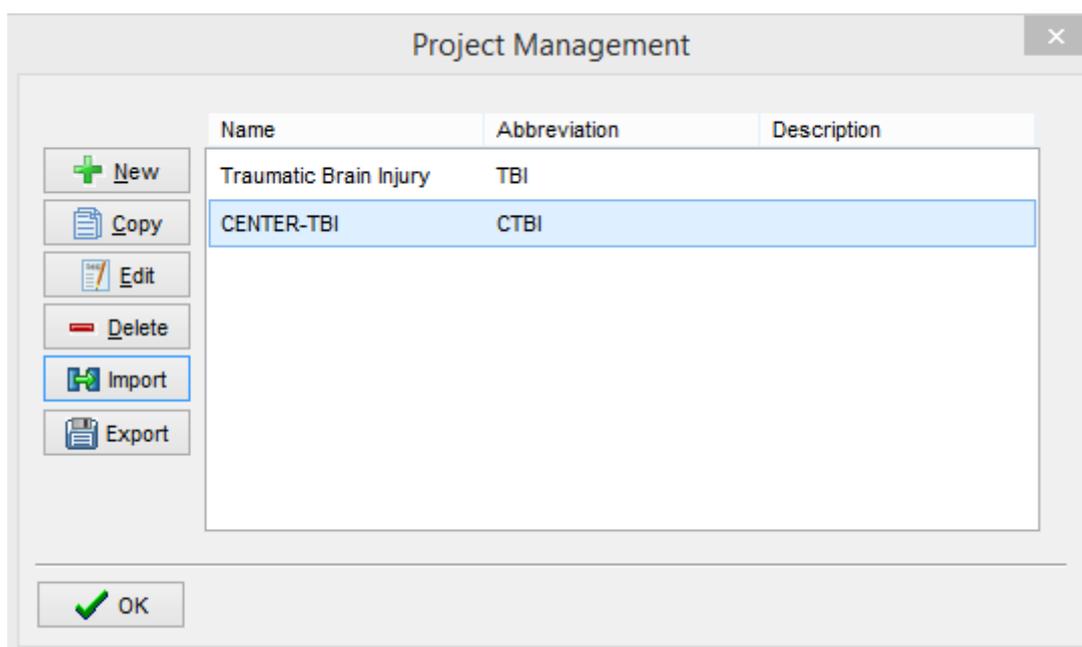
Appendix – Restoring and uploading ICM+ Files

If a session was for some reason closed an 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.
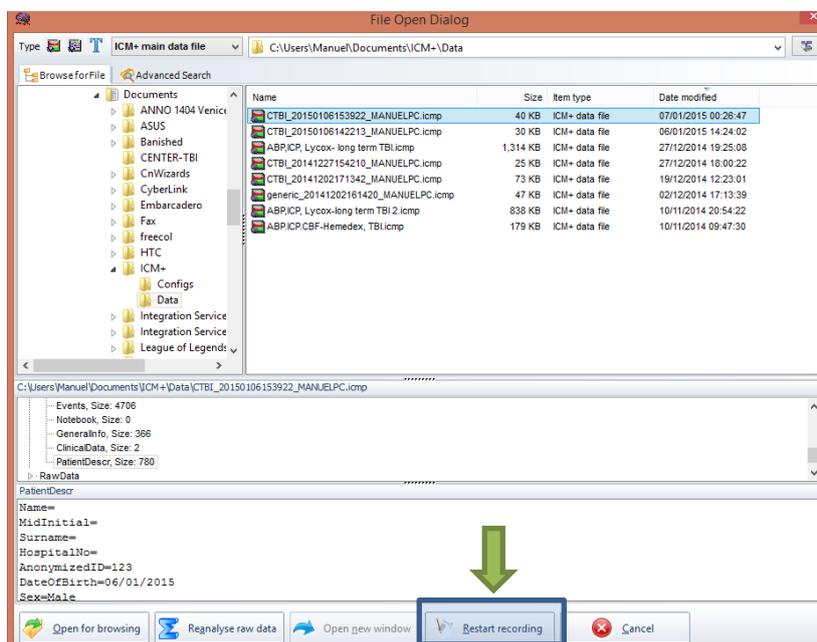
To reopen a file for inspection or to upload it is only necessary to double-click the desired file.

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

SOP-CENTRE-TBI ICU High Resolution Data collection

To manually upload a file the button Upload Data can be pressed. This button is located on the Tools tab of the main task-bar. The upload procedure is the same as the one described in the document body.
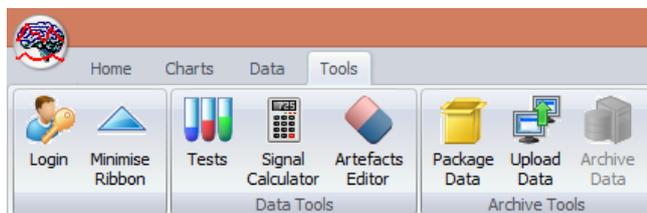
Appendix – Monitors Connectors

Philips Intellivue

USB-to-Serial adapter connected to the computer

Monitor requires a cable with RJ45 (network type) connector at one end and a male DSub 9 connector (RS232) at the other:

MP20-90   **MX Series**
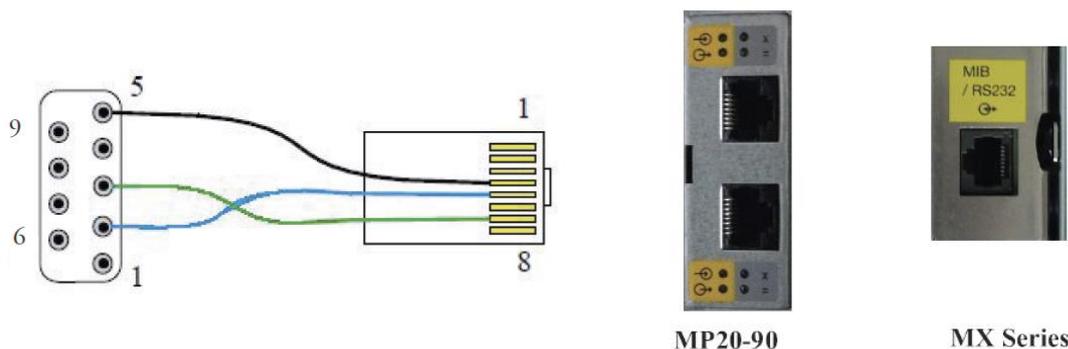
The MIB/RS232 interface provides a RS232 port with the following pin assignment. This table is valid when the MIB/RS232 Interface is in DCC mode (DCC LED on the MIB/RS232 board is on).

Computer Client	Pin and Signal Direction	IntelliVue monitor
	1 <=	dDPWR
GND	4 <=>	GND
RxD	5 <=	TxD
TxD	7 =>	RxD

The pins of the RJ45 are counted from 1 for the lowest pin to 8 for the highest pin when looking at the RS232/MIB interface board.

The configuration of a specific MIB/RS232 port can be viewed in config mode and altered in service mode. To alter the configuration of an MIB port select **Main Setup** then **Hardware** then **Interfaces.** This brings up the MIB/RS232 card configuration. The port that you are using must be set to DtOut1 for the "Data Out" function. If the MIB/RS232 port is configured for data export the yellow arrow out LED will be lit.


MX800: Cable shown connecting the MIB/RS232 port on the Intellilvue monitor and the internal PC USB port, using a USB-Serial adapter.

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GE Datex Ohmeda S/5

USB-to-Serial adapter connected to the computer

Standard null modem serial cable connecting the monitor (fig below) and the USB-to-Serial adapters

Female – Female
'Crossover' cable

```
2          2
3    X     3
5 ———————— 5
7    X     7
8          8
```
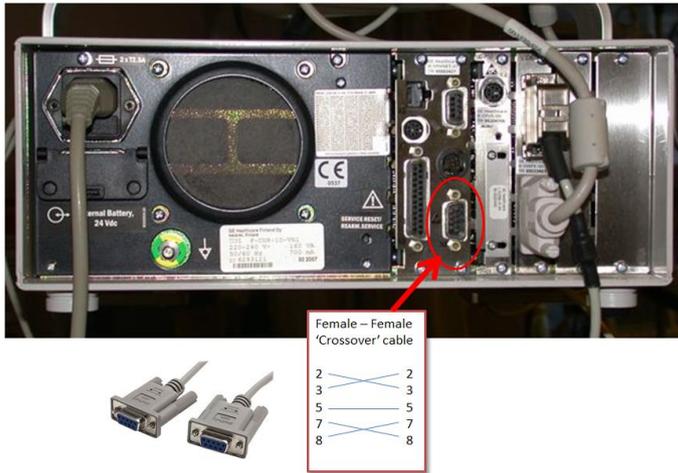
GE Carescape B 650/850

USB-to-Serial adapter connected to the computer

Standard null modem serial cable connecting the two USB-to-Serial adapters

ATEN UC-232A USB-to-Serial adapter connected to any USB ports on the Carescape monitor

ATEN UC-232A
USB to Serial adapter

Female – Female
'Crossover' cable

```
2          2
3    X     3
5 ———————— 5
7    X     7
8          8
```

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Appendix – Login Passwords

In this section you will find all the passwords that should only be known by the Administrator, Manager and Operator. Please detach this appendix from the main document.

Administrator – 2718

Manager – 1618

Operator – 3142

Nurse – 1414