

CENTER-TBI & High Resolution Monitoring

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Brain Physics Lab

CENTER-TBI, HR-ICU main objectives



- **Main aspirations of the project:**

- Creation of a multi-centre database (20+ centres) of high-resolution data:
 - 200+ patients with at least 24h of monitoring time
 - Minimum data set including ICP, ABP at 100Hz and ECG at 200Hz minimum
 - A minimum number of 7 clinical annotations for every 24 hours
- Creation of files that are:
 - Open source and compatible with the majority of the most used data processing tools
 - Homogenous data throughout all the centres despite differences in the data collection process

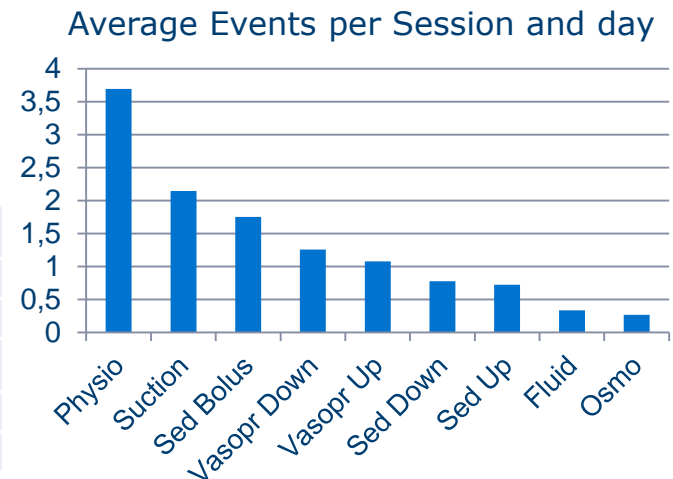
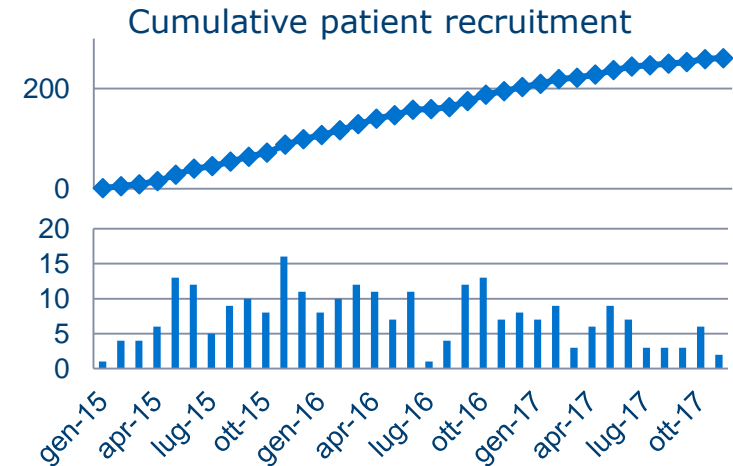
CENTER-TBI, HR-ICU main accomplishments



• Main accomplishments of the project:

- **280 files** collected, with >95% of the files with the minimum data set and >75% with data collected on the first 24 hours post ictus
- Average recording time was 6.8 days/patient with a total of **2500 days** of recordings
- **20000 clinical events** collected with an average of 12 events/day

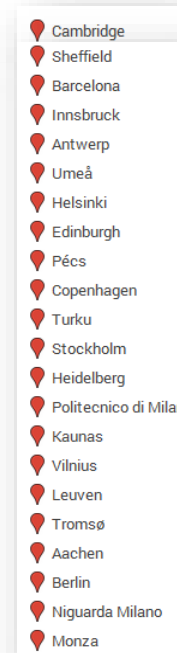
<u>Name</u>	<u>ICP</u>	<u>ABP</u>	<u>ECG</u>	<u>SpO2</u>	<u>Temp</u>	<u>CVP</u>
# Files	285	285	281	245	109	99
%	100.00%	100.00%	98.60%	85.96%	38.25%	34.74%
<u>Name</u>	<u>PbtO2</u>	<u>MicroD</u>	<u>etCO2</u>	<u>EEG</u>	<u>FiO2</u>	<u>ECoG</u>
# Files	79	68	44	4	3	2
%	27.72%	23.86%	15.44%	1.40%	1.05%	0.70%



HR-ICU participants



- **22 Centres participated:**
 - ICM+ used as the central piece in the data acquisition process on 21 centres
 - 1 centre used their own data acquisition system.
- **4 major data acquisition configurations:**
 - ICM+ directly connected to monitors
 - ICM+ (master) and CNS Monitor (slave) directly connected to monitors
 - ICM+ connected to monitors via A/D converter for waveforms and CNS Monitor directly connected to monitors for numerics only
 - Local data acquisition systems
- **Data collected from 9 different monitors throughout the centres**



Different ICM+ configuration throughout the centres

Philips Intellivue GE Solar CERESCAPE Licox Microdialysis Ventilators



ICM+ only

Laptop with ICM+



CNS Monitor and ICM+



Moberg CNS monitor

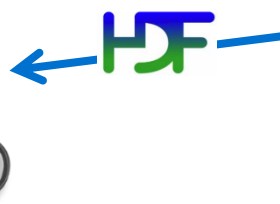


Laptop with ICM+

incf International Neuroinformatics Coordinating Facility



UNIVERSITY OF CAMBRIDGE



Drager special case

Drager Infinity



Numerics



Moberg CNS monitor

Surgical Display Controller



AD converter

Waveforms



Laptop with ICM+

Licox



Different interfaces of the monitors

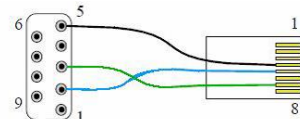
- Most monitors will have their own unique communication protocols and communicating cables
- Every centre will have their own combination of monitors
 - Installation of ICM+ is therefore different in every centre

Drager Infinity



BNC Cable for analogue communications

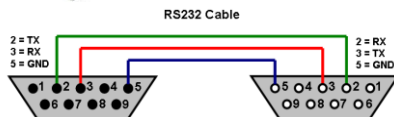
Philips Intellivue



RS232 that looks like an RJ45

Ventilators

CERESCAPE



RS232 with different wirings

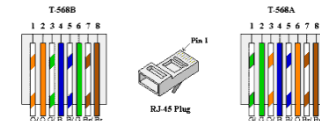
Licor



Different pin RS232



GE Solar



RJ45 cable for networked monitors

Initial steps in setting up for the study and special adaptations made to ICM+

- Initial assessment of the equipments used by the centres and estimation of the necessary equipment to provide them with,
- Remote and on-site installation of the recording systems,
- Remote and on-site training sessions,
- Tailored installers of ICM+ :
 - Simplified procedure to start recording sessions ,
 - Use of homogenized ICM+ configuration profiles,
 - Dedicated project containing a simplified event form.
- Creation of a dedicated, open source, data format to store and upload all the generated data.
- SFTP data transfer embedded in ICM+

How did we set up this study – The event form

Trade-off between “ask” and “get”

Changes more important than absolute values

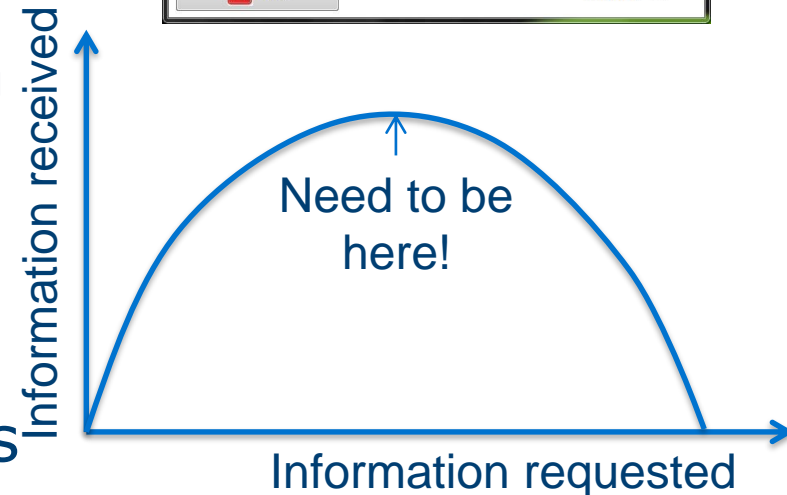
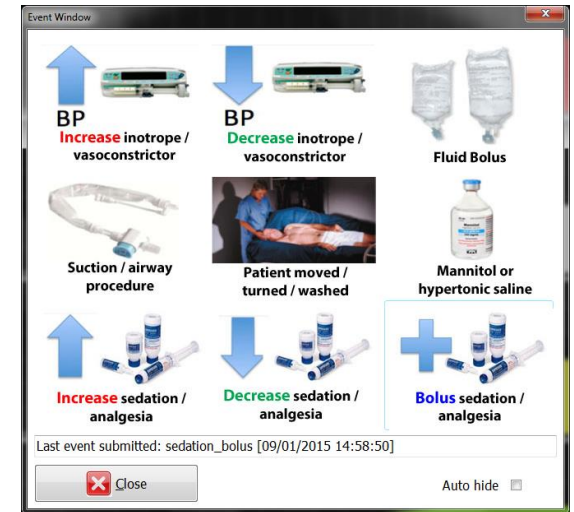
- “Vasopressor increased”

VS.

- Noradrenaline increased from 0.05 to 0.075mcg/kg/min

Minimal clicking and browsing effort

Possibility to insert detailed notes



HDF5 data format



- The files that will be made available for analysis will be composed as follows:
 - Attributes on the root of the file will contain Summary information on the contents of the file (1)
- The file is organized as in 2:
 - Annotations will contain clinical events
 - Numerics and Waves will contain the raw data as recorded from the monitors
 - The summaries will contain data that is easily copied to Excel (3)
 - Definitions contain general information on how to interpret the file
- The data is anonymised and all the dates are corrected for the date of ictus with all the time points being days after ictus

(96)
Group size = 5
Number of attributes = 12
DataAvailable = [spo2,abp,ecg,icp]
GUPI = 2DLL573
dataCollectionSoftware = ICM+ 8.1.2.15
dataEndTime = 5 11:42:52
dataEndTimeUnix = 474172
dataProcessingSoftware = ICM+ 8.2.1.7
dataStartTime = 0 07:10:07
dataStartTimeUnix = 25807
dateTimeFormat = d HH:mm:ss
duration = 448365 seconds
formatVersion = 1.2
invalidValue = -99999

1

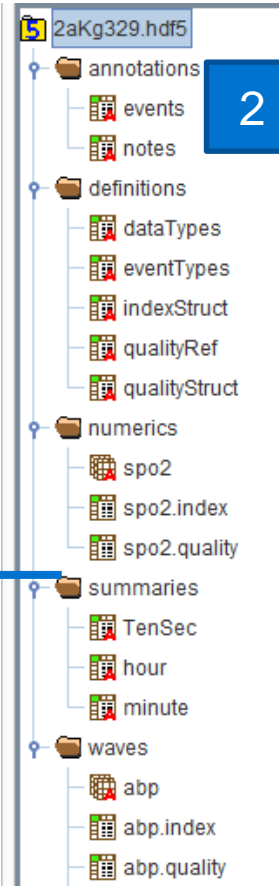
hour at /summaries/ [2DLL573.hdf5 in Z:\NCF\Stage5]

Table

3

U-base

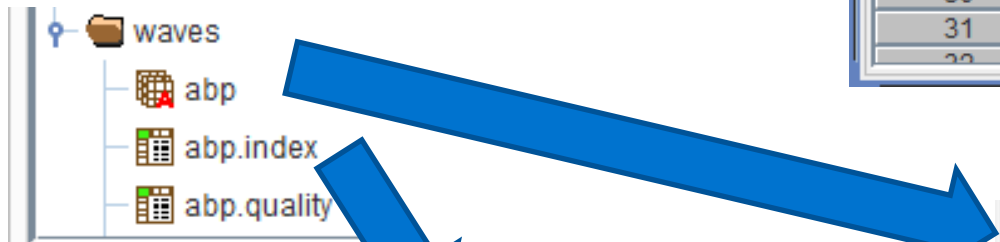
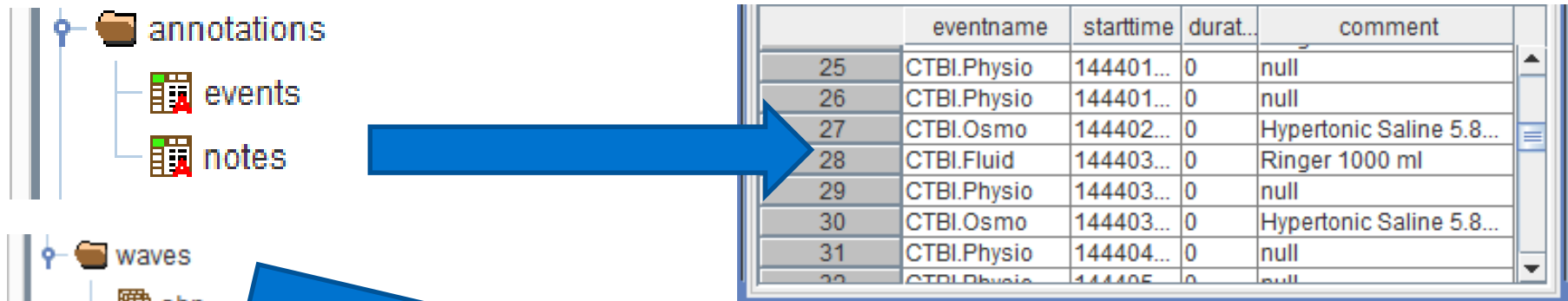
	datetime	spo2	abp	icp
0	0.3333449...	98.738594	99.76996	13.245641
1	0.3750115...	98.12713	83.40361	12.804171
2	0.4166782...	97.98007	77.630875	11.514758
3	0.4583449...	98.71487	97.63642	11.029398
4	0.5000115...	98.66751	99.112274	13.511339
5	0.5416782...	97.851036	84.332375	13.905914
6	0.5833449...	95.94246	81.92112	13.297709
7	0.6250115...	95.776505	89.24158	13.225138
8	0.6666782...	95.91012	95.64042	12.674233
9	0.7083449...	97.85513	91.5615	12.745529
10	0.7500115...	97.29117	97.55473	15.597423
11	0.7916782...	97.2676	96.62931	16.5295
12	0.8333449...	98.64641	102.06984	16.034761
13	0.8750115...	97.27155	102.13086	16.759117
14	0.9166782...	97.20968	97.18572	17.367867
15	0.9583449...	97.23055	91.90818	16.768438
16	1.0000115...	97.19911	90.11584	16.984268



2

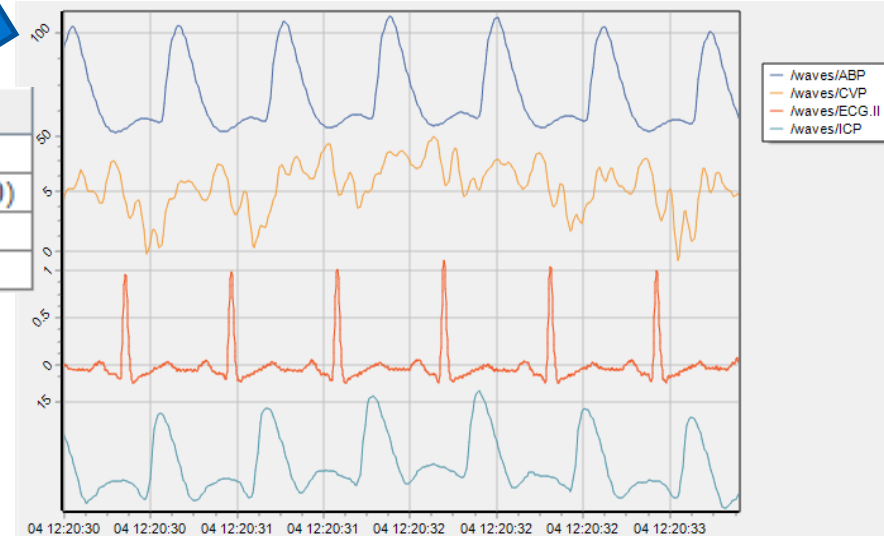
3

New data format HDF5



field	description
startidx	index of the first sample in this continuous data block
starttime	modified UNIX format time stamp (microseconds since 1/1/1970)
length	number of data samples in this data block
frequency	data sampling frequency [Hz]

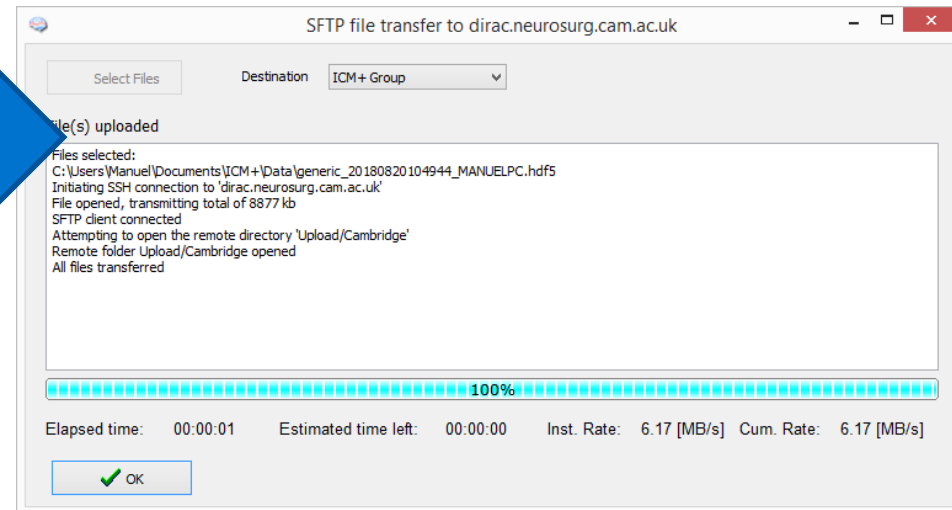
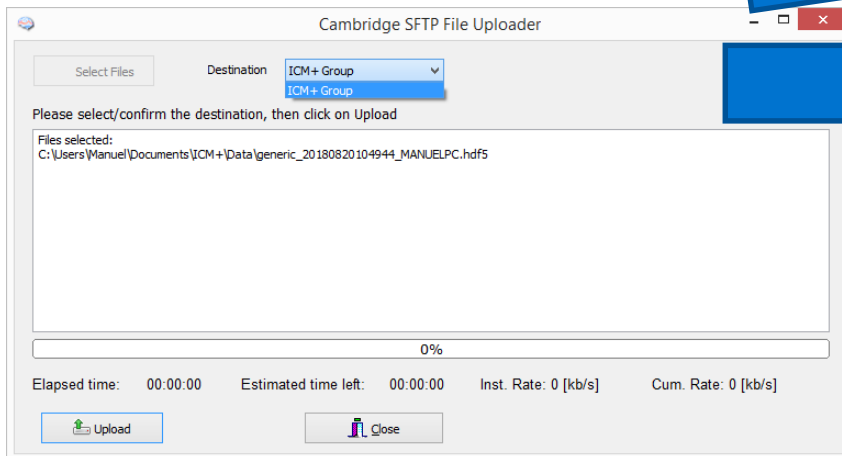
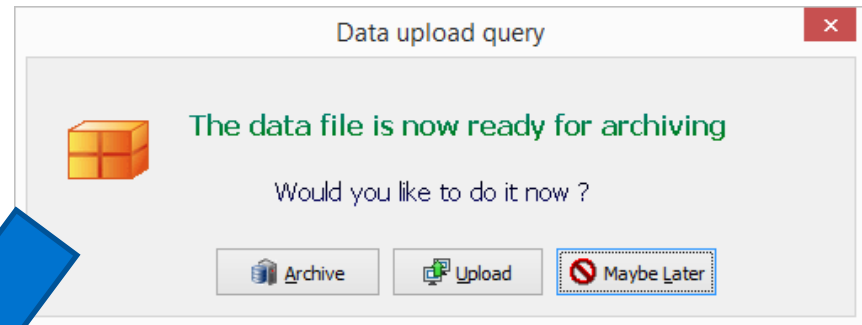
	startidx	starttime	length	frequency
0	0	132772458432	3583700	100.00200...
1	3583700	168610783463	1500	100.00250...
2	3585200	168626126455	4404900	100.00256...
3	7990100	214303170393	575760	99.980963...



Easy and safe data transfer to centralized locations

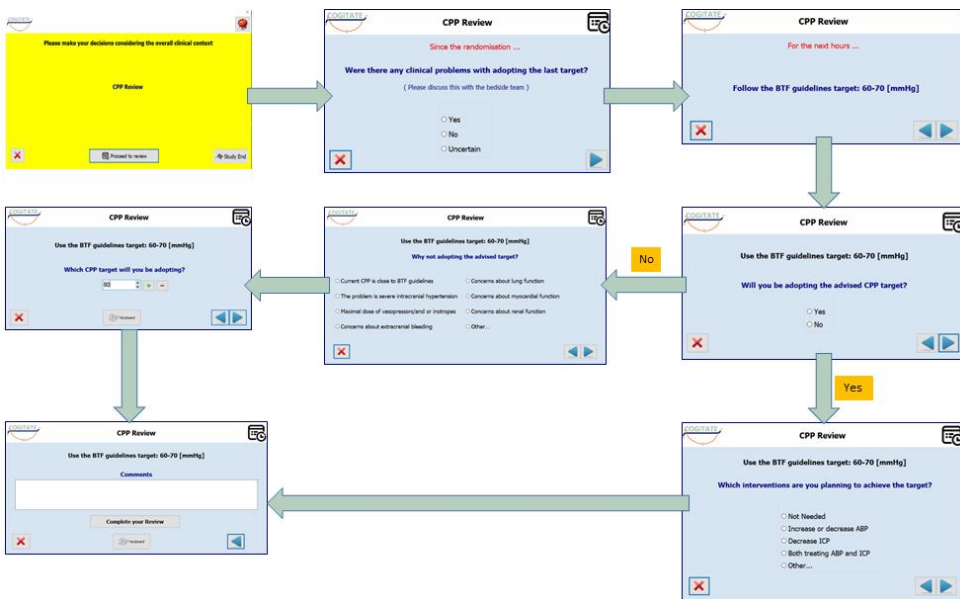
SFTP, stands for Secure File Transfer Protocol

- Allows for transfer of data through the internet in a very secure way
- Very easy way to gather all the data of a study in a centralized place



Custom forms and wizards

- Custom forms can now be loaded in the project configuration.
- These can be tailor made to best suit the study



Project Configuration

General | Data Fields | Events | Data Archiving

Project Definition

Name: Abbreviation:

Description:

Custom Module:

Data Folder: C:\Users\Manuel\Documents\UCM+Data\

Config Folder: C:\Users\Manuel\Documents\UCM+Configs\

Data File Name Format: <project>_<date><time>_<computer>

Default config profiles:

Enforce default configuration profiles ☐

OK Cancel Keyboard

- The example shows the sequence of forms that will be triggered at the moment of a CPP target review of a COGiTATE patient where the CPP target must be adjusted. (more about this to come in a later talk)

Other ICM+ multi-centre trials

- COGiTATE
 - 3 centre randomised control trial that will make use of ICM+ capabilities for CPPopt calculation and make use of the custom forms and wizards

More on this to come by **Dr. Marcel Aries**

- STARSHIP
 - 11 UK centres in the first study where ICM+ is used on a trial about studying autoregulation in paediatric TBI

More on this to come by **Dr. Shruti Agrawal**

Effects of 3 years of CENTER-TBI



After 3 Years of
HR ICU



3 more years of
STARSHIP ???

ICM+ powered clinical trials: main advantages

- CRFs very much simplified as the majority of the CRFs where daily values are collected are not necessary
- The quality of the data is much higher as you can record high resolution waveforms instead of the hourly values usually collected in these types of studies
- With the custom forms and wizards, all of the CRFs could in theory be managed within ICM+
- With the HDF5 data format all of the data relative to a patient can be saved in a single file and easily extracted to the analysis tools
- Multi-centre trials are much easier to organise as ICM+ can deal with many different inputs of data while still generating homogenous data files