Cerebral function monitor

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Requirements Celebral Function Monitor From A to Z

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Eindhoven, October 2007

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Specification of the CFM simulator

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Requirements

In this report the extended requirements of the CFM simulator will be described. This is a guide for a programmer, who can write this program. The requirements are split up into an introduction, functional requirements in the form of use cases, interface requirements and other requirements.

1 introduction/overall description

Purpose
The CFM simulator is a screen-based educational program designed to teach medical personnel in the performance and interpretation of CFM signals. Medical specialists, residents, and nurses will use this program to be able to train individually in this area. They will first receive a theoretical introduction to update and upgrade their basic knowledge concerning CFM. Subsequently they will enter different levels of CFM measurements, to simulate the performance of the measurements and evaluate the interpretation.

Scope
The scope of the requirements for the CFM simulator described in this appendix is based on the following restrictions:

- the program only includes that CFM signals of full-term newborns
- the program only includes newborns with the following diagnosis:
  - cerebrally healthy
  - asphyxia, SARNAT 1/2/3
  - suspected seizures
- this means the program will include:
  - all different types of background patterns
  - sleep-wake cycles
  - seizures and status epilepticus
  - artifacts: muscle, movement and HFO

Vision
The CFM simulator might be extended to include signals of prematures as well. Moreover, signals of newborns with othor cerebral dysfunctions, like cerebral infections and hemorrhages, may be included as well. As a more broad vision, this type of CFM simulator can easily be manipulated to be used for other types of biological signals, like EEG or ECG.

Stakeholders/user classes
The target groups, i.e. expected users of the CFM simulator have been thoroughly described in the training needs analysis of appendix G2. They include medical specialists, residents, and nurses. One more user needs to be described, the instructor of the program. The instructor is one person at the department that is responsible for the CFM simulator. The instructor will install the specific settings for his department and will have access to the results of training, where the individual trainees will either remain anonymous or not. Finally, the instructor needs to help the trainees if necessary. This will be either done through

questions they can ask in the help documentation, that will be sent to the instructor by email, or the trainee will be sent to the instructor if he has an insufficient score.
Furthermore, as stakeholders can be described the industry that sells CFM devices, and the institutions that uses this type of monitor.

Operating environment
The CFM simulator will run on any regular PC in the hospital environment. It will be installed preferably on the hospital's server. Access will be gained through the different computers connected to the server. Possibly industry might have a preference to have it running on their CFM device.

Design and implementation constraints
Most constraints are obvious in the functional and other requirements. However, some specific constraints for the program will be given here. They are:

- A pause and a safe option needs to be available at every point in the program.
- The functionality of the simulated monitors needs to be exactly like in the real monitors, not more and not less.
- The program needs to be able to read in the database of CFM signals. These signals are stored in EDF+ format. The annotations in this for format include remarks concerning the background and events in the signal. This needs to be used for the pop-up the questions in the training program. (see also *Other requirements*)
- The database needs to be able to be extended with new signals.

User documentation
The user documentation includes the protocols from the specific department. Furthermore the instructor needs to be able to answer questions of trainees, and possibly have some more documentation to help them.
For the instructor, documentation should be included how to install the training program and how to set the department specific protocols and data. Finally, a document is needed with the instruction of how to add your own CFM signals to the training program.

2 Functional requirements: the use cases.

Instruction

The use cases start with a diagram of the summary, user goals, subfunctions and documentation, that together make the functional requirements of the training program. Subsequently these items are described in the form of use cases or documents.

The general set up for a use case is as shown below, where the preconiditions only exist for user goal use cases.

Use case :

Scope:
UC level:
Primary actor:
Preconditions:
Trigger:
Success guarantee:
Minimal guarantee:
Main success scenario:
Extensions:

Within the use cases reference to different use cases, documents or user interfaces are as follows:
Underlined (UC B1): reference to a different use case (UC) in this case B1.
Dotted (Doc1): reference to a document, in this case D1.
Striped (UI1): reference to user interface, in this case User Interface 1.

Finally some words or letters are written italic. These are either variables, or parts for the SuD to fill in.

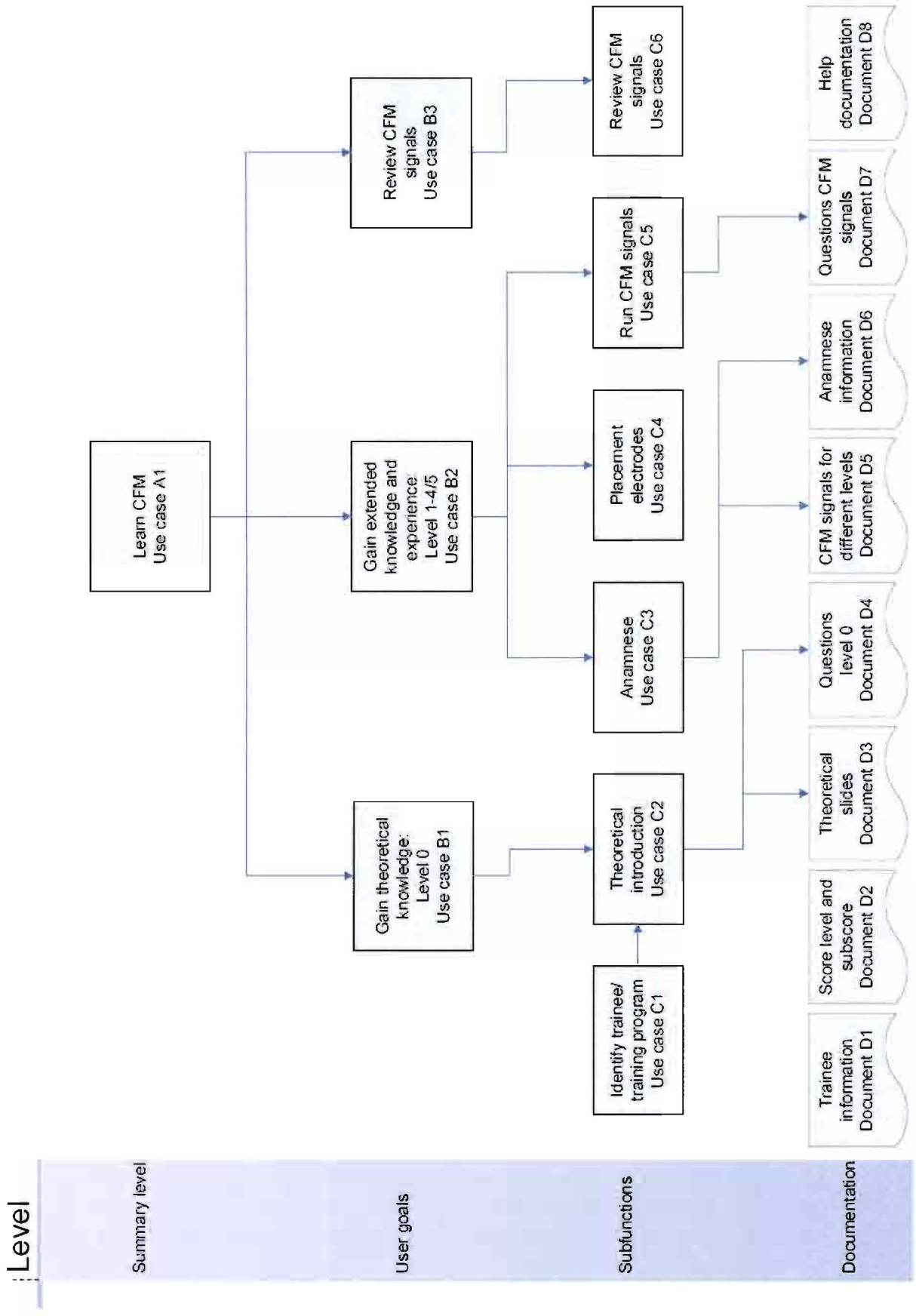


Figure. Diagram of the set up of the use cases and documents.

Use case A1: Learn CFM

Scope: SuD
UC Level: Overall summary
Primary actor: Trainee
Trigger: Start software
Success guarantee: gain theoretical knowledge and experience concerning CFM
Minimal guarantee: get help to learn CFM
Main success scenario:

1. Trainee enters SuD.
2. Trainee trains theoretical knowledge (UC B1) in level 0.
3. Trainee gains extended knowledge and experience (UC B2) in levels 1and higher.

Next step can be performed by the trainee at any time after finishing 2.

4. Trainee reviews CFM signals (UC B3) to gain insight in signals of specific category.

5. Trainee closes SuD.

Extensions:
2a/3a. Trainee can pause or save and close SuD at any time.

Use case B1: Gain theoretical information, level 0

Scope: Level 0: theoretical introduction
UC level: User goals
Primary actor: Trainee
Preconditions: trainee does not have score level -0.5
Trigger: SuD confirmed level 0

- After entering SuD (Identify trainee/training program (UC C1)):
  - Trainee score level is 0 or 0.5
  - Trainee score level is higher, trainee chooses level 0

Success guarantee: gain theoretical knowledge concerning CFM
Minimal guarantee: get help to learn CFM
Main success scenario:

Both next steps are described in Theorectical introduction (UC C2)

1. Trainee gains theoretical information
2. Trainee is tested on theoretical information

Extensions:
1a. Trainee may use Help at any time (see Doc8)

Use case B2: Gain extended knowledge and experience, level 1-4/5

Scope: Levels 1-4/5, current level: *i*
Use case level: User goals
Primary actor: Trainee
Preconditions: Trainee has score level of at least *i* (see D2)
Trigger: 3 options:

- Trainee successfully finished level *i*-1
- Trainee starts SuD and has score level *i* or *i*+0.5
- Trainee has score level higher than *i*+0.5, but chooses in main menu to go back to level *i*

Success guarantee: gain extended knowledge and experience concerning CFM
Minimal guarantee: get help to learn CFM
Main success scenario:

1. SuD shows "Entering level *i*..."

The next steps are repeated using CFM signals according to Doc5, until sufficient signals are trained and conditions of Score level and subscores (Doc2) are met.

2. SuD randomely chooses signal from category according to Doc5.
3. SuD gives anamnese (UC C3)
4. Trainee needs to start measurement and place electrodes (UC C4)
5. SuD starts measurement (UC C5)
6. SuD validates sufficient subscore.
7. SuD rises score level trainee according to Score level and subscore (D2)
8. SuD gives pop-up: "Congratulations! You successfully finished level *i*."
9. Trainee clicks "Enter level *i+1*".

Extensions:

5a. Trainee may use Help at any time (see Doc8)
6a. Trainee answered some questions incorrect, score was slightly insufficient (see Doc2).
6a1. SuD shows extra signals.Trainee score sufficient: go back to 7.
6a2. SuD shows extra signals. Trainee score insufficient:
SuD saves subscore and puts score level to *i*-0.5
SuD gives pop-up: "Unfortunately your score is insufficient."
SuD shows in which category (/categories) the trainee has wrong answers.
SuD: "Please go to the instructor (*name instructor*) and ask for help."
SuD: "On next entry of CFMsim, you may enter in level *i-1*."
SuD closes.
6b. Trainee has insufficient subscore (see Doc2)
SuD saves subscore and puts score level to *i*-0.5
SuD gives pop-up: "Unfortunately your score is insufficient."
SuD shows in which category (/categories) the trainee has wrong answers.
SuD: "Please go to the instructor (*name instructor*) and ask for help."
SuD: "On next entry of CFMsim, you may enter in level *i-1*."
SuD closes.

Use case B3: Review CFM signals

Scope: Review level
UC level: User goals
Primary actor: Trainee
Preconditions: Score level ≥ 1
Trigger: Trainee chooses review level in main menu
Success guarantee: Trainee reviews CFM signals from database, without questions asked
Minimal guarantee: -
Main success scenario:

1. Trainee chooses category
2. SuD shows random signals from category, including annotations (UC C6)

Extensions:
2a. Trainee may use Help at any time (see Doc8)

Use case C1: Identify trainee / training program

Scope: SuD
Use case level: Supporting subfunctions
Primary actor: Trainee
Trigger: SuD started
Success guarantee: trainee and training program identified
Minimal guarantee: recognized if trainee is included in trainee list
Main success scenario:

1. Trainee: enters personnel ID
2. SuD: Checks in trainee list to which target group trainee belongs:
    a. Medical specialists: MS
    b. Residents and nurse practitioners: R
    c. Nurses: N
3. SuD: Checks the number of previous visits *i* of the trainee

Depending on i, SuD goes to step 4 or 5.

4. $i = 0$ previous visits
    - Trainee enters password, and a personal question and answer in case he/she forgets the password.
    - SuD: "This is your first visit to the CFM simulator. Welcome!! Let's start with some background information."
    - Trainee: clicks next
    - SuD: goes to level 0
5. $i > 0$ previous visits
    - Trainee enters password.
    - SuD validates password.
    - SuD: "You have visited the CFM simulator before, and will now continue your training session."
    - Trainee: clicks next
    - SuD gives trainee options to go to his current level, or any level below that. If trainee has score level ≥ 1, there is an extra option to enter review mode.
    - SuD: goes to choosen level

Extensions:
3a. trainee is not included in the trainee list.

- SuD: Give pop-up message: "This personnel ID is not included in the trainee list. Please check if you entered your personnel ID correctly."
- Trainee: enters personnel ID.
- SuD: checks personnel ID in trainee list.
  If personnel ID is in trainee list:
    - SuD: goes back to step 3 of use case E1.

  If personnel ID is not in trainee list:
    - SuD: "You are not included in the trainee list. To solve this problem, please contact the instructor of the CFM simulator: *name instructor.*"
    - SuD: close SuD.

5a. password is not correct:

- SuD: "Your password is not correct. Please enter password again: []"
- SuD: checks password:
  If password is correct:
    - SuD: goes back to 5

  If password is incorrect:
    - SuD uses personal question and answer to validate the trainee.

Use case C2: Theoretical Introduction

Scope: Level 0
Level: Subfunctions
Primary actor: Trainee
Trigger: Entered level 0
Success guarantee: enter level 1
Minimal guarantee: get feedback how to learn CFM.
Main success scenario MS:

1. SuD: starts showing slides Theoretical introduction (Doc3) for the specific target group.

The next 2 steps are repeated until next is clicked on the final slide

2. Trainee clicks next, for next slide
3. Trainee clicks back for previous slide

4. Trainee enters Quiz of level 0:
5. SuD shows one by one questions from the list: Questions introduction (Doc4), for the specific target group. SuD picks questions randomly, with condition that at least one question of each category is asked. Number of questions according to Score level and subscore (Doc2).
6. Trainee answers questions.
7. SuD validates answers were correct.
8. SuD saves subscore and rises score level trainee according to Score level and subscore (Doc2)
9. SuD gives pop-up: "Congratulations! You successfully finished level 0."
10. SuD shows list of asked questions.
11. Trainee can click on any question to view argumentation of correct answer.
12. Trainee "Enter level 1".

Extensions:

2a. SuD encounters optional slide (only applies for nurses).
    2a1. SuD gives trainee option to view optional slides.

7a. Trainee answered some questions incorrect, but score was sufficient (see Doc2).
7a1. Go to 8 and 9, at 10 the feedback is given for every question that was answered incorrect.
7b. Trainee answered some questions incorrect, score was slightly insufficient (see Doc2).
7b1. SuD shows extra questions.Trainee score sufficient: go back to 8
7b2. SuD shows extra questions. Trainee score insufficient:
SuD saves subscore and puts score level to -0.5
SuD gives pop-up: "Unfortunately you have too many wrong answers"
SuD shows wrong answers with explanations.
SuD shows in which category (/categories) the trainee has wrong answers.
SuD: "Please go to the instructor (*name instructor*) and ask for help."
SuD closes.
7c. Trainee has insufficient subscore (see Doc2)
SuD saves subscore and puts score level to -0.5
SuD gives pop-up: "Unfortunately you have too many wrong answers"
SuD shows wrong answers with explanations.
SuD shows in which category (/categories) the trainee has wrong answers.
SuD: "Please go to the instructor (*name instructor*) and ask for help."
SuD closes.

Use case C3: Anamnese

Scope: Level 1-4/5
Use case level: Subfunctions
Primary actor: Trainee
Trigger: SuD choose CFM signal in level 1 and higher
Success guarantee: Anamnese of newborn will be given
Minimal guarantee: -
Main success scenario:

1. SuD reads anamnese data at start measurement.
2. SuD gives Anamnese description according to Anamnese information Doc6.

Extensions:
1a. No anamnese data available in file.
2a1. SuD sends warning email to instructor, and chooses other CFM signal from the same category.

Use case C4: Placement of electrodes

Scope: Levels 1-4/5
UC level: Subfunctions
Primary actor: Trainee
Trigger: Trainee clicks next after reading Anamnese
Success guarantee: Trainee places electrodes and checks reliability of measurement
Minimal guarantee: Trainee gets help how to place electrodes
Main success scenario:

1. If applicable, trainee chooses the type of monitor
2. Trainee chooses the type of electrodes
3. SuD shows electrodes, head of a newborn, and impedance signal of monitor (UI28).
4. Trainee drags electrodes to the right place on the head of the newborn

5. SuD validates correct placement and updates subscore PE +1.
6. SuD gives impedance below 10 kOhm

Extensions:

1a. Trainee chooses wrong monitor

1a1. SuD gives explanation for type of monitor (according to protocol department)

2a. Trainee chooses wrong type of electrodes.

2a1. SuD gives explanation for type of electrodes (according to protocol department)

4a. Trainee drops electrodes at wrong place on the head of the newborn.

4a1. SuD shows right place for electrodes and gives explanation: "The placement of these electrodes is parietal. This area was chosen since it should be most sensitive for ischemia, and least sensitive for muscle activity in face or torso."

6a. SuD gives impedance higher than 10 kOhm, according to Score level and subscores (Doc2).

6a1. Trainee clicks "Check electrodes"

6a1a SuD gives image of good attachement electrodes
Trainee clicks on replaces electrodes
SuD updates subscore PR +1

6a1b SuD gives image of bad attachement electrodes
Trainee clicks on electrodes to improve attachement.
SuD shows impedance < 10 kOhm
SuD updates subscore PR +1

6a2. Trainee does not react to high impedance
SuD gives pop-up: "The impedance is too high, which means that the measurement is not reliable. You need to check the electrodes".
SuD will only react when trainee clicks "Check electrodes"
SuD will not add to subscore.

Use case C5: Run CFM signals

Scope: Level 1-4/5
UC level: Subfunctions
Primary actor: Trainee
Trigger: Electrodes are placed.
Success guarantee: Trainee trains to mark events, check reliability and interpret CFM signals
Minimal guarantee: Trainee gets help how to mark events, check reliability and interpret CFM signals
Main success scenario:

1. SuD starts to show CFM signal according to UI29 at a speed of 5 seconds per hour.

Next three steps are repeated until the end of the signal.

2. SuD reads annotations and gives pop-up questions and comments according to Questions CFM signals (Doc7).
3. SuD expects reactions of trainee according to Doc7.
4. SuD gives feedback and updates subscores according to Doc7.

5. SuD updates final subscore

Extensions:

-

Use case C6: Review CFM signals

Scope: Review mode
UC level: Subfunctions
Primary actor: Trainee
Trigger: Trainee chooses Review mode at main menu
Success guarantee: CFM signal is shown without questions
Minimal guarantee:
Main success scenario:

1. Trainee chooses category of signals
2. SuD shows signal from requested category, including annotations.
3. Trainee can click on each annotation, and an explanation according to D7 will be given.

Extensions:

3a. SuD cannot find explanation with given annotation.

3a1. SuD responds " No explanation available"

Document 1: Trainee information

The trainee information is saved in the SuD. This will be saved by the SuD, even after closing a training session. It needs to be constantly updated by the SuD. The list is introduced to the SuD by the instructor, and can at all times be viewed by the instructor. The SuD list to recognise trainees, to which target group they belong, and information concerning previous training sessions with the SuD.

Table: Trainee information

Personnel ID	**Target group (MS/R/N)**	**Nr of previous visits**	**Score level**	**Subscore**	**Password** (not visible to instructor)

Document 2: Score level and subscore

Table: Score levels for beginning and end of each level. Level can be entered with a higher score level than the given one. In that case, after sufficient subscore, the score level will go at least to given score level, but will not drop compared to score level at beginning of level.

	Beginning of level	End of level	
		Sufficient subscore (not below score level at beginning of level)	Insufficient subscore
Level 0	≥ 0	1	0.5
Level 1	≥ 1	2	1.5
Level 2	≥ 2	3	2.5
Level 3	≥ 3	4	3.5
Level 4	≥ 4	5	4.5
Level 5	≥ 5	6	5.5
Review level	≥ 1		

The subscore is divided into 8 categories:

- Theory (T)
- Performance – electrodes (PE)
- Performance – marking events (PM)
- Performance – checking reliability (PR)
- Interpretation – artifacts (IA)
- Interpretation – background patterns (IBP)
- Interpretation – sleep-wake cycles (ISW)
- Interpretation – seizures (IS)

Table: Sufficient and insufficient subscores for level 0.

		Condition		
	Nr. of questions	**Subscore per category**		**Total subscore**
Categories		T-PE-PM-PR-IA-IBP-ISW-IS		
Sufficient	15	1-1-1-1-1-1-1-1	and	≥ 12
Slightly insufficient	15	Not more than 2 categories 0	and	≥ 10
Sufficient after extra questions	15 + 5	1-1-1-1-1-1-1-1	and	≥ 15
Insufficient	15 or 20	More than 2 categories 0	or	< 10 out of 15 < 15 out of 20

Table: Categories in subscore for levels 1-4/5

Level	**Target groups**	**Categories**
Level 1	MS R/N	PE-PM-PR-IA-IBP-ISW-IS PE-PM-PR-IA-IBP-ISW
Level 2	MS/R N	IA-IBP-ISW-IS PE-PM-PR-IA-IBP-ISW-IS
Level 3	MS/R N	IA-IBP-ISW-IS PE-PM-PR-IA-IBP-ISW-IS
Level 4	MS/R N	IA-IBP-ISW-IS PE-PM-PR-IA-IBP-ISW-IS
Level 5	R	IA-IBP-ISW-IS

Table: Sufficient or insufficient subscores, for level 1-4/5.

			Condition		
	Nr. of signals	**Nr. of questions**	**Subscore per category**		**Ratio: total subscore / nr.of questions**
Sufficient	7	≥ 15	Each category ≥ 1	And	3 / 4
Slightly insufficient	7	≥ 15	Not more than 2 categories 0		1 / 2
Sufficient after extra signals/questions	10	≥ 20	Each category ≥ 1		3 / 4
Insufficient	7 or 10	≥ 15	More than 2 categories 0		< 3 / 4

Document 3: Theoretical slides

Slides of the theoretical introduction for medical specialists (MS), residents (R) and nurses (N), with for each slide denoted for which target groups they are, and which user interfaces (UI) belongs to this slide (see appendix user interfaces).

Nr.	Target group	UI	Slide content
Importance of CFM			
1	MS/R/N	-	The cerebral function monitor (CFM) has been introduced to the NICU because it gives extra information about the state of the brain and the occurrence of seizures.
2	MS/R/N		Besides CFM, the function of the brain can be assessed using neurologic examination, like looking at the activity and reactions (like pupil reactions) of the newborn. Furthermore EEG measurements can be performed, which are extended measurements, using between 11 and 23 electrodes, for a limited period of time, usually about half an hour.
3	MS/R/N	UI2	CFM can be regarded as a simplified EEG measurement. Actually, it is derived from EEG: It is a one- or two-channel EEG measurement, where this (/these) EEG signal(s) is(/are) processed and compressed into CFM signal(s). This means that EEG is measured at more places at the same time, which gives a better overview over the activity in the whole brain, and the signal is interpreted in more detail. The advantage of CFM is that it can be used to monitor the newborn: to measure the signal of the brain even for days!!
EEG: what is measured			
4	MS/R N-opt		Nerve impulses in the brain are electrical stimuli, conducted by chemical substances like Na^+ and K^+. Due to these nerve impulses, potential differences arise in the extracellular areas. These potential differences can be measured using electrodes.
5	MS/R N-opt		The EEG signal is the difference in potential measured between two different electrodes.
6	MS/R N-opt	UI3	The potential difference in the extracellular fluid caused by one nerve impulse is very small. However, due to the summation of many nerve impulses, a potential difference can be measured by putting electrodes on the skin.
7	MS/R N-opt		Since the measured signal is originated in many different nerve cells, the EEG signal is generally a chaotic signal, with no clear organisation.
8	MS/R N-opt	UI4	For clinical EEG of newborns generally either 9 or 21 active electrodes are used, i.e. electrodes that measure the actual signals, as opposed to the reference and ground electrodes (will be explained later). From these electrodes many channels (i.e. the potential difference between two electrodes) can be measured. These channels are plotted underneath each other, generally at a speed of 3 cm/second.
9	MS/R N-opt		Besides the time-consuming installation of the electrodes and the inconvenience for the newborn, the interpretation of the EEG signal is time-consuming and needs to be performed by experience neurophysiologists. This makes EEG not suitable for long-term monitoring of newborns at the NICU department.
How is CFM calculated from EEG			
10	MS/R N-opt	UI5	CFM only measures one- or two-channel EEG. Let's consider a one-channel CFM measurement.
11	MS/R N-opt		The measured EEG signal is processed into a CFM signal, basically in five steps: filtering – rectification and smoothing – time-compression – amplitude-compression.

12	MS/R N-opt	UI6 UI7 UI8	Filtering: filtering of a signal is based on their frequency content, i.e. the speed of fluctuations in the signal. The EEG of the newborn contains signals from 0.5 to 30 Hz. For CFM this is filtered to a signal from 2 to 15/16 Hz. This means that the slow fluctuations and the fast fluctuations are filtered out of the signal. The slow fluctuations underneath 2 Hz often contain artefacts, i.e. signals not originated from the brain, like for example breathing fluctuations. The fast fluctuations in the EEG signal have relatively low significance to the EEG signal. The band between 2 and 15 Hz is attenuated in an asymmetrical manner: the higher frequencies are amplified more compared to the low frequencies. This is because the low frequencies generally have a higher amplitude, and the slope in the filter causes all frequencies to have a similar influence on the signal.
14	MS/R N-opt	UI9	Rectification and smoothing: in this step the peaks of the EEG signal are detected. The rectifier works as a condensator, which means that the potential difference rises with higher peaks, and with descending peaks, the potential difference slowly decharges. Because of this process, short periods (smaller than 1 second) of low activity are not recognised, only periods of longer low activity, like interburst intervals that have a length of at least one second, are recognised. This is followed by smoothing of the signal, where very sharp peaks are smoothed.
15	MS/R N-opt	UI10	If at this point the CFM and the original EEG are plotted at the same scale, in the same graph, it can be seen that CFM is an envelope of the EEG signal.
16	MS/R N-opt		The signal is compressed in time: where EEG is generally displayed in 3 cm/second, the CFM is plotted in 6 cm/hour. (image)
17	MS/R N-opt	UI11	Finally, the CFM is plotted on a amplitude scale that is partly "logarithmic". The signal is plotted linear below 10 uV (i.e. the distance between 1 and 2 and between 2 and 3 etc is equal). Above 10 uV the signal is plotted logarithmic. On a logarithmic scale the distance between 1 and 10 and between 10 and 100 is equal. The result is that the signal below 10 uV is very clear, which is important since low activity is a bad sign. However, in the same graph fit all the signals until 100 uV, which is the maximum amplitude plotted in CFM.
18	MS/R N-opt	UI12	Finally, this is the CFM signal that can be seen in the graph.
CFM: what is measured			
19	N		Nerve impulses in the brain are electrical stimuli. These electrical signals can be measured using electrodes. The measured signal is called the electroencephalogram, or EEG signal.
20	N	 UI13 UI14	CFM can either be a one or two-channel measurement (i.e. either one or two signals will be measured); we will consider here a one-channel measurement. For this measurement electrodes are placed that will measure one EEG signal. This signal is subsequently converted into the CFM signal.
21	N	UI15	When comparing the EEG and CFM signal, the most remarkable difference is that the CFM signal shows 3 hours in one screen, while the EEG signal shows only 7 seconds in one screen. The 7 seconds of EEG that are shown are in the CFM signal marked by the red line. Furthermore you can see that this normal EEG signal looks chaotic, and fluctuates around 0. The CFM signal only has positive values, that more or less correspond to the amplitude (height) of the fluctuations of the EEG signal.
Electrodes			

22	MS/R/N	UI16	A one channel CFM signal is measured using two active electrodes, i.e. the electrodes that measure the actual signal. The placement of these electrodes is parietal, at P3P4 according to the international 10-20 system, see image. This area was chosen since it should be most sensitive for ischemia, and least sensitive for muscle activity in face or torso.
23	MS/R/N		Besides these two active electrodes one or two other electrodes are used: the ground electrode and possibly a reference electrode.
24	MS/R/N		The ground electrode is used to suppress noise that is common to both the active and the ground electrodes. The placement of the ground electrode is of no importance, however it is wise to keep the forehead as regular place for the ground.
25	MS/R/N		The reference electrode is used to measure each active electrode compared to this general electrodes. When a reference electrode is used, the signals that are saved are from each separate electrode compared to this reference. This makes it possible to make signals of all possible combinations of electrodes after the measurement is finished. Let's take as example a two channel CFM measurement, C3P3 and C4P4 is measured with a reference electrode (Ref). The signals saved are C3Ref, P3Ref, C4Ref and P4Ref. When subtracting afterwards for example C3Ref and C4Ref, the signals that appears is C3Ref-C4Ref = C3C4. So any possible combination can be made, since the reference signal will be vanished after subtracting two signals.
26	MS/R/N		To summarize, the signals that will appear in your screen are measured with the active electrodes. The ground and reference electrodes are supportive electrodes.
27	MS/R/N	UI17	The signals that are measured are very small, which is called small in amplitude. This amplitude can easily be further reduced by dead cells in the upper skin or oily skin. One possibility to avoid this problem is the use of needle electrodes. When using adhesive electrodes it is very important to clean and scrub the skin according to protocol, before attaching the electrodes.
Impedance			
28	MS/R/N		The reduction of signals caused by dead cells in the upper skin, oily skin or a bad attachment of the electrodes can be measured by the impedance. The impedance is measured by a signal that is generated by the monitor, transmitted by one electrode and then measured by another electrode. When the conductance between skin and electrode is sufficient for both electrodes, the impedance will be low. There are different opinions concerning the accepted threshold of the impedance, ranging from 5 kOhm up to 20 kOhm. With current equipment, our advice is that impedance below 10 kOhm is sufficient.
29	MS/R/N	UI18	Using needle electrodes, the impedance will stay generally very low, provided that the needles did not come off. Using adhesive electrodes, depending among others on the types of electrodes used, the impedance may rise in time, like shown in the given example. It is important to be aware of this, and regularly check the impedance.
Classification CFM			
30	MS/R/N		So what can be seen in this CFM signal. First, it is important to realize that the height of the CFM signal is related to the activity of the brain: a higher signal means higher activity in the brain.
31	MS/R/N	UI19	There are three main features recognizable in the CFM signal: • The background pattern: the background pattern is the general height and width of the signal, without taking short events into account. In the given example the newborn received

		UI20 UI21	medication about halfway in the signal. This caused an enormous decrease in brain activity. • Sleep-wake cycles: sleep-wake cycles are visible in the CFM signal as variations in the width of the CFM. The wider areas denote quiet sleep, and the more narrow parts of the signal denote either active sleep or wakefulness. • Seizures: seizures are a sudden excessive and simultaneous discharge of many neurons. Therefore they are visible in the CFM signal as a sudden rise of the signal, mainly of its lower boundary. Seizures may have a duration of below one minute until up to half an hour or more, image A shows seizures of a few minutes, up to 15 minutes. Image B shows a signal with seizures of very low amplitude.
32		UI22	Seizures are very important to detect, since they may have a damaging effect on the newborn (this is not proven, but generally accepted), and a decision concerning treatment of seizures needs to be made according to your protocol. When you doubt whether or not a pattern is caused by a seizure, you can look into the EEG signal during this period. The normal EEG shows a chaotic pattern. During seizure activity there is a rhythmic pattern of waveforms visible. The statement: "whenever a EEG looks like a ECG this is a bad sign" comes from these patterns. However, as can be seen in the image, the rhythmic waveforms may have very different shapes, be aware of that!!
33		UI23	A continuing state of seizures, with no sign of recovery from these seizures, is known as a status epilepticus. This is a very severe state of seizures.
34	MS/R	UI12	For the classification of the background patterns the amplitude of the signal is used. It is therefore important to remember the semi-logarithmic distribution of the amplitude.
35	N	UI12	For the classification of the background patterns the amplitude of the signal is used. For this it is important to realize that there is an abnormal distribution of the amplitude in the CFM display. The signal is plotted linear below 10 uV (i.e. the distance between 1 and 2 and between 2 and 3 etc is equal). Above 10 uV the signal is plotted so-called logarithmic. The only thing you have to realize from this is that this part of the signal is compressed: 50 uV is relatively close to 10 uV, and 100 uV is relatively close to 50 uV. The result is that the signal below 10 uV is very clear, which is important since low activity is a bad sign. However, in the same graph fit all the signals until 100 uV, which is the maximum amplitude plotted in CFM. Optional: On a logarithmic scale the distance between 1 and 10 and between 10 and 100 is equal.
36	MS/R/N	UI24	The background is classified as follows: A) CNV(Continuous Normal Voltage) amplitude lower boundary: 5-10 μV; upper boundary: 10-50 μV. This is a normal background pattern for term newborns. This background pattern is generally not seen in preterm newborns. B) DNV(Discontinuous Normal Voltage) amplitude lower boundary < 5 μV; Upper boundary >10μV. This pattern is a normal pattern for preterm newborns. C) BS(Burst Suppression) discontinuous activity with a very tight lower boundary of around 0 to 1 μV with many peaks of high activity. This pattern is abnormal.

			D) CLV (Continuous Low Voltage) continuous low voltage with around or just below 5μV. E) FT (Flat Trace) inactive background <<5μV; this pattern is also called iso-electric. CLV and FT are abnormal background patterns that are related to brain injury or disability. It is believed that the speed of recovery from an abnormal background pattern is related to outcome.
Artifacts and marking of events			
37	MS/R/N		Because of the small amplitude of the EEG/CFM signal, the effect of the electrical signals surrounding the brain or the EEG equipments are relatively large. Patterns in the EEG or CFM signal are not originated from the nerve impulses of the brain of the newborn, are called artifacts.
38	MS/R/N	UI25 UI26 UI27	Possible sources of artifacts are: • Movements artifact: artifact caused by movement of the electrodes or the electrode wires. These artifacts are mostly visible as spikes with a very high amplitude. In the example the electrodes where loose and the newborn was lying on the electrodes, giving movement artifacts. • Muscle artifacts: muscle movement close to the electrodes will also be visible in the EEG and CFM signal. In the CFM signal these muscle artifacts may be very similar to seizures, it is very important to be aware of this! Looking in the EEG signal, a high frequent (fast) fluctuation of the signal is visible. • Electrical devices: the general frequency of electrical devices is 50 Hz, which means that they are outside the range of the CFM signal, and have no effect on it. However, there are some devices that have some other frequency in their performance. For example the high frequent ventilation, which is set to ventilate with a frequency of generally about 10 Hz. This might be visible in CFM as well as the EEG signal, as shown in the example. Care should be taken that this is not misinterpreted as seizure!
39	MS/R/N		There may be other sources of artifacts that have not been mentioned. Be aware that this may happen, and that any electrical source may have an influence.
40	MS/R/N		Because of these artifacts it is very important that all events during the measurement that may have an influence on the signal are marked in the signal. In that way the signal can afterwards be interpreted, without confusing these artifacts for other types of events. Examples of events that need to be marked are: • care • cuddling by parents • cerebral ultrasound • High frequent ventilation Besides these possible sources of artifacts, there are some events that need to be marked that may have an influence on the nerve activity and therefore on the EEG or CFM signal: • Medication, this may cause a decrease in cerebral activity • Clinical seizures, when seizures are clinical or subclinical (only visible in EEG and CFM signal). Moreover, not all clinical seizures may be visible in CFM, and it is important to notice this.
Showing protocol of department			
41	MS/R/N		Show the protocol that is specific for the department of the trainee.

Document 4: Theoretical questions

The questions are asked in terms of statements that can be true or false. They are categorized. Furthermore, in front of each question the target groups to which this question can be asked is mentioned, after it if the statement is true or false, and in the next line an explanation is given.

Theory

MS/R/N	CFM is calculated from EEG.	T
This is true. For CFM measurements an EEG signal is measured, which is than processed into a CFM signal.		
MS/R/N	CFM is a replacement for EEG.	F
False!!!! CFM is not a replacement for EEG, since it misses spatial information and is interpreted less detailed in time.		
MS/R	An EEG signal measures the electrical signals that come from nerve impulses, are transported through the extracellular fluid, the tissue surrounding the brain and are finally measured by electrodes.	T
True, these electrical signals are measured.		
MS/R	The CFM signal is an envelope of the EEG signal.	T
This is true. When the CFM and EEG signal are plotted at the same time and amplitude scale, it becomes visible that the CFM signal is an envelope of the EEG signal.		
MS/R	The filtering of the EEG signal in the process to calculate the CFM signal will remove fast fluctuations.	F
This is false. Besides the fast fluctuations also slow fluctuations are filtered, since they often contain artifacts.		
N	CFM measures the nerve impulses from the brain of the newborn.	T
This is true. These nerve impulses are electrical stimuli that can be measured.		
N	CFM has only positive values, and the height of the signal corresponds to the activity of the brain.	T
This is true. A higher CFM signal is caused by higher cerebral activity.		

Performance – electrodes

MS/R/N	One-channel CFM uses 2 electrodes.	F
False, 2 electrodes are used to measure the signal, however, at least one extra electrode is used as a ground electrode, and possibly another extra electrode as reference (depending on the type of monitor used)		
MS/R/N	The active electrodes are placed parietal.	T
This is true. The parietal placement of the electrodes is chosen since it would be most sensitive to ischemia, and it is least sensitive to muscle artifacts from the face and torso.		
MS/R/N	Either 1 or 2 supporting electrodes are placed on the chest of the newborn.	F
False, the supporting electrodes are placed on the forehead of the newborn.		
MS/R/N	Scrubbing the skin is necessary before placement of needle electrodes.	F
False, scrubbing the skin will remove dead cells from the upper skin, which is useful for adhesive electrodes. For the use of needle electrodes, the skin needs to be cleaned, but not scrubbed.		
MS/R/N	Adhesive electrodes can be used to measure CFM	T
True, care needs to be taken that the skin is prepared according to protocol, to ensure a reliable measurement. In that case adhesive electrodes are		

Performance – checking reliability

MS/R/N	An impedance be below 10 kOhm is sufficient for a reliable measurement.	T
True, with current equipment an impedance below 10 kOhm is sufficient for a reliable measurement.		
MS/R/N	When the impedance is too high, the measurement needs to be stopped.	F
False! The electrodes need to be checked, and if necessary, new electrodes need to be placed. When adhesive electrodes are used, it might be necessary to switch to needle electrodes.		
MS/R/N	The impedance can get higher when the newborn is lying on the electrodes.	T
This is true. When the newborn is lying on the electrodes, either		

Performance – marking events

MS/R/N	The marking of events is just to see that the signal is unreliable at that moment.	F
False. Some markings may be used to mark the areas where the signal may be unreliable, however, markings are also used to highlight events like clinical seizures and medication.		
MS/R/N	When a newborn receives medication that may influence the brain activity, this needs to be marked in the signal.	T
This is true. Medication that has an influence on the cerebral activity, will therefore also have an influence on the CFM signal. To be able to remember afterwards the cause of this change in the signal, it is important that the administration of medication is marked in the signal.		
MS/R/N	During care of the newborn, start of care needs to be marked.	F
False, depending on the type of monitor either the whole care period needs to be marked, or both the start and end of the care period need to be marked.		
MS/R/N	When a newborn shows trekkingen and this can be seen in the CFM signal as well, they do not need to be marked in the signal.	F
False! It is very important to mark clinical seizures, even when they are visible in the CFM signal. This information can be used to have a better idea of the severity of the seizures.		
MS/R/N	When cerebral ultrasound is performed, this needs to be marked in the signal.	T
This is true, since the transducer of the ultrasound may cause movement artifacts.		

Interpretation – artifacts

MS/R/N	Movement artifacts are mostly visible as peaks of very high amplitude.	T
This is true. Movement artifacts are caused by movement of the electrodes or leads, and this may lead to sudden peaks of very high amplitude.		
MS/R/N	Muscle activity can cause artifacts in the CFM signal.	T
True, muscle activity is electrical activity and can therefore cause artifacts in the CFM signal.		
MS/R/N	Electrical devices do not cause artifacts in the CFM signal.	F
False, although power of the circuit is 50 Hz, a frequency that has no influence on the CFM signal, there are some devices that have signals of other frequencies. An example is the high frequent ventilation.		
MS/R/N	Artifacts are rare.	F
This is false! Movement artifacts and other types of artifacts can be caused by many events, especially during a measurement that lasts for a day or longer.		
MS/R/N	Artifacts are not easily mistaken for other events.	F
This is false!! Some events, like muscle artifacts and artifacts from high frequent ventilation are similar to seizures. It is very important to be aware of this!		

Interpretation – background patterns

MS/R/N	A normal pattern for the full term newborn is Continuous Normal Voltage.	T
True, this CNV pattern is a pattern of high activity, and is normal for full term newborns.		

MS/R/N	The Discontinuous Normal Voltage pattern is a normal pattern for full term newborns.	F
False, this DNV pattern is a normal pattern for preterm newborns.		
MS/R/N	Burst suppression is a pattern of low activity with peaks of high activity.	T
True, there are at least 10 peaks of high activity within 10 minutes, and the baseline is around 0 to 1 uV.		
MS/R/N	The Continuous Low Voltage pattern is a pattern of high acticivity	F
False! This CLV pattern is a pattern of very low activity. It is an abnormal pattern for both full term and preterm newborns.		
MS/R/N	The Flat Trace pattern is a pattern of an (almost) inactive brain.	T
This is true. This FT pattern is also called "iso-electric".		

Interpretation – sleep-wake cycles

MS/R/N	Sleep-wake cycles are visible in CFM as a variation of the width of the CFM signal.	T
True, a variation of a more narrow part of the signal for active sleep or wakefulness and a broad part of the signal for quiet sleep makes the sleep-wake cycle.		
MS/R/N	The narrow part of the signal of a sleep wake cycle can either be active sleep or wakefulness.	T
This is true. The broad part is of quiet sleep.		
MS/R/N	The broad part of the signal is of active sleep.	F
False, the broad part of the signal is of quiet sleep.		
MS/R/N	Sleep wake-cycles can be seen in prematures of 26 weeks.	F
False, prematures of 26 weeks do not show a sleep-wake cycle yet. Only between 30 and 35 weeks the sleep-wake cycle evolves.		

Interpretation – seizures

MS/R/N	Seizures can be recognized as a sudden decrease of the CFM signal.	F
False!! Seizures are a sudden excessive and synchronous … and are therefore characterized in the CFM signal by an increase of mainly the lower boundary of the signal.		
MS/R/N	Seizures have a characteristic duration.	F
False!! Seizures may have a duration of less than one minute and up to more than 30 minutes.		
MS/R/N	A status epilepticus is the most severe state of seizure activity.	T
This is true. Status epilepticus is a state of seizures where the signal does not seem to recover of these seizures. It is very important to detect a status epilepticus.		
MS/R/N	Seizures only occur during CNV or DNV background patterns.	F
False, seizures can be seen on any type of background pattern.		
MS/R/N	Seizures have a sudden beginning and end.	T
True, this can be seen in the CFM signal by the sudden increase and finally decrease again of the CFM signal.		

Document D5. CFM signals for different levels

Table. Categories of CFM signals

Category	Subcategory	
1		Cerebrally healthy newborns with sleep wake cycles.
2	a	Clear DNV
	b	Clear BS
	c	Clear CLV
	d	Clear FT
	e*	Clear seizure activity
3	a	Unclear DNV/BS
	b	Unclear BS/CLV
	c	Unclear FT/BS
	d*	Unclear seizures
4	a	Fast recovery patterns
	b	Slow recovery patterns
	c	No recovery
	d*	Status epilepticus, clear
	e*	Status epilepticus, unclear
	f	Different types of artifacts
5	a	Uncategorized
	b	From own department

* From these subcategories at least two signals need to be trained in the corresponding level.

Table. The categories of CFM signals that need to be trained by target groups in the different levels. From each subcategory at least one signal needs to be trained, and from subcategories including seizures at least 2 signals need to be trained.

Level	Medical specialists		Residents		Nurses	
	category	Nr of signals				
1	1,2	7	1	7	1	7
2	3	7	2	7	2	7
3	4	7	3	7	3	7
4	5	7	4	7	4	7
5		7	5	7		

Document D6. Anamnese information

The details of the anamnese are included in the CFM signal as the first annotation.
Subsequently are given:
GA, Sex, APGAR, pH, Pregnancy, Birth,

Anamnese description:
A newborn enters the NICU....

- *Name* was born with *GA* weeks + days gestational age.
- Details during pregnancy: *pregnancy.*
- Details of birth: *birth*
- After birth *name* had APGAR of *APGAR* 1 and 5 minutes. The umbilical pH was *pH.*
- *Name* has just been brought into the NICU. Due to possible brain damage the cerebral function needs to be monitored

Document D7: Questions CFM signals.

Annotations in CFM signals: the annotations are categorized. First the annotation is given, to the right the full name of the pattern is given. Below this there is at least one line of explanation. For the background patterns two lines are given, they are called a. and b. where a. is the explanation, and b. gives some extra medical information concerning the pattern. These will be used in the questions.

Clear background patterns:

BG – CNV	Continuous Normal Voltage
a. This background pattern has amplitudes between 5-10 μV and 10-50 μV	
b. It is a normal background pattern	
BG – DNV	Discontinuous Normal Voltage
a. The Discontinuoud Normal Voltage has a lower boundary beneath 5 μV and an upper boundary above 10 μV.	
b. It is an abnormal for fullterm newborns, but a normal pattern for prematures.	
BG – BS	Burst Suppression
a. The Burst Suppression pattern is a pattern of low activity, below 5 μV, with peaks of high amplitude.	
b. It is an abnormal background pattern for the fullterm newborn.	
BG – CLV	Continuous Low Voltage
a. The Continuous Low Voltage pattern is a pattern of low activity around or just below 5 μV.	
b. It is an abnormal pattern of very low cerebral activity.	
BG – FT	Flat Trace
a. The Flat Trace pattern has is very low, far below 5 μV.	
b. It is an abnormal pattern of an inactive brain, also called iso-electric.	

Unclear background patterns:

BG – CNV/DNV	Unclear background pattern between CNV and DNV.
a. It is unclear if the lower boundary is above or below 5 μV.	
b. This is close to a normal pattern for a fullterm newborn.	

BG – DNV/BS	Unclear background pattern between DNV and BS.
a. It is unclear if this is a DNV pattern with a lower boundary beneath 5 μV or if the pattern is below 5 μV with high peaks.	
b. It is an abnormal for fullterm newborns, but may be a normal pattern for prematures.	
BG – BS/CLV	Unclear background pattern between BS and CLV
a. It is a pattern of low activity with peaks of high activity that may belong to either burst suppression or continuous low voltage.	
b. It is an abnormal background pattern for the fullterm newborn.	
BG – BS/FT	Unclear background pattern between BS and FT
a. It is a pattern of very low activity, with some peaks of high activity that may either be burst suppression of flat trace.	
b. It is an abnormal pattern of very low cerebral activity, with some peaks of high activity.	
BG – CLV/FT	Unclear background pattern between CLV and FT
a. The Flat Trace pattern has is very low, far below 5 μV.	
b. It is an abnormal pattern of an inactive brain, with some peaks of high activity.	

Seizure events

Seizures	Unclear background pattern between CNV and DNV.
a. It is unclear if the lower boundary is above or below 5 μV.	
b. This is close to a normal pattern for a fullterm newborn.	
BG – DNV/BS	Unclear background pattern between DNV and BS.
a. It is unclear if this is a DNV pattern with a lower boundary beneath 5 μV or if the pattern is below 5 μV with high peaks.	
b. It is an abnormal for fullterm newborns, but may be a normal pattern for prematures.	
BG – BS/CLV	Unclear background pattern between BS and CLV
a. It is a pattern of low activity with peaks of high activity that may belong to either burst suppression or continuous low voltage.	
b. It is an abnormal background pattern for the fullterm newborn.	
BG – BS/FT	Unclear background pattern between BS and FT
a. It is a pattern of very low activity, with some peaks of high activity that may either be burst suppression of flat trace.	
b. It is an abnormal pattern of very low cerebral activity, with some peaks of high activity.	

Seizure events:

E – seizure	Seizure
A seizure is visible in the CFM signal by a sudden rise mainly in the lower boundary of the signal.	
E – suspected seizures	A pattern suspected of seizure
Even from the EEG signal it is not very clear if this event is a seizure.	
E – status epilepticus	Status epilepticus
The status epilepticus is a pattern of continuous seizure activity, where the background pattern does not seem to recover from the seizures.	
E – suspected status epilepticus	A pattern suspected of status epilepticus.
It is not totally clear whether this is a pattern of continuous seizure activity.	

Sleep wake cycles:

E – SWC	Sleep wake cycle
Sleep-wake cycles are visible in the CFM signal as variations in the width of the CFM. The wider areas denote quiet sleep, and the more narrow parts of the signal denote either active sleep or wakefulness.	
E – immature SWC	Immature sleep wake cycle
In an immature sleep-wake cycle some variation of the width of the band is visible, but this is not evolved or smooth.	

Artifacts:

E – artifact	Artifact
An artifact can have many different sources.	
E – movement artifact	Artifact caused by movement of the electrodes or leads
Artifacts caused by movement of the electrodes or the electrode wires are visible as spikes with a very high amplitude.	
E – muscle artifact	Artifact caused by muscle activity
Muscle movement close to the electrodes is visible in the CFM signal is a rise in the lower boundary of the signal, that might look similar to seizure patterns. Looking in the EEG signal, a high frequent (fast) fluctuation of the signal is visible, clearly different from seizure activity.	
E – HFO	Artifact caused by high frequent ventilation.
The high frequent ventilation might be visible in CFM as a rise in the lower boundary. In the EEG signal a rhythmic pattern is visible, and care needs to be taken that this is not misinterpreted as seizure! The pattern in EEG is very steady with a frequency of 10 Hz (10 waves per second).	

Questions to annotations in CFM signals:

Background patterns:

- Question: "What type of background pattern is this:" *SuD gives three random options, among which the correct answer.*
- After trainee clicks on the answer, either positive or negative feedback is given, including explanation in a.
- Second question: "Is this a normal of an abnormal pattern for the fullterm newborn?" *SuD gives three random options from explanations b., among which the correct answer.*
- Positive or negative feedback is given based on the answer of the trainee. No further explanation.

Unclear background patterns:

- Question: "What type of background pattern is this:" *SuD gives three random options from both clear and unclear background patterns, among which the correct answer.*
- After trainee clicks on the answer, either positive or negative feedback is given, including explanation in a.
- Second question: "Is this a normal of an abnormal pattern for the fullterm newborn?" *SuD gives three random options from explanations b. only from unclear background patterns, among which the correct answer.*
- Positive or negative feedback is given based on the answer of the trainee. No further explanation.

Seizure events:

- Question: "What is this type of event:" *SuD gives three options, two from the seizure events (among which the correct answer), and one option being "artifact".*
- SuD gives positive or negative feedback with explanation.

Sleep-wake cycles:

- Question: "What can you see in this signal:" *SuD gives the two options from sleep-wake cycles and artifact.*
- SuD gives positive or negative feedback with explanation.

Artifacts:

- Question: SuD asks either same question from seizure events, or same question from sleep-wake cycles.
- SuD gives positive or negative feedback.
- Second question: "Can you define the type of artefact?" *SuD gives three options from type of artefact (the full names), among which the correct answer.*
- SuD gives positive or negative feedback with explanation.

Table. Questions will only be asked in appropriate level

Target group	**Level**	
Medical specialists	1	Cerebrally healthy newborns, with sleep-wake cycles. Clear background patterns, seizures. Some movement artifacts. Impedance check, marking events, review problem.
	2	Unclear background patterns, suspected seizures. Different types of artifacts.
	3	Status epilepticus, recovery patterns, immature SWC and artifacts.
	4	Suspected status epilepticus, everything mixed, signals included by own department,
Residents	1	Cerebrally healthy newborns, with sleep-wake cycles. Impedance check, marking events, review problem.
	2	Clear background patterns, seizures. Some movement artifacts.
	3	Unclear background patterns, suspected seizures. Different types of artifacts.
	4	Status epilepticus, recovery patterns, immature SWC and artifacts.
	5	Suspected status epilepticus, everything mixed, signals included by own department,
Nurses	1	Cerebrally healthy newborns, with sleep-wake cycles. Impedance check, marking events, review problem.
	2	Clear background patterns, seizures. Some movement artifacts. Impedance check, marking events, review problem.
	3	Unclear background patterns, suspected seizures. Different types of artifacts. Impedance check, marking events, review problem.
	4	Status epilepticus, recovery patterns, immature SWC and artifacts. Impedance check, marking events, review problem.

Questions / reactions concerning performance of measurement:

- Impedance check: in levels that state impedance check, the impedance should get at least twice above 10 kOhm. The trainee needs to react on this. When reaction is correct, SuD updates subscore PR +1
- Marking events: The general markings are kept in the signals: care, different types of medication, ultrasound, etc. When SuD reads these annotations, SuD gives pop-up of either:
    - "It is time for care of the newborn.", followed later by "Care is finished"
    - The newborn receives a dose of *medication*
    - Cerebral ultrasound is performed on the newborn.

  The trainee needs to react by himself by adding a marking to the signal. In that case SuD updates subscore PM +1. If the trainee does not mark the signal, a warning will be given by a pop-up.
- This is only for the Olympic CFM6000: For all levels that have "review problem stated" the SuD gives in level one twice, in other levels once the remark: "A colleague just reviewed the CFM signal" or "A colleague just looked at the EEG signal." After that the CFM screen is no longer updated, but the time on the clock is running. The trainee has to update the screen. If done so: PR +1, otherwise a warning will be given.

Document D8. Help documentation

The help button hides a menu, that consists of:

- Protocols of the own department.
- A summary of the theory.
- Option to email a question to the instructor.

Summary of the theory:

CFM is a one or two-channel measurement (i.e. either one or two signals will be measured); where the measured signal is the electroencephalogram (EEG) and this signal is processed into the CFM signal. A one channel CFM signal is measured using two active electrodes, i.e. the electrodes that measure the actual signal. The placement of these electrodes is parietal, at P3P4.Besides these two active electrodes a ground electrode and possibly a reference electrode.

There are three main features recognizable in the CFM signal:

- The background pattern: the background pattern is the general height and width of the signal, without taking short events into account.
- Sleep-wake cycles: sleep-wake cycles are visible in the CFM signal as variations in the width of the CFM. The wider areas denote quiet sleep, and the more narrow parts of the signal denote either active sleep or wakefulness.
- Seizures: seizures are a sudden excessive and simultaneous discharge of many neurons. Therefore they are visible in the CFM signal as a sudden rise of the signal, mainly of its lower boundary. A continuing state of seizures, with no sign of recovery from these seizures, is known as a status epilepticus.

The background is classified as follows:

- CNV(Continuous Normal Voltage) amplitude lower boundary: 5-10 μV; upper boundary: 10-50 μV. This is a normal background pattern for term newborns. This background pattern is generally not seen in preterm newborns.
- DNV(Discontinuous Normal Voltage) amplitude lower boundary < 5 μV; Upper boundary >10μV. This pattern is a normal pattern for preterm newborns.

- BS(Burst Suppression) discontinuous activity with a very tight lower boundary of around 0 to 1 μV with many peaks of high activity. This pattern is abnormal.
- CLV (Continuous Low Voltage) continuous low voltage with around or just below 5μV.
- FT (Flat Trace) inactive background <<5μV; this pattern is also called iso-electric.

CLV and FT are abnormal background patterns that are related to brain injury or disability. It is believed that the speed of recovery from an abnormal background pattern is related to outcome.

Possible sources of artifacts are:

- Movements artifact: artifact caused by movement of the electrodes or the electrode wires. These artifacts are mostly visible as spikes with a very high amplitude.
- Muscle artifacts: in the CFM signal a sudden rise of the lower boundary is visible. Looking in the EEG signal, a high frequent (fast) fluctuation of the signal is visible.
- Electrical devices: the general frequency of electrical devices is 50 Hz, which means that they have no effect on the CFM siganls. However, some devices have other frequencies, like high frequent ventilation. This can be visible in CFM as a rise of the lower boundary and in EEG as a rhythmic pattern of 10 waves per second (10 Hz). Care should be taken that this is not misinterpreted as seizure!

Because of these artifacts it is very important that all events during the measurement that may have an influence on the signal are marked in the signal. Marked should be:
Care, cuddling by parents, cerebral ultrasound, high frequent ventilation, medication, clinical seizures.

3 Interface requirements

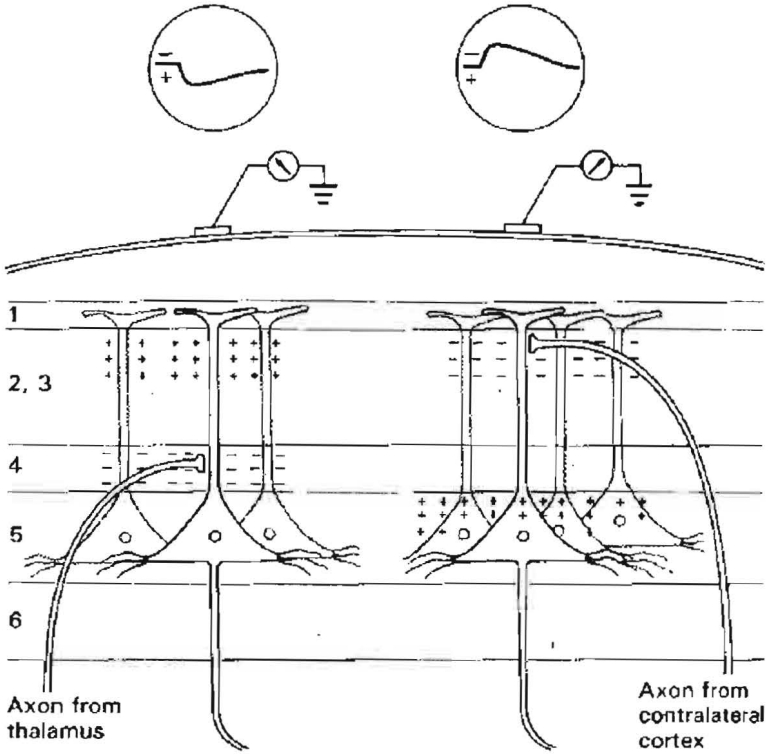
User interface

User Interface 1
Besides the given text and images, the slides of the theoretical introduction all need to include the functions:

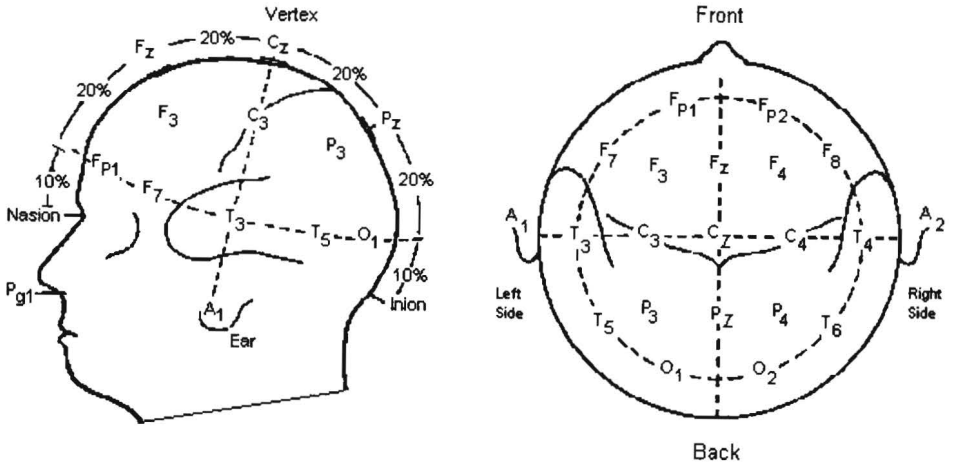
- Previous slide
- Next slide
- Help (see help documentation)

User Interface 2
Image of newborn with EEG electrode placement, and one with CFM electrode placement, like image below.

User Interface 3
Image of nerves and how their electrical energy is measured, like below (Cluitmans)

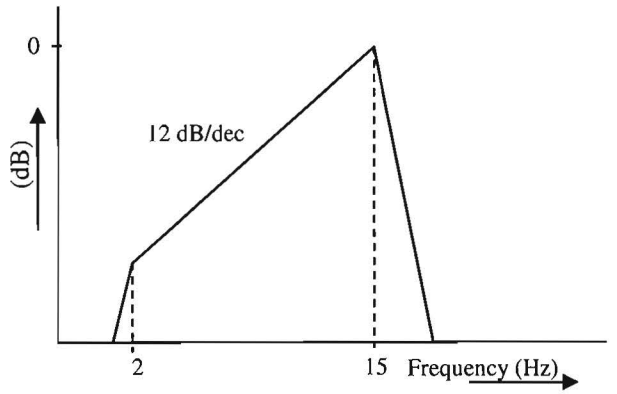


User Interface 4



User Interface 5: Image of 1-channel CFM and image of 2-channel CFM measurement set-up (child with electrodes and signals)

User Interface 6

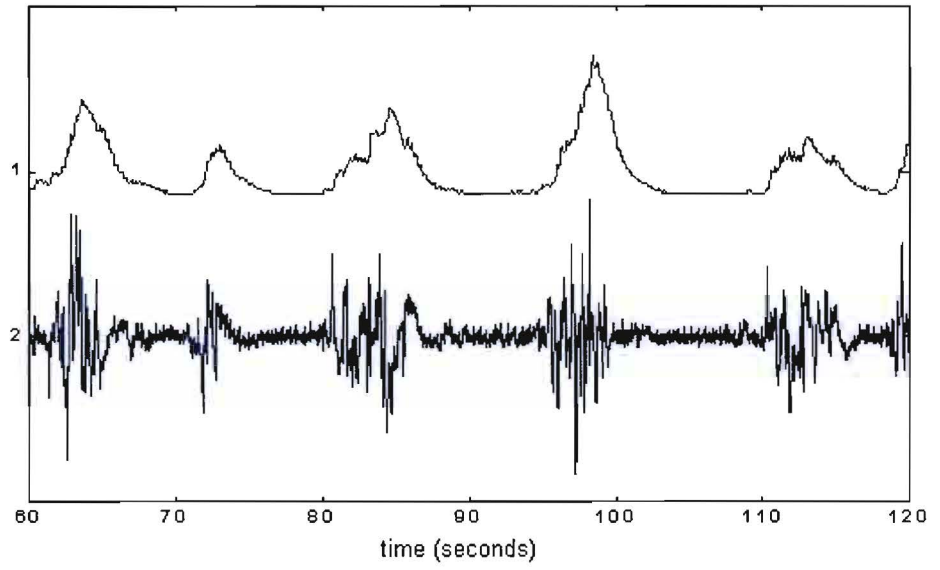


User Interface 7: Image of signal, filter moves over signal, low frequencies are removed from signal.

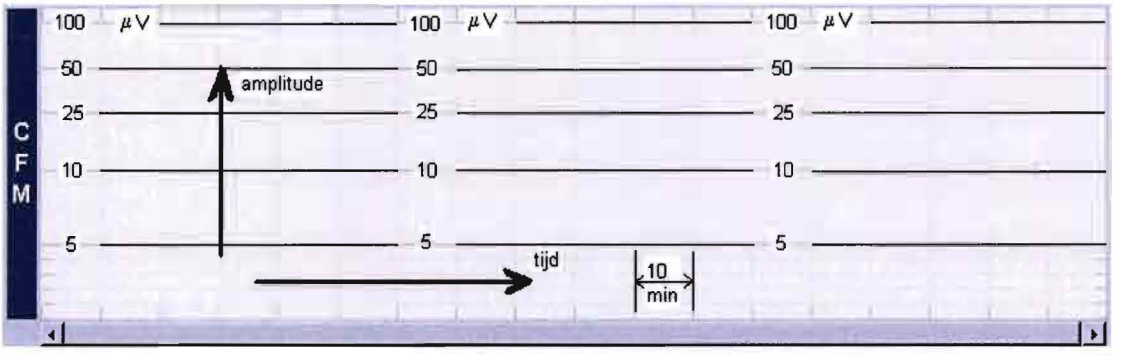
User Interface 8: Image of signal, filter moves over signal, high frequencies are removed from signal.

User Interface 9: Rectifier effect on signal, see article Brainz.

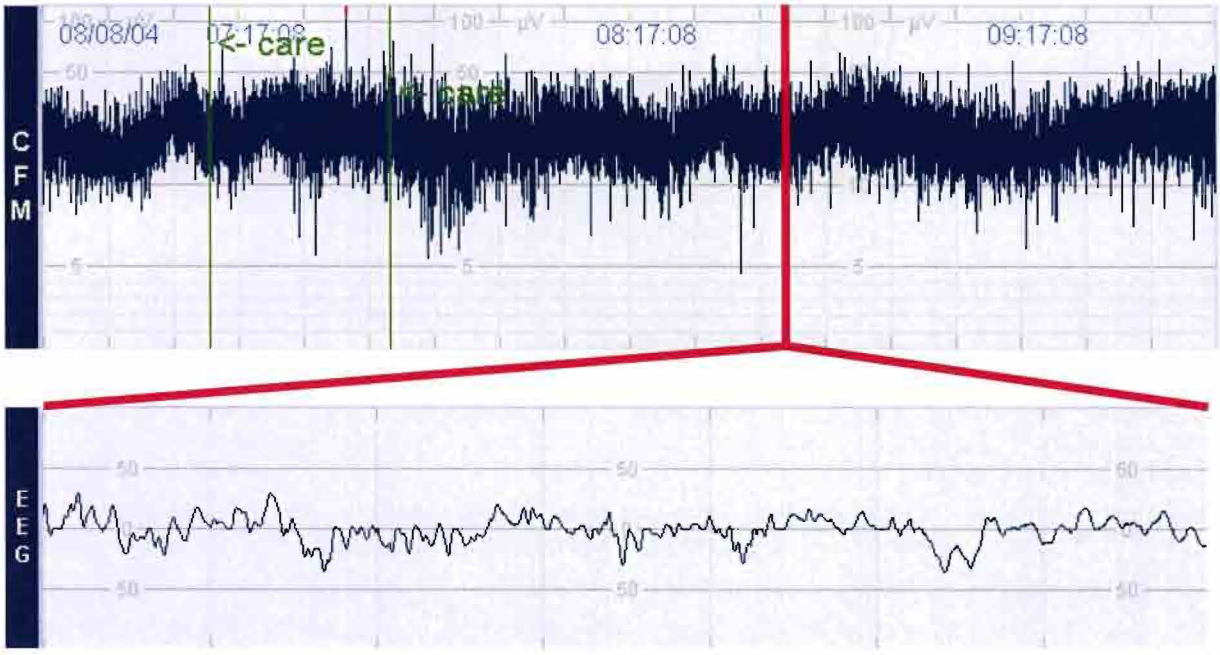
User Interface 10



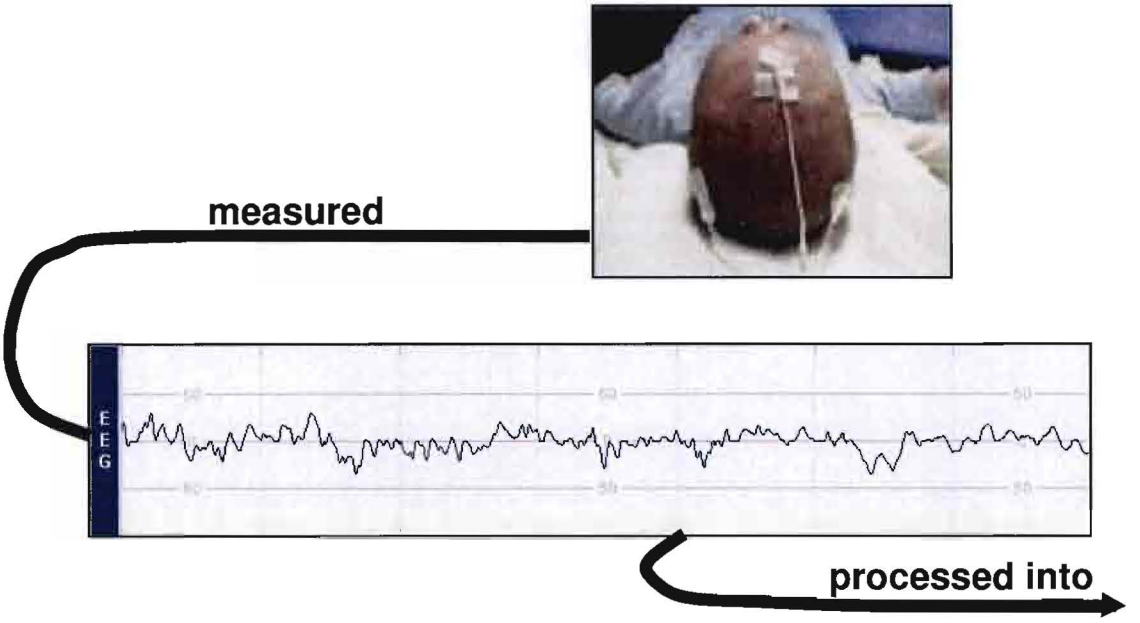
User Interface 11



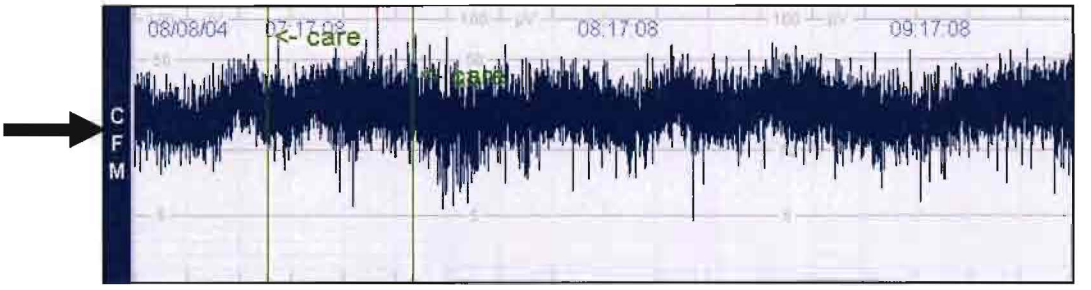
User Interface 12


08/08/04
07:17:08
care
care
08:17:08
09:17:08
CFM
EEG

User Interface 13

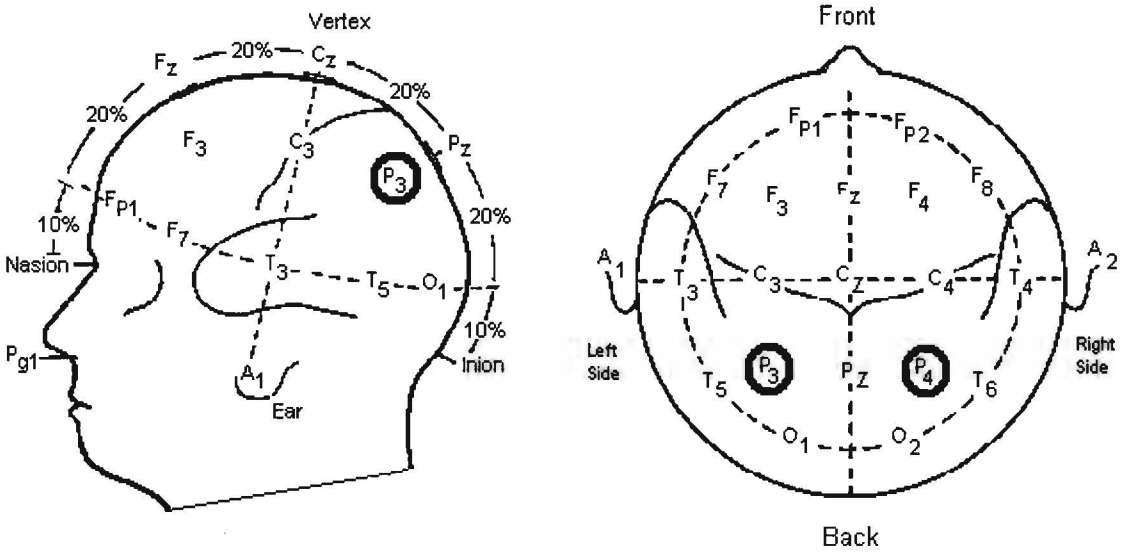


User Interface 14



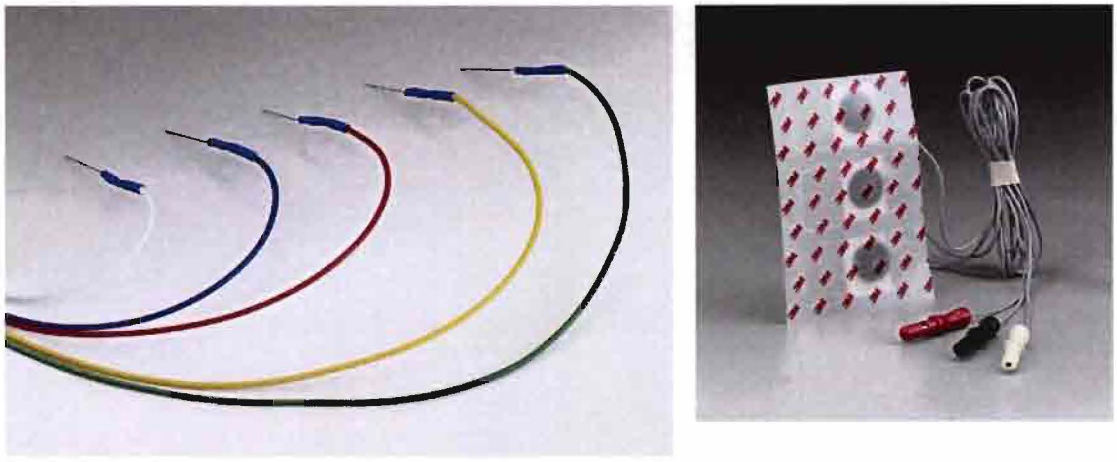
User Interface 15

User Interface 16



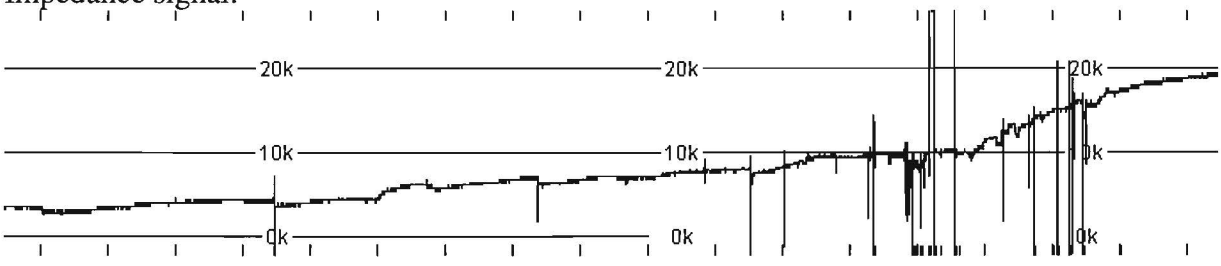
User Interface 17

These need to be exchanged for images of the electrodes used by the specific department.

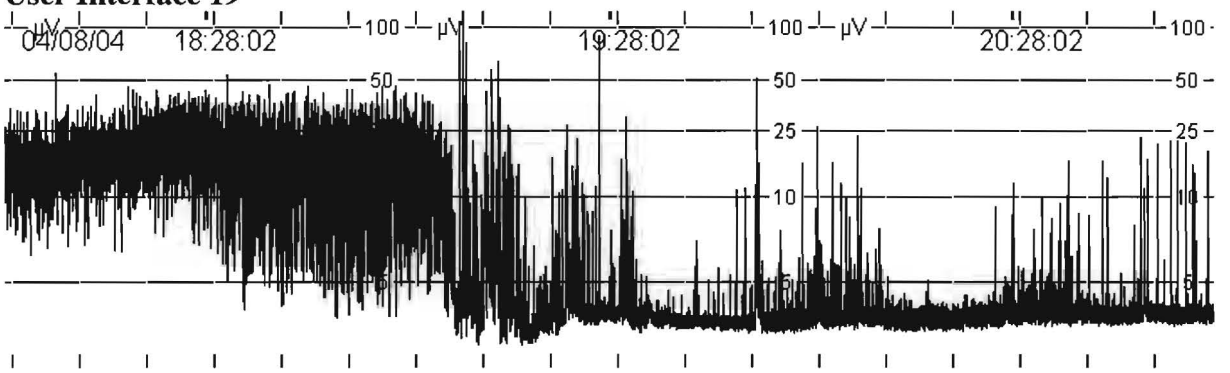


User Interface 18

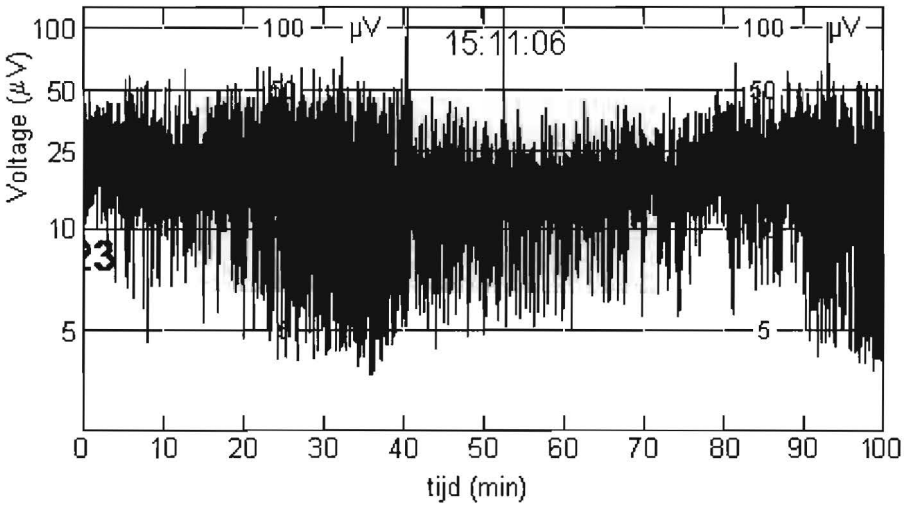
Impedance signal:



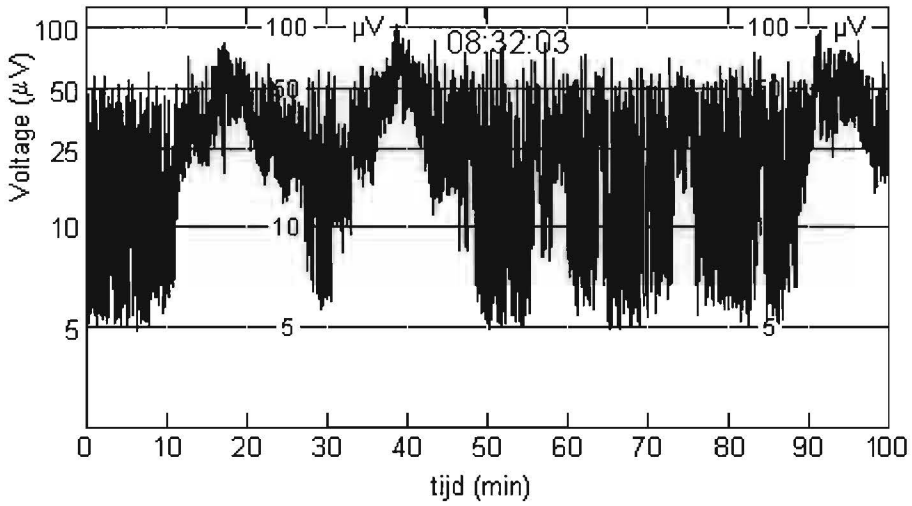
User Interface 19



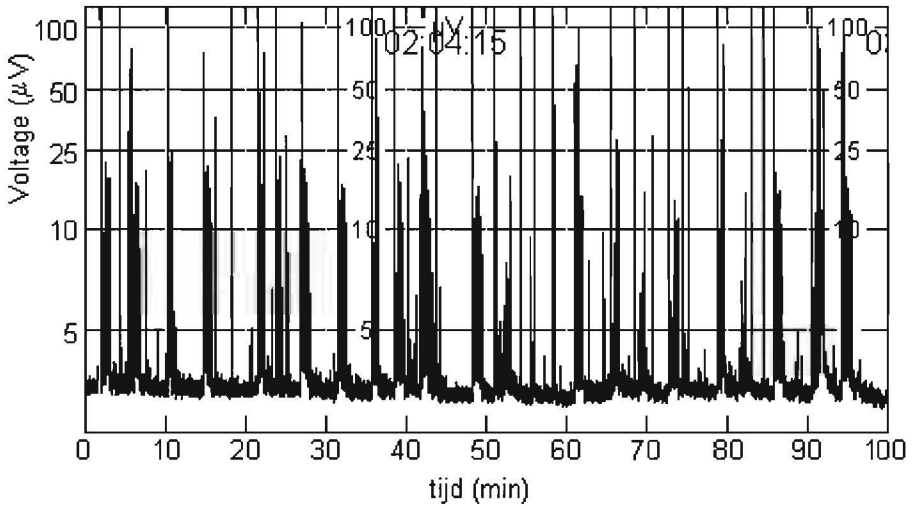
User Interface 20



User Interface 21

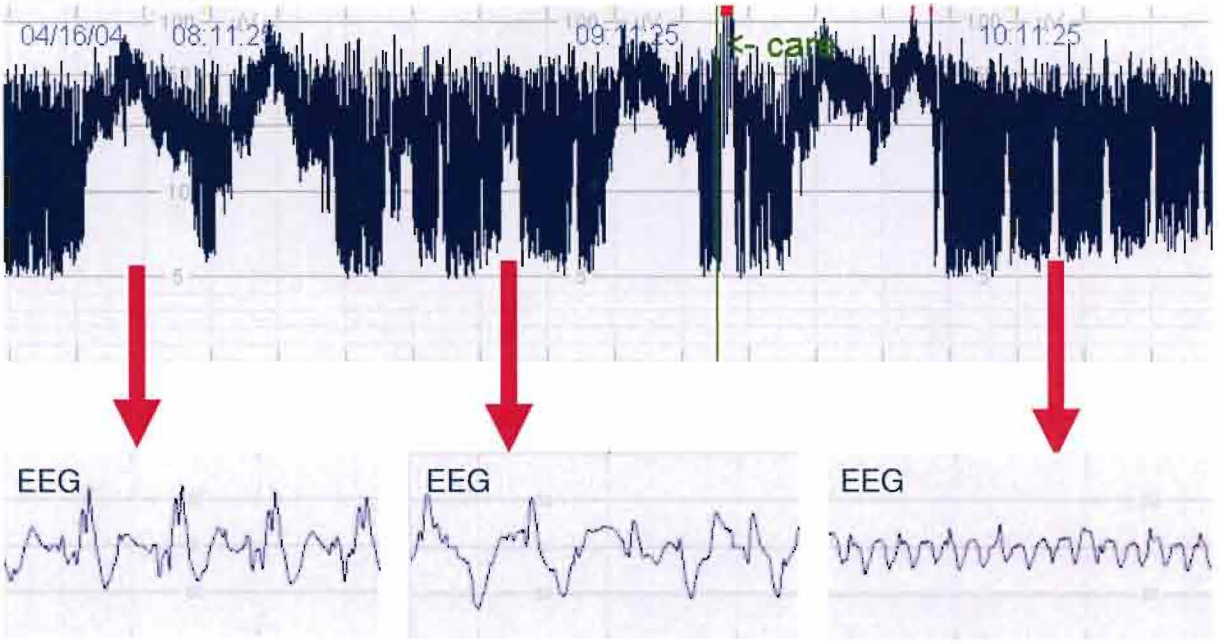


A

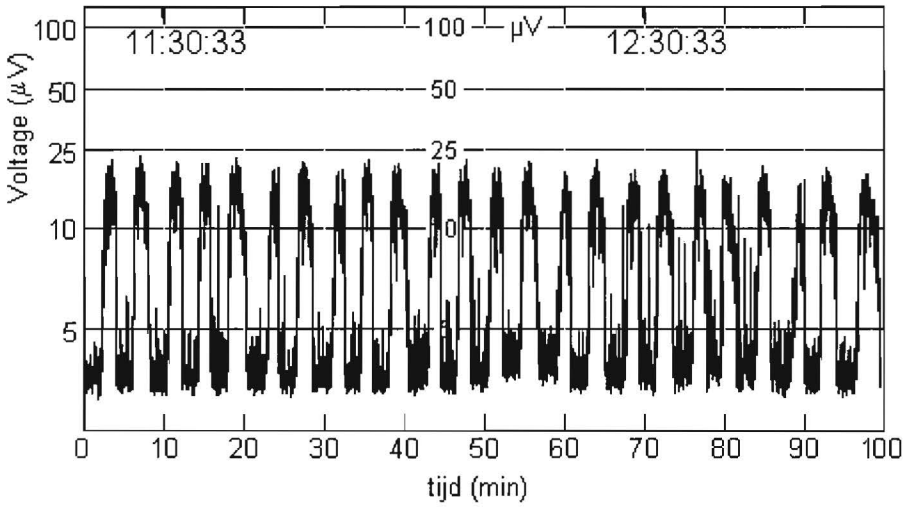


B

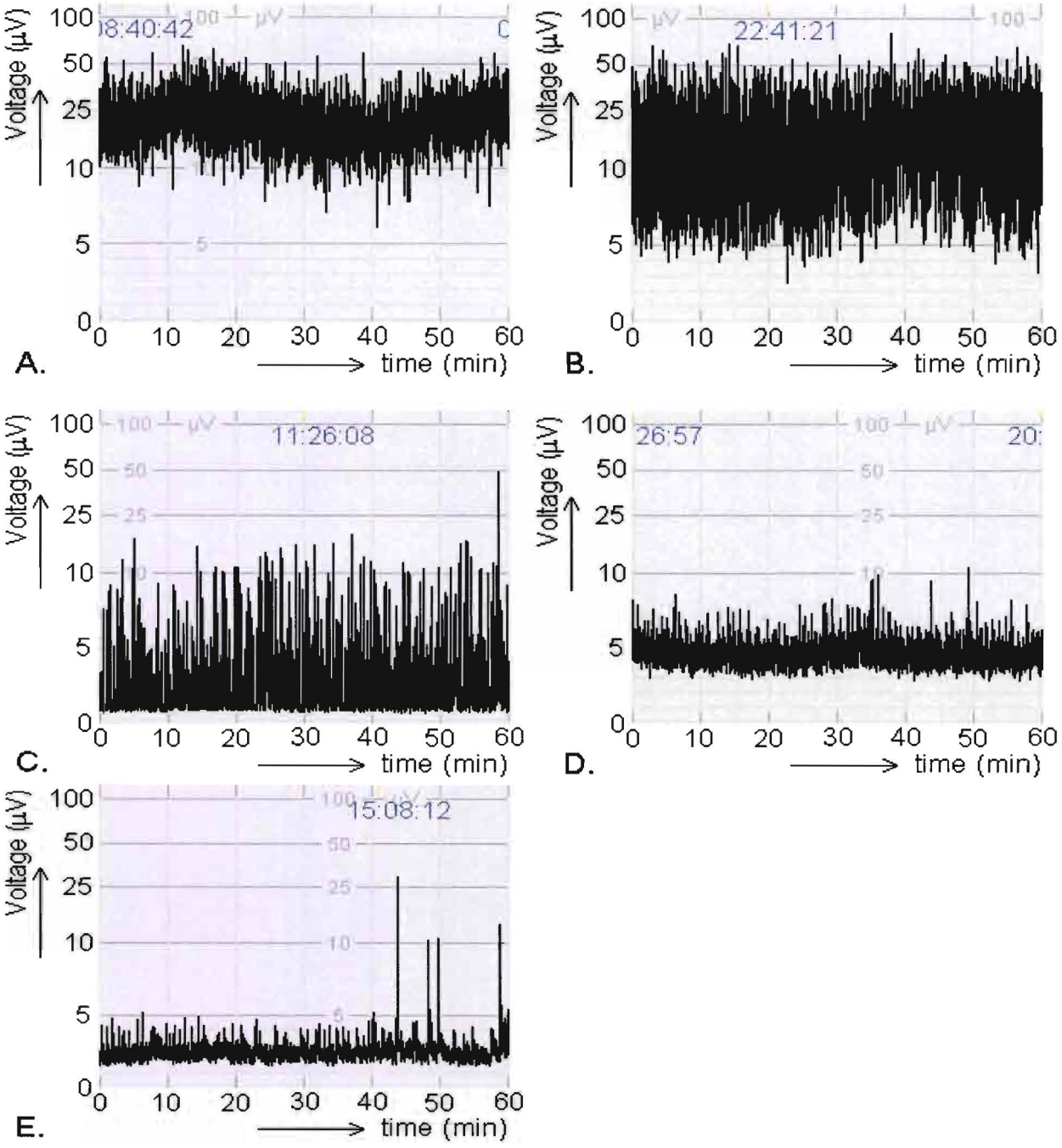
User Interface 22



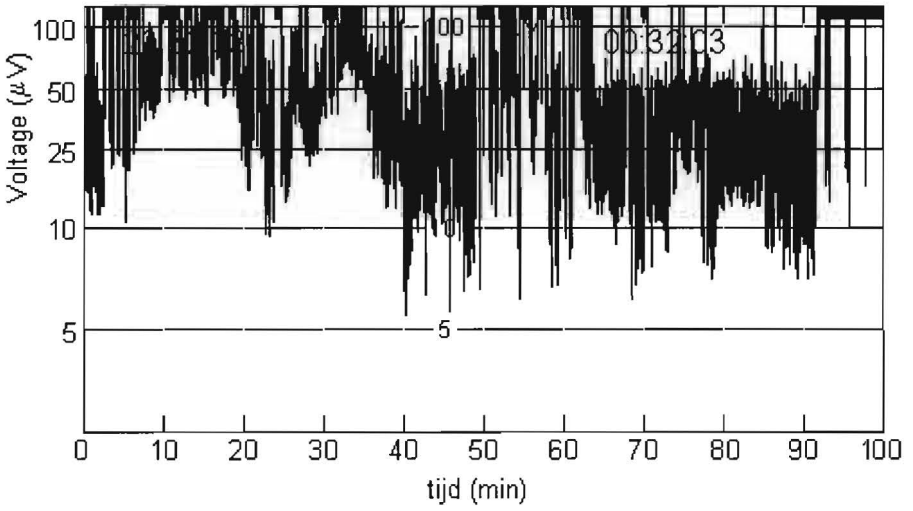
User Interface 23



User Interface 24

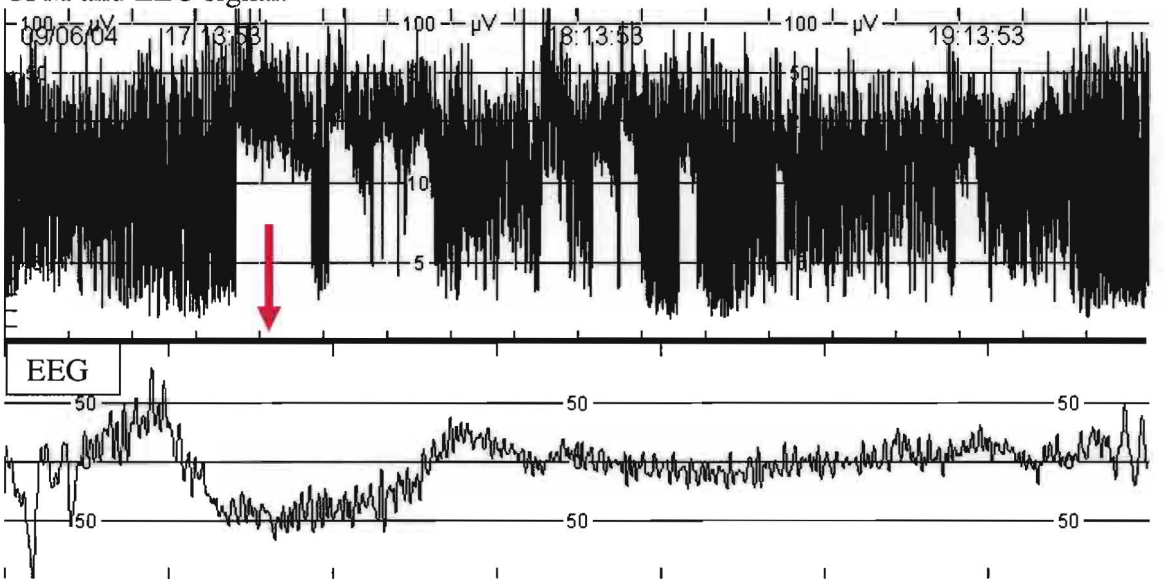


User Interface 25



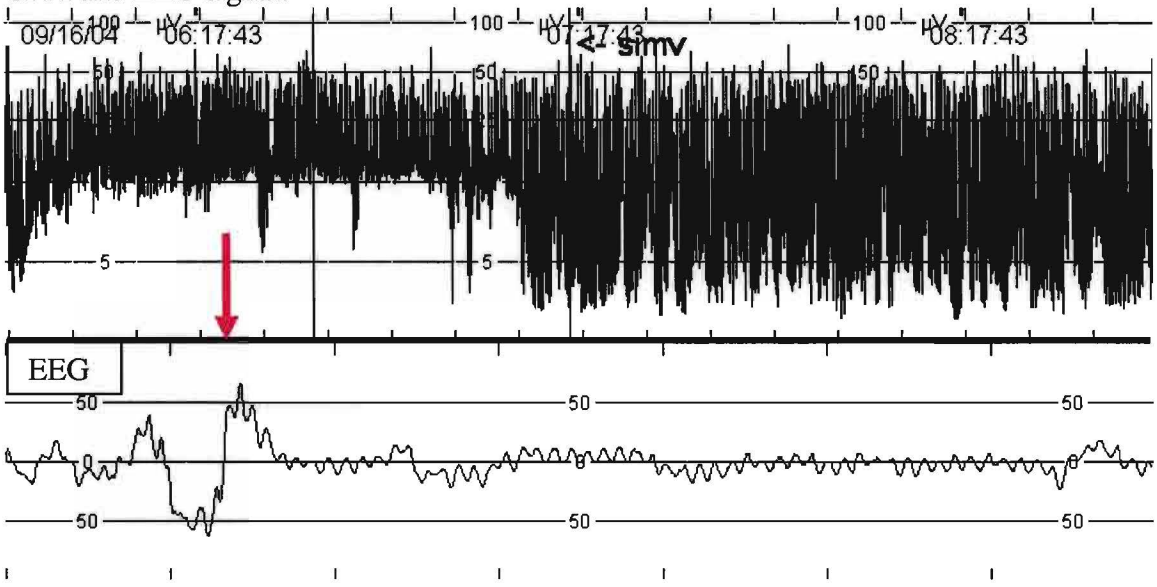
User Interface 26

CFM and EEG signal.

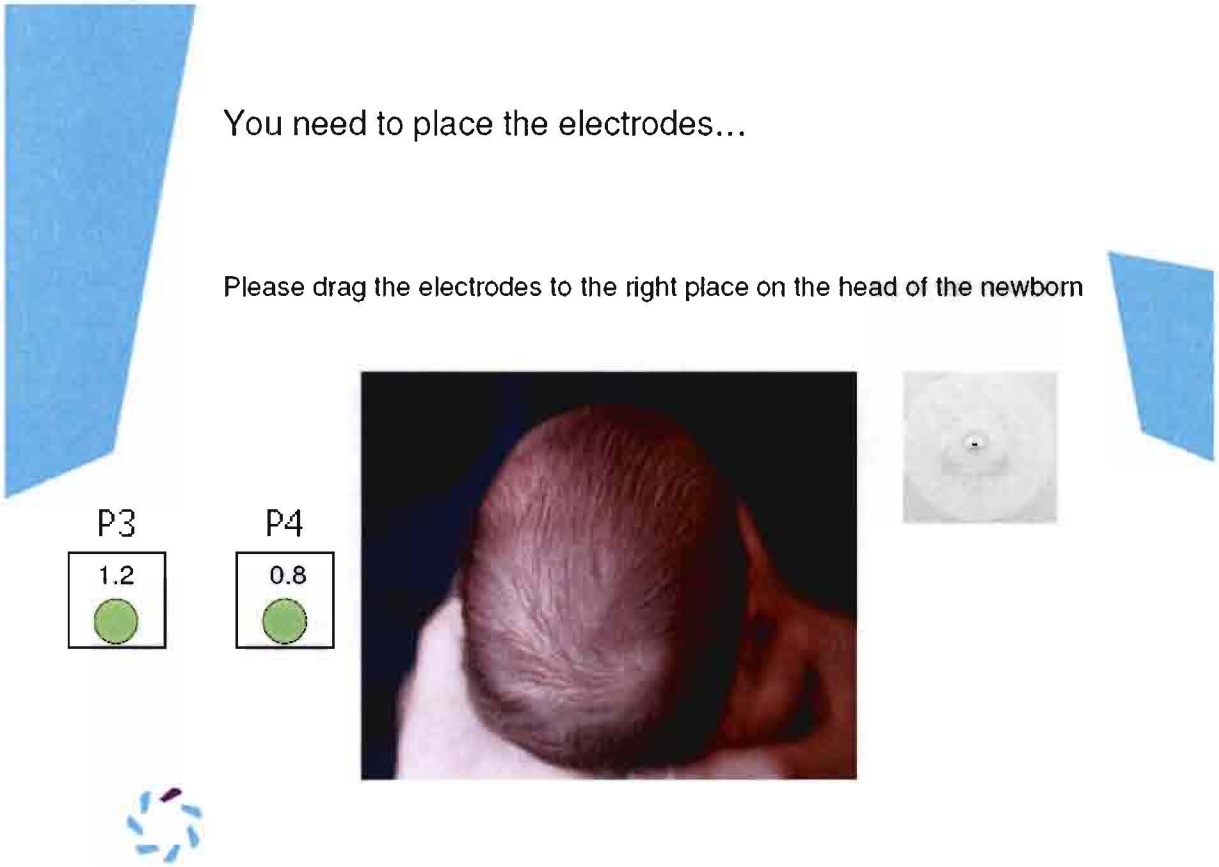


User Interface 27

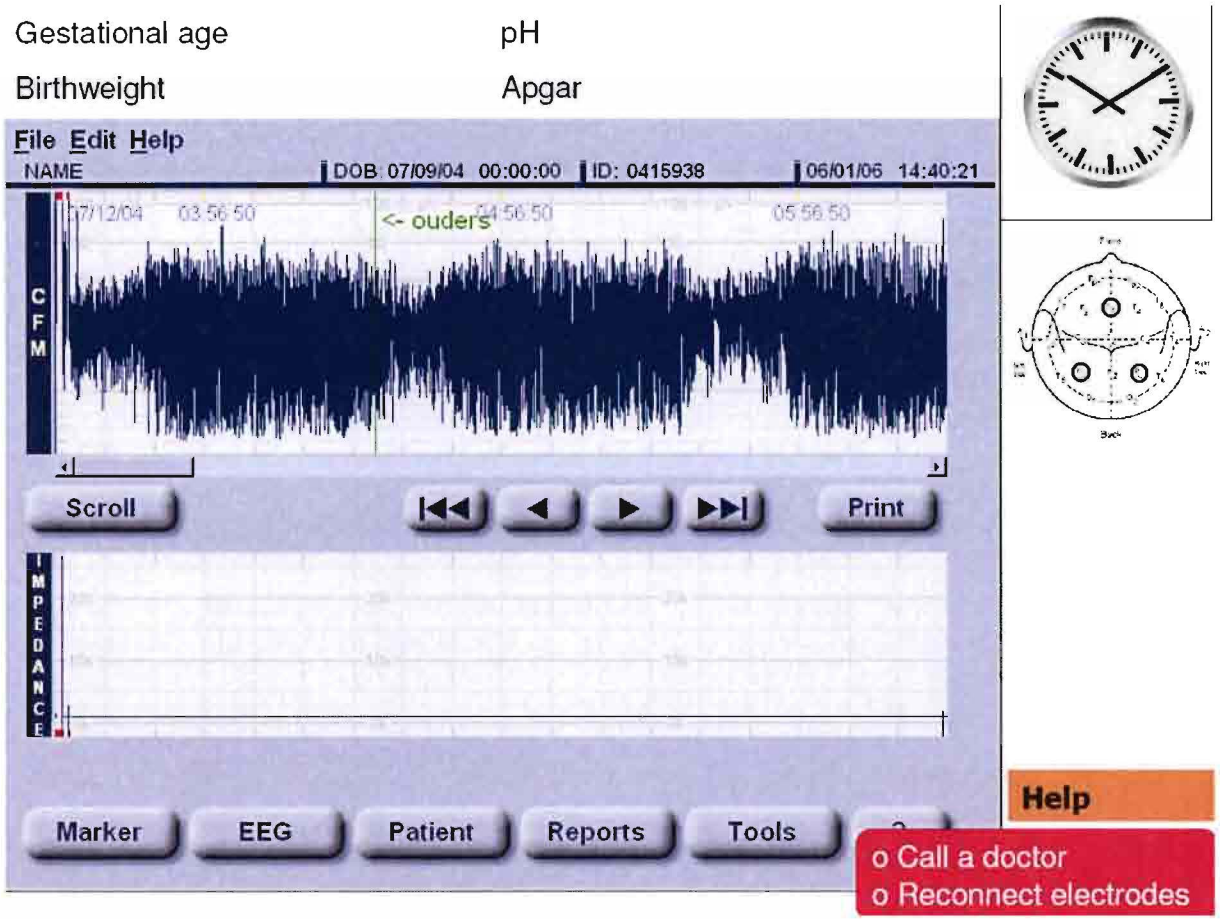
CFM and EEG signal:



User Interface 28



User Interface 29



Instructor interface

The instructor needs to install the department specific information:

- ***All trainees, their personnel ID and the target group to which they belong.***
- ***The CFM protocols of the department (will be added to the Help documentation)***
- ***The type(s) of electrode(s) and type(s) of monitor(s) used at the department.***
- ***His (or her) name and email address (will be available for trainees)***
- Whether the instructor has access to individual scores of trainees, or they stay anonymous.

The instructor will have access to the trainee data (anaonymous or not) according to Doc1.
The instructor will receive questions from the trainees through the Help documentation (Doc8).
When a trainee had insufficient score at level 0, and receives score level -0.5, the instructor is the only one who can put the score level to 0, and with that action give the trainee access again to the training program.

4 Other nonfunctional requirements

Performance requirements

- The calculation time needs to be as fast as to support maximum speed of writing the CFM signal, which is 5 seconds per hour. (sample frequency of 200 to 256 Hz).
- The space needed for the training program should be limited, and needs to be in balance with the number of signals needed. As reported in the Training Media Specifications (G4), with a number of signals of 80, the disk space needed for just the data is 3.52 GB, and the training program would easily fit on a DVD. This will be useful for distribution of the training program.

Security requirements

- It is extremely important that the identity of the newborns to whom the data belongs to is not used in any part of the software/training program. This means that neither names, nor birthdates are revealed. Fictive names may be used in the anamnese
- The department has the option to have access to anonymous trainee performance or not.
- A security is included for trainees that perform insufficient, to prevent them from training infinite long with the training program. Insufficient subscores will make them go one level lower. Insufficient scores at level 0, will close the training program. The only way the trainee is able to access the program again, is by having the instructor change his score level from -0.5 tot 0.

Other quality requirements

- It should be possible to add a part of the training program for data of prematures or data of full-term newborns with other types of pathology.

Use and usability

- The training program needs to be very user-friendly, since not all medical personnel is used to work with computers.

Database

Format

The database of the CFM simulator will contain signals stored in EDF+ format. The EDF+ format is a European standard for physiological signals, especially EEG signals. This format stores the signals efficiently, and makes it possible to exchange signals between institutions. The EDF+ format also has the advantage that annotations can be saved together with the signals. For the CFM simulator these annotations will be used as queues for the program. This means that the types of background patterns and all the events need to be annotated within the signal.

The NicoletOne monitor saves signals in EDF format, a pre-defense of PDF plus that does not contain the annotations of the signal. Viasys Healthcare is working on a new version of the software, it does contain EDF+ format of the signals. The monitor of ice is health care is very user-friendly concerning the making of annotations within signals. Therefore this monitor will be used to make the annotations concerning background patterns and events.

As long as EDF+ is not incorporated in the monitor, a Matlab m-file will be used to combine the signals (EDF format) and the annotations (text format) to a combined EDF+ format.

In the MMC Veldhoven most signals have been measured using the Olympic CFM6000, and these signals will be used as input for the database. The CFM6000 saves the signals in its own format, but they can be exported to ASCII. The process of converting an Olympic CFM 6000 ASCII file into an EDF file that is readable by the NicoletOne, is as follows:

- ***export only the raw EEG signal to ASCII***
- use software ASCII to EDF converter. Enter sample frequency, for older version CFM6000 viewer the sample frequency is 200 Hz.
- use EDF editor to change the signal name from signal 0 to P3.
- enter file to NicoletOne software. Make a trend in the montage that makes the CFM from the P3 signal compared to ref.

Annotations

The annotations in the CFM signals will be made using the NicoletOne software. The different annotations used are mentioned in Doc7.