1. Special safety issues
   1. Algorithm’s area of use

Fetal monitoring is a part of health assessment methods for biological system, containing mother and her baby. The method described here receive a bit of information in the whole feature dimension. Fetal electrocardiogram as well as methods which include signals obtained from electrodes evaluate the work of organs and system in general.

Fetal electrocardiography is a promising alternative to cardiotocography continuous fetal monitoring. Robust extraction of the fetal signal from the abdominal mixture of maternal and fetal electrocardiograms presents the greatest challenge to effective fECG monitoring.

Fetal heart rate monitoring in its early form was based on the auscultation methods, i.e. intermittent observations of the fetal heart sounds. Progress in electronics and computers science brought to the introduction of the first fetal monitors based on phonocardiography in the middle of the 20th century. Yet these inventions were still challenged by the need to automatically distinguish between the maternal and fetal heart sounds. Consequently, in 1953, the first attempt was made to continuously monitor fetal heart rate by means of non-invasive fetal electrocardiography [1].

To the time, the number of successful attempts in fetal electrocardiography, fetal monitors is in the tens. Overall, they can be divided in two categories:

1. Stationary fetal monitors (ex. Meridian Mindchild,)
2. Mobile fetal monitors (ex. Monica AN24)

Main difference of categories in their number of features to be extracted, their quality and comfort of use. The idea of their use presented in figure 3.1. It is important to notice the size of calculation modules.

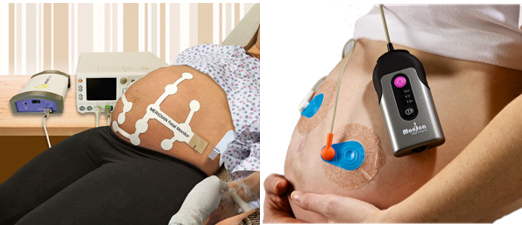


Figure 3.1 – Fetal monitors a) Meridian Mindchild stationary monitor

b) Monica AN24 Mobile monitoring system

While those are ready to use devices, my algorithm is intended to use in computer systems first of all. However, there are a lot of common parts, methods which can be used both in mobile, stationary or not lifetime systems.

For example, filter methods, including wavelet baseline removal, are ready to use in practically most of systems with little limitations. Fetal heart rate analysis, which is described in 2.3 intended mostly on telemedicine fetal monitors, while still can be used on non-lifetime data.

* 1. Software safety

Software to be developed do not complete any safety functions and activities which can directly hurt operator or patient. However, the field of biotechnology and medical science tightly communicated with human health.

Fetal heart rate analysis algorithm as well as other diagnosis tools perform assessment tasks and outputs biomedical indicators and decisions. Algorithm presented in current master’s thesis may harm people with imprecise data in case of unforeseen situations, which are mostly depend on the data acquired.

1. Complex high electrical interferences.
2. Continues artifacts with morphology similar to ECG
3. Non-compliant data acquisition

Algorithm as the list of instructions can’t misbehave, hence, difficult noises and problems described above should be eliminated in future releases.

* 1. Software ergonomics

Software ergonomics is a subcategory of ergonomics that concerns the software design, rather than the hardware design, of systems. Software ergonomics includes the determination of user needs, interface design, user support and usability testing.

Software-ergonomics standards contain guidance which assists both the specification of user requirements and the design and evaluation of the user interface of an interactive system. These standards do not aim at standardizing the user interface; rather, they give recommendations that should be applied in order to ensure the usability of the user interface of the product and eliminate design solutions which can be predicted to cause usability problems to users [2].

There is a list of fields in standards, which describes the most of features connected with software ergonomics

1. General guidance on software ergonomics (ISO 9241-110 to ISO 9241-119);
2. input, output and interaction (ISO 9241-120 to ISO 9241-129);
3. performance support (ISO 9241-130 to ISO 9241-139);
4. interaction techniques (ISO 9241-140 to ISO 9241-149);
5. topic-specific guidance (ISO 9241-150 to ISO 9241-159);
6. interface control components (ISO 9241-160 to ISO 9241-169);
7. cross-topic guidance on accessibility (ISO 9241-170 to ISO 9241-179).

Fetal heart rate algorithm analysis is mostly hand written and code is for personal use, but some parts could be extended and used by other people. Thus, there is a sense to describe ergonomic part of human-software communication in the way of updates and research.

* + 1. Dialogue principles

Seven principles have been identified as being important for the design and evaluation of interactive systems, which serve as a set of general goals for the design and evaluation of dialogues [3]:

1. Suitability for the task;
2. self-descriptiveness;
3. conformity with user expectations;
4. suitability for learning;
5. controllability;
6. error tolerance;
7. suitability for individualization.

Algorithm is presented as a number of intuitive functions gathered together in the order of doing the task step by step. However, there is no graphical user interface for people to easy follow these steps. The majority of functions are presented in the way of providing user comfort, default parameters are set, all function are called with clear understandable names.

In addition, items 4 and 5 are mostly depends on the development environment and still can’t be achieved by code perfection. While the program is intended for qualified people, for example, in programming language it is written in, items 6 and 7 may be performed.

* + 1. Individualization

Individualization is used in a wide variety of ways to enhance applications both for users. The wide variety of different implementations includes many instances where individualization creates considerable challenges for the users that it ought to be helping. This becomes an even greater challenge when users have to deal with different individualization approaches in each of the several applications that they use [4].

Individualization is a very delicate question. Algorithm for fetal extraction and analysis like a constructor, where signal flows through the independent blocks. To this time, researched can adjust block parameters, rework some of them or even exclude from the algorithm. However, huge changes should be performed with rules. First of all, dependencies must be fit and not violates in any way. Signal flow are not to be changed, because of algorithm interruption.

From the other hand, human factor may impact on the code changes badly, because of misunderstanding that is shown in [4] chapter 6.3. For example, a number of nonsense commands might lead to increase of computational cost and accessibility to other functions.