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Development and testing of infant colic cradles

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THE NORWEGIAN UNIVERSITY
OF SCIENCE AND TECHNOLOGY
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MASTER THESIS
FOR
STUD.TECHN. CHRISTIAN BÖRNER

COLIC CRIB TESTING
Testing av kolikk vogge

There is no single treatment that gives relief to all infants with colic. But American research has identified at least seven treatments with good sleeping effects. Five of these treatments are supported by the first ColiCot prototype. However, there are both technical and psychological issues related to the use of advanced technology in baby cribs. These technologies represent radical innovation which has to be optimized and tested before a commercial product can be launched with minimum risk.

The following tasks will be completed:

1. Determine a test procedure
2. Prepare and perform pilot testing of the colic crib
3. Analyze the test result
4. Evaluate and optimize the crib design and auxiliary functions

If time permits:

5. Outline a first draft of a research paper

Three weeks after start of the thesis work, an A3 sheet illustrating the work is to be handed in. A template for this presentation is available on the IPM's web site under the menu "Masteroppgave" (http://www.ntnu.no/ipm/masteroppgave). This sheet should be updated one week before the Master's thesis is submitted.

Performing a risk assessment of the planned work is obligatory. Known main activities must be risk assessed before they start, and the form must be handed in within 3 weeks of receiving the problem text. The form must be signed by your supervisor. All projects are to be assessed, even theoretical and virtual. Risk assessment is a running activity, and must be carried out before starting any activity that might lead to injury to humans or damage to materials/equipment or the external environment. Copies of signed risk assessments should also be included as an appendix of the finished project report.

The thesis should include the signed problem text, and be written as a research report with summary both in English and Norwegian, conclusion, literature references, table of contents, etc. During preparation of the text, the candidate should make efforts to create a well arranged and well written report. To ease the evaluation of the thesis, it is important to cross-reference text, tables and figures. For evaluation of the work a thorough discussion of results is appreciated.

The thesis shall be submitted electronically via DAIM, NTNU's system for Digital Archiving and Submission of Master's thesis.

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Abstract

Colic is a frequently encountered problem. It is very common among infants. The colic time is a high physical and psychological stress for the entire family. Parents and siblings often do not know how to deal best with the cry attacks which seemingly occurre randomly. There is no universal treatment for dealing with colic. To facilitate the exhausting time, Colicot AS has developed a special colic crib. This product combines several different ways to deal with colic. Previously, there was no confirmation that the cradle has a somnific effect. For the verification tests with colic infants are performed using prototypes of the colic crib. Therefore, a testing procedure will be developed, suitable participants will be found and an appropriate test environment will be established. In the following steps the test will be run and evaluated. Furthermore, design- and function-technical aspects will be proved and suggestions for modifications provided. The result of this work shows how much the cradle can assist the infants to fall asleep and keep them sleeping without waking up. It shows the potential of the product to improve family life and possible changes to the cradle.

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dB	Decibel
EEA	European Economic Area
EFTA	European Free Trade Association
ICD	International Classification of Diseases
NREM	non-rapid-eye-movement
NTNU	Norwegian University of Science and Technology
REM	rapid-eye-movement
WHO	World Health Organization

1. Introduction and purpose of the study

Sleep is one of the most important things for humans. Especially infants need a lot of it. The quality of the sleep they get influences not only themselves, but also their parents, siblings, neighbors and all the other people surrounding the young child.
Colic infants present in this respect a big problem. It takes long for them to fall asleep and sleeping intervals are mostly short. This takes often themselves and their parents to a physical and psychological limit. Around 16-29 % of the infants suffer from colics. [1]
The team of the start-up company ColiCot AS, a spin-off of the NTNU, developed the patented colic crib named ColiCot and built a first prototype (Fig.1). This crib was developed to calm the children and help them to have a better and longer sleep, which would also have a positive effect to the parents during the colic time.
Since there is no single specific treatment to deal with colic patients, the in 2014 developed prototype is based on the outcome of an American study about treatments with colic which was published by Karin Bilich at “americanbaby.com”. The result of the study are at least seven recommendations for dealing with colic, for example rocking the child or running the vacuum cleaner, of which the prototype considers five.

Fig. 1: Prototype of the colic crib by ColicCot AS

Until now it has not been tested if the crib is besides the theoretical success also successful in the reality. It would show if the idea and the wish to improve the family life during this hard time comes true or if the product will need some major changes. Furthermore, a successful test would be a great advantage in the competition with products of other companies regarding the same topic. Most of them do not have any scientifically proven evidence that they have a positive effect to the children.

The aim of this thesis is to develop a suitable test procedure, to create the conditions for valid test results, run and evaluate tests.

One of the many challenges is to respect ethical guidelines and laws and to find matching participants.

The results of the tests should show any necessary or recommended changes to the design, the features and the quality processing of the crib.

The first and very important step to manage all the challenges on the way is to get a basic knowledge about sleep, colic and how to treat colic.

2. Sleep and influences

2.1 What is sleep

Sleep is a behavior of physical rest and relaxation of the body and the brain. Impairment of the sleep can have serious consequences. This state claims around 30 % of a human's life. Reactions to external stimuli are significantly reduced. An awaking only occurs for strong stimuli, such as light or vibration, or exhaustion of sleep needs. Sleep has an effect on many body functions. It has an influence on the energy needs during the recovery phase, the release of hormones like appetite hormones, the function of the immune system, but also the brain, especially the memory, and many other body functions. [2]; [3]

The required amount of sleep of each person is different and depends a lot on age. Infants need, especially at the age colic occurs, about 12-15 hours of sleep (daily), spread over the entire day into shorter and longer naps. With getting older the requirement for sleep decreases, so that adults only need 7-9 hours of sleep each day. [4]

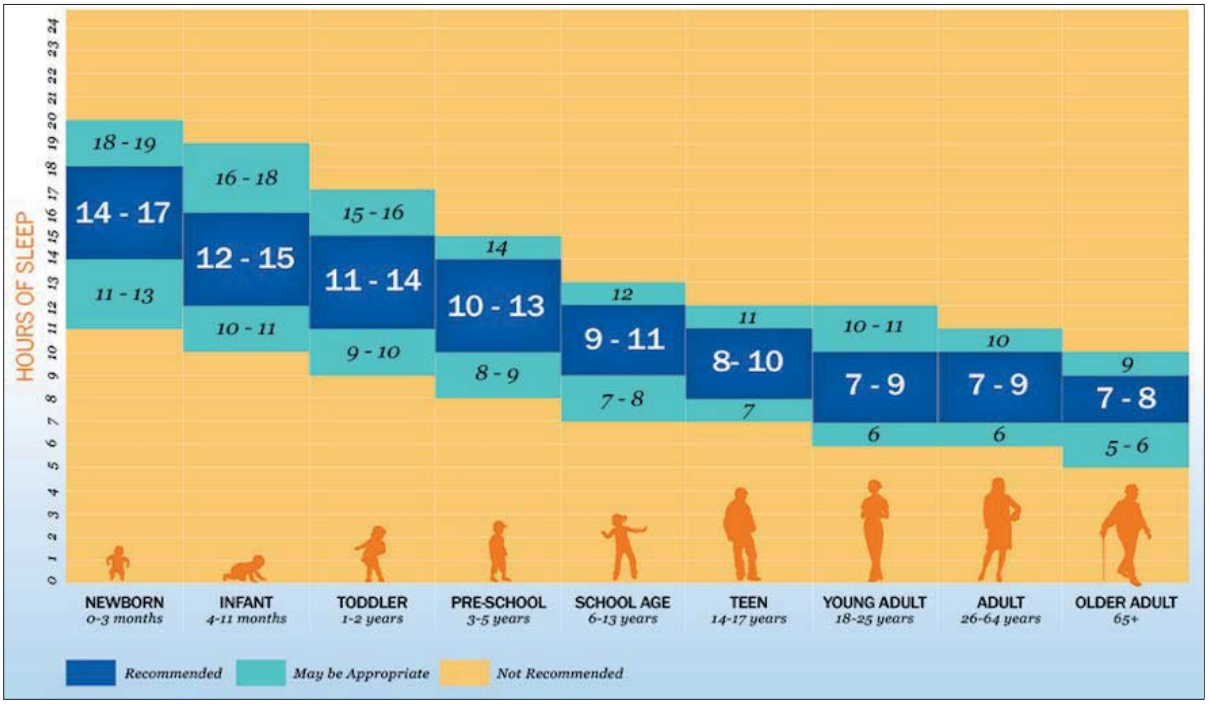

Fig. 2: Sleep duration in different states of the life [4]

Figure 2 shows how important sleep is, especially for young children. In extreme cases, a lack of sleep can lead to death. Therefore, sleep is something very important in our lives. [2]; [5]

Sleep itself is divided into three different phases (Figure 3): Wake, NREM (non-rapid-eye-movement) and REM (rapid-eye-movement). The NREM phase is again divided into four stages, of which stage III and IV will be grouped according to the classification of the American Academy of Sleep Medicine (AASM) to a single deep sleep phase. [6]; [3]

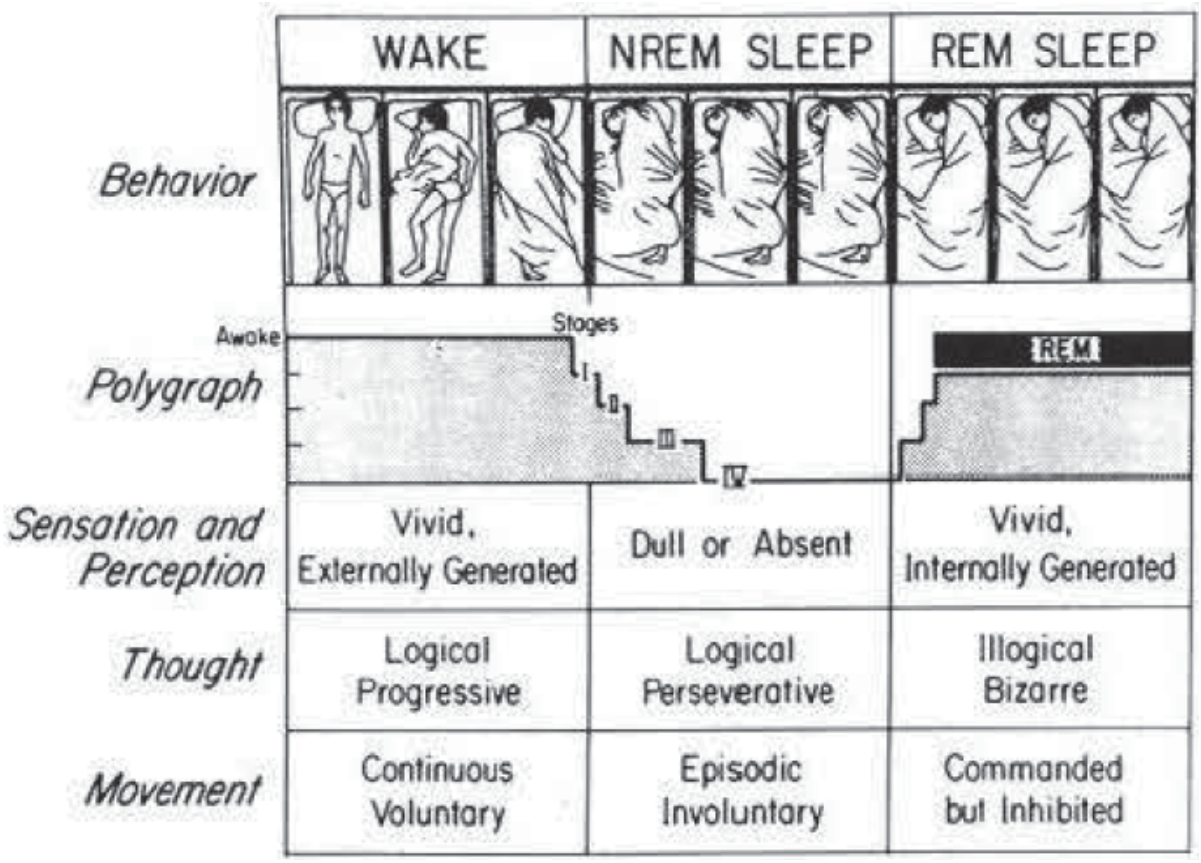

Fig. 3: The three main phases of sleep: Wake, NREM and REM [6]

The four steps of sleep (NREM 1; 2; 3 and REM) and the wake phase are listed with their properties in the Table 1 below.

Table 1: Phases and characteristics of sleep [3]; [7]

Phase	Characteristics
Wake (phase between full attention and sleepiness)	- Blinking eyes, reading movement of the eyes, fast eye movement to search surroundings and a high tension of the muscles
NREM 1 (transitional stage between weakness and sleep)	- Slow and regular eye movements, reduced sensorial response of the brain and decreasingly tension of muscles - With beginning of sleep the body temperature, breathing, pulse and blood pressure decrease
NREM 2 (actually beginning of the sleep)	- Eyes are still and muscles are relaxed compared to the wake-phase - More than 50 % of the sleeping time
NREM 3 (deep sleep phase)	- Tension of muscles even lower than in NREM 2, steady eyes - End of this phase is marked with short episodes of body movements and jump back to NREM 2
REM (phase with dreams)	- Fast and irregular eye movements, muscle activity at a minimum with irregular short activations - Also irregularities in breathing, pulse and blood pressure, volume changes in the phallus - After REM falling back to NREM 2 and beginning of a new cycle, REM phase is getting longer with each cycle

The NREM and REM phases repeat cyclically throughout the sleep. In the beginning of life, the REM phase and NREM stage 4 phase are major parts of the sleep (Figure 4 and 5). So is the REM phase for newborns around 50 % of the sleep time and at an age of 20 only 25 %. [2]

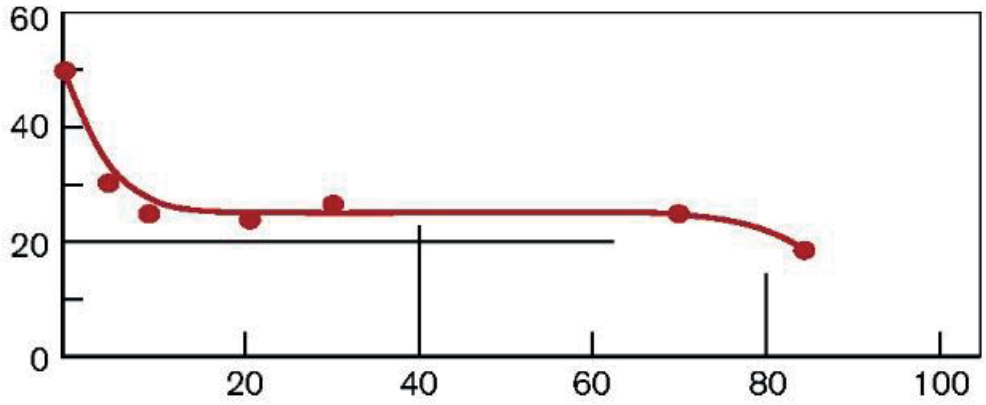

Fig. 4: Quantity of REM sleep in percent during lifetime in years [2]

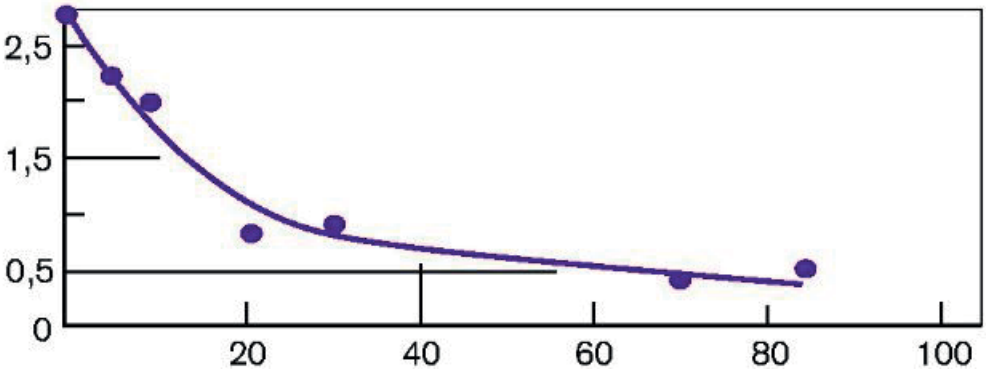

Fig. 5: Length of NREM stage 4 in hours/day during lifetime in years [2]

A profile of sleep with the sequence of the various phases for a total sleep duration is displayed in a hypnogram. Figure 6 shows a hypnogram with the sleep profile of a healthy young adult.

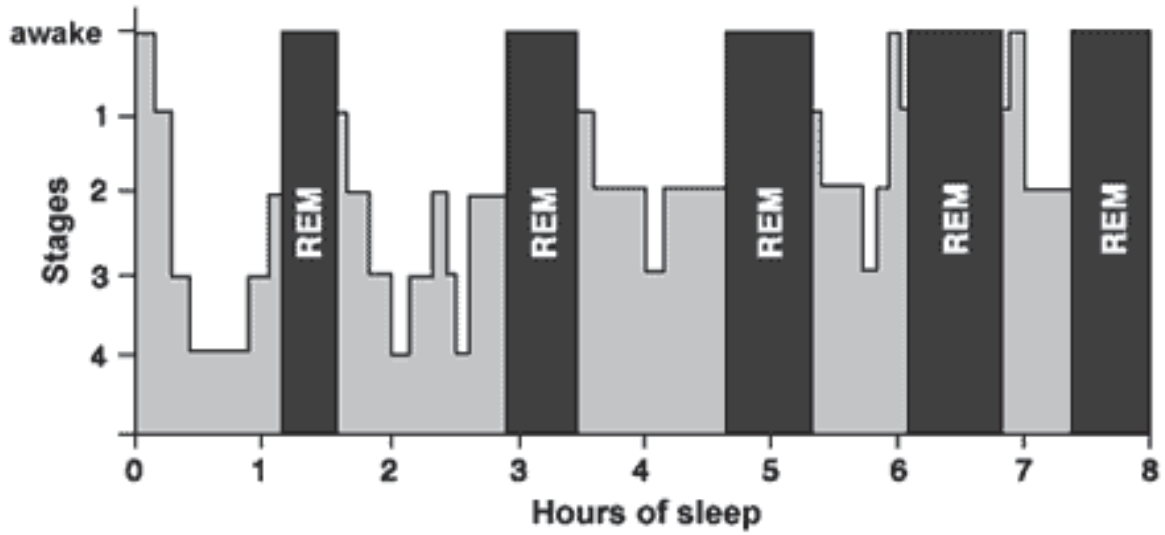

Fig. 6: Hypnogram [5]

At the end of the sleep, just before waking up, the body temperature rises and the number of body movements increases. [7]
In sleep research are various parameters measured and observed for analysis. There are for example EEG (Electroencephalography) for measuring the brain activity, EOG (Electrooculography) for monitoring eye movements, EMG (Electro-myography) for recording the muscle activity, cardiological parameters, lying positions, breathing and movements of extremities. All these factors can be used to divide the sleep systematically into the different phases. [3]

2.2 Baby colic

2.2.1 Crying

In normal cases, cry of infants is an emergency and alarming signal to get attention. It is hearable over long distances, but does not differentiate between the reasons for crying. For adults, especially parents, crying triggers stress and spontaneous reactions to soothe the crying child. After birth the newborns increase the amount of crying continuously until a peak around the sixth week of life and decrease the crying afterwards.
Some of the children cry much more than usual, so-called excessive screaming infants. Most of them stop with excessive crying in the third or fourth month of life. If an infant continues with crying that much it is an excessive crying infant, which is often known as colic. It is not apparent why they cry and therefore it is difficult to soothe them. Some of the possible reasons causing the excessive crying are described in the following chapters 2.2.2-2.2.4. [8]

2.2.2 Allergies and stomach problems

Some of the children have problems with digestion. Factors showing this are for example permanent movements, a distended abdomen and bloating. Possible reasons can be allergies and intolerances to different food. On the other hand, bloating is also a result from foaming in the stomach during crying.
Another possible reason is reflux, the flow of gastric content back into esophagus. Reflux is also common for less crying infants, but definitely a factor, which needs attention during the work with the colic crib. [8]

It has been proven that only a few excessively crying babies have actual disorders of the gastrointestinal tract. [9]

2.2.3 Sensory overload

The in current research most probable factor of colic is sensory overload. Crying is in this case an expression of the child that it has problems with the adaption of its new environment. The ability of deep sleep, which influences the quality of the wake phases, is connected to the central nervous system (CNS). Because of their hyper-sensitivity, excessive crying infants react often hastily and intensively. In order to treat this kind of children external regulatory assistance is a big help. [8]

2.2.4 Other factors

Other factors causing excessive crying are for example preterm births (before 32nd week of gestation), high temperament of the child or a communicative problem between parents and child in which parents misunderstand the signals of the child. [8]

2.3 Treatment to calm colic

2.3.1 Treatment in general

There are various ways and options to treat colic. Some of them are listed in Table 2 below.

Table 2: Colic treatment [8]; [10]; [11]

Type of treatment	Treatment
Physical	- Belly massage - Flying baby position - Driving around in a car - Gently rocking of the baby - Swaddle the baby snugly
Acoustic	- Sound of a washing machine, hair dryer, fan, vacuum cleaner - Car Sounds - Singing by the parents - White noise
Pharmacy/Nutrition	- Medication with Simethicone against foaming in the stomach - Special hypoallergenic nutrition - Diets

In addition to the cradle of ColiCot AS, there are already other technical products on the market which intend support in calming the children. There are software products like applications for mobile devices, which play specific sounds to calm the children or give advice to parents how to treat their kids but also themselves. But there are also a lot of physical devices which will be in competition with the cradle of ColiCot AS. Some of them are listed with a short description in the following chapters 2.3.2-2.3.5.

2.3.2 Sleepy Relax

Sleepy Relax is a special system for vibration. It consists of four Sleepy-Discs. Each of them is placed under one of the bedposts of the child's bed (Figure 7). To get the system into oscillation, the child itself is the actuator. Impulses of the child, such as breathing, heartbeat and pulse are enough to get the whole system into movement. This avoids the problem that everyone has its own natural frequency, which is not constant. The whole system supports a total weight up to 80 kg. According to the manufacturer, 60 % of the infants using "Sleepy" fall faster asleep and 70 % sleep better. [12]; [13]

Fig. 7: Sleepy-Disc [13]

2.3.3 Lullababy TBM

Lullababy “Therapeutically Baby Movement” (TBM) is basically an oscillation system with a mass and a spring. A spring system with a kind of hammock can be attached for example to a frame. The actual bed for the child is placed in the hammock. Figure 8 shows the full system. To get the whole system into movement, the parents need to start moving the system by their own. In addition to the promised soporific effect, Lullababy is also supposed to have positive influence to the sense of balance.
[14]; [15]

Fig. 8: Lullababy [14]

2.3.4 Lolaloo

The “lolaloo” is an inconspicuous vibration bar, which has a battery powered actuator included. The Velcro holders allow it to attach the bar flexibly to strollers or cradles (Figure 9). It is required, that the objects the “lolaloo” is attached to, are able to oscillate. For normal, stiff beds are elastic accessories available, called BRIO Bed Rocker (Figure 10), which are attached under each of the bedposts to make the bed able to oscillate. [16]

Fig. 9: Lolaloo attached to a stroller [17]

Fig. 10: BRIO Bed Rocker [18]

2.3.5 Putnams Bed Wedge Positioner

The British company “Putnams” offers a bed wedge positioner (Figure 11), which is developed help against colic and reflux. It is slightly tilted to prevent the reflux, consists of hypoallergenic materials and has two placeable lateral supporting pillows to fix the lying position of the child. [19]

Fig. 11: Putnams Bed Wedge Positioner [19]

3. Colic Crib and testing procedure

3.1 ColiCot

3.1.1 ColiCot AS Company

ColiCot AS is a spin-off from NTNU. The start-up was founded in 2013 and is registered in Tønsberg, Norway. Chief executive officer is Terje Rølvåg, who is also the owner of an international patent regarding the ColiCot. [20]; [21]

3.1.2 The crib prototype

The ColiCot cradle prototype consists of a wooden frame (A) with four leather straps (B) which are attached to a wooden bed basket (C).

Fig. 12: ColiCot cradle

An actuator with an eccentric mass (D) is located under the bed basket. Furthermore, the cradle has a control unit for the actuator (E1), a processing unit with a Wi-Fi chip (E2) and a speaker unit (F) located inside the bed basket.

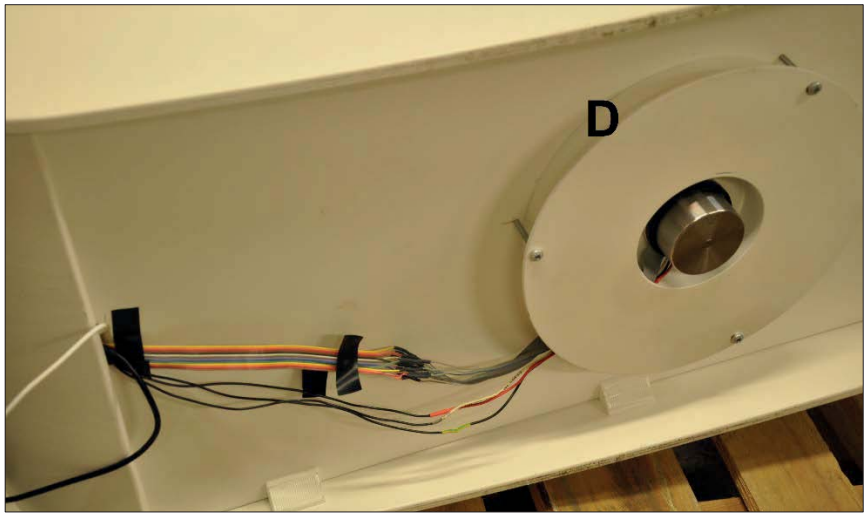

Fig. 13: Actuator with attached eccentric mass (covered)

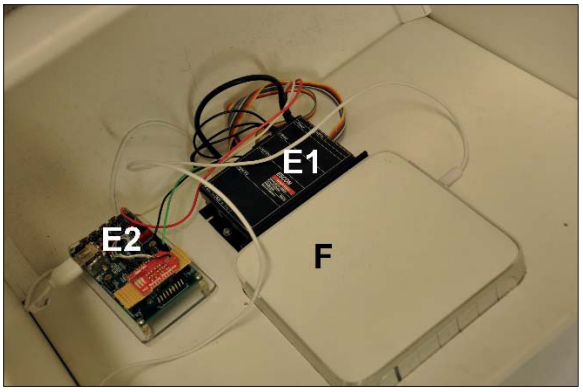

Fig. 14: Speaker, control and computer unit

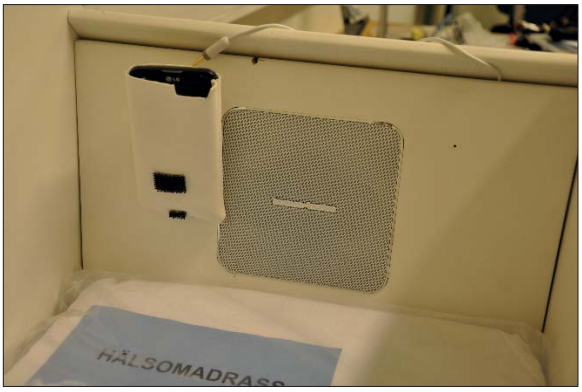

Fig. 15: Speaker from the front side

To prevent allergic problems, the cradle is mostly made of wood, a natural and harmless material. However, it can also cause problems. Just one year after production, one of the bed baskets is already twisted and also some of the frames are deformed.

The bed basket itself exists in different versions with the idea to attract parents by giving them the opportunity to choose a shape and color they prefer and also to engrave for example the name of the infant. Examples are the cloud design (Figure 16) and the car design (Figure 17). The high sidewalls give the infant less opportunity to get distracted by the environment, which should help the child to sleep easier.

Fig. 16: Cloud Design

Fig. 17: Car Design

The leather straps are designed to have a higher second moment of area in sideway direction, which means less sideway movements. One problem however is the different length of the leather straps. For the oscillation of the cradle and also for the resonance frequency, the length of the straps is important.

The processing unit is the communication interface between the control unit for the actuator and a via Wi-Fi connected mobile device with the ColiCot application as a user interface.

The speakers are currently powered by an accumulator and can be connected to the via Bluetooth or audio cable with the mobile device running the ColiCot application.

The ColiCot application (Colicot Control and Log Application) is an Android based application. The functions of the app are:

- Enable and disable the crib functions
- Adjust the sensibility of the microphone of the device running the application
- Setting a timer for how long the cradle is active after the cradle got activated through noise
- Enable/disable playing sounds
- Enable/disable the front camera of the device running the application and display the picture
- Enable/disable the rocking function of the cradle
- Choosing a listed song which is played after activation of the cradle
- Add songs to the list from the phone memory
- Showing a log when the cradle was active

If the cradle is active and the sound level of the environment hits the set value, the cradle starts to run the set functions for the chosen time. After the set time is over,

the cradle stops automatically until the microphone of the mobile device recognizes that the set sound level is reached again. Figure 18 shows the current user interface of the application.

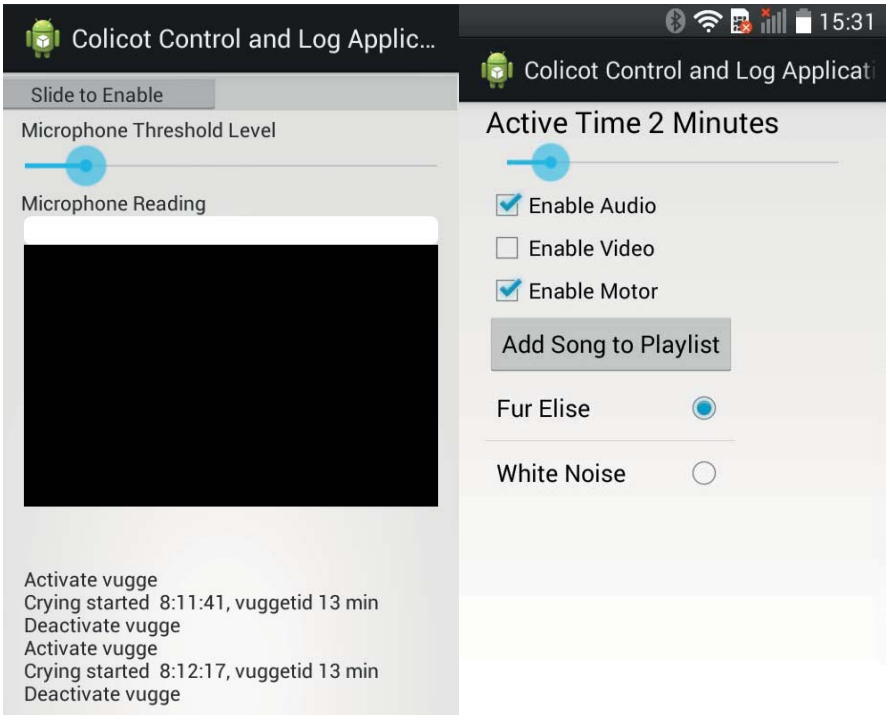

Fig. 18: ColiCot application running on an Android device

Problems regarding the application are that it is not possible to set up the engine speed and that songs added to the playlist disappear after closing the application. It is also required to adjust the speed of the actuator before the test. Since the natural frequency depends here on the length of the leather straps, which have variations in the length. Adjusting the speed is important.

In 2014, four prototypes in the cloud design were build and one in the car design. In preparation for the pilot testing, all of the existing cradles were checked in terms of completeness, damages, proper functioning and potential problems. The result of this check is that most of the cradles are not complete, which is problematically. Other problems regarding the quality are already described in this chapter. It was required to measure and sort all the leather straps. Each four straps with an equal, or almost the same length, build one group for one cradle to ensure a uniform motion for the rocking function. Table 3 shows the reassigned parts for the cradle and which of the cradles are ready to use.

Table 3: Sorting of ColiCot racks and leather straps

Leather strap number	Length of the strap in cm	Letter of the Rack	Letter of bed	Usable? Yes/No
1	27	A	A (Without name, white) “colicot2” Phone: LG white	Yes
2	26,5			
3	26,5			
4	26,9			
5	26,9	B	B (name: June) “colicot1” Phone: LG black	Yes
6	27,1			
7	27,2			
8	26,9			
9	21	C	C (unpainted)	No
10	19,5			
11	19,5			
12	21			
13	27,6	D	D (name: Mette)	No
14	27,5			
15	26,8			
16	26,8			
17	25	E	Bed basket is not available	No
18	26,5			
19	25			
20	26			
Car-Design Cradle (actuator missing)				No

For a proper function, each usable cradle has one specific smartphone assigned, which alone has the specific profile for the Wi-Fi network of the cradle saved. All unimportant functions of the phone itself were deactivated and the home screen only shows the ColiCot application to make the usage for the parents as easy as possible.

The deformed frames and bed baskets causes in the wrong configuration critical distances between bed basket and frame (Figure 19) or bed basket and ground. A too short distance leads to a contact and problems regarding the rocking function.

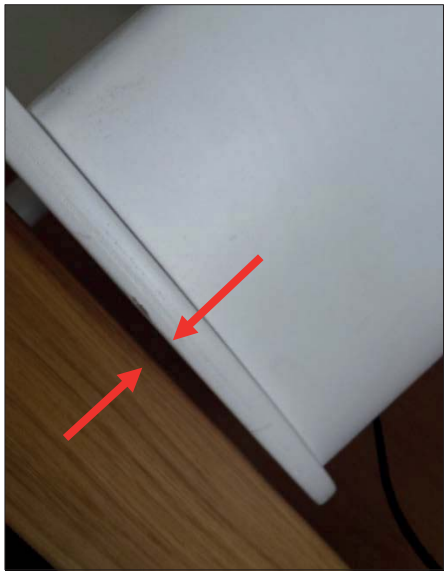

Fig. 19: Critical distance between bed and frame

As a result of this check, there are only two complete cradles for the pilot testing available.

3.2 Actually testing procedure and challenges

3.2.1 Sleep laboratories

Studies about sleep patterns sleep disorders like insomnia or sleep apnea and sleep quality are usually performed in sleep laboratories of psychiatric institutions, but also with mobile sleep labs. The studies are made at specific times and supported by healthcare professionals. The studies usually last two nights. The first night is for acclimatization to the environment where the study takes place. In the second night the actual study with the measurements is performed. Studies with adults start around 11 pm and end 7 am the next morning by waking the test candidate. Studies with infants are also possible during the day. There are several recommendations in preparation for tests with infants, for example to bring extra clothes for changing and stuffed animals.

During the study itself multiple biological data are recorded. With this data it is possible to get information about length, depth and continuity of the sleep and the sequence of the sleep cycles. Furthermore, the data contains information about

sleep patterns. It is for example possible to diagnose disorders of respiratory regulation or to find disorders during sleep, which can be recognized by periodic leg movements. Standard parameters for measurement are brain activity (EEG), eye movements (EOG), muscle activity (EMG) and heart activity by electrocardiogram (ECG). Further parameters, which can be measured during the study, are:

- Blood pressure
- Pulse
- Body temperature
- Oxygen saturation in the blood
- Respiratory flow mouth / nose
- Snoring sounds
- Breathing movements thorax and abdomen
- Movements of the extremities

In addition, the room where the study takes place can be monitored via microphone and infrared camera. The electrodes and sensors which are needed to be attached to the body for measurements are attached in a way to make movements during the sleep possible and disturbing the test candidate as less as possible. The data from these electrodes and sensors is transmitted wirelessly.

On suspicion of sleep patterns by reflux, an esophageal motility study can be performed to check if the muscles can close the opening between esophagus and stomach. Because of the measuring method, this is just performed in a separate study. [22]; [23]; [24]

Fig. 20: Infant in a sleep laboratory with attached electrodes and sensors [25]

3.2.2 Testing procedure previous project

In a previous project a testing procedure was developed to perform pilot testing with the ColiCot. The goal was to have just as much data as necessary and it is already a simpler version of the testing procedure, which is usually performed in sleep laboratories. To identify the quality of the sleep of the children, the following factors are observed:

- Arousal index/pain level
- Number of awakenings
- Duration of crying/fussing episodes
- Number of crying/fussing episodes
- Sleep-onset time/settling time

To create a dataset for the chosen parameters, the decision in the project was to use following equipment:

- Accelerometer
- Pulse oximeter
- Decibel meter
- Video camera
- Study diary and questionnaire

To have reliable data from testing, products for each kind of equipment were selected. All of them were tested to prove if they fulfil the requirements for the testing procedure. The chosen pulse oximeter was not suitable for infants. In case of using this testing procedure, a suitable pulse oximeter needs to be found. For the use of the accelerometer a special sock was designed. The testing phase itself is designed for a duration of three nights, following the steps below:

1) Finding infants (with and without colic) around three months of age
2) Carrying the test equipment and the ColiCot to the home of the infant and setting it up
3) Instruct the parents how to use the cradle and how to start and stop the test equipment to record the required data
4) The 24h study diary called “Døgnklokke” (Figure 21) needs to be completed by the parents during the testing period
5) Analyzing the collected data

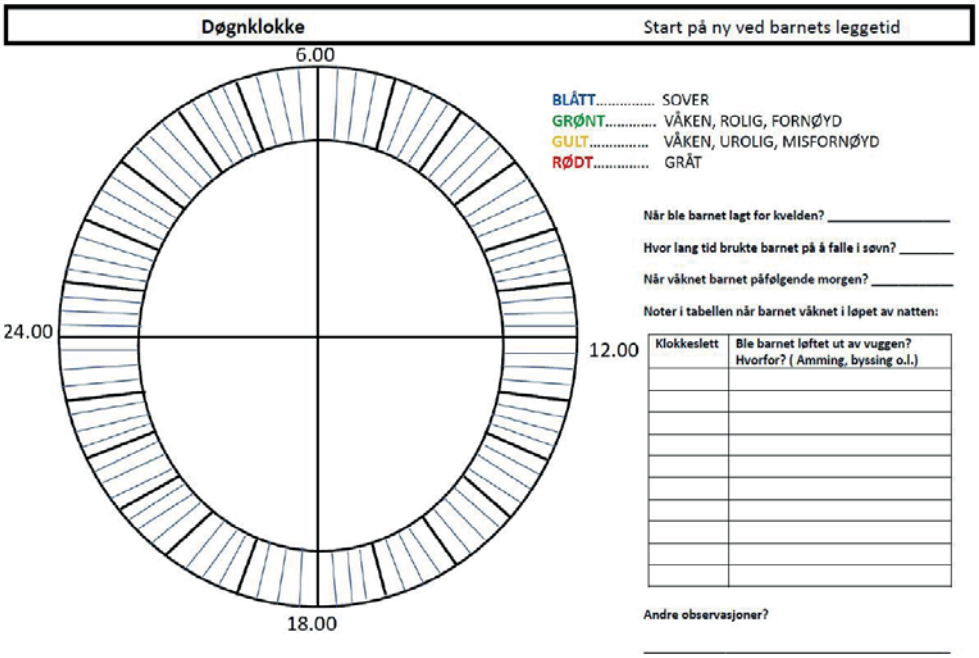

Fig. 21: Study diary "Døgnklokke" [26]

For analyzing the data, the datasets of the video, sound level and accelerometer recording are collected in a single excel sheet. The video analysis needs to be added manually in the sheet. Therefore, events like movements, crying and being picked up by parents are listed in the sheet with specific times for the beginning and the end.

For evaluating the test, data from one test candidate were used to calculate the average, minimum and maximum sound level for each event. The dataset of the accelerometer was scanned for the data of each specific event and an information about the intensity of the movements during the events were added in the evaluation sheet. A part of an excel sheet of one of the tests is shown in Table 4.

Table 4: Extract of a data sheet during the study [26]

19.05.2014 Video			Decibel			13.05.2014 Aktigraf		
			Gj.	Min	Max			
Legger seg	21:06:45		55,07	43,7	61,9	21:41:28	sokk på	
Gråter	21:07:55	21:15:02	69,35	33,8	100,8	21:06	tydelig bevegelse	22:22
Tar han opp	21:15:02		35,90	28,7	47,6	22:22	skurring	22:36
Legger seg	22:22:09		59,23	42,6	88	23:11	liten bevegelse	
Gråter	22:22:19	22:30:32	67,20	30,6	94,3	00:25	tydelig bevegelse	00:29
Urolig/Sipper	22:30:32	22:32:15	50,27	29,6	80,1	02:34	skurring	03:06
Rolig/Sover	22:32:15		33,97	28,7	75,5	03:06	tydelig bevegelse	
Gråter	22:35:48	22:35:55	61,00	46,5	75,5	03:23	skurring	03:37
Rolig/Sover	22:36:00		31,46	29,1	38,9	03:37	tydelig bevegelse	03:39
Rolig/Våken	22:37:14	22:38:00	34,42	29,6	44,8	03:39	skurring	03:54
Rolig/Sover	22:38:00	00:24:52	30,05	27,8	48,5	04:31	tydelig bevegelse	04:45
Snur seg	22:49:14		29,65	29,1	30,2	04:45	skurring	05:15
Snur seg	22:49:28		36,40			05:50	tydelig bevegelse	06:16
Snur seg	23:10:51		33,45	29	37,9	06:16	skurring	06:41
Snur seg	23:11:06		29,25	29,1	29,4	07:08	skurring	07:41
Snur seg	23:26:16		31,85	29,2	34,5	08:11	tydelig bevegelse	08:25
Snur seg	23:29:30		30,73	28,3	34,1			
Snur seg	23:31:06		30,30	30,2	30,2			

The outcome of the evaluation was that the sound level above 65dB in addition to clear movements mean that the child is crying. If there are just small movement or/and the sound level below 65dB, the child is calm or sleeping. [26]

3.2.3 Laws and regulations

For scientific studies and especially for product testing exists several laws and regulations. The laws and regulations depend on the kind of product and the kind of testing procedure used. Therefore, it is important to know before testing which of the rules need to be considered. Laws, which are valid for products, are sorted by kinds of products. The ColiCot is an automatic cradle, which is designed to help excessive crying children with their sleep patterns. Specific product categories are as a consequence thereof the categories “medical devices” and “electrical equipment”.
A medical product is by definition a product that is used with the purpose or function of at least one of the following points [27]; [28]:

1. Diagnosis, prevention, monitoring, treatment or alleviation of disease
2. Diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap
3. Investigation, replacement or modification of the anatomy or of a physiological process
4. Control of conception
5. Which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function

Since points 2-5 can be excluded for the use of the ColiCot, only the first point needs to be considered. That means it needs to be proved whether excessive crying in infancy is a disease or not. A classification with the ICD-10 list of the WHO is not possible. The only possible classification here is an adjustment disorder according to ICD-10 F43.2. Therefore, excessive crying in infancy is not understandable as a disease. [29]
In addition, the DC-03R classification of the ZERO TO THREE organization does not classify excessive crying as a disease. [30]

Here it is important to say that the ColiCot is just developed to sooth excessive crying infants. It is not developed to cure disorders of the gastro-intestinal system, sleep disorders like sleep apnea or feeding disorders.

The side effect to reduce the stress level of the parents is just a desirable side effect. The ColiCot is not a special product to cure stress related diseases and therefore it is not needed to be considered for the definition whether ColiCot is a medical device or not.

That means that the ColiCot is not developed for diseases and that point one of the definition of medical devices is not fulfilled. That implies that the ColiCot cannot be defined as a medical device and therefore the specific rules or laws for medical devices are not valid for both testing as well as a later release of the finished product on the market. [27]; [28]

The special directive 2014/35/EU for electrical equipment designed for use within certain voltage limits is valid for electrical equipment between 50 and 1000 V alternating current and 75 and 1500 V direct current. Power source for the ColiCot is a certified power supply with an output voltage of 20V. This means that the directive 2014/35/EU is not valid for the ColiCot. [31]

The only valid directive for the ColiCot is the directive 2001/95/EC for general product safety. This directive becomes law with placing the product on the market through making it available. According to the “Blue Guide on the implementation of EU product rules 2016” making a product available is not the case if a product is [32]:

1. Manufactured for one’s own use. Some Union harmonization legislation however covers products manufactured for own use in its scope
2. Bought by a consumer in a third country while physically present in that country
3. Transferred from the manufacturer in a third country to an authorized representative in the Union whom the manufacturer has engaged to ensure that the product complies with the Union harmonization legislation
4. Introduced from a third country in the EU customs territory and has not been released for free circulation. This includes the cases of products in transit, placed in free zones, warehouses or temporary storage
5. Manufactured in a Member State with a view to exporting it to a third country (this includes components supplied to a manufacturer for incorporation into a final product to be exported into a third country)

6. Transferred for testing or validating pre-production units considered still in the stage of manufacture
7. Displayed or operated under controlled conditions at trade fairs, exhibitions or demonstrations
8. In the stocks of the manufacturer (or the authorized representative established in the Union) or the importer, where the product is not yet made available, unless otherwise provided for in the applicable Union harmonization legislation

The actual case of the ColiCot and this project is described in point six. Therefore, the directive for general product safety is not valid and the ColiCot does not need to fulfill the required regulations yet. [32]; [33] In Norway the same product regulations are applied like in the European Union, because of Norway's membership as one of the EEA-EFTA states.

Because humans are involved in the pilot test, the paragraphs §§2-4 of the Norwegian Act „LOV 2008-06-20-44: Act on medical and health research" make it necessary to consider this act. In §11 of the act about medical and health research it is written that it is required to contact the Regional Committee for Medical and Health Research Ethics (REC) before doing pilot testing. After submitting a Remit Assessment form, the REC decides whether the research can be performed independently from the REC or if a joint project in cooperation with REC is necessary. The paragraphs §§5-8 of the act describe the organization and execution how the project needs to be done. Therefore, we need to take into account ethical, medical, health, scientific and privacy factors. The project needs to have a responsible person, a project manager and a research protocol and personal data must be protected as good as possible. After the end of the project, the project manager has to deliver a final report to the REC. Paragraphs §§13-21 describe the regulations of the consent. Participants need to be informed about the concrete project and consent to take part in it voluntarily, which can be withdrawn any time. The whole consent needs to be documented. For children under the age of 16, the Patients' Rights Act 1999-07-02-63 applies. In section 4-4 it is written that the child's parents, other persons with parental responsibility or the child welfare service can give consent for their children. [35]

Further §18 of the medical and health research act describes how to handle research including people which have a lack of competence. To get their consent, the potential

risks need to be insignificant, the involved person is not averse to it and there need to be a reason using people with the specific lack of competence for the research. The paragraphs §§22-24 in the act of medical and health research are specific for research involving people. In §22 is written that it is only allowed to involve people if there is no other reasonable method for this research and evaluated risks and hazards are smaller than possible advantages. Further describes §23 the duty to report adverse medical incidents and §24 states that the project manager must inform the participants about their right for compensation if they have been injured in the course of the research. The paragraphs §§32-38 describe research using personal health data. In the main rule, §32, it is written that all medical and health data collected need to be relevant for the project and it is not allowed to use them otherwise. Other points in this chapter are that it is required to have the authority to process data, the REC is allowed to decide to hand over the collected data, the project manager decides about deletion of the data, regulations for data transfer outside EEA area and that it is not allowed to store data after the end of the project. Another important paragraph (§39) of this law is that the research needs to be transparent for the participant.

In our case, it is important to do testing with infants suffering from colics and to figure out whether the cradle helps or if there is no other reasonable method for doing this research. The required list with potential risks and hazards is provided in form of a risk analysis in Appendix A. The REC was already contacted during a previous project. The decision about the necessity of a joint project was made during a call between the project leader, Terje Rølvåg, and May Britt Rossvoll from the REC in 2014. The result is that no joint project is necessary and that all requirements for the act for medical and health research are fulfilled. The contact to the responsible REC is in Appendix B. [34]; [35]; [36]

3.3 Simplified testing procedure

3.3.1 Simplifying of the testing procedure

The goal of the pilot testing is to figure out whether the ColiCot helps colic affected infants or not. Therefore, it needs to be tested if test candidates cry less and sleep more if they use the ColiCot for sleeping. As a starting point for a testing procedure, the result from the previous project (Chapter 3.2.2) will be used and simplified. In this procedure, lengths of cry and sleep phases were recorded using an accelerometer, a video camera and a microphone. In addition, a pulse oximeter needs to be used for the observation.

A required simplification of this test method according to REC is that no test equipment is attached to the child for testing. In addition, this kind of simplification would make the pilot testing more comfortable for the stressed parents. The testing procedure of the previous project required a pulse oximeter and an accelerometer to be attached to the child. The first step for a simplification is to prove if the pulse oximeter and the accelerometer are necessary for the tests. If they are required to record if and when the child is crying or sleeping it needs to be found a replacement, which does not need to be attached to the child.

Pulse oximetry is used to measure both the pulse and the oxygen saturation in the blood. In the validation test with a “normal” infant the pulse oximeter was not used but recommended. [26] Pulse oximetry is an optical method using two light sources and a photodetector. It measures how much light the human body absorbs. Even if it is an optical method, a body contact for the measurement is still required. In sleep research and sleep laboratories pulse oximetry is used to identify sleep apnea. [37] The primary goal of the pilot testing is to evaluate the functions of the ColiCot and not to identify sleep disorders of the test candidates. This means that pulse oximetry is not necessary for the pilot testing.

The in the validation test used wireless accelerometer was used to record movements and their intensity. The recorded data were used together with the data from the microphone and the camera to identify if the child was actually in the cradle and if yes, if it was crying, calm or sleeping.

Following results are the outcome [26]:

- Sound level ≥ 65 dB and clear movements = crying
- Sound level ≥ 65 dB and small/no movements = calm/asleep and background noise
- Sound level < 65 dB and small/no movements = calm/asleep
- Sound level < 65 dB and clear movements = infant lifted up or laid into cradle

It is not specified in which distance the microphone was placed to measure the sound level, and it just can be assumed that it was close to the cradle. Other research about infant behavior showed similar results. One of the systems to classify infant behavioral states is divided into six different stages [38]:

1. Eyes closed, regular respiration, no movements
2. Eyes closed, irregular respiration, no gross movements
3. Eyes open, no gross movements
4. Eyes open, gross movements, no crying
5. Eyes open or closed, crying
6. Others (for example coma)

State one and two are asleep states. State number three is the transition state and states four and five are awake states. [39] The result of the previous project shows that a child is sleeping if there are no gross movements and/or if it is not crying.

The conclusion of this fact is that it is required to measure and record the movements and to observe the sound level to get the required information about the child’s behavior.

Since the movement observation is required, the accelerometer needs to be replaced with another method to measure movements without attaching anything to the child. To detect movements that way, electromagnetic radiation can be used. The table below shows possibilities to detect human bodies with different wavelengths of the electromagnetic spectrum and shows advantages and disadvantages.

Table 5: Electromagnetic radiation for body detection [40]; [41]

Class	Type of usage	Advantages and Disadvantages
X-rays	X-Ray imaging - security scanning - medical usage	+ - differentiates between different types of materials
		- - expensive and big equipment - health risky radiation → not usable for ColiCot
Visible Light	Camera (CMOS/CCD) - industrial image processing - standard video and photo cameras - image intensifier - detection of heart rate - motion tracking user interface	+ - cheap equipment available - common use in private, industrial and military sectors - high compatibility
		- - equipment usable under low light conditions is cost intensive
Infrared	Thermal imaging - non-destructive testing of materials - thermal performance of buildings - night vision - condition monitoring - search and rescue - optical activity recognition	+ - usable under all light conditions - cheap cameras with night vision available - active systems provide no hazards and does not bother humans
		- - passive systems with image processing are expensive - passive systems do not detect heat covered things (by a blanket for example), active systems only detect outer shapes
Terahertz radiation	Body detection - body scanner - detection of vital signs like heart and breath rate	+ - remote detection of human vital signs - possibility to see through non-metallic materials - passive systems without representing a risk
		- - technology is still under development

Taking a closer look on the table shows that using passive terahertz technology would be the best solution. In addition to the possibility to track vital signs, all body movements could be observed regardless of clothing or covering of the child. But this technology is not ready to use yet and for example the Novelda impulse radar, which is developed by one of the ColiCot initiators, is still under development. Therefore, using active infrared technology will be the best solution for this project. This technology makes it possible to observe movements of the children under any light condition for a reasonable price. In addition, there are no negative effects known using active instead of passive technology. The only restriction here is that only movements of the head can be observed and tracked. Since the cameras of the smartphones are not usable, extra cameras need to be bought.

Several software for face recognition and tracking with several options are available. One of them is using the relatively expensive Microsoft Kinect system, which has an infrared function included. The software itself needs to be self-programmed using the software-development-kit (SDK) for Kinect by Microsoft. [42]

The other option is to use much cheaper ordinary IP cameras or web cameras with infrared function. Either the required software can be self-programmed or it is possible to use already available software. Existing software that is able to detect faces and track the movements is for example FaceTrackNoIR. This program is a non-commercial open source program based on C++ and was developed to control games just using a webcam for face tracking.

The tracking software uses a simple pattern to identify and recognize faces. The used pattern is a kind of u-shape tube and uses eye corners, mouth corners and the tip of the nose as face-landmarks. FaceTrackNoIR uses the faceAPI v3.2.6 toolkit by Seeing Machines to detect and track faces.

An example of a recognized face is shown in Figure 22. The red lines show the currently detected shape of the pattern.

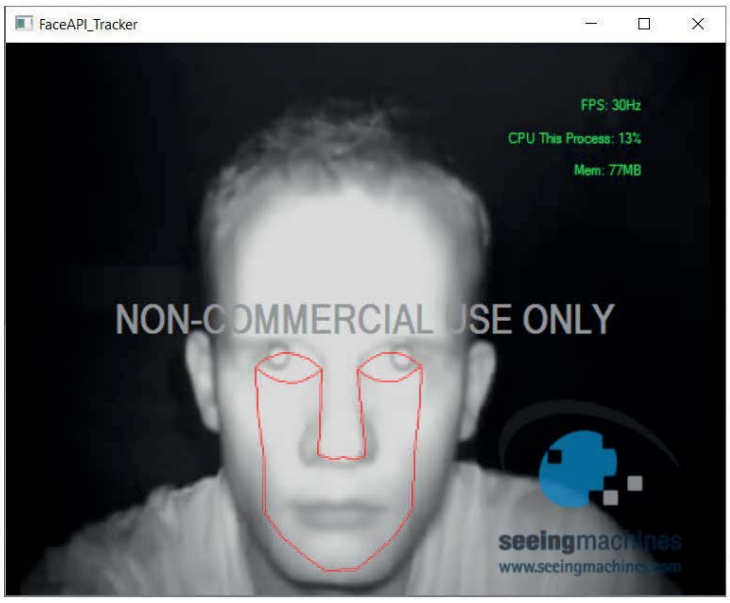

Fig. 22: Detected face in FaceTrackNoIR

Features of the software are to track in real-time fast head movements in a three-dimensional space. It is possible to track horizontal head rotations around the ear to ear axis from -30° to +60° and around the vertical axis from -90° to +90° which is almost the whole possible range of the human body. In a self-test the face recognition was sometimes lost within the threshold. The rotational error is less than 3° and the positional error less than 1cm. Since it is only an 8-bit greyscale video input required, the software is also able to use input from an infrared source. Because of the low number of face-landmarks, all kinds of human faces can be tracked. A test with a baby doll showed that it works with infants as well.

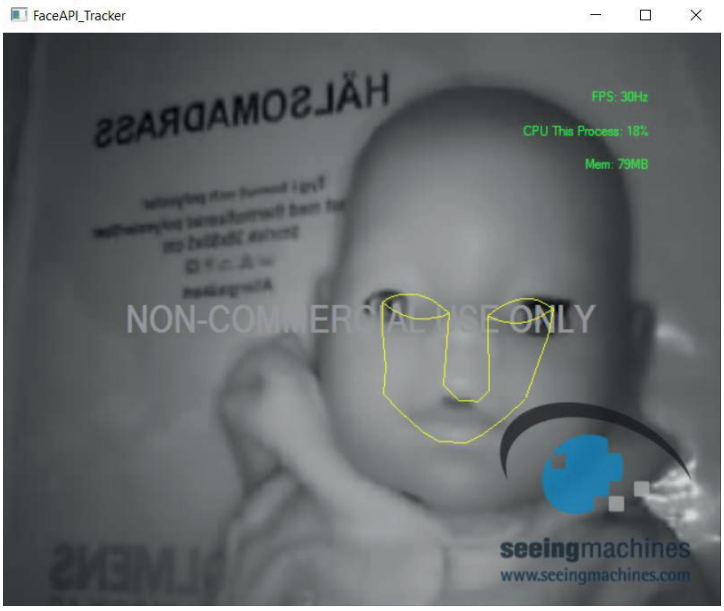

Fig. 23: Detected face of a baby doll

More features and all technical details about faceAPI are shown in Appendix C.
In the latest version of FaceTrackNoIR (v200) there is an additional function included to write the output values into a comma-separated values (CSV) file. The output values are the raw coordinates (x, y, z and the three rotation coordinates) and the smoothed coordinates from the stabilized raw head position data. To smooth the raw head positions two filters are available. One is using acceleration and velocity to stabilize the head position. The other filter is designed to respond to fast movements while it also has no negative influence when the head is not moving. In addition to the smoothing function, the program intensifies the head movements. [43] To get the direct output from faceAPI just the unprocessed raw data will be used. The output values are rotational in degrees and positional in cm. The standard version of FaceTrackNoIR writes output data 100 times per second in the CSV file. To get a for the testing more useful output file, the following changes need to be done to get a usable output file:

1. Reducing the amount of data (one time per second)
2. Including a timestamp
3. Adding an indicator if the face was successfully recognized each time

The source code of the current version of the program is not public. Therefore, including the required changes needed to be done by the program developers themselves. To be sure the face of the child is pointing to the camera, it needs to be ensured the child is sleeping on its back. Another important point is to prevent suffocation of the child, which is one reason of the sudden infant death syndrome (SIDS). To lower the risk, the child should be laid on its back in the cradle and it should not wear any headgear. [8]
The sound observation was previously done with an accurate sound level meter. To simplify the testing procedure here, it is possible to reduce the needed equipment and to use the microphone of the smartphone instead of an additional microphone. Since no suitable application for tracking producing an output file was found, an own application providing this function is required. Therefore, the programmer of the ColiCot App implemented a function in the current application. The added function has to consider following needs:

1. Measuring continuously the sound level
2. Logging the timespan and the values in which the sound level is above 65dB
3. Creating an output file with the logged times

Especially because the microphones of the smartphones are not designed for measurements, it is necessary to prove before usage that the smartphones just have minor deviations of the measured sound level. The result of the previous project was that the sound level is higher than 65dB if the child is crying. The measured sound level depends on the distance and direction of the microphone. It just can be assumed that microphone used for evaluating the 65dB was placed in a similar distance the phone is. In addition, it needs to be ensured that no other noise of the environment is continuously louder than the set value. The ColiCot application needs to get several changes for the pilot testing. These required changes are:

- Adding missing lullabies like electric razor, fan, hair dryer, driving in a car, vacuum cleaner and washing machine
- Function to play the selected sound continuously in a loop for the set active time of the cradle
- Turning of the screen automatically and let the app stay active with locked screen to let the phone battery last the whole night

The programming work for the changes of the application was done in a parallel project. Just the function with turning of the screen is not working yet. Therefore, a permanent charging of the phone is required. The speed setting needs to be done only once. The adjustment is done by connecting the control unit directly to a PC and finding a value which is or is close to the eigenfrequency. A problem occurring here is that the motor is not strong enough to hold the set speed continuously.

The pilot testing will include two phases. The first phase will be in the ColiCot with deactivated functions and the second phase with active functions. This is necessary to be able to compare results and conclude if the children sleep better with the ColiCot functions. Furthermore, the first night of the first phase will be used for acclimatization, like it is done in professional sleep laboratories. The second phase will include two days as well. The first day to have a direct comparison and the second day to see if this was not only a first time effect. The observations cannot be done the whole day. Therefore, the observations will be done just in the “main-sleeping-time” of the children. In preparation for the testing, a questionnaire (Appendix D) will be used to get required information such as if the child really has colic or what helps to sooth the child. Furthermore, a checklist is included to ensure that the parents have all required information and got informed about risks. The second part of this

questionnaire will be used for the conversation after the testing. In that questionnaire, information regarding the ColiCot itself and if the test was completed are collected. The “Døgnklokke” of the previous project was translated into English and simplified to have less work for the parents and to ensure that most important information were collected. The new behavior diagram is in Appendix E.

The final and simplified test will follow the following procedure:

Before testing:

- Conversation with the parents using the first part of the questionnaire
- Set-up of the equipment

Phase 1:

Day 1:

- Usage of the ColiCot as a normal cradle with deactivated functions for acclimatization and without observation

Day 2:

- Usage of the ColiCot as a normal cradle with deactivated functions
- Parents need to complete the behavior diagram
- Observation during the night (start of the tracking software)
- Collection of the tracked data the next morning

Phase 2:

Day 3:

- Usage of the ColiCot with activated functions
- Parents need to complete the behavior diagram
- Observation during the night (start of the tracking software)
- Collection of the tracked data the next morning

Day 4:

- Usage of the ColiCot with activated functions
- Parents need to complete the behavior diagram
- Observation during the night (start of the tracking software)
- Collection of the tracked data the next morning

After Testing:

- Collection of the observation equipment, the cradle can be used by the parents until the next test candidate is ready
- Conversation with the parents using the second part of the questionnaire

Figure 24 shows the dataflow, beginning with the input until the final evaluation.

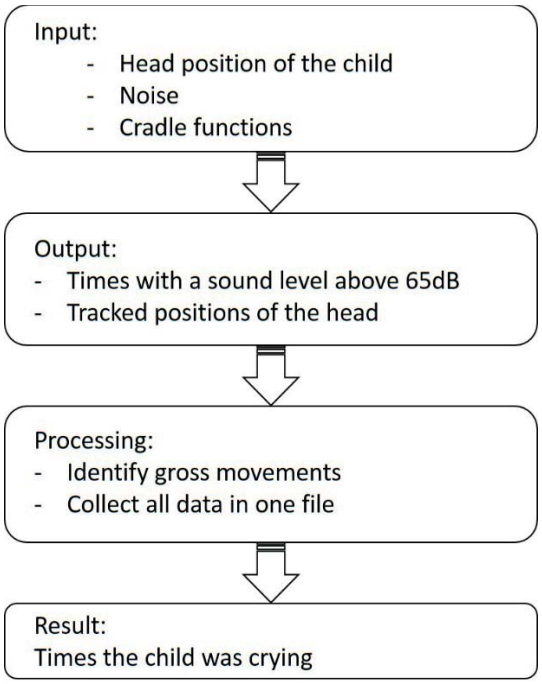

Fig. 24: Dataflow

3.3.2 Setup of the test equipment

To perform the testing procedure an infrared IP camera and a mobile device running the ColiCot control application are required for the observations. The measured data will be collected with a laptop. In order to power all the devices and also to ensure that battery powered devices will not run out of power, a power socket extender is needed to power the ColiCot, the smartphone with the control application, the laptop, the speakers and the infrared IP camera.

The camera needs to be attached directly to the cradle. Otherwise the rocking function of the cradle would have a direct influence on the movement detection and would give wrong output values.

The position of the camera needs to fulfill two requirements:

- Allowing the parents two lay the child in the cradle and pick it
- Have the head of the child always in the field of view

To allow the parents free access to the cradle, the camera needs to be attached to one of the walls, since a frame over the cradle would make an access to the cradle more difficult. The wall down to the feet (child lays in the cradle as shown in Figure 25) does not allow a usable field of view for the camera. The program for face recognition cannot recognize faces upside down. To get the camera in a position with

a usable field of view would take too much space. Therefore, the only reasonable position for the camera are the sidewalls, which provides a position allowing good access to the cradle and giving a good view. The for the test prepared cradle is shown in Figure 25.

Fig. 25: Camera position in the cradle

The camera is attached with strong self-adhesive double-sided strip to avoid any mechanical changes to the cradle.

The required laptop needs to be able to run the following Windows programs or other programs providing similar functions:

- MyPublicWiFi - to connect the network camera via Wi-Fi with the laptop (http://www.mypublicwifi.com/)
- IP Camera Adapter - to use the network camera with applications like a regular camera (http://ip-webcam.appspot.com/)
- FaceTrackNoIR - software for face detection and movement tracking (http://facetracknoir.sourceforge.net/)

The network settings and the access data for the cameras are in Appendix F.

3.3.3 Recruiting of parents and infants

For usability testing the number of test users participating is important. The bigger the sample size is the higher the validity of the test results are. To have a valid test a minimum sample size is required. In behavior research the minimum size is often set to five, since five users are enough to find about 80 % of all usability problems. But other tests showed that with five users sometimes just discover 55 % of the product problems. Therefore, it is recommended to test with at least 15 users, which means that not less than 90 % of the problems are discovered. With 10 users it is possible to identify at least 80 % of the problems. The focus of the pilot testing with the ColiCot is to find out whether the cradle helps the children or not. Because finding problems in the usability is not the priority, the minimum sample size can be lower, but a wished sample size is at least 10 test users. [44]

The search for candidates will be focused in Trondheim itself. In the delivery ward of the hospital in Trondheim, the St. Olavs Hospital, around 4000 births are registered every year. [45]

With a minimum rate of 16 % of colic children (→ Chapter 1) and a wished age of the children between 6 weeks and 4 months (→ 2,5 months timespan) statistically 130 children suffering from colics are available in Trondheim. To get 10 test candidates out of the small potential group, it is required to inform as many parents as possible and to make testing attractive for them.

To inform parents and other people which possibly know parents with children suffering from colics various ways are used, such as programing a website and designing a flyer and a poster. They need to contain information about the project itself, requirements how the tests will be performed and how to get in contact. The website is programmed with html5 using bootstrap for auto-sizing of the website to provide a high compatibility for all kinds of devices and screen sizes. The selected colors are warm and calming and pictures and drawings have a childlike theme. All of the media contains the logo of the NTNU to show that it is a serious project and to make it more attractive for participants. The website layout, flyer and contact-poster are all designed similar and shown in Appendix G-I.

To get in contact with parents several options are used. The first one is using social media and contacting groups for pregnant women, women who just gave birth, groups of parents and special groups of mothers. The second option is to contact

kindergartens. Even if there are no colic children in the groups, are there probably some parents which know parents with infants suffering from colics. There are too many kindergartens in Trondheim to contact all of them. Therefore, just a few of them can be contacted. One of them is for example the big active kindergarten of Trondheim. The probably best option is to contact the municipal well child clinics (helsestasjoner) of Trondheim. There are 14 of them scattered all over the city area of Trondheim and they are especially for check-ups during pregnancy, regular check-ups and vaccinations of infants and young children. Parents have to visit them first if they have health related problems with their children. Also the women's clinic in the St. Olavs hospital can be contacted to find potential test candidates. Another option is to contact acquaintances which have potential contact with infants suffering from colics and their parents. [46]

4. Performing of the pilot testing

4.1 Preparation

The test candidates participating in the pilot test are listed with their candidate number, the trial period the testing took place and other data in the table below.

Table 6: List of test candidates

Candidate number	Trial period	Age	Comments
1	22.05.-25.05.2016	7 Weeks	- child was crying during the explanation of the use of the cradle and the test equipment - test placed ≈150 km away from Trondheim
2	23.05.-02.06.2016 (Further use after end of the test)	8 Weeks	- frame of the cradle needed to be rotated 180° because the cradle was not leveled and the head was at lowest point in the cradle - test placed ≈100 km away from Trondheim

Together with a parallel project for the development of the ColiCot application a flyer was created, which works as a user manual for the test. It includes for example information about the usage of the application, how to use the 24 hours clock diary and other information required for collection of the tracked data. This is especially required because many of the test candidates are living outside of Trondheim and a daily visit is not possible. This manual for testing can be found in Appendix J.

The questionnaires which were completed before testing are in Appendix K.

Frequently occurring problems during the preparation appear especially while explaining the use of the cradle and the equipment to parents with a crying child in their arms. It was also not expected that participants need to move the cradle and the test equipment in order to use it during the day in the living room and for the night in the sleeping room. Having the tests conducted outside of Trondheim did not allow to visit the participants every day and required that participants need to do the test more on their own.

4.2 Testing

All of the tests were completed and none of them were terminated earlier. During the tests several problems occurred. In general, collecting data from the face tracking was a problem and failed either for an unknown reason (possible reasons in Chapter 5) or because the parents had problems handling the test equipment. Also the 24h diagram was just completed partly. Furthermore, during the test with the first candidate, the child stopped crying naturally what made the use of the cradle unnecessary. In addition to that, the parents used the functions of the cradle already the first day instead of the third day. But also some technical problems with the cradle appeared during testing. These are for example connection errors between the phone and the cradle and that the head was lower than the feet because of wrong levelling of the cradle.

The completed questionnaires from the conversation after the test can be found in Appendix L.

5. Analyzation and evaluation of the test

Before actually starting the analysis and evaluation of the test it is first necessary to find a way how to specifically do that. The goal is to compare phases with crying for testing with and with deactivated functions of the cradle. These phases can be identified by gross movements and a sound level above 65dB.

The gross movements can be identified by using the tracked head position data. Here only the tracked angles are most important, because of the type of movements which can be performed by the head. Figure 26 shows the coordinate system which is used for face tracking. The face detection software guarantees that the measured rotational error is less than 3°.

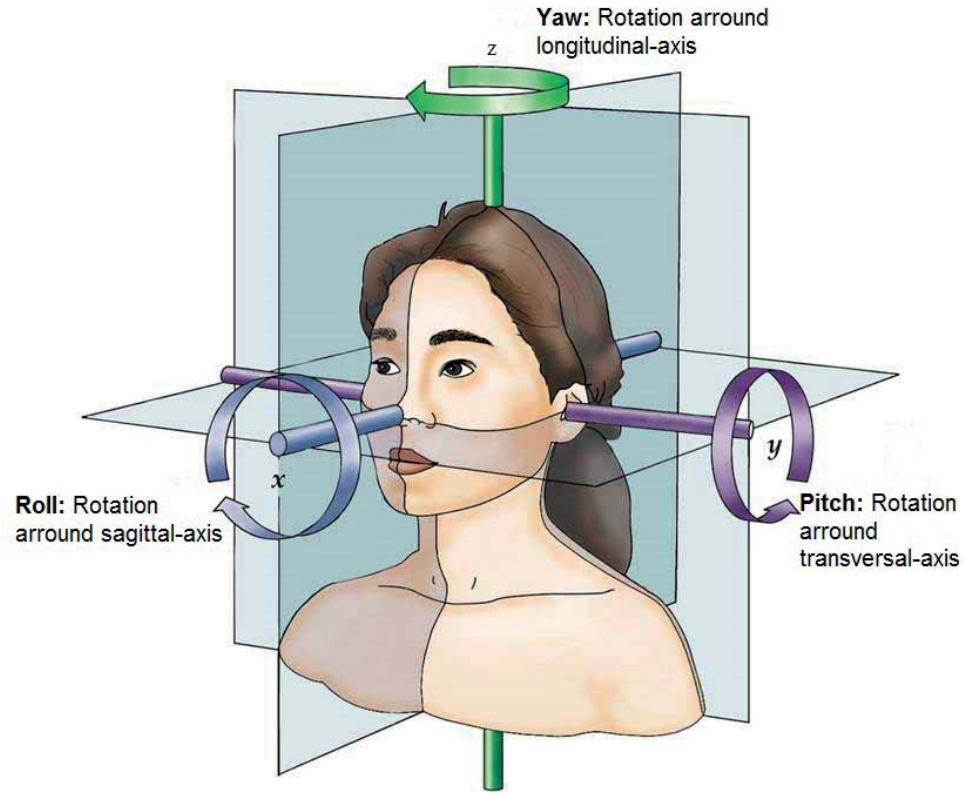

Fig. 26: Coordinate system [47]

The definition of gross movements is that they are generalized movements involving two or more limbs and trunk muscles, which last longer than 0.5 second. [48] For gross head movements no specific definition was found, just that it can be described as nodding or shaking. [49] Therefore it needs to be defined by itself. A movement in general is a change of the position of a body and can be characterized by time and

way. Saving the position of the head is done only once a second. Therefore, the minimum time is two seconds to screen movements over a timespan, which is more than the 0.5 seconds in the definition of gross movements. The definition of gross head movements (nodding, shaking) just includes one of the angles for each of the movements. To consider all of the three movements several options exist, for example using each time the maximum angle, arithmetic mean, root mean square or using a vector for the three different angles and calculating the length of it. Using the length of a vector seems to be the best solution, especially because greater angles, or in our case stronger movements, have a bigger impact than smaller angles.

The complete calculation will follow the following steps:

1. Absolute value for the moved angle with the current angle and the angle one second before (for pitch, roll and yaw) using the Excel command → =ABS(current value - value before)
2. Calculating the length of the vector to have a combined movement using the command → =SQRT(movement_roll^2+movement_pitch^2+movement_yaw^2)
3. Adding current value for combined movement and from one second before to get the total movement for a timespan of two seconds using the command → =current value + value_one_second_before

To get values for identifying strong movements, the definition of gross head movements is used, which can be described for example as head shaking. The data is created by performing the head shakes self and can be found in Appendix M. It is visible, that the total combined movement over two seconds needs to be greater than 20°.

The times when the sound level was over 65dB are directly written in an extra file and just need to be added to the sheet with the data from face tracking.

The next step in the evaluation process is to search for overlapping times. The times with an overlapping between gross movements and high sound level are crying periods. The final step is to compare the crying times for each of the three days with data tracking for a conclusion whether the cradle helps or not. A graph showing the total time of crying for day two of the test (without functions) and day three and four (with functions) for each candidate can make the result visible.

As already described in chapter 4.2, no head tracking data was successfully collected during the tests. That makes an evaluation using identification of gross movements impossible.

Tracking the sound level worked well and the output files were successfully created. The data in the file shows that sometimes the sound level was above 65dB just for one second, several hours after the last and before the next tracked time. This could mean that it is with a high confidence noise from the environment and not crying. If there was just a short break between two tracked intervals, it is a high chance that it is one single interval. A shortened output file (Appendix N) for the nights marked in the 24h diagram considers these points. Because the ColiCot functions were used by the parents already from the beginning of the test phase, it is not possible to compare crying times with activated and deactivated functions of the ColiCot. But there is still an effect of the ColiCot visible using the 24h diagrams of the test candidate number 2 in Appendix O. The marked crying periods during the nights decreased every day, and day three of the pilot testing has already no marked crying intervals anymore. The data in Appendix N shows long noisy periods especially in night two. The long periods are probably something different than crying, otherwise the beginning of the actual night at 11pm, which was noisy, would not be marked as “sleeping” in the diagrams. The short noisy intervals (30 seconds – 1 minute) during the middle of the night could be either noise from the environment, or as described by the parents in the final questionnaire the well working calming effect of the ColiCot, which kept crying at a minimum that the parents did not wake up.

The cradle for the first test candidate was just used for the first four days. The crying periods decreased during the 8th week of life naturally. Usually crying periods decrease after the 6th week (Chapter 2.2.1). A noticeable decrease in the 8th week could indicate that the infant was not suffering from colics and that decreasing of the periods was just not noticeable before. Also the 24h diagrams show that the child was crying less than three hours per day, and on the last day even less than one hour, which is an indicator for not having colic or not have it anymore.

In general, the feedback was positive and it seems like the cradle may help children. It is important to judge this conclusion critically. Every child has its own behavior and responds differently. Much more tests need to be done before the results can be treated validly. There are in addition several assumptions which have been done and also errors which occurred during testing. Some of them are having a small or no

influence, others have a bigger influence. One problem is the limited data output which was created and which can be used for the evaluation process. To ensure that the test is running as it is supposed to be and create a usable data output, it would be necessary to be present during the tests. All the participants live outside of Trondheim. It was not expected that the participants need to work with the test equipment completely on their own and that they need to move the cradle and the test equipment in order to use it during the day in the living room and for the night in the bedroom. Being always available for the parents, or accessing the PC via remote control, could avoid problems and ensure that everything is working.

Problems leading to a failed face tracking could be caused by:

- Lost Wi-Fi connection between camera and PC
- Camera setting, for example brightness was wrong and made the data unusable
- head of the child was outside the field of view of the camera
- face tracking software failed in finding landmarks

Other problems which have been figured out with the test equipment are regarding the testing procedure itself. The tracking software writes each value twice, what requires to delete or ignore every second line. Furthermore, there are no movements tracked which happen in between two tracked values. This means that faster movements may not be identified. This risk can be decreased by increasing the tracking rate. The 24h diagram should have numbers for every full hour to make it easier. Using the “main-sleeping-time” in the diagram seemed to be helpful and further work should focus just on that.

6. Changes resulting from testing and other modifications

During the work with the cradles and especially during the tests with them several problems occurred, but also ideas for improvement and feedback about positive things. Technical modifications recommended for further work are the following:

- The cradle is too heavy and unhandy to get moved by a single person, for example between living room and bedroom (one feedback said, that the cradle is much bigger than expected)
- The components of the cradle are too expensive
- The actuator is noisy and not strong enough to keep the speed constantly (rethinking the concept for the rocking function)
- Quality problems are already visible one year after production with rarely usage
    - Frame and bed basket are deformed
    - Wood has visible cracks
    - Leather straps stretched during the time (textile straps which were used for the car cradle do not have this problem
- Cradle needs to be opened to control or charge the speaker system
- Adding a monitoring system to avoid sudden infant death syndrome
- Changes regarding the application for controlling the cradle were required (more information can be found in the project for the development of the application “Utvikling av mobil app for testing av kolikkvogge”)

The “cloud” design was liked very much by the mothers. For the “car” design no feedback is yet available.

Other ideas and required changes regarding the project are:

- Create a “colic guide” for the parents to inform them about colic in general, how to identify colic and which treatments help (parents of the test candidates needed to diagnose and collect all information themselves)
- Products of competitors are usually rented out instead of selling them, what is also an option here
- Using hypertext access for the website in order to use it without the “www.” in front

7. Summary and perspective projects

The aim of this thesis was first to determine a testing procedure to evaluate whether the ColiCot cradle helps to soothe children suffering from colics, then to perform tests based on this procedure and finally to analyze the results of the tests and evaluate changes resulting from it. This is important to show the potential of the product and to test the prototype before going on in the development process. A first draft of a research paper about the testing procedure and the results was an additional objective. An exhaustive research about sleep, colic and colic treatment created a solid basis for further work. The next step was to learn more about the cradle prototype and valid laws to set the framework conditions for the test. Based on that, a test procedure was developed by simplifying actual applied procedures in sleep research and considering several solutions to do testing. To find test candidates, a website, flyer and poster were designed and several media were used to inform as many parents as possible and to attract them to participate in the pilot test. Parents all over Norway were interested in participating the pilot test. As many tests as possible with parents in a reachable distance were performed with the limited time given, the results evaluated and resulting changes collected. In addition, a first draft of a research paper was created (Appendix P). However, several issues appeared during the tests. The probably biggest issue is the limited number of test candidates. There were also problems regarding the tests themselves. For example, parents performed the test in a different way than planned and creating data, especially face tracking failed. It is also important to consider that the test cannot replace a test in an actual sleep laboratory and that the behavior of every child is different.

For projects in future it is required to perform tests with more candidates to approve positive tendency of the results. It is highly recommended to be present during the tests to ensure that the test is performed the way it is planned and that the test equipment is working. Also the set minimum of 65dB for the sound and the definition of gross movements should be checked.

Even if just few people were interested in participating in a pilot test, the interest for the ColiCot cradle is high and the positive effects to the candidate suffering actually from colic motivates to continue the development.

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Appendix

A	Risk analysis
B	REC contact
C	Technical specifications and features of faceAPI
D	Questionnaire
E	24h diagram
F	Settings for connection to the network cameras
G	Website layout
H	Flyer
I	Contact poster
J	Manual for testing
K	Questionnaire before testing
L	Questionnaire after testing
M	Data head shaking
N	Noise tracking (candidate 2)
O	24h diagrams (candidate 2)
P	First draft of a research paper
Q	Risikovurdering

ID nr.	Risk	Possible effects when it appears	Potential that the risk appear	actions to avoid the risk
1	failures of electrical parts	fire	low	using CE certified parts
2	breakdown of electrical parts	ColiCot stops working	low	using CE certified parts
3	wrong values for the engine speed	rocking function stops working	medium	speed is controlable and parents need to be informed not to change the value
4	Loosing control via smartphone	crib is not responding during using it	medium	crib is set on "disabled" automatically
5	intoxication/allergic reactions	allergic reactions, breathing problems	low	use of hypoallergene materials
6	swallowing small parts	suffocate/ breathing problems	low	small parts are hidded unreachable for the children
7	electric shocks	disfunction of the heart	low	covering connections, using CE certified parts
8	sudden infant death syndrom	death of the infant	low	informing the parents about it
9	sharp edges/splinter	small injuries/blood poisoning	high	removing them with abrasives or covering them
10	power failure	ColiCot stops working	low	-
11	wrong settings using the application	ColiCot respond different than expected	high	userfriendly programming of the app/giving instructions
12	hazards for the environment	noise	low	it is developed to play sounds to calm the child which is supposed to be more silent compared to a crying child

Actions to avoid the risk:

red	changes of the testing procedure and/or the ColiCot are required
yellow	information about this risk must be given to the parents before start of the pilot testing
green	no actions required

Appendix B: REC contact

Sekretariat
Komité
Møter
Referater

REK nord – sekretariat

Til forsiden Utskriftsversjon

Publisert 17.8.2015

Geografisk region:
Nordland, Troms og Finnmark

Postadresse:
UiT Norges arktiske universitet, Postboks 6050 Langnes, 9037 Tromsø

Besøksadresse:
MH-bygget, 10. etasje, Breivika, Universitetet i Tromsø – Norges arktiske universitet

Telefon: 77 64 61 40

Elektronisk post: rek-nord@asp.uit.no

Kontaktpersoner rådgiving

rådgiver Monika Rydland Gaare 77620756

Seniorrådgiver Veronica Sørensen 77620758

Rådgiver Lill Martinsen 77646140

sekretariatsleder May Britt Rossvoll 77620757

Kontakt REK

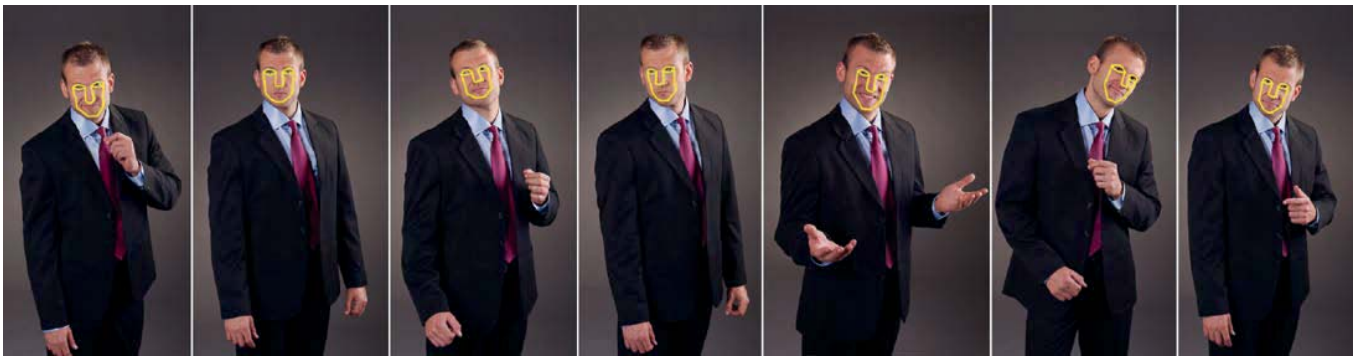
- Generelle spørsmål skal rettast til REK i din geografiske region
- Spørsmål om saker som er sende inn, skal rettast til den REK som har saka
- Du må skrive namn på aktuell REK (REK sør-øst, REK vest, REK midt eller REK nord) i emnefeltet på e-post til post@helseforskning.etikkom.no
- Komitésekretariata kan også kontaktast på telefon, e-post eller kontoradresse, som du finn under menyvalet Komiteer og møter

Ofte stilte spørsmål

faceAPI

Download now at faceAPI.com

The Real-Time Face Tracking Toolkit for Developers and OEMs



Technical Specifications

faceAPI allows you to integrate Seeing Machines world-class face-tracking technology into your product or software application. Now available under both development and production licenses, faceAPI provides your development team with the ability to quickly incorporate ultra-reliable face-tracking, with no image-processing or computer vision expertise necessary.

faceAPI is the only comprehensive, commercially supported solution for developing products that leverage real-time face-tracking.

Features

- Highly robust, real-time, 6 degree-of-freedom (3D) monocular face tracking
- Able to track up to +/- 90 degrees of head rotation and fast head movements
- Optional real-time tracking of lips and eyebrows
- Face-texture "mugshot" delivery upon tracking commencement
- Two types of head-trackers, trading CPU load for tracking capability.
- Requires only 8-bit greyscale video input. Algorithms do not rely on color and are therefore able to track faces in the dark using infra-red illumination
- Automatic tracking startup and immediate reacquisition when face is hidden then shown
- Facial feature detection and tracking – locates facial feature "landmarks" from a single image or real-time for video sequences
- Designed for all human faces (it doesn't matter what you look like). Robust to occlusion, fast movement, large head rotations, lighting changes, dimly lit rooms, facial deformation, skin color, beards, glasses etc
- Can track with as few as 40 pixels across the face (typically 2m from a VGA camera)
- Works with any webcam or video file
- Full control over all tracking parameters for purposes of software integration
- Low-level image input interface for custom camera integration
- "Offline" tracking algorithm for high-quality tracking of faces in movie files where real-time performance is not required
- Separate low-level "face-search" algorithm for finding multiple faces in images and short image sequences. This algorithm has three "depth" levels, with level 0 providing fast results to level 2 which accurately locates facial features and estimates head-pose in 3D.

Technical Details

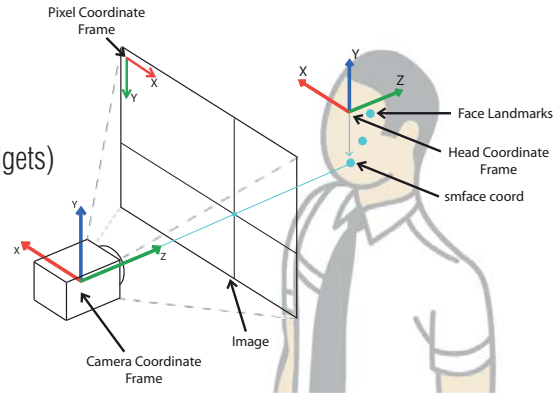
At the heart of faceAPI lies a number of sophisticated multi-threaded tracking "engines". Each engine appears as a "black-box" with a minimal set of C functions that allow the developer to tune engine behaviour and performance.

faceAPI

The Real-Time Face Tracking Toolkit for Developers and OEMs

The API is provided as a closed-source library consisting of:

- C header files
- A DLL binary
- Concise HTML documentation
- Several sample applications (including a full game engine demo)
- A set of open-source object-oriented wrapper classes (C++ and Qt widgets)
- A tool for calibrating camera lenses (enabling precision tracking)
- A command-line tool for tracking faces in movie files
- Redistributable third-party APIs required for installation



faceAPI can track with a variety of video inputs:

- Webcams, or any WDM compatible camera (DirectShow driver)
- PointGrey Flea, Flea2 or Firefly MV cameras (recommended for high-performance applications)
- Movie files. Can read Windows avi or Apple Quicktime files.
- Low-level “shared-memory” image interface (allows for integration of custom video devices).

The tracking engine provides:

- Methods to “call back” your application whenever a new tracking measurement occurs
- A function that sets the current estimate of head-pose into a C structure (interpolates between samples)
- Head-pose measured in cartesian 3D coordinates relative to the camera, (X,Y,Z). Position is in meters and rotation is expressed in euler angles (rads).
- Positions of key facial locations (face-landmarks) including lip and eyebrow points, expressed in “face-coordinates” (inside the face, independent of head-pose)
- “Mugshot” face-texture is provided via a function callback that occurs when the face starts tracking. This texture is 256x256 resolution in RGB color format and is a synthetic orthographic projection of the front of the face. Face outline (texture-mask) points are provided with the texture.
- Head-pose measurements include a confidence weighting, from 0 to 1, allowing your application to determine when tracking quality is acceptable
- Latency of measurement is ~11ms (processing time) + exposure time. Eg, for a 30Hz camera, latency = ~44ms

Licensing

Non-Commercial, Development and Production license options now available.
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faceAPI

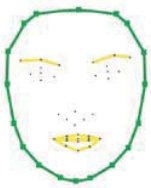
The Real-Time Face Tracking Toolkit for Developers and OEMs

faceAPI enables Desktop VR and 3D effects using just a web camera.

Track and understand faces like never before with faceAPI from Seeing Machines - now available for license.

faceAPI turns any camera or standard webcam into a 3D face tracking device – no other hardware required. Designed for developers, faceAPI streamlines the integration of Seeing Machines world class face-tracking technology into your product or software application. Our state of the art image processing techniques detect and track faces as they move, delivering information on appearance, position, rotation, key facial features and facial expression.

3D Head-Pose Tracking: faceAPI tracks the position and rotation of the head in X, Y and Z, relative to the camera. Know where your users are, know if they're paying attention, detect head nods, shakes and other head gestures. This six degree-of-freedom tracking information is normally only available with specialized motion capture hardware.



Facial Landmark Detection: faceAPI discerns the position of key locations on the face such as eye corners, mouth corners, and the tip of the nose. Understand where your viewers' eyes are in 3D for Desktop VR, autosteroscopy and 3D visualization applications.

Facial Expression Tracking: real-time lip and eyebrow tracking delivers facial expression information for animating avatars, recognizing when users are talking, and detecting moods.

Face Texture Extraction: faceAPI outputs the pose-normalized image of the face upon commencement of tracking. This face texture information is annotated with facial landmarks, and can be used to skin avatars or 3D models.

faceAPI gives your development team the ability to quickly add face-tracking functionality for locating and tracking faces and facial features in images and video. faceAPI is automatic and simple to integrate, and handles all image processing itself, removing the need for computer-vision expertise. faceAPI is structured as a library of C header files, a Windows DLL, concise HTML documentation, several sample applications, a set of open-source object-oriented wrapper classes (C++), a tool for calibrating lenses, and dependent redistributable third-party APIs suitable for including in an application installer program.

Applications

- Interactive 3D Games, Virtual Worlds
- Humanoid Robotics and AI Interaction
- Performance-driven Avatar Animation
- Automotive Advanced Driver Assistance Systems (ADAS)
- Smart Screens, Billboards, Kiosks
- 3D Displays
- Advanced, adaptive visualisations
- Intelligent Video Conferencing

Advantages

- 3D face-tracking from a webcam or image-stream
- Unrivalled performance & capabilities leveraging unique, patented tracking algorithms
- Completely automatic operation – zero user interaction required
- Ultra-robust to changes in facial expression, illumination, and head motion
- Straightforward operation & deployment

faceAPI is available now under both development and production licenses. We have licensing models that suit a wide variety of business types, and non-commercial licenses are available. To find out how your application can be powered by faceAPI, please visit www.faceapi.com and contact our team.

faceAPI Performance

Tracking State	HeadTrackerV1	HeadTrackerV2	Tracking a face at framerate
Min Face Size (pixels)	40.00		
Max Face Occlusion (%)	50.00		
Head Rotation X (deg)	-20<X<45	-30<X<60	Horizontal axis (ear to ear)
Head Rotation Y (deg)	-30<Y<30	-90<Y<90	Vertical axis (up through head)
Head Rotation Z (deg)	-90<Z<90		Camera axis (nose)
Positional Error (cm)	<1cm		Even illumination, no occlusion
Rotational Error (deg)	<3 deg		Even illumination, no occlusion
CPU Load (30hz USB webcam) (Total% / Process%)	12% / 5%	30% / 25%	Intel Core-2 Duo, 2.4GHz, 4MB Cache, Logitech Quickcam Pro 5000
CPU Load (60hz firewire) (Total% / Process%)	6% / 1%	8% / 1%	Intel Core-2 Duo, 2.4GHz, 4MB Cache, PointGrey Flea

Initializing State	HeadTrackerV1	HeadTrackerV2	Finding a new face
Min Face Size (pixels)	40		Distance between outer eye corners
Head Rotation X (deg)	< 15		Horizontal axis (ear to ear)
Head Rotation Y (deg)	< 15		Vertical axis (up through head)
Head Rotation Z (deg)	< 30		Camera axis (nose)
Time to Acquire (typical) (secs)	0.3 - 3.0		Assuming head is within in geometric constraints
CPU Load (Active) (%)	50%		Intel Core-2 Duo, 2.4GHz, 4MB Cache
Searching State	HeadTrackerV1	HeadTrackerV2	Quick recovery from tracking failure
Recovery Conditions	Face front, no occlusion	Any pose, no occlusion	
Recovery Time	1 frame		
CPU Load (%)	20%		Intel Core-2 Duo, 2.4GHz, 4MB Cache

Appendix D: Questionnaire

Test candidate No.:		**Testing period:**	
Age:			
Contact (voluntary):			

Conversation before start: Date:

How was colic identified?:

How is the child sleeping currently? (main sleeping time, ho often waking up):

Which methods tried to calm the child, which are helping?:

Checklist: - Talking about us

- Talking about that participating is voluntary and can be withdrawn any time
- Talking about testing procedure (How we want to do that and key factors for evaluation)
- Talking about risks (risk assessment children)
- Instructions to the cradle
- Instructions to the app
- Instructions to the equipment
- Questions? Concerns?

Notes:

Test candidate No.:		**Testing period:**	
Age:			
Contact (voluntary):			

Conversation after test: Date:

Test completed? (if no, reasons for termination?):

Did the cradle help?:

Any problems during the trial?:

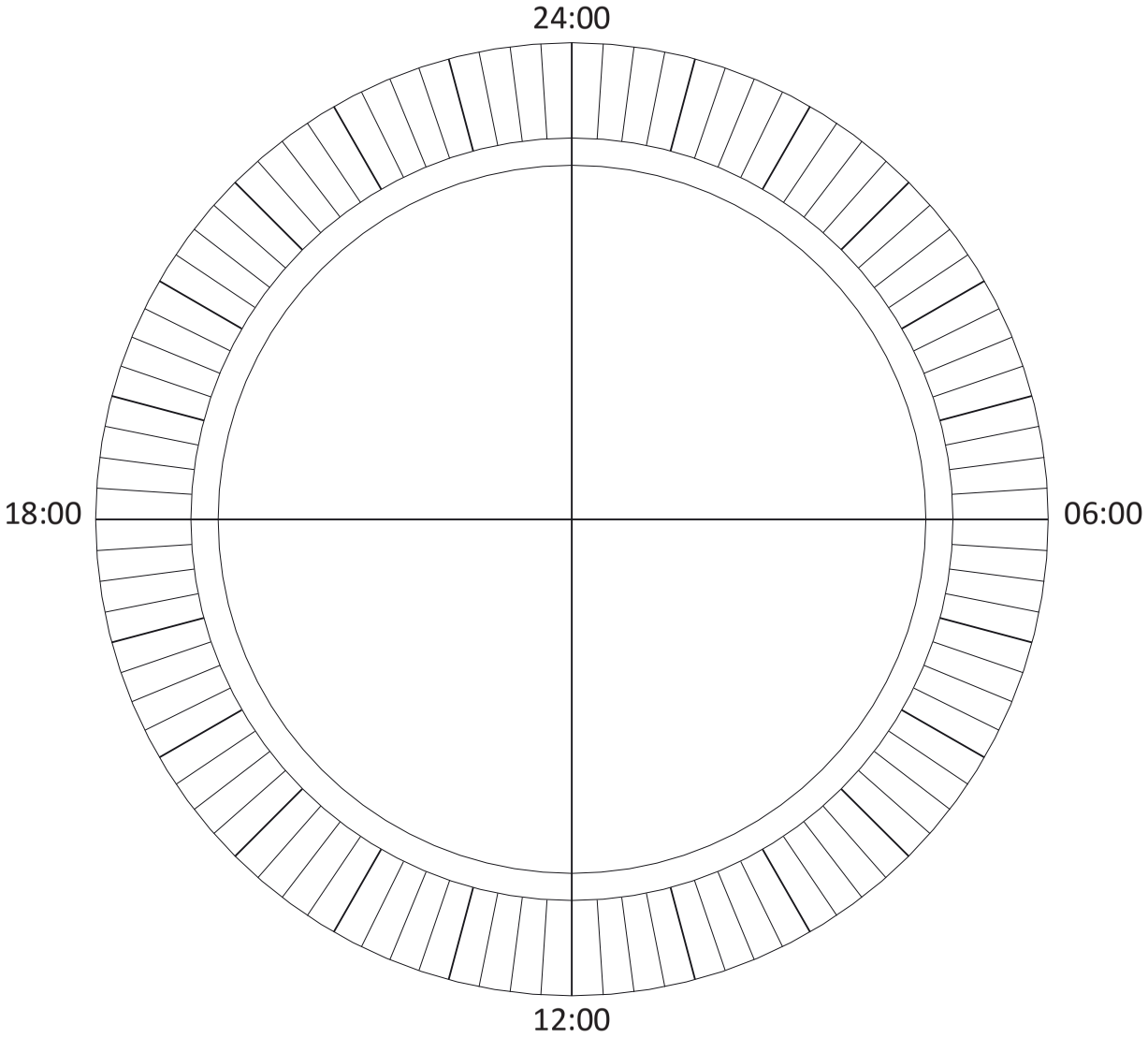
What do you like?:

What do you dislike?:

Notes:

Crying times without functions	Crying length in total without functions	Crying times with functions	Crying length in total with functions

Test candidate No.:		**Testing period:**		**Date:**
Age:				
Contact (voluntary):				



Blue……Sleeping

Red……Crying

Green…Awake, calm, happy

Yellow.. Awake, moving, unhappy

IMPORTANT

"Sleep time for the night" marked in the inner circle area

Longer times the child was outside the cradle during the night?

Yes ☐ No ☐

Own impression if the cradle helps:

Yes ☐ No ☐

Other observations:

_____

_____

Appendix F: Settings for connection to the network cameras

Programs:
1 MyPublicWiFi - Hosting a network for the connection between webcam and pc
2 IP Camera Adapter - Using the Webcam stream via ip adress to create a virtual webcam
3 FaceTrackNoIR and Plugin Package - Tracking software (After installation original
files need to be overwritten with the modified files. Webcam is chosen automatically, all unused
webcams should be deactivated)
(4) VLC media player and VLC2Vcam plugin - can be used to use video files for face tracking by
creating a virtual webcam

FaceTrackNoIR
Smoothing: 1 sample
Tracker Source (1st Master): faceAPI
Game protocol: CSV
Game protocol (2nd): CSV

Output file in the install folder: CSV_output.txt

Webcam 1
http://xxx.xxx.xxx.xx/ (IP adress)
Camera configuratiuon
User name: admin
Password: baby1234

Network (WPA2):
SSID: babycam1
Password: baby1234

IP Camera Adapter
Camera feed URL: http://xxx.xxx.xxx.xx/video/mjpg.cgi

Webcam 2
http://xxx.xxx.xxx.xx/ (IP adress)
Camera configuratiuon
User name: admin
Password: baby1234

Network (WPA2):
SSID: babycam2
Password: baby1234

IP Camera Adapter
Camera feed URL: http://xxx.xxx.xxx.xx/video/mjpg.cgi

If the network camera is connected, but not in the list of connected devices:
use showing all network clients with: cmd.exe --> command: "arp /a"

Appendix G: Website layout

COLICOT | HOME | TESTING | DOWNLOADS | ABOUT | CONTACT

ColiCot

ColiCot is a cradle with an automated soothing function for children. It is developed by engineers of NTNU Trondheim and designed especially to help colic-affected children to sleep better.
Currently we are looking for test candidates.

Are you interested?

Show me more

TESTING

COLIC? | WE WANT TO HELP!

There is no single treatment to calm children suffering from colics. Seven of the nine most common treatments are united in this cradle. It is very easy to control the functions via smartphone. You can choose the treatment your child likes best, as a single function or combination. The crib activates itself and helps your child to sleep better. After safely testing of the functions with normal crying children in 2014, we now want to see what ColiCot can do for infants actually suffering from colic. Therefore we want to ask you to help us by taking part in a trial in April and May. We want to perform a home-testing trial for 4 days with colic suffering children in the age group between 6 weeks and 4 months. After you contact us, we will have an informational meeting where we will answer questions you may have and give you more details. In the next step of the trial we will deliver the ColiCot cradle to your home, set it up for you and give you an introduction. During the trial there will be a video and audio observation to measure the sleeping differences with and without ColiCot. These data will be used for our research purposes only, we take your privacy seriously and will anonymise the collected data. After the end of trial period we will talk with you about your experiences. If you like it, we can offer you to use the ColiCot after the end of trial until we will need one of them for a next test candidate.

DOWNLOADS

INFO.PDF | PDF Brochure

Download Link

ABOUT US

HISTORY | PROJECTS & MOTIVATION

In 2012 Terje Rølvåg and Ole-Johan Ellingsen, both expirienced in colic with their own children, started the SPIDERNET project. The outcome was a full development plan for the patented ColiCot. In 2014 first prototypes were produced and a function test with "normal" babys took place. Now we want to know if it helps actually excessive crying infantsto improve the life of you and your child.

CONTACT INFO

terje.rolvag@ntnu.no

+47 735 937 62

Terje Rølvåg
Richard Birkelands vei 2 B
Institutt for produktutvikling og materialer, NTNU
7491 Trondheim

NTNU IPM Department

NTNU
Norwegian University of Science and Technology

Does your newborn cry a lot?

We want to help you!

Contact.

Christian Börner
Master's student
Department of Engineering
Design and Materials, NTNU
Phone: +47 457 942 17

Terje Rølvåg
Professor
Department of Engineering
Design and Materials, NTNU
CEO ColiCot AS
Phone: +47 735 937 62

Do you want to participate or have any questions about ColiCot? Feel free to contact us via phone or mail: terje.rolvag@ntnu.no

-Colic-
Facts and how we want to help

- About 15 % of newborn infants suffer from colics
- Sleeping problems stress both child and parents
- There are several treatments, ColiCot unites and starts them automatically
- We want to test and improve our cradle in collaboration with you

Find us on web:
www.colicot.net/testing

NTNU
Norwegian University of Science and Technology

The ColiCot

ColiCot is a special crib developed by engineers, inspired and motivated by their own colic affected kids.

There is no single treatment to calm children suffering from colics. Seven of the nine most common treatments are united in this cradle.

Easy control of the functions via smartphone - choose the treatment your child likes best, as a single function or combination. The crib activates itself and helps your child to sleep better.

After safely testing of the functions with normal crying children in 2014, we now want to see what ColiCot can do for infants suffering from colics.

What we want to do?

We want to do a trial to verify the benefit of the ColiCot.

Trial period: April and May

Test population: Children between 6 weeks and 4 months suffering from colics

Testing period: 4 days

Test setting: Conveniently at your home

Equipment: Delivered and set up for you

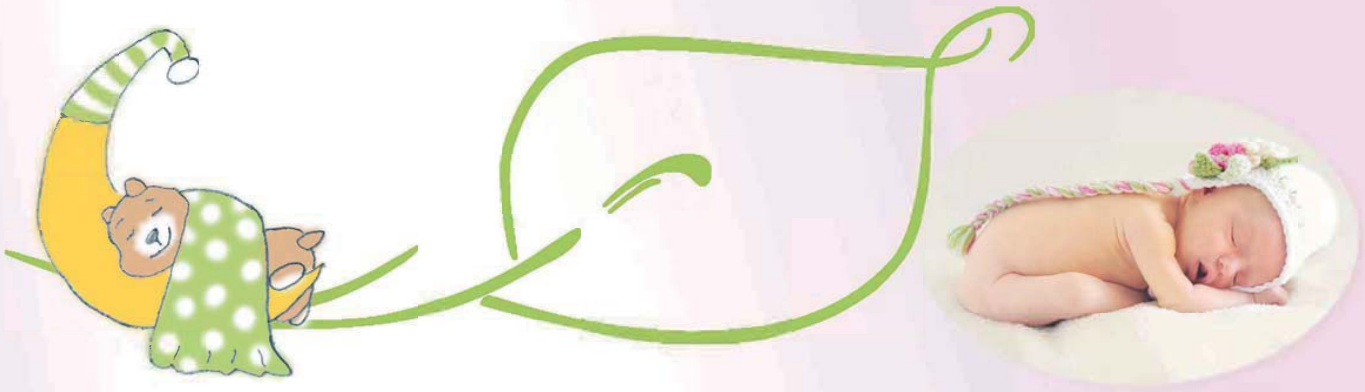
We want to improve your life and the life of your child.

How we want to do that

The objective of the test is to observe whether ColiCot helps your child to sleep more easily.
These are the test steps:

1) Conversation with you in preparation for the trial
2) We deliver the equipment, set it up for you and give you an introduction to the ColiCot cradle
3) Video and audio observation for scientific data of the soothing effect
4) After 4 days we will want to talk with you about your experiences

Appendix I: Contact poster



Does your newborn cry a lot?
We want to help you!

-Colic-
Facts and how we want to help

- About 15 % of newborn infants suffer from colics
- Sleeping problems stress both child and parents
- There are several treatments, ColiCot unites and starts them automatically
- We developed a special cradle at NTNU to help the children and the parents and want now to test and improve our cradle in collaboration with you

What we want to do?

We want to do a trial to verify the benefit of the ColiCot.

Trial period: April and May

Test population: Children between 6 weeks and 4 months suffering from colics

Testing period: 4 days

Test setting: Conveniently at your home

Equipment: Delivered and set up for you

We want to improve your life and the life of your child.

How we want to do that

The objective of the test is to observe whether ColiCot helps your child to sleep more easily.
These are the test steps:

1) Conversation with you in preparation for the trial
2) We deliver the equipment, set it up for you and give you an introduction to the ColiCot cradle
3) Video and audio observation for scientific data of the soothing effect
4) After 4 days we will want to talk with you about your experiences

Contact

Do you want to participate or have any questions regarding ColiCot? Feel free to contact us via phone or mail: terje.rolvag@ntnu.no
Or visit us online: www.colicot.net/testing

NTNU
Norwegian University of Science and Technology

ColiCot Testing
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ColiCot Testing

- Colic -

Facts and how we want to help

- About 15 % of newborn infants suffer from colic
- Sleeping problems stress both child and parents
- There are several treatments, ColiCot unites and starts them automatically
- We want to test and improve our cradle in collaboration with you

Test procedure

- 1st night with deactivated functions for acclimatization
- 2nd night with video camera, app on and motor off. Please remember to turn on the computer and the app and fill out the diagram
- 3rd night with all functions of the cradle. Please remember to turn on the computer, activate all functions of the app and fill out the diagram
- 4th night with all functions of the cradle. Please remember to turn on the computer, activate all functions of the app and fill out the diagram

Contact:
Terje Rølvåg, CEO ColiCot AS
terje.rolvag@ntnu.no
400 65 114

Christian Börner, test organizer
chriborn@stud.ntnu.no
457 94 217

Johanna Bech, app developer
johannab@stud.ntnu.no
450 99 594

Power supply

Please remember to charge at all times:

- The cradle
- The laptop
- The video camera
- The telephone

Charge during daytime:

- The speakers

How to: computer

Please remember to start the Face Track program, found on the desktop on the 2nd, 3rd and 4th night. Rename the data and save in a folder on the desktop.

Playlists

We have selected songs that sooths babies. Please choose from this selection, record your own songs or download songs to create a custom playlist.

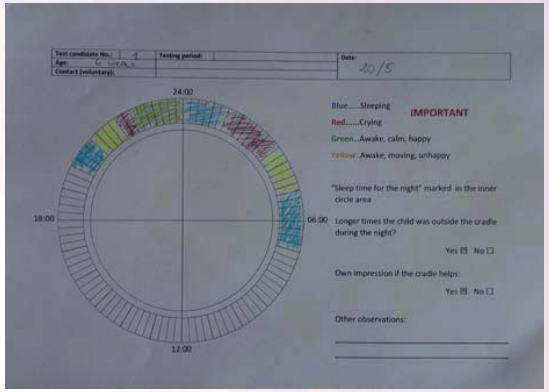
- "ColiCot playlist" plays all songs that were preinstalled.
- "Baby's favourites" will play the songs where the baby has been crying the least, in order.

How to: app

For the app to track the baby's noise during the night it is important to turn on the app the 2nd night.
The two following nights the audio and motor should be enabled. Please remember to slide the bar to enable the cradle, and make sure that audio and motor are enabled. When the app is closed the bar is set to disabled. Therefore, you need to make sure it is enabled after closing.

How to: diagram

The diagram only needs to be completed when the baby is sleeping in the cradle.
The diagram can be filled out approximately.



Appendix K: Questionnaire before testing

Test candidate No.:	**1**	**Testing period:**	**22.05.2016-25.05.2016**
Age: 7weeks		**7 weeks**	
Contact (voluntary):			

Conversation before start: Date: 22.05.2016

How was colic identified?:

- child is crying around six hours per day, especially during the evenings

How is the child sleeping currently? (main sleeping time, ho often waking up):

- going to bed around 10/11 pm

Which methods tried to calm the child, which are helping?:

- bathing the child warm
- listening to waterfalls

Checklist: - Talking about us ✓

- Talking about that participating is voluntary and can be withdrawn any time ✓
- Talking about testing procedure (How we want to do that & key factors for evaluation) ✓
- Talking about risks (risk assessment children) ✓
- Instructions to the cradle ✓
- Instructions to the app ✓
- Instructions to the equipment ✓
- Questions? Concerns? ✓

Notes:

- cradle needs to be moved between living room (daytime) and bedroom (night)

Test candidate No.:	2	Testing period:	23.05.2016-27.05.2016
Age:		8 weeks	
Contact (voluntary):			

Conversation before start: Date: 23.05.2016

How was colic identified?:

- self-diagnose, crying at least three hours per day on more than three days in a row

How is the child sleeping currently? (main sleeping time, ho often waking up):

- going to bed around 11/12 pm

Which methods tried to calm the child, which are helping?:

- carrying around
- vacuum cleaner

Checklist: - Talking about us ✓

- Talking about that participating is voluntary and can be withdrawn any time ✓
- Talking about testing procedure (How we want to do that & key factors for evaluation) ✓
- Talking about risks (risk assessment children) ✓
- Instructions to the cradle ✓
- Instructions to the app ✓
- Instructions to the equipment ✓
- Questions? Concerns? ✓

Notes:

Appendix L: Questionnaire after testing

Test candidate No.:	**1**	**Testing period:**	**22.05.2016-25.05.2016**
Age:		**7 weeks**	
Contact (voluntary):			

Conversation after test: Date: 05.06.2016

1. Test completed? (if no, reasons for termination?):
- Yes

2. Did the cradle help?:
- difficult to say, the child stopped crying naturally

3. Simplicity of using:
- yes, easy after reading the brochure

4. Any problems during the trial?:
- handling the test equipment

5. What do you like?:
- rocking function

6. What do you dislike?:
- music started suddenly to play

7. Notes:
- creating face tracking file only worked the first hours during the test (problems handeling the test equipment)
- child stopped naturally crying during the test

Crying times without functions	Crying length in total without functions	Crying times with functions	Crying length in total with functions

Test candidate No.:	**2**	**Testing period:**	**23.05.2016-27.05.2016**
Age:		**8 weeks**	
Contact (voluntary):			

Conversation after test: Date: 02.06.2016

1. Test completed? (if no, reasons for termination?):
- Yes

2. Did the cradle help?:
- Yes

3. Any problems during the trial?:
- one time speaker stopped working
- after setup of the cradle was the head lower than the feet
- Wi-Fi connection between cradle and phone lost
  → solution was restarting the cradle

4. What do you like?:
- motion function was really good
- automatically start when the child starts crying

5. What do you dislike?:
- cradle is a little bit too low

6. Notes:
- face tracking failed for an unknown reason
- 24h diagram not completely filled

Crying times without functions	Crying length in total without functions	Crying times with functions	Crying length in total with functions

Appendix M: Data head shaking

date_time	raw rotX (roll)	raw rotY (pitch)	raw rotZ (yaw)	tracking		roll	pitch	yaw	combined movement	total for 2s
Mi Jun 1 15:18:38 2016	-3,5	-29	-3,5	1		3,5	29	3,5	29,42	29,42
Mi Jun 1 15:18:38 2016	-3,5	-29	-3,5	1						
Mi Jun 1 15:18:39 2016	0,087	-27	7,5	1		3,587	2	11	11,74	41,16
Mi Jun 1 15:18:39 2016	0,087	-27	7,5	1						
Mi Jun 1 15:18:40 2016	-3,8	-29	-8,9	1		3,887	2	16,4	16,97	28,71
Mi Jun 1 15:18:40 2016	-3,8	-29	-8,9	1						
Mi Jun 1 15:18:41 2016	-3,5	-29	-13	1		0,3	0	4,1	4,11	21,08
Mi Jun 1 15:18:41 2016	-3,5	-29	-13	1						
Mi Jun 1 15:18:42 2016	1,1	-29	13	1		4,6	0	26	26,40	30,51
Mi Jun 1 15:18:42 2016	1,1	-29	13	1						
Mi Jun 1 15:18:43 2016	-3,1	-28	-18	1		4,2	1	31	31,30	57,70
Mi Jun 1 15:18:43 2016	-3,1	-28	-18	1						

Appendix N: Noise tracking (candidate 2)

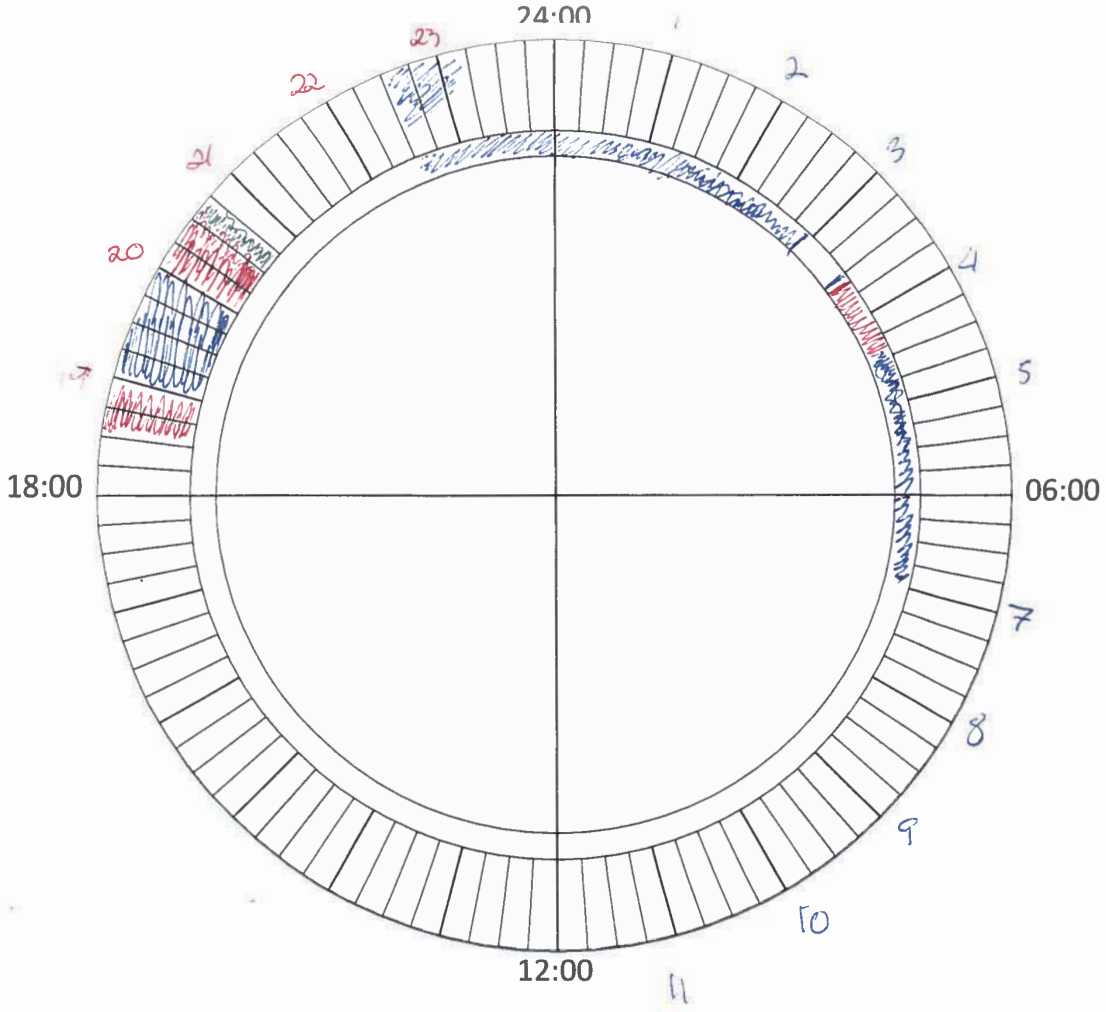
Nights - Candidate 2

Day 1 23.05.2016 22:30-07:00
2016-05-24 03:01:00, started crying
2016-05-24 03:01:36, stopped crying
2016-05-24 03:43:35, started crying
2016-05-24 03:45:30, stopped crying
2016-05-24 03:55:46, started crying
2016-05-24 04:03:36, stopped crying

Day 2 24.05.2016 23:00-06:30
2016-05-24 22:58:16, started crying
2016-05-24 23:10:52, stopped crying
2016-05-24 23:13:03, started crying
2016-05-24 23:20:06, stopped crying
2016-05-24 23:20:26, started crying
2016-05-24 23:43:58, stopped crying
2016-05-24 23:44:47, started crying
2016-05-24 23:55:12, stopped crying
2016-05-25 05:13:18, started crying
2016-05-25 05:40:47, stopped crying
2016-05-25 05:43:22, started crying
2016-05-25 05:45:56, stopped crying

Day 3 25.05.2016 23:30-07:00
2016-05-25 23:30:02, started crying
2016-05-25 23:37:25, stopped crying
2016-05-25 23:38:00, started crying
2016-05-25 23:38:51, stopped crying
2016-05-25 23:40:11, started crying
2016-05-25 23:40:42, stopped crying
2016-05-25 23:41:23, started crying
2016-05-25 23:41:50, stopped crying
2016-05-25 23:42:01, started crying
2016-05-25 23:43:31, stopped crying
2016-05-25 23:58:49, started crying
2016-05-25 23:58:55, stopped crying
2016-05-26 03:50:11, started crying
2016-05-26 03:50:41, stopped crying
2016-05-26 06:23:41, started crying
2016-05-26 06:23:51, stopped crying

Test candidate No.:	2	**Testing period:**		**Date:**	23. MAI 2016
Age:	8 weeks				
Contact (voluntary):					



Blue.....Sleeping

Red.....Crying

Green...Awake, calm, happy

Yellow..Awake, moving, unhappy

IMPORTANT

"Sleep time for the night" marked in the inner circle area

Longer times the child was outside the cradle during the night?

Yes ☐ No ☐

Own impression if the cradle helps:

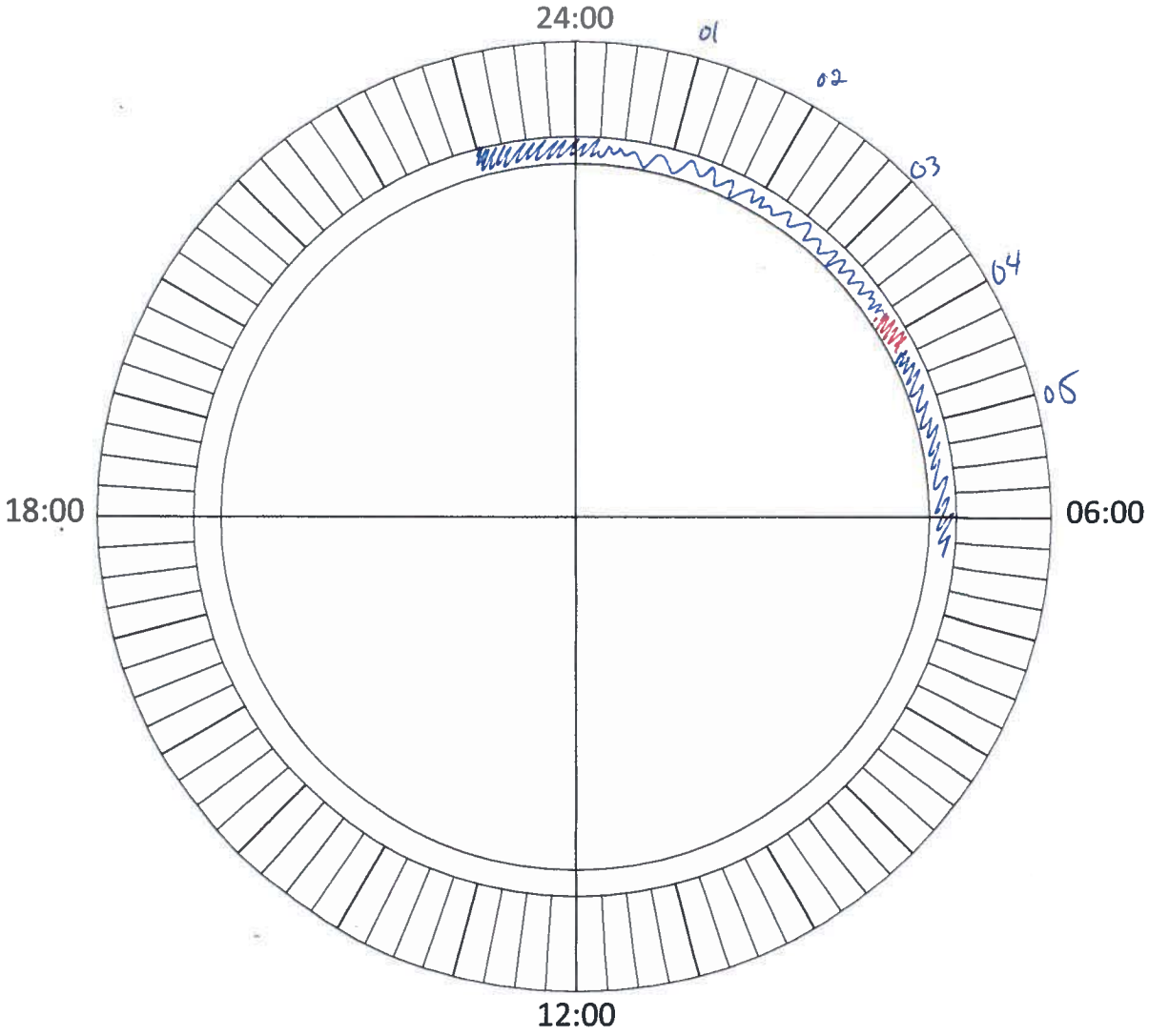
Yes ☐ No ☐

Other observations:

_____

_____

Test candidate No.:	0	**Testing period:**		**Date:**	24. mai 2016
Age:	8 weeks				
Contact (voluntary):					



Blue.....Sleeping

Red.....Crying

Green...Awake, calm, happy

Yellow..Awake, moving, unhappy

IMPORTANT

"Sleep time for the night" marked in the inner circle area

Longer times the child was outside the cradle during the night?

Yes ☐ No ☐

Own impression if the cradle helps:

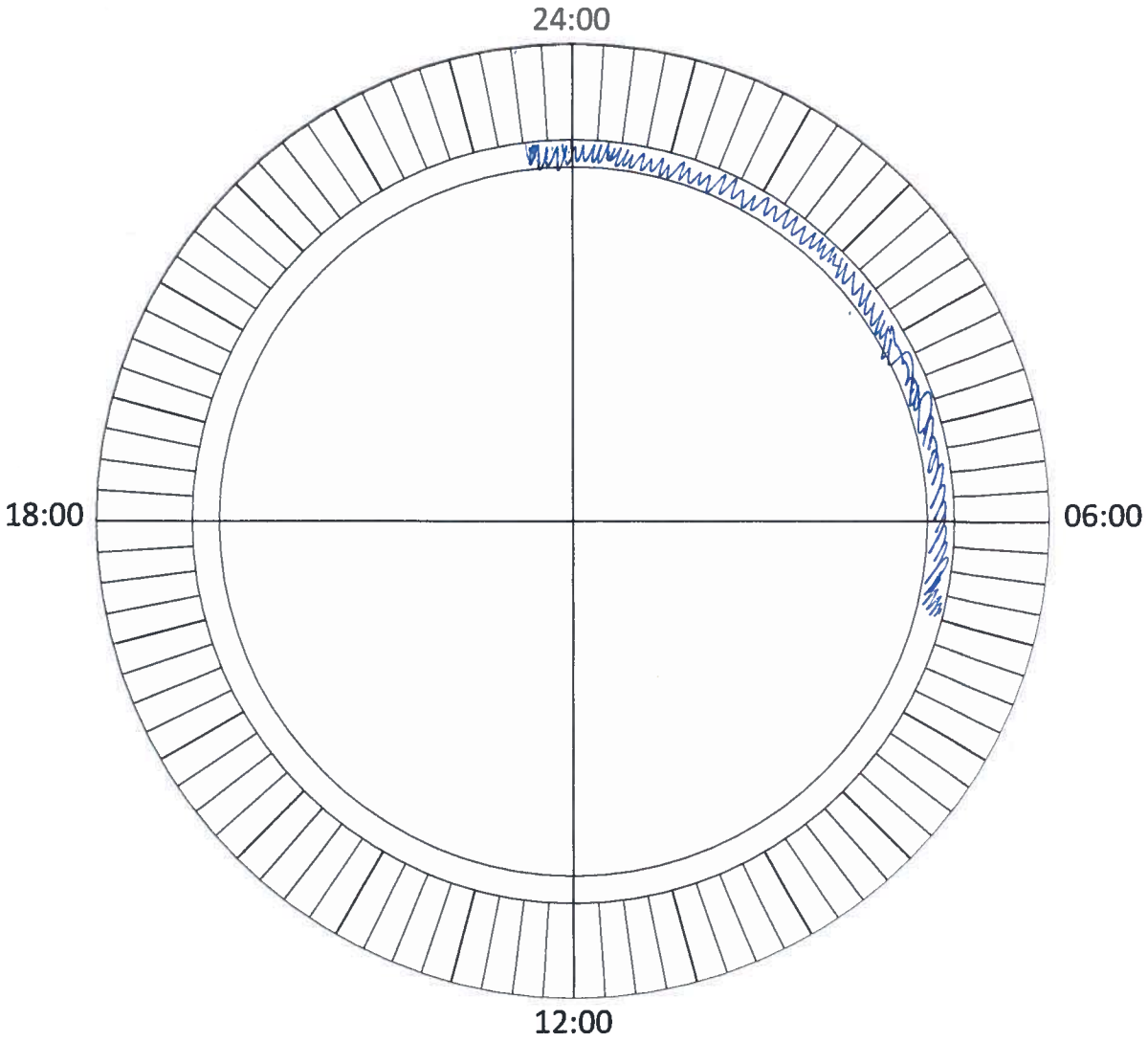
Yes ☐ No ☐

Other observations:

_____

_____

Test candidate No.:	2	**Testing period:**		**Date:**	25. mai 2016
Age:	8 weeks				
Contact (voluntary):					



Blue.....Sleeping

Red.....Crying

Green...Awake, calm, happy

Yellow..Awake, moving, unhappy

IMPORTANT

"Sleep time for the night" marked in the inner circle area

Longer times the child was outside the cradle during the night?

Yes ☐ No ☐

Own impression if the cradle helps:

Yes ☐ No ☐

Other observations:

_____

_____

Testing of the soothing effect of the ColiCot cradle on colic infants

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Abstract

Colic is a condition in which an otherwise healthy infant cries or displays symptoms of distress frequently and for extended periods of time. The symptoms occur without any discernible reason. 16-29 % of all infants suffer from colic during their first three months. Infant crying can have an influential effect on the stability of the family. Crying and the fatigue that typically accompanies colic, can inflict enormous emotional strain causing parents to feel they are providing inadequate care, triggering anxiety, stress, resentment and low self-esteem. Research has not proven the reason for colic, but several measures are identified which have efficient soothing effects. These are mainly related to sounds and rocking motions.

To help infants and parents in this exhausting time, NTNU professors and students have developed a smart colic crib (ColiCot) that combines adaptive and patented soothing sounds and rocking motions.

To benchmark the soothing effects, prototypes and test procedures have been developed. The test procedures focus on all functional aspects to support further design improvements.

Keywords: colic; cradles; testing; soothing effects

Introduction

Colic infants have difficulties falling asleep and sleeping intervals are mostly short. Colic is defined as a healthy and well-fed infant with seizures of fussing, irritability or crying that last for a total of more than three hours a day. The seizures occur for at least three days in a week during three weeks. At the time of these attacks the infant is inconsolable [1]. Around 16-29 % of all infants from a few weeks to three months of age suffer from colic [2] – [5].

The crying of colic infants has not yet been explained medically [1], [6].

Soothing the infant has little effect leaving the mother with feelings of humiliation and failure. The parents of colicky infants often have a lack of sleep and are physically exhausted [5], [7]. This leads to feelings of anger, agitation, anxiety, depression, frustration, helplessness, fear, resentment and loneliness [5] and [8] – [10]. Mothers of infants with colic have reported having physical symptoms from the infant's colic. This includes headaches, shortness of breath, nausea, exhaustion and muscle strain from holding the infant [5].

Drugs, diets and physical treatments exist to relieve the symptoms of colic [6], [11], [12]. The effect of the remedies is however difficult to evaluate since colic usually stops by itself around

the age of three months [6], [13]. A cradle that mechanically rocks the infant has positive effects. Both the rocking movement and the monotonous sound is soothing [1].

On today's market there are several mechanical products imitating the movement of a cradle [14]-[17]. These are all put into motion either by the parents or the infant itself. The rocking movement and the sounds that sooths some infants are not combined in these products. Therefore a new cradle, the ColiCot, is under development.

The ColiCot cradle relieves symptoms of colic by rocking and swinging the infant. There is also a built-in audio system which plays music. The cradle is fully automatic with a stationary mobile phone comprising an app that controls the cradle. It measures the sound level of the infant, and starts to move the cradle when the level is sufficiently high, set by the parents. In addition, music starts playing when the cradle starts moving. There exists two working prototypes of the cradle.

The aim of the present study is to evaluate if the ColiCot cradle relieves symptoms of colic for infants.

Method

Two infants tested the cradles. The parents of the infants presumed they were suffering from colic.

The test should indicate what state the infant is in. The infant's sound level and movement indicates whether the infant is calm or crying [18]:

- Sound level ≥ 65 dB and gross movements = crying
- Sound level ≥ 65 dB and small/no movements = calm/asleep and background noise
- Sound level < 65 dB and small/no movements = calm/asleep
- Sound level < 65 dB and gross movements = infant lifted up or laid into cradle

These values are similar to earlier studies by Prechtl and Beintema [19].

Active infrared technology is used to track the movement of the infant. This technology allows observation of movements under any light condition for a reasonable price. In addition, there are no known negative effects using active instead of passive technology. The restriction is that exclusive movements of the head can be observed and tracked.

The software FaceTrackNoIR is used for tracking the head movement of the infant. This software uses input from an infrared source. FaceTrackNoIR tracks fast head movements in a three-dimensional space in real-time. It is possible to track horizontal head rotations around the ear-to-ear axis from -30° to +60° and around the vertical axis from -90° to +90° which is approximately the entire possible range of the head rotations of a human. The rotational error is less than 3°. The head angles are registered every second.

An infrared camera is connected via local Wi-Fi to a laptop that stores the registered values of the head movement.

The gross movements are identified using the head position data. The complete calculation follows these steps:

- Absolute value for the angle of movement is calculated by subtraction of current angle with the previous angle (for pitch, roll and yaw)
- Calculating the length of the vector from previous to current position in order to get the combined movement for all angles
- Adding the current and the previous value for the combined movement to get the total movement for a timespan of two seconds

The total combined movement over two seconds needs to be greater than 20° to be classified as a gross movement.

The microphone of the mobile phone is used for registering the sound level.

The observations are performed in the “main-sleeping-time” of the infant. Children in this age sleep naturally on their back. This allows the camera to recognize their face and track their head movements.

Before testing:

- Conversation with the parents about the infant’s preferences
- Set-up of the equipment

Phase 1:

Day 1:

- Usage of the ColiCot with deactivated functions, without observation, for acclimatization

Day 2:

- Usage of the ColiCot with deactivated functions
- Parents need to complete a 24hr behavior diagram
- Observation during the night (start of the tracking software)
- Collection of the tracked data the next morning

Phase 2:

Day 3:

- Usage of the ColiCot with activated functions
- Parents need to complete a 24hr behavior diagram
- Observation during the night (start of the tracking software)
- Collection of the tracked data the next morning

Day 4:

- Usage of the ColiCot with activated functions
- Parents need to complete a 24hr behavior diagram
- Observation during the night (start of the tracking software)
- Collection of the tracked data the next morning

After Testing:

- Conversation with the parents evaluating the effectiveness of the cradle

Results

For the first test candidate the files for face tracking were overwritten each day. Because of this there only exists data for face tracking of the last day of the test period.

There was no active face tracking for the second infant. The parents of the infant experienced a soothing effect of the cradle on their infant.

Analysis

There is only data for one day of the test period for the first infant. Therefore this family is excluded from the study.

Since the head movement of the second infant was never observed, this child is excluded from the results.

A major error source is a low number of test participants, which can't give a high validity for the test result.

The limited data output is a major issue. To ensure that the test is running as it is supposed to and to create a usable data output, it would be necessary for the examiner to be present during the tests. All the participants were too far away in order to follow them up every day of the testing period. Therefore the parents needed to handle the test equipment themselves. Always being available for the parents, or accessing the laptop via remote control could avoid problems and ensure that everything is working properly.

Possible reasons for the failed face tracking are:

- Lost Wi-Fi connection between camera and laptop
- Wrong camera settings causing errors in the head tracking software
- The infant's head was outside the field of view of the camera
- Face tracking software failed in finding landmarks on the face of the infant

Movements faster than the time between two registrations of the head position may not be identified. Increasing the tracking rate will detect these movements.

Conclusion

A sufficient number of tests have not been performed. For the tests that were performed, the registering equipment did not work properly. This means there are no valuable results. Hence, a proper validation of the ColiCot cradle's effect in reducing symptoms of colic in infants is impossible based on the current test results.

Further tests need to be executed in order to evaluate how helpful the ColiCot cradle is.

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NTNU HMS	Kartlegging av risikofylt aktivitet	Utarbeidet av	Nummer	Dato
		HMS-avd.	HMSRV2601	22.03.2011
		Godkjent av		Erstatter
		Rektor		01.12.2006

Enhet: **Department of Engineering Design and Materials** **Dato:** 02.02.2016

Linjeleder: **Torgeir Welo**

Deltakere ved kartleggingen (m/ funksjon)**:** **Terje Rølvåg, veileder/ Christian Börner, student**

(Ansv. veileder, student, evt. medveiledere, evt. andre m. kompetanse)

Kort beskrivelse av hovedaktivitet/hovedprosess: Masteroppgave student Christian Börner. Colic Crib Testing

Er oppgaven rent teoretisk? (JA/NEI)**:** NEI *«JA» betyr at veileder innestår for at oppgaven ikke inneholder noen aktiviteter som krever risikovurdering. Dersom «JA»: Beskriv kort aktiviteteten i kartleggingskjemaet under. Risikovurdering trenger ikke å fylles ut.*

Signaturer: *Ansvarlig veileder:* Terje Rølvåg 2/2-16 *Student:* C. Börner

ID nr.	Aktivitet/prosess	Ansvarlig	Eksisterende dokumentasjon	Eksisterende sikringstiltak	Lov, forskrift o.l.	Kommentar
1	Cradle Transport					
2	Handling infants					
3	Lab Work					

NTNU HMS	Risikovurdering	Utarbeidet av	Nummer	Dato
		HMS-avd.	HMSRV2601	22.03.2011
		Godkjent av		Erstatter
		Rektor		01.12.2006

Enhet: **Department of Engineering Design and Materials** **Dato:** 02.02.2016

Linjeleder: **Torgeir Welo**

Deltakere ved kartleggingen (m/ funksjon): **Terje Rølvåg, veileder/ Christian Börner, student**

(Ansv. veileder, student, evt. medveiledere, evt. andre m. kompetanse)

Risikovurderingen gjelder hovedaktivitet: Masteroppgave student Christian Börner. Colic Crib Testing

Signaturer: *Ansvarlig veileder:* *Student:*

ID nr	Aktivitet fra kartleggings-skjemaet	Mulig uønsket hendelse/ belastning	Vurdering av sannsyn-lighet	Vurdering av konsekvens:				Risiko-Verdi (menn-eske)	Kommentarer/status Forslag til tiltak
			(1-5)	Menneske (A-E)	Ytre miljø (A-E)	Øk/ materiell (A-E)	Om-dømme (A-E)		
1			A2	A2					
2			A2	B1					
3			A2	A2					

NTNU HMS	Risikovurdering	Utarbeidet av	Nummer	Dato
		HMS-avd.	HMSRV2601	22.03.2011
		Godkjent av		Erstatter
		Rektor		01.12.2006

Sannsynlighet vurderes etter følgende kriterier:

Svært liten 1	Liten 2	Middels 3	Stor 4	Svært stor 5
1 gang pr 50 år eller sjeldnere	1 gang pr 10 år eller sjeldnere	1 gang pr år eller sjeldnere	1 gang pr måned eller sjeldnere	Skjer ukentlig

Konsekvens vurderes etter følgende kriterier:

Gradering	Menneske	Ytre miljø Vann, jord og luft	Øk/materiell	Omdømme
E Svært Alvorlig	Død	Svært langvarig og ikke reversibel skade	Drifts- eller aktivitetsstans >1 år.	Troverdighet og respekt betydelig og varig svekket
D Alvorlig	Alvorlig personskade. Mulig uførhet.	Langvarig skade. Lang restitusjonstid	Driftsstans > ½ år Aktivitetsstans i opp til 1 år	Troverdighet og respekt betydelig svekket
C Moderat	Alvorlig personskade.	Mindre skade og lang restitusjonstid	Drifts- eller aktivitetsstans < 1 mnd	Troverdighet og respekt svekket
B Liten	Skade som krever medisinsk behandling	Mindre skade og kort restitusjonstid	Drifts- eller aktivitetsstans < 1uke	Negativ påvirkning på troverdighet og respekt
A Svært liten	Skade som krever førstehjelp	Ubetydelig skade og kort restitusjonstid	Drifts- eller aktivitetsstans < 1dag	Liten påvirkning på troverdighet og respekt

Risikoverdi = Sannsynlighet x Konsekvens
Beregn risikoverdi for Menneske. Enheten vurderer selv om de i tillegg vil beregne risikoverdi for Ytre miljø, Økonomi/materiell og Omdømme. I så fall beregnes disse hver for seg.

Til kolonnen "Kommentarer/status, forslag til forebyggende og korrigerende tiltak":
Tiltak kan påvirke både sannsynlighet og konsekvens. Prioriter tiltak som kan forhindre at hendelsen inntreffer, dvs. sannsynlighetsreduserende tiltak foran skjerpet beredskap, dvs. konsekvensreduserende tiltak.

NTNU	Risikomatrise	utarbeidet av	Nummer	Dato
		HMS-avd.	HMSRV2604	08.03.2010
		godkjent av		Erstatter
HMS/KS		Rektor		09.02.2010

MATRISE FOR RISIKOVURDERINGER ved NTNU

KONSEKVENS						
	Svært alvorlig	E1	E2	E3	E4	E5
	Alvorlig	D1	D2	D3	D4	D5
	Moderat	C1	C2	C3	C4	C5
	Liten	B1	B2	B3	B4	B5
	Svært liten	A1	A2	A3	A4	A5
		Svært liten	Liten	Middels	Stor	Svært stor
		SANNSYNLIGHET				

Prinsipp over akseptkriterium. Forklaring av fargene som er brukt i risikomatrisen.

Farge	Beskrivelse
Rød	Uakseptabel risiko. Tiltak skal gjennomføres for å redusere risikoen.
Gul	Vurderingsområde. Tiltak skal vurderes.
Grønn	Akseptabel risiko. Tiltak kan vurderes ut fra andre hensyn.