University of Twente

Systems Engineering

Engineering Report

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Abstract

This report describes the design of a neonatal mechanical respiratory system. The system performance specifications can be found in the beginning of the report along with some background information about the disease the machine will be used for. Then a description of the system is given by stating the boundaries, so where the system ends, the subsystems and the interfaces between them. This helps create a better idea of how the system looks like and what it can do. Further a thorough description of each module can be found. The choices made are explained and compared to other technologies.
A risk analysis is then performed to the system and how the modules and the device as a whole will be tested to minimize the risk is described. Finally the user scenarios are discussed, so how the device will be handled after its been built and left the company. The report is concluded with a short discussion and conclusion of this project.

Contents

1 Introduction

DEMCON's goal is to develop a new neonatal respirator system for use on a neonatal intensive care unit. In contrast to existing devices, this new system should be less complex to use, integrate all subsystems more efficiently, have a decent robustness to it, increased safety and a cost effective design. The integration of systems allows for increased usability by reducing the amount of cables and monitors. This engineering report assesses different design options for neonatal respiratory system, presents a solution to each subsystem case and argues its trade-offs. Due to the safety issues of possible power loss and moving patients around the system will be semi-mobile and prepared with several different breathing patterns.

2 System Performance Specifications

2.1 Top Level Business Requirements

The initial work process of this product development is to formulate the top level business requirements, more precisely, aspects and features that have to be improved or delivered to provide value for the business. The top level requirements for this new product to bring value to DEMCON are:

- Usability
- System Integration
- Robustness
- Safety
- Cost Effectiveness
- Compatibility

2.2 User Specifications

User specifications describe the user's expectation of the project scope, with emphasis on product parameters and process performance parameters. They can further be subdivided into functional, design and application specifications.
The functional specifications concern the health of the baby. The main interest of the user is to maintain the patient properly by applying the proper breathing pattern and clearly monitoring all relevant information.
The design specifications include requirements to fulfil the mobility of the device as well as the affordability. The application specifications include requirements for the mode of operation as well as the time dimension of the functioning of the device. The future users want to use the device in one specific location but allow for transportation and off-grid usage. The

system must be built to be moved around both effectively and efficiently. All these conditions which need to be considered are:

- Neonates' health
  - SpO_2 between 95 and 100% ideally, below 90% is unhealthy, 1% precision [1]
  - Apply breathing frequencies from 1-30 Hz, 1 Hz precision
  - Heart rate and blood pressure should be monitored constantly
  - Humidification between 40-60 % [2]
- Mode of Operation: Two Modes of Operation: Grid & Battery
  - Operating Temperature: Temperature range in which device works with full capacity 10-40 °C
  - Shock Resistance: Robustness towards intensive usage. Like bouncing around hospital walls
  - Mobility System: Room to room, should not topple over when leaned against, be able to stay stable and stationary if wanted.
- Operating time
  - Grid Mode: 10 year life span, check-up maintenance every year
  - Battery Mode: 1 Hour at full capacity, 2 Hour recharge, battery lifespan of 10 years, be able to deliver 2kWh

3 Background Information

The neonatal respiratory distress syndrome (RDS) is a condition which often occurs with premature babies which are born too early (before 37 to 39 weeks). The lungs of the baby are then not yet fully developed. The alveoli cannot fully inflate themselves due to the lack of surfactants in the alveoli. This reduces the gas exchanging capacities significantly. Special ventilation systems are required together with other systems for the baby to keep it alive.

Over time, there has been significant development in respirator systems (see the 9 window diagram). In the past they used to have so called iron lungs. A baby in need of such an iron lung was placed into a cylindrical steel drum which only allowed the head and neck to remain free. Pumps were attached to the drum to periodically decrease and increase the air pressure within the chamber. Downsides with this kind of system was that the baby continuously needs to be in the chamber, making it impossible to for example have surgery. It has therefore been superseded by high end respirator systems, which we need to develop as well. [3]
This system consists of multiple subsystems which work together in order to keep the baby

alive. All these subsystems will be explained later on. Later in the future this system may be superseded by another system, which may work fully automated and doesn't need regular supervision by a doctor. This enables the baby to be placed at home for example. This is of course far away but still worth noting as it can be an interesting development.

	Past	**Present**	**Future**
Environment	Hospital	NICU	NICU/home
System	Iron Lung	High end ICU respirator system	Fully automated respiratory system
Computer	Iron Chamber and Pressure Pump	Subsystems (see section 3)	-

Table 1: The 9 window diagram. Vertically is the hierarchical development, horizontally the temporal development.

The 9 window diagram seen in Table 1 is a useful tool that can help cut through the complexity so that the problem that needs to be solved becomes clear.

4 Boundaries

To have a better idea about how the entire system is placed in the hospital or NICU, the boundaries of the system are looked at. A schematic of how it would look like can be seen in Figure 1.

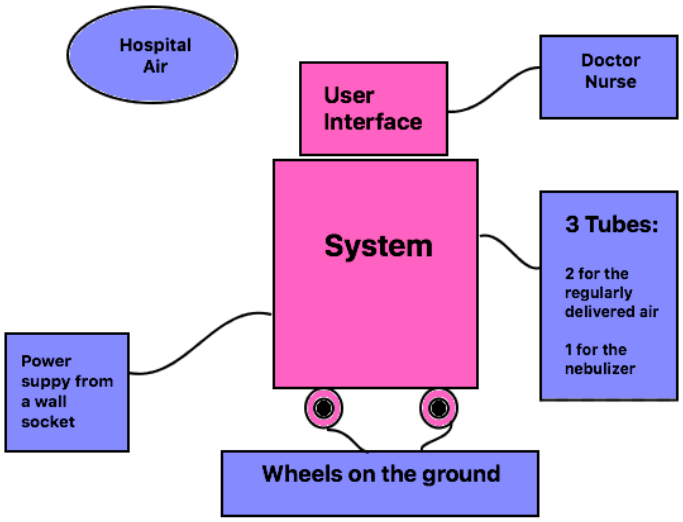

Figure 1: Boundaries of the system

When the system is in use and is not being transported it is connected to the wall through a plug to supply the needed power.
The wheels are the influence between the ground and the system. They make the transportation much easier and and also it makes it less likely to tip over. When the system is not being moved of course there will be some breaks that can be manually triggered with a pedal.
The user interface's boundary speaks for itself; its interface is with the user, so the doctor or nurse. This interface is thoroughly explained in Section 4.
The air control module has an interface with 3 tubes; two for supplying the air regularly, so they make the breathing possible, and one to distribute the medicine from the nebulizer. These tubes should be chosen to be bio-compatible and tested to be non-toxic to the patient. The lifetime of the tube should also be looked at to provide the best care and insure that no harm will be caused to the patient. The system itself is compatible with most standard tubes used for this function, but our company does not provide these tubes so they should be ordered by other companies.
The rest of the system has an interface with the hospital air (or the air of the environment around it). This air is also used as an air supply for the ventilator.
As specified in Section 2 the system should be sturdy. They system is designed in such a way that if someone leans on it it will not easily tip over. This is done by controlling where the weight is. The power supply, which is the heaviest module, is placed at the bottom of the system. This makes the centre of mass to be lower, hence makes the system harder to tip over. The systems sturdiness and robustness makes it possible for the hospital staff to work around it and transport it without having to be too careful around it.

5 Subsystem Diagram

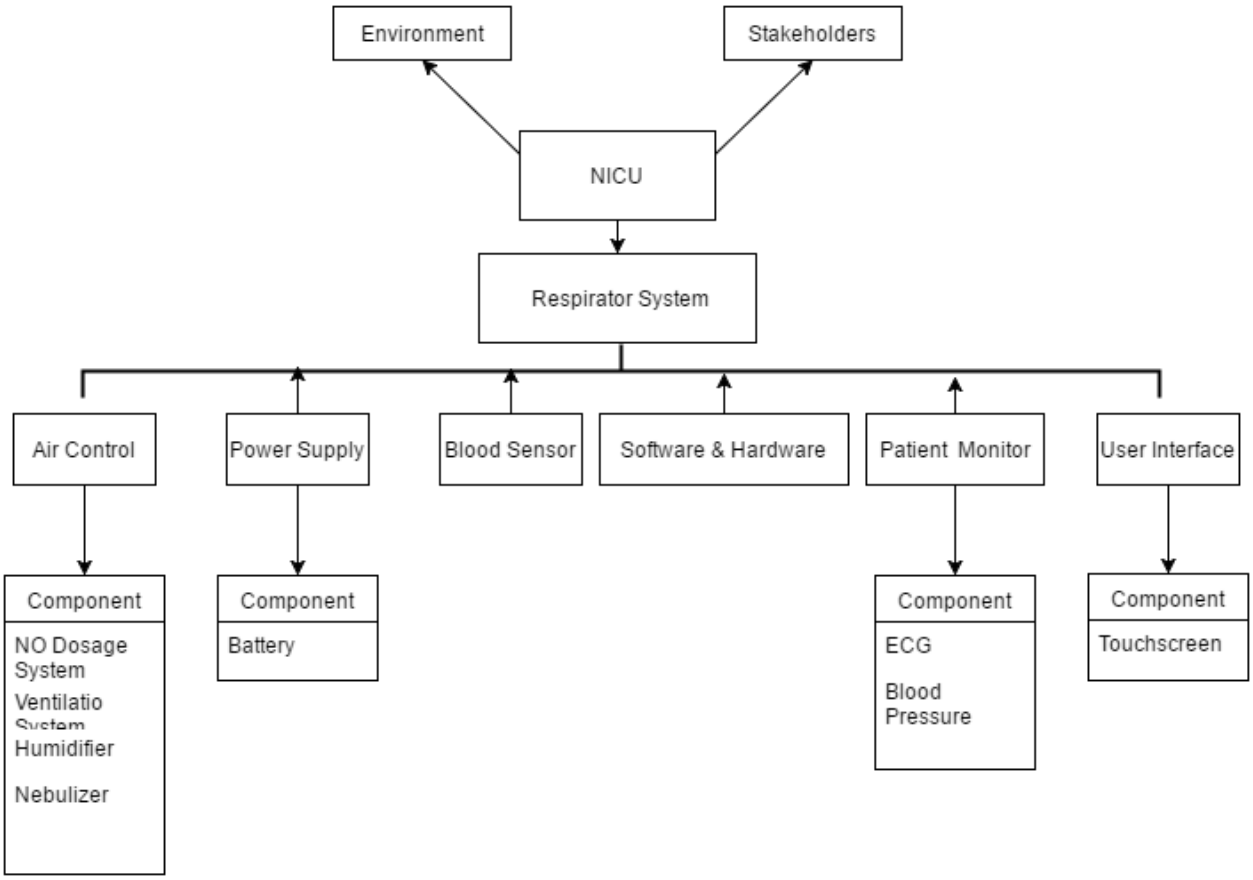

Figure 2: Subsystem Diagram

6 N2 Diagram

Figure 3 shows a modular N2 diagram. In this diagram all subsystems and the interfaces between them are shown. The surroundings provide all sensors with the information they need. With This information the sensors can provide data to the software. With the data received the software can control the air control unit. At the user interface the the date is depicted for the nurses and doters to see and interact with. The adjustments given to the interface by the surroundings go to the software which will adjust the air control. The power supply subsystem receives power from the surroundings and distributes it to all other subsystems.

Surroundings	patient's blood	hospital air	patient's heart rate & blood pressure	x	electrical power	nurse/doctor input
x	Blood sensor	x	x	data	x	x
x	x	Air Control	x	data	x	x
x	x	x	Patient Monitoring	data	x	x
x	x	feedback	x	Software	power allocation	processed data
x	power	power	power	power	Power Supply	power
information	x	x	x	adjustments	x	User Interface

Figure 3: 2 diagram

7 Budgets

Several system budgets (Table 2) were made to state the available quantity and the way it is divided over the system. For the budget below mass, space, power and costs (which are the costs of building the system, so not the costs of the client) were considered.

7.1 Mass

As decided in the specifications section, the total system could weigh 50 kg. Calculated in the budget was an approximate weight of 47.3 kg which gives a 2.7 kg margin for errors, which should be sufficient. The most weight goes to the batteries, as there should be a large battery powering the system in case of emergency. The rest is divided by using guesstimation, common sense and knowledge to get to reasonable numbers.

7.2 Space

The whole system should be about 1 cubic metre in size. It was decided to look at percentages of space here. As can be seen in Table 2 there is still a 13% error margin, which should be more than sufficient in the end. Most of the space again goes to the batteries which makes sense as it also uses most weight. Again the rest was divided by using guesstimation, common sense and knowledge.

Item	Mass(kg)	Space(%)	Power(%)	Costs(Euro)
Blood Sensor	2	2	5	2000
Ventilation System	3.5	10	30	12000
Humidifier	2.8	5	8	500
NO Dosage System	5.3	10	5	1500
Nebulizer	0.2	2	4	1000
Patient Monitor	5	7	17	4000
Software, Hardware and User Interface	4	5	25	8000
Housing	4.5	6	-	500
Power Supply	15	30	-	10000
Transport System	2.5	5	-	200
Interfaces(cables, etc)	2.5	5	-	200
Total	47.3	87	94	39900
	50 kg in total	1 cubic metre in total	2 kWh (maximum)	
	2.7 kg margin for error	13% margin for error	6% margin for error	

Table 2: Mass, space, power and costs budget.

7.3 Power

The system should at maximum draw 2 kWh. Again, it was decided to look at percentages here. The most power is drawn by the ventilator system, as that is the main module of the system. Also, the hardware, software and user interface can draw lots of energy to process all the data. Again, the numbers were divided using guesstimation, common sense and knowledge.

7.4 Costs

The costs considered in this section are the costs of building the system, which means either buying the raw materials to build the module or component or buying it directly from another company. The costs of the client will be higher than these costs. The total costs of the system is approximately 40000 Euro. It was hard to get these numbers, as there was not a lot of information on the internet on how much the separate modules will cost. Using the information we got from DEMCON plus common sense and guesstimation, this budget was made.

8 Module 1: Blood Sensor

Function: measure the amounts of certain gases dissolved in the blood of the baby
Decision: TCM CombiM and Nellcor Forehead SpO_2 Sensor
Options considered: TCM CombiM, Nellcor Forehead Sensor, V-Sign Sensor 2, Transmission Pulse Oximetry device
Criteria: non-invasive, continuous measurements, accuracy, size and weight, price, life years and maintenance

The blood monitor is needed to measure the amounts of certain gases dissolved in the blood of the baby. This information will then be used to alter the values in the air control to match that for what the baby needs. Measurements are constantly carried out by the blood sensor to ensure that the required adjustments are on time.

The blood gas monitor has to measure these values:

- pO_2: The partial pressure of oxygen is a measure of the pressure of oxygen in the blood and determines how well oxygen is able to flow from the lungs to blood.
- pCO_2: The partial pressure of carbon dioxide is a measure of the pressure of carbon dioxide dissolved in the blood and it determines how well carbon dioxide is able to flow out of the body.

The final decision will be made on the following criteria:

- **Non-invasiveness:** As the baby makes unexpected and uncontrolled movements it seems better to have a non-invasive blood sensor. This way is safer for the baby and easier to control.
- **Continuous measurements:** The more continuous it measures the pO_2 and pCO_2, the more information you have for keeping the values of the baby as good as possible. As stated in the specifications, it should measure new data at least every 1 minute.
- **Accuracy:** The more accurate the measurements are the better the values of gases can be altered.
- **Size and weight:** The more compact and small the device is the easier it is to implement in the total system.

To measure pO_2 of the blood two options are available that meet the non-invasive and continuous measurements criteria. These options are Transmission Pulse Oximetry(TPO) or Reflectance Pulse Oximetry(RPO).The measurements also need to be provided in extreme conditions such as severe cardiovascular collapse.[4]
Measuring the pCO_2 if The blood has 2 non invasive options the TCM CombiM and the V-Sign Sensor 2. The TCM CombiM is latex free, this is important as the patient might have a latex allergy. The range of both of the devices is up to 26.7 kPa $tcpCO_2$.[5][6]

	Accuracy	Continuous measurements	Size and weight
RPO	+	++	+
TPO	+	+	+

Table 3: O2

	Accuracy	Continuous measurements	Response Time
V-Sign	+	+	75 sec
CombiM	+	+	60 sec

Table 4: CO2

Conclusion: Due to the Reflectance Pulse Oximetry being able to measure the patients pO_2 in more situations than other options, including the invasive pO_2 measurement methods, makes it the best option. A good option for the RPO is the Nellcor Forehead SpO_2 Sensor. To measure the patients CO2 the TCM CombiM is the best option. The reason for this is the faster response time and that it is latex free.Another option considered was using only the TCM CombiM as this also measures the SpO_2 but due to the advantages of the Nellcor forehead sensor both systems will be used

Safety: It is important to make sure that the sensor is made of non-toxic material such that it is safe to use for neonates. As the immune system of neonates is not yet fully developed the chances of getting infected by a disease or virus should be kept as low as possible. For this reason the sensor needs to be cleaned thoroughly for each new patient.

9 Module 2: Air Control

9.1 Component 1: Ventilation System

Function: designed to move breathable air into and out of the lungs of an infant at the appropriate frequency
Decision: HAMILTON-C2
Options considered: HAMILTON-C2[7], Eternity SH180[8]
Criteria: frequency control, safety, size, infant compatibility

A mechanical ventilator is a breathing machine that delivers warmed and humidified air to a baby's lungs and it temporarily breathes for them while they recover. The air is delivered to the baby's lungs through an endotracheal tube (a small plastic tube that is inserted through a baby's nose or mouth down into the windpipe). The amount of oxygen, air pressure and number of breaths per minute can be regulated to meet each baby's needs. In babies receiving oxygen, it should be administered to pre-term infants in concentrations sufficient to maintain PaO_2 between 50-70 mmHg or saturation (by pulse oximetry) between

85-92%. Higher O_2 concentrations may exacerbate lung injury and may increase the risk of retinopathy. [9] Assisted ventilation at fast rates (more than 40 breaths per minute) improves outcome more than at lower rates. Ventilators that are triggered and integrate with the baby's respiratory effort, high-frequency oscillatory ventilation (HFO) and high-frequency jet ventilation are claimed to be more effective and safer but there is currently no major evidence of clinical benefit. HFO ventilation uses respiratory rates that greatly exceed the rate of normal breathing, up to frequencies of 30 Hz. However, eventually the baby needs be able to breathe on its own without the help of the system. For this reason a mechanical ventilator can only be used for up to 2 weeks otherwise the babies lungs get used to the help and are not able to recover they're function completely. In order to do so the ventilation is slowly reduced during this time frame to give the lungs a chance to develop. Thus, it is important that all the criteria above be easily adjustable and should be very reliable.

	Frequency Control	Compatibility	Advantages	Disadvantages
HAMILTON-C2	++	++	lung-protective ventilation, >6hr battery life, low tidal volumes (2ml)	expensive
Eternity SH180	+	o	cheap, high accuracy sensor	1 hour battery life

Safety: Several complications can arise in patients that are on mechanical ventilation for long periods of time. Perhaps most feared among medical complications occurring during mechanical ventilation are pneumothorax, bronchopleural fistula, and the development of nosocomial pneumonia. Complications are fortunately rare and do not occur in every patient, but due to their seriousness and severity they require extensive knowledge, experience and responsibility by healthcare workers. [10] The HAMILTON-C2 features an intelligent ventilation mode, Adaptive Support Ventilation (ASV) which continuously adjusts respiratory rate, tidal volume, and inspiratory time depending on the patient's lung mechanics and effort in order to avoid detrimental patterns. For this reason it is the much safer choice of the two options.

Conclusion: Based on the data in the table above the HAMILTON-C2 is clearly a better choice for a neonatal ventilator system due to its intuitive user interface, increased safety and comfort for the patient. This device can administer tidal volumes as low as 2ml which allows to minimize barotrauma. The HAMILTON-C2 is a high-performance non-invasive ventilator that supports several modes such as ASV, pressure controlled and volume controlled. Nonetheless, this is only an example of the type of ventilator that would be ideal for this application. Any other type or model that fits the same specifications and criteria may also be used.

9.2 Component 2: Humidifier

Function: regulate temperature and moisture level of air that goes into the infant
Decision: HAMILTON-H900
Options considered: MR850 Heated Humidifier form Fisher&Paykel [11], HAMILTON-H900 from Hamilton Medical [12]
Criteria: compatible with infants, easy to control

The airflow generated by a ventilator is often greater than what the body is used to. Using a humidifier with a ventilator can make a positive difference to therapy comfort by adding moisture and warmth to the air delivered by the devices, reducing the symptoms of dryness and congestion, and improving comfort and compliance. Humidification is necessary to prevent hypothermia, disruption of the airway epithelium, bronchospasm, atelectasis, and airway obstruction. When providing active humidification to patients who are invasively ventilated, it is suggested that the device provide a humidity level between 33 mg H_2O/L and 44 mg H_2O/L and gas temperature between 34°C and 41°C with a relative humidity of 100%. [13]

	Ease of use	Compatibility	Safety
MR850 Heated Humidifier	+	+	+
HAMILTON-H900	++	++	+

Conclusion: Based on the criteria mentioned above a better choice for the humidifier in this case is the HAMILTON-H500 due to its intuitive user interface and better compatibility with infants than the other choice.

9.3 Component 3: NO Dosage System

Function: increases oxygen into the blood flow
Decision: INOmax DS
Options considered: INOmax DS,
Criteria: Dosage accuracy

Inhaled nitric oxide is used in our system because it has very selective vasodilator properties which increases the flow of oxygen into the blood. In our system the NO gas will be administered directly into the infant's lungs mixed with ventilator gases and will be absorbed into the pulmonary circulation.[14] In addition a pulmonary artery dilation occurs which reduces the pulmonary artery pressure this will improve the short-term oxygenation in the infant's lungs.
Although NO has good short-term advantages for the neonatal patient it also has some long-term disadvantages. High dosages of NO can affect the blood with platelet formation and bleeding time which can potentially increase the risk of haemorrhage which can pose a serious risk to infants. Therefore to reduce the risk of toxicity or side effects it is desirable to

to use the lowest effective dose.Attempts should be made to reduce iNO dose to the minimal effective dose assessed by response to changes in nitric oxide delivery. If a trial of increased nitric dose did not have any benefit in oxygenation, then reduce the dose back to the original dose.

INOMAX drug is stored as a gas mixture of NO/N2 in an aluminium cylinder at a nominal pressure of 2000 psig. The cylinder is attached to a high pressure regulator, which incorporates a pressure gauge that indicates cylinder pressure when the cylinder valve is open (see Figure 4). An injector module is placed in the ventilator gas flow between the ventilator inspiratory outlet and the humidifier. Based on the ventilator flow, the INOMAX cylinder concentration and set INOMAX dose, the proportional solenoid valve delivers 800 ppm INOMAX into the ventilator circuit via the injector module where it mixes with the breathing circuit gas flow to achieve the set dose.[15] A flow sensor inside the INOmax DS also monitors the NO flow out of the machine. A check valve is included prior to the INOmax DS drug outlet to prevent pressure effects from the ventilator breathing circuit interfering with the NO flow sensor reading.

Safety: The NO dosage system needs to be accurately controlled as the amount of NO delivered to the baby must not exceed its lowest effective dosage. This means the Flow Meter sensor needs to be extremely accurate in measuring the amount of NO in the system.

Conclusion: Based on the criteria mentioned above a better choice for the NO dosage system in this case is the INOmax DS due to its accurate method of delivering NO gas to the patient and better measurement method of analysing the NO gas content than any other choice currently available.

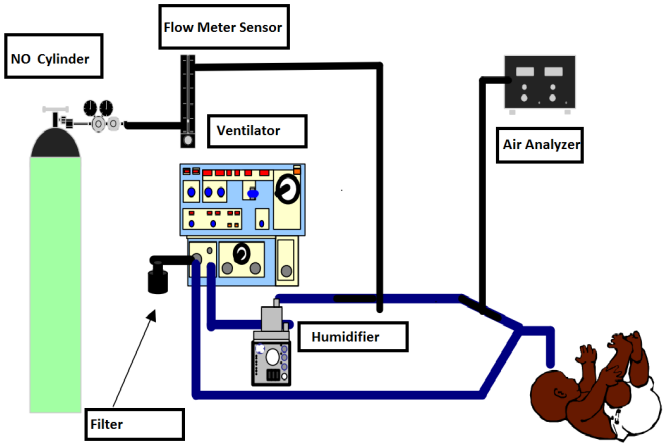

Figure 4: Ventilator diagram

9.4 Component 4: Nebulizer

Function: interface with infant, delivers aerosol gases
Decision: pneumatic nebulizer
Options considered: pneumatic nebulizer , electric nebulizer
Criteria: neonatal use , compatibility

The nebulizer is an aerosol generator that converts liquid drug solutions or suspensions into aerosol and is powered by compressed air, oxygen, a compressor, or an electrically powered device. An integrated pneumatic nebulizer An integrated synchronized Aerogen nebulizer helps to conserve expensive medications. It improves drug delivery efficiency, and offers the potential to reduce drug and personnel costs associated with in-patient treatment, while maintaining the integrity of ventilator-dependent care. The nebulizer is a more effective way of delivering the medication because infants are unable to use dry powder inhalers (the alternative delivery component to the nebulizer). The nebulizer offers the advantages because minimal patient cooperation or coordination is needed. It also has the ability to aerosolize many drug solutions and the drug concentrations and dose can be modified The aerosols can be administered using either a mouthpiece or a face mask. Ideally, a mouthpiece should be used. The nose tends to filter more aerosol than the mouth, so use of a mouthpiece should be encouraged, when appropriate. Mouthpieces cannot be used for infants and small children. In addition, the use of a mouthpiece may be uncomfortable for longer aerosol therapy. For a visual overview of the ventilation system see Figure 4.

	Compatibility	Neonatal Use
Penumatic (Aeroneb nebulizer)	++	++
Electric Nebulizer	–	–

Safety: To prevent the expiratory valve from sticking due to nebulized medications, use only medications approved for nebulization and regularly check and clean or replace the expiratory valve membrane.

Conclusion: Internal nebulizer: Pneumatic nebulizer specified for 8 l/min. The pneumatic nebulizer is inactive when low-pressure oxygen is used. Delivered ventilation is compensated for the contribution of the internal nebulizer so that the expected volume and pressure are delivered.

10 Module 3: Patient Monitoring

Function: measure the heart rate and blood pressure of the patient
Decision: ECG + oscillometric measurement device
Options considered: oscillometric measurement device + pulse oximeter/ECG

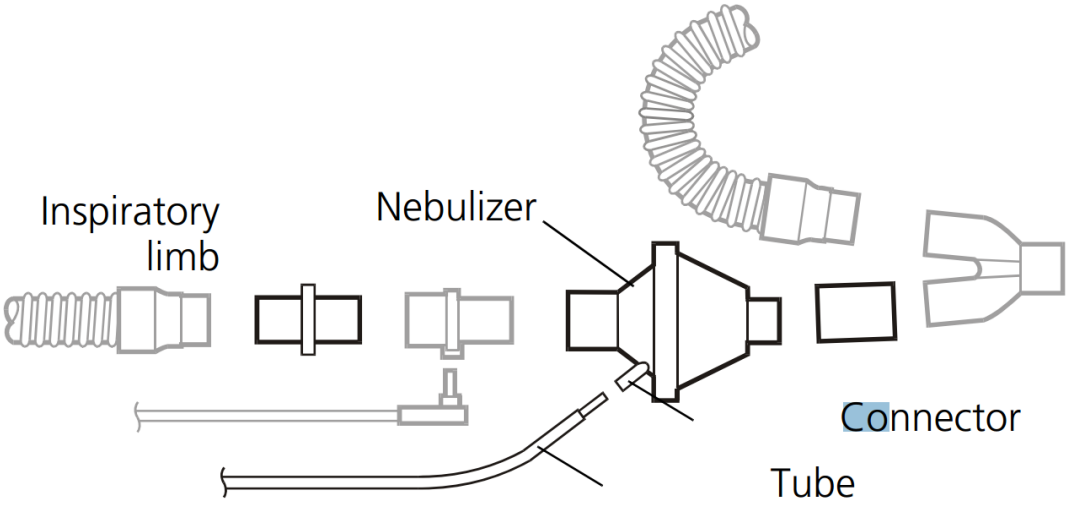

Figure 5: Nebulizer Diagram

Criteria: non-invasiveness, accuracy, continuous measurements

The patient monitoring is important to the systems as it shows that the patient is still alive. The pulse oximeter(PO) and the ECG both measure the patients heart rate continuously and in a non-invasive way. The advantage of the ECG over the pulse oximeter is that the ECG is easier to apply to the patient and measures more accurately in the first few minutes. In the first minute in 27/30 cases the ECG found the heart rate while only in 12/30 cases the PO found a heart rate in the first minute. [16].

	Accuracy	Continuous measurements	Time till measurement starts
ECG	+	+	+
PO	+	+	o

Table 5: ECG

Safety: Because the baby's immune system is not yet fully developed they are very susceptible to diseases and viruses. To minimize the chance to get infected all equipment that comes into contact with the baby must be sterile. The best way to do this is to use disposable equipment. The cuffs used by the Oscillometric measurement device should be disposable. The attachment electrodes from the ECG should also be disposable, The cable to the attachment points need to be cleaned after each use.

Conclusion: Due to the small market of blood pressure measurements devices for neonatal use and the criteria of using non-invasive device the Oscillometric measurement device is the only option available that fits the requirements. For this reason the Oscillometric measurement device will be used for this function. The important part is to make sure that the cuffs used

with the oscillometric fit on the neonatal. The best cuffs for this are the Non – Invasive Blood Pressure Cuff from ConMed[17] as this gives options for disposable and reusable cuffs. These cuffs have a range form 3-15 cm for neonatal use. For the heart rate monitor the ECG will be chosen as it gives data the moment it is applied to the the patient. This is a crucial advantages as it gives doters and nurses the information the quickest, allowing them to make important decisions sooner which could be life saving. A good system that combines the ECG and oscillometric measurement device is the Datex ohmeda s5.[18]

11 Module 4: Software, Hardware & User Interface

Function: provide patient information and enable user to control system
Decisions: Dual CPU, ECC Memory, Secured integrated Computer
Criteria: ease of use, performance & reliability, cleanability, security, advantages, disadvantages

Software is needed in the system in order to make the hardware function, without software, hardware is not doing anything. The software is located on the device itself, it is running on an closed operating system, so that it is safe and secure from changes to it by unauthorized people. It takes over a very crucial role in the device, because it controls inputs and output throughout the whole system and needs to make changes if necessary.

The user interface is important for the system because it is where the gathered data from the patient is displayed such as heart rate, blood pressure, blood oxygen levels etc. Therefore, it is strongly connected with the software, since the mentioned inputs and outputs are linked to the user interface, where personnel can make changes. It is of importance that the interface is easy to use and doesn't require extensive introduction to handling principles. On these grounds the different options will be compared with each other by ease of use and performance.

As already mentioned, hardware is a crucial aspect as well, and strongly connected with both the software and the user interface, which is why it was decided to make it one module. The hardware is the base of the integrated computer, where the software is running on. The fact that the software is needed to be absolutely reliable influences the hardware as well. There are different choices for hardware available, which are compared below.
Together, the software and user interface have the following functions:

- **Collecting Data:** Since the software is connecting all the different hardware parts, its core job is collecting the data from the blood sensor and the air control. From the sensor and the control, the data is sent to the software and stored.
- **Evaluating Data:** Based on the previously collected data, the software evaluates if the hardware (blood sensor and air control) is working correctly, in terms of air humidifying and dosage.

- **Adjusting Parameters**: If the collected and evaluated data and feedback from the sensor and the air control is determined to be insufficient (meaning, the dose or humidity is differing from certain values), it adjusts the parameters so that the dose and humidity fit the needs.
- **User Input and Control:** With the user interface of the system, the software makes the collected data accessible for nurses and employees. They can evaluate the results themselves as well as using the monitor, can send inputs such as adjustments to the software, which are then taken into account when adjusting parameters.

Criteria and Requirements: The software needs to be reliable, any wrong inputs or outputs can have serious consequences. Therefore, it should carefully being developed, tested, sand-boxed and evaluated several times before going into use. It is absolutely necessary that it does not crash or fail, because it would lead to wrong outputs and thus to the patient being in danger.

Furthermore, it needs to run on reliant hardware, which can run 24/7 without issues such as heat or crashing. Memory loss and crashes can not be tolerated.
The user interface needs to be clean, easy to use and stable, which depends on the software. It should not require a lot of training to use it, which saves time and prevents the developers from making the user interface overly complicated.

Options Considered: User Interface

	Ease of use	**Performance**	**Advantages**	**Disadvantages**
Touch-screen monitor with buttons	+	+	cheaper in comparison	touch screen requires specific conditions
Integrated computer with keyboard	++	++	direct access, more options	expensive

Options Considered: Hardware

CPU Options	**Advantages**	**Disadvantages**
Desktop-grade CPU (Intel i7 or similar)	+ In General faster + Cheaper	- Little error checking - Less reliable
Server-grade CPU (Intel Xeon or similar)	+ Better error checking + Supports ECC Memory	- More expensive
Memory Options	**Advantages**	**Disadvantages**
Standard DDR Memory	+ Cheap	- No error checking
Server-grade ECC Memory	+ Error checking, automatic finding & correcting	- More expensive

Options Considered: Software
There are not many options to choose from when it comes to software, since it has to be programmed especially for our device, it will be proprietary. It will be written by a software company which is hired on a contract. Ideally, 2 isolated development teams will work on it, as mentioned above. Other than that, there are no other options to choose from.

Safety:
The risks of the software and the user interface is mostly wrong inputs or outputs. It always needs to work. Looking at the criteria and requirements above, safety can be achieved by the following. By having two teams developing the software in parallel, but isolated to the other team, prevents a single software error from being a single point of failure. For the hardware of the computer inside the system, server grade hardware is the best and only choice. It is designed for such critical applications, can run 24/7 over the course of several years before it has to be replaced. It has further lower heat output and more safety fall-backs. The safety of the system can be increased by having two CPUs instead of one, where both are doing the same task in parallel and their outputs have to agree in the end, before a parameter adjustment is made. ECC memory is special memory for scientific applications, where it is crucial to not have any errors in the memory.[19] This adds a huge value to the system, since in combination with the server-grade CPU, it is on a very high safety level, compared to normal desktop hardware. In comparison to non-ECC memory, ECC memory reached an error ratio of 0.00% in some studies.[20]
For the safety of the user interface, the main concern lies in the cleanness of the interface. It will have a protection layer above the keyboard and screen, such that it can be easily cleaned when necessary. Since the environment is a hospital, only authorized personnel should have access to the system, which is why it will be secured with a security card.

Conclusion:
After considering the two options above for the user interface the integrated computer together with a keyboard is clearly a better choice for the user interface. Even though this option may cost somewhat more than the alternative it is a safer and better option for this application. The computer can perform different and more advanced tasks that can also be customizable by the user while the monitor mainly provides information and less customizability. Furthermore, the specific working conditions that a touch-screen monitor requires make it a less desirable choice, especially in an environment where a lot of time sensitive events take place. Security is also a priority in order to keep unauthorised personnel from accessing and modifying the settings. For this reason the access to the system will only be possible with a security card. This can be implemented for both options which is why it wasn't included in the above table as a criteria.
For the software, there are no options to consider, but emphasis is on the reliability of the developed software, making sure it is developed by 2 teams independently, tested enough, and later running on 2 CPUs, such that errors can be prevented.
For the hardware, the choices are pretty clear as well, considering how critical its working

environment is. Therefore ECC memory and server-grade CPUs will be used, considering that they work perfectly together and combine each other to a more error-proof system than desktop hardware. Eventhough this hardware is more expensive, it is crucial to the application and the system needs to be equipped with it, in order to be considered reliable.

12 Module 5: Power Supply

Function: deliver power to other vital Modules as described in N2 diagram
Decision: Lead-Acid
Options Considered: nickel cadmium, nickel-metal hydride, lead-acid, lithium ion, lithium ion polymer
Criteria: specific energy, life cycles, charge time, maintenance, working temperature range, cost and mass

In general there should only be two cases in which the NCU is disconnected from the grid, one in which the power fails and it may take up to 30 minutes for the hospital's generator to recover all devices electrically or when moving a patient and relying on the battery to power the unit. To ensure both these scenarios don't end in any harm to the baby in care the battery should be able to solely power the unit for up to 4 hours. In order to properly evaluate which battery is required for this task, different rechargeable batteries have been considered as these are less expensive over long periods of time and tend to provide longer lifetimes than non-rechargeable batteries. The evaluation may be seen in Table 6 below. No matter which battery is chosen, all must be coupled with a transformer to provide the right amount of voltage. The criteria has been chosen like this to incorporate all vital information required to make an educated decision on which battery is best. To sense whether the battery is feasible within the environment of the hospital the working temperature as well as the mass have been included. For determining whether the battery is reliable over longer periods of time the amount of life cycles and life span have been included. Furthermore it is important to know as a company how often our equipment has to be repaired, therefore maintenance has been included as an evaluation tool. Finally we require an efficient system and therefore have to relate the specific energy to the costs involved.

Safety: In terms of safety all battery types considered have their own drawbacks. The lithium-ion batteries for instance have certain safety concerns which require a protection circuit to maintain proper functionality. Nickel-metal-hydride batteries include mild toxic metals while nickel-cadmium batteries raise environmental concerns although their aircraft safety record is unharmed. The lead-acid batteries obviously include the toxic material which is lead and cannot be disposed off in landfills. Within the context of this project however the nickel-metal-hydride batteries are the only ones to decide against purely based on safety. The toxic material within the lead-acid batteries would have to be maintained and possibly cleaned regularly whilst using lithium-ion or lithium-ion polymer batteries would only require proper electrical engineering to remain safe.

Specifications	**Nickel Cadmium**	**Nickel-Metal Hydride**	**Lead-Acid**	**Lithium Ion**	**Lithium Ion Polymer**
Specific Energy (Wh/kg)	45-80	60-120	30-50	110-160	100-130
Life Cycles	1500	300-500	200-300	500-1000	300-500
Charge Time (Hours)	1	2-4	8-16	2-4	2-4
Maintenance	30-60 days	60-90 days	3-6 months	not req.	not req.
Working Temperature (°C)	-40 to 60	-20 to 60	-20 to 60	-20 to 60	0 to 60
Cost	Moderate (5cent/cycle)	Moderate (11cent/cycle)	Low (9cent/cycle)	High (13cent/cycle)	High (28cent/cycle)

Table 6: Battery Selection Table.[21] [22] [23]

Conclusion: Based on the information given in the table above the different types of batteries have been evaluated. The term used to describe the cost of the batteries is in reference to investment required to purchase such a unit. From this alone we must remove the lithium-ion and lithium-ion polymer batteries from our closer selection as they are simply not economical enough. These would have been good choices given a larger budget and a requirement to provide more possible cycles. Looking at the required maintenance frequency both the Nickel-Cadmium and Nickel-Metal-Hydride show a very low number of days. Both these types of batteries have low charge times and sufficient energy supply but are more expensive than the Lead-Acid battery and require more frequent maintenance making the Lead-Acid battery the optimal choice from this selection. This is the final choice as it provides enough energy, a decent amount of cycles which is still more than required, a nice maintenance schedule and the lowest cost. The only disadvantage of using these batteries, apart from the previous safety concern, is the fact that they have a longer charge time than the other options. It is important to note that the desired Lead-Acid battery would be in the form of a wet cell battery, commonly used as a backup power supply for servers and off-grid homes, and would have to be designed into a portable station.

13 Risk Analysis

For the risk analysis two ways of analysing the system were considered: the FMEA Risk Analysis and the top bottom analysis. First a table was made using the FMEA analysis. Here a top bottom analysis was used to grade the different parts to eventually come up with the Risk Priority Number (RPN). Below the table, explanations for every module are given. What should be noted is that this table is from a second evaluation of the risks.

	Severity	Detection	Frequency	Risk Priority Number
Blood Sensor	7	2	2	28
Ventilator	10	1	3	30
Humidifier	8	3	1	24
NO dosage	5	1	2	10
Nebulizer	3	8	2	48
Patient Monitor	6	1	2	12
Software, Hardware & UI	10	3	1	30
Power Supply	10	1	1	10

Table 7: Risk analysis of several components

13.1 Blood Sensor

Without the right measurements of the blood sensor, the ventilator system will not supply the right values of oxygen and carbon dioxide to the baby. Therefore, it has a quite high severity when it breaks down. On the other hand, the sensor won't break down fast and, through the data on the user interface, it is noticeable for a doctor when the blood sensor is not measuring the right values.

13.2 Ventilator

If the ventilator breaks down, this will obviously result in death of the baby and therefore has the highest severity number. If it fails, it is directly detected through the patient. As the system only has to work for about 25 to 30 babies a year and yearly check ups of the system are provided, the frequency of the system to break down is also low.

13.3 Humidifier

The temperature and moisture level of the air that the infant breaths in is essential for the infants life. Therefore, breaking down of the system will result in serious damage. It won't be noticed immediately, but through the patient it will be detected quite fast. As there is not much what can break down in the humidifier, plus the regular check ups, the chance of it breaking down is seldom to never.

13.4 NO Dosage System

When the NO dosage system fails, the baby won't be affected immediately and in a severe way. There is also a flow meter sensor attached to the NO cylinder, so when it breaks down it will be noticed directly. The frequency of the cylinder breaking down is also low, as there is nothing much to break down. Yet, the sensor may eventually break down, but just like the blood sensor this will happen seldom.

13.5 Nebulizer

This module has the highest risk priority number. This has to do with the detection of the failure. This is hard as the patient won't directly show signs and it won't show up in the data on the user interface when the nebulizer doesn't work properly. Yet, if it breaks down, there is no substantial damage to the infant and has a low severity therefore. Again, due to the regular check ups the chance of it breaking down are low.

13.6 Patient Monitoring

When the patient monitoring fails, an important sub-function is lost but it has no direct influence to the infant's health. Therefore it is not considered too severe. Failure of the patient monitoring is directly noticed on the user interface. Also, breaking down will occur seldom.

13.7 Software, Hardware and User Interface

The severity of the software breaking down is high, as no data between the measurement devices and the ventilator will be exchanged, resulting in immediate damage, and probably death, to the infant. Problems in either of the three components is noticed fast, as you will encounter problems with the system itself. After a second evaluation the frequency of the failure was considered to be seldom to never. Yet, next to the yearly check ups, the system must be reset after every time it is used to ensure the software and hardware will work as expected.

13.8 Power Supply

The power supply is either used in an emergency or for transporting the patient. When the power supply fails at that moment, the patient dies as the whole system doesn't work. You will notice it immediately when it is not working of course. Also, the frequency of the battery breaking down is seldom to never.

14 Testing the modules and system

In this section the testing of the modules and system will be described. There are two ways of testing a component or module: on a module level or at a system level. Testing on module level means you test the module on its own, to see if it works as required. Testing at system level means you already integrated the module in the system, to see if it works well together with the other modules.

14.1 Blood sensor

As the blood sensor has an essential function in the whole system, it should be tested both on a module and system level.

To test it on a module level, the blood sensor should measure the levels of pO_2 and pCO_2 of various known blood samples. If it measures the levels accurately, the blood sensor works fine and can be tested at a system level.

To test the blood sensor at a system level, again some known blood samples will be provided for testing. As the data of the blood sensor has to be processed by the software, hardware and user interface, this is also a test on a system level for these components. If there are any problems with the measurements, the problem is likely to come from the interaction between the blood sensor and the software as the blood sensor has already been tested on a module level. This means a closer look at the software will be needed.

14.2 Air Control

The air control has the most essential function of all the modules. Therefore all components should be tested separately before testing the air control on a module and system level.

14.2.1 Ventilator system

The air that the ventilator pumps into and out of the lungs of the infant should be analysed with the use of a few sensors. The ventilator should pump air, with a desired level of oxygen and carbon dioxide, into a sealed box in which some sensors are placed that can measure the levels of oxygen and carbon dioxide. If these coincide after a few test runs, the ventilator can be tested further in the air control.

14.2.2 Humidifier

The humidifier should be tested in the same way as the ventilator system but then of course with different sensors that can measure the moisture level and the temperature of the air.

14.2.3 NO Dosage system

As the amount of NO can be very critical to the condition of the baby it makes sense to test it. As NO is a gas it makes sense to test it the same way as the humidifier and the ventilation system. With the appropriate sensors the concentration of NO within a certain volume of air can be detected. This would be a test on an individual level. When going to the system level the NO dosage system could be controlled from the user interface and then be tested.

14.2.4 Nebulizer

The nebulizer is primarily used to transfer surfactant or other medicines into the baby through the breathing tube. Nebulizers are widely available and cannot be put onto the market without the appropriate testing procedures. Therefore it is good to test the nebulizer in the complete system but on a component level one can quite safely assume the component works correctly.

14.2.5 Air Control module level

The ventilator system should also be tested together with the humidifier, NO dosage system and the nebulizer as they make up the air control module. It should be noted that first the all the components of the air control should be tested on a module level before testing it together. The testing should be done in the same way as described above using a sealed box and some sensors. First only a combination of two out of the four components should be tested together. If these measurements are fine, other combinations should be tested until combinations of three components can be tested. These should also be tested in different combinations until the total air control can be tested. In this way it is easier to identify where the problem is coming from whenever there is a problem with the measurements.

14.2.6 Air Control system level

In the end, the whole air control can be tested at a system level to see how it interacts with the rest of the system. Again this can be seen as a system level test for the software, hardware and user interface, as these provide the data to the air control. These tests should be done in a similar way as described above for the air control by making different combinations until the whole system can be tested. Again, as the air control is tested thoroughly before testing it on a system level, any problems that occur should come from the interaction with the software.

14.3 Patient Monitoring

With the patient monitoring it is always important that it displays the correct values. Input to the patient monitoring will come from the blood sensor and from the heart rate monitor. Thus this module is already tested at a smaller system level. One thing that is possible is to hook up the patient monitoring to a verified frequency generator which will then input certain known electrical signals that could be verified on the screen of the patient monitoring. As soon as this is correct the blood sensor and heart rate monitor can be tested. This could be done alongside an already calibrated patient monitoring system so that the results can be verified. If it surpassed both these test it can be integrated to the rest of the system.

14.4 Software, Hardware and User Interface

As depicted above most modules will be tested on a system level through the software, hardware and user interface. It is harder to test these modules separately. Hardware has been made so frequently and has been tested widely en thoroughly by it's companies that we can safely assume that the hardware does not need separate testing. Software however can be tested on its own. Most coding programs can be run in a virtual environment to track down any errors. If for instance the virtual doctor would adjust a parameter and an error would pop up, this error could be solved beforehand. The user interface will be an integrated computer with keyboard. The same holds here as it was for the hardware, one expects that the keyboard and computer have been tested extensively and should work accordingly. After all the individual test the other systems can be hooked up and tested.

14.5 Power Supply

Without the power supply none of the others would work. Thus the need for testing is big. One would not want that the system stops in its tracks halfway through medication. As the system has two options when being used, plugged into the wall socket or going on battery, it is wise to see if you can test both. As the power supply from the hospital is not considered in our system it makes no sense to test it on its own. One can plug the system in and run all the tests accordingly. For the battery it is the same case as for the previously mentioned hardware and user interface. Batteries are produced on a large scale and are tested well. Thus when picking the battery one can assume it is working correctly.

15 User Scenarios

Some things that should be kept in mind during the whole project are the user scenarios, so how the product is going to be sent to the user, it's going to be set up, maintenance, etc. User scenarios are of utmost importance, because ultimately this project is made to be used by the customers, so how it is going to reach them and if it can reach them should be thought through. Some of the most important points of this section are:

- **Packaging** The system itself is quite large, large meaning that the screen is about eye-level for the average person. For transportation purposes it is best that the system be divided in parts. So the user interface and power supply will be in a different box than the rest of the system. The cables and transport system will also be in a separate package. This also makes it possible for one person to be able to lift one box at a time, since the limit one person can carry while working in most countries is 25 kg. The system is robust and shock resistant which makes it possible for it to travel without being damaged. The packaging will also keep it protected.
  If the product is going to be shipped overseas, so by plane, it will have special packaging to protect it form the lower temperatures in the cargo compartment and the pressure difference.

The product will of course be accompanied by manuals that explain how the product is used, just in case they are needed. They are also helpful in case something goes wrong. This way the hospitals engineers have a better chance of figuring out how it can be fixed more easily.

- **Transportation** The transportation will be done by other companies, depending on where the final destination of the product is. The system is made to survive aviation, land and ship transportation. The products are also packed in such a way that no harm will come to them during the transportation. This does not include extreme cases, like accidents.

- **Installation** An engineer hired by our company will be at the final destination of the product to put the device together and install it, so this service is provided by the company. This engineer also knows the system very well and he will be the one training part of the staff how to use the device, which will later share this knowledge with the rest. The system is made to be easy to use so this will not be a problem.

- **Maintenance** Yearly maintenance will be provided by our company for 10 years after the product has been purchased. This maintenance includes checking the air control, power supply and software. The blood sensor and patient monitoring do not need much maintenance, but if something happens during to these modules, they will be fixed or replaced within the devices warranty. This holds for the other parts of the system as well.

- **Storage** When the machine is not being used it can be stored in a storage room with something covering it. A cover will be provided with the machine when purchased. It is recommended to store the device as a whole, but if splitting it into the original three parts is needed it is advised to ask an engineer with previous experience with the machine to do that. The engineer that first installs it can train engineers hired by the hospital how to take it apart and put it back together again.

16 Discussion

The main problem in the project, especially in the beginning before the first draft of this report, was that it was unclear on what had to be done and how that should be done. After handing in that report, presenting the findings and getting feedback on how to improve, there was clarity about the end product. Also splitting up in two groups, the system engineers and the non system engineers, helped to make scheduling easier and gave team members a better understanding of individual roles. Using the feedback, final decisions on components and modules could be made. Using some tools that had been presented in the system engineering lectures, the system engineers were able to make several analysis on the system to ensure everything would be looked at. One thing that the system is lacking is a self-made part that would make it unique. Although the software used will be made by the company, it still

would be better if a module or component would be made in-house. This makes it more difficult for a competitor to copy the design.

Yet, what could have been done earlier was meeting on regular basis with the DEMCON contacts, Wouter Hakvoort and Benno Aaldrink. Only in the last week, when almost everything was finished, a meeting was scheduled to ask them about some uncertainties and problems that occurred along the way. This meeting showed that what was done until now, lacked depth and insight. There was more to consider than what was done. For example, the user scenarios was something that was not considered but showed more insight in costumer service (packaging of the system, transportation, maintenance etc.). This also helped giving more insight in other parts of the project, such as specifications (there were some added) and in budgets of the system. In the end, regular meetings would have helped a lot, as they could have not only offered a more in depth look on the project, but also on an earlier basis. This would have helped to more difficult analysis in a faster way.

17 Conclusion

In conclusion the tool and techniques presented during the lecture enabled the project group to identity the key modules and aspects of the project.The division between system engineers and module engineers allowed task to be properly allocated to team members. In addition to delegating task the knowledge depth and continuous feedback from team member meant that each module and the overall system analyses went through a rigorous process before completion. However the lack of our own developed product to improve the system was as a result of the lack of in-depth knowledge required. We believe that with time as more knowledge is developed we would have been able to create or improve a module within the system with our own ideas.

We conclude that creating efficient, well working devices that provides a client with good user experience is very difficult to achieve for any project group.Through a collaborative effort of system engineers and module engineers who use system engineered techniques and tools a much better results can be achieved.

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