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Blower based ventilator with High Frequency Oscillation functionality.

by

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Abstract

Currently different technologies are available that help a patient to breath. Two of these technologies are Intermittent Positive Pressure Ventilation (IPPV) and High Frequency Oscillatory (HFO) ventilation. There are no ventilators with HFO functionality on the market that can work without a pressurized gas source. The goal of this research is to combine an IPPV ventilator module based on a blower technology with a ventilator with HFO functionalities to create a ventilator module with IPPV and HFO functionality that uses ambient air a gas source.

The requirements near the patient are translated to system's requirements based on a simulation model of the hose system and the patient. The system requirements are used to make a simulation based design of the new Respiratory Module.

Between the IPPV ventilator module and the HFO module a membrane valve is designed to connect both modules. This valve passively controls the flow during negative pressures near the IPPV ventilator module. This is needed because the blower inside the IPPV ventilator module has an open connection with ambient during negative pressures of the HFO module. A voice-coil controlled membrane valve is chosen to use as expiration valve in the design of the Respiratory Module.

The designed membrane valve and expiration valve fulfil the main requirements and are feasible designs for further design iterations. The control of the Respiratory Module was out of the scope of this research, but the control determines if the total Respiratory Module fulfils the requirements. The membrane valve between the IPPV ventilator module and the HFO Module complicates the control.

Preface

This thesis is the result of my Master Science research project at Macawi in collaboration with the University of Technology at Delft, The Netherlands. This research is done for the master BioMedical Engineering at the faculty of Mechanical, Maritime and Materials Engineering.

I wish to thank my supervisors Ing. G van Dijk en Ir. E. Herben from the company Macawi. I also want to thank Prof.Dr. J. Dankelman and Ir. T. Goos for their supervision from the university.

Contents

Chapter 1

Introduction

In the past, if a person couldn't breathe, he would die. Currently different technologies are available that help the patient to breath. Two of these technologies are Intermittent Positive Pressure Ventilation (IPPV) and High Frequency Oscillatory (HFO) ventilation (Figure 1.1). An IPPV ventilator can support a patient with breathing or can even take over the breathing of the patient. An IPPV ventilator applies positive pressure at the mouth of the patient and mimics the normal breathing pattern of the patient (work of breathing) with a frequency up to 150 breaths per minute (bpm). IPPV is used from neonates to adults. HFO ventilation is mostly used for neonates. This technique ventilates a patient at a high breath rate (between 150 and 1200 bpm) and at a small breathing volume compared to IPPV. This technique is comparable to the technique of panting of dogs. Some studies showed that the advantages of HFO ventilation over IPPV for neonates are creating less lung injury, less long-term lung diseases and a better gas exchange. [1–3]

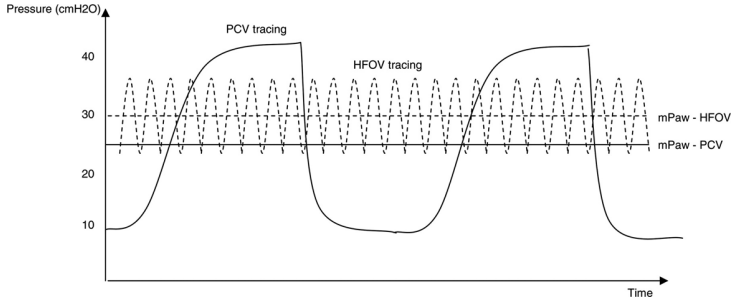


FIGURE 1.1: IPPV (PCV, pressure controlled ventilation) vs HFO ventilation (HFOV). On the y-axis the pressure is visible and on the x-axis the time. mPaw stands for the mean airway pressure. 1 cmH_2O = 98 Pa [Redrawn from K.P.W. Chan [4]]

There are different HFO ventilators on the market. Each HFO ventilator has a different working principle to create the high frequency oscillatory pressure and flow waveforms. Each

ventilator with HFO functionality uses a high pressure gas source for air, none of them can use ambient air. The benefit of using ambient air is the ability to use the ventilator when no pressurized gas is available. IPPV ventilators can operate both on high pressure gas source and on ambient air. Modern transport ventilators are mostly based on ambient air operated ventilator systems.

The company Macawi has designed a ventilator module based on blower technology (the Bonemine Module). This ventilator uses ambient air as a gas source. The blower inside the Bonemine Module pressurizes the air and can ventilate anyone from neonate up to adult patients. There are no other known blowers that have that high performance over such dynamic range.
Macawi wants to add HFO functionalities to its Bonemine Module (Figure 1.2). The HFO Module will create a sine or block pressure waveform superimposed on the pressure waveform created by the Bonemine Module. The HFO Module can generate negative pressure (relative to ambient). A negative side-effect of negative pressure between the Bonemine Module and the patient is that air is drawn through the Bonemine Module. The blower inside has an open connection to ambient when the pressure becomes negative. This has a negative effect on the performance of the HFO functionality.
A valve (connection valve) has to be designed between the Bonemine Module and HFO Module. The valve has to ensure that the flow can still be controlled even if the pressure of the HFO Module becomes lower than the mean pressure.
Also the right expiration valve has to be chosen that controls the exhalation gas of the patient. With a good design of a connection valve and the choice of an expiration valve the Respiratory Module can meet the requirements.

The goal of this study is to make a feasible design for a new Respiratory Module that can apply IPPV and HFO ventilation. Therefore a connection valve and expiration valve has to be designed. The method to address this new Respiratory Module is described in Chapter 2. The market potential of this new design is described in Chapter 3. The requirements are described in Chapter 4. A simulation model to get the system' requirements and to support the design process is described in Chapter 5. The design process of the connection valve and the final design is described in Chapter 6. The choice of the right expiration valve completes the Respiratory Module and is described in Chapter 7. The discussion and conclusion of the whole research is described in Chapter 8 and 9.

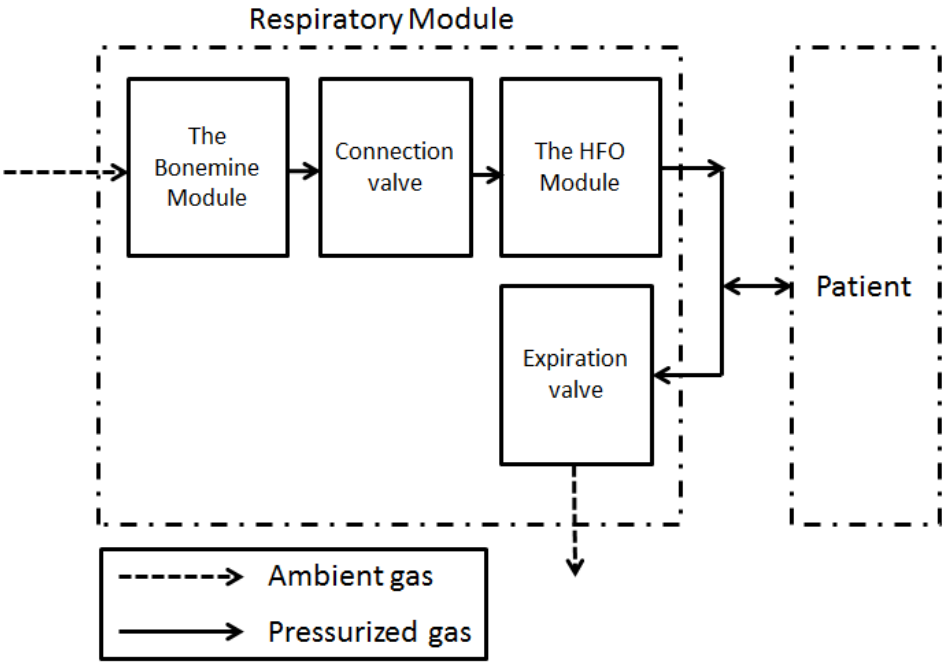


FIGURE 1.2: Respiratory Module

Definitions

(a)	Absolute pressure.
Base-flow	The minimal gas flow to assure the washout of expiratory gas of the patient. ($\frac{L}{min}$)
Bonemine Module	Ventilator module of Macawi based on blower technology.
Connection valve	Valve positioned between the Bonemine Module and the HFO Module. The valve controls the flow from the Bonemine Module when the pressure of the HFO Module becomes below ambient.
IPPV	Intermittent Positive Pressure Ventilation. Ventilate a person with a normal breathing pattern.
Delta Pressure	Pressure difference from minimum to maximum. ($mbar$)
Expiration valve	Valve that controls the exhaled gas of the patient. The valve is positioned between the patient and ambient.
(g)	Gauge pressure.
HFO Module	Module that creates high frequency oscillatory pressure and flow waveforms.
HFO Ventilation	High Frequency Oscillatory ventilation. Ventilate a person with a small volume on a higher frequency (2.5-20 Hz).
HTM	How To Measure.
I:E ratio	Ratio between Inspiration and Expiration.
MAP	Mean airway pressure ($mbar$)
Minute volume	The total ventilation volume of the patient per minute. ($\frac{L}{min}$)
Respiratory Module	Combination of the HFO Module, the Bonemine Module, connection valve and expiration valve.
Tidal Volume (V_T)	Volume the patient inhales or exhales per breath. (ml)
Total flow	All the flow that is needed for ventilation: minute volume + base-flow + leakage of components. ($\frac{L}{min}$)

Chapter 2

Methods

This research consists three elements: theoretical analysis, measurement analysis and design process. Every chapter has a more detailed method section.
During this report two modules are provided by Macawi: the Bonemine Module and the HFO Module. The Bonemine Module delivers IPPV and the mean pressure during HFO ventilation. The HFO Module generates a high frequency pressure waveform on the mean pressure during HFO ventilation. The total module is called the Respiratory Module (Figure 1.2). Appendix F provides a more detailed list of all used sensors, devices and software.

2.1 Theoretical analysis

Simulations are necessary to:

- derive the system's requirements
- visualize the impact of performance limits of sub-system components on the performance of the ventilator
- support the design process of the connection valve and to visualize the working principle of the valve

Simulation results are derived with Matlab and Simulink R2013b.

Also an additional survey among clinicians is conducted to know the requirements of clinicians for HFO ventilation (Appendix A). Five hospitals in the Netherlands with a neonatal

intensive care and three hospitals in three other countries filled in the questionnaire.

2.2 Measurement analysis

Empirical data is acquired for simulation, to verify the simulation models and to validate the new designs. The hose system configuration (figure 2.1) used during experiments is selected from information of the survey among clinicians. The Bonemine Module and the HFO Module are provided by Macawi. All empirical test are done with the system Dspace 1.4x combination with Matlab and Simulink R2013b.

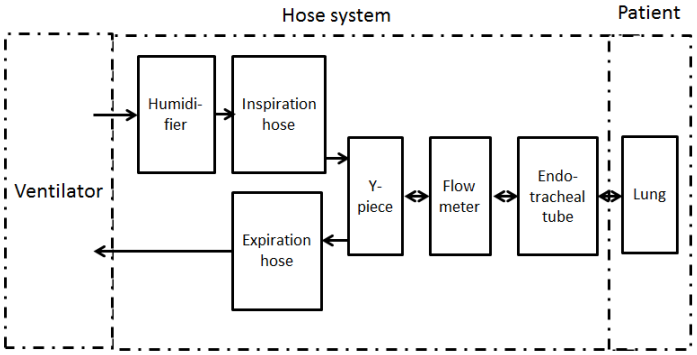


FIGURE 2.1: Hose system between the patient and the ventilator

2.3 Design process

First the problem and goal for the connection valve and expiration valve are clarified. After that a study about current solutions is done. This information is used to decide if a new design is made or if current solutions are sufficient. The right valve is chosen from a review of design requirements.

Chapter 3

Market Potential

This chapter gives an overview of:

- the market potential of the new Respiratory Module
- the users of the new Respiratory Module
- the applied field of the new Respiratory Module

3.1 Product description

The product described in this document is a respiratory module which consists of the Bonemine Module combined with a HFO module and is called the Respiratory Module. The Respiratory Module will be an OEM (Original Equipment Manufacturer) module. Other ventilator manufacturers can buy the Respiratory Module from Macawi and use it for their ventilator development.

3.1.1 Competitive advantages

A state-of-the-art transportable ventilators can be developed. HFO ventilation and IPPV can be applied to the patient with the same ventilator and without the use of pressurized gas. Companies are saving development time and cost by using this Respiratory Module for their own ventilator. This leads to a faster return on investment.

3.2 Market

This section describes the customers and the users of the Respiratory Module and what the customer benefits and unique selling points are.

3.2.1 Target customers

The target customers of Macawi for this Respiratory Module are companies that provide ventilators in the HFO and/or in the IPPV market.

3.2.2 Users

Users (who directly handle or access the Respiratory Module) of the Respiratory Module will be:

- R&D department of Macawi
- R&D department of the customers
- Service personnel

Clinicians and patients will not directly access the Respiratory Module. Therefore clinicians are not seen as users of the Respiratory Module.

3.2.3 Key Customer Benefits and Unique Selling Poins

Key customer benefits are:

- Reliable blower-module design
- Intelligent blower-module design
- Proven technology, complying with the standards for medical equipment notable for Emergency and Transport ventilators for neonates, children and adults and for clinical use
- Integral system solution for pressure, flow and oxygen delivery
- Complete design
- Reusable in future products for neonatal, child and adult ventilation

Unique selling points are:

- Suitable for neonates, children and adults
- Combination of IPPV and HFO ventilation
- Suitable for transport use without pressurized gas sources
- Improved non-invasive ventilation performance
- Combination of IPPV and HFO ventilation
- State of the art ventilation performance

3.3 Intended purpose

This section describes for which patient population the Respiratory Module can be used, in which environment and how it can be used.

3.3.1 Intended patient population

The Respiratory Module can be used for the following patient populations:

IPPV:

- Adults: 50-200 kg ($300 \leq V_T \leq 1500$ ml)
- Children: 5-50 kg ($20 \leq V_T \leq 350$ ml)
- Neonates: 0.4-8 kg ($2 \leq V_T \leq 30$ ml)

HFO ventilation:

- Neonates: 0.4-8 kg

3.3.2 Intended use environment

The Respiratory Module will have the following intended use environments:

- Hospital
- Ambulance

It might also be used in helicopters and air planes.

3.3.3 Intended Use

The Respiratory Module is intended to be a sub-system of a ventilator. The module delivers complete ventilation functionality without human interfacing to the outside of the module.

Chapter 4

Requirements

4.1 Introduction

System's and customer's requirements are used to translate the customer needs to technical specifications. Clear requirements are important to prevent mismatch between the performance of the system and the market expectancy.

The scope of this chapter will be to give a detailed view of the requirements and the impact of individual subsystems on the requirements. First the method is explained (Section 4.2). After that the customer's requirements (Section 4.3), the system's requirements (Section 4.4) and the sub-system's requirements (Section 4.5) are described. This chapter ends with a conclusion (Section 4.6).

Abbreviations Chapter 4

(a)	Absolute pressure
(g)	Gauge pressure
HTM	How To Measure
I	Inspection
MAP	Mean Airway Pressure
PEEP	Positive End Expiratory Pressure
S	Simulation
T	Test

4.2 Method

The requirements are described in a Tom Gilb overview. The Tom Gilb overview shows:

- the requirements
- the scale of the requirements
- how the requirements are measured (HTM)
- the target of the requirement

There are three different methods to verify the requirements (HTM), indicated by:

- Simulation (S): If the requirement is a quantitative parameter that first has to be proven by simulation, either because it damages the system, or the test procedure becomes too complex.
- Test (T): If the requirement is a quantitative parameter that can be proven by means of well-defined test procedure.
- Inspection (I): If the requirement is of the type that can be proven by visual inspection.

There are also three target levels for the requirements:

- "Must do" is to indicate the minimum achieved level of the requirements.
- "Plan" is to indicate the wanted achieved level of the requirements.
- "Wish" is to indicate the best achieved level of the requirements.

4.2.1 Customer's requirements

Customer's requirements are requirements near the patient. The requirements for IPPV are provided by Macawi. The requirements for HFO ventilation are collected with a survey among clinicians and from a customer of Macawi. Simulation is used to visualize the impact of performance limits of sub-systems.

4.2.2 System's and sub-system's requirements

The system's and sub-system's requirements were derived by simulation from the customer's requirements (Chapter 5).

4.3 Customer's Requirements

The customer's requirements determine the gas conditions near the patient. This section consists of requirements for IPPV and for HFO ventilation.

4.3.1 IPPV

For the requirements for IPPV only the "Must do" target is filled in (Table 4.1). The combination Bonemine Module and expiration valve can fulfil these requirements, based on earlier experiences of Macawi.

Requirement	Scale	HTM	Must do	Plan	Wish
Breath rates	BMP	T	1-200	-	-
Inspiration time	s	T	0.1-30	-	-
Expiration time	s	T	0.1-30	-	-
PEEP	mbar	T	1-40	-	-
Inspiration Pressure	mbar	T	≤ 95	-	-
Time of slope up	ms	T	50-$5e^3$	-	-
Time of plateau	ms	T	$\leq 3e^3$	-	-
Tidal volume, flow controlled	ml	T	≥ 2	-	-
Tidal volume, pressure controlled	ml	T	≥ 5	-	-

TABLE 4.1: Customer's requirements for IPPV

4.3.2 HFO ventilation

Customer's requirements for HFO ventilation are combined out of customer's requirements of a customer of Macawi and of clinicians (Table 4.2).
The requirements of clinicians for HFO ventilation are collected from a questionnaire among clinicians. In total 8 clinicians filled in the questionnaire. The clinicians came from 8 different hospitals from 3 different countries. Five of the nine hospitals in the Netherlands that are having a neonatal intensive care filled in the questionnaire. The requirements of clinicians correspond with the performance of current HFO ventilators, according to the authors literature study [5].
The requirements of the customer of Macawi (Appendix A) are higher than the requirements of the clinicians, because the customer of Macawi want to compete with the current HFO ventilators.
In Appendix A more information about the requirements of the customer of Macawi and the clinicians and the questionnaire can be found.

The performance of the HFO Module fulfils the requirements of the clinicians but can not reach all the requirements of the customer of Macawi (Figure 4.1 and Chapter 5.4.1.1). The final HFO requirements are based minimal on the requirements of the clinicians and maximal on the performance of the HFO Module and the requirements of the customer of Macawi.

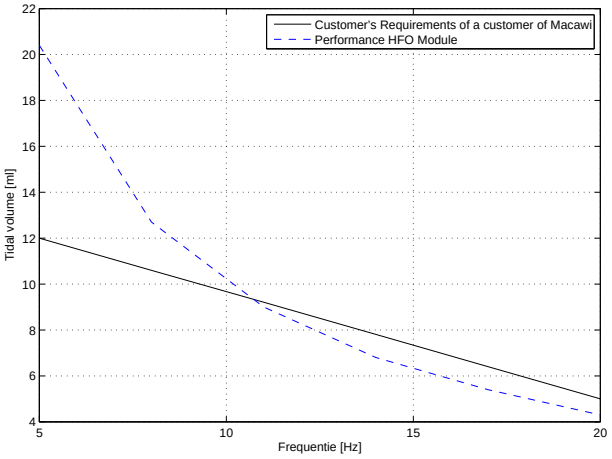
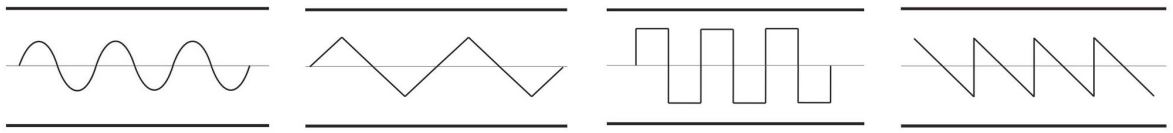


FIGURE 4.1: Comparison between customer's requirement of a customer of Macawi and the performance of the HFO Module of the tidal volume at the patient with an endotracheal tube with a diameter of 2.5 mm. The results of the HFO Module are simulated at 5, 8, 11, 17 and 20 Hz.

Requirement	Scale	HTM	Must do	Plan	Wish
Frequency	Hz	S,T	5 to 10	3 to 15	3 to 20
I:E ratio	ratio	S,T	1:1	1:1 / 1:2 / 1:3	variable
Amplitude (g)	mbar	S,T	1 to 40	1 to 45	1 to 50
Supported body weight	kg	S,T	0.4 to 5	0.4 to 7	0.4 to 8
Tidal volume vs body weight	ml/kg	S,T	0.5 to 4	0.1 to 5	0.1 to 6
Flow wave form (see Figure 4.2)	shape	S,T	sinus	sinus	sinus, triangle, square, sawtooth
MAP (g)	mbar	S,T	5 to 35	5 to 40	5 to 50

TABLE 4.2: Finial customer's requirements for HFO ventilation.



(A) Sine Wave (B) Triangle Wave (C) Square Wave (D) Sawtooth Wave

FIGURE 4.2: Different waveforms.

4.4 System's Requirements

There are non-functional (Table 4.3) and functional requirements for the Respiratory Module. The functional requirements are different between IPPV and HFO ventilation.

Requirement	Scale	HTM	Must do	Plan	Wish
Power consumption	W	T	< 70	< 50	< 40
Noise	dB	T	< 52	< 50	<40
Weight	kg	S,T	< 2	< 1.5	< 1
External leakage	L/min	T	< 1.5	< 1	< 0.5

TABLE 4.3: Non-functional system's requirements.

4.4.1 IPPV

For the requirements for IPPV only the "Must do" target is filled in (Table 4.4). The requirements are base on experiences of Macawi.

Requirement	Scale	HTM	Must do	Plan	Wish
Inspiration rise time	ms	S,T	60 to $3e^4$	-	-
Output pressure (g)	mbar	S,T	0 to 105	-	-
Output Flow (g)	L/min	S,T	0 to 170	-	-

TABLE 4.4: Functional system's requirements for IPPV.

4.4.2 HFO ventilation

The system's requirements for HFO ventilation are determined by simulation(Table 4.5). These requirements are higher than the customer's requirements because of the impact of the hose system in between the patient and the ventilator.

Requirement	Scale	HTM	Must do	Plan	Wish
Oscillation frequency range	Hz	S,T	5 to 10	3 to 15	3 to 20
I:E ratio	ratio	S,T	1:1	1:1 / 1:2 / 1:3	variable
Mean pressure	mbar	S,T	5 to 35	5 to 40	5 to 50
Delta pressure (g)	mbar	S,T	1 to 70	1 to 80	1 to 100
Maximum pressure (g)	mbar	S,T	90	100	110
Minimum pressure (g)	mbar	S,T	-10	-20	-30
Maximum peak flow	L/min	S,T	$1.5e^2$	$1.8e^2$	$2.0e^2$
Base-flow	L/min	S,T	$\geq 4 \cdot V_t \cdot freq \cdot 60$	$\geq 3 \cdot V_t \cdot freq \cdot 60$	$\geq 2 \cdot V_t \cdot freq \cdot 60$
Flow wave form (see Figure 4.2)	shape	S,T	sinus	sinus	sinus, triangle, square, sawtooth
Tidal volume	ml	S,T	5 to 12	5 to 15	5 to 20

TABLE 4.5: Functional system's requirements for HFO ventilation.

4.5 Sub-system's requirements

The requirements for the total Respiratory Module are translated to requirements for the sub-system components. The Respiratory Module consists of components that are already available and components that still have to be designed. Not the requirements but the specifications are outlined for the available components. The requirements for the non-available components are based on the requirements for the total Respiratory Module and the performances of the available components.

4.5.1 Available components specifications

The components that are provided by Macawi are the Bonemine Module (Table 4.6) and the HFO Module (Table 4.7).

Performance	Scale	Do
Maximum inspiration pressure (g)	mbar	100
Maximum flow	L/min	170
Power consumption	W	30

TABLE 4.6: The performance of the Bonemine Module

Performance	Scale	Do
Maximum pressure (g)	mbar	120
Maximum delta pressure (g)	mbar	100
Maximum volume per stroke	L	$118e^{-3}$
Power consumption	W	unknown

TABLE 4.7: The performance of the HFO Module

4.5.2 Non-available components

The components that will be designed are the connection valve and the expiration valve. The requirement for the flow through differs from IPPV.

4.5.2.1 Connection Valve

The situation of the connection valve are shown in Table 4.8. The requirements can be seen in Table 4.9 and 4.10.

Situation	Scale	Will be
Constant pressure from Bonemine Module (g)	mbar	10 to 70
Delta pressure from HFO Module	mbar	1 to 100
Maximum pressure (g)	mbar	$\leq$ 110
Minimum pressure (g)	mbar	$\geq$ -30
Pressure ramp	mbar/msec	$\geq$5

TABLE 4.8: Circumstances of the connection valve

Requirement	Scale	HTM	Must do	Plan	Wish
Minimal flow during HFO ventilation	L/min	S,T	$4 \cdot V_t \cdot freq \cdot 60$	$3 \cdot V_t \cdot freq \cdot 60$	$2 \cdot V_t \cdot freq \cdot 60$
Flow during IPPV	L/min	S,T	$\leq$ 100	$\leq$ 150	$\leq$ 200
Resistance during IPPV	mbar at 30L	S,T	$<$ 2	$<$ 1	$<$ 0.5
Switching speed	msec	S,T	$<$ 50	$<$ 25	$<$ 5

TABLE 4.9: Functional requirements for the connection valve

Requirement	Scale	HTM	Must do	Plan	Wish
Leakage	L/min/mbar	T	0.5	0.2	0
Power consumption	W	T	< 30	< 15	0
Power supply	V	I	24	24	0

TABLE 4.10: Non-functional requirements for the connection valve

4.5.2.2 Expiration Valve

The circumstances of the expiration valve is visible in Table 4.11. The requirements are visible in Table 4.12 and 4.13.

Circumstance	Scale	Will be
Ambient pressure (a)	mbar	700-1060
Delta pressure from patient	mbar	1 to 100
Maximum pressure (g)	mbar	≤ 100
Minimum pressure (g)	mbar	$\geq$ -20
Pressure ramp	mbar/msec	$\geq$3

TABLE 4.11: Circumstances of the expiration valve.

Requirement	Scale	HTM	Must do	Plan	Wish
Minimal base-flow during HFO ventilation	L/min	S,T	$4 \cdot V_t \cdot freq \cdot 60$	$3 \cdot V_t \cdot freq \cdot 60$	$2 \cdot V_t \cdot freq \cdot 60$
Peak flow during IPPV	L/min	S,T	≤ 150	≤ 200	≤ 250
Minimum resistance	mbar at 30 L	S,T	< 2	< 1	< 0.5

TABLE 4.12: Functional requirements for the expiration valve.

Requirement	Scale	HTM	Must do	Plan	Wish
Leakage	L/min/mbar	T	0.5	0.2	0
Power consumption	W	T	< 30	< 15	0
Power supply	V	I	24	24	0
Disposable	-	I	True	True	True

TABLE 4.13: Non-functional requirements for the expiration valve.

4.6 Conclusion

The Bonemine Module can fulfil the requirements for IPPV only if the connection valve and expiration valve fulfil the requirements. The connection valve is a resistance during IPPV and therefore the minimal resistance of the valve is important. For the expiration valve the flow and the minimal resistance is important for compatibility with IPPV. The Bonemine Module generates together with the expiration valve the pressure and flow curves during IPPV.

The requirements of the customer of Macawi are set too high for the Respiratory Module. During the simulation it became clear that the performance of the HFO Module was not sufficient to fulfil the requirements of the customer of Macawi, see also Chapter 5. The performance is enough to fulfil the requirements of the clinicians. The reason for the high requirements of the customer of Macawi is that they want to exceed the performance of current HFO ventilators. The final HFO requirements are based minimal on the requirements of the clinicians and maximal on the performance of the HFO Module and the requirements of the customer of Macawi.

The requirements from clinicians are conducted with a survey from 8 clinicians from 8 different hospitals. It is reliable to use the answers assuming that among neonatal intensive cares in different hospital one policy is used; more than 50% of all hospitals in the Netherlands with a neonatal intensive care filled in the questionnaire and the answers of clinicians are very much same.
The requirements for IPPV of Macawi are not compared with external requirements for IPPV, because of the years of experience of Macawi with different customers.

Chapter 5

Simulation

5.1 Introduction

Simulation is an important tool to reduce development time and cost by limiting the need for expensive and time consuming laboratory testing.[6] It can be used for design analysis, validation and optimization.[7] During simulation the non-linear effects of a system can be easily included. It is also easier to see the effect of changing parameters.[8]
Most of the current simulations of mechanical ventilation are about the patient: what the response of the patient is and how the effort of breathing can be reduced.[9, 10] There are no papers about simulation of the ventilator and the hose system between the ventilator and the patient.[11]

The main goal using simulation in this research is to develop a model based design of the new Respiratory Module.
The simulation model consists of a patient model of the hose system and the patient and a system model of the Respiratory Module (Figure 5.1). The patient model is used to translate the customer's requirements to system's requirements and the system model is used to validate the working principle of the connection valve. Both models are validated with empirical data.

The simulation is based on SI units (pressure = $\frac{N}{m^2}$ and flow = $\frac{m^3}{s}$), while the rest of the research is based on common units for ventilators (pressure = $mbar$ and flow = $\frac{l}{min}$). The conversion factor for pressure is 1 $mbar$ = 100 $\frac{N}{m^2}$ and for flow is 1 $\frac{l}{min}$ = $1.67e^{-5}$ $\frac{m^3}{s}$.

In this chapter the theory behind the simulations will be explained first (Section 5.2). After that the complete simulation model including verification (Section 5.3) is explained. The results are described in Section 5.4. The discussion and conclusion are described in Section 5.5 and 5.6.

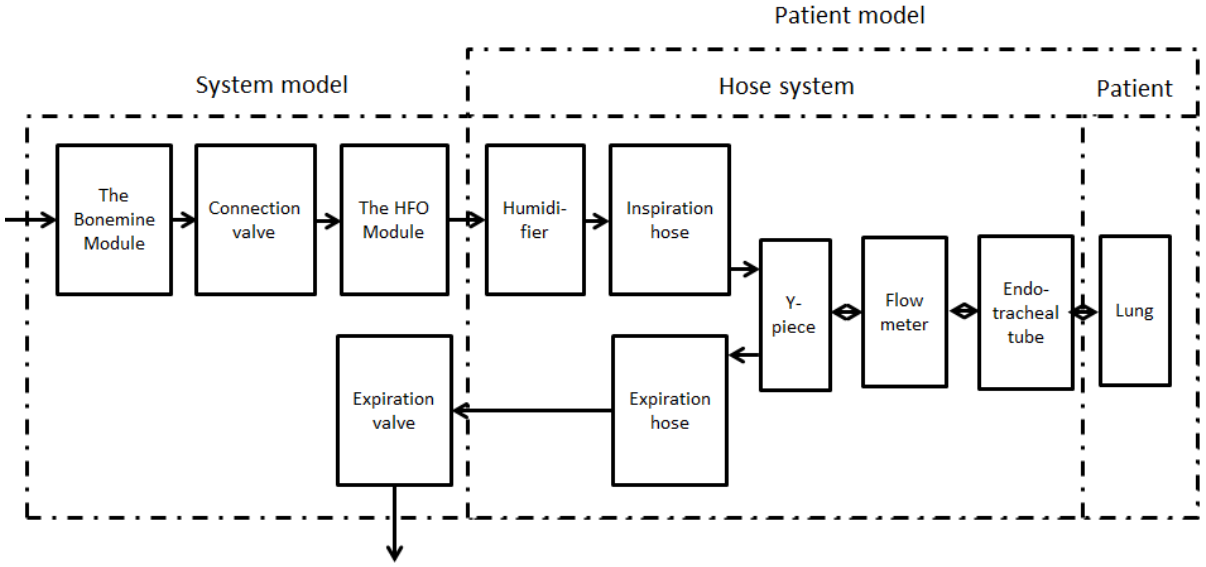


FIGURE 5.1: Simulation Model

Variables Chapter 5

$A_{Bonemine}$	Area of the Bonemine pressure on the membrane (m^2)
A_{HFO}	Area of the HFO pressure on the membrane (m^2)
A_{Pilot}	Area of the Pilot pressure on the membrane (m^2)
Q	Flow (m^3/s)
P	Pressure (N/m^2)
R	Resistance ($\frac{Ns}{m^5}$)
C	Compliance ($\frac{m^5}{N}$)
ρ	Density of the gas, air = 1.204 ($\frac{kg}{m^3}$)
M	Molar mass, air = 28.9e-3 ($\frac{kg}{mol}$)
R_{gas}	Gas constant, air = 8.1314 ($\frac{J}{Kmol}$)
T_0	Environment temperature, T_0 = 293.15 (K)
V	Volume (m^3)
C_d	Discharge coefficient, air = 0.7071 ($-$)
A	Surface of the orifice (m^2)
Y	Coefficient to include the influence of the compressibility of gasses, air = 0.9733 ($-$)
k	Specific heat ratio, air = 1.4 ($-$)
μ	Viscosity of the fluid, air = 18.46e-6 ($\frac{Ns}{m^2}$)
κ	Intrinsic permeability of the medium (m^2)
κ_1	Inertial permeability (m^3)
L_R	Length over which the pressure drop is taken place (m)
S_{rpm}	Speed of the blower (rpm)

5.2 Theory

The pneumatic response of the ventilator and patient is simulated with resistances and compliances. The resistance is simulated from pressure to flow (Equation 5.1 and Figure 5.2) and the compliance from flow to pressure (Equation 5.2 and Figure 5.3). In this way a stable simulation is created.

Small resistances and compliances are not simulated, because the influence is negligible compared to other resistances and compliances. The simulation model becomes also less compute-intensive when they are left out.

$$Q = -\frac{1}{R}\Delta P \tag{5.1}$$

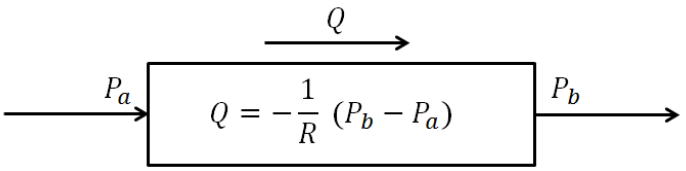


FIGURE 5.2: Resistance

$$P = -\frac{1}{C}\int \Delta Q \tag{5.2}$$

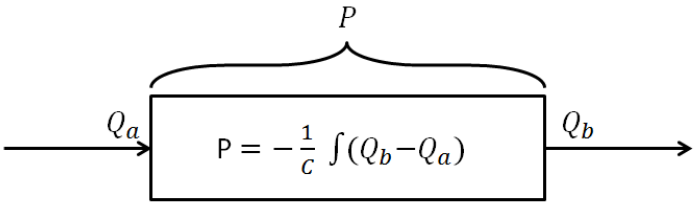


FIGURE 5.3: Compliance

5.2.1 Compliance

Three different ways are used to simulate the compliance in this simulation model: the ideal gas law, the law of Boyle and a compliance value based on empirical data.

5.2.1.1 Ideal Gas law

The principle of the ideal gas law is based on a hypothetical ideal gas (Equation 5.3). This law gives a good approximation of gas behaviour. The result will deviate from empirical data, because the gas is no ideal and this law takes the temperature changes by expansion or compression of the gas not into account. This will be less a problem in this simulation model, because the gas flow and pressure will oscillate with frequencies between the 5 and 20 Hz. The ideal gas law can be used as approximation of the compliance if the volume is known.

$$P = -\frac{\rho}{M}\frac{RT_0}{V}\int \Delta Q \tag{5.3}$$

5.2.1.2 Law of Boyle

The law of Boyle is based on the fact that a fixed amount of molecules of a gas is kept at a fixed temperature. If the volume of the gas becomes smaller, the pressure of the gas becomes higher (Equation 5.4, where P_0 and V_0 are the initial pressure and volume, P and V are the pressure and volume at a new moment). In some cases the result will deviate from the empirical results, because the temperature changes caused by expansion and compression of the gas are not taken into account. This will be no problem in this simulation model, because of the high frequency oscillations of the gas pressure and flow.

$$P = \frac{P_0 V_0}{V} \tag{5.4}$$

5.2.1.3 Empirical compliance

An empirical compliance can be applied instead of the ideal gas law and the law of Boyle. The empirical compliance (C) can be a constant, a linear or non-linear function (Equation 5.2).

5.2.2 Resistance

Three different ways are used to simulate the resistance in this simulation model: the orifice model, the Darcy-Forchheimer law and a resistance based on empirical data.

5.2.2.1 Orifice model

The orifice model is based on the Bernoulli principle and assumes laminar flow and incompressible gas (Equation 5.5).[12] The coefficient of discharge C_d is introduced for influence of the viscosity and turbulence effects and Y is introduced for the effect of the compressibility of gasses. If the orifice is known this equation can be used to model the resistance.

$$Q = -C_d A Y \sqrt{\frac{2\Delta P}{\rho}} \tag{5.5}$$

5.2.2.2 Darcy-Forchheimer Law

The Darcy-Forchheimer Law (Equation 5.6) is based on the fact that for very high velocities in porous media, turbulent effects can also become significant. A turbulence term (Q^2) is added to the Darcy's equation(Equation 5.7), known as the Forchheimer term. The inertial permeability κ_1 is able to account for the non-linear behaviour of the pressure difference vs Flow.

$$\Delta P = -\frac{\mu}{\kappa L_R} Q - \frac{\rho}{\kappa_1 L_R} Q^2 \tag{5.6}$$

$$Q = \frac{-\kappa A}{\mu} \frac{\Delta P}{L_R} \tag{5.7}$$

5.2.2.3 Empirical resistance

The resistance can also be measured and used as an empirical resistance in the model (Equation 5.1). The resistance can be a constant or a function fit of the measured data. Sometimes it is easier to use no empirical resistance to simulate for example the influence of the orifice size.

5.3 Simulation model

The two main parts of the simulation model are the patient model (Section 5.3.1) and the system model (Section 5.3.2). These parts can also be divided in smaller parts (Figure 5.4).

5.3.1 Patient model

The patient model consists of more than the patient only, it includes also the humidifier, inspiration hose, expiration hose, y-piece, flow sensor and endotracheal tube (Figure 5.4). All the components, except the y-piece and lung are modelled according to empirical data.

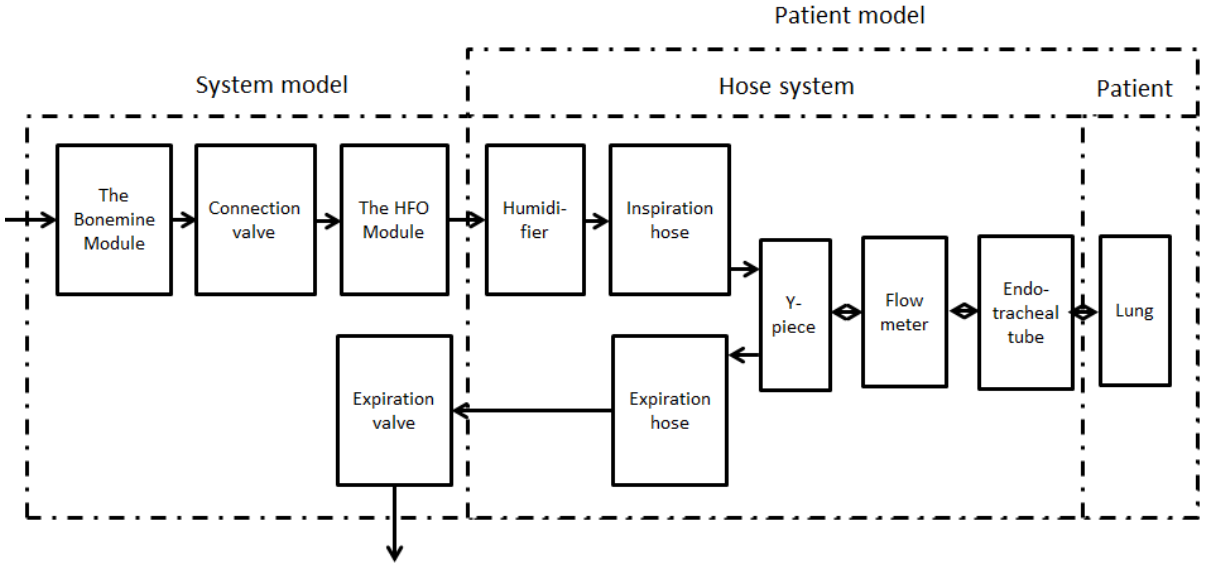


FIGURE 5.4: Simulation Model

$C_{humidifier}$	$5.0e^{-9}\ \frac{m^5}{N}$
$C_{InspirationHose}$	$2.3e^{-9}\ \frac{m^5}{N}$
$C_{Y-piece}$	$1.0e^{-10}\ \frac{m^5}{N}$
$C_{ExpirationHose}$	$2.4e^{-9}\ \frac{m^5}{N}$
$C_{Flowmeter}$	$3.0e^{-11}\ \frac{m^5}{N}$
$C_{EndotrachealTube}$	not modelled
C_{lung}	$6.6e^{-9}\ \frac{m^5}{N}$

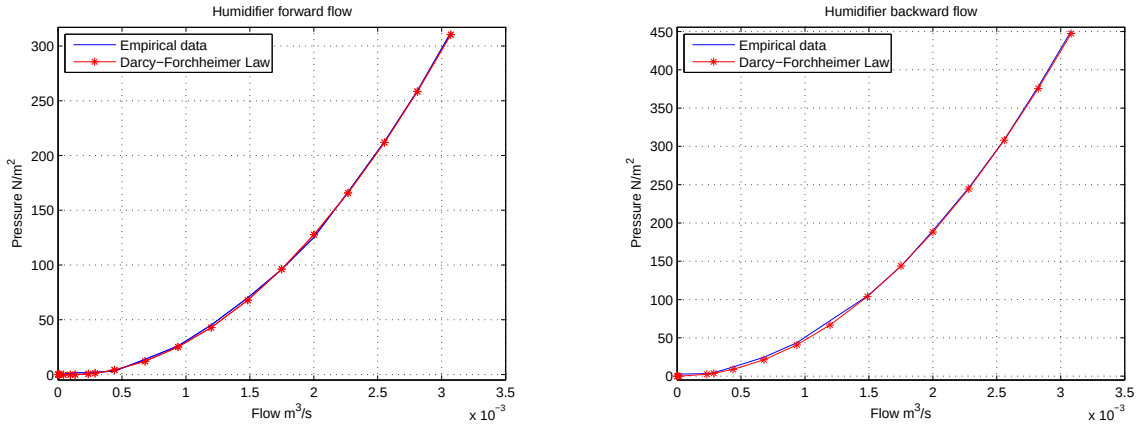
TABLE 5.1: Compliances in the Patient Model

	Pressure drop ($\frac{N}{m^2}$) at $3.3e^{-4}\ \frac{m^3}{s}$ flow
Humidifier forward flow	$1.9\ \frac{N}{m^2}$
Humidifier backward flow	$5.0\ \frac{N}{m^2}$
Inspiration hose forward flow	$1.2e^2\ \frac{N}{m^2}$
Inspiration hose backward flow	$1.4e^2\ \frac{N}{m^2}$
Y-piece	not modelled
Expiration hose forward flow	$1.9e^2\ \frac{N}{m^2}$
Expiration hose backward flow	$2.1e^2\ \frac{N}{m^2}$
Flow meter forward flow	$8.2e^2\ \frac{N}{m^2}$
Flow meter backward flow	$7.6e^2\ \frac{N}{m^2}$
Endotracheal tube forward flow	$5.2e^3\ \frac{N}{m^2}$
Lung	not modelled

TABLE 5.2: Resistances in the Patient Model

5.3.1.1 Humidifier

The humidifier is connected between the ventilator and the inspiration hose. It is a big volume that adds moisture to the patient gas. For the simulation the compliance of the humidifier has a great influence on the model; it is after the lung the biggest compliance in the model (Table 5.1). The resistance is negligible in comparison with the rest of the resistances (Figure 5.5 and Table 5.2). Therefore only the compliance of the humidifier is modelled, this is done according Equation 5.2, where C is the empirical measured. $C_{humidifier}$ is $5e^{-9}$ $\frac{m^5}{N}$ (Table 5.1).



(A) Forward flow

(B) Backward flow

FIGURE 5.5: Resistance of the humidifier during forward and backward flow. The empirical data is fitted by the Darcy-Forchheimer law. The resistance of the humidifier is not modelled, because the influence is negligible (Table 5.2).

5.3.1.2 Inspiration hose

The inspiration hose connects the humidifier with the y-piece that is close to the mouth of the patient. The inspiration hose is, together with the expiration hose, the longest part in the simulation model. The hose is divided in four elements to have a good representation of flow and pressure in the inspiration hose and a good representation of the response of the system (Figure 5.6). Every element is simulated as a resistance and compliance. The resistance and compliance of every element is one fourth of the total resistance and compliance.

The compliance is modelled with the empirical measured value, $C_{InspirationHose}$ is $2.3e^{-9}$ $\frac{m^5}{N}$ (Table 5.1). The value of $C_{InspirationHose}$ in Table 5.1 is the compliance of the whole inspiration hose.

The resistance is modelled by fitting the empirical data with the Darcy-Forchheimer Law

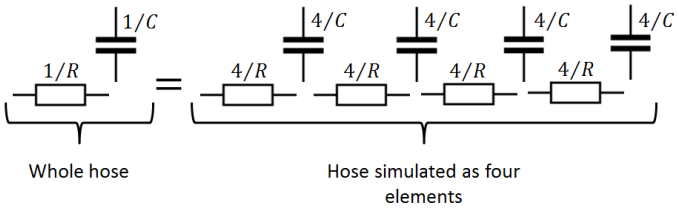
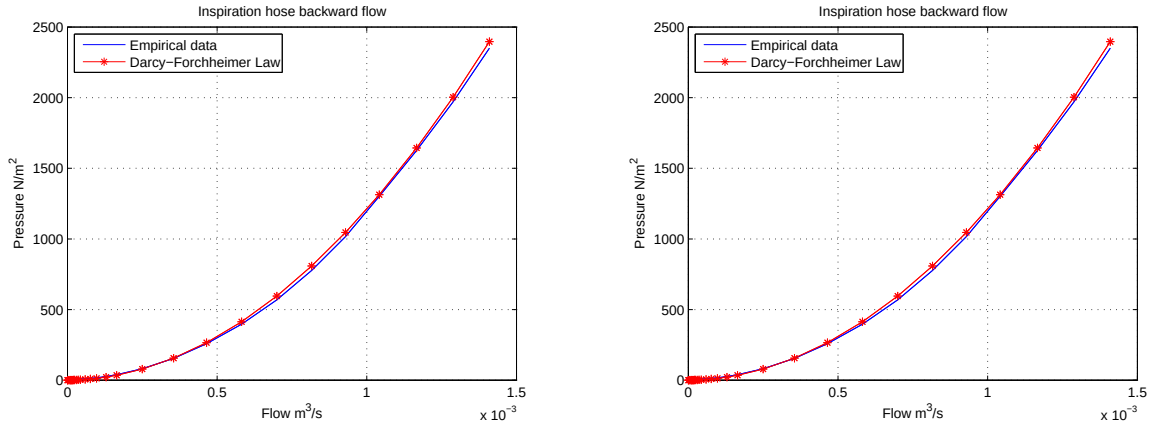


FIGURE 5.6: The inspiration and expiration hose is in the simulation model divided in four elements. The empirical data is fitted by the Darcy-Forchheimer law. The Darcy-Forchheimer law is used during the simulations.

(Equation 5.6, Table 5.3, Figure 5.7 and Table 5.2). The resistance during forward flow is different from the resistance during backward flow, because of the asymmetry between the inlet and outlet of the hose.



(A) Forward flow (B) Backward flow

FIGURE 5.7: Resistance of the whole inspiration hose during forward and backward flow. The empirical data is fitted by the Darcy-Forchheimer law. The Darcy-Forchheimer law is used during the simulations.

	forward flow	backward flow
κL_R	$3.82e^4\ m^3$	$1.51e^4\ m^3$
$\kappa_1 L_R$	$1.00e^9\ m^4$	$1.20e^9\ m^4$

TABLE 5.3: Values of the Darcy-Forchheimer law of the inspiration hose.

5.3.1.3 Y-piece

The y-piece connects the inspiration hose, expiration hose and flow meter with each other. The resistance of the y-piece is not measured based on the configuration of the y-piece. The resistance of the y-piece is not easy to measure and to implement in the simulation, because there are three kinds of flow through the y-piece that have a resistance and influence on the resistance of the other flows through the y-piece (Figure 5.8). With the experience of all the measured resistances of the patient model and the knowledge inside Macawi, the influence of the

y-piece will be expected negligible and therefore not simulated. The compliance of the y-piece is modelled according to the ideal gas law with volume of $1e^{-5}\ m^3$ (Equation 5.3, Table 5.1). $C_{Y-piece} = 1.0e^{-10}\ \frac{m^5}{N}$.

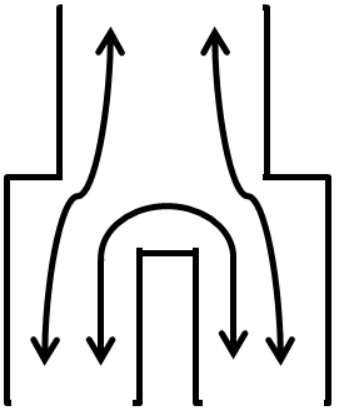
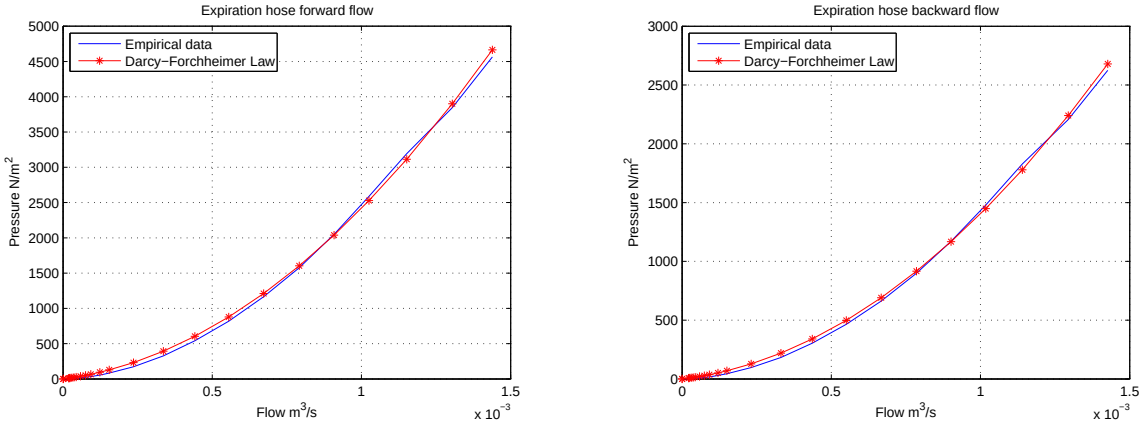


FIGURE 5.8: The flows through the y-piece.

5.3.1.4 Expiration hose

The expiration hose connects the y-piece with the ventilator. Through the expiration hose the gas during expiration leaves the patient model. This hose is like the inspiration hose divided in four elements and every element is modelled with a compliance and a resistance (Figure 5.6). The compliance is modelled with the empirical measured value, $C_{ExpirationHose} = 2.4e^{-9}\ \frac{m^5}{N}$ (Table 5.1). The value of $C_{ExpirationHose}$ in Table 5.1 is the compliance of the whole expiration hose.

The resistance is modelled by fitting the empirical data with the Darcy-Forchheimer Law (Equation 5.6, Table 5.4, Figure 5.9 and Table 5.2). The resistance during forward flow is different from the resistance during backward flow, because of the asymmetry between the inlet and outlet of the hose. The inlet and the outlet of the expiration hose differs from the inspiration hose.



(A) Forward flow (B) Backward flow

FIGURE 5.9: Resistance of the whole expiration hose during forward and backward flow. The empirical data is fitted by the Darcy-Forchheimer law. The Darcy-Forchheimer law is used during the simulations.

	forward flow	backward flow
κL_R	$2.69e^5\ m^3$	$2.94e^5\ m^3$
$\kappa_1 L_R$	$0.94e^9\ m^4$	$1.11e^9\ m^4$

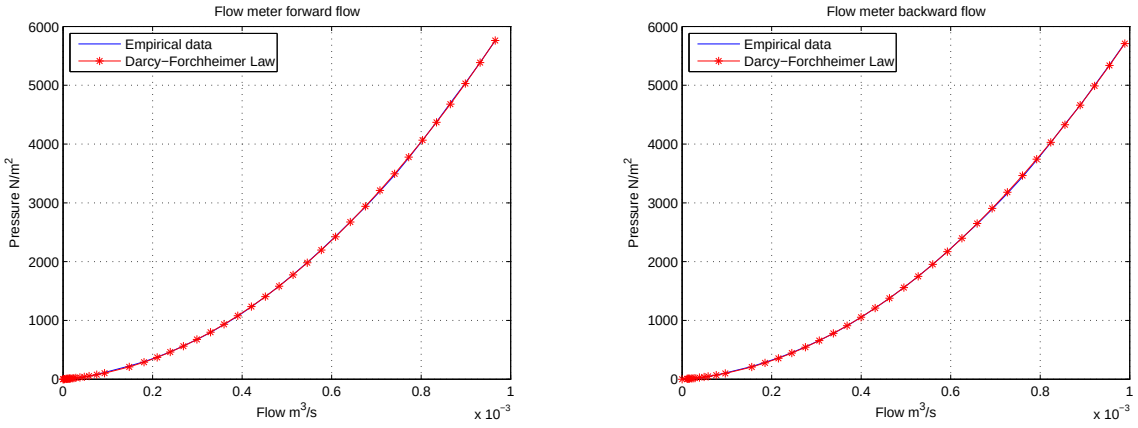
TABLE 5.4: Values of the Darcy-Forchheimer law of the expiration hose.

5.3.1.5 Flow meter

The flow meter is placed between the y-piece and the patient. The function of the flow meter is to measure the flow and pressure that enters the patient. The flow meter has the second largest resistance of the patient model (Table 5.2) and is modelled with a resistance and a compliance.

The compliance is modelled with the empirical measured value, $C_{Flowmeter} = 3.0e^{-11}\ \frac{m^5}{N}$ (Table 5.1).

The resistance is modelled by fitting the empirical data with the Darcy-Forchheimer Law (Equation 5.6, Table 5.5 and Figure 5.10). The resistance during forward flow is different from the resistance during backward flow, because asymmetry inside the flow meter.



(A) Forward flow

(B) Backward flow

FIGURE 5.10: Resistance of the flow meter during forward and backward flow. The empirical data is fitted by the Darcy-Forchheimer law. The Darcy-Forchheimer law is used during the simulations.

	forward flow	backward flow
κL_R	$5.94e^5\ m^3$	$5.09e^5\ m^3$
$\kappa_1 L_R$	$5.56e^9\ m^4$	$5.32e^9\ m^4$

TABLE 5.5: Values of the Darcy-Forchheimer law of the flow meter.

5.3.1.6 Endotracheal tube

The endotracheal (ET) tube links the flow between the flow meter and the patient's upper airways. The endotracheal tube exists of different tube diameter sizes range from 2.0 to 3.5 mm (neonate) to about 4.0 to 5.0 mm (pediatric) to 5.5 to 10 mm (adult). Both the diameter and length of the ET tube effect the resistance.[11] For the model the resistance of the ET tube with a diameter of 2.5 mm is used. This is chosen because the Respiratory Module has also to be capable to ventilate with a small tube and the 2.5 mm tube was the smallest tube available at the moment.

The ET tube has the biggest resistance of the patient model and is modelled by fitting the empirical data with the Darcy-Forchheimer Law (Equation 5.6, Table 5.6, Figure 5.11 5.2). The resistance during forward flow and backward flow is modelled the same.

The compliance of the ET tube is not measured and modelled. In reality the ET tube is placed

inside the trachea of the patient. The trachea influences the compliance of the ET tube, but this influence cannot be measured. With also considering the shape of the ET tube, it is expected that the compliance of the ET tube will not have much influence on the simulation data and will be therefore be neglected.

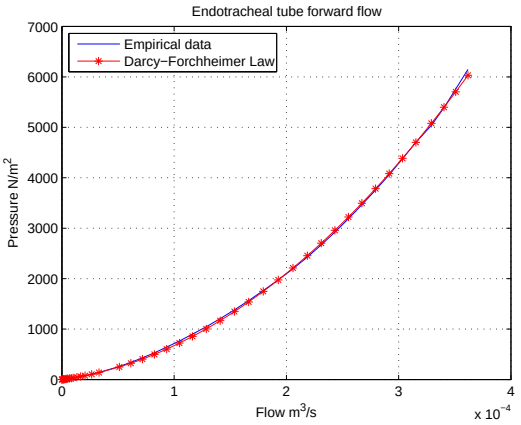


FIGURE 5.11: The resistance of the endotracheal tube. The backward resistance is modelled the same as the forward resistance. The empirical data is fitted by the Darcy-Forchheimer law. The Darcy-Forchheimer law is used during the simulations.

	forward flow
κL_R	$2.91e^6\ m^3$
$\kappa_1 L_R$	$3.81e^{10}\ m^4$

TABLE 5.6: Values of the Darcy-Forchheimer law of the Endotracheal tube. The backward resistance is modelled the same as the forward resistance.

5.3.1.7 Lung

The lung is a compartment with flexible walls. The lung expands during inhaling and shrinks during exhaling of the patient. The compliance of the lung is non-linear for large expansion, caused by the diaphragm and its actuating muscles.[11] During HFO ventilation the lung only experiences small expansion, therefore the lung is modelled as a linear compliance. The compliance of the lung is the most important of the model and comparable with the compliance of a sick neonate (Table 5.1).[13] The resistance of the lung is negligible, because during HFO ventilation the air enters the lung with a high impulse and turbulent flow [14].

5.3.1.8 Verification of the patient model

The patient model is verified by two test set-ups it was not possible to measure everything in each test set-up (Figure 5.12).

In test set-up 1 is measured:

- the inlet pressure of the humidifier
- the outlet pressure of the flow meter
- the inlet pressure of the expiration valve

In test set-up 2 is measured:

- the inlet flow of the humidifier
- the tidal volume
- the outlet pressure of the flow meter

Both test set-ups included the whole hose system and a patient with a compliance of $1e^{-6}$ $\frac{m^5}{N}$. The first test set-up used the same flow meter as in the patient simulation model. The second test set-up used a flow meter with a lower resistance. The patient model is verified according

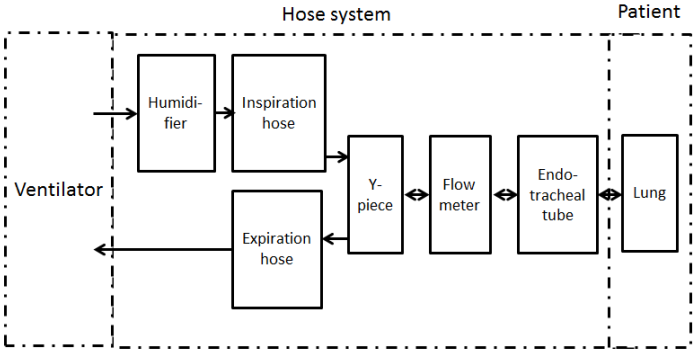


FIGURE 5.12: Hose system between the patient and the ventilator

Figure 5.13 and Figure 5.14. In Figure 5.13 the tidal volume during the test at the different frequencies is tuned to be the same as in the simulation. The pressure at the patient is in the simulation a bit higher than during the test and the flow is also a bit higher. The pressure difference can partly be explained by the difference in tidal volume. The difference in flow can be explained by a lower resistance of the hose system during the testing and imperfections of the test set-up. The discontinuity in the flow at the humidifier during testing can be explained by imperfections of the test set-up. The test set-up isn't able to retain the shape of the wave-form during higher frequencies.

In Figure 5.14 the pressure at the humidifier and the flow at the expiration valve are tuned in the same way. There is no flow out of the expiration valve. The pressure and the MAP at the patient are quite the same, but the pressure at the end of the expiration hose differs during this test with the simulation. In reality the pressure amplitude is more damped and the MAP is

more increased. This test was also performed at a MAP of 25 mbar and a delta pressure of 30 mbar (Figure C.1). The conclusion is the same as Figure 5.14.

The simulation model gives a good representation of the pressure (Figure 5.14), but an overestimate of the flow (Figure 5.13). The flow was hard to verify because of performance limits of the test set-up.

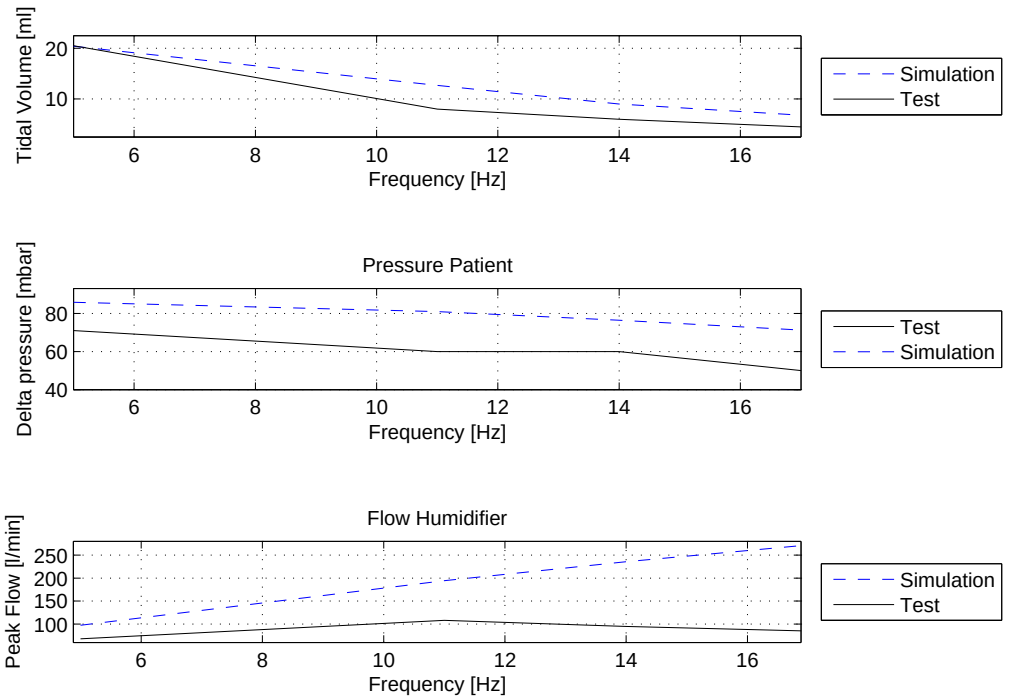
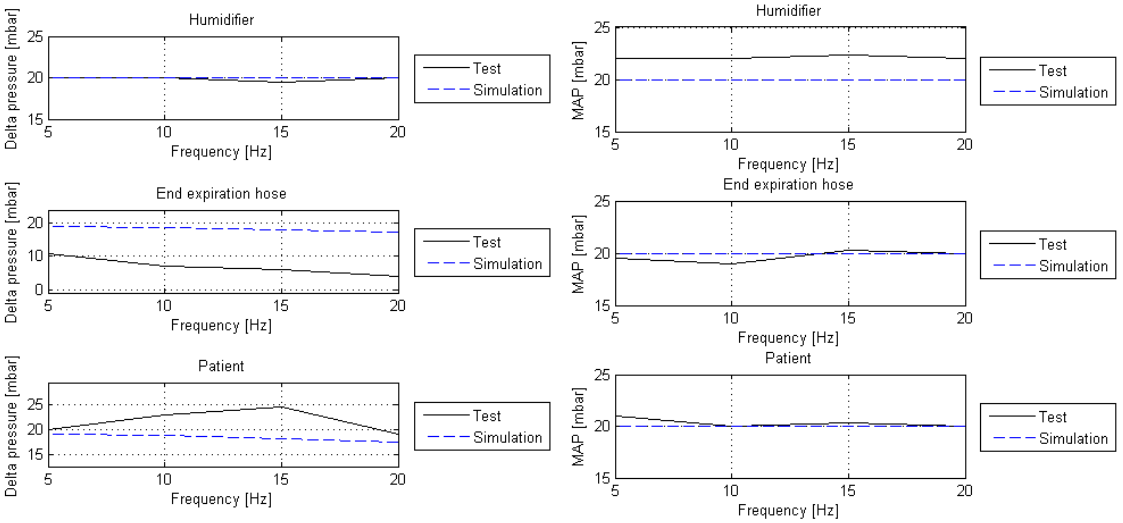


FIGURE 5.13: Verification of the pressure inside the patient model. The tidal volume is tuned the same. The test is measured at 5, 11, 14 and 17 Hz. This is achieved with the test set-up with another HFO ventilator. The simulation is simulated at 5, 8, 11, 14 and 17 Hz.



(A) dP (B) MAP

FIGURE 5.14: Verification of th pressure inside the patient model. The flow at the expiration valve and the pressure at the humidifier are tuned in the same way. There was zero flow out of the expiration valve. The test is achieved with the test set-up with the Respiratory Module. Both the test and the simulations are done at 5, 10, 15 and 20 Hz for a delta pressure of 20 mbar and a MAP of 20 mbar.

5.3.2 System model

The model of the Respiratory Module includes: the Bonemine Module, the HFO Module, the connection valve and the expiration valve (Figure 5.4).

5.3.2.1 The Bonemine Module

The Bonemine Module consists of a blower, a mixing chamber and a check valve. The blower air goes into the mixing chamber and after that through the check valve before it leaves the Bonemine Module (Figure 5.15).

The blower consist of a impeller (Figure 5.16a) inside a housing (Figure 5.16b). When the impeller is rotating air is forced to the outside out of the blower by centrifugal forces.
The mixing chamber is a volume were air and oxygen is coming together and mixed before the gas is going to the patient.
The check valve is a valve that permits the gas to flow in only one direction. When the gas flows in the desired direction the valve opens, while back-flow closes the valve.

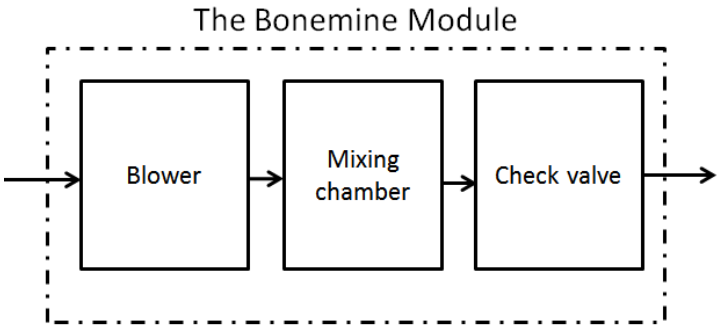
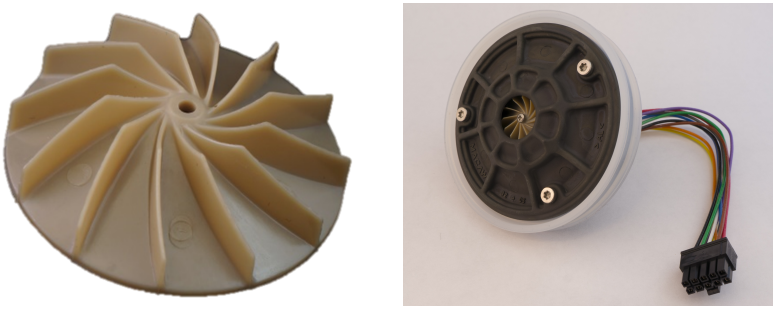


FIGURE 5.15: The Bonemine Module



(A) Impeller (B) Total blower

FIGURE 5.16: The blower (b) consist of a impeller (a) inside a housing.

Blower

The blower is characterized by the outlet pressure (P) and the speed of the blower (S_{rpm}). The blower can create with a certain speed a maximum pressure. The intern resistance of the blower determine the flow through the blower (Q) (Figure 5.17). The relationship in the model is measured and fitted with an ellipse formula. The general ellipse (Equation 5.8) is formed to the formula that gives the best fit of the empirical data. The values of the parameters in Equation 5.8 are visible in Apendix B in Equation B.2. The blower is modelled with pressure and speed as input and flow as output (Equation 5.8). This simulation model was provide by Macawi.

$$\begin{aligned} \frac{(c_1 Q - h)^2}{b^2} + \frac{(c_2 P - k)^2}{a^2} &= c_3 \\ Q = \frac{1}{c_1}(b\sqrt{c_3 - \frac{(c_2 P - k)^2}{a^2}} + h) & \end{aligned} \tag{5.8}$$

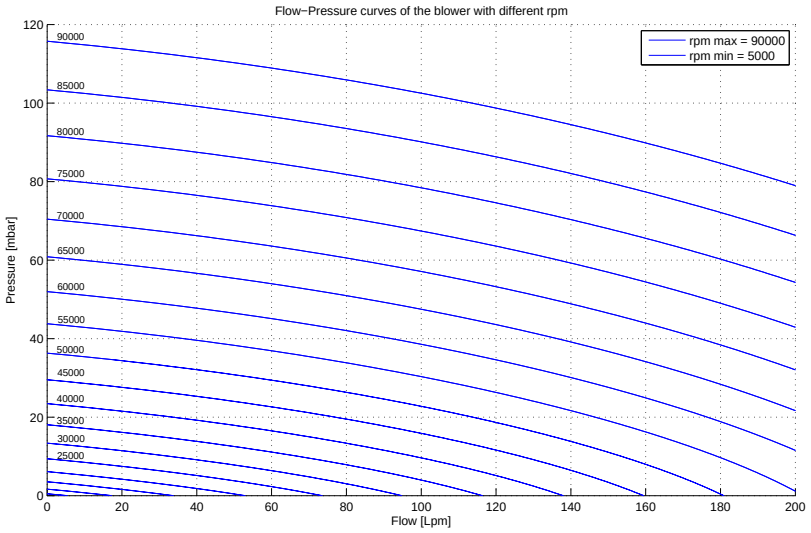


FIGURE 5.17: Relationship of the blower between pressure, rpm and flow during the intended circumstances. The pressure on the y-axis is is P_{outlet} (g) $(mbar)$. Positive flow on x-axis is directed from the blower to the mixing chamber $(\frac{l}{min})$.

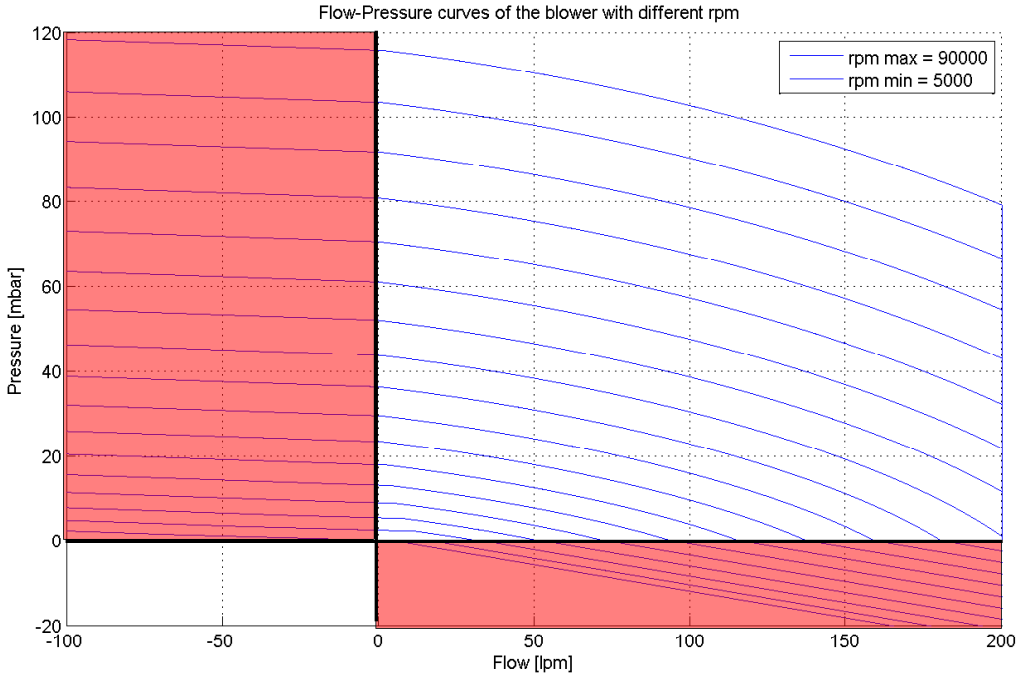
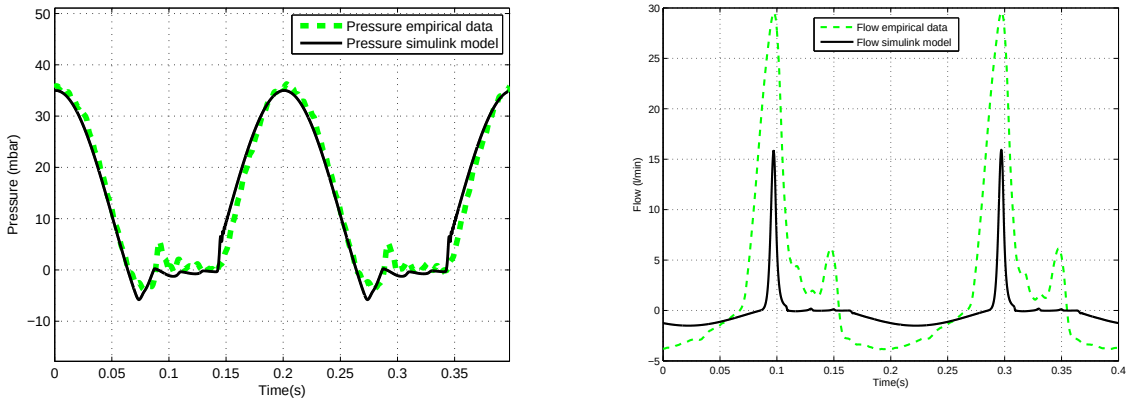


FIGURE 5.18: Relationship of the blower between pressure, rpm and flow. When the Bonemine Module is combined with the HFO Module the pressure can become higher than the maximum pressure generated by the Bonemine Module or even negative (red area). The response is derived from the empirical response of the Bonemine Module. The white area is the same as Figure 5.17. The pressure on the y-axis is P_{outlet} (g) $(mbar)$. Positive flow on the x-axis is directed from the blower to the mixing chamber $(\frac{l}{min})$.

When the Bonemine Module is combined with the HFO Module, the pressure between the blower and the mixing chamber can also become higher than the maximum pressure by the blower ($P_{outlet} > P_{max}$) or even negative relative to the ambient ($P_{outlet} < 0$) (red areas in Figure 5.18).

The response of the Bonemine Module is measured during experiments with the connection valve (Chapter 6). The resistances in the red areas are modelled with a linear resistance (Equation 5.1) and were modified till the response of the whole Bonemine Module was close to the response during the experiments (Figure 5.18). This resulted in a linear resistance Equation 5.9 of 0.025 $\frac{Ns}{m^5}$ when $P_{outlet} > P_{max}$ and a resistance of -0.125 $\frac{Ns}{m^5}$ when $P_{outlet} < 0$ (Equation 5.10). The response of the blower is well-conditioned for pressure, but ill-conditioned for flow. A small pressure difference result in a large flow difference. Therefore it was easier to map the pressure response of the simulation on the empirical data, than it was for flow.
The discontinuity (Figure 5.18)) between the ellipse formula and when $P_{outlet} > P_{max}$ is caused by the difference in resistance between positive and negative flow through the blower. The discontinuity between the ellipse formula and when $P_{outlet} < 0$ was needed to fit the pressure and flow response. This discontinuity can be explained by that the ellipse is measured static and not dynamic and the way the resistance of the check-valve is modelled.



(A) Pressure (B) Flow

FIGURE 5.19: The empirical and simulation response of the blower when the connection valve closes.

$$Q = \frac{1}{0.025}(c_3 - P) \tag{5.9}$$

$$Q = -\frac{1}{0.125}P + \frac{1}{c_1}(b\sqrt{c_3} + h) \tag{5.10}$$

Mixing chamber

The mixing chamber (Figure 5.15) is a big volume, where the resistance is negligible of. Therefore the mixing chamber is only modelled as a compliance (Equation 5.3) with a fixed volume of $3e^{-4}\ m^3$. $C_{MixingChamber} = 3.0e^{-9}\ \frac{m^5}{N}$.

Check valve

The check valve is modelled as a resistance and a compliance. The resistance is variable. If there is positive flow through the check valve the check valve is open. If there is a negative flow (positive ΔP, Figure 5.2) the check valve is almost closed, a small bleeding flow is allowed. During positive flow (negative ΔP, Figure 5.2) there are two resistances, the bleeding resistance and the resistance of the orifice of the check valve (Equation 5.12). During negative flow $R_{checkvalve}$ changes in $2R_{bleed}$ this results in Equation 5.11. The bleeding resistance is much bigger than the resistance of the orifice of the check valve. Both resistances are modelled as linear resistances based on empirical data (Table 5.7). The model of the check valve was provided by Macawi and based on emperical data.
The compliance of the check valve is modelled despite the small value. The compliance ensures that the output of the Bonemine Module is pressure (Equation 5.2) and creates a more stable simulation model without influencing the outcome. The compliance of the check valve is modelled (Equation 5.3) with a fixed volume of $1e^{-5}\ m^3$. $C_{CheckValve} = 1.0e^{-10}\ \frac{m^5}{N}$.

$$Q = -\frac{\Delta P}{R_{bleed}} \tag{5.11}$$

$$Q = -(\frac{1}{R_{checkvalve}} + \frac{1}{2R_{bleed}})\Delta P \tag{5.12}$$

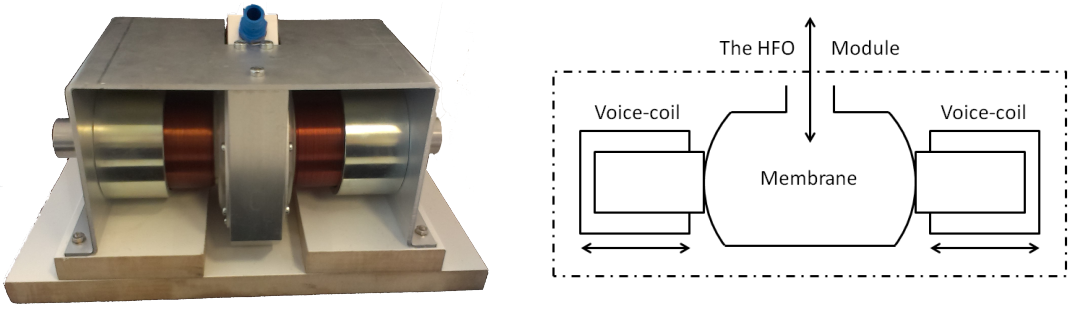
$R_{checkvalve}$	$2.00e^5\ \frac{m^5}{Ns}$
R_{bleed}	$1.40e^8\ \frac{m^5}{Ns}$

TABLE 5.7: Values of the resistances in Equation 5.12.

5.3.2.2 The HFO Module

The HFO Module exists of a membrane moved by two voice-coils (Figure 5.20). The HFO Module is modelled as an ideal flow source, because the outcome flow is only important for the

simulation.



(A) The HFO Module (B) Schematic overview

FIGURE 5.20: HFO-module: Two membranes in front of each other controlled by two voice coils. The movement of the voice-coils determine if the flow is going out of in the HFO Module.

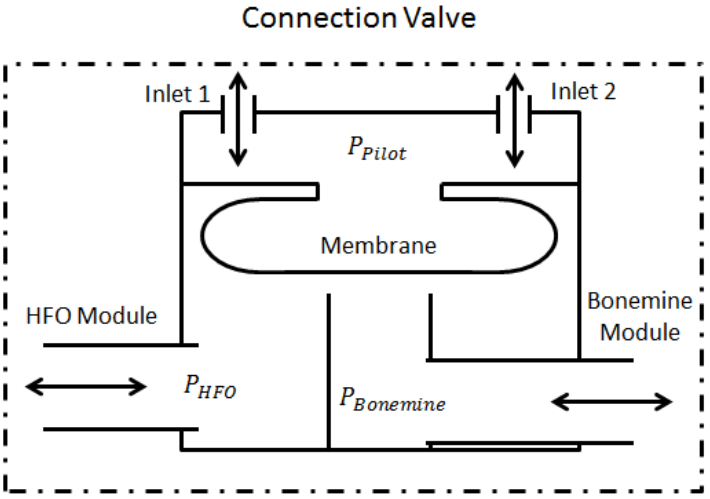


FIGURE 5.21: Connection Valve

5.3.2.3 Connection Valve

The connection valve connects the Bonemine Module with the HFO Module (Figure 5.4). The connection valve can close the connection between the Bonemine Module and the HFO Module with a membrane (Figure 5.21). The simulation of the connection valve consists of kinematic and pneumatic equations (Table 5.8). The kinematic equations simulate the movement of the membrane. The pneumatic equations simulate the pilot pressure inside the membrane and the flow through the connection valve.

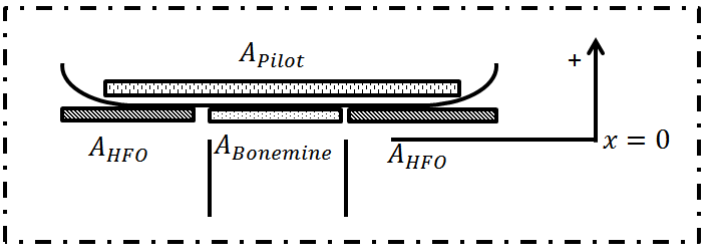


FIGURE 5.22: Surface area of each active pressure on the membrane.

The kinematic simulation consists of (Equation 5.13 and 5.14 and Figure 5.22):

- the inertia, damping and stiffness of the membrane
- the force equilibrium

$$M_{membrane}\ddot{x} + C_{membrane}\dot{x} + K_{membrane}x = \Delta F \tag{5.13}$$

$$\Delta F = P_{HFO}A_{HFO} + P_{Bonemine}A_{Bonemine} - P_{Pilot}A_{Pilot} - F_{pre-tension} \tag{5.14}$$

The boundary conditions of the membrane are: the height of the membrane cannot become lower than x=0 mm or higher than x=5 mm. The seat of the connection valve determines the lower boundary condition and the ceiling of the connection valve determines the upper boundary condition.
When the height of the membrane reaches the seat (x=0mm) or the ceiling (x=5mm) the $K_{membrane}$ changes in $K_{infinitive}$ which eliminates the rest of the forces on the membrane (Equation 5.14). $K_{infinitive}$ changes again in $K_{membrane}$ if ΔF is the same as at the moment that $K_{membrane}$ changed in $K_{infinitive}$.
$C_{membrane}$ also changes in $C_{infinitive}$ when the height of the membrane reaches the boundary conditions. The damping changes $1e{-}4$ m before the membrane reaches the boundary condition. Increasing the stiffness suddenly generates oscillations. The oscillations are damped by increasing the damping before the stiffness to infinity. The damping is reset to $C_{membrane}$ on the same way as $K_{membrane}$.

Pneumatic simulation of the connection valve consist of two parts: the change of P_{Pilot} and the flow through the connection valve (Figure 5.22).
P_{Pilot} changes according to the law of Boyle (Equation 5.15). The pilot pressure is influenced by the height of the membrane (x) and the two inlets in the chamber above the membrane (Figure 5.21). Inlet 1 is connected to ambient and inlet 2 is connected to the HFO pressure (Equation 5.17 and 5.18). The flow through both inlets influences the initial. The height of the membrane influence the actual volume (Equation 5.16).

The flow through the connection valve is calculated with the orifice model (Equation 5.19). The surface ($A_{ConnectionValve}$) where the gas can go through is dependent on the height of the membrane (x) and the perimeter of the seat (P_{Seat}) (Equation 5.20).

$$P = \frac{P_0 V_0}{V} \tag{5.15}$$

$$P = \frac{P_0(V_0 - \int(Q_{inlet1} - Q_{inlet2}))}{V_0 - xA_{Pilot}} \tag{5.16}$$

$$Q_{inlet1} = C_d A_{inlet1} Y \sqrt{\frac{2(P_{Pilot} - P_{ambient})}{\rho}} \tag{5.17}$$

$$Q_{inlet2} = C_d A_{inlet2} Y \sqrt{\frac{2(P_{HFO} - P_{Pilot})}{\rho}} \tag{5.18}$$

$$Q = C_d A_{Seat} Y \sqrt{\frac{2(P_{Bonemine} - P_{HFO})}{\rho}} \tag{5.19}$$

$$A_{Seat} = xP_{Seat} \tag{5.20}$$

A_{HFO}	$4.9106e^{-4}\ m^2$
$A_{Bonemine}$	$1.4957e^{-4}\ m^2$
A_{Pilot}	$6.4063e^{-4}\ m^2$
$M_{membrane}$	$1.0e^{-3}\ kg$
$C_{membrane}$	$0.1789\ \frac{kg}{s}$
$C_{infinitive}$	$3.58\ \frac{kg}{s}$
$K_{membrane}$	$100\ \frac{kg}{s^2}$
$K_{infinitive}$	$\Delta F\ \frac{kg}{s^2}$
P_0	$1e^5\ \frac{N}{m^2}$
V_0	$5e^{-6}\ m^3$
A_{inlet1}	$7.0686e^{-6}\ m^2$
A_{inlet2}	$1.7671e^{-6}\ m^2$
P_{Seat}	$4.56e^{-2}\ m$

TABLE 5.8: Variables of Equation 5.15- 5.20

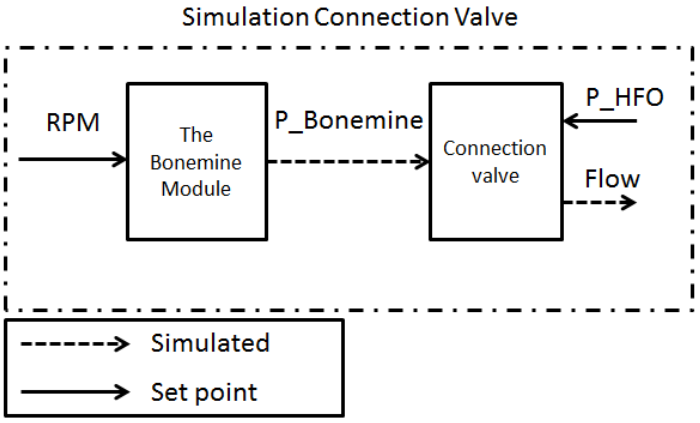


FIGURE 5.23: Simulation of the control range of the connection valve. The pressure from the HFO Module and the speed of the blower are the set-points and the flow through the connection valve and the pressure from the Bonemine Module are simulated.

The working principle of the connection valve inside the Respiratory Module is modelled by combining the Bonemine Module and the connection valve (Figure 5.23). The inputs of the model are the pressure from the HFO Module and the rpm of the blower. The simulation model is used to model the pressure from the Bonemine Module and the response of the connection valve.

5.3.2.4 Expiration Valve

The expiration valve simulation was not needed to determine if the connection valve function correctly, therefore the expiration valve is not modelled.

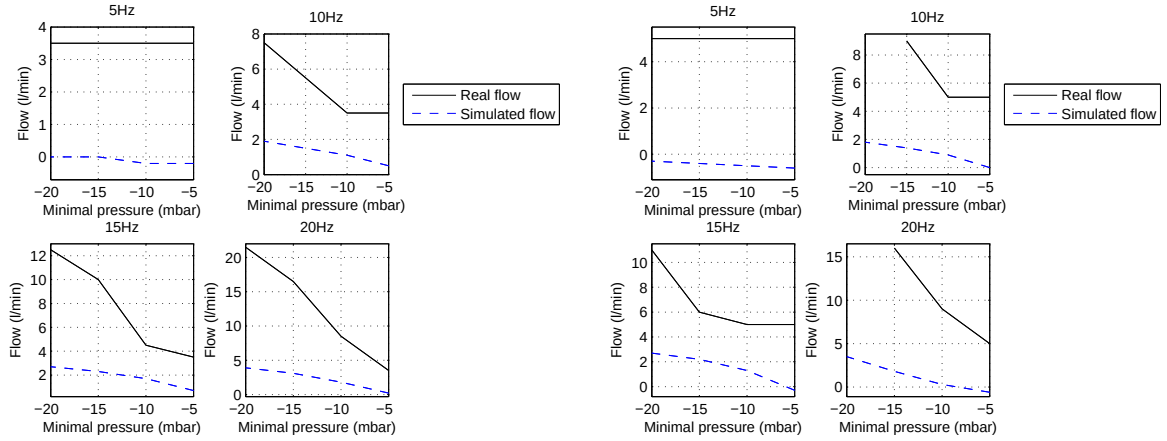
5.3.2.5 Verification of the control range of the connection valve

The minimal flow through the connection valve is simulated and measured with a sinus pressure at the HFO Module of a MAP of 10 and 20 mbar and a minimum pressure of -5, -10, -15 and -20 mbar at the frequencies 5, 8, 11, 14, 17 and 20 Hz. The speed of the blower is 0 rpm. These measurement point are chosen to capture the most common and extreme requirements when a part of the sine waveform HFO pressure becomes below ambient.

The flow through the connection valve during testing is more than the simulated flow (Figure 5.24). The difference can be explained by the flow under-estimation in the simulation of the Bonemine Module and the difficulty to verify the distance between the seat and the membrane between simulation and experiments.

The pressure of the Bonemine Module and the pilot pressure during the simulation and experiments are a good match (Figure 5.25). The pilot pressure is in the experiment more damped than during the simulations. The pressure of the Bonemine Module is less damped in the experiment.

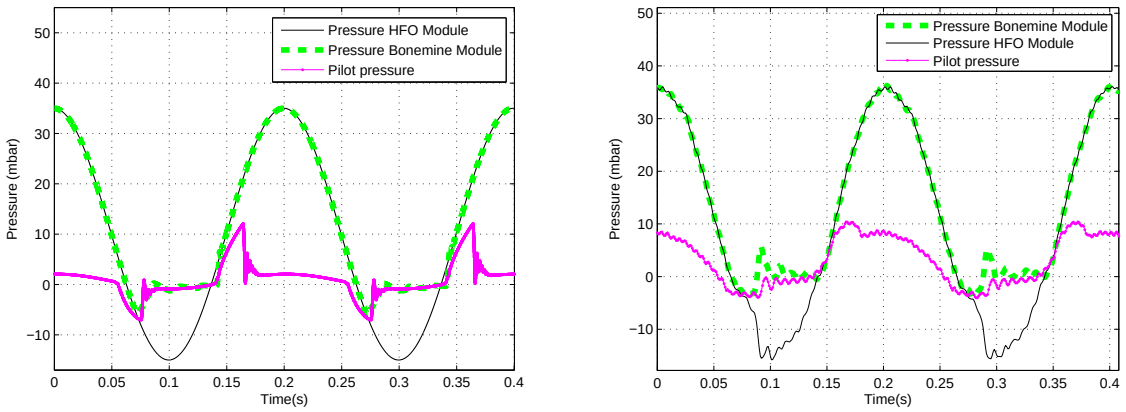
There are some differences between the simulation model and the experiments, but the simulation model is a good model to see the impact of the parameters.



(A) MAP of 10 mbar

(B) MAP of 20mbar

FIGURE 5.24: Comparison of the flow measured during testing (Figure 6.30) and the simulated flow (Figure 5.30 and 5.31). Measured at 5, 10, 15 and 20 Hz.



(A) Simulation (B) Experiment

FIGURE 5.25: Verification of the pressure near the connection valve.

5.4 Results

The simulation is used:

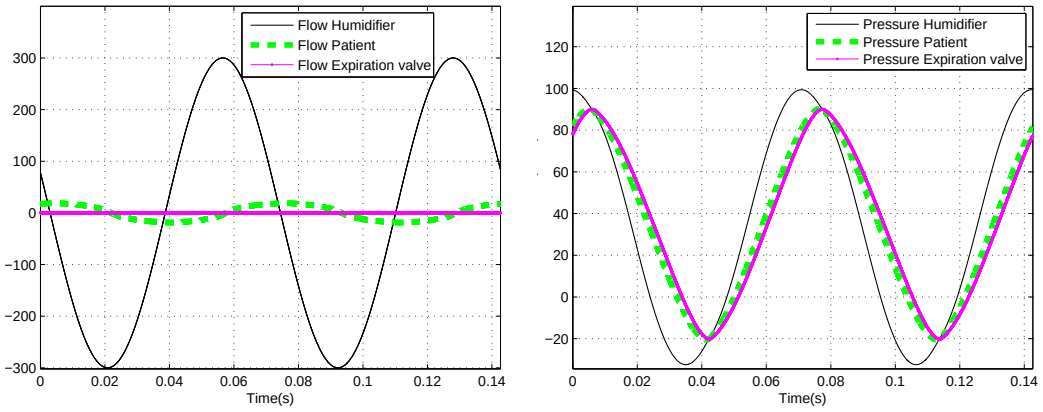
- to translate the customer's requirements to the system's requirements
- to investigate the impact of the performance limits of the HFO Module on the customer's requirements
- to investigate the influence of different frequencies on the requirements for the ventilator side
- to investigate the control range of the base flow with the connection valve

5.4.1 System's Requirements

The patient model is used to determine the system's requirements. The input at the patient model is increased till the requirements at the patient are met. This is done for the frequencies 5, 8, 11, 14, 17 and 20. The important parameters for the system's requirements are the pressure and flow at the humidifier and the pressure and flow at the expiration valve. The flow from the expiration hose is set to zero during simulations with the patient model, because the expiration valve is a part of the system model and not of the patient model.

Figure 5.27, 5.26 and Table C.1 in Appendix C show the response of the ventilator when the tidal volume satisfies the customer's requirement (see also Chapter 4). There is a big difference

between peak flow and delta pressure at the patient side and at the ventilator side. The compliance of the humidifier and the resistance of the inspiration hose are the main causes of this difference.



(A) Flow (B) Pressure

FIGURE 5.26: Simulation results of the flow and pressure in the patient model, with a tidal volume of 7.8 ml at 14 Hz.

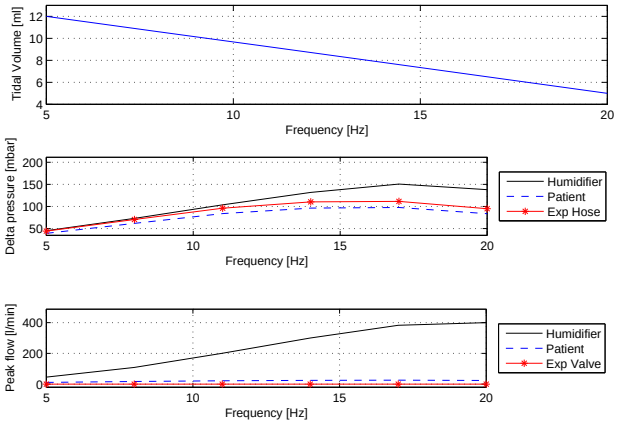
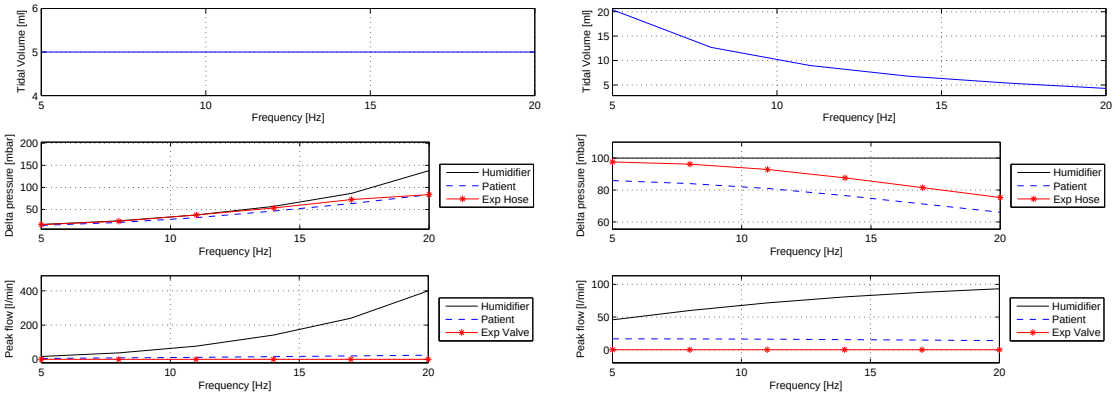


FIGURE 5.27: Simulation results of the tidal volume, the pressure at the humidifier, the patient and expiration valve and the flow at the humidifier, patient and expiration valve. The tidal volume fulfils the customer's requirements of a customer of Macawi.



(A) Constant tidal volume

(B) Constant pressure

FIGURE 5.28: Simulation results of the tidal volume, pressure at the humidifier, the patient and the expiration valve and the flow at the humidifier, patient and expiration valve. (A) the tidal volume is constant, (B) the pressure at the humidifier is equal to the maximum performance of the HFO Module.

5.4.1.1 Impact of the performance limit of the HFO Module

The HFO Module cannot deliver more pressure than 100 mbar delta pressure. The performance of the ventilator near the patient is simulated through a constant delta pressure of 100 mbar at the humidifier at the frequencies 5, 8, 11, 14, 17 and 20. The assumption is made that there is no flow performance limit of the HFO Module. It became visible if the performance limit of the HFO Module has an influence on the customer's performance.

Figure 5.28b and Table C.3 in Appendix C shows the effect for the patient side when the pressure at the humidifier is 100 mbar. This is the maximal pressure amplitude of the HFO Module. The tidal volume customer's requirements of the customer of Macawi are not reached at higher frequencies (Figure 5.29), but the customer's requirements of the clinicians are reached (see Chapter 4).

5.4.2 Influence of different frequencies with a constant tidal volume

The effect of a constant tidal volume during higher frequencies on the pressure and flow at the humidifier and expiration valve is also modelled. The used tidal volume is 5 ml and the results are simulated at the frequencies 5, 8, 11, 14, 17 and 20.

Figure 5.28a and Table C.2 in Appendix C shows when the pressure and the peak flow at

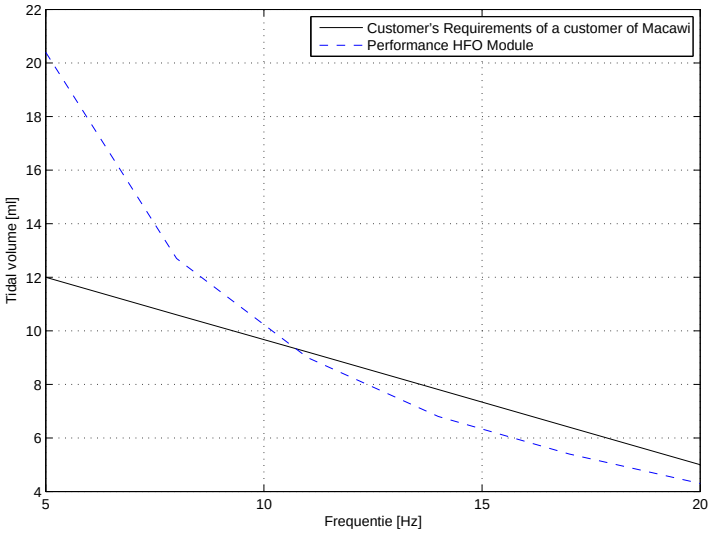


FIGURE 5.29: Comparison between customer's requirement of a customer of Macawi and the performance of the HFO Module of the tidal volume at the patient with an endotracheal tube with a diameter of 2.5 mm. The results of the HFO Module are simulated at 5, 8, 11, 17 and 20 Hz.

the humidifier increase parabolic with the increasing frequency. The tidal volume stays the same.

5.4.3 Control region connection valve

The simulation of the connection valve is used to visualize the working principle of the connection valve and the impact of the connection valve on the minimal reached flow out of the Bonemine Module. This is simulated with a sinus pressure at the HFO Module of a MAP of 10 and 20 mbar and a minimum pressure of -5, -10, -15 and -20 mbar at the frequencies 5, 8, 11, 14, 17 and 20 Hz. The speed of the blower is 0 rpm.

The minimal flow out of the Bonemine Module without connection valve is higher at lower frequencies than at higher frequencies (Figure 5.30 and 5.31). The Bonemine Module can be compared with a RC-network. The higher the frequency the more damped is the pressure signal towards the blower. This results in less flow out of the blower during higher frequencies.
The connection valve limits the flow out of the Bonemine Module. The response time of the connection valve explains the increase of flow out of the Bonemine Module at higher frequencies.

The flow out of the Bonemine Module is also sensitive for the mean pressure (Figure 5.30 and 5.31). The ratio between the area of the pressure above P_{max} of the blower and below

determine also the netto amount of flow out of the Bonemine Module. During the simulations P_{max} was zero to simulate the worse case of minimal flow.

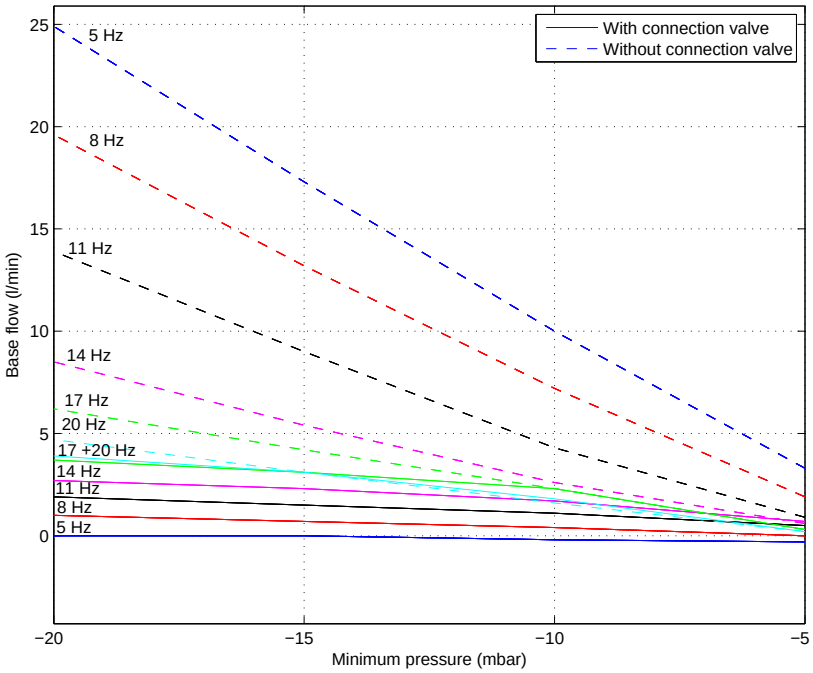


FIGURE 5.30: Flow out of the Bonemine Module simulated with and without connection valve. Simulated with a MAP of 10 mbar, a minimum pressure of -20, -15, -10 and -5 mbar and a frequency of 5, 8, 11, 14, 17 and 20 Hz.

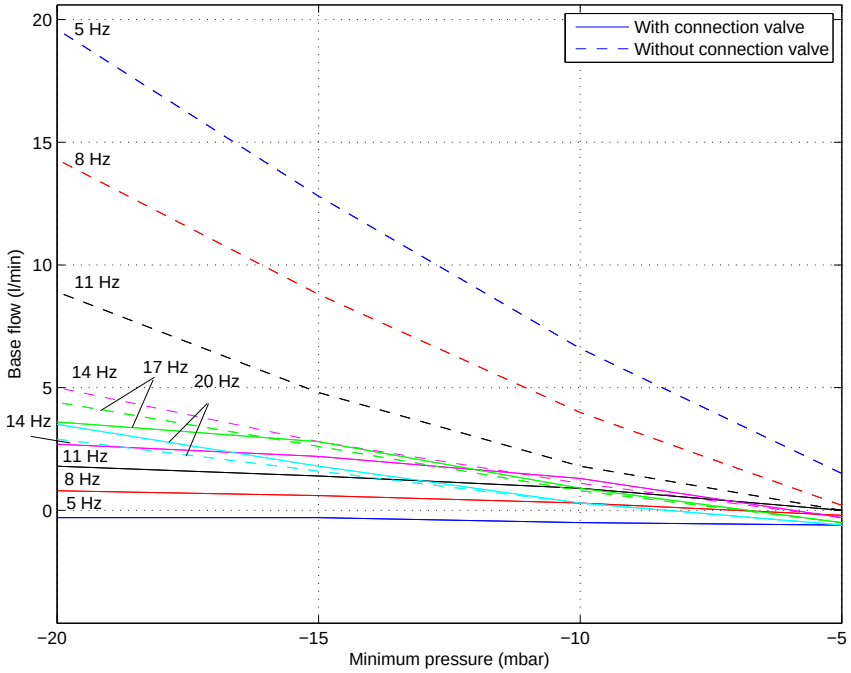


FIGURE 5.31: Flow out of the Bonemine Module simulated with and without connection valve. Simulated with a MAP of 20 mbar, a minimum pressure of -20, -15, -10 and -5 mbar and a frequency of 5, 8, 11, 14, 17 and 20 Hz.

5.5 Discussion

The most important findings in this chapter are:

- the patient model gives a good representation of the hose system and the patient
- the patient model shows an increase of pressure and flow for system's requirements compared to customer's requirements
- the system model gives a good understanding of the working principle of the connection valve
- the system model shows that the connection valve will restrict the flow from the Bonemine Module

The goal of this chapter is to develop a simulation model that helps in developing a new Respiratory Module. Therefore a patient model is developed to translate the customer's requirements to system's requirements and a system model is developed to theoretically validate the design of the connection valve.

In the verification of the patient model is concluded that in reality the pressure was more damped in the expiration hose compared to the simulations. Simulating the expiration hose with more elements could make the patient model more accurate. The step size of the simulation model would then be increased, which makes the simulation model more compute-intensive. If the patient model would be used for a design that requires a higher accuracy, a good consideration between accuracy and the demand for computing should be made.
It was not possible to do a good verification of the flow from the patient model. During this verification it seems that the patient model has an overestimation of the flow, but the verification was influenced by the lack of performance of the test set-up. During later experiments of Macawi it appeared that the flow overestimation of the patient model is very small, but no real verification has been done. It is recommended to do another flow verification when a better HFO ventilator is available.

The resistances and compliances inside the patient model create a damping and a phase-shift. The damping of the model is verified, but the phase-shift is not verified. The phase-shift has no influence on the outcome of the simulation and is also hard to measure during experiments, because pressure sensors and data acquisition also create a phase-shift in the measured signals.

In this simulation model some parts of the Bonemine Module model are provided by Macawi. During verification of the response of the Bonemine Module model is shown that the pressure response of the model is accurate, but the flow response is less accurate. A redesign of the check valve with non-linear resistance can be considered. Also better measurements and simulation of the response of the blower during $P_{HFO} > P_{blower,max}$ and $P_{HFO} < 0$ will improve the simulation. The lower flow response of the Bonemine Module during the simulations can have an effect on the simulated minimal flow through the connection valve.

The verification of the simulation model of the connection valve shows that there is indeed an underestimation of the flow through the connection valve. The pressure response of the connection valve during simulation has a good match with the experiments.

About all of the simulation models can be said that there are still opportunities to improve, but that the outcome of the simulation gives a good match with the reality. The results of the simulations can be used during this research.

5.6 Conclusion

5.6.1 Patient Model

The pressure representation of the patient model is correct according to the verification. It was not possible to do a good verification of the flow at the humidifier, because the test set-ups were not capable to get such high performance. The patient model consists of compliances and resistances and it can be concluded that the ideal gas law and empirical compliance are a good way for modelling the compliance. The orifice model and the Darcy-Forchheimer law are a good way for modelling the resistance.
The damping in the expiration hose is not modelled sufficient, this could be improved by modelling the expiration hose with more elements.

5.6.2 System Model

The system model gives a good representation of the pressure response and a slightly underestimation of the flow response. The system model consists of a pneumatic and a kinematic part. It can be concluded that the Law of Boyle, the ideal gas law, orifice model and empirical

resistance give a good representation of the pneumatic part. The kinematic part gives a good representation of the working principle of the connection valve.

5.6.3 Requirements for the ventilator side

The needed flow and pressure near the patient is not the same as the flow and pressure from the ventilator. The big compliance of the humidifier and the resistance of the inspiratory hose have a large impact on the difference in flow and pressure between system's and customer's requirements. The higher the frequency the more flow and pressure is needed from the ventilator to deliver the same tidal volume at the patient. The performance of the HFO Module cannot fulfil the requirements of the customer of Macawi, but can fulfil the requirements of the clinicians.

5.6.4 Control region connection valve

The system model gives a good understanding of the working principle of the connection valve. The connection valve has a better control on the flow at lower frequencies than at higher frequencies. The control of the connection valve is also more needed at lower frequencies than at higher frequencies.

Chapter 6

Connection Valve

6.1 Introduction

A good design starts with a good design process and a good understanding of the needed performance. Like Steve Jobs said: "In most people's vocabularies, design means veneer. It's interior decorating. It's the fabric of the curtains or the sofa. But to me, nothing could be further from the meaning of design. Design is the fundamental soul of a human-made creation that ends up expressing itself in successive outer layers of the product service."[15]
A design process is a closed loop process and has multiple iterations. The aim is to make a design right the first time, but it is more realistic to try the design to be right when it goes to the market.[16]

The goal of this chapter is to design a connection valve.
First a good overview will be created of the problem, the requirements and the current solutions (Section 6.2). After that the following issues will be described:

- current solutions (Section 6.3)
- design process (Section 6.4)
- conceptual designs (Section 6.5)
- winning concept (Section 6.6)
- final design (Section 6.7)
- experiments (Section 6.8)

- results (Section 6.9)
- discussion (Section 6.10)
- conclusion (Section 6.11)

6.2 Problem definition and requirements

The Bonemine Module cannot control the flow when the pressure of the HFO Module is lower than ambient pressure (Figure 6.1 and 5.18). This has negative influence on the mixing of air with oxygen and the control on the oxygen concentration is lost. During negative pressure the blower is an open connection with ambient. This makes it hard for the HFO Module to generate a negative pressure and influence the performance of the device at the patient. The connection valve has to prevent this problem.
The minimal amount of flow out of the Bonemine Module is the problem. The Bonemine Module can always generate more flow by increasing the speed of the blower.

6.2.1 Goal

The connection valve has to limit the flow from the Bonemine Module to the HFO Module when the Bonemine Module cannot control the flow. The connection valve has to control the flow or pressure up to 20 Hz. The valve shall not prevent flow from the Bonemine Module to the patient during IPPV.

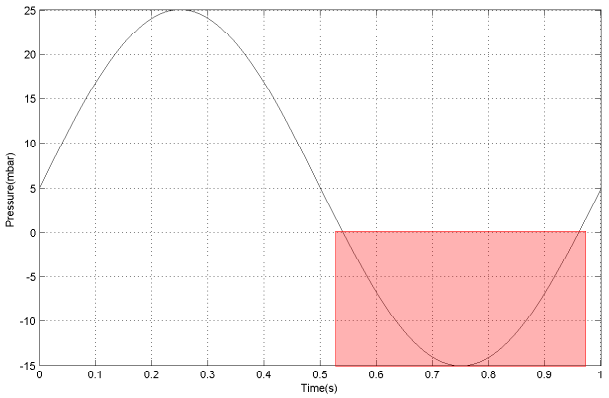


FIGURE 6.1: Pressure waveform of the HFO Module. When the pressure is lower than ambient pressure the Bonemine Module has no control of the base flow, because the blower has an open connection to ambient in this situation. The pressure on the y-axis is the pressure between the Bonemine Module and the HFO Module and is relative to ambient pressure (*mbar*).

6.2.2 Control strategy of the Respiratory Module

The behaviour of the connection valve has an influence on the control of the Respiratory Module. The connection valve can behave in two ways:

1. The connection valve can close when the pressure of the HFO Module drops below ambient pressure.

2. The connection valve can close when the pressure of the HFO Module drops below mean pressure.

The control of the Respiratory Module has to respond on the increase of resistance of the connection valve. The control is easier when the connection valve closes frequently (behaviour 2) instead of only when the pressure become under ambient (behaviour 1). The impact of the final design on the control strategy is more explained in the discussion (Section 6.10).

6.2.3 Requirements

The circumstances among which the connection valve has to function is shown in Table 6.1 and Figure 6.2. The requirements are split into functional (Table 6.2) and non-functional requirements (Table 6.3). For the requirements see also Chapter 4. There are also criteria and guidelines with no hard numbers.

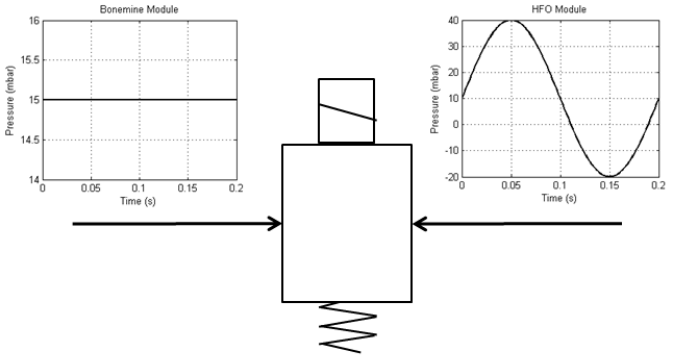


FIGURE 6.2: Schematic overview of the circumstances of the connection valve. The Bonemine Module delivers a constant pressure and the HFO Module a sinusoidal pressure.

Circumstance	Scale	Will be
Constant pressure from Bonemine Module (g)	mbar	10 to 70
Delta pressure from HFO Module	mbar	1 to 100
Maximum pressure (g)	mbar	$\leq$ 110
Minimum pressure (g)	mbar	$\geq$ -30
Pressure ramp	mbar/msec	$\geq$5

Table 6.1: Circumstances of the connection valve

Requirement	Scale	HTM	Must do	Plan	Wish
Minimal flow during HFO ventilation	L/min	S,T	$4 \cdot V_t \cdot freq \cdot 60$	$3 \cdot V_t \cdot freq \cdot 60$	$2 \cdot V_t \cdot freq \cdot 60$
Flow during IPPV	L/min	S,T	≤ 100	≤ 150	≤ 200
Resistance during IPPV	mbar at 30L	S,T	< 2	< 1	< 0.5
Switching speed	msec	S,T	< 50	< 25	< 5

Table 6.2: Functional requirements for the connection valve

Requirement	Scale	HTM	Must do	Plan	Wish
Leakage	L/min/mbar	T	0.5	0.2	0
Power consumption	W	T	< 30	< 15	0
Power supply	V	I	24	24	0

Table 6.3: Non-functional requirements for the connection valve

6.2.3.1 Criteria

For these criteria no real numbers are available:

- Low cost
- Low weight
- Small size
- Safe
- Simple to control
- biocompatible materials

6.3 Information about current high frequency valves

First, current valves in HFO ventilators are investigated, before the decision to make a new design for the connection valve was made. This is done based on the authors literature study

[5] and information from Macawi.

6.3.1 Existing solutions

All ventilators with HFO functionality are using a high pressure gas source. In these ventilators the combination of a pressure regulator and a proportional valve is used or only proportional valves are used to control the flow and pressure to the patient (Figure 6.3). No examples are found as good example for a connection valve.

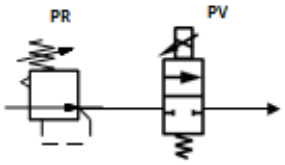


FIGURE 6.3: Pressure regulator (PR) in combination with proportional valve (PV)

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6.3.2 Idea from feasibility study

Macawi has done a feasibility study about another HFO ventilator for a valve which will be designed. In this study the blower in combination with the expiration valve and a venturi behind the expiration valve is used to generate HFO ventilation. A valve between the blower and the patient has to be designed. The designed valve has only to control the flow on a low frequency. This valve is not suitable as connection valve, because the connection valve has to be designed for higher frequencies and the response time of this valve is too long for this purpose. The valve in this study was a combination of a proportional valve and a membrane valve. The proportional valve controls the pilot pressure above the membrane (Figure 6.4).

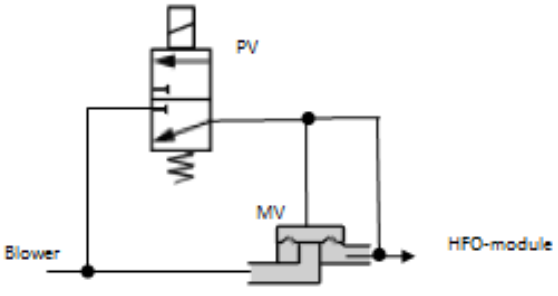


FIGURE 6.4: Schematic overview of the valve from the feasibility study: A combination of a proportional valve (PV) and a membrane valve (MV). The proportional valve controls the pilot pressure above the membrane.

6.3.3 Conclusion

Existing valves in current HFO ventilators and the feasibility study of Macawi didn't reveal a good solution for the connection valve. Therefore a new design is made. The information about the current valves is considered during the design process.

6.4 Design approach

A lot of different design models and methodologies are available.[17] The way the design process is approached in this chapter is: First the essence of the problem is translated in technical principles (Section 6.2). After that current solutions are examined based on the authors literature study (Section 6.3). Then a brainstorm session was organized with a group of five people of Macawi. The brainstorm session started with a small presentation to introduce the subject, then individual brainstorming and brainstorming in the group was organized.
The different concepts are further elaborated by a morphological analysis and assessed by an analysis of design solutions and a decision matrix. (Section 6.5)

First the final design is simulated (Chapter 5). After that the design is more detailed in SolidWorks 2012 (Appendix D) and printed with rapid prototyping with the technique Stereo lithography (SLA). The testing of the connection valve is done with the system Dspace 1.4x in combination with Matlab and Simulink R2013b. A control loop for the Bonemine Module, HFO Module and Expiration valve is provided by Macawi to use during the experiments. During the experiments design parameters and the requirements are tested, this is further explained in Section 6.8.

6.5 Conceptual designs

Before the winning concept is chosen, first some calculations are done on the problem and a brainstorm session is held. After that a morphological analysis is done and concepts are made. The winning concept is chosen with a decision matrix. This will be described in the following paragraphs.

6.5.1 Calculations

Some calculations are made to conceive more information and understanding about the forces on the valve and the response time of the valve.

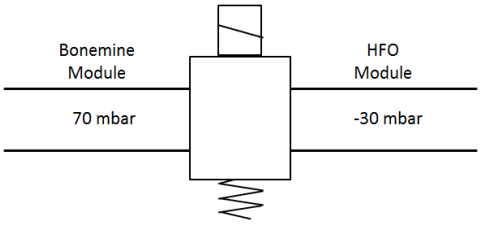


FIGURE 6.5: Most extreme circumstance for the connection valve.

The most extreme circumstance for the connection valve is when the Bonemine Module delivers the maximum pressure and the HFO Module the minimal pressure (Figure 6.5 and Section 6.2.3). This creates a delta pressure of 90 mbar over the connection valve. The hoses connected to the connection valve have a diameter of 13 mm. The force that is needed to close the valve is 1.53 N ($F = P \cdot A$, Table 6.4)
The period that the pressure is under ambient is no longer than half the period of the wave form (figure 6.1), because the mean airway pressure is never lower than 0 mbar. The maximum frequency is 20 Hz. The valve has to respond faster than a quarter of a period, to be closed and open in half a period. The minimal response time for a frequency of 20 Hz is 12 milliseconds.

Diameter Orifice (m)	$13e^{-3}$
Size Orifice (m^2)	$1.77e^{-4}$
Delta Pressure $(mbar)$	90
Delta Force (N)	1.53

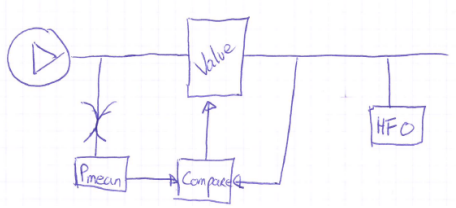
TABLE 6.4: Force on valve with delta pressure 90 mbar. The valve has to respond in at least 12 milliseconds.

6.5.2 Brainstorm session

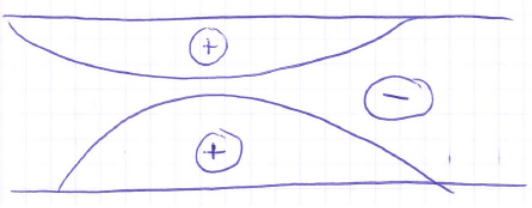
During the brainstorm session it became clear that the control of the valve and changing the orifice size of the valve are independent designs of each other. For both parts different solutions are possible.

The valve can be passively or actively controlled. Passive will be based on pressure difference between the Bonemine Module and the HFO Module (Figure 6.6a).

The size of the orifice can be changed by membrane (Figure 6.6b), a ball (Figure 6.6c) or a parachute (Figure 6.6d).

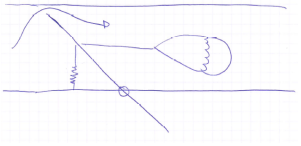


(A) Passive way of controlling the valve. The pressure difference over the valve is used to close or open the valve.



(B) A membrane to change the orifice size.

(C) A ball will roll back and forth and will open or close a orifice. The orifices at both sides have different shapes.



(D) Parachute will be pulled backwards by the flow.

FIGURE 6.6: Ideas from the brainstorm session.

6.5.3 Morphological analysis

The problem can be divided into two parts, how to control the valve and how to change the orifice diameter of the valve. The different options that are possible for every part are visible in Table 6.5. The grey parts are combined to concepts.

Options	Control	Orifice
1	pneumatic	fixed resistance
2	voice coil	variable resistance
3	piezo valve	membrane
4	electric	symmetric disc
5	mechanical	non-symmetric disc
6	solenoid	pressure sensing valve
7	step motor	bar
8		check valve
9		pneumatic screen
10		governor

TABLE 6.5: Morphological analysis, the grey parts are combined to concepts.

6.5.4 Concepts

Different options of the morphological analysis are combined to concepts (Table 6.6). Concept A and B are active controlled. Concepts C,D and E are passively controlled.

Concept	Control	Orifice
A	voice coil	membrane
B	piezo valve	bar
C	passive	membrane
D	passive	variable resistance
E	passive	check valve + pressure sensing valve

TABLE 6.6: Concepts A - E

6.5.4.1 Active way of controlling

Concept A is a membrane in combination with a voice coil (Figure 6.7). The distance of the membrane to the seat determines the orifice size of the valve. The membrane is controlled by the voice coil.

Concept B is a bar in combination with a piezo valve (Figure 6.8). A bar from piezo ceramic material deforms when an electrical charge is applied.

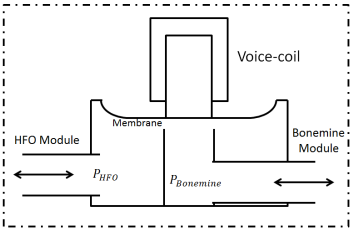


FIGURE 6.7: Concept A: A membrane can change the orifice size and is controlled by a voice-coil.

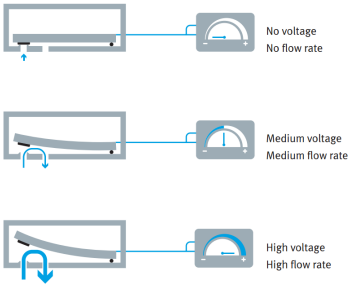


FIGURE 6.8: Concept B: A bar can change the orifice size and is controlled by a piezo valve. [Redrawn from Festo [18]]

6.5.4.2 Passive way of controlling

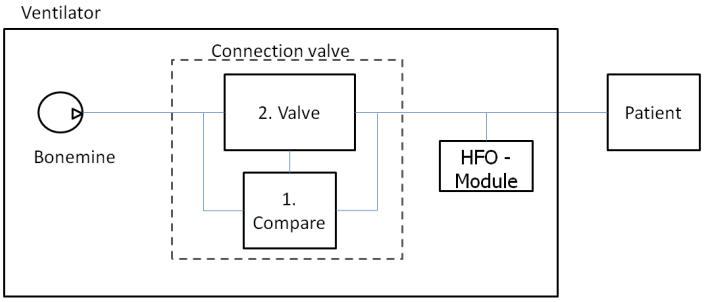


FIGURE 6.9: Passive way of controlling

The passive control of the valve is based on the difference between the pressure of the HFO Module and the Bonemine Module (Figure 6.9). Chamber one compares the pressure between the Bonemine Module and HFO Module and controls with the result a valve. The way of comparing and controlling differs per concept.

Concept C (Figure 6.10) uses a membrane (number 3) to change the orifice size . The pressure difference between the pilot pressure, pressure of the Bonemine Module and the HFO Module determines the position of the membrane. The pilot pressure can be changed by a resistance (number 1). The pilot pressure can be the pressure of the Bonemine Module, or the HFO Module of a combination or both. Also a pre-tension can be applied on the membrane (number 2).

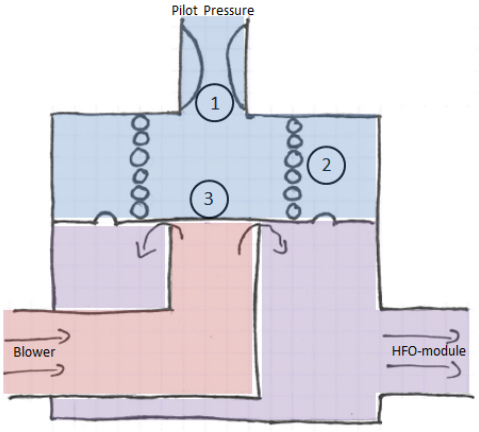
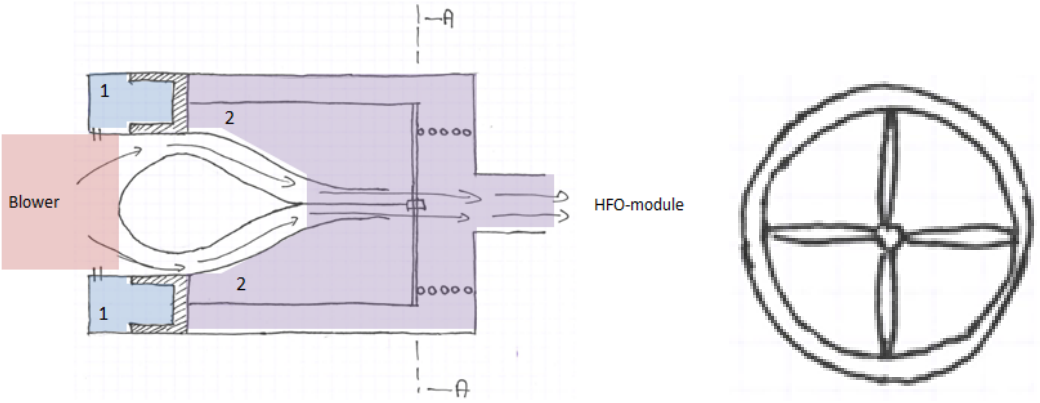


FIGURE 6.10: Concept C: A membrane valve where the pressure difference between the blower (Bonemine Module), HFO Module and pilot pressure determines the distance between the membrane and the seat.

Concept D uses variable resistance (droplet) to change the orifice size (Figure 6.11). The pressure difference between the Bonemine Module (number 1) and the HFO Module (number 2) apply a force on the plunger. The plunger is connected to the droplet. When the pressure of the HFO Module becomes lower than the pressure of the Bonemine the droplet moves to

the right and blocks the entrance. If the pressure of the HFO Module become higher than the Bonemine Module the droplet moves to the left and the size of the orifice increase.

Because of the shape of the droplet the flow from the Bonemine Module (blower) to the HFO Module will encounter a lower resistance than the flow from the HFO Module to the Bonemine Module. In this way the flow to the patient encounters the least resistance.



(A) Concept D (B) Cross-section A-A

FIGURE 6.11: Concept D: A valve where the pressure difference between the Bonemine Module (1) and HFO Module (2) apply a force on a plunger that is connected to the droplet. The droplet restricts the orifice.

Concept E (Figure 6.12) uses a pilot check-valve and a pressure sensing valve to control a membrane valve (Figure 6.10). Flow will go through the piloted check-valve when the pressure of the HFO Module is lower than the pressure of the Bonemine Module. The flow out of the pilot check-valve activates the pressure sensing valve and the normally close port will open. The normally close port is connected to a membrane valve. Through the pilot check-valve and a pressure sensing valve the membrane valve is controlled when $P_{HFO} < P_{Bonemine}$.

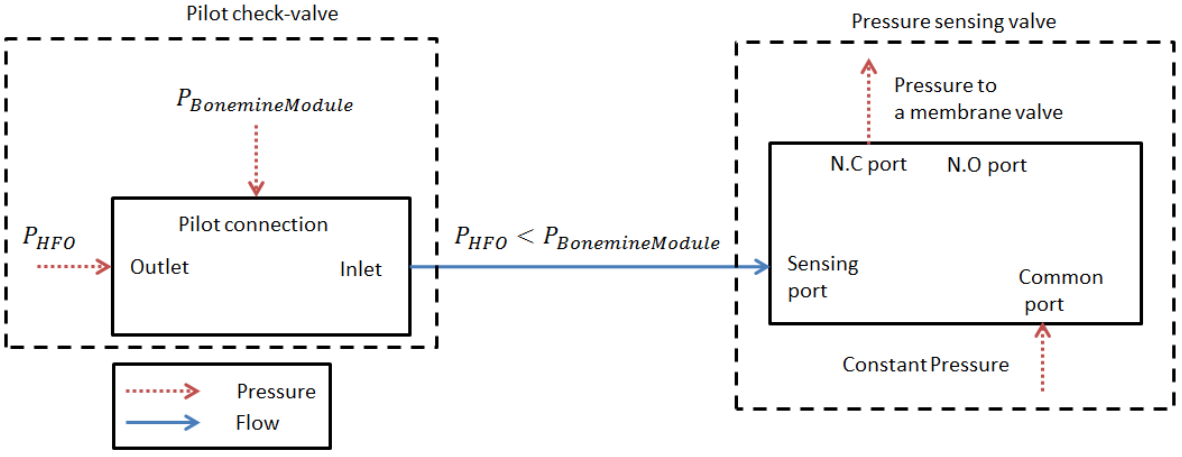


FIGURE 6.12: Concept E: Flow will go through the pilot check-valve when the pressure of the HFO Module is lower than the pressure of the Bonemine Module. The flow out of the pilot check-valve activates the pressure sensing valve and the pressure at the common port will go the a membrane valve.

6.5.5 Analysis of Design Solutions

Different types of analysis will be performed to examine the different concepts. If a concept fails one of the analysis, the concept is a failure and will be eliminated from further analyses.

- Functional analysis: This part determines whether the given design solution will function the way it should. According the criteria in section 6.2.3.
- Mechanical/Strength analysis: This part determines if the given design solution will be strong enough. The evaluation is done on every subsystem. According the criteria in section 6.2.3 and 6.5.1
- Electrical analysis: This part determines the amount of power consumption and electrical difficulties/risks. According to the criteria in section 6.2.3.
- Control analysis: This part determines the control strategy of the valve and the influence on the control of the Respiratory Module. According the criteria in section 6.2.3.

6.5.5.1 Functional analysis

This analysis determines whether the given design solution will function the way it should. This will be analysed according to the following situations:

1. Is the orifice partly or totally closed in the situations: pressure between the Bonemine Module and the connection valve is higher than ambient and the pressure between the HFO Module and the connection valve is lower than ambient.
2. Is the connection valve open in the situations: pressure between the Bonemine Module and the connection valve is higher than ambient and the pressure between the HFO Module and the connection valve is also higher than ambient.
3. Is the connection valve open in the situation: the HFO module is not used and only the Bonemine Module determines the pressure in the system. The pressure at both sides of the connection valve are almost the same.

Concept A: The function of this concept depends on the control of the voice-coil, but in theory fulfils this concept all needs.

Concept B: The function of this concept depends on the control of the piezo valve, but in theory fulfils this concept all needs.

Concept C: The response of the membrane valve depends of the pilot pressure. If the force of the pilot pressure on the membrane is smaller than the force of the HFO pressure on the membrane and smaller than the force of the Bonemine Module, the concept fulfils all needs.

Concept D: This concept compares the pressure between the HFO Module and the Bonemine Module and fulfils all needs. If the pressure of the HFO Module becomes lower than the pressure of the Bonemine Module the droplet will restrict the orifice more, independent if the pressure of the HFO Module is lower than ambient.

Concept E: Most pressure sensing valves won't function at the low pressures that are available from the pilot check-valve. Therefore this concept fails this analysis.

6.5.5.2 Mechanical/Strength analysis

This part determines if the given design solution will be strong enough and has a low enough resistance. This will be analysed according to the following situations:

1. The maximum pressure difference between the Bonemine Module and the HFO Module is 90 mbar. Can the valve close or restrict the orifice under this circumstance?
2. If the valve is completely open, would it be have a resistance lower than 2 mbar when 30 l/min is flowing through the valve.

Concept A: The force on the membrane is dependent on the force of the voice coil. For most of the voice coils it is easy to apply a force greater than 1.53 N (Section 6.5.1).
A membrane valve can create a large enough orifice to have a low resistance at high flows.

Concept B: The force of most piezo valves can be bigger than 1.53 N (Section 6.5.1). Only most piezo valves have a higher resistance at 30 l/min than 2 mbar. Most piezo valves cannot handle flows bigger than 10 l/min [18]. Therefore this concepts fails this analysis.

Concept C: If the pilot pressure is lower than the Bonemine Module the resulting force on the membrane is downwards and can close the valve. This is still dependent on the force area of the Bonemine Module, HFO Module and the pilot pressure on the membrane. If the pilot pressure is too high, the contact area of the HFO Module pressure has to increase.
A membrane valve can create a big enough orifice to have a low resistance at high flows.

Concept D: This concept will work with big pressure differences between the Bonemine Module and the HFO Module, but not with small pressure differences. The resistance of the valve has to be tested empirical.

6.5.5.3 Electrical analysis

This analysis determines the amount of power consumption and electrical difficulties and risks. This will be analysed according to the following questions:

1. What will be the estimated power consumption?
2. What happens if the electrical board of the connection valve fails?

Concept A: The voice coil of concept A is controlled by current. The maximum current will be 2 A at 24 V. This concept will have a maximum power consumption of 48 Watt. The connection valve will not work without power supply, the control over the base flow will be lost. However the voice-coil will not get stuck and the patient can still be ventilated.

Concept C: This concept has no power consumption and electrical failure has no influence on the working of the valve.

Concept D:This concept has no power consumption and electrical failure has no influence on the working of the valve.

6.5.5.4 Control analysis

This analysis determines the flexibility, easiness of the control of the concept. This will be analysed according to the following questions:

1. What will be the control strategy of the concept, close below ambient of mean pressure?
2. What are the causes of time delay?

Concept A: The control strategy of this concept will be active control. A pressure sensor measures the pressure from the HFO Module. Both control strategies can be applied. There will be a time delay between the moment that the pressure becomes below ambient and the moment the voice-coil will close the valve, because of the time delay of the pressure sensor, filter of the pressure sensor. There is also time delay between software and hardware control of the voice-coil.

Concept C: The control strategy of this concept will be a passive control. The moment the valve closes can be influenced by the height of the seat, the pre-tension of the membrane, the stiffness of the membrane, the force ratio between the pressure of the Bonemine Module, the pressure of the HFO Module and the Pilot pressure. The pilot pressure can be changed by the resistance at the inlet of the cap and can be controlled by the pressure of the Bonemine Module and of the HFO Module. Both control strategies are possible dependent on the chosen design parameters. The time delay is caused by the minimal needed pressure difference before the valve closes. The design parameters can influence the time delay.

Concept D: The control strategy of this concept will be a passive control. The moment the valve closes can be influenced by the distance between the orifice and the droplet, the pre-tension of the plunger, the resistance of the plunger, the force ratio between the pressure of the Bonemine Module and the pressure of the HFO Module. The valve can only close below mean pressure. The time delay is caused by the minimal needed pressure difference before the valve closes. The design parameters can influence the time delay.

6.5.6 Decision matrix

Concept A, C and D didn't fail the analyses and will be evaluated according this decision matrix (Table 6.7).

6.5.6.1 Criteria

Criteria for the decision matrix are:

- Ease of control: 22%
- Durability and strength: 22%
- Ease of manufacturing: 18%
- Weight: 14%
- Use of standard parts: 10%
- Power consumption: 14%

Durability and strength and ease of control are the most important criteria. This determines the most likelihood concept for the goal of the connection valve. On the second most important criterion is the ease of manufacturing. The concept has to be useful for large scale of production. On the third place is the power consumption and weight. This criterion determines whether the concept is suitable for a transportable ventilator. On the fourth place is the use of standard parts. The less amount of unique parts are used the cheaper the concept will be.
To give all criteria influence on the result, the minimum criteria is set on 10%. The other levels differs 4 % with each other.

1. Durability and strength & Ease of control: 22%
2. Ease of manufacturing: 18%
3. Power consumption & Weight: 14%
4. Use of standard parts: 10%

The rating factor R is assigned according the following scale:

- Excellent 4
- Good 3
- Fair 2
- Poor 1
- Unsatisfactory 0

6.5.6.2 Matrix

Concept A: A membrane valve with a voice coil is a tried-and-true concept. Therefore it can be said that the ease of manufacturing is good. The difficulty of this concept is the alignment of the voice-coil with the seat, therefore the ease of manufacturing is not excellent. The ease of control is fair. It is possible to control the valve, but time-delay and filtering in the pressure sensors and time-delay in the actuation, makes it a bit difficult. Durability and strength of the valve is excellent. The voice-coil can deliver enough force to close the valve. Also the use of standard parts is excellent, because it is a tried-and-true concept. The weight of the concept is fair. The voice coils can be light, but the lighter the voice coil, the less force the voice-coil can produce. Also the power consumption is relatively high for the transport situation (Section 6.5.5.3); the more force the voice coil has to deliver the more power it will use.

Concept C: Like concept A it is a pneumatic membrane valve a tried-and-true concept and because in this concept there is no difficulty of alignment of the voice coil, the ease of manufacturing is excellent. The ease of control is good. There are no time-delay and filtering effects because of electronics, but the control is dependent on the geometry of the valve. Therefore the control is not excellent. The durability and strength is fair. The strength of the valve is dependent on the geometry and the pressure drop over the valve. Like concept A is here the use of standard parts also excellent. The weight of the concept is excellent, because everything can be made of light polymer. Also the power consumption is excellent, because there is no need of electronics.

Concept D: This concept is not a tried-and-true concept and doesn't consists of standard parts. Therefore the ease of manufacturing and standard parts is poor. The ease of control depends like concept C on the geometry of the valve and the pressure drop over the valve. Therefore the ease of control is good. The durability and strength is like concept C fair. This concept would weight more than concept C, because it consists of more components. Therefore the weight is good. The power consumption is excellent, because there is no need of power.

Criteria	Weight (%)	Concept A	Concept C	Concept D
Ease of manufacturing	18	3	4	1
R x Weight		54	72	18
Ease of control	22	2	3	3
R x Weight		44	72	66
Durability and strength	22	4	2	2
R x Weight		88	44	44
Use of standard parts	10	4	4	1
R x Weight		40	40	10
Weight	14	2	4	3
R x Weight		28	56	42
Power consumption	14	2	4	4
R x Weight		28	56	56
Total	100	282	340	236

TABLE 6.7: Decision matrix for evaluating options for the connection valve

6.5.7 Conclusion

The best concept is concept C (Table 6.7). The main reasons to choose concept C is that it is a tried-and-true concept that needs no power.

6.6 Winning Concept

The design of concept C consists of five parts (figure 6.14b):

1. the base part (Section 6.6.1)
2. the seat (Section 6.6.2)
3. the cap (Section 6.6.3)
4. the membrane (Section 6.6.4)
5. the supply pilot pressure (Section 6.6.5)

The valve is made in such way that different parameters can be changed during testing:

- the height of the seat (Section 6.6.2)
- the pressure area ratio between the Bonemine and HFO pressure on the membrane (Section 6.6.2)
- the stiffness of the membrane (Section 6.6.4)
- the pilot pressure (Section 6.6.3)

These parameters are influencing the control of the connection valve.

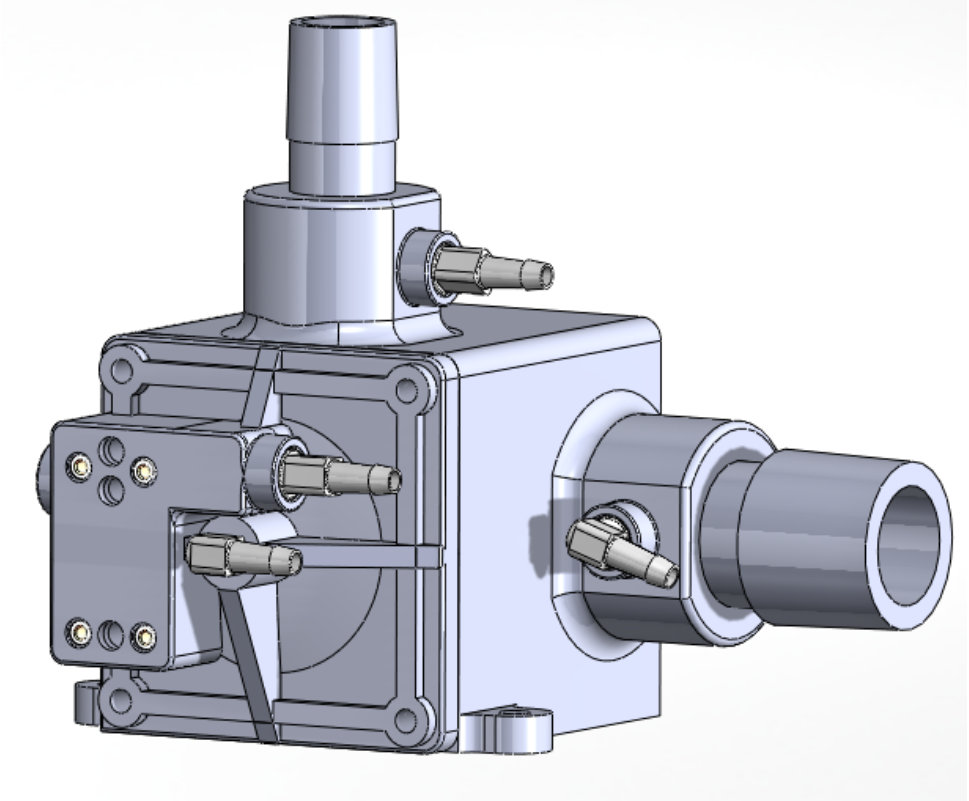
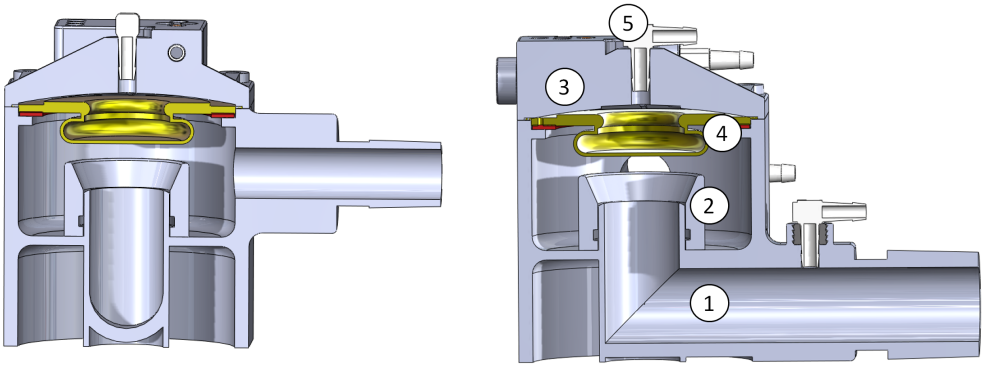


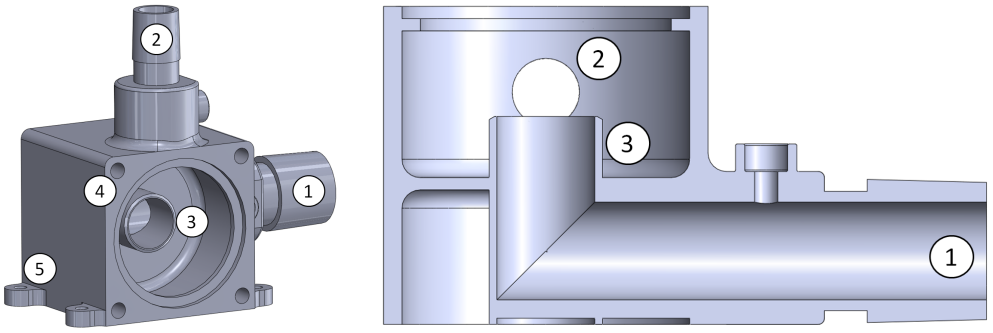
FIGURE 6.13: Connection Valve



(A) Cross section of the Connection Valve (B) Cross section of the Connection Valve

FIGURE 6.14: Connection Valve consists of five different parts: (1) base part, (2) seat, (3) cap, (4) membrane, (5) supply pilot pressure.

6.6.1 Base part



(A) The whole base part (B) Cross section of the base part

FIGURE 6.15: Base part consists of (1) hose connection for the Bonemine Module, (2) hose connection for the HFO Module, (3) small seat, (4) mounting connection for the cap, (5) connections to mount the connection valve on the HFO Module.

The base part(Figure 6.15) consists of:

1. a hose connection for the Bonemine Module
2. a hose connection for the HFO Module
3. a small seat
4. mounting connections for the cap
5. connections to mount the connection valve on the HFO Module

The connection for the Bonemine Module is a hose connection with an outer diameter of 21 mm. This is the same outer diameter as the tube of the Bonemine. A connection hose with an inner diameter of 21 mm can be connected between the Bonemine Module and the connection valve.
The connection for the HFO Module is a tube with an outer diameter of 15 mm. This is the same diameter as the tube of the HFO Module. A connection hose with an inner diameter of 15 mm can be connected between the HFO Module and the connection valve.
In front of the hose connection for the Bonemine Module and the HFO Module there is a hole for a pressure sensor connection.
Inside there is a small seat, this is used to fix the variable seat.

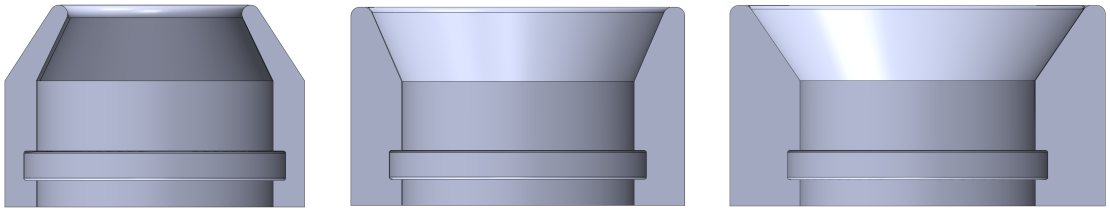
6.6.2 Seat

With the variable seat (Figure 6.16) the area ratio between the pressure of the Bonemine Module and the HFO Module on the membrane can be changed (Figure 6.17) and the maximal distance

between the top of the seat and the membrane. The maximal height between the seat and the membrane is 4 mm and can be decreased by extra rings under the seat. The seat is constructed with a O-ring to prevent leakage along the seat.
Three different seats are made. Seat A (Figure 6.16a) has a Pilot:Bonemine:HFO surface ratio of 1:0.3:0.7. Seat B (Figure 6.16b) has a surface ratio of 1:0.8:0.2. Seat C (Figure 6.16c) has a surface ratio of 1:1.0:0.0.
With these seats different force circumstances on the membrane can be tested:

- a lot of force of the Bonemine Module and less force of the HFO Module (Seat A)
- a lot of force of the HFO Module and less force of the Bonemine Module (Seat B)
- almost no force of the HFO Module (Seat C)

No force of the Bonemine Module was no option because than the seat is too small to have a low resistance during IPPV.



(A) Seat A (B) Seat B (C) Seat C

FIGURE 6.16: Base part

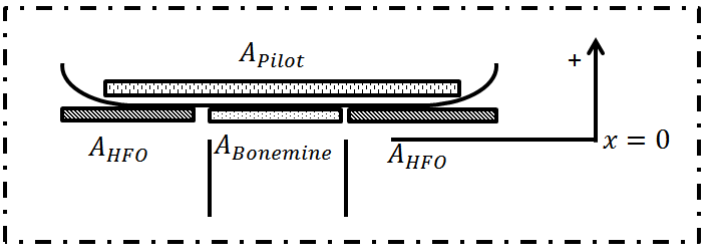


FIGURE 6.17: Surface of each pressure on the membrane.

6.6.3 Cap

The cap is made in such a way that the pilot pressure can be changed (Figure 6.18). The cap has a small volume, so that the settling time between the supply pilot pressure and the pilot pressure inside the cap is minimal. There is also a leakage hole to reduce the pilot pressure. Under the cap (Figure 6.20b) small ridges are made to prevent that the membrane sticks to the cap.

The supply pilot pressure is connected to the cap (Figure 6.19a) and a pneumatic solenoid

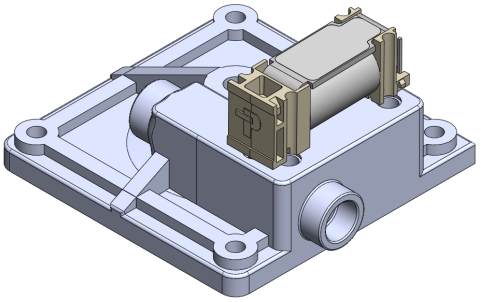
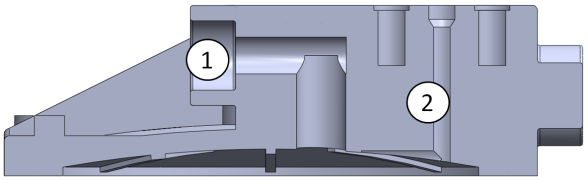
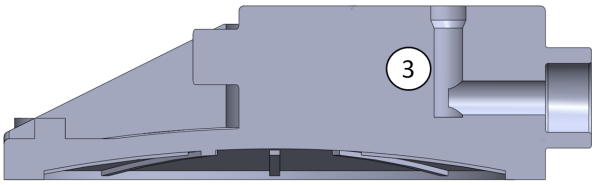


FIGURE 6.18: Surface of each pressure on the membrane.

valve (Figure 6.18). The pneumatic solenoid valve can control the amount of leakage from the cap (number 2 in Figure 6.19a and number 3 in Figure 6.19b). When the pneumatic solenoid valve is not mounted on the cap, the amount of leakage is the biggest. All the leakage is going through number 2 in Figure 6.19a.

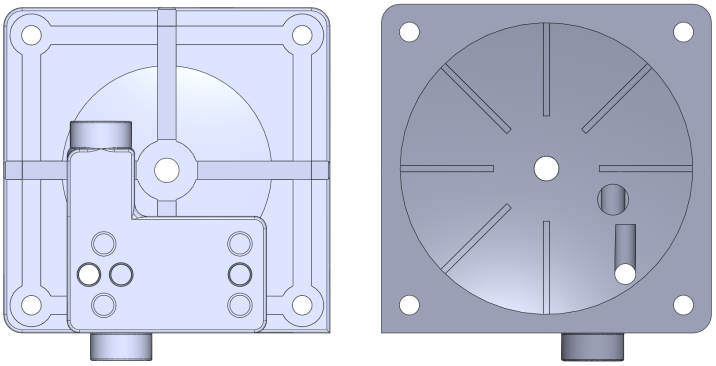


(A) Pilot Pressure supply cannula and cannula to the pneumatic solenoid valve



(B) Leakage cannula

FIGURE 6.19: Cross section of the cap. (A) shows the connection of the supply pilot pressure (number 1) and the cannula to the Parker valve (number 2). (B) shows the cannula of the leakage hole from the Parker valve (number 3).

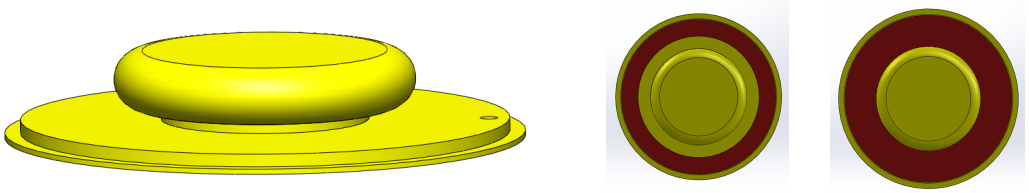


(A) Top view (B) Bottom view

FIGURE 6.20: Cap top and bottom view

6.6.4 Membrane

A standard membrane of Draeger is used (Figure 6.21a). This is chosen because of the flexibility of the membrane, the small surface and the excellent performance with other membrane valves. Also this membrane has the possibility to increase the stiffness by adding an extra ring between the base part of the connection valve and the membrane.



(A) Membrane (B) 5mm ring (C) 10 mm ring

FIGURE 6.21: The membrane consists of a flat plate with a flexible membrane on it. Between the base part of the connection valve and the flat plate different rings can be added to increase the stiffness of the membrane.

6.6.5 Supply pilot pressure

For the supply pilot pressure can be chosen out of the pressure from the Bonemine Module and the pressure from the HFO Module. During the testing is chosen for pressure from the HFO Module, because it can be tried to modify the pressure in such way it helps the membrane to close and open. Modifying can be done by playing with the amount of leakage and adding some resistances to the supply pilot pressure to create a phase shift.

6.6.6 Purchasing Parts

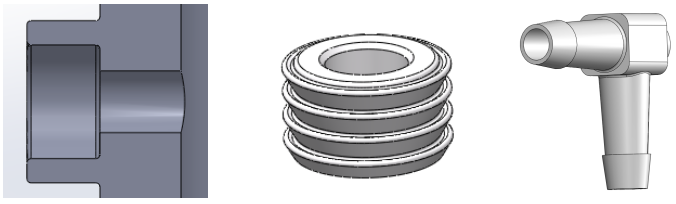
Some standard parts are bought to change parameters of the valve and to measure the pressure inside the connection valve.

To change the height of the seat small rings with a thickness of 0.1, 0.5 and 1 mm are bought. To change the stiffness of the membrane rings with an outer diameter 46.5 and inner of 36 en 29 mm rings are chosen.

To prevent leakage around the seat a O-ring is used with diameter of 17.17mm and a thickness of 1.78 mm.

6.6.6.1 Pressure sensor connections

There are in total four connections on the connection valve to measure pressure (Figure 6.13). In a standard connection hole (Figure 6.22a) a grommet (Figure 6.22b) and a elbow push-on connector (Figure 6.22c) are mounted. On the elbow push-on connector a flexible tube can be connected with a pressure sensor or another small tube.
The pressure sensors were needed to compare the results of the connection valve of experiments with the simulation results, also is the measured pressure used to create a good understanding of the working principle of the valve. The pressures that are measured are the pressure from the Bonemine Module, the pressure of the HFO Module and the pilot pressure.
The used elbow push-on connectors are the Norma WS3.

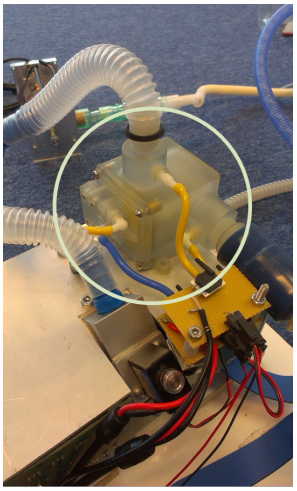


(A) Standard connection hole (B) Grommet (C) Elbow push-on connector

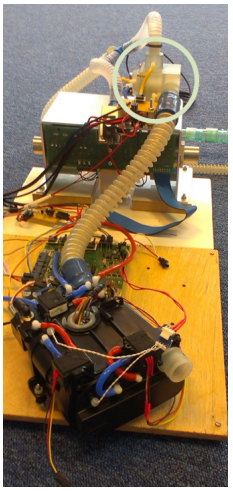
FIGURE 6.22: Pressure sensor Connections

6.6.7 Position of the valve

The valve is positioned on the HFO-Module and connected with a hoses to the Bonemine Module and the HFO-Module (Figure 6.23).



(A) Connection valve positioned on the HFO Module



(B) Connection valve positioned on the HFO Module and connected to the Bonemine Module

FIGURE 6.23: Position of the connection valve between the HFO Module and the Bonemine Module. The connection valve is circled.

6.7 Final Design

For the final experiments the variables are fixed, this is based on experiences with earlier experiments. With these settings the connection valve gives a good result. The argumentation is more explained in the results (Section 6.9).

6.7.1 Seat

During the final experiments seat A is used. The bigger the surface of the HFO Module is, compared to the surface of the Bonemine Module on the membrane, the better the response time of the connection valve.
The height of the seat is not increased with additional rings. A smaller distance between the membrane and the seat was not desirable. The response time became than smaller and the control of the Respiratory Module couldn't handle that.

6.7.2 Cap

During the final experiments the solenoid valve is left out. There was a continuous leakage hole of 2 mm. Otherwise the pilot pressure above the membrane was too big.

6.7.3 Membrane

No extra stiffness is added to the membrane during the final experiments. The ring with an outer diameter of 46.5 and an inner diameter of 36 mm is used under the membrane. Extra damping is added to the membrane. Acoustic foam is used as damping (Figure 6.24). The effect of the extra damping is shown in Section 6.9.2.

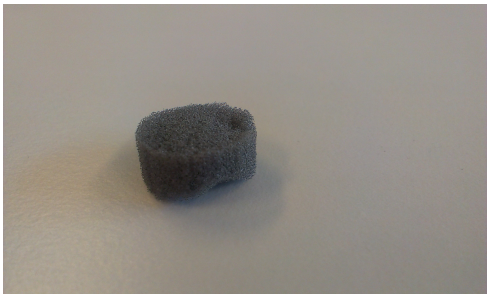


FIGURE 6.24: Acoustic foam used as damping for the membrane inside the cap.

6.7.4 Patent situation

A study is done about patents of membrane valves. The patents of membrane valve that are assigned to the ventilator companies: Acutronic, Carefusion, Sensormedics, Siemens, Maquet, Philips and Draeger are investigated. For the companies Philips and Siemens the word ventilator is also added to the search term. In total 3456 patents are investigated. Most patents exists multiple time, because the patents were available in multiple patent offices.

Acutronic has no patents on membrane valves that regulate flow or pressure.
Carefusion has only patents on membrane valves for needles valves[19, 20] or manual controlled exhalation valve[21]. This is not the kind of valve that is used here.
Sensormedics has only patents on piston valves for pressure regulating[22, 23].
Siemens has patents for i.a. membrane valves with voice-coil, linear motor and solenoid[24–26]. The company has also a membrane valve that is passively controlled on differential pressure, but the valve isn't used to regulate flow[27].
Maquet has no patents on membrane valves.
Philips has also no patents on membrane valves.
Draeger has a patent for a differential pressure membrane valve[28]. In this patent the pressure above the membrane is actively controlled on low frequencies. The company has also a patent on another pneumatic membrane valve[29]. This valve is not used to control flow.

There is also looked for patents with the search term: "membrane valve" ventilator pneumatic. 193 results came from this search term. There are pneumatic membrane valves like a pneumatic exhalation valve, but non are passively controlled[30].

The conclusion of this study is that there are no patents for membrane valves that are passively controlled and are used to regulate flow.

6.8 Experiments

During the experiments the impact of the design parameters are invested and during the final experiments the result of the connection valve is compared with the requirements.

6.8.1 Design parameters

The final design is validated by testing the requirements and the influence of some design parameters. The pressure at the patient is measured at the flow meter in front of the mouth of the patient. The working principle of the connection valve during HFO ventilation is measured during a mean airway pressure (MAP) of 10 and 20 mbar and a minimum pressure of -5, -10, -15 and -20 mbar at the patient and a frequency 5, 10, 15 and 20 Hz. These checkpoints are determined in cooperation with Macawi about the most used values and the extremities of clinicians.

6.8.2 Requirements

The requirements that only could be checked during the final experiments are the control of the flow, the leakage and the resistance during IPPV.

6.8.2.1 Flow out of the blower

The flow out of the blower is measured with and without the connection valve. This is measured during a sinus pressure at the patient of a MAP of 10 and 20 mbar and a minimum pressure of -5, -10, -15 and -20 mbar at the frequencies 5, 10, 15 and 20 Hz. With these settings the flow out of the blower up to the maximum requirements (minimum pressure of -20 mbar and delta pressure of 80 mbar) are tested.

6.8.2.2 Leakage

The leakage of the connection valve is calculated by measuring the flow out of the blower when no flow is going out of the expiration valve and the system is kept at a constant pressure. This is measured at a pressure of 5, 10, 20, 30, 40, 50, 60 and 80 mbar at the connection valve.

6.8.2.3 Resistance during IPPV

The resistance during IPPV is determined by measuring the pressure drop over the connection valve by a flow of 30 $\frac{l}{min}$ out of the blower.

6.9 Results

In this section is shown:

- the pressure response of the connection valve
- the results of the design parameters
- the requirements

6.9.1 Pressure response

The only parameter measured at the connection valve is pressure. The pressure response shows if the connection valve is closed or not (Figure 6.25). The connection valve is open if the pressure of the Bonemine Module and the HFO Module are the same. The connection valve is closed if the pressure of the Bonemine Module and the HFO Module are not the same.

6.9.2 Design parameters

The pilot pressure is the most dynamic design parameter. The behaviour of the membrane, like stiffness and damping have influence on the pilot pressure. But also the amount of leakage out of the cap. The pilot pressure has te most influence on the response time of the connection valve. The height of the seat has also influence on the response time. Only the influence of the height of the seat is more straight forward. The higher the seat the shorter the response time.

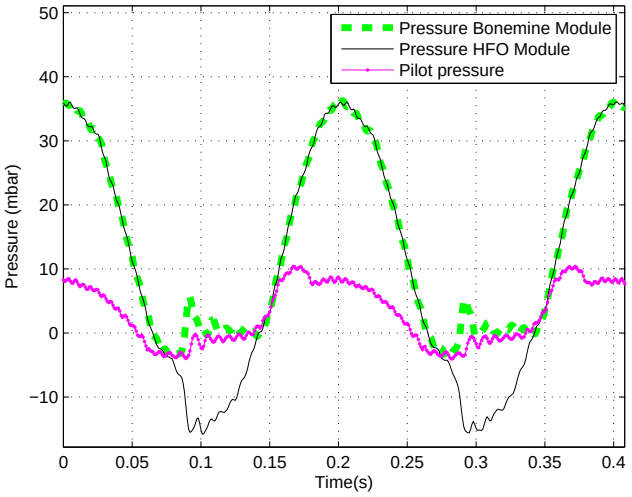


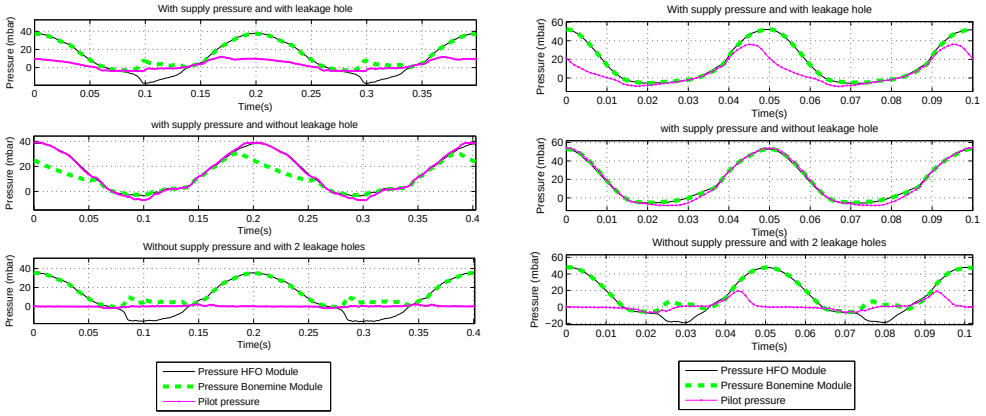
FIGURE 6.25: Pressure response of the connection valve at 5 Hz with a mean pressure of 10 mbar and a minimum pressure of -15 mbar.

The relation between the pilot pressure and the response time of the connection valve is less straight forward. Three situations are compared with each other:

1. with supply pressure and with leakage hole
2. with supply pressure and without leakage hole
3. without supply pressure and with 2 leakage holes

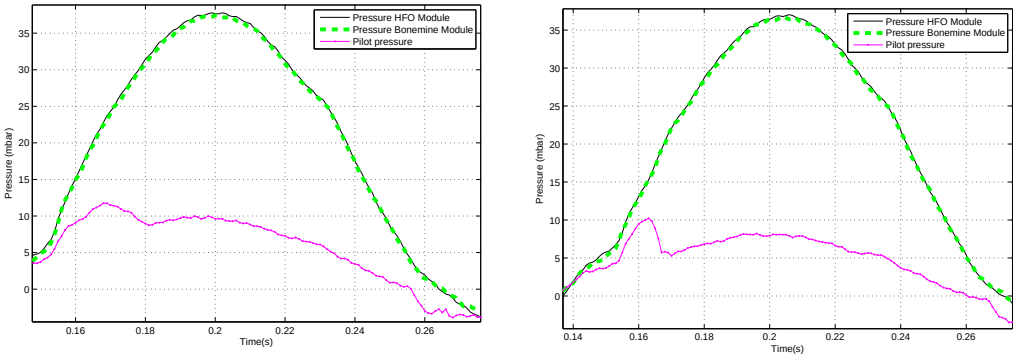
Situation 1 is used during the experiments of the requirements and has a good combination between response time and a good control of the Respiratory Module. The valve closes when the HFO pressure become less than ambient. This is further explained in Section 6.9.3.
During situation 2 the valve closes during positive pressure of the HFO (Figure 6.26a) instead of during negative pressure. The response time is too long to close the valve during 20 Hz. In this situation is creating negative pressure more difficult for the HFO Module, because during the negative stroke the resistance toward the blower is very low (the connection valve is open and the blower has a low resistance).
During situation 3 the valve closes when the HFO pressure drops below ambient and has a faster response time than in situation 1. This is not used during the final experiments, because it was not feasible with the available control for the Respiratory Module (Section 6.9.3.5).

During the final experiments extra damping is added to the membrane. The extra damping creates a smoother response of the pilot pressure and less chance that the membrane sticks to the cap (Figure 6.27).



(A) 5 Hz (B) 20 Hz

FIGURE 6.26: Pilot pressure with damping for three different situations: (1) with supply pressure and with leakage hole, (2) with supply pressure and without leakage hole and (3) without supply pressure and with 2 leakage holes.



(A) With damping (B) Without damping

FIGURE 6.27: Pilot pressure at 20 Hz with supply pressure and with leakage hole.

6.9.3 Requirements

In Table 6.8 is a overview of the realized requirements. The requirements that are explained in more detail are:

- response time of the valve
- flow out of the Bonemine Module
- leakage of the valve
- waveform accuracy
- control of Respiratory Module

Requirement	Scale	Fulfils
Minimal flow during HFO ventilation	L/min	Wish: $\geq 2 \cdot V_t \cdot freq \cdot 60$
Flow during IPPV	L/min	Wish: ≤ 100
Resistance during IPPV	mbar at 30L	Wish: < 0.5
Leakage	L/min/mbar	Plan: <0.5
Power consumption	W	Wish: 0
Power supply	V	Wish: 0

TABLE 6.8: Overview about the fulfilments of the requirements.

- noise

6.9.3.1 Response time of the valve

The response time of the connection valve is between the plan and the must do requirement. The response time is for the frequencies 5 and 10 Hz fast enough (Figure 6.29). The response time is too long to close the valve during 20 Hz.

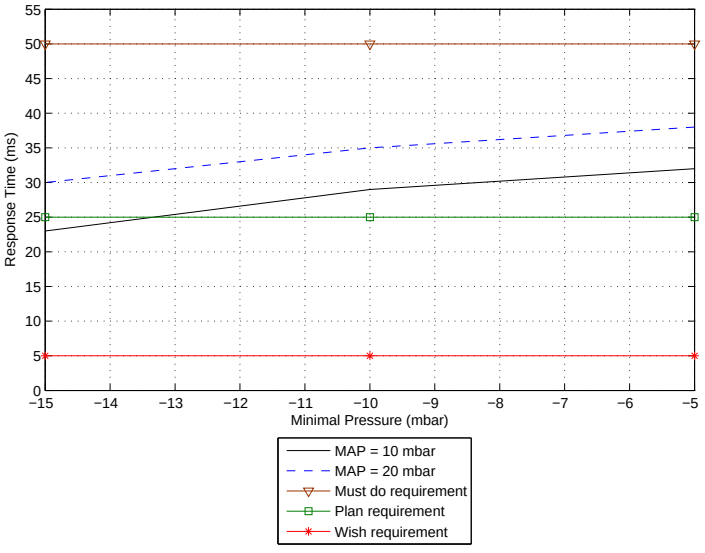
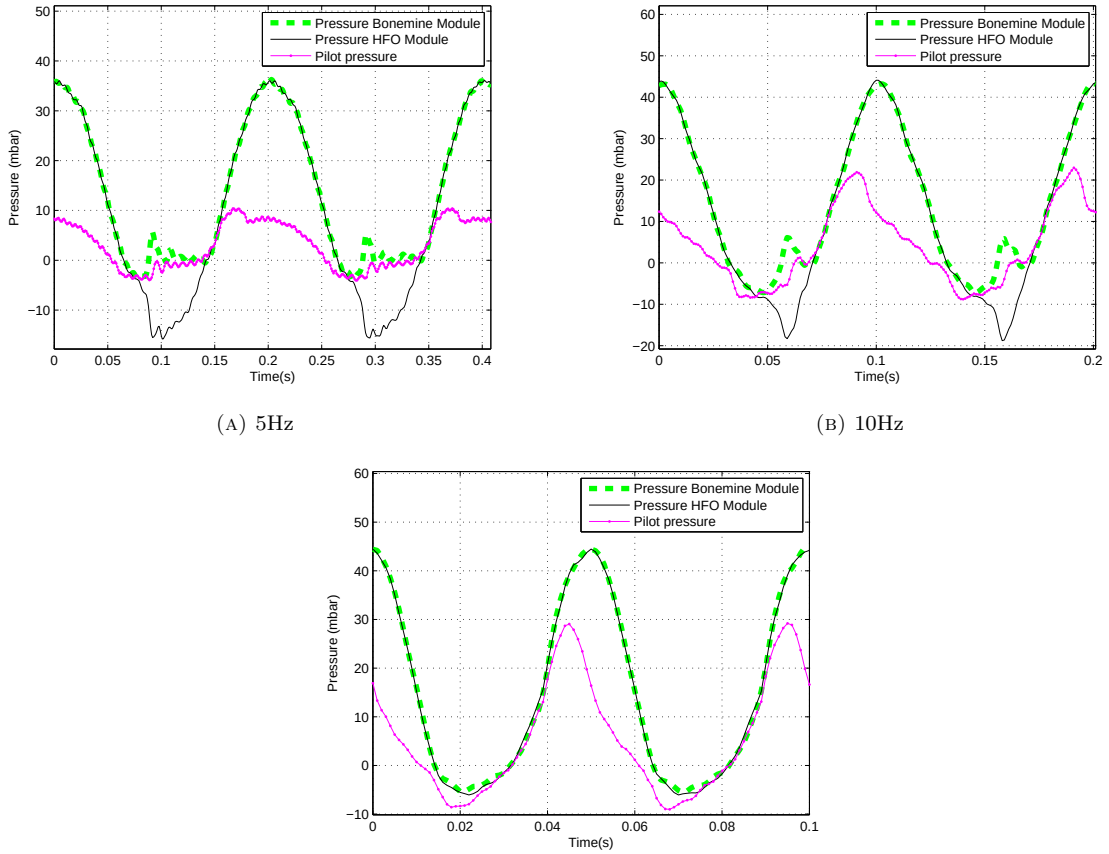


FIGURE 6.28: Response time (ms) of the connection valve at different MAP and minimal pressures. The pressure is measured near the HFO Module and not at the patient.



(A) 5Hz

(B) 10Hz

(C) 20Hz

FIGURE 6.29: The pressure at the connection valve, during a MAP of 10 mbar and a minimum pressure of -15mbar at 5 and 10 Hz and a MAP of 20 mbar and a minimum pressure of -5mbar at 20 Hz.

6.9.3.2 Flow out of the Bonemine Module

The flow at the Bonemine Module (Figure 6.30) is compared with the strictest base-flow requirement of 2 times the tidal volume that the patient inhales during a minute. Some measurement points are missing at a minimal pressure of -20 mbar, because of the performance limits of the HFO Module.

The results are:

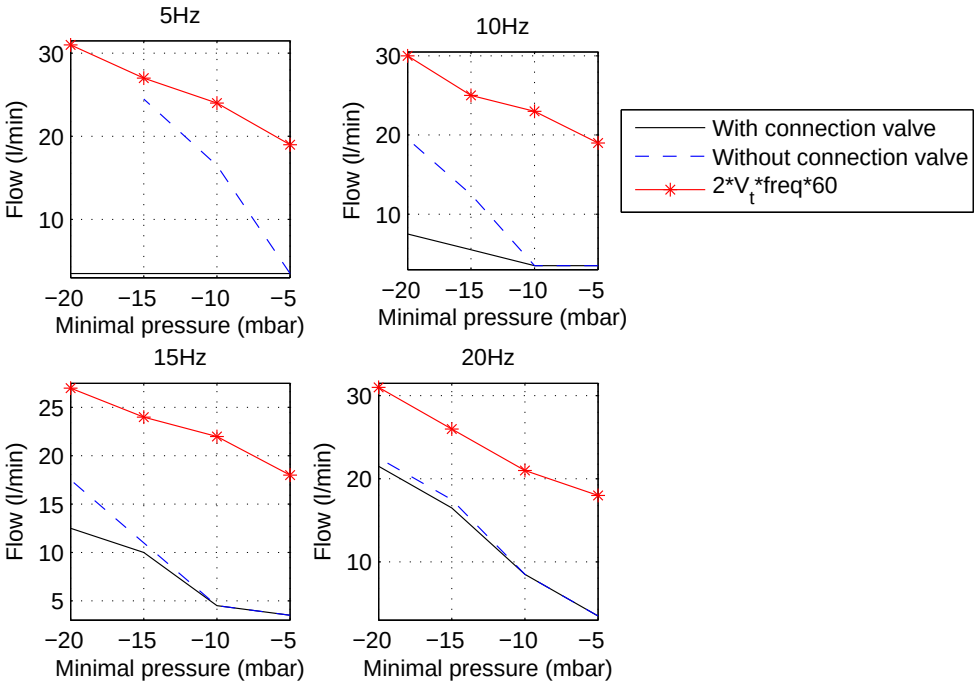
- The flow out of the blower when there is no connection valve is increased if the amplitude becomes bigger and is also MAP dependent.
- The flow out of the blower with connection valve at 5 Hz is the most constant and independent of the minimal pressure or the MAP

- The flow out of the blower with the connection valve at 10 till 20 Hz is increased when the amplitude becomes higher and is also MAP dependent. The flow with connection valve is mostly lower than the flow without connection valve except at 15 Hz with a MAP of 20 mbar. The flows are in that situation the same.
- The proportion between pressure above the pressure of the Bonemine Module and under ambient of the HFO Module determines also the amount of flow out of the blower, because when the HFO pressure becomes above the Bonemine Module there is some negative flow through the Bonemine Module and when the pressure of the HFO Module is below ambient there is a lot of positive flow through the Bonemine Module (see also Figure 5.19 in chapter 5).

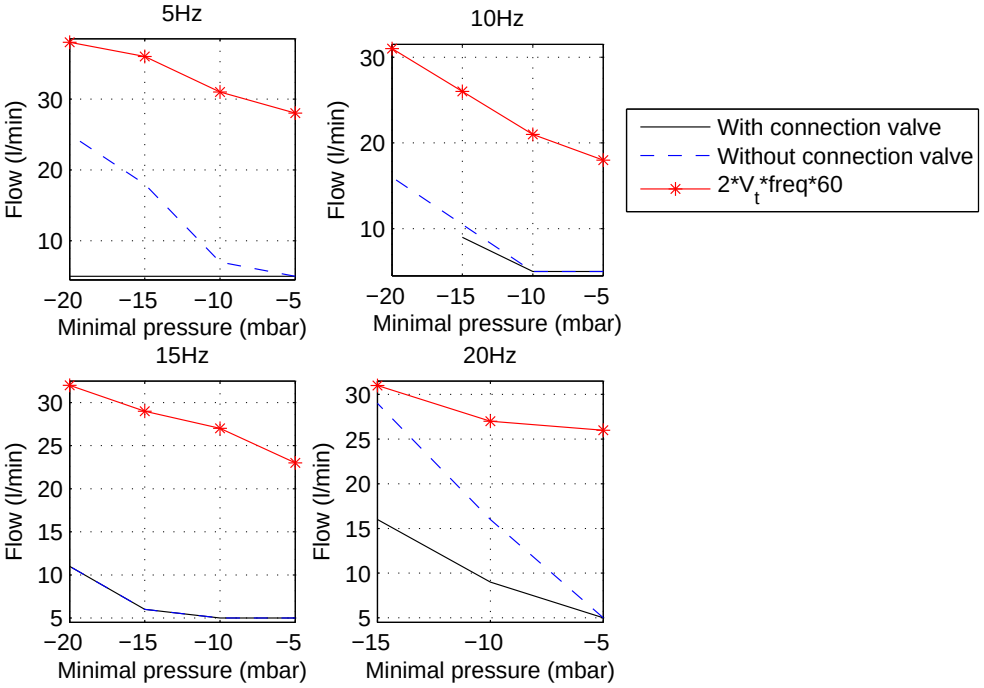
6.9.3.3 Leakage of the valve

All the leakage of the connection valve is leakage of the supply pressure through the leakage hole in the cap (Figure 6.31a). This leakage is at low pressures between the must do and the plan requirement and is at high pressure between the plan and the wish requirement (Figure 6.31b). There is no leakage of the connection of the base part with the cap of the connection valve. This leakage fulfils the wish requirement.

The HFO Module has also a big share in the leakage of the system, but the design of the HFO Module was out of scope.

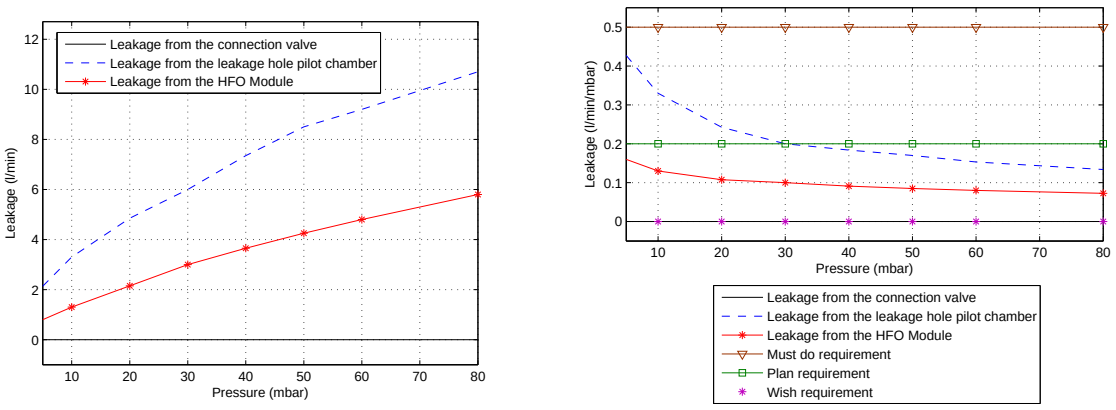


(A) MAP of 10mbar



(B) MAP of 20mbar

FIGURE 6.30: Flow out of blower.

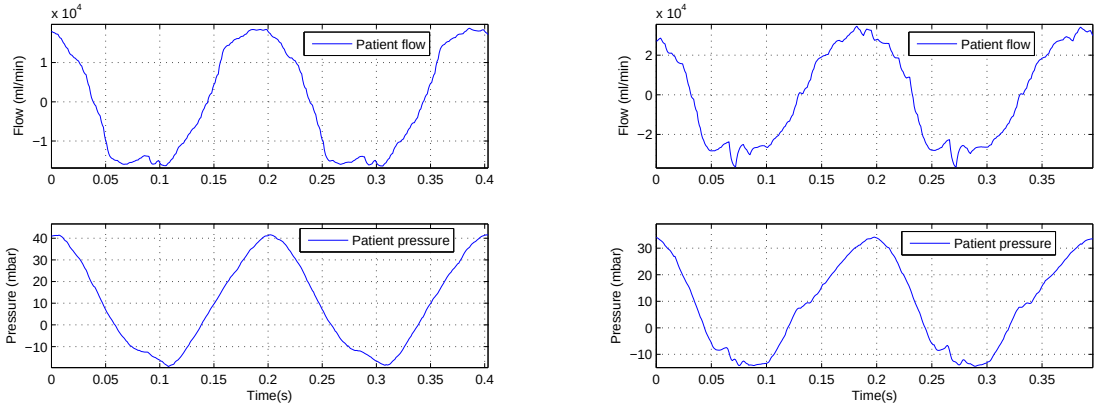


(A) Measured Leakage (B) Measured Leakage divided by the pressure

FIGURE 6.31: Leakage results of the HFO-Module, connection valve (without considering the leakage from the leakage hole in the pilot chamber) and leakage hole in the pilot chamber. (A) is the measurement results, (B) is the measurement results divided by the pressure (to compare with the requirement).

6.9.3.4 Waveform accuracy

The waveform at the patient has less spikes with connection valve (Figure 6.32a) compared without connection valve (Figure 6.32b).



(A) With Connection Valve (B) Without Connection Valve

FIGURE 6.32: The flow and pressure pattern at the patient with and without connection valve. The same settings as Figure 6.29a.

6.9.3.5 Control of Respiratory Module

During HFO ventilation the HFO Module creates the oscillating pressure signal on the MAP created by the Bonemine Module. The speed of the blower changes with a small amplitude and frequency, because the speed of the blower is only changed by a MAP deviation (Figure 6.33).

The connection valve closes around ambient pressure, instead of around MAP. This has a impact on the control of the Respiratory Module. Instead that the connection valve adds in a constant rhythm an extra resistance to the system, now the connection valve only adds an extra resistance to the system when the pressure of the HFO Module becomes below ambient. This depends on settings of the clinicians. Especially the transition part of that the connection valve is continuous open and the connection valve is closed partly during that the pressure of the HFO Module is negative. The blower needs to increase its speed to deliver the same amount of flow in a shorter period of time, when the connection valve is closed part of a pressure period. Only when the blower increases its speeds, the pressure the blower creates also increases. This results in that the connection valve will be a longer period open and the blower has more time to deliver the needed flow. The blower can again decrease its speed, but then the connection valve will be again shorter open. The blower speed is constant when the blower finds its equilibrium between the needed flow and the openings period of the connection valve. To have a fluent response of the Respiratory Module, in the period that the connection valve starts to work, the Bonemine Module and the expiration valve have to be very responsive to each other, more than in the period when the connection valve does nothing or works constant. The faster the response time, the harder it is to let the Bonemine Module collaborate with the expiration valve.

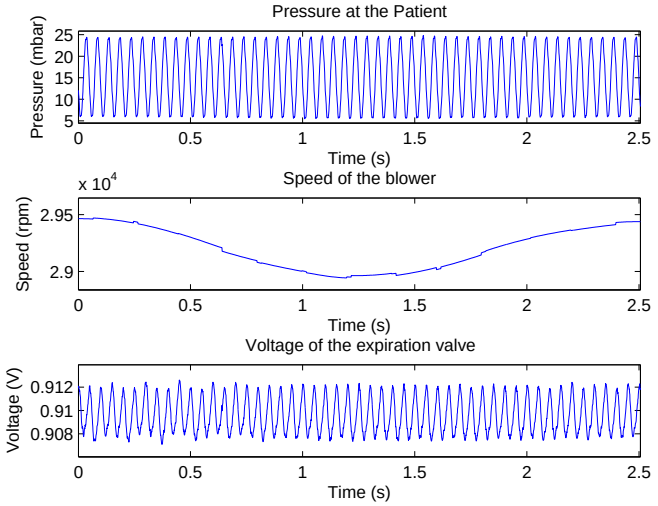


FIGURE 6.33: Frequency is 20 Hz

6.9.3.6 Resistance during IPPV

The pressure drop over the connection valve at 30 l/min through the connection valve is 0.2 mbar.

6.9.3.7 Noise

The valve doesn't rattle or creates a flute noise.

6.10 Discussion

The most important findings in this chapter are:

- A passively controlled membrane valve has the right behaviour to limit the flow out of the Bonemine Module.
- The control of the Respiratory Module during HFO ventilation determines the ideal response time of the connection valve.

The goal of the connection valve is to limit the flow out of the Bonemine Module when the Bonemine Module cannot control the flow. This goal is fulfilled. The response time of the connection valve is fast enough to close the valve when the pressure of the HFO Module becomes below ambient till a frequency of 15 Hz. Above 15 Hz the connection valve doesn't close, but only restricts the flow out of the Bonemine Module. Without connection valve the most flow comes through the blower during low frequencies. Therefore it is not harmful that the connection valve doesn't close during high frequencies. During higher frequencies the pressure towards the blower is more damped and less flow comes from the Bonemine Module when the HFO Module generates pressure below ambient pressure.

The feasibility of the connection valve is proven, but the design isn't finished. In this design the combination between diameter membrane and diameter seat is good, other membranes are also possible, as long as the ratio between the both diameters is maintained. The membrane in the final design is chosen because of the good performance in other membrane valves and the flexibility of the membrane.

The connection valve closes when the pressure of the HFO Module becomes below ambient and not when the pressure becomes below MAP. This makes the control of the Respiratory Module a bit harder, because the connection valve closes infrequently. The Bonemine Module can only deliver flow to the patient when the connection valve is open. When the Bonemine Module has to deliver more flow two things happens. The speed of the Bonemine Module increases therefore more flow is generated, but also the pressure of the Bonemine Module increases

with as result that the connection valve is longer open. This also generates more flow. If the Bonemine Module changes its speed too fast, an overshoot of flow is generated. The control of the Bonemine Module has become more sensitive when the response time of the connection valve becomes faster.

The height of the seat and the pilot pressure determine the response time. When the response time becomes longer the flow out of the Bonemine Module is restricted less. A good consideration have to be made between the response time, the control of the Bonemine Module and the amount of minimum flow out of the Bonemine Module during HFO ventilation. The fastest response time would be when there is no cap at all on the connection valve. In that case the pressure above the membrane is always ambient.

The connection valve has a better response when the pressure of the HFO Module has more contact surface with the membrane than the blower. The contact surface of the Bonemine Module has to be as small as possible in that way that it still creates not a too high resistance during IPPV. To decrease the influence of the Bonemine Module pressure on the response time of the valve the connection of the HFO Module and the Bonemine Module can be switched and another seat has to be chosen. This is not further investigated during this study, but can be done in the next iteration of the design.

The simulation model underestimates the flow of the connection valve, but gives a good pressure response of the pressure of the Bonemine Module, HFO Module and pilot pressure. The simulation model is used to create a good understanding of the connection valve.

During the experiments it was only possible to test with one kind of HFO Module. Not all circumstances could be tested because of a limited performance of the HFO Module.

It seems that the connection valve fulfils all the requirements, but with a good control of the Respiratory Module a definitive answer can be given.

6.11 Conclusion

The connection valve is a membrane valve that is passively controlled by the differential pressures on the membrane. The connection valve limits the flow from the Bonemine Module when

the HFO pressure becomes below ambient pressure. The valve also increases the HFO functionalities. With the connection valve it is easier for the HFO Module to create negative pressure and a smoother waveform near the patient.
Current solutions were not sufficient, therefore a new design has been made and simulated. The simulation model gives a good understanding of the connection valve. The model has a good match of the pressure, but a slightly underestimation of the flow.
The connection valve is especially needed to control the flow from the Bonemine Module during lower frequencies. The response time of the connection valves determines that the connection valve closes up to a frequency of 15 Hz. When the frequency is higher to connection valve only restricts the flow. The connection valve doesn't interrupt IPPV.
The control of the Respiratory Module was out of the scope of this research. During the experiments a beta version is used. This version caused that not all extreme requirements could be tested. Also the performance of the HFO Module limited the experiments. The connection valve fulfils all the requirements within the performance limits of the HFO Module (Table 6.9). When the final control of the Respiratory Module is designed a final feasibility of the connection valve can be done.

Requirement	Scale	Fulfils
Minimal flow during HFO ventilation	L/min	Wish: $2 \cdot V_t \cdot freq \cdot 60$
Flow during IPPV	L/min	Wish: ≤ 100
Resistance during IPPV	mbar at 30L	Wish: < 0.5
Leakage	L/min/mbar	Pan: <0.5
Power consumption	W	Wish: 0
Power supply	V	Wish: 0

TABLE 6.9: Overview about the fulfilments of the requirements.

Chapter 7

Expiration Valve

7.1 Introduction

Besides the Bonemine Module and the HFO Module at the beginning of the hose system a variable resistance at the end of the hose system is also needed (figure 7.1). The air that the patient inhales comes from the Bonemine Module and the HFO Module and the air that the patient exhales leaves the system through the expiration valve. The three sub-systems control the flow and pressure near the patient.

In this chapter a design will be chosen for an expiration valve. First a good overview will be created of the problem, the requirements and the current solutions (Section 7.2). After that is described:

- current solutions (Section 7.3)
- design process (Section 7.4)
- conceptual designs (Section 7.5)
- final design (Section 7.6)
- experiments (Section 7.7)
- results (Section 7.8)
- discussion (Section 7.9)
- conclusion (Section 7.10)

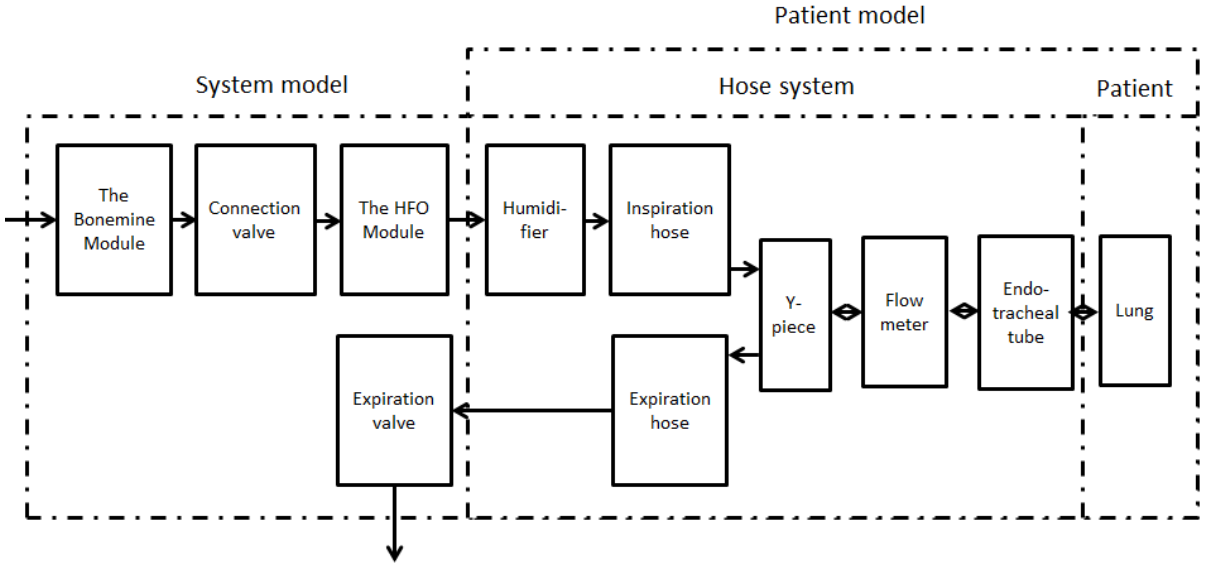


FIGURE 7.1: The different parts inside the ventilator and between the ventilator and the patient.

7.2 Problem definition and requirements

A controllable expiration valve is needed to control the flow and pressure near the patient (Figure 7.1 and 7.2). The expiration valve is close during inhaling of the patient and open during exhaling. This has to be an actively controlled expiration valve to fulfil the requirements for IPPV. Polluted air from the patient goes through the expiration valve.

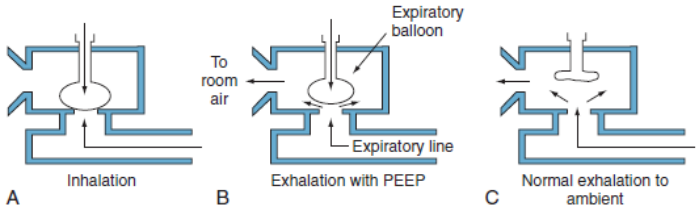


FIGURE 7.2: Functioning of a diaphragm expiratory valve. The diaphragm is illustrated with a balloon. A, the balloon is fully inflated during inspiration, blocking the expiratory channel. B, The expiratory valve remains partially pressured during exhalation and gives resistance on the gas stream to keep positive pressure in the hose (PEEP, Positive End-Expiratory Pressure). C, The expiratory valve opens completely to allow unimpeded flow of the exhaled gas. [Redrawn from Mosby's respiratory care equipment[31]]

7.2.1 Goal

The expiration valve has to control the polluted flow from the patient actively.

7.2.2 Requirements

The circumstances among which the expiration valve has to function are visible in Table 7.1 and Figure 7.3. The requirements are split into functional (Table 7.2) and non-functional requirements (Table 7.3). The expiration valve has to be disposable, because polluted air is going through the valve. Every time the ventilator is used for a new patient the expiration valve has to be replaced.

During HFO ventilation the flow through the expiration valve is called base-flow, because only the flow that ensures that the patient inhales fresh air is going through the expiration valve. This is not the case during IPPV.

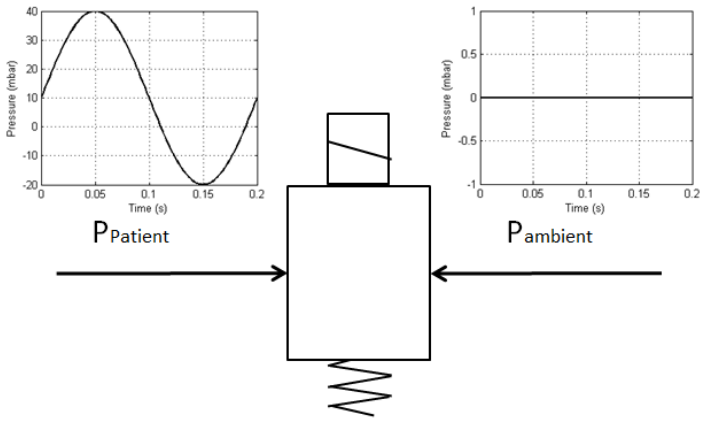


FIGURE 7.3: Schematic overview of the circumstances of the expiration valve. At the one size is the pressure from the patient part (Figure 7.1) and at the other side is ambient pressure.

Circumstance	Scale	Will be
Ambient pressure (a)	mbar	700-1060
Delta pressure from patient (g)	mbar	1 to 60
Maximum pressure (g)	mbar	$\leq$ 70
Minimum pressure (g)	mbar	$\geq$ -20
Pressure ramp	mbar	$\geq$3

TABLE 7.1: Circumstances of the expiration valve.

Requirement	Scale	HTM	Must do	Plan	Wish
Base-flow during HFO ventilation	L/min	S,T	$\geq 4 \cdot V_t \cdot freq \cdot 60$	$\geq 3 \cdot V_t \cdot freq \cdot 60$	$\geq 2 \cdot V_t \cdot freq \cdot 60$
Flow during IPPV	L/min	S,T	≤ 2	≤ 10	≤ 100
Minimum resistance	mbar at 30 L	S,T	< 2	< 1	< 0.5

TABLE 7.2: Functional requirements for the expiration valve.

Requirement	Scale	HTM	Must do	Plan	Wish
Leakage	L/min/mbar	T	0.5	0.2	0
Power consumption	W	T	< 30	< 15	0
Power supply	V	I	24	24	0
Disposable	-	I	True	True	True

TABLE 7.3: Non-functional requirements for the expiration valve.

7.3 Information about current expiration valves

Only information about actively controlled expiration valves is collected, because that is one of the requirements. The existing expiration valves are based on my literature study [5].

There are two types of actively controlled expiration valves on the market: a pneumatic controlled membrane valve (Figure 7.2) and a voice-coil controlled membrane valve (Figure 7.4). The benefit of a membrane valve is that it is possible to make a cheap cartridge for the disposable expiration valve. For example Figure 7.4. Everything that is visible in the figure can be the disposable expiration valve and the plunger and voice-coil or the pneumatic control can be fixed parts of the ventilator.

Both the pneumatic membrane valve and the voice-coil membrane valve are options for the needed expiration valve.

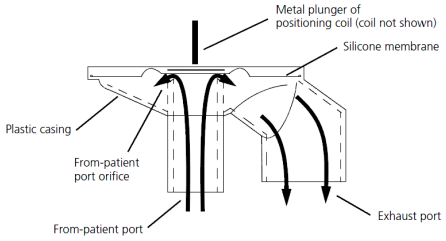


FIGURE 7.4: Electromagnetic expiration valve with a diaphragm (silicone membrane). The air enters the valve and the membrane controlled by the metal plunger determined the easiness in flowing to the exhaust port. The metal plunger is controlled by a voice coil. [Redrawn from Galileo Service Manual[32]

7.4 Design approach

Good options of current expiration valves are available. Therefore one of these two expiration valves will be chosen and no new one will be designed.

The best option for an expiration valve will be chosen by analysing some functional requirements. The expiration valve that scores the best during the analyse will be used during the final experiments.

7.5 Conceptual designs

The two designs that are compared with each other are the pneumatic controlled membrane valve and the voice-coil controlled membrane valve. By looking at the control of both valves the pro's and con's are compared and the best valve is chosen.

7.5.1 Control

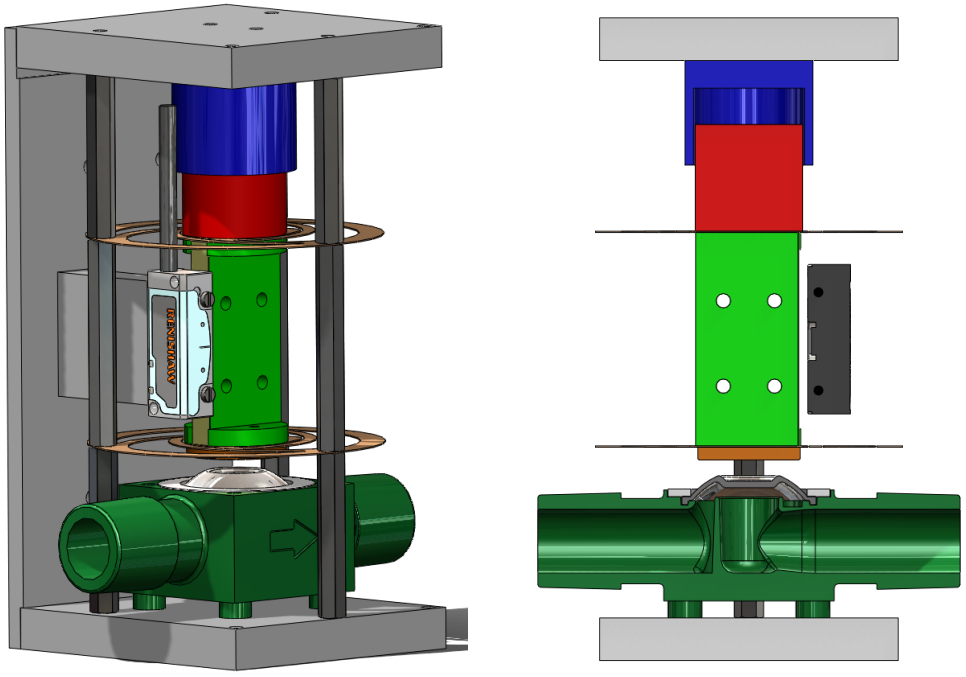
The expiration valve controls the flow and pressure near the patient together with the Bonemine Module. The two designs of expiration valve are controlled differently. The way that the two designs are controlled to regulate the flow and pressure differs per design.

Pneumatic controlled membrane valve: In this valve the resistance of the valve is regulated by the back pressure on the membrane (Figure 7.2). This pressure has to come from the Bonemine Module during IPPV. This is no problem during IPPV. Macawi has several years of experience with the combination Bonemine Module and a pneumatic membrane valve. During HFO ventilation the back pressure can be created by the HFO Module and the Bonemine Module. During positive pressure the expiration valve shall be partly closed with only a base flow flowing out, during a phase when the pressure is lower then environmental pressure, the expiration valve shall be kept closed. That can't be done with the HFO pressure. As extra problem the phase shift because of delay in the patient hoses makes it difficult to control a pneumatic valve. Therefore a pneumatic controlled membrane valve is not suitable for the Respiratory Module.

Voice-coil controlled membrane valve: In this valve the membrane is regulated by a voice-coil that is connected with a plunger to the membrane. The voice-coil can be controlled as needed, close and open during the right moments. Therefore this valve is suitable for the Respiratory Module.

7.6 Final design

The final expiration valve (Figure 7.5a) that is chosen was made available by Macawi. The expiration valve is based on the commercial available voice-coil to build a membrane valve. The valve exists of a voice-coil, a moving mass, a position sensor and a disposable cartridge with a membrane. This expiration valve of Macawi was still in development phase and didn't close well enough when the patient inhaled. Therefore an extra check check-valve was added to the expiration valve during the final experiments.



(A) Total expiration valve (B) Cross section of the expiration valve

FIGURE 7.5: Expiration valve

7.6.1 Voice-coil

The voice-coil that is used in this expiration valve is commercially available voice-coil from A-drive, type AVM30-15. The permanent magnet (Figure 7.6) is attached to the housing of the expiration valve.

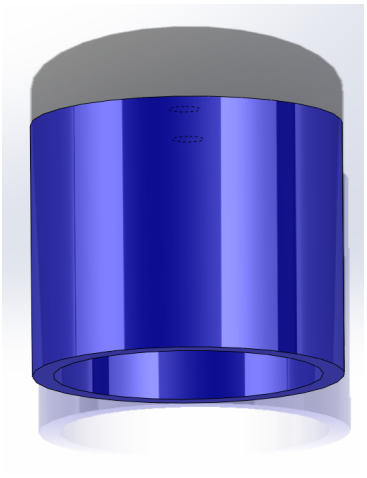


FIGURE 7.6: The permanent magnet of the voice-coil

7.6.2 Moving mass

The moving mass consists of the voice-coil, a plunger and two leaf springs (Figure 7.7). The leaf springs have a stiffness of 1 $\frac{N}{mm}$.

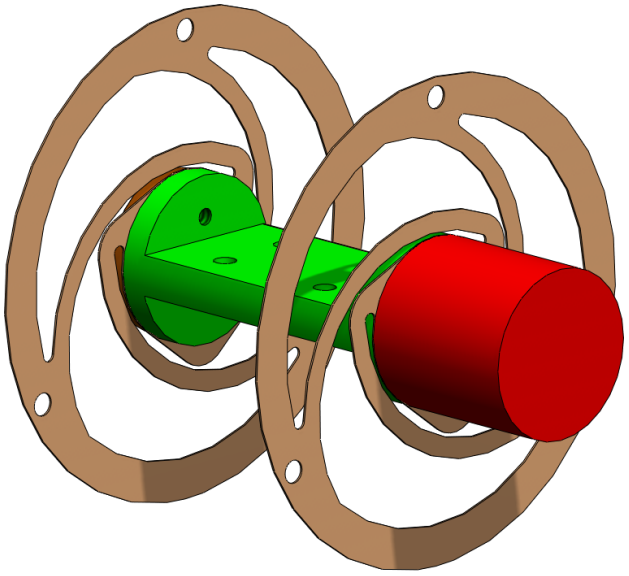


FIGURE 7.7: Voice-coil (red part) including moving mass (green part) and linear springs (brown parts).

7.6.3 Position encoder

A linear encoder is used to have a good control of the expiration valve. The linear encoder is commercially available at Renishaw, type TONiC T1000. It can read up to 35 mm with a

maximum speed of 10 m/s and a resolution of 1 nm. The encoder has a cyclic error of typically ± 30 nm.

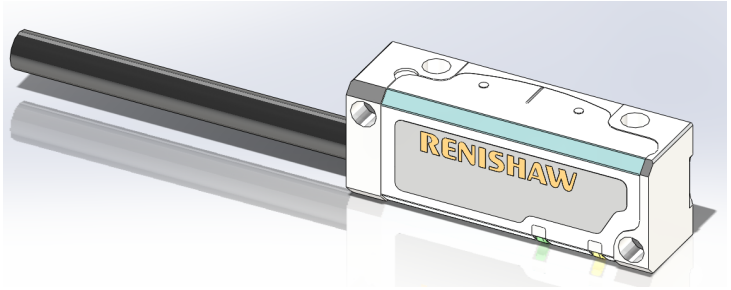
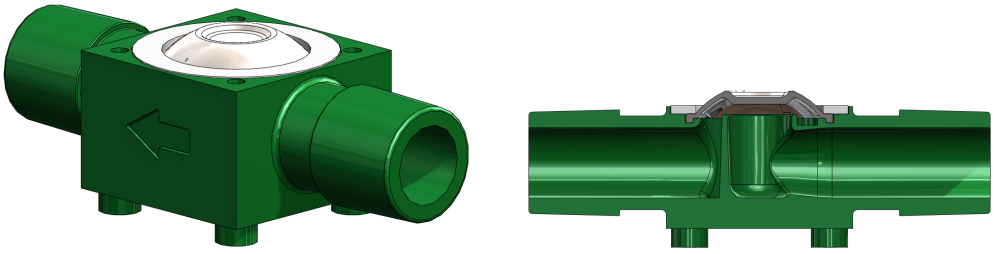


FIGURE 7.8: Linear position encoder.

7.6.4 Disposable cartridge

The disposable cartridge consists of the membrane valve (Figure 7.9). The valve consists of a seat with a sealed plunger. This membrane is secured on the valve with a ring.



(A) Total disposable cartridge (B) Cross section of the disposable cartridge

FIGURE 7.9: Expiration valve. The patient hose is connection on the right hose connection and ambient pressure is at the left side of the valve.

7.7 Experiments

During the experiments the performance of the expiration valve is compared with the requirements and the working principle of the expiration valve is identified.

The working principles are the control parameters, strategy and behaviour of the expiration valve during HFO ventilation.

The most important requirement of the expiration valve is the control of the base-flow and is explained in the results in more detail. This is measured during a sinus pressure at the patient of a MAP of 10 and 20 mbar and a minimum pressure of -5, -10, -15 and -20 mbar at the frequencies 5, 10, 15 and 20 Hz. With these settings the flow out of the blower up to

the maximum requirements (minimum pressure of -20 mbar and delta pressure of 80 mbar) are tested.

7.8 Results

The result consists of the working principle of the expiration valve and the testing of the requirements.

7.8.1 Working principles

The control parameters of the expiration valve, control strategy the flow through the expiration during HFO ventilation are important to get a good understanding of the expiration valve.

7.8.1.1 Control parameters

The control parameters of the expiration valve are the pressure in front of the expiration valve, the flow through the expiration valve and the position of the voice-coil. The expiration valve has a high sensitivity at low flows and a lower sensitivity at higher flows (Figure 7.10). This is positive to have a good control near closing of the expiration valve, because this improves the control of the total Respiratory Module and waveform accuracy near the patient.

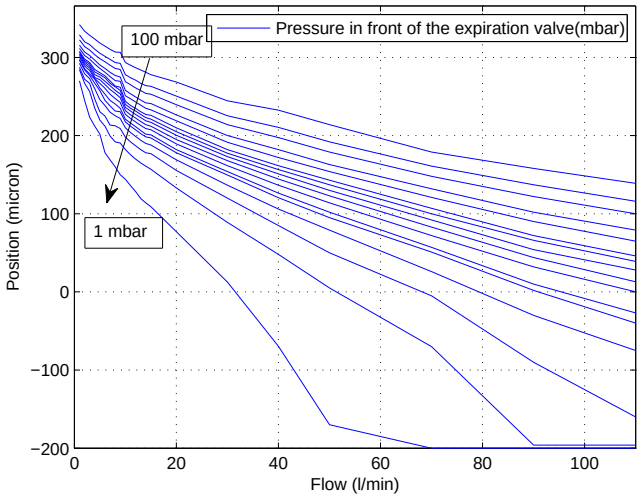


FIGURE 7.10: The relationship between the position of the voice-coil, the flow trough the valve and the pressure near the valve at patient side. The pressure is relative to ambient. The pressure is measured in the rang of 1 to 100 mbar.

7.8.1.2 Control of the expiration valve during HFO ventilation

The choice was made to control the expiration valve on flow and the Bonemine Module on pressure. This is chosen because of the control algorithm that was made available by Macawi.

The expiration valve has to control the base-flow. The expiration valve has to be controlled at a high frequency (Figure 7.11), while the base-flow changes at a very low frequency. This is because the pressure near the expiration valve changes at a high frequency. Therefore the position of the expiration valve also needs to change at a high frequency to keep a constant base-flow.

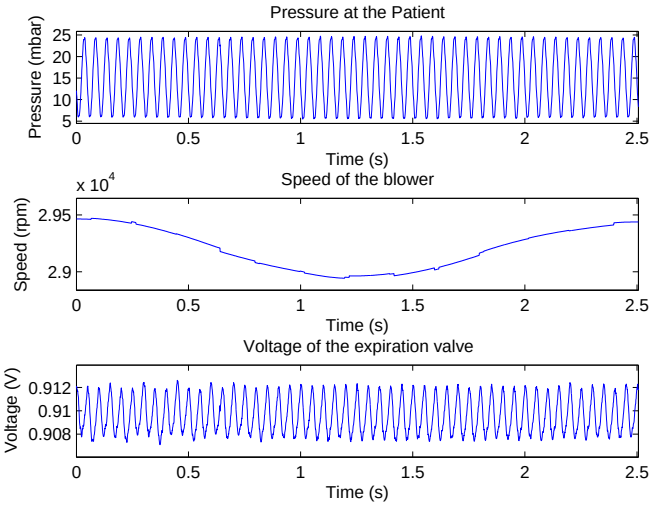


FIGURE 7.11: Frequency is 20 Hz

7.8.1.3 Flow pattern during HFO ventilation

There is only flow out of the expiration valve when there is a positive pressure in front of the expiration valve. The base flow is coming out of the expiration valve with pulses (Figure 7.12), when the patient is ventilated with a pressure waveform that also drops below ambient and also during the expiration the pressure goes negative. The pulses of flow out of the expiration valve occur during positive pressure, that means during the positive pressure phase.

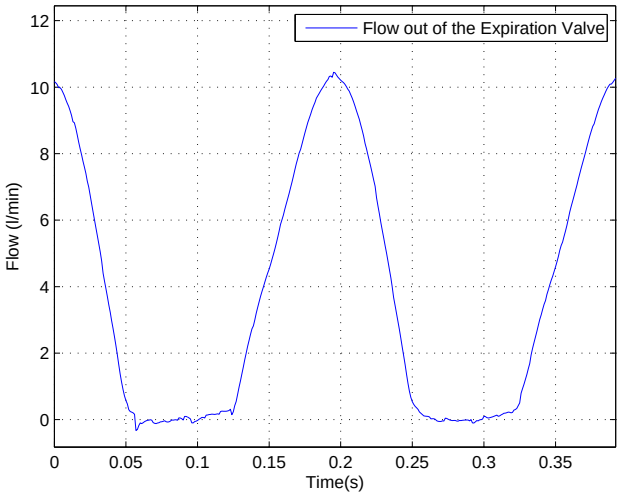


FIGURE 7.12: Flow out of the expiration valve, during HFO ventilation of 5 Hz. There is no negative flow measured at the expiration valve, because of the check valve in front of the expiration valve. The mean base flow is 4 l/min

7.8.2 Requirements

In Table 7.4 is a overview of the realized requirements. The requirements that are explained in more detail are:

- Base-flow control during HFO ventilation
- Minimal resistance
- leakage of the valve
- Power consumption

Requirement	Scale	Fulfils
Minimal Base-flow during HFO ventilation	L/min	Wish: $2 \cdot V_t \cdot freq \cdot 60$
Flow during IPPV	L/min	Wish: ≤ 100
Minimum resistance	mbar at 30 L	Wish: < 0.5
Leakage	L/min/mbar	Wish: 0
Power consumption	W	Must do: < 30
Power supply	V	Plan: 24
Disposable	-	Wish: True

TABLE 7.4: Overview of the fulfilment of the requirements of the expiration valve.

7.8.2.1 Base-flow during HFO ventilation

The base-flow at the expiration valve (Figure 7.13) is compared with the base-flow requirement of 2 times the tidal volume the patient inhales during a minute. Some measurement points are missing at a minimal pressure of -20 mbar, because of the performance limits of the HFO Module. The base-flow through the expiration valve is lower than the flow through the connection valve, because of the leakage of the connection valve and HFO Module. The flows through the connection valve and expiration valve differ not more than the amount of leakage measured at the same mean airway pressure (Figure 6.31). This implies that the connection valve determines the amount of base flow and the expiration valve is not a limiting factor.

7.8.2.2 Minimal resistance at the expiration valve

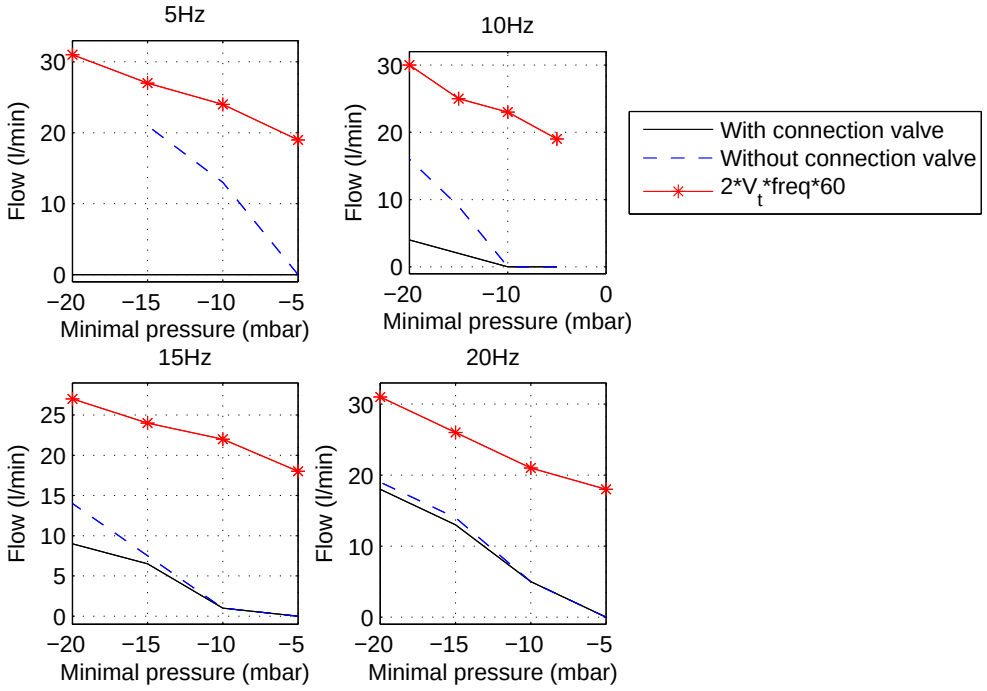
The resistance is dependent on the distance between the membrane and the seat of the valve determined by the position of the voice-coil. The minimal resistance is measured at 0.3 mbar.

7.8.2.3 Leakage

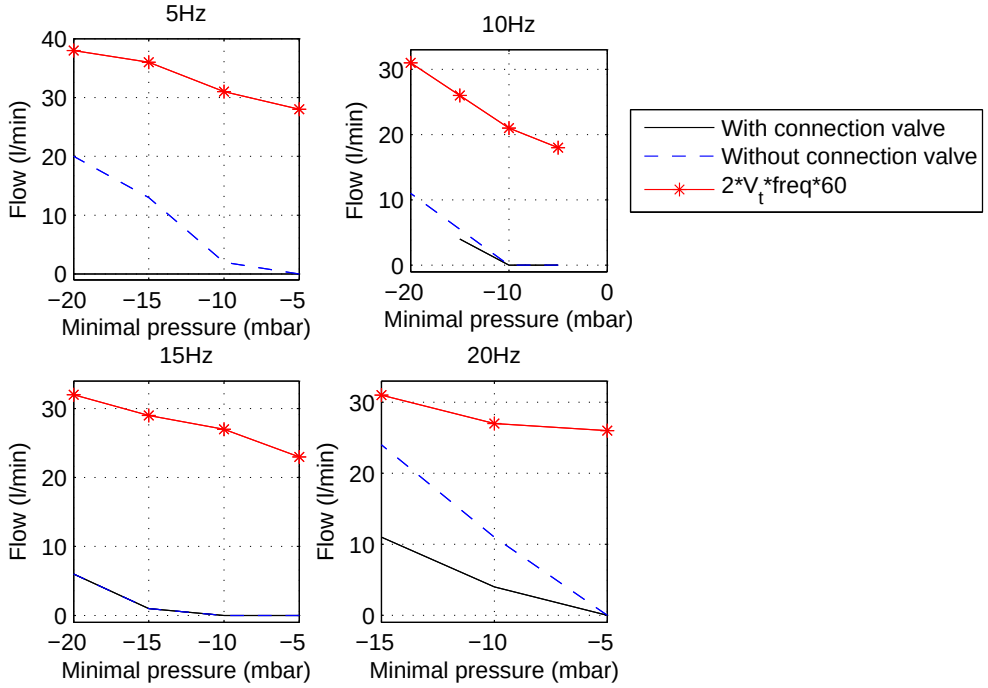
There is no external leakage to the environment from the expiration valve.

7.8.2.4 Power consumption and supply

The maximal power of 48 Watt (2 A at 24 V) is needed when the expiration valve is totally closed. The mean power will be lower then the must do requirement of 30 Watt. The power supply is 24 V.



(A) MAP of 10 mbar



(B) MAP of 20mbar

FIGURE 7.13: Base-flow out of expiration valve.

7.9 Discussion

The most important findings in this chapter are:

- A voice-coil controlled membrane valve has the right control possibility.
- The expiration valve is important for the control of the Respiratory Module during HFO ventilation.

The goal of this chapter was to design a valve at the end of the hose system that controls the expiratory gas from the patient. The voice-coil controlled membrane valve is the best choice. The valve that is used during the experiments was available at Macawi. Other voice-coil membrane valves are not considered, but are also possible if they fulfils the requirements of the power consumption, power supply and control region. With this study the feasibility of this type of expiration valve is proven.

The expiration valve is important for stability during the control of HFO ventilation. Both the Bonemine Module and the expiration valve are influencing the MAP and the base-flow. The control of the Bonemine Module and the expiration valve have to collaborate with each other, because they can make it hard for each other to fulfil the control task. When the connection valve closes the blower can have a difficulty to find the correct speed. The expiration valve can make it harder for the blower.
During the final experiments it was chosen to control the expiration valve on the flow settings and the Bonemine Module on pressure, because of the control algorithm that was available. When the expiration valve measures too little flow the expiration valve will open further. If the Bonemine Module doesn't deliver enough flow at that moment, the effect of a more open expiration valve will not be more flow through the expiration valve, but a lower MAP. If the Bonemine Module doesn't react fast enough the MAP will drop significantly. When the connection valve closes the Bonemine Module has to react slowly to find the right speed. To help the Bonemine Module, the expiration has also to be controlled on the MAP when the MAP is too far off the set-point.

The expiration valve determines the amount of base-flow during HFO ventilation. The minimal amount of base-flow is determined by the connection valve and the amount of leakage of the system. The maximal amount of base-flow is determined by the maximal speed of the Bonemine Module. The clinicians determine the needed amount of base-flow. The clinicians have to be aware that for this Respiratory Module the needed amount of base-flow is different when the

minimal pressure is lower than ambient compared to higher than ambient. In both cases the tidal volume is the same. The expiration valve only lets flow through when the pressure is above ambient and closes when the pressure is below ambient to prevent backwards flow. When the minimal pressure is below ambient the expiration valve is open when the patient inhales and the expiration valve is closed when the patient exhales. In this situation when the patient exhales the exhaled gas goes to the HFO Module instead of the expiration valve. The clinicians have to be aware that the base flow setting has to be higher in this case to prevent that the patient inhales exhaled gas than in the situation when there is constant flow out of the expiration valve.

The voice-coil controlled membrane valve is used in multiple ventilators and is also for this ventilator the best choice of all available expiration valves.

7.10 Conclusion

The current available expiration valves are promising enough to make a choice for them. The voice-coil controlled expiration valve has the best control with the available options from the Respiratory Module. The expiration valve is more sensitive at low flows what is positive for a stable control of the Respiratory Module. The connection valve and not the expiration valve is the limiting factor for the minimal amount of base-flow.
The control of the Respiratory Module was out of the scope of this research. During the experiments a beta version is used. This version caused that not all extreme requirements could be tested. Also the performance of the HFO Module limited the experiments. The expiration valve fulfils all the requirements within the performance limits of the HFO Module (Table 7.5).Also the requirement for a transportable ventilator like power consumption and supply are fulfilled by the expiration valve.

Requirement	Scale	Fulfils
Minimal Base-flow during HFO ventilation	L/min	Wish: $2 \cdot V_t \cdot freq \cdot 60$
Flow during IPPV	L/min	Wish: ≤ 100
Minimum resistance	mbar at 30 L	Wish: < 0.5
Leakage	L/min/mbar	Wish: 0
Power consumption	W	Must do: < 30
Power supply	V	Plan: 24
Disposable	-	Wish: True

Table 7.5: Overview of the fulfilment of the requirements of the expiration valve.

Chapter 8

Discussion

The goal of this study is to do a feasibility study about the Respiratory Module. The combination Bonemine Module, HFO Module, connection valve and expiration valve fulfils the requirements. The limits of the Respiratory Module are caused by the connection valve and the HFO Module.

The simulation patient model consists of resistances and compliances. These components create a damping and a phase-shift. The damping in the model is verified. The verification of the patient model shows that there is a good match of the pressures inside the model with the reality. It was not possible to do a good verification of the flow, because of the limited performance of the test set-up. The verification that is done showed that there is a small overestimation of the flow. The phase-shift inside the system is not verified, because the phase-shift has no influence on the outcome of the simulation. It is also hard to measure the phase-shift, because pressure sensors and data acquisition also create a phase-shift in the measured signals.
The verification of the connection valve model showed that there was also a good representation of the pressure inside the model, but an underestimation of the flow. The response of the blower is well-conditioned for pressure, but ill-conditioned for flow. This makes it hard to make a model with a good flow response.
The simulation models can be more accurate, by modelling it in more elements and adding more non-linear effects. Damping effects and high peak-flows would then be modelled better. The simulation models were accurate enough to use them for the requirements and the design of the connection valve. For each new project, a consideration should be made between accuracy of the models and the demand for computing.

The response time of the connection valve limits the connection valve to close during the higher frequencies ($> 10Hz$). This is not an issue, because during higher frequencies less flow comes through the blower without connection valve then when the frequencies are lower. The RC-network inside the Bonemine Module damped the pressure from the HFO Module during higher frequencies. Therefore it is less a problem that the connection valve restricts the flow less during higher frequencies. It was not possible to validate the connection valve for the most extreme requirements, because of the limited performance of the HFO Module and the control of the Respiratory Module.

The control of the Respiratory Module was out of the scope of this feasibility study, but during this study it became clear that the control would be more complicated than thought. The connection valve closes around ambient, therefore the extra resistance created when the connection valve closes is not frequent. The connection valve could also be closed frequently around MAP, but this was not possible with the passively controlled connection valve. When the connection valve is working, the control of the Bonemine Module, together with the control of the expiration valve, has to become more sensitive. The Bonemine Module then has an increased impact on the flow and pressure inside the Module. Increasing the speed of the Bonemine Module amplifies the amount of flow through the connection valve, but also the pressure of the Bonemine Module. The increased pressure increases the opening time of the connection valve which also allows more flow through the connection valve. An overshoot of flow from the Bonemine Module can be an effect. If the expiration valve is more senstive during this time, the overshoot can be prevented.

Another complicated item for the control of the Respiratory Module is the mean airway pressure (MAP). Both, the Bonemine Module, the HFO Module and the expiration valve are influencing the MAP. During the final experiments the control of the HFO Module was approached as a black-box. The relation between the pressure inside the HFO Module, the movement of the voice-coil and the control current was not known. If the control current is not compensated for an increase of MAP the movement of the voice-coils changes when the MAP increases and the other way around: a change in the movement of the voice-coil can influence the MAP. The Bonemine Module and the expiration valve have to compensate for these changes in the MAP during the final experiments. When a new HFO Module is designed, so that it is not a black-box any more, the control of the Respiratory Module can control the MAP and the amplitude of the pressure waveform easier. All the requirements that are influenced by the HFO Module, like shape of the waveform and I:E ratio could not be tested with this black-box HFO Module.

In this design process some parts of the requirements, simulation and elements of the connection valve are provided by Macawi. The requirements for IPPV are assumed to be correct, because of the years of experience of Macawi. Some provided simulation parts could have a higher accuracy if non-linear effects were included.

The connection valve and expiration valve create a good Respiratory Module, but the total design of the Respiratory Module is not finished. The design of the connection valve can still have some design iteration till it is perfect to go to the market and also the design of the HFO Module needs some design iterations.

Chapter 9

Conclusion

The goal of this study is to do a feasibility study about the Respiratory Module. The combination Bonemine Module, HFO Module, connection valve and expiration valve fulfils the requirements.

At the moment there are no ventilators that can ventilate IPPV and HFO ventilation with ambient gas source. Bringing the Respiratory Module on the market as OEM (Original Equipment Manufacturer) Module gives medical device manufacturers the possibility to bring ventilators on the market with a short development time.

The customer's requirements of the customer of Macawi for HFO ventilation are stricter than the Respiratory Module can fulfil. The customer's requirements of clinicians for HFO ventilation and the IPPV requirements are fulfilled by the Respiratory Module.

After verification the simulation model of the patient appears to give a good translation of the customer's requirements to the system's requirements. The patient model has a good pressure representation, but a slightly overestimation of the flow. The resistances and compliances inside the patient model give a good pressure and flow representation of what happens when the frequency increases. The ventilator has to deliver more flow and pressure at high frequencies, than when it delivers the same tidal volume at low frequencies. This has an important effect on the system's requirements.
Also the simulated representation of the working principle of the connection valve corresponds with the experiments. The simulation model of the connection valve has a good representation of the pressure, but a slightly underestimation of the flow. The model can be used to create a

good understanding of the connection valve.

The connection valve is a membrane valve that is passively controlled by the differential pressure on the membrane. It limits the flow from the Bonemine Module when the pressure of the HFO Module becomes lower than ambient. The lower the frequency the more flow from the Bonemine Module has to be limited. The connection valve works best at low frequencies till 15 Hz. At 20 Hz the response time of the connection valve is too long to close the valve but it still restricts the flow from the Bonemine Module. The extra resistance that is created by the connection valve makes it easier for the HFO Module to create negative pressure near the patient and a smoother waveform. The extra resistance created by the connection valve makes control of the Respiratory Module harder.

When a good control of the Respiratory Module is designed by Macawi the optimal response time can be determined. The response time of the connection valve can be adjusted by the height of the crater and the pilot pressure above the membrane. The pilot pressure can be adjusted by a supply pressure from the HFO Module and a leakage in the cap of the connection valve.

The expiration valve is a voice-coil controlled membrane valve and has a good response time and an active control. The expiration valve has a high sensitivity at low flows and a lower sensitivity at higher flows. This ensures a good controllability of the expiration valve.

The design of the Bonemine Module in combination with the HFO Module, connection valve and expiration valve fulfils the main requirements and is a feasible design for further design iterations. The control of the Respiratory Module was out of the scope of this research, but it determines a part of the design parameters. When the control is designed the design of the Respiratory Module can be further fine-tuned.

Appendix A

Requirements

This appendix consists of an overview of the customer's requirements for HFO ventilation of a customer of Macawi and of clinicians. This appendix consists also questionable and answers from clinicians.

A.0.0.5 Customer of Macawi

The requirements for HFO ventilation that are collected at a customer of Macawi are visible in Table A.1.

Requirement	Scale	HTM	Must do	Plan	Wish
Frequency	Hz	S,T	5 to 15	3 to 20	3 to 25
I:E ratio	ratio	S,T	1:1 / 1:2 / 1:3	3:7 / 2:3 / 1:1	variable
Amplitude (g)	mbar	S,T	1 to 35	1 to 45	1 to 60
Supported body weight	kg	S,T	0.4 to 8	0.4 to 10	0.4 to 15
Tidal volume vs body weight	ml/kg	S,T	0.5 to 4	0.1 to 5	0.1 to 6
Flow wave form (see Figure 4.2)	shape	S,T	sinus	sinus	sinus, triangle, square, sawtooth
MAP (g)	mbar	S,T	5 to 35	5 to 50	5 to 60

Table A.1: Customer' requirements for HFO ventilation of customer of Macawi.

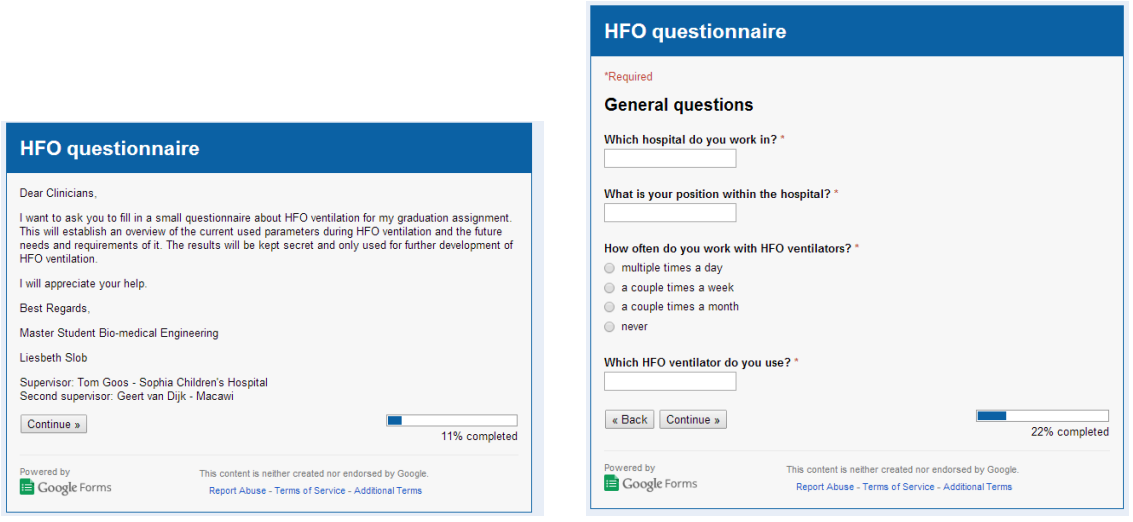
A.0.0.6 Clinicians

Customer' requirements for HFO ventilation that are collected from a questionnaire among clinicians are visible in Table A.2. In total 8 clinicians filled in the questionnaire. The clinicians came from 8 different hospitals from 3 different countries. Five of the nine hospitals in the Netherlands that are having a neonatal intensive care filled in the questionnaire (Appendix A).

Requirement	Scale	HTM	Must do	Plan	Wish
Frequency	Hz	S,T	5 to 10	5 to 14	5 to 15
I:E ratio	ratio	S,T	1:1	1:1 / 1:2	1:1 / 1:2 / 1:3
Amplitude (g)	mbar	S,T	5 to 20	5 to 40	5 to 60
Supported body weight	kg	S,T	0.4 to 5	0.4 to 7	0.4 to 8
Tidal volume vs body weight	ml/kg	S,T	0.5 to 3	0.1 to 5	0.1 to 6
Flow wave form (see Figure 4.2)	shape	S,T	sinus	sinus	sinus, triangle, square, sawtooth
MAP (g)	mbar	S,T	5 to 25	5 to 30	5 to 40

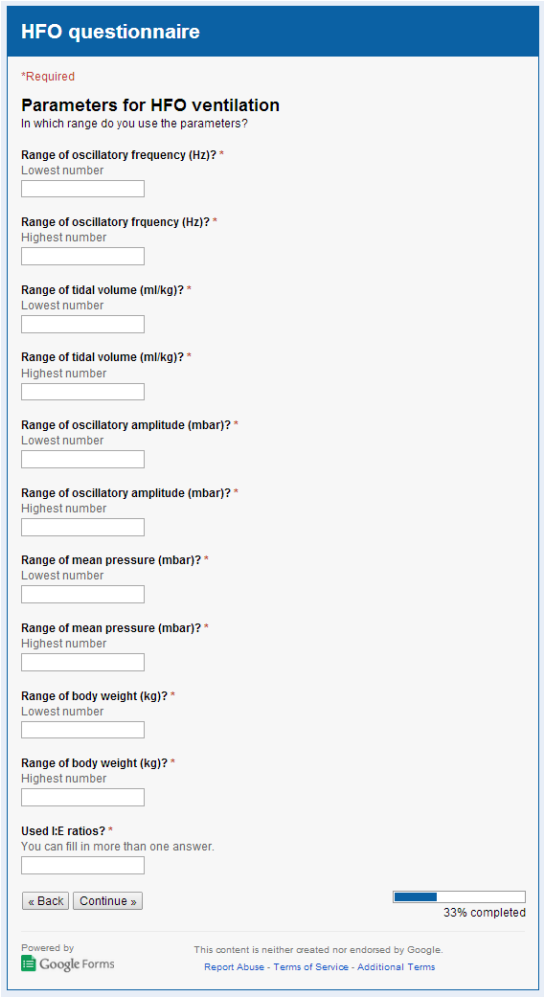
TABLE A.2: Customer' requirements for HFO ventilation of clinicians.

A.1 Questionnaire

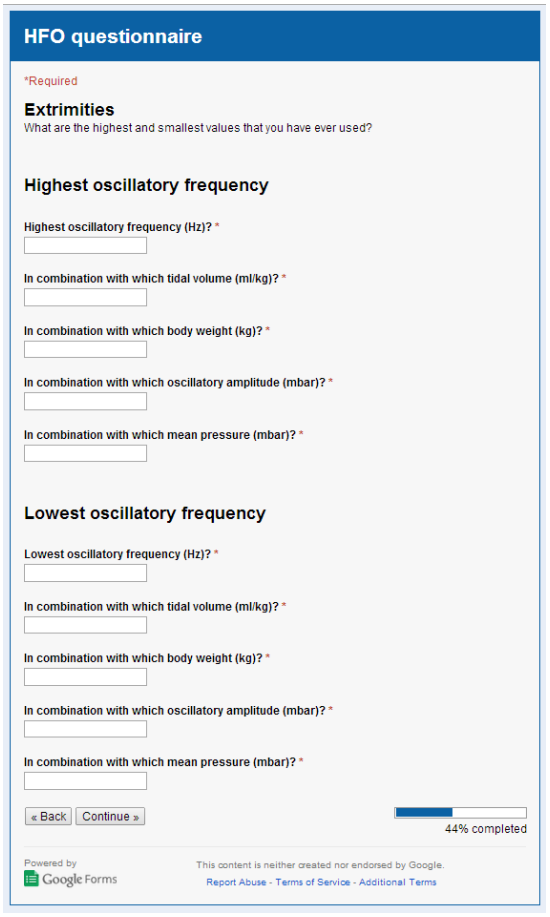


(A) Introduction (B) General questions

FIGURE A.1: Questionnaire: Introduction and General questions

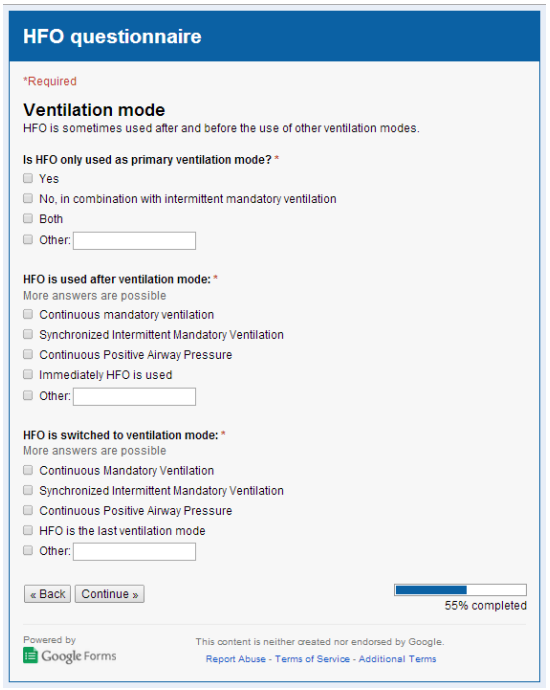


(A) Parameters for HFO ventilation

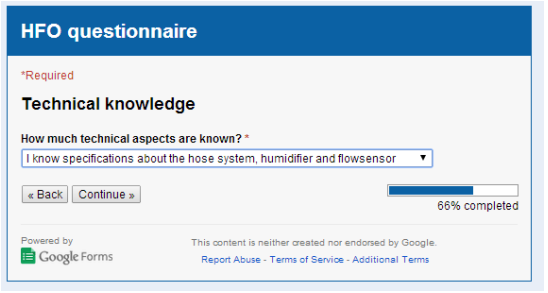


(B) Extremities

FIGURE A.2: Questionnaire: Parameters for HFO ventilation and extremities during HFO ventilation

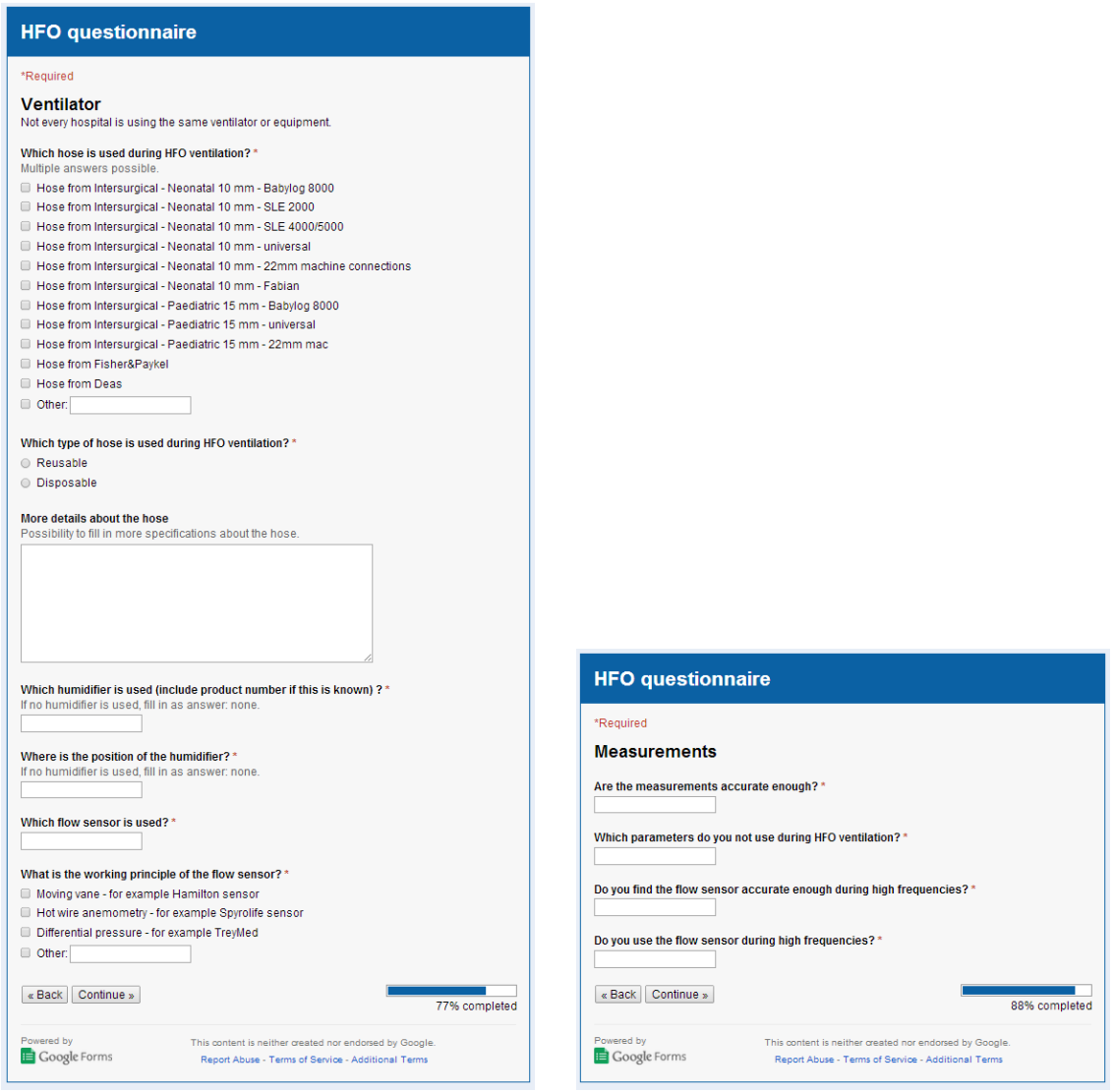


(A) Ventilation mode ventilation



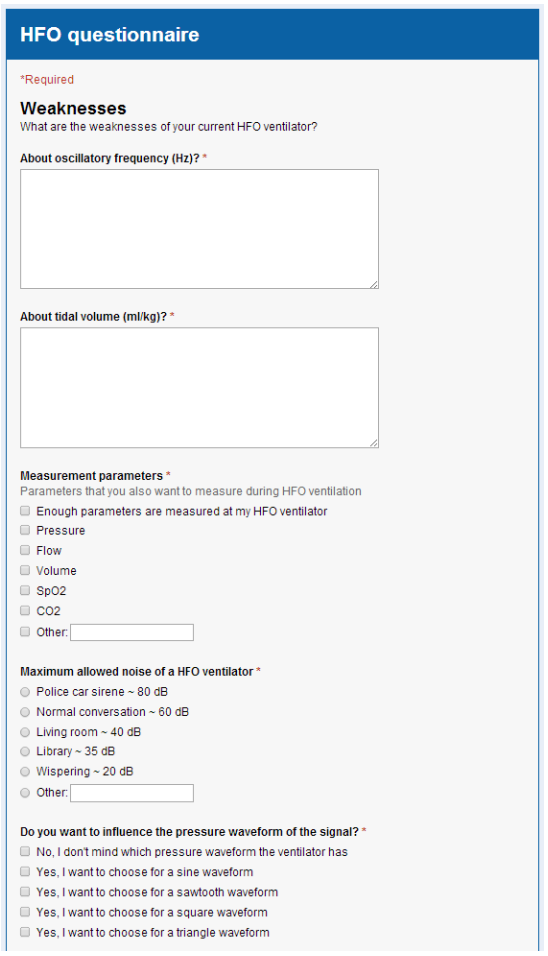
(B) Technical knowledge

FIGURE A.3: Questionnaire: Ventilation mode and Technical knowledge.

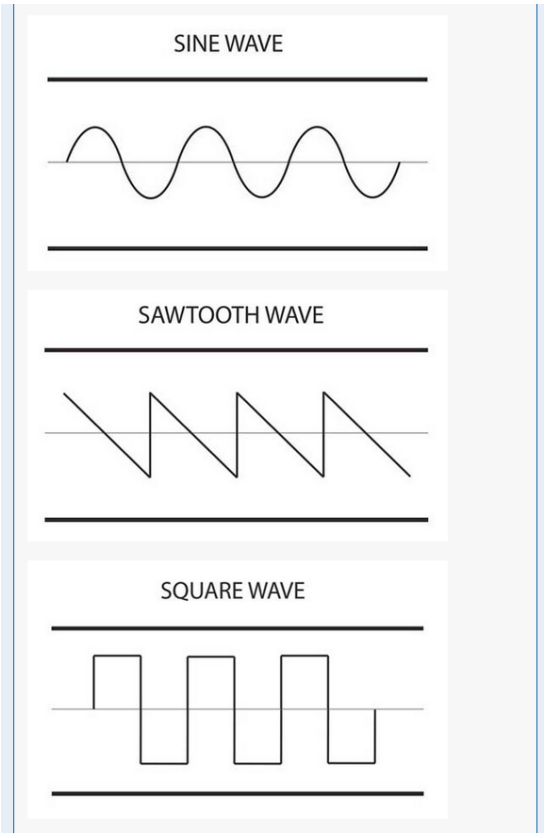


(A) Ventilator ventilation (B) Measurements

FIGURE A.4: Questionnaire: Ventilator and Measurements.

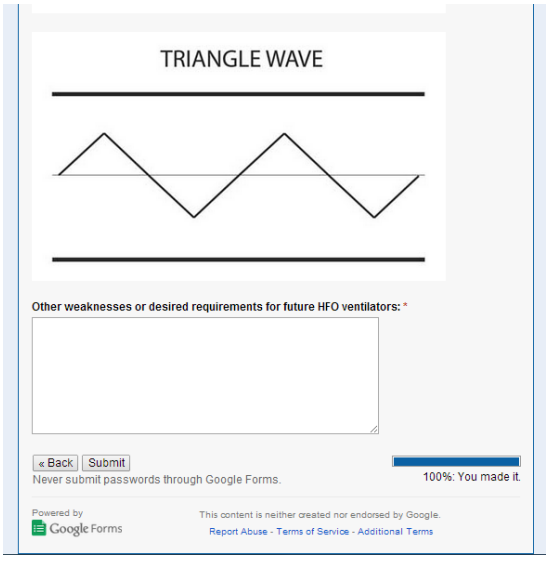


(A) Weaknesses- part 1 ventilation



(B) Weaknesses- part 2

FIGURE A.5: Questionnaire: Weaknesses part 1 and 2.



(A) Weaknesses- part 3 ventilation

(B) Thank you

FIGURE A.6: Questionnaire: Weaknesses part 3 and the end.

A.2 Result

Some clinicians filled in delta pressure instead of amplitude. Some clinicians filled in tidal volume (ml) instead of ml/kg.

General questions

Which hospital do you work in?	ErasmusMC-Sophia	Royal Alexandra Hospital, Edmonton, Canada	UMCU	Maxima Medical Centre
What is your position within the hospital?	staff member	Consultant	Neonatologist	Neonatologist
How often do you work with HFO ventilators?	a couple times a week	multiple times a day	a couple times a week	multiple times a day
Which HFO ventilator do you use?	Fabian-HFO	VN 500, Leonie, Babylog 8000, Sensormedic	Leoni plus	Fabian HFO

Parameters for HFO ventilation

Lowest number oscillatory freq (Hz)?	6	8	7	5
Highest number oscillatory freq (Hz)?	14	12	15	15
Lowest number tidal volume (ml/kg)?	2	1.5	no specified under limit	0.5
Highest number tidal volume (ml/kg)?	6	3	no specified upper limit	0.5
Lowest number oscillatory amplitude (mbar)?	14	15	5	8
Highest number oscillatory amplitude (mbar)?	80	60	120	80
Lowest number mean pressure (mbar)?	6	8	5	8
Highest number mean pressure (mbar)?	28	24	25	35
Lowest number body weight (kg)?	0.4	0.5	0.46	0.5
Highest number body weight (kg)?	5	4	8	5.5
Used I:E ratios?	1:3	1:2	33:66,50:50	1:1, 1:2, 1:3

Table A.3: Results of first four clinicians - part 1

Extremities

Highest oscillatory freq (Hz)?	14	15	12	15
In combination with which tidal volume (ml/kg)?	-	3	not adjustable	0.5
In combination with which oscillatory amplitude (mbar)?	-	60	20	10
In combination with which mean pressure (mbar)?	-	20	10	8
Lowest oscillatory freq (Hz)?	6	6	7	6
In combination with which tidal volume (ml/kg)?	-	2	Not adjustable, about 2 ml/kg	3.5
In combination with which oscillatory amplitude (mbar)?	-	13	80	80
In combination with which mean pressure (mbar)?	-	7	20	25

Table A.4: Results of first four clinicians - part 2

Ventilation mode

Is HFO only used as primary ventilation mode?	Both	No, in combination with intermittent mandatory ventilation	Both	Yes
HFO is used after ventilation mode:	Synchronized Intermittent Mandatory Ventilation, Continuous Positive Airway Pressure, Immediately HFO is used	AC/VG or PSV/VG	Synchronized Intermittent Mandatory Ventilation, Continuous Positive Airway Pressure, Immediately HFO is used	Continuous mandatory ventilation, Synchronized Intermittent Mandatory Ventilation, Continuous Positive Airway Pressure, Immediately HFO is used
HFO is switched to ventilation mode:	Synchronized Intermittent Mandatory Ventilation, Continuous Positive Airway Pressure, HFO is the last ventilation mode, CPAP is niet endotracheaal	AC/VG or PSV/VG	Synchronized Intermittent Mandatory Ventilation, Continuous Positive Airway Pressure	Continuous Mandatory Ventilation, Continuous Positive Airway Pressure

Table A.5: Results of first four clinicians - part 3

Technical knowledge

How much technical aspects are known?	I know specifications about the hose system, humidifier and flowsensor	I know no specifications about the hose system, humidifier and flowsensor	I know specifications about the hose system, humidifier and flowsensor	I know specifications about the hose system, humidifier and flowsensor

Technical knowledge

Which hose is used during HFO ventilation?	Hose from Fisher&Paykel	-	Hose from Fisher&Paykel	Hose from Fisher&Paykel
Which type of hose is used during HFO ventilation?	Disposable	-	Disposable	Disposable
More details about the hose	-	-	-	-
Which humidifier is used?	F&P	-	F&P	F&P 850
Where is the position of the humidifier?	in de inspiratie	-	Attached to the ventilator	below incubator
Which flow sensor is used?	disposable	-	-	Acutronic
What is the working principle of the flow sensor?	-	Hot wire anemometry	Hot wire anemometry	Hot wire anemometry

Measurements

Are the measurements accurate enough?	lastig te beantwoorden; want hoe valt een tidal volume te controleren? Wat is de standaard?	NO, needs improvement	Think so, no comparison	Yes
Which parameters do you not use during HFO ventilation?	compliance	VT	-	MV
Do you find the flow sensor accurate enough during high freq?	lastig te beantwoorden	No	Usually, although TV are low, especially in low ampl low MAP settings and active ventilation, readings can be inaccurate	Yes
Do you use the flow for third party high freq?	-	-	-	yes

TABLE A.6: Results of first four clinicians - part 4

Weaknesses

About osccillatory frequency (Hz)?	nog geen betrouwbare EtCO2 meting, geen closed loop zuurstof	I am not sure if the device measures the Hz accurately.	No	Tubing circuit and heater in situation of very sick patient - Maximum pressure (80 mmHG) is not enough for adequat ventilating baby ¿ 5 kg - power of ventilator is good but compliance of tubing circuit is too high - so lower frequencies have to be used (bigger tv) for adequat ventilation
About tidal volume (ml/kg)?	-	No evidence about what VT should be used and if the flow sensor can accurately measure it.	Not adjustable, nonTV garantee	Because of problem described above we have to use bigger volumes than we would like to
Measurement parameters	CO2	Pressure, Flow, Volume, CO2	CO2	CO2
Maximum allowed noise of a HFO ventilator	Wispering 20 dB	Living room 40 dB	Normal conversation 60 dB	Living room 40 dB
Do you want to influence the pressure wave form of the signal?	No, I don't mind which pressure waveform the ventilator has	Yes, sine waveform, sawtooth waveform, square waveform, trangle waveform.	Yes, sinve waveform	Yes, sine waveform
Other weaknesses or desired requirements for future HFO ventilators:	graag closed loop CO2 en O2. Automatisch optimale CDP instelling	assess lung aeration and guide HFVO accordingly	Loss of amplitude in tubing is a problem. Furthermore the bias flow is not adjustable	I would like a ventilator with same performance (at patient) in all ranges of ventilation.

Table A.7: Results of first four clinicians - part 5

General questions

Which hospital do you work in?	Royal Children's Hospital, Melbourne, Australia	medical University of Graz	AMC	Radboudumc
What is your position within the hospital?	Neonatologist	Neonatologist	Head	Neonatologist
How often do you work with HFO ventilators?	multiple times a day,a couple times a month	a couple times a month	multiple times a day	multiple times a day
Which HFO ventilator do you use?	Sensormedics 3100A & B, SLE5000	Acutronic	Sensor Mediscs 3100	Leonie Plus

Parameters for HFO ventilation

Lowest number oscillatory freq (Hz)?	5	6	6	6
Highest number oscillatory freq (Hz)?	15	10	15	15
Lowest number tidal volume (ml/kg)?	1.5	0.5	-	-
Highest number tidal volume (ml/kg)?	4	-	-	-
Lowest number oscillatory amplitude (mbar)?	14	10	15	10
Highest number oscillatory amplitude (mbar)?	50	35	50	100
Lowest number mean pressure (mbar)?	6	6	6	6
Highest number mean pressure (mbar)?	35	35	40	35
Lowest number body weight (kg)?	0.5	0.5	0.4	0.5
Highest number body weight (kg)?	5	5	5	5
Used I:E ratios?	1:2, 1:1	1:2, 1:3	1:2	1:2, 1:1

Table A.8: Results of second four clinicians - part 1

Extremities

Highest oscillatory freq (Hz)?	15	10	15	15
In combination with which tidal volume (ml/kg)?	1.5	0.5-..	-	never use this
In combination with which oscillatory amplitude (mbar)?	14	10-35	15	-
In combination with which mean pressure (mbar)?	6-28	6 to 30	8	-
Lowest oscillatory freq (Hz)?	5	6	6	6
In combination with which tidal volume (ml/kg)?	3.5	0.5-..	-	-
In combination with which oscillatory amplitude (mbar)?	40	10 to 35	50	-
In combination with which mean pressure (mbar)?	10 to 24	6 to 30	40	-

Table A.9: Results of second four clinicians - part 2

Ventilation mode

Is HFO only used as primary ventilation mode?	Both	Both	Yes	Both, nasal CPAP/nasal IPPV
HFO is used after ventilation mode:	Continuous mandatory ventilation, Synchronized Intermittent Mandatory Ventilation, Continuous Positive Airway Pressure, High-frequency Jet Ventilation	Continuous mandatory ventilation, Synchronized Intermittent Mandatory Ventilation	TCPL AC	Synchronized Intermittent Mandatory Ventilation
HFO is switched to ventilation mode:	Continuous Mandatory Ventilation, Synchronized Intermittent Mandatory Ventilation, Continuous Positive Airway Pressure, High-frequency Jet Ventilation	Continuous Mandatory Ventilation, Synchronized Intermittent Mandatory Ventilation	Continuous Positive Airway Pressure	Synchronized Intermittent Mandatory Ventilation, nasal CPAP/ nasal IPPV

Technical knowledge

How much technical aspects are known?	I know specifications about the hose system, humidifier and flowsensor	I know no specifications about the hose system, humidifier and flowsensor	I know specifications about the hose system, humidifier and flowsensor	I know specifications about the hose system, humidifier and flowsensor

Table A.10: Results of second four clinicians - part 3

Technical knowledge

Which hose is used during HFO ventilation?	Hose from Fisher&Paykel, Sensormedics (Carefusion) circuit	-	SM3100	Leonie plus
Which type of hose is used during HFO ventilation?	Disposable	-	Disposable	Disposable
More details about the hose	We use the dedicated and only system for the SM3100A/B from Carefusion and the disposable F&P SLE5000 circuit with flow restrictor for SLE5000 (with disposable flow sensors)	-	-	-
Which humidifier is used?	F&P	-	F&P	F&P
Where is the position of the humidifier?	Inspiratory limb	-	Inspiration circuit	In the inspiration limb
Which flow sensor is used?	SLE5000 = manufacturers disposable. SM3100 = Florian reusable sensor with Florian monitor	-	none	Leonie Plus
What is the working principle of the flow sensor?	Hot wire anemometry	-	-	Hot wire anemometry

Table A.11: Results of second four clinicians - part 4

Measurements

Are the measurements accurate enough?	Yes (see Scafaro paper re Florian) and we have checked SLE5000 in our lab	no	-	which measurements?
Which parameters do you not use during HFO ventilation?	CMV+HFO (SLE5000)	tidal volume	-	tidal volume
Do you find the flow sensor accurate enough during high freq?	Yes	no	-	We can use the DCO2 (CO2-exchange coefficient) adequately
Do you use the flow sensor during high freq?	yes	yes	no	yes

Table A.12: Results of second four clinicians - part 5

Weaknesses

About oscillatory frequency (Hz)?	No weaknesses with either device regarding delivered Frequency	-	none	none
About tidal volume (ml/kg)?	No weaknesses with either except that the SM3100 do not allow measurement of Tidal Volume using the device (third party system needed)	measurement	not measured	not needed; not interesting
Measurement parameters	SpO2, CO2	CO2	SpO2, TcPCO2	DCO2
Maximum allowed noise of a HFO ventilator	Normal conversation 60 dB	Library 35 dB	Normal conversation 60 dB	Wispering 20 dB
Do you want to influence the pressure wave form of the signal?	Yes, sawtooth waveform, square waveform	Yes, sine waveform, sawtooth waveform, square waveform, trangle waveform.	No, I don't mind which pressure waveform the ventilator has	Yes, sine waveform
Other weaknesses or desired requirements for future HFO ventilators:	Validated monitoring and feedback algorithms need to be developed for new devices. VG modes need to be validated. Integration of SpO2 and CO2 feedback systems in devices needed.	Volume garantuee	Piston!	-

TABLE A.13: Results of second four clinicians - part 6

Appendix B

Simulink model

The Simulink model is divided in two models: the Respiratory Module model en de Patient model (Figure B.1). The models made by the author are provided in more detail. The models provided by Macawi are only showed with a top model and not in detail.

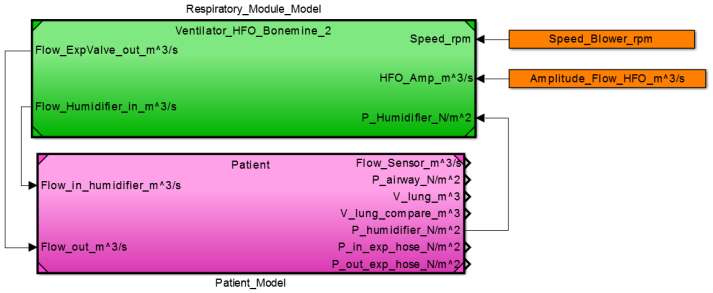


FIGURE B.1: Top Model

B.0.1 Respiratory Module

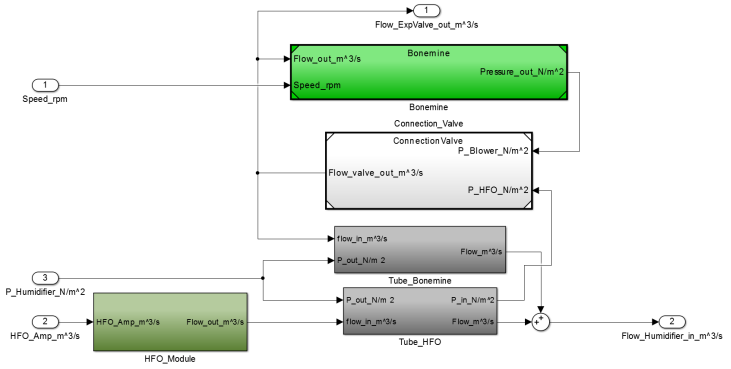


FIGURE B.2: Respiratory Module simulation model

B.0.1.1 Bonemine Module

The blower and the check-valve model are provided by Macawi and therefore not shown in detail. The mixing camber is modelled with only a compliance. How a compliance is modelled is visible in Figure B.22. The constants of Equation B.1 are visible in Equation B.2.

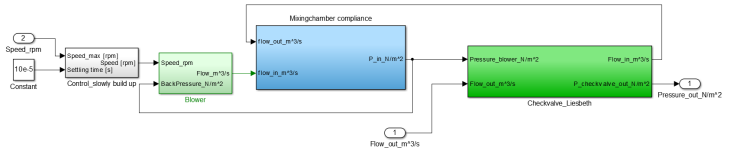


FIGURE B.3: Bonemine Module simulation model

$$\frac{(c_1 Q - h)^2}{b^2} + \frac{(c_2 P - k)^2}{a^2} = c_3$$
$$Q = \frac{1}{c_1}(b\sqrt{c_3 - \frac{(c_2 P - k)^2}{a^2}} + h) \tag{B.1}$$

$$\begin{aligned} a &= 1 \\ b &= 1.4e^{-8} S_{rpm}^2 + 2.6e^{-5} S_{rpm} \\ c_1 &= 3.5e^{-14} S_{rpm}^3 + 1.8e^{-10} S_{rpm}^2 + 3.1e^{-5} S_{rpm} \\ c_2 &= 1 \\ c_3 &= 1.4e^{-16} S_{rpm}^4 + 7.2e^{-13} S_{rpm}^3 + 1.2e^{-7} S_{rpm}^2 \\ h &= -3.5e^{-5} S_{rpm} P \\ k &= 0 \end{aligned} \tag{B.2}$$

B.0.1.2 HFO Module

The HFO Module is modelled as a ideal flow source.

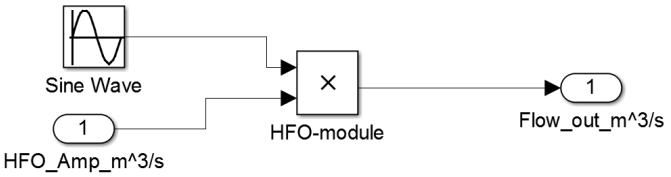


FIGURE B.4: HFO Module simulation model

B.0.1.3 Connection Valve

The connection valve is provided in detail (Figure B.5 - B.18). The figures show the pneumatic and kinematic simulations. In Figure B.8-B.14 is visible how the model switched between normal damping and stiffness to 'infinity' damping and stiffness. Figure B.6 and Figure B.15-B.18 show the pneumatic simulations.

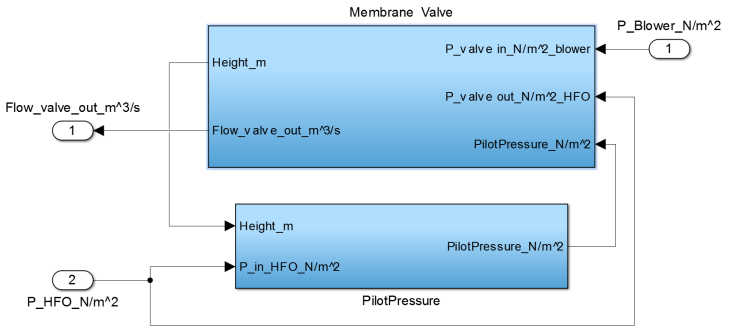


FIGURE B.5: Connection Valve simulation model

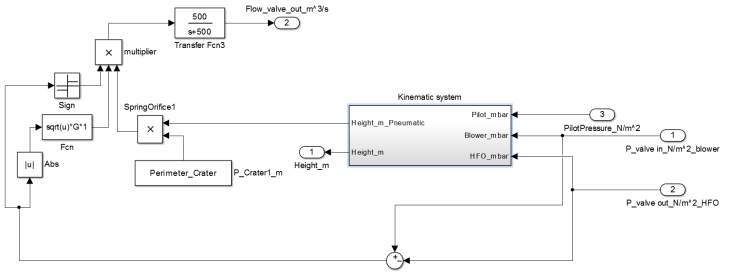


FIGURE B.6: Membrane Valve in Connection Valve simulation model

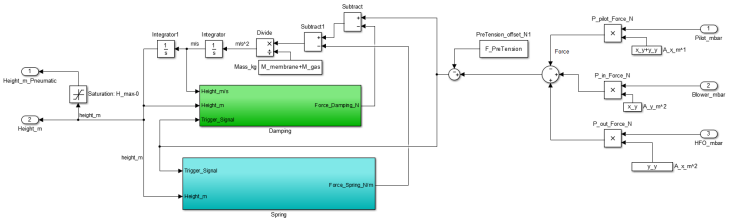


FIGURE B.7: Kinematic System in Membrane Valve in Connection Valve simulation model

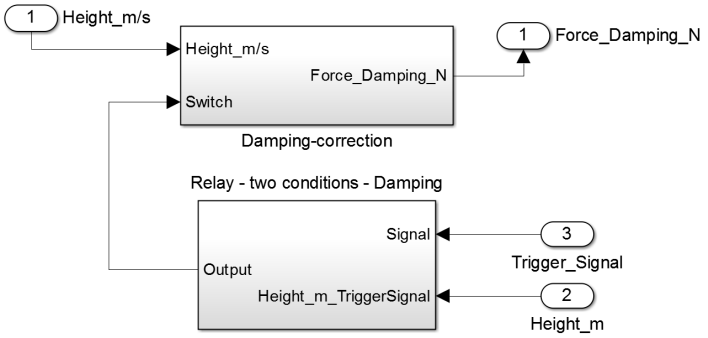


FIGURE B.8: Damping inside Kinematic System

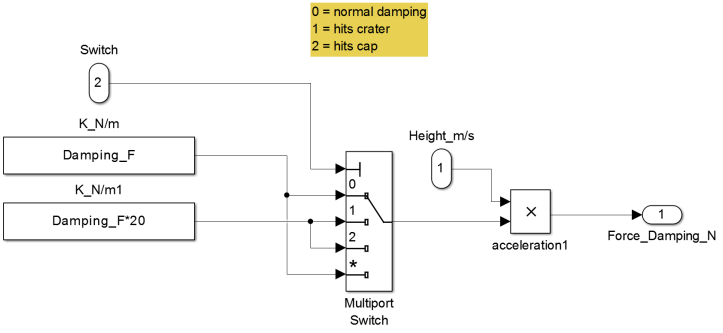


FIGURE B.9: Damping correction inside Damping

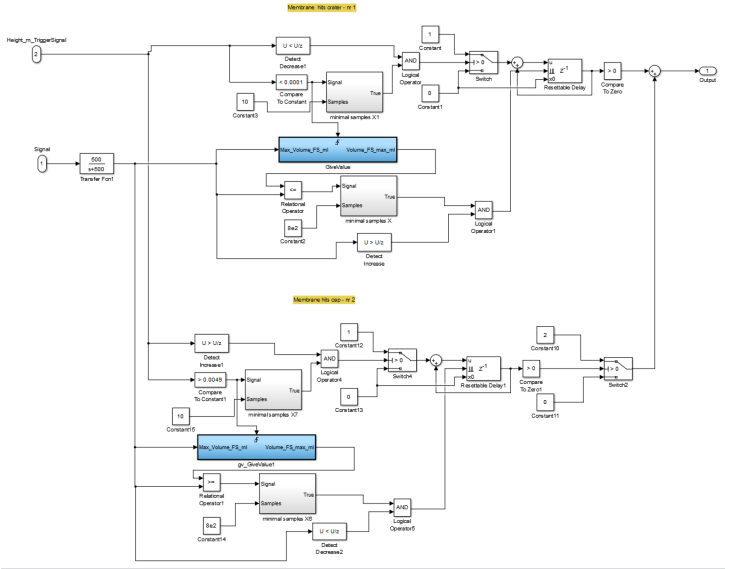


FIGURE B.10: Damping relay inside Damping

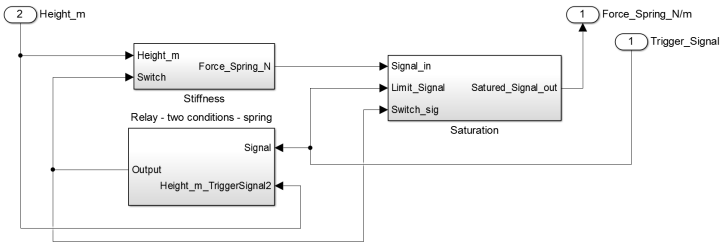


FIGURE B.11: Spring inside Kinematic System

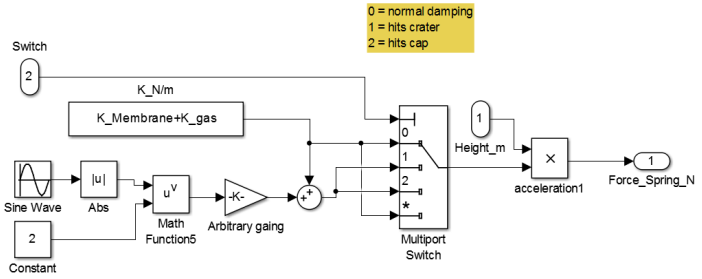


FIGURE B.12: Spring correction inside Spring

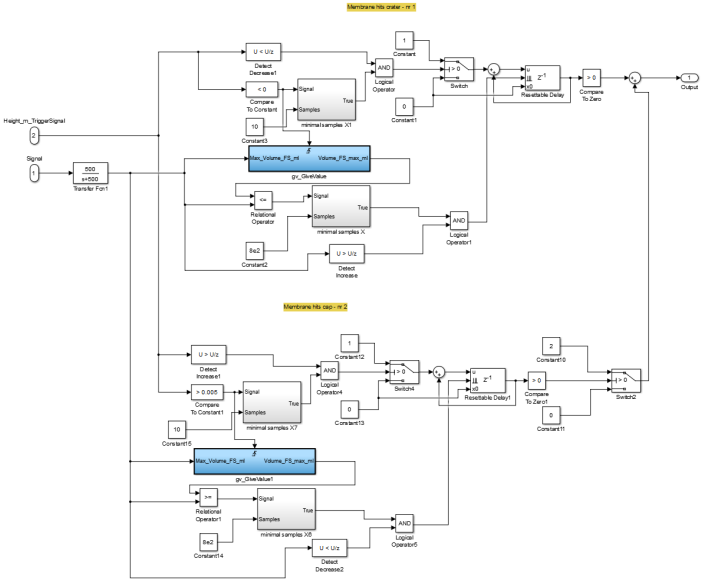


FIGURE B.13: Spring relay inside Spring

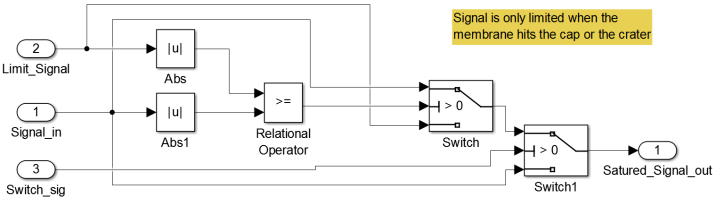


FIGURE B.14: Spring saturation inside Spring

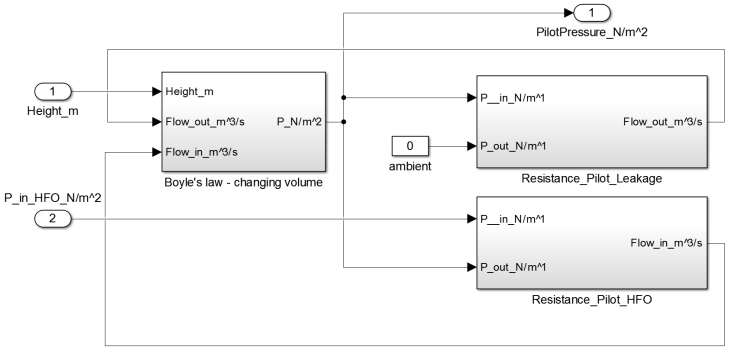


FIGURE B.15: Pilot pressure inside connection valve

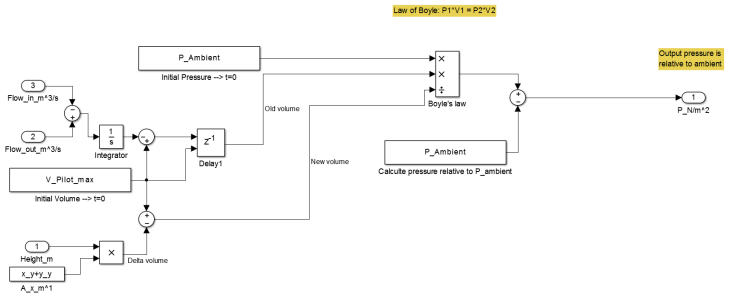


FIGURE B.16: Law of Boyle inside pilot pressure.

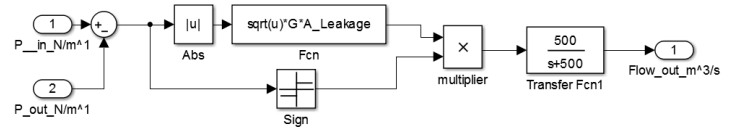


FIGURE B.17: Leakage hole inside pilot pressure.

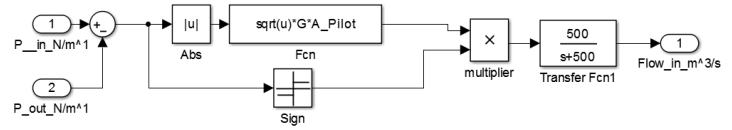


FIGURE B.18: Supply hole inside pilot pressure.

B.0.2 Patient model

The patient model consists out of multiple parts (Figure B.19). The resistance is modelled according Figure B.20 and B.21 and the compliance is modelled according B.22.

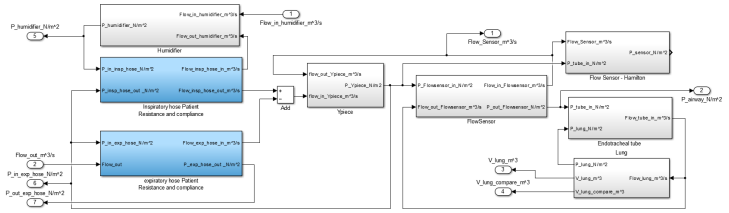


FIGURE B.19: Patient

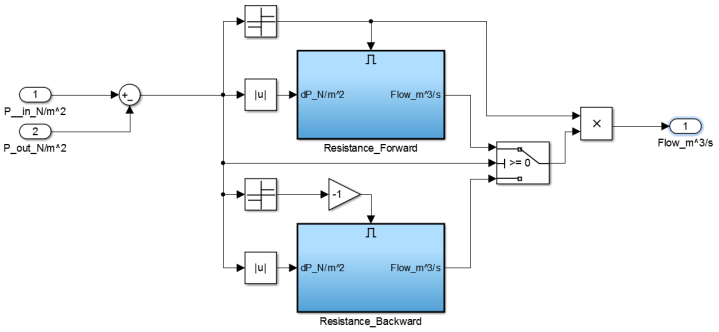


FIGURE B.20: Patient - resistance - forward - backward

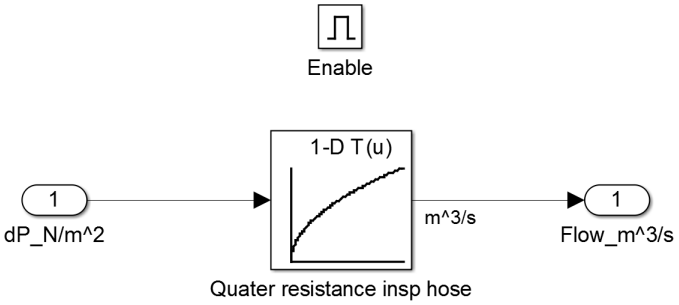


FIGURE B.21: Patient - resistance

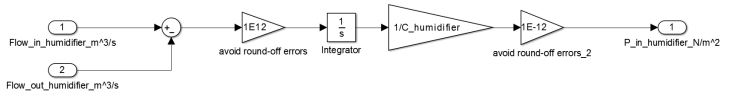


FIGURE B.22: Patient - Compliance

Appendix C

Simulation results tables

All the figures in Chapter 5 are established out of the tables in this chapter.

C.1 Requirements at the ventilator

Oscillatory frequency (Hz)	5	8	11	14	17	20
Tidal volume (ml)	12.0	10.6	9.2	7.8	6.4	5.0
Delta pressure humidifier ($mbar$)	45.1	72.9	103.7	131.8	150.6	138.0
Peak flow humidifier ($\frac{l}{min}$)	46	109	201	300	383	400
Delta pressure end expiration hose ($mbar$)	44.2	70.5	96.1	110.2	111.5	94.8
Flow expiration valve out ($\frac{l}{min}$)	0	0	0	0	0	0
Delta pressure flow meter ($mbar$)	39.2	61.6	83.7	96.3	97.6	83.6
Peak flow flow meter ($\frac{l}{min}$)	11.2	17.2	22.3	24.9	25.9	24.3
Delta pressure lung ($mbar$)	18.1	16.0	14.1	11.7	11.4	7.6

TABLE C.1: The effect of the requirements to the tidal volume (Figure **??**) on the ventilator and components in the patient model.

C.2 Influence of different frequencies with a constant tidal volume

Oscillatory frequency (Hz)	5	8	11	14	17	20
Tidal volume (ml)	5.00	5.00	5.00	5.00	5.00	5.00
Delta pressure humidifier ($mbar$)	16.1	24.2	37.6	57.1	86.6	138.0
Peak flow humidifier ($\frac{l}{min}$)	17	38	77	142	240	400
Delta pressure end expiration hose ($mbar$)	15.7	23.5	36.4	53.4	72.6	83.6
Flow expiration valve out ($\frac{l}{min}$)	0	0	0	0	0	0
Delta pressure flow meter ($mbar$)	14.2	20.6	31.7	46.5	63.4	83.6
Peak flow flow meter ($\frac{l}{min}$)	5.5	8.3	11.8	15.9	19.9	24.3
Delta pressure lung ($mbar$)	7.6	7.6	7.5	7.6	7.6	7.6

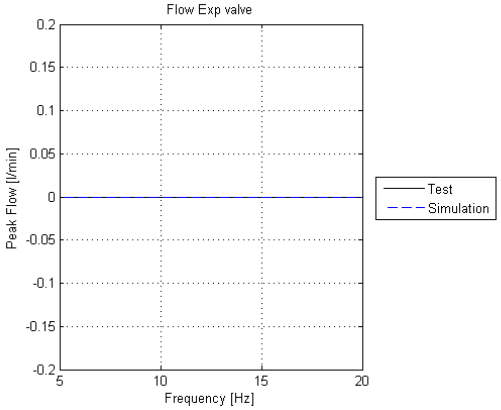
TABLE C.2: The effect of a higher frequency simulated with a constant tidal volume of 5 ml.

C.3 Impact of the performance limit of the HFO Module

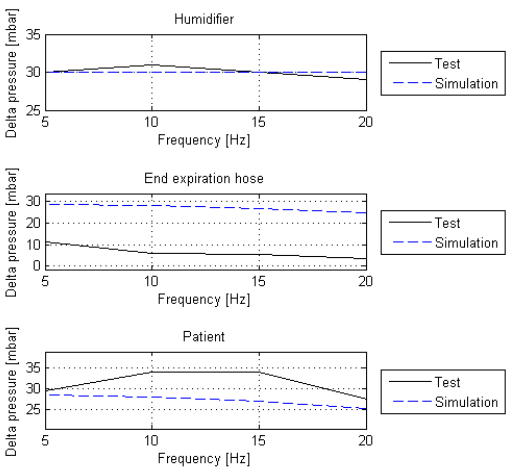
Oscillatory frequency (Hz)	5	8	11	14	17	20
Tidal volume (ml)	20.4	12.7	9.0	6.8	5.4	4.3
Delta pressure beginning inspiration hose ($mbar$)	100	100	100	100	100	100
Peak flow humidifier ($\frac{l}{min}$)	97.3	147.4	194.4	235.5	272.0	304.8
Delta pressure end expiration hose ($mbar$)	97.6	96.2	92.9	87.6	81.5	75.3
Flow expiration valve out ($\frac{l}{min}$)	0	0	0	0	0	0
Delta pressure flow meter ($mbar$)	85.9	84.0	81.0	76.5	71.3	66.1
Peak flow flow meter ($\frac{l}{min}$)	19.4	21.24	21.9	21.9	21.5	21.0
Delta pressure lung ($mbar$)	30.8	19.2	13.6	10.3	8.1	6.7

TABLE C.3: The impact of the limits of the HFO Module on the requirements. The HFO Module can not deliver more than 100 mbar delta pressure.

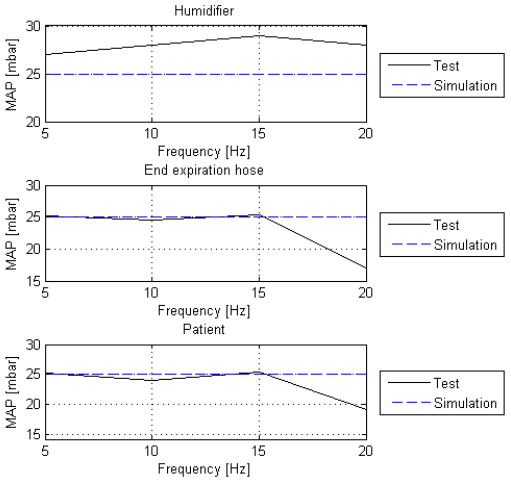
C.4 Verification of the Patient model with reality



(A) Flow



(B) dP



(C) MAP

FIGURE C.1: As well as in the simulation as in the test set-up the pressure at the beginning of the humidifier is a sinus pressure signal of 30 mbar delta pressure and a mean of 25 mbar.

C.5 Control region connection valve

With Connection Valve					Without Connection Valve				
	Minimal Pressure ($mbar$)					Minimal Pressure ($mbar$)			
MAP ($mbar$)	-5	-10	-15	-20	MAP ($mbar$)	-5	-10	-15	-20
10	-0.3	-0.2	0.0	0.0	10	3.3	10.0	17.3	24.9
20	-0.6	-0.5	-0.3	-0.3	20	1.5	6.6	12.8	19.6

TABLE C.4: BaseFlow ($\frac{l}{min}$) at 5 Hz for different MAP and minimal pressure with 0 rpm

With Connection Valve					Without Connection Valve				
	Minimal Pressure ($mbar$)					Minimal Pressure ($mbar$)			
MAP ($mbar$)	-5	-10	-15	-20	MAP ($mbar$)	-5	-10	-15	-20
10	0.0	0.4	0.7	1.0	10	1.9	7.2	13.2	19.6
20	-0.2	0.3	0.6	0.8	20	0.2	4.0	8.8	14.3

TABLE C.5: BaseFlow ($\frac{l}{min}$) at 8 Hz for different MAP and minimal pressure with 0 rpm

With Connection Valve					Without Connection Valve				
	Minimal Pressure ($mbar$)					Minimal Pressure ($mbar$)			
MAP ($mbar$)	-5	-10	-15	-20	MAP ($mbar$)	-5	-10	-15	-20
10	0.5	1.1	1.5	1.9	10	0.9	4.3	9.0	13.9
20	0.0	0.9	1.4	1.8	20	0.0	1.8	4.8	8.9

TABLE C.6: BaseFlow ($\frac{l}{min}$) at 11 Hz for different MAP and minimal pressure with 0 rpm

With Connection Valve					Without Connection Valve				
	Minimal Pressure ($mbar$)					Minimal Pressure ($mbar$)			
MAP ($mbar$)	-5	-10	-15	-20	MAP ($mbar$)	-5	-10	-15	-20
10	0.7	1.7	2.3	2.7	10	0.6	2.6	5.4	8.5
20	-0.3	1.3	2.2	2.7	20	-0.3	1.1	2.8	5.0

TABLE C.7: BaseFlow ($\frac{l}{min}$) at 14 Hz for different MAP and minimal pressure with 0 rpm

With Connection Valve					Without Connection Valve				
	Minimal Pressure ($mbar$)					Minimal Pressure ($mbar$)			
MAP ($mbar$)	-5	-10	-15	-20	MAP ($mbar$)	-5	-10	-15	-20
10	0.3	2.3	3.1	3.7	10	0.3	2.3	4.2	6.2
20	-0.5	0.9	2.8	3.6	20	-0.5	0.8	2.6	4.4

TABLE C.8: BaseFlow ($\frac{l}{min}$) at 17 Hz for different MAP and minimal pressure with 0 rpm

With Connection Valve					Without Connection Valve				
	Minimal Pressure ($mbar$)					Minimal Pressure ($mbar$)			
MAP ($mbar$)	-5	-10	-15	-20	MAP ($mbar$)	-5	-10	-15	-20
10	0.2	1.8	3.1	3.9	10	0.2	1.6	3.1	4.7
20	-0.6	0.3	1.8	3.5	20	-0.6	0.3	1.6	2.9

TABLE C.9: BaseFlow ($\frac{l}{min}$) at 20 Hz for different MAP and minimal pressure with 0 rpm

Appendix D

CAD drawings

The drawings of the parts that are used during the final experiments are visible in Figure D.1-D.3. Not all dimensions are visible in the figures. Only the dimensions that gives a better understanding of the part.

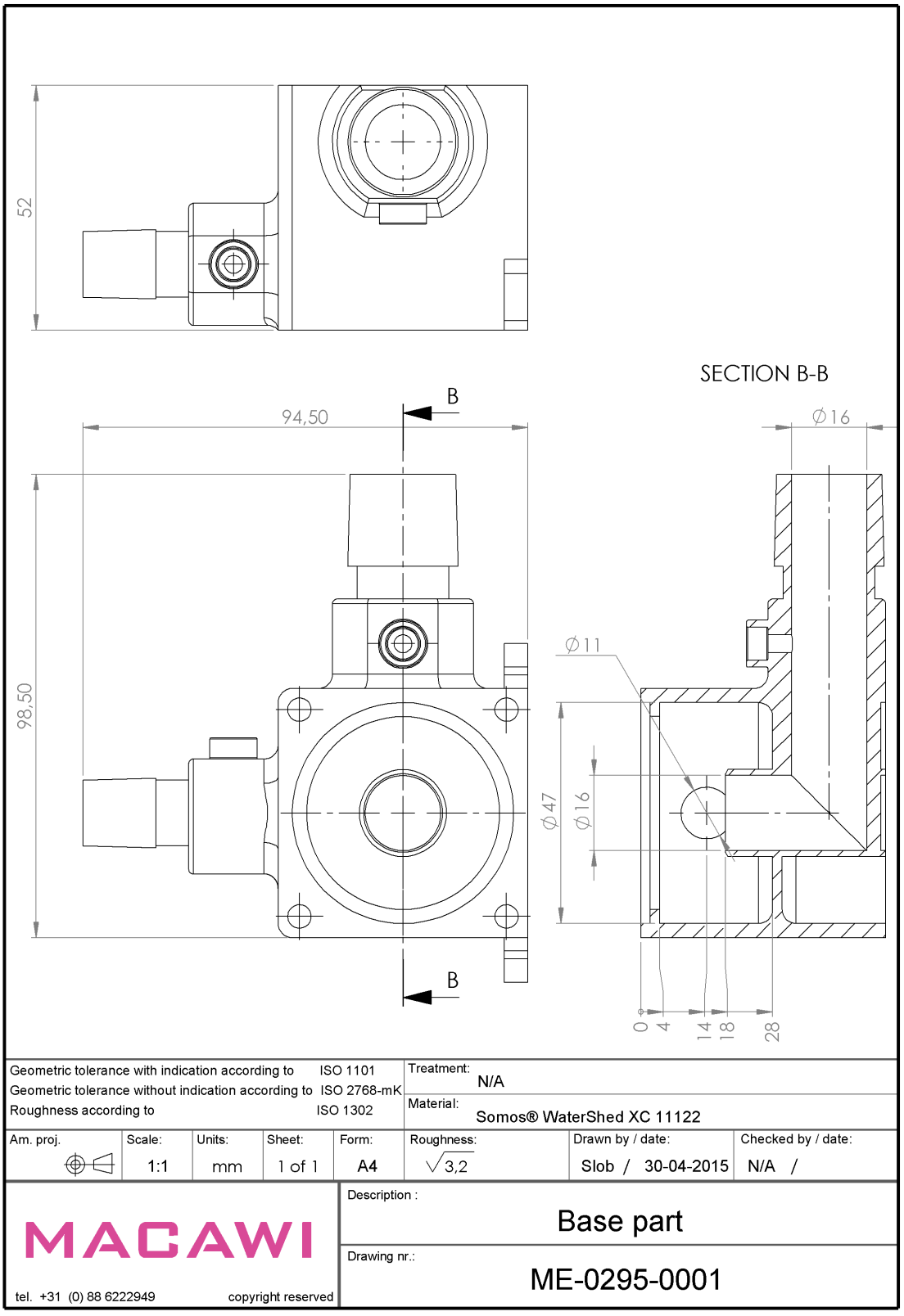


Figure D.1: Base Part

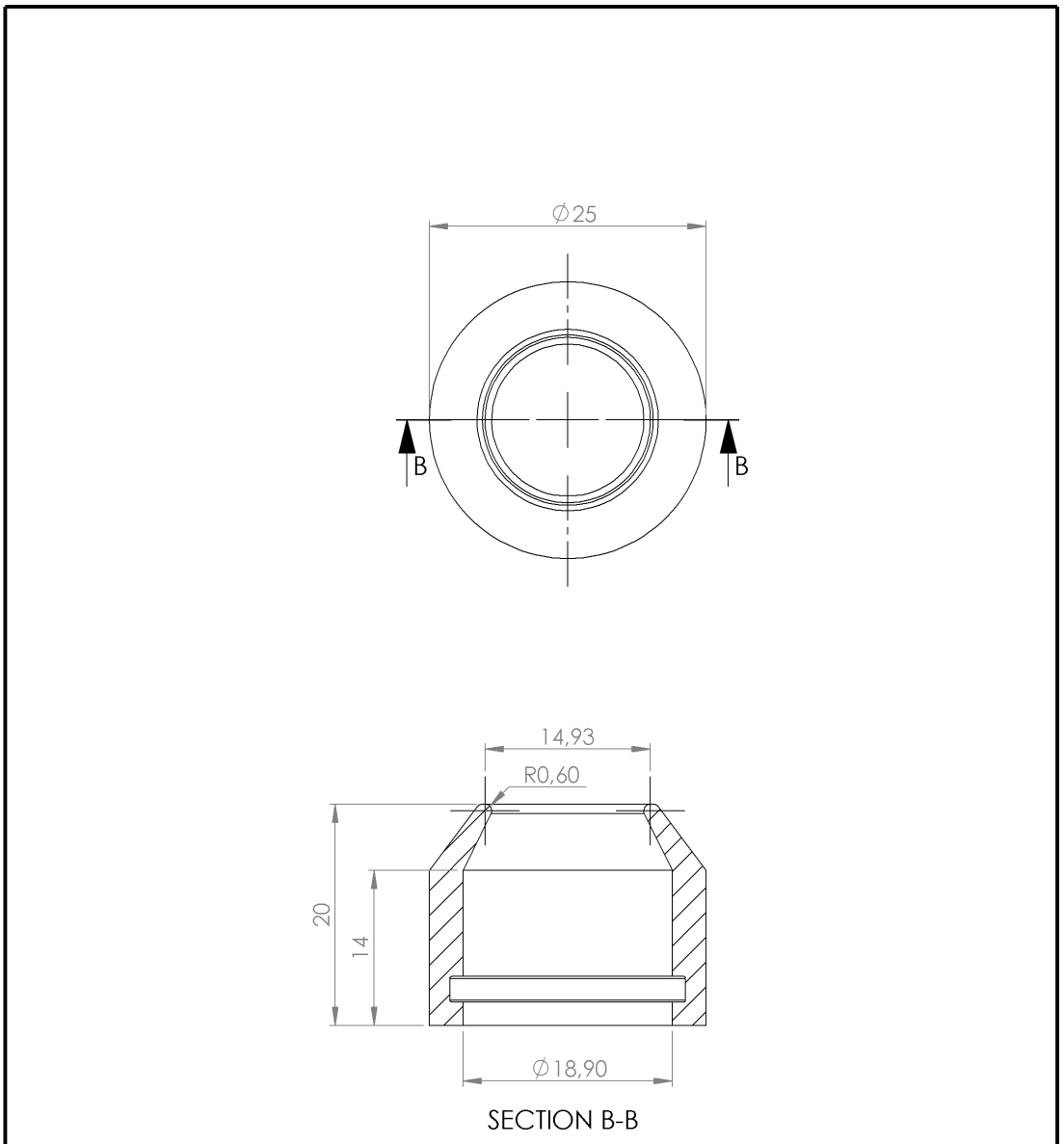


FIGURE D.2: Seat

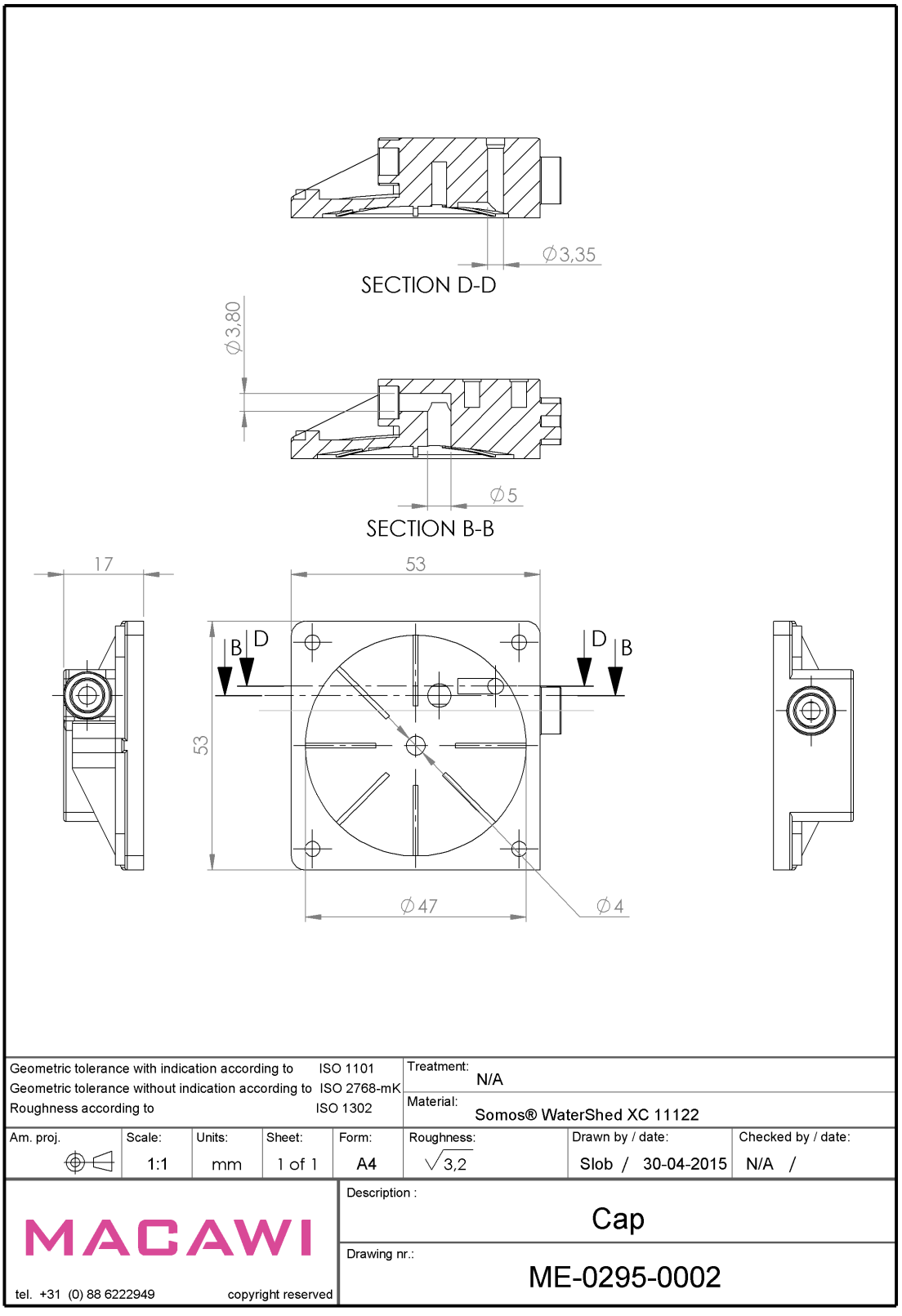


FIGURE D.3: Cap

Appendix E

Connection Valve results tables

All the figures in Chapter 6 are established out of the tables in this chapter.

E.1 Response Time of the valve

	Minimal Pressure ($mbar$)		
MAP ($mbar$)	-5	-10	-15
10	32	29	23
20	38	35	30

TABLE E.1: Response time Connection Valve (ms). The minimal pressure is the pressure of the HFO Module and not at the patient.

E.2 Leakage of the valve

Pressure ($mbar$)	Leakage (lpm)
1	1.026
5	2.936
10	4.600
20	7.000
30	9.000
40	11
50	12.75
60	14
80	16.5

TABLE E.2: Leakage HFO - zonder CV + met pilot chamber –¿ plotje van maken

Pressure ($mbar$)	Leakage (lpm)
1	0.25
5	0.8
10	1.3
20	2.15
30	3.00
40	3.65
50	4.25
60	4.8
80	5.8

Table E.3: Leakage HFO - zonder CV + zonder pilot chamber –¿ plotje van maken

Pressure ($mbar$)	Leakage (lpm)
1	1.08
5	3.03
10	4.7
20	7.3
30	9.15
40	10.8
50	12.5
60	13.7
80	16.2

Table E.4: Leakage HFO - met CV + met pilot chamber –¿ plotje van maken

E.3 Base-flow

* = The expiration valve can't not open enough to let through enough flow

** = The HFO Module can not deliver enough pressure amplitude

With Connection Valve				
	Minimal Pressure ($mbar$)			
MAP ($mbar$)	-5	-10	-15	-20
10	0	0	0	0
20	0	0	0	0

Without Connection Valve				
	Minimal Pressure ($mbar$)			
MAP ($mbar$)	-5	-10	-15	-20
10	0	13	21	*
20	0	2	13	20

Table E.5: Base flow (l/min) at 5 Hz for different MAP and minimal pressure with the connection valve

With Connection Valve

MAP (*mbar*)	Minimal Pressure (*mbar*) -5	-10	-15	-20
10	0	0	2	4
20	0	0	4	**

Without Connection Valve

MAP (*mbar*)	Minimal Pressure (*mbar*) -5	-10	-15	-20
10	0	0	9	16
20	0	0	5.5	11

TABLE E.6: Minimal base flow (l/min) at 10 Hz for different MAP and minimal pressure with the connection valve

With Connection Valve

MAP (*mbar*)	Minimal Pressure (*mbar*) -5	-10	-15	-20
10	0	0.5	6.5	10
20	0	2	5	**

Without Connection Valve

MAP (*mbar*)	Minimal Pressure (*mbar*) -5	-10	-15	-20
10	0	0	7	15
20	0	0	8	14

TABLE E.7: Minimal base flow (l/min) at 15 Hz for different MAP and minimal pressure with the connection valve

With Connection Valve

MAP (*mbar*)	Minimal Pressure (*mbar*) -5	-10	-15	-20
10	0	5	13	18
20	0	4	11	**

Without Connection Valve

MAP (*mbar*)	Minimal Pressure (*mbar*) -5	-10	-15	-20
10	0	5	14	19
20	0	11	24	**

TABLE E.8: Minimal base flow (l/min) at 20 Hz for different MAP and minimal pressure with the connection valve

E.3.1 Tidal Volume

Tidal Volume (ml)

MAP (*mbar*)	Minimal Pressure (*mbar*) -5	-10	-15	-20
10	31	40	45	51
20	46	51	59	63

2· Minute volume (l/min)

MAP (*mbar*)	Minimal Pressure (*mbar*) -5	-10	-15	-20
10	19	24	27	31
20	28	31	36	38

TABLE E.9: Tidal volume (ml) and Minute volume (l/min) during 5 Hz for different MAP and minimal pressure.

Tidal Volume (ml)

MAP (*mbar*)	Minimal Pressure (*mbar*) -5	-10	-15	-20
10	16	19	21	25
20	23	26	29	-

2· Minute volume (l/min)

MAP (*mbar*)	Minimal Pressure (*mbar*) -5	-10	-15	-20
10	19	23	25	30
20	28	31	35	-

TABLE E.10: Tidal volume (ml) and Minute volume (l/min) during 10 Hz for different MAP and minimal pressure.

Tidal Volume (ml)				
	Minimal Pressure (*mbar*)			
MAP (*mbar*)	-5	-10	-15	-20
10	10	12	14	16
20	14	16	17	-

2· Minute volume (l/min)				
	Minimal Pressure (*mbar*)			
MAP (*mbar*)	-5	-10	-15	-20
10	18	22	25	29
20	25	29	31	-

TABLE E.11: Tidal volume (ml) and Minute volume (l/min) during 15 Hz for different MAP and minimal pressure.

Tidal Volume (ml)				
	Minimal Pressure (*mbar*)			
MAP (*mbar*)	-5	-10	-15	-20
10	8	9	11	-
20	10	11	13	-

Base flow (l/min)				
	Minimal Pressure (*mbar*)			
MAP (*mbar*)	-5	-10	-15	-20
10	18.24	20.64	25.92	30.72
20	25.68	27.84	31.92	-

TABLE E.12: Tidal volume (ml) and Minute volume (l/min) 20 Hz for different MAP and minimal pressure.

Appendix F

Used instruments

Different instruments are used for the simulation, the designs and experiments.

F.1 Simulation

The simulation models are derived with Matlab and Simulink R2013b.

F.2 Design

The connection valve is designed in SolidWorks 2012.

F.3 Experiments

All experiments are done with the system Dspace 1.4x combination with Matlab and Simulink R2013b.
The one type of hose system is used during the experiments. The survey showed that the clinicians mainly use a hose from Fishel & Paykel for neonates, humidifier MR 850 from Fishel & Paykel. The hose that is used in this research is the RT225 infant breathing circuit. The humidifier that is used is the MR 850 from Fishel & Paykel. These hose and humidifier were available inside Macawi. A EZ-FLOW Airway flow sensor of Treymed (a fixed orifice flow meter for neonates) is used as flow meter during this research. The flow meter was provided by Macawi.

The emperical data of resistances and compliances for in the simulation model are measured with different instruments. For the resistance is the flow through the component is created by the Bonemine Module and checked by the TSI 4040G, calibrated in October 2013 and the pressure drop over the component is by a pressure sensor, SensorTechnics HDIM200DBF8H5. For the compliance is the volume is inserted with a gas-tight syringe, Hamilton model 1100 TLL SYR. The pressure increase is measured with a pressure transducer, Setra C239 1437109, and displayed with a Red Lion's Pax meter, PAXP0000.

The pressure during the final experiments are measured by a pressure sensor, SensorTechnics HDIM200DBF8H5. The expiration valve is controlled by a Texas Instruments current driver, type DRV595EVM, which can control up to 4 A. The current driver is driven by a differential voltage from 0 to 10 V from Dspace.

Bibliography

[1] P. P. Hamilton, A. Onayemi, J. A. Smyth, J. E. Gillan, E. Cutz, A. B. Froese, and A. C. Bryan. Comparison of conventional and high-frequency ventilation: oxygenation and lung pathology. *J Appl Physiol Respir Environ Exerc Physiol*, 55(1 Pt 1):131–8, Jul 1983.

[2] R. Ramanathan and S. Sardesai. High frequency ventilation : Basic concepts and clinical application. *The Indian Journal of Pediatrics*, 67(1):3–8, January 2000. ISSN 0019-5456.

[3] S. Zivanovic, J. Peacock, M. Alcazar-Parisand J.W. Lo, A. Lunt, N. Marlow, S. Calvert, B. Chir, and A. Greenough. Late outcomes of a randomized trial of high-frequency oscillation in neonates. *The new england journal of medicine*, 370(12), March 2014.

[4] Kenneth P. W. Chan, Thomas E. Stewart, and Sangeeta Mehta. High-frequency oscillatory ventilation for adult patients with ards*. *CHEST Journal*, 131(6):1907–1916, 2007. ISSN 0012-3692.

[5] L. Slob. High frequency oscillatory ventilation: current state. *BioMedical Engineering TuDelft*, 2015.

[6] V. Bahel and S. Shivashankar. Using simulation model to reduce system design time and cost. *International Refrigeration and Air Conditioning Conference*, 2014.

[7] S. Shan and G.G. Wang. Metamodeling for high dimensional simulation-based design problems. *Journal of Mechanical Design*, 132(5), 2010.

[8] S.J. Corbridge, R. McLaughlin, J. Tiffen, L. Wade, R. Templin, and T. Corbridge. Using simulation to enhance knowledge and confidence. *Nurse Practitioner*, 33(6):12–13, 2008.

[9] L.Y. Serna, A.M. Hernandez, and M.A. Mananas. Computational tool for modeling and simulation of mechanically ventilated patients. *32nd Annual International Conference of the IEEE EMBS*, September 2010.

[10] M.A. Borrello. Modeling and simulation of pressure regulated control systems for ventilation of the lung. *Engineering in Medicine and Biology Society*, 13, 1991.

[11] A. Mulper and P. Darnell. *Biomedical Systems: Modeling and simulation of lung mechanics and ventilator controls design*. VisSim, 1997.

[12] F.M. White. *Fluid mechanics*. McGraw-Hill Higher Education, 2009.

[13] P. Scalfaro, J.J. Pillow, P.D. Sly, and J. Cotting. Reliable tidal volume estimates at the airway opening with an infant monitor during high-frequency oscillatory ventilation. *Critical Care Medicine*, 29(10), 2001.

[14] H. K. Chang. Mechanisms of gas transport during ventilation by high-frequency oscillation. *J Appl Physiol Respir Environ Exerc Physiol*, 56(3):553–63, Mar 1984.

[15] S. Jobs. Apple's one dollar man. *Fortune*, 2000.

[16] P. Ogrodnik. *Medical Device Design*. Elsevier, 2011.

[17] P.R.N. Childs. *Mechanica Design Engineering Handbook*. Elsevier, 2014.

[18] Festo. Piezo valves in medical technology and laboratory automation, April 2015. URL http://www.festo.com/net/SupportPortal/Files/172927/Piezo_Broschuere_en_M.PDF.

[19] Carefusion. Self-flushing valve, 2011. URL https://www.google.nl/patents/US20130060205.

[20] Carefusion. Tailless needleless valve system, 2015. URL https://www.google.nl/patents/US20140135709.

[21] Carefusion. Exhalation valve for mechanical ventilator, 2015. URL https://www.google.nl/patents/EP2044921B1.

[22] Sensormedics. Pressure regulating valve for use in continuous positive airway pressure devices, 2015. URL https://www.google.nl/patents/US6766800.

[23] Sensormedics. High frequency ventilation, 2015. URL https://www.google.nl/patents/US4805612.

[24] Siemens-Elema Ab. Valve assembly, 2015. URL https://www.google.nl/patents/US6886801.

[25] Siemens Elema Ab. Valve with valve body which is non-linearly movable relative to a valve seat, 2015. URL https://www.google.nl/patents/US6349922.

[26] Siemens Elema Ab. Membrane valve wherein the membrane is displaced by a combination of fluid flow and operation of a solenoid, 2015. URL https://www.google.nl/patents/US6082705.

[27] Siemens Aktiengesellschaft. Valve for the controlling of a pressure differential, 2015. URL https://www.google.nl/patents/US4836241.

[28] Drager Medical Gmbh. Combi-valve for a blower driven ventilator, 2015. URL https://www.google.nl/patents/US20110232640.

[29] Drager Medical Ag&Co. Slot valve for use in the pneumatic switching circuit of a respirator, 2015. URL https://www.google.nl/patents/US8662104.

[30] The Boc Group. Exhalation valve, 2015. URL https://www.google.nl/patents/US4699137.

[31] J.M. Cairo. Introduction to ventilators. In *Mosby's Respiratory Care Equipment, 9th Edition*, chapter 12, pages 363–420. 2013. ISBN 9780323096256.

[32] Hamilton. *GALILEO Service Manual including Maintenance, Repairs and Test*, October 2005.