ASSESSMENT OF THE CAPABILITY OF PULMOVISTA 500 TO CONTINUOUSLY MONITOR CHANGES OF VENTILATION OVER TIME.

„PULMOVISTA“

Statistical analysis plan

Version Final 01 from 01.03.2018

Sponsor: Drägerwerk AG & Co. KGaA, Moislinger Allee 53-55, 23558 Lübeck

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TABLE OF ABBREVATIONS

AE	adverse event
ALI	acute lung injury
CCF	cross-correlation function
CT	computed tomography
DLT	double lumen tube
(e)CRF	(electronic) case report form
EIT	electrical impedance tomography
FPFV	first patient first visit
GCP	good clinical practice
ICD	implantable cardioverter defibrillator
ICH	International Counsil on Harmonization
ICU	Intensive Care unit
IfU	Instructions for Use
ITT	Intent To Treat
KKS	Coordination Centre for Clinical Trials
LPLV	last patient last visit
MPG	german medical device law
MRI	magnetic resonance imaging
NA	not applicable
NaCl	Sodium chloride
ND	not done
OLV	one lung ventilation
PDA	pidural anesthesia
PEEP	positive end-expiratory pressure
SAE	serious adverse event
SAS	statistical analysis system
SBT	spontaneous breathing trial
SDV	source data verification
SOP	standard operating procedure
SPSS	statistical package for the social sciences
TEA	thoracic epidural anesthesia
VT	tidal volume

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1.1 STUDY OBJECTIVE

PulmoVista 500 is a lung function monitor for clinical use which continuously generates cross-sectional images of the lung function by applying the technique of electrical impedance tomography (EIT).

To perform bioimpedance measurements, an electrode belt containing 16 electrodes is placed around the chest wall. Additionally, one reference electrode must be attached to a central point to the body, preferable on the abdomen. The reference electrode ensures that all measurements at different electrode pairs are referenced to the same electric potential[1]. PulmoVista 500 provides graphical information about the regional distribution of ventilation and changes of end-expiratory lung volume. The spatial resolution of this information allows continuously observing specific conditions of different lung regions.

The primary objective of this study is to assess the capability of PulmoVista 500 to continuously monitor ventilation and changes of lung volume

For this propose cross-correlations between the global impedance waveforms created by a ventilator shall be evaluated.

1.2 STUDY DESIGN

The study is a multicenter, prospective, non-interventional, and open observation study. The clinical trial will be conducted according to the German Medical Device Act as §23b clinical trial and in compliance with the ISO 14155.

1.3 DEFINITIONS

The intention-to-treat collective comprises all patients for which both, the impedance waveforms and parallel to them volume waveforms have been generated during ventilation. If one of the two waveforms has not been created or cannot be evaluated, the patient is considered as drop out.

A waveform is not generated if

a) it has not been recorded correctly, so all the individual values are zero or
b) there is no complete 1-minute file before the "PRE" marker or behind the "POST" marker available for the statistical calculation of the cross-correlation coefficient.

[1] Teschner E, Imhoff M, Leonhardt S. Electrical Impedance Tomography: The realisation of regional ventilation monitoring. Drägerwerk AG & Co. KGaA 2015; Reference-Nbr 90 66 788; 19

1.4 APPLICATIONS

The primary efficacy analysis is performed on the Intention-to-treat collective. Additionally a collective will be evaluated in which the impedance waveforms are probable without external disturbances. The decision about his patient classification will be done in the Data Review Meeting.

1.5 PATIENTS

The following patients will be enrolled:

a) Intensive care unit (ICU) patients, who are mechanically ventilated via an artificial airway (endotracheal tube or tracheostomy cannula) and who are expected to be subjected to major changes in their ventilator settings will be monitored with the PulmoVista 500 device before, during and after the changes.

Examples of such interventions are:

- Spontaneous breathing trial (SBT) using the ventilator (as opposed to SBT using a T-piece)
- Switching between different modes of ventilation (e.g. volume controlled, pressure controlled, pressure support, CPAP)
- Initial adjustment of ventilation after ICU admission
- Weaning of ventilation in preparation of extubation
- PEEP trials and recruitment maneuvers
- Suctioning maneuvers

b) One lung ventilation (OLV) patients who are scheduled for planned surgical procedures requiring ventilation of only one lung wing (e.g. DLT- intubation using a double lung tube or placement of a bronchus blocker).

1.6 SERIOUS PROTOCOL VIOLATIONS

Serious protocol violations are documented. In the Data Review Meeting, the classification of patients with serious protocol violations is decided. The data review meeting takes place after completion of the data input and the data correction (answering all queries). Participants are usually coordinating investigator or his representative, a representative of the sponsor, the data manager, the study manager / monitor and the biometrics.

2 TRIAL SITES

Currently involved centers are:

Trial site 1:
Dr. med. Peter Spieth,
Medizinische Fakultät „Carl Gustav Carus“,
Klinik und Poliklinik für Anästhesiologie und Intensivtherapie,
Fetscherstr. 74, 01307 Dresden

Trial site 2:
Dr. med. Jan Frederik Karsten
Medizinische Hochschule Hannover (MHH)
Klinik für Anästhesiologie und Intensivmedizin
Carl-Neuberg-Str. 1
30625 Hannover

Trial site 3:
Prof. (UCSF) Dr. med. Oliver C. Radke
Klinikum Bremerhaven-Reinkenheide gGmbH
Klinik für Anästhesiologie und Operative Intensivmedizin
Postbrookstraße 103, 27574 Bremerhaven

3 VARIABLE IN THE ANALYSIS

3.1 DEMOGRAPHY AND BASELINE CHARACTERISTICS

The following demographic variables are recorded and evaluated: age and gender. It also detects whether a (pseudo) allergy to silicone or sweat is present. Concomitant diseases are recorded and listed.

Physical features such as height, weight, BMI, chest circumference on day 1 and vital signs (systolic and diastolic blood pressure, heart rate) are displayed with mean and standard deviation.

If necessary, systolic and diastolic blood pressure and heart rate are recorded and displayed on the following day.

Problems with skin before applying the belt are detected.

The characteristic "one-lung ventilation patient" (OLV) or not (ICU) is recorded and evaluated.

If applicable, it is additionally subdivided into Double Lumen Tube (DLT) / Bronchus Blocker (BB) or others.

Electrode belt details such as size, closure position (plughole), belt application in accordance with the clinical investigation plan, electrode mode and signal quality are recorded.

The reasons, why the intervention or surgical procedure has to be done are listed separately according to OLV and ICU group.

The baseline parameters also include the basic data of the ventilation procedure, such as saturation of s_aO_2, s_pO_2, p_aO_2, p_aCO_2, FiO_2 before and after the intervention. Depending on the distribution, they are determined as mean and standard deviation or as median and percentiles.

If present, auscultation findings, imaging findings (CT, X-ray, or ultrasound) before and after the intervention and the radiological findings are recorded and listed. These findings were collected for the duration of the study (day -2 - day +3).

3.2 PRIMARY STUDY OBJECTIVE

3.2.1 Efficacy

It should be demonstrated that PulmoVista 500 is able to monitor ventilation with the associated interventions of a patient. The global impedance waveforms of PulmoVista 500 should be comparable to the volume waveforms of the ventilator. For this purpose, the cross-correlation coefficient between these two waveforms is calculated twice per patient (before and after an intervention) for all 80 patients.

3.3 SECUNDARY STUDY OBJECTIVES

3.3.1 Efficacy

- To demonstrate the ability of PulmoVista 500 to display regional ventilation changes, a quantitative evaluation is performed using the cross-correlation coefficient between the impedance waveforms of PulmoVista 500 and the ventilator volume waveforms in the subgroup of OLV patients.

- To evaluate Pulmo Vista 500's monitoring features, it assesses whether changes in tidal volumes induced by ventilation settings are represented by the "main view". For this purpose, the plausibility questionnaire is evaluated.

- Assess that changes of the end-expiratory lung volumes (induced by e.g. PEEP changes, recruitment and suctioning maneuvers) can be monitored by "dEELI trend view". The plausibility questionnaire is also evaluated for this.
- To evaluate the clinical usefulness of PulmoVista 500, the questionnaire on clinical utility across all patients is evaluated.
- In order to demonstrate the ability of PulmoVista 500 to produce controlled induced regional changes, an evaluation is performed using the OLV subgroup. Three blinded rater evaluate the corresponding waveforms.

3.3.2 Safety

A documentation of all safety-related events related to the use of PulmoVista 500 is provided.

4 TREATMENT OF MISSING, UNUSED OR SPURIOUS DATA, INCLUDING DROP OUTS AND WITHDRAWALS

4.1 MISSING VALUES

No missing data imputation techniques will be applied, and patients with missing efficacy data will used as censored in the time to event analysis. Therefore any effort should be undertaken to avoid missing data, notably in case of the primary outcome measures.

When a patient is withdrawn from the trial before the scheduled end of a treatment phase, and an end-of-study visit can be performed, the data of this visit will be used for computing the primary outcome measure.

The handling of missing data will be specified in the Data Review Meeting.

Only data from patients for whom appropriate ventilation waveforms are available can be evaluated. Patients without evaluable ventilation waveforms are drop-outs.

4.2 OUTLIERS

Outlier criteria, especially for peeks in the impedance waveform, are set in the Data Review Meeting. These criteria decide on an additional evaluation collective without these outliers.

5 STATISTICAL ANALYSIS

5.1 PARTICIPANTS

A sample size of n=80 patients (including at least 25 patients for the OLV subgroup) has been calculated with an assumed drop-out rate of 15%.

OLV subgroup consists of patients who have been scheduled for surgical procedures that require the ventilation of only one lung (e.g., intubation using a double-lumen tube or placement of a bronchus blocker).

The remaining 55 patients are patients mechanically ventilated in an intensive care unit (ICU) via an artificial airway access (endotracheal tube or tracheostomy tube). For those, it can be assumed that significant changes to the ventilation settings will have to be made, which are continuously recorded with the PulmoVista 500 during the study.

5.2 DEMOGRAPHY AND BASELINE CHARACTERISTICS

The features of Chapter 3.1 are presented according to their distribution characteristics.

5.3 PREMEDICATION, CONCOMITANT MEDICATIONS AND PRE-DISEASES

All recorded pre-diseases and concomitant medications were listed.

5.4 EXPOSURE TO THERAPY/COMPLIANCE

Attention must be paid to patients with (pseudo-) allergies to sweat or silicone.

5.5 PRIMARY ANALYSIS

The basic data for the analysis is recorded in a database. The ventilation data for both waveforms- the global impedance waveforms and the volume waveforms- are stored for each patient in a cloud and prepared using a statistical analysis algorithm (see Appendix 7.2 Workflow for determining the time ranges used to calculate the cross correlation between the global impedance waveform (PulmoVista 500) and the volumetric waveform (Evita V500)).

The two EXCEL tables per patient contain the two waveforms to be compared (Appendix 7.2, Section 14, Columns A, B, C and N). From this, two cross-correlation coefficients per patient were calculated. The cross-correlation coefficients are a measure of the relationship between the two waveforms.

Figure 1 shows a section of both waveforms unstandardized. The numbers and diagrams are examples from the study „Assessment of the capability of PulmoVista 500 to

continuously monitor regional ventilation distribution and its changes over time", Investigation reference number PulmoVista 500-30022.

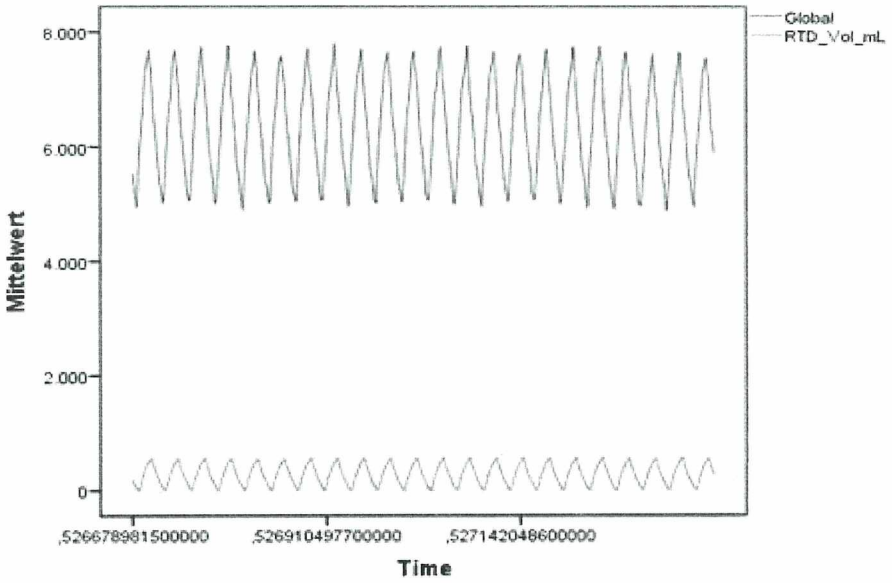


Fig. 1: PulmoVista 500 Impedance Waveform (Global- blue) and Reference Volume Waveform (RTD_Vol_mL- green) unstandardized over time

If you standardize both waveforms, you get the following figure:

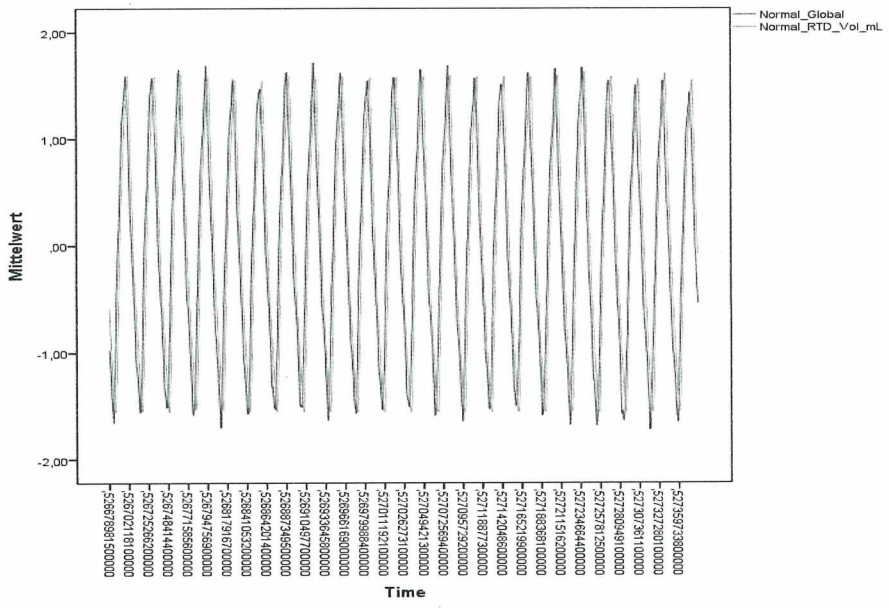


Fig. 2: PulmoVista 500 Impedance Waveform (Global- blue) and Reference Volume Waveform (RTD_Vol_mL- green) standardized over time

Figure 2 shows a slight time shift of the waveforms to each other.

In this example there is e.g. a correlation coefficient (Pearson) of 0.871 for the waveforms. Taking into account the shift (here Lag = 10: Shift from one curve to the other by 10 measuring times in both directions from 0) it results in a cross-correlation coefficient of 0.995.

To refute the hypothesis of independence of both waveforms, it has to be shown that the global impedance waveforms (as measured by the PulmoVista 500) and the global volume waveforms (of the EvitaV500 ventilator) correlate significantly (rejection of the null hypothesis "no correlation"). Because 2 experimental steps (before and after each intervention) should be performed in 80 patients, 80 averaged (from the pre- and post-values) cross-correlation coefficients will be obtained in total. If, for technical reasons (for example, incorrectly set markers), there are only pre- or post-values, the averaging in this patient is omitted and only one cross-correlation coefficient is used. From these averaged cross-correlation coefficients, a 95% confidence interval is calculated and a one sample t-test is performed to determine if the mean of the cross-correlation coefficients is significantly different from zero. The significance level is $\alpha = 0.05$.

5.6 SECUNDARY ANALYSIS

5.6.1 Efficacy

- To demonstrate the ability of PulmoVista 500 to visualize regional ventilation changes, a quantitative evaluation is performed by calculating the cross-correlation coefficients between the impedance waveforms of PulmoVista 500 and the ventilator volume waveforms of OLV patients. The evaluation is carried out as in the primary analysis.
- In addition, a qualitative evaluation of the regional changes will be carried out. To do so, three blinded raters compare the corresponding sections of all OLV patients independently. Based on the information from the PulmoVista 500 video sequence provided, the raters evaluate which of the two halves of the lung is ventilated. The results are entered patient-related (pseudo-patient number) in the following table by the rater:

Pseudo-Patnr.	Valuation	
1	1	
2	2	
3	0	
4	1	
.	.	

Description of valuation:	0	not assessable
	1	right ventilated / left blocked
	2	left ventilated / right blocked

Tab. 1: Example of table for the qualitative evaluation of the OLV patients and the associated rating

The PulmoVista 500 video sequences to be assessed are created according to a workflow (see Appendix 7.3 Workflow for the creation of OLV videos) and made available to the raters. The pseudo-patient numbers are randomly generated by lot. These three tables of the raters will be merged into the KKS. A decision is considered positive or negative if at least two raters have come to the same result. In the opinion of one or more raters, is it not possible to judge the waveform (Code 0), the following assignment applies:

1x not evaluable & 2x same decision -> clear assignment in the table,

1x not assessable & unequal decision of the remaining 2 raters -> drop out,

2x or 3x not evaluable -> drop out.

A 2x2 Table will be created in the following form from the 3 tables of the raters (one of each rater):

Reference	Evaluation of the raters (with information provided by PulmoVista 500)	
	right ventilated / left blocked	left ventilated / right blocked
right ventilated / left blocked	a	b
left ventilated / right blocked	c	d

Tab. 2: Table for the accordance of rater and reality of the OLV patients

From this table, the success rate (a + d) / (a + b + c + d), the sensitivity a / (a + b), the specificity d / (c + d) and the corresponding confidence intervals are calculated. The reverence (real side of the ventilation) is taken in the study documentation (e.g. Name of corresponding Marker and/or MACRO Database) of the individual patients.

- To assess the ability of PulmoVista 500 to display changes in ventilation-induced tidal volumes through the "Trend View", the plausibility questionnaire across all patients is evaluated. The questions of the plausibility questionnaire in relation to the "main view" are individually counted according to their categories (yes / no / n.a.) and listed as a percentage.
- To assess the ability of PulmoVista 500 to display changes in end-expiratory lung volumes (induced by e.g. PEEP changes, recruitment and suction maneuvers) using the "dEELI Trend View", the plausibility questionnaire is evaluated across all patients. The questions of the plausibility questionnaire in relation to the "dEELI trend view" are individually counted according to their categories (yes / no / n.a.) and listed as a percentage.
- The evaluation of clinical usefulness, the nine questions of the questionnaire on clinical usefulness, are individually counted according to their category level (1 very difficult ... to ... 5 very useful) and listed on a percentage basis. Furthermore, the mean and standard deviation are calculated for each of these nine questions.

5.6.2 Safety / Compatibility

5.6.2.1 Adverse events

Information on AEs will be collected from the time of enrollment until regular completion of study, death or withdrawal (whichever comes first).

The investigator will report all AEs as soon as possible (preferably within 7 days) to their knowledge by entering them in the eCRF.

AEs are documented on an AE form (eCRF). Diagnosis, onset, and end of the AE, seriousness, severity, causal relationship with the investigational medical device, with the study procedures, treatment of the AE, and the outcome of the event will be documented. The Investigator will follow-up the event until the AE has been resolved, resolved with sequelae or was fatal.

All AEs will be listed in the final report with the above criteria.

5.6.2.2 Laboratory parameters

If measured, the saturation of s_aO_2, s_pO_2, p_aO_2, p_aCO_2, FiO_2 before and after the intervention are documented and displayed with their distribution.

5.6.2.3 Vital signs

Height, weight, BMI, systolic and diastolic blood pressure, heart rate and chest circumference are recorded and displayed with their distribution parameters.

5.7 SUBGROUP ANALYSIS

Depending on the type of ventilation there are 2 subgroups:

- ICU patients (planned number 55) mechanically ventilated in an intensive care unit via an artificial airway access (endotracheal tube or tracheostomy tube), which are expected to require significant changes in ventilation settings, occur before, during and after changing the ventilation settings with PulmoVista 500. The changes in ventilation settings should be reflected in noticeable changes in ventilation distribution.
- OLV patients (planned number 25) enrolled for surgical interventions requiring ventilation of only one lung (single-lung ventilation) (e.g., intubation using a double-lumen sub- stance or placement of a bronchus blocker).

For the different questions of the study, either the entire collective or the separate subgroups are analyzed.

5.8 INTERIM REPORTS

Interim reports are not planned.

6 SOFTWARE

Programm Dräger EIT Data Analysis Tool 6.1

SAS
SPSS
EDITOR for Windows
EXCEL

7 APPENDIX

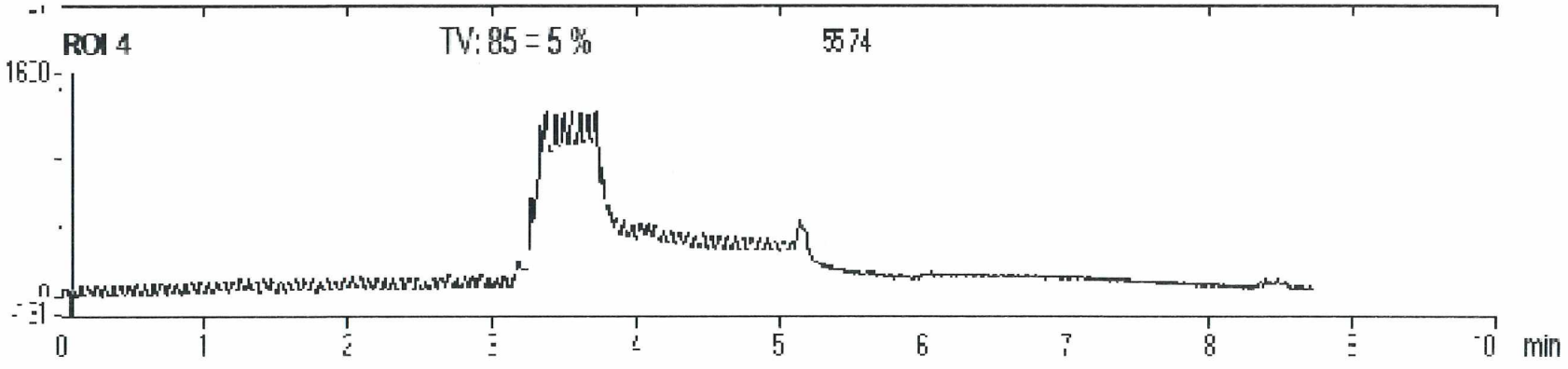
7.1 REFERENCE VALUES OF LABORATORY PARAMETERS

Omitted

7.2 WORKFLOW FOR DETERMINING THE TIME RANGES USED TO CALCULATE THE CROSS CORRELATION BETWEEN THE GLOBAL IMPEDANCE WAVEFORM (PULMOVISTA 500) AND THE VOLUMETRIC WAVEFORM (EVITA V500).

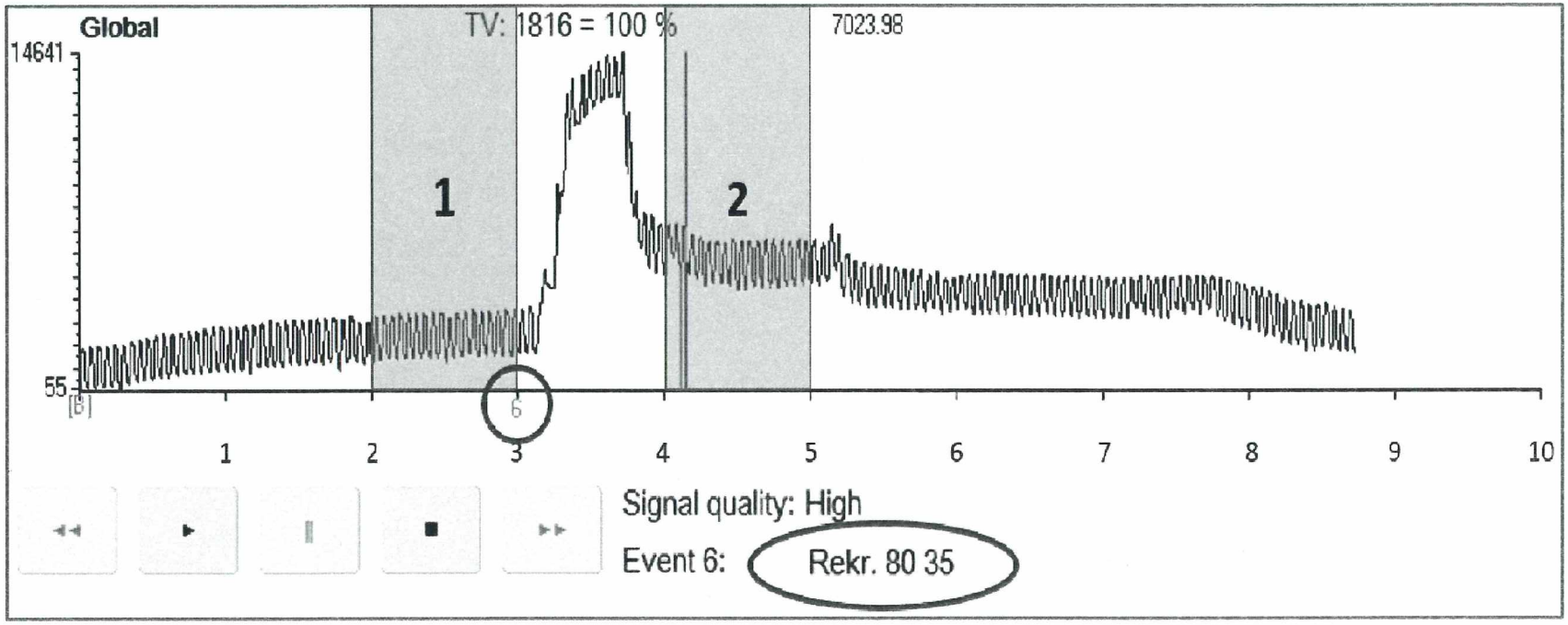
Workflow for determining the time ranges used to calculate the cross correlation between the global impedance waveform (PULMO VISTA 500) and the volume waveform (EVITA V500)

Step	Description
1	Open EIT Data Analysis Tool SW 6.1
2	Use the ***Load*** button to load the first file in the series containing the intervention to be evaluated; the beginning and the type of intervention are marked by an event marker (see example below)
3	Use the button ***Sequence to*** ... to load the last file of the series containing the intervention to be evaluated
4	Record the total length of the loaded files (time scale below ROI 4)



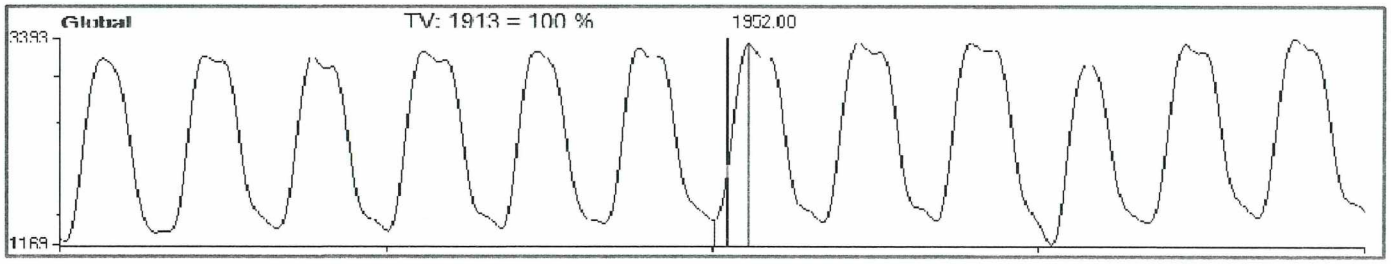
5 Select the files (1 min each) that lie directly before (1) or after (2) the intervention, in which a uniform impedance waveform, and in particular no artifacts, can be seen and in which no parts of the intervention itself are contained.

Example: series of 10 files per 1 min, in which the interventions took place between min 3 and 4.



6 Place cursor in the area of file 1 (exact position does not matter, in this example within the third minute)

7 Use the buttons ***Display ..., Time scale*** to set the time scale to 60 sec

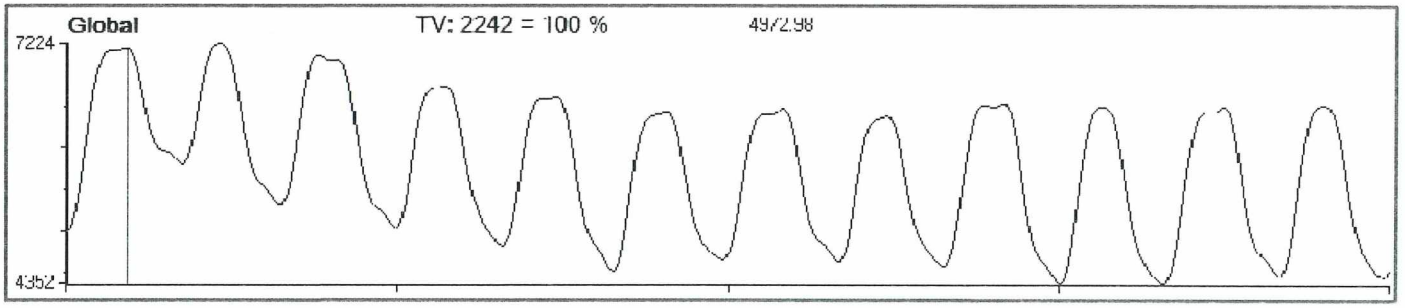


8 Use the button ***File ..., save as ASC*** to convert the selected file 1 as ASCII file
(the created ASC file is saved in the same directory with the same file name as the selected EIT file, and a two-digit, incremental counter is added to the file name)

9 Use the Buttons ***Display ..., Time scale*** to increase the time scale so that the recorded total length is displayed again.

10 Place cursor in the area of file 2 (exact position does not matter, in this example within the 5th minute)

11 Use the buttons ***Display ..., Time scale*** to set the time scale to 60 sec



12 Use the button ***File ..., Save as ASC*** to convert the selected file 2 as ASCII file

13 Now open the two generated ASC files with the statistical evaluation software

14 In the area below the line (Image; Time; Global; ....), Determine the cross-correlation between column C (Global) and column N (~ Volume [ml]).

	A	B	C	D	E	F	G	H	I	J	K	L	M	N	
97															
98	Image	Time	Global	Local 1 (X:16	Local 2 (X:16	Local 3 (X:16	Local 4 (X:15	MinMax	Event	EventText	Timing Error	~Paw [mbar]	~Flow [L/mi	~Volume [m	~CO
99	7201	0,51702906	3502,14771	285,251526	1413,7627	1647,13147	155,002075	0	6		0	15,2	-9,4	53	-
100	7202	0,51702964	3483,25464	283,758667	1407,53735	1639,75952	157,139203	0	6		0	15,2	-9,1	44	-
101	7203	0,51703022	3479,07935	282,592102	1403,01392	1634,83862	153,634644	0	6		0	15,2	-8,8	38	-
102	7204	0,5170308	3475,05151	281,994568	1401,00293	1632,85327	160,230729	-1	6		0	15,2	-8,5	29	-
103	7205	0,51703138	3480,70776	282,248383	1402,36475	1634,34448	161,750122	0	6		0	15,2	-8	22	-
104	7206	0,51703196	3496,59839	283,65271	1407,93933	1639,83844	163,108002	0	6		0	15,2	-7,8	14	-
105	7207	0,51703253	3519,15405	286,490509	1418,46863	1650,09717	164,097702	0	6		0	15,3	-7,7	9	-
106	7208	0,51703311	3555,48242	290,984161	1434,5	1665,42517	154,57312	0	6		0	15,3	-8	3	-
107	7209	0,51703369	3604,16602	297,246277	1456,28699	1686,13213	164,450729	0	6		0	15,2	-7,5	0	-
108	7210	0,51703427	3655,1272	305,242462	1483,71704	1712,43787	163,729797	0	6		0	15,2	-6,8	0	-
109	7211	0,51703485	3737,58008	314,782196	1516,28919	1744,01856	162,490189	0	6		0	15,1	-6,3	0	-
110	7212	0,51703543	3820,07129	325,54129	1553,15466	1780,50732	160,858057	0	6		0	16,4	2,9	0	-
111	7213	0,51703601	3910,58862	337,107178	1593,20581	1821,25232	159,023163	0	6		0	18	26,5	13	-
112	7214	0,51703659	4005,71265	349,030304	1635,18018	1865,39075	157,111557	0	6		0	22,8	49,5	52	-

15 For each ASCII file, the correlation is first calculated individually. Subsequently, the correlations of the individual files are then averaged.

7.3 WORKFLOW FOR THE CREATION OF OLV VIDEOS

This workflow describes the creation of the video sequences which are used to assess the capability of PULMO VISTA 500 to monitor regional changes during mechanical ventilation within the OLV-subgroup.

Software:

- Dräger EIT Simulation Tool
- Camtasia Recorder 8
- Camtasia Studio 8

Workflow:

1. Identify the acquisition dates and the patient/site IDs of all OLV patients
2. Identify relevant markers which are set prior and post the induction of one lung ventilation
    a. document time-stamp of each marker
3. Load EIT-data into *Dräger EIT Simulation Tool*
    a. Select the "Folder" which is contains the acquisition date
    b. Select the "Subfolder" which contains the relevant patient ID (xx_yyy)
    c. Select the start-"File" which includes the relating "PRE-Marker"
    d. Select the "Sequence to file" which includes the relating "POST-Marker"
4. *Start Camtasia Recorder 8*
5. Adjust the recording window according to the size of the "Main"-view
6. Start the simulation within *Dräger EIT Simulation Tool*
7. Start the recording
8. After the simulation has completed one entire loop of simulation, stop the recording
9. Save the recorded video file (use site and patient ID, as well as date of recording) for the definition of the file name
10. Load recorded video file into *Camtasia Studio 8*
11. Crop video sequence according to the previously identified time-stamps of the pre and post markers (the video sequence now contains only the EIT information between the two markers)
12. Process the final video sequence as MP4-file
13. Save the MP4-file containing the respective site and patient ID as well as the date of video processing.

7.4 PLANNED TABLES (EXEMPLARY)

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7.5 PLANNED DATA LISTS (EXEMPLARY)

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7.6 PLANNED FIGURES (EXEMPLARY)

nn

7.7 EVALUATION ROUTINES

Example of the calculation of the cross correlation coefficients: (in the example the maximum cross-correlation coefficient is CCF=0.984 by a lag-shift of 8)

```
GET DATA
  /TYPE=XLSX
  /FILE='U:\Verz_Studien\PULMOVISTA\XXX\XXX_prae.xlsx'
  /SHEET=name 'Tabelle1'
  /CELLRANGE=FULL
  /READNAMES=ON
  /DATATYPEMIN PERCENTAGE=95.0
  /HIDDEN IGNORE=YES.
EXECUTE.
DATASET NAME DataSet1 WINDOW=FRONT.

SAVE TRANSLATE OUTFILE='U:\Verz_Studien\PULMOVISTA\XXX\XXX_prae.xlsx'
  /TYPE=XLS
  /VERSION=12
  /MAP
  /FIELDNAMES VALUE=NAMES
  /CELLS=VALUES
  /REPLACE.

Data written to U:\Verz_Studien\PULMOVISTA\ XXX\XXX_prae.xlsx'.
4 variables and 3000 cases written to range: SPSS.
Variable: Image              Type: Number   Width:   5   Dec: 0
Variable: Time               Type: Number   Width:  12   Dec:10
Variable: Global             Type: Number   Width:  18   Dec:13
Variable: RTDVol.mL          Type: Number   Width:  19   Dec:15

SAVE OUTFILE='U:\Verz_Studien\PULMOVISTA\XXX\XXX_prae.sav'
  /COMPRESSED.
DATASET ACTIVATE DataSet1.
CCF
  /VARIABLES=Global RTDVol.mL
  /NOLOG  /MXCROSS 15.
```

CCF

[DataSet1] U:\Verz_Studien\PULMOVISTA\XXX\XXX_prae.sav

Model Description

Model Name		MOD_1
Series Name	1	Global
	2	RTDVol.mL RTD: Vol. [mL]
Transformation		None
Non-Seasonal Differencing		0
Seasonal Differencing		0
Length of Seasonal Period		No periodicity
Range of Lags	From	-15
	To	15
Display and Plot		All lags

Applying the model specifications from MOD_1

Case Processing Summary

Series Length		3000
Number of Excluded Cases	User-Missing Value	0
Due to	System-Missing Value	0
Number of Valid Cases		3000
Number of Computable Zero-Order Correlations After Differencing		3000

Global with RTDVol.mL RTD: Vol. [mL]

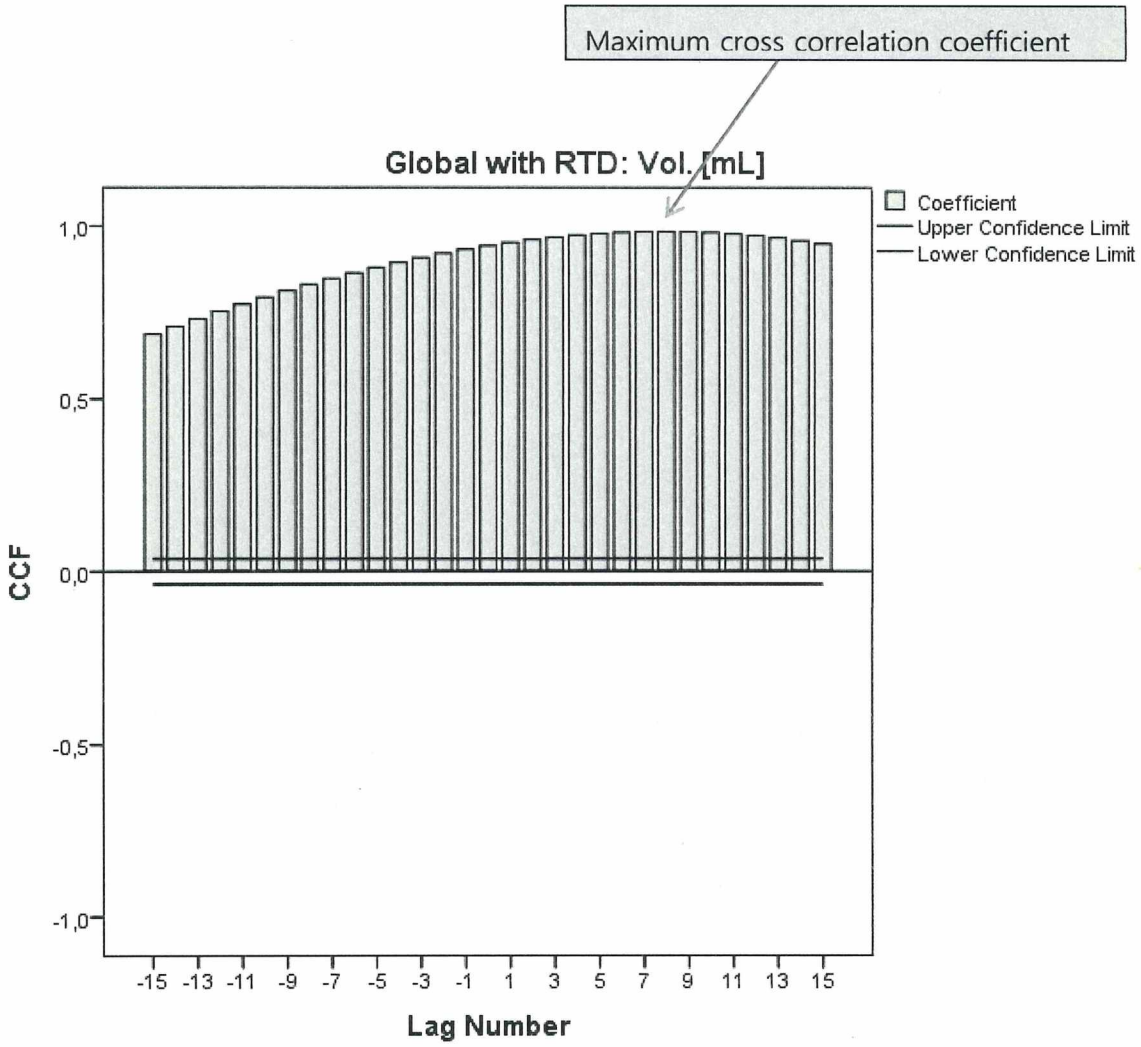
Cross Correlations

Series Pair: Global with RTDVol.mL

RTD: Vol. [mL]

Lag	Cross Correlation	Std. Error[a]
-15	,687	,018
-14	,710	,018
-13	,732	,018
-12	,754	,018
-11	,774	,018
-10	,794	,018
-9	,813	,018
-8	,831	,018
-7	,848	,018
-6	,865	,018
-5	,880	,018
-4	,895	,018
-3	,909	,018
-2	,921	,018
-1	,933	,018
0	,943	,018
1	,953	,018
2	,961	,018
3	,968	,018
4	,974	,018
5	,978	,018
6	,981	,018
7	,983	,018
8	,984	,018
9	,983	,018
10	,981	,018
11	,977	,018
12	,972	,018
13	,966	,018
14	,958	,018
15	,949	,018

a. Based on the assumption that the series are not cross correlated and that one of the series is white noise.


Maximum cross correlation coefficient
Global with RTD: Vol. [mL]
Coefficient
Upper Confidence Limit
Lower Confidence Limit
CCF
1,0
0,5
0,0
-0,5
-1,0
-15 -13 -11 -9 -7 -5 -3 -1 1 3 5 7 9 11 13 15
Lag Number