ISO Standards based Ventilator Terminology

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Chair, ISO TC 121, SC4 Vocabulary and Semantics

Current State

ISO TC 121 SC4

- Anesthesia and Respiratory Care—Terminology and Semantics
- Requested by ISO TC121/IEC62D JWG Critical care ventilators to devise a terminology for all ventilators in January 2009
- Chair: Steven Dain MD
- Secretary: Ken Ledez MD
- Project Manager: Norman Jones PhD

Process

- Scientific and medical literature review
- Collection and review of current ventilator manuals (over 30) and marketing material
- Review of MAUDE reports
- Informal discussions and surveys with Anesthesiologists, Intensive Care Physicians, Respiratory Therapists, RT Educators, Manufacturer’s R&D and marketing

Conclusions

- It’s a mess
- Need to establish the conceptual framework that underlies advanced artificial ventilation
- Need to test currently used terminology against that framework
- Need to cooperate with other SDO’s to have all related standards using consistent terms

Objectives

- Need to start from first principles and create a patient-focused terminology with the patient seen as an independent active system
- Need to clearly delineate between:
  - settings (intent) → what you want the ventilator to do and how you want it to respond to the patient
  - observations of what really happened to the patient and ventilator system of systems (maybe non-deterministic based on settings)

Any material presented after this point is subject to change

ISO 19223 Lung ventilators and related equipment—Vocabulary and semantics

Scope

This International Standard specifies vocabulary and semantics for all fields of respiratory care such as Intensive care ventilation, anaesthesia ventilation, and home care ventilation including sleep apnoea breathing therapy equipment, emergency and transport ventilation, that may be used:

- in lung ventilator and breathing therapy device standards
- in health informatics standards
- for labelling on me equipment and me systems
- in me equipment and me systems instructions for use and accompanying documents
- for me equipment and me systems interoperability
- in electronic health records

Ventilators do not breathe

Colin J Morley,[1,2] Martin Keszler[3]

"We needed to find words to describe clearly the detailed interaction of a baby with the ventilator" We then realized the serious problems with the terminology used for ventilation and resuscitation. If we wrote about *breaths*, it was not clear to the reader whether this referred to the baby breathing or inflations by the ventilator…"

Arch Dis Child Fetal Neonatal Ed 2012;0:F1–F3. doi:10.1136/archdischild-2012-302137

Inflation

<setting> application of a ventilator-generated elevated pressure to the patient-connection port, with the intention of causing an increased volume of gas in the lung

Spontaneous Breath

- This term has been the most contentious issue in development of ISO 19223
- Consensus definition after much discussion

Spontaneous Breath

breath initiated by the patient

*This has ramifications when calculating rate

Spontaneous Breath Rate

- Number of spontaneous breaths per minute.
- Measure of the respiratory drive of the patient, which cannot be currently determined with the current terminology

Mandatory Inflation

Dictionary definition

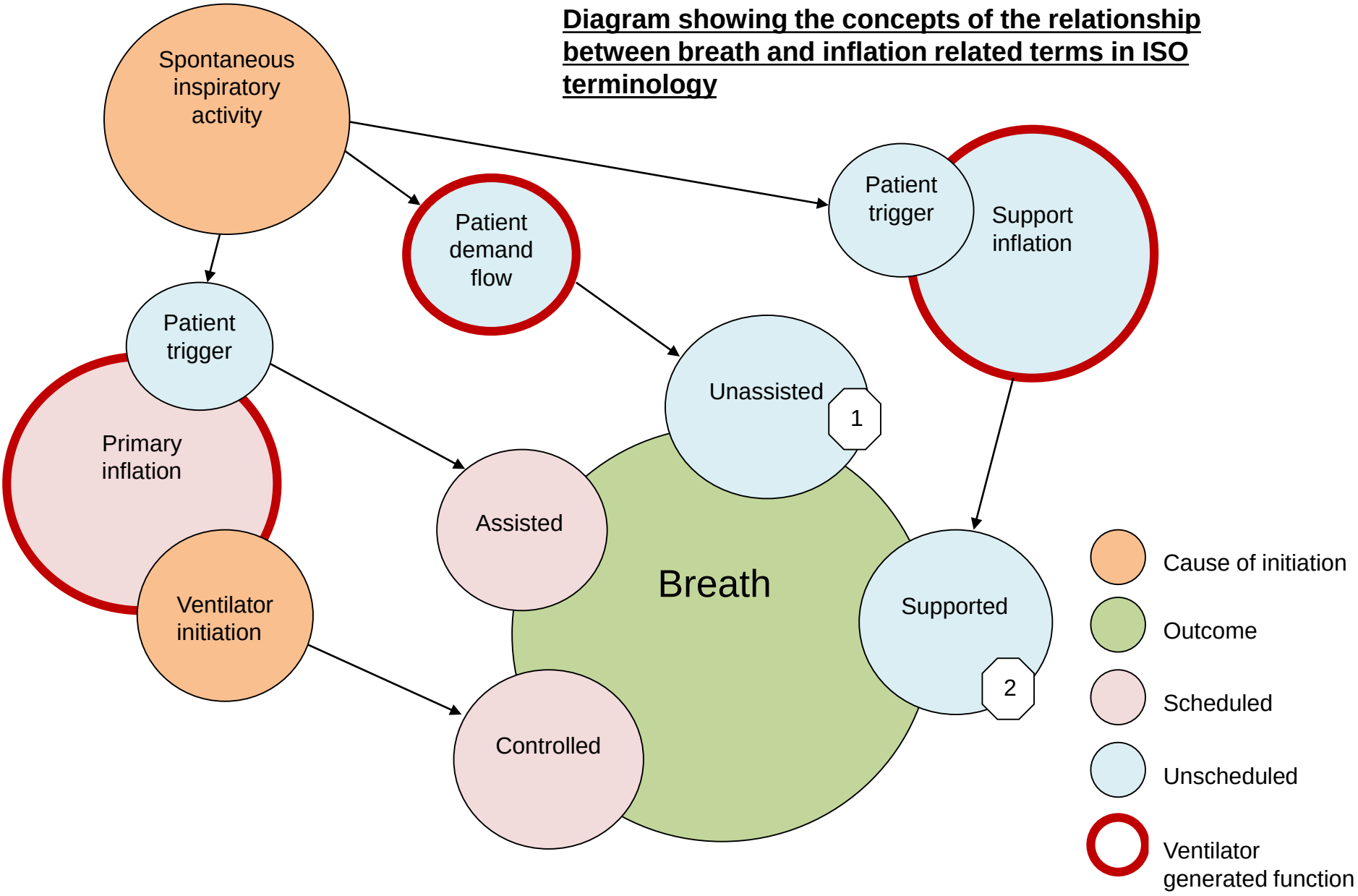
mandatory

required to occur

Mandatory inflation

<setting> inflation that is assured to be initiated or instigated at the set rate

Diagram showing the concepts of the relationship between breath and inflation related terms in ISO terminology



1 or 2 can occur as separate breaths concurrently with a primary inflation if this is of the *e*PC type.
1 or 2 can occur as separate breaths concurrently with a primary inflation cycle in Group (ii) modes

Mode Patterns

- Mode pattern 1
  - One inflation type generating a controlled or assisted breath, on a set baseline airway pressure level
- Mode Pattern 2
  - One or more inflation types, primary inflation assured to be delivered at set rate; patient is free to breathe between primary inflations, unassisted or supported by a support inflation, on a set baseline airway pressure level
- Mode Pattern 3
  - Spontaneous breathing with one support inflation-type, or unassisted, on a set baseline airway pressure level

Inflation Types

- Flow control (volume control)
- Pressure control
- Enhanced pressure control
- Volume-targeted pressure control
- Proportional pressure control
- Pressure support
- Proportional pressure support
- Dual control e.g., VC/PC

PEEP CPAP Bilevel

- What is PEEP?
- Is it a measurement?
- Is it a setting?
- Is it both?
- Then what is CPAP?
- What do you call the levels of bilevel?
- I’m very confused……..

Baseline Airway Pressure (BAP)

<setting> setting for the intended minimum pressure in the alveoli during the exhalation phase

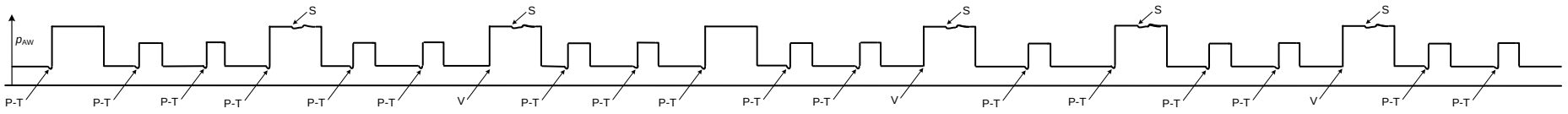
End Exhalation Pressure (EEP)

- <observation> airway pressure at the end of an exhalation phase
- is a measurement only, not a setting
- can be zero
- could be negative

Ventilator Mode

- specified manner in which a ventilator performs its function when connected to a patient
- Includes:
  - mode group pattern
  - inflation types
  - breath types
  - baseline airway pressure
  - extras -- e.g., tube compensation

Representation of a typical SIMV-*e*PC/PS waveform over 1 minute, illustrating respiratory rate terminology



P-T patient-trigger initiation of inflation (following detection of patient initiation of spontaneous breath)
V ventilator initiation of inflation
S patient initiation of unassisted spontaneous breath

Standardised Term	Type of respiratory feature counted	Value
ventilator set rate	(setting)	7
ventilator-initiated inflation rate	Time initiated ePC inflation	3
patient-triggered primary-inflation rate	Patient-triggered ePC inflations	4
unassisted (spontaneous) breath rate	Unassisted spontaneous breaths	5
patient-triggered inflation rate	Patient-triggered ePC+PS inflations	17
patient-triggered support-inflation rate	Patient-triggered PS inflations	13
(total) inflation rate	Sum of all ePC and PS inflations	20
spontaneous breath rate	Spontaneous inspiratory breaths taken by patient	22
patient-triggered concurrent-inflation rate	Patient-triggered concurrent inflations	NA
unassisted concurrent-breath rate	Unassisted concurrent spontaneous breaths	5
total respiratory rate	All respiratory cycles	25
unassisted & supported breath rate	Unassisted breaths + support inflations	18

Ident No.	Mode Class	Basic Generic Mode-Group Name	Illustrative Inflation Types Selected for Mandatory Delivery	Means of Initiation	Means of Termination	Means of Exhalation Control	Spontaneous-support Inflation Type	Corresponding Mode Name	Optional 'bi-level' Superordinate Class Name	Name of Set Value for Inflation Type Selected for Mandatory Delivery	Name of Set baseline level	Name of Primary Inflation Phase	Name & Symbol of Set Primary Inflation Time		Name & Symbol for Set Lower Baseline-airway-pressure Time (if set)	
1	(i)	CMV	VC	t	t	See commen	None	CMV-VC	N/A	Tidal volume	BAP	Inflation phase	Inflation time	t_I	Expiratory time	t_E
2			PC	t	t	"	None	CMV-PC	N/A	Inflation pressure	BAP	Inflation phase	Inflation time	t_I	Expiratory time	t_E
3			vtPC	t	t	"	None	CMV-vtPC	N/A	Tidal volume	BAP	Inflation phase	Inflation time	t_I	Expiratory time	t_E
4			*e*PC	t	t	"	None	CMV-*e*PC	CMV bi-level	Inflation pressure	BAP	Inflation phase	Inflation time	t_I	Expiratory time	t_E
5			vt*e*PC	t	t	"	None	CMV-vt*e*PC	CMV bi-level	Tidal volume	BAP	Inflation phase	Inflation time	t_I	Expiratory time	t_E
6																
7		A/MV aka A/C	VC	t/trig	t	"	None	A/C-VC	N/A	Tidal volume	BAP	Inflation phase	Inflation time	t_I	Expiratory time	t_E
8		aka A/C	PC	t/trig	t	"	None	A/C-PC	N/A	Inflation pressure	BAP	Inflation phase	Inflation time	t_I	Expiratory time	t_E
9		aka A/C	vtPC	t/trig	t	"	None	A/C-vtPC	N/A	Tidal volume	BAP	Inflation phase	Inflation time	t_I	Expiratory time	t_E
10		aka S/T	PC[q/t]	t/trig	q/t	"	None	A/C-*e*PC[q/t]	N/A	Inflation Pressure	BAP	Inflation phase	Inflation time	t_I	Expiratory time	t_E
11		aka A/C	*e*PC	t/trig	t	"	None	A/C-*e*PC	A/C bi-level	Inflation Pressure	BAP	Inflation phase	Inflation time	t_I	Expiratory time	t_E
12		aka A/C	vt*e*PC	t/trig	t	"	None	A/C-vt*e*PC	A/C bi-level	Tidal volume	BAP	Inflation phase	Inflation time	t_I	Expiratory time	t_E
13		aka A/C	*e*PC[S]	t/trig	[S]	"	None	A/C-*e*PC[S]	A/C bi-level	BAP_H (or p_H)	BAP	BAP_H phase(or p_L)	BAP_H (phase)time	t_H	BAP time	t_L
14																
15	(ii)	IMV	VC	t	t	"	PS	IMV-VC/PS	N/A	Tidal volume	BAP	Inflation phase	Inflation time	t_I	Expiratory time	t_E
16			PC	t	t	"	PS	IMV-PC/PS	N/A	Inflation Pressure	BAP	Inflation phase	Inflation time	t_I	Expiratory time	t_E
17			vtPC	t	t	"	PS	IMV-vtPC/PS	N/A	Tidal volume	BAP	Inflation phase	Inflation time	t_I	Expiratory time	t_E
18			*e*PC	t	t	"	PS	IMV-*e*PC/PS	IMV bi-level	Inflation Pressure	BAP	Inflation phase	Inflation time	t_I	Expiratory time	t_E
19			*e*PC	t	t	"	PS	IMV-*e*PC	IMV bi-level aka APRV	BAP_H (or p_H)	BAP	BAP_H phase(or p_L)	BAP_H phase time	t_H	BAP time	t_L
20			vt*e*PC	t	t	"	PS	IMV-vt*e*PC/PS	IMV bi-level	Inflation Pressure	BAP	Inflation phase	Inflation time	t_I	Expiratory time	t_E
21			*e*PC[S]	t	[S]	"	PS	IMV-*e*PC[S]/PS	IMV bi-level	BAP_H (or p_H)	BAP	BAP_H phase(or p_L)	BAP_H (phase)time	t_H	BAP time	t_L
22			*e*PC[S]	t	[S]	"	PS	IMV-*e*PC[S]	IMV bi-level aka APRV	BAP_H (or p_H)	BAP	BAP_H phase(or p_L)	BAP_H (phase)time	t_H	BAP time	t_L
23																
24		SIMV	VC	[S]t	t	"	PS	SIMV-VC/PS	N/A	Tidal volume	BAP	Inflation phase	Inspiratory time	t_I	Expiratory time	t_E
25			PC	[S]t	t	"	PS	SIMV-PC/PS	N/A	Inflation pressure	BAP	Inflation phase	Inspiratory time	t_I	Expiratory time	t_E
26			vtPC	[S]t	t	"	PS	SIMV-vt*e*PC/PS	N/A	Tidal volume	BAP	Inflation phase	Inspiratory time	t_I	Expiratory time	t_E
27			*e*PC	[S]t	t	"	PS	SIMV-*e*PC/PS	SIMV bi-level	Inflation Pressure	BAP	Inflation phase	Inspiratory time	t_I	Expiratory time	t_E
28			vt*e*PC	[S]t	t	"	PS	SIMV-vt*e*PC/PS	SIMV bi-level	Tidal volume	BAP	Inflation phase	Inspiratory time	t_I	Expiratory time	t_E
29			*e*PC[S]	[S]t	[S]	"	PS	SIMV-*e*PC[S]/PS	SIMV bi-level aka Bi-level	BAP_H (or p_H)	BAP	BAP_H phase	BAP_H(phase)time	t_H	BAP time	t_L
30																
31	(iii)	CSV aka SPONT	None	N/A	N/A	"	PS	CSV-PS	N/A	N/A	BAP	N/A	N/A		N/A	
32		aka SPONT	None	N/A	N/A	"	pPS	CSV-PS	N/A	N/A	BAP	N/A	N/A		N/A	
33		aka SPONT	None	N/A	N/A	"	vtPS	CSV-vtPS	N/A	N/A	BAP	N/A	N/A		N/A	
34		aka CPAP	None	N/A	N/A	"	None	CSV	N/A	N/A	BAP	N/A	N/A		N/A	
35																
		Modes on rows of this color all come under the general superordinate classification of 'bi-level' but the name 'Bi-level' is normally only used as the primary classification for mode Ident No 26													NSJ v10 11-Feb-14	

Multi SDO Cooperation

- IEEE 11073 Committee
- ISO TC215 Health Informatics
- IHE (Integrating the Health Enterprise) PCD
- International Healthcare Terminology Standards Development Organization Anesthesia Special Interest Group
  - SNOMED CT
- HL7 Anesthesia Special Interest Group

Summary

- still a work in progress
- concurrently writing a handbook to facilitate the understanding of the standard
- Draft International Standard (DIS) will be out for ballot June 2015 depending on time for translation

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