vyaire™
MEDICAL

ATS/ERS spirometry guidelines 2019
SentrySuite Update

Content

Introduction

Spirometry requires a high degree of patient understanding and cooperation, which makes this type of measurement unique. But also the operator is key to guide and motivate the patient through the spirometry measurement. To improve the quality in conducting spirometry, the most common pulmonary function test, the American Thoracic Society (ATS) and the European Respiratory Society (ERS) have updated the Standardization of Spirometry guideline in October 2019 – for the first time since 2005.

To achieve clinically meaningful, interpretable results, various factors with impact on test quality need to be taken into account during measurement:

- a motivated operator capable to elicit maximum performance from the patient
- a patient capable of performing acceptable and repeatable measurements
- accurate and precise equipment
- correct performance of the manoeuvres with help of visual, textual and audio online tools
- the analysis of the measurement regarding acceptability and repeatability

In the past, the importance of the operator has been neglected, although his or her training in combination with experience is key to observe and engage with the patient in order to achieve optimal results. Also, the spirometry device and its software need to meet the current standard of ISO 26782 to be able to provide assistance.

Therefore, Vyaire has enhanced their SentrySuite spirometry software (Version 3.20 and higher) to the full extent and implemented many features to meet the 2019 spirometry guidelines such as

- ✓ new patient data fields for height calculation (ulna)
- ✓ new calibration and verification limits
- ✓ new online measurement guidance for the End of Forced Exhalation (EOFE)
- ✓ new quality parameters and error codes for acceptability and repeatability criteria
- ✓ differentiation between acceptable, usable and unusable FEV_1 and FVC
- ✓ edit mode for acceptability
- ✓ grading for FEV_1 and FVC
- ✓ new guidance and acceptability/repeatability criteria for the slow spirometry
- ✓ new definitions for Best values
- ✓ new ATS/ERS spirometry reports

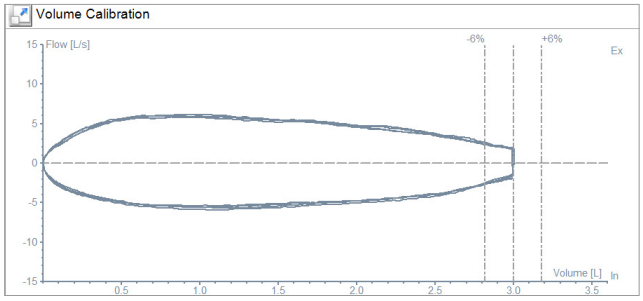
This informative white paper describes how our newest SentrySuite spirometry software helps you achieve the best possible results according to the latest ATS/ERS 2019 Spirometry guidelines.

Equipment, Calibration and Verification

To meet quality standards according to the ATS/ERS 2019 spirometry guidelines, manufacturers need to ensure that their spirometers meet the **ISO 26782 standards** including the C1-C13 wave form testing. Accordingly, our Pneumotach based systems Vyntus SPIRO, Vyntus PNEUMO, Vyntus IOS and ultrasonic sensor (USS) based systems like Vyntus BODY and Vyntus ONE do meet these standards.

New calibration factor tolerance for volume calibration

It is important for the operator to know when it is necessary to clean, maintain or repair the spirometer. Therefore alerts should emerge if the new calibration factor varies by more than 2 standard deviations (SDs) from the mean calibration factor or changes by more than 6% from the previous calibration factor.

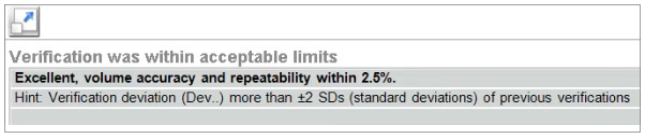


Volume calibration with 6% limit from previous calibration factor

Accordingly, the previously at 10% set marker in SentrySuite's volume calibration program has been lowered to 6%. Additionally, an alert appears, if the standard deviation (SD) for calibration and verification over the last 5 manoeuvres vary by more than ±SDs.

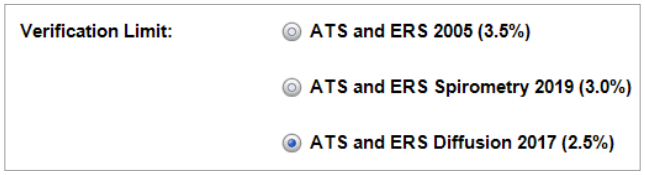
New volume verification accuracy tolerance

In addition to ISO 26782 the new guidelines request a **new volume verification accuracy tolerance of ±3%** with ±2.5% for the spirometer plus ±0.5% for the calibration syringe. The guideline additionally states, that systems capable of performing DLCO measurment should meet an accuracy of 2.5%. A warning should be issued if the verification error differs from the historical mean verification error by more than +/-2 SDs.



Quality message after verification procedure within SentrySuite software

This new volume verification limit is now available to select within the volume verification/calibration program. This default setting can vary by instrument or by geographic region.



New setting in program Volume Calibration for selection of verification accuracy

According to the guidelines the daily volume verification must be undertaken using a calibrated 3 litre syringe cycled at least three times at low, medium and high flow between a range of flows of 0.5 and 12 L/s, (one stroke per flow range).

The new guideline contains no further specifications where weekly flow linearity (verification with three strokes each in three different flows) is concerned.

Forced Spirometry

The most important changes in the field of the forced spirometry according to the ATS/ERS 2019 spirometry guidelines are the following:

New definition for End of Forced Expiration

End-of-Forced-Expiration (EOFE): To stress the importance that each forced spirometry maneuver (in order to be considered complete), include a maximal inspiratory maneuver this guideline does away with the former naming and criteria of EOT/end of test, and it is replaced with EOFE/end of forced expiration.

The EOT criteria from 2005 with reaching a plateau and exhale more than 6 seconds for adults or 3 seconds for children are not relevant anymore.

To adequately achieve this newly defined end point, EOFE, the maneuver must meet **one of three different criteria**:

- **either** reach a plateau (defined as ≤ 25 mL change in volume for at least 1 second at the end of the expiration) – the most reliable indicator of complete expiration
- **or** exhale for more than 15 seconds
- **or** can repeatedly achieve the same FVC (FVC must be larger than or within the repeatability tolerance of the largest FVC observed prior to this manoeuvre in the current testing set). This third criteria is added for patients who cannot expire long enough to achieve a plateau e.g. children with high elastic recoil or patients with restrictive lung disease.

New guidance during forced spirometry

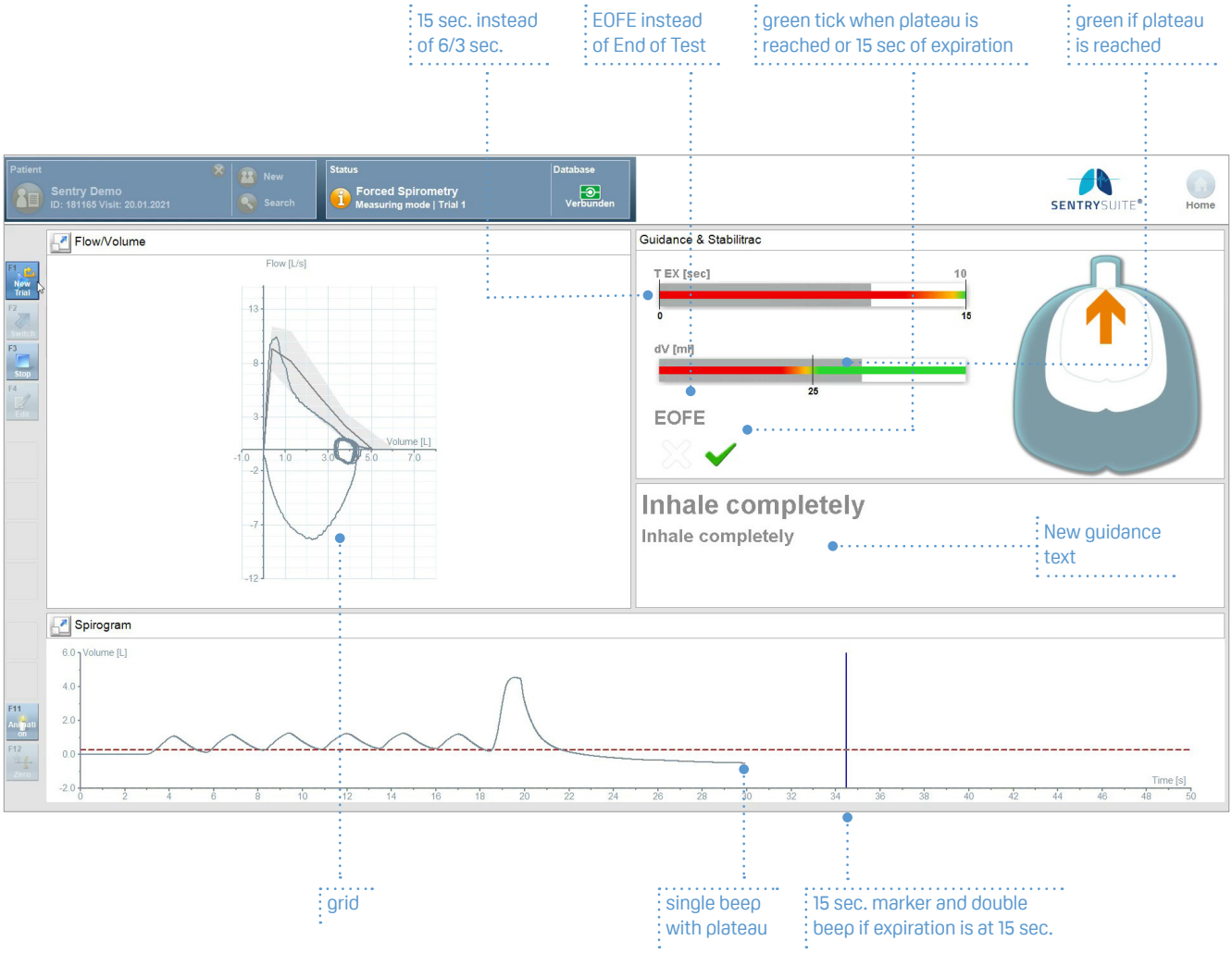
According to the ATS/ERS 2019 spirometry guidelines, **audio and optical alerts** must be provided by the system to signal to the technician when/if the above criteria are reached. Compliant to the guidelines, a **single beep** in SentrySuite signals the operator that the patient has reached a plateau during the forced exhalation, whereas a **double beep** can be heard when the patient has achieved an exhalation time of 15 seconds.

These acoustic signals are accompanied by visual signals:

- a green tick appears on the display when patients have reached a plateau or exhaled for more than 15 seconds.
- a bar graph for the plateau recognition
- a 15 seconds marker within the spirogram and the 15 seconds bar graph

NOTE: According to ATS/ERS guidelines the criteria of a plateau is defined as a change in volume ≤ 25 mL within the last second of expiration. **Only the last second of expiration is relevant.** The green tick for a plateau and the single beep within the SentrySuite software indicate a plateau has been reached for **the first time** during the forced expiration. That means, it is possible to see a green tick and to hear a single beep but with followed inspiration a plateau was not reached because the plateau was ultimately not within the last second of expiration.

The parameter EOTV (End of Test Volume) shows the change in volume within the last second of expiration.



Forced Spirometry during the measurement within SentrySuite software

New acceptability/usability criteria

In the new ATS/ERS 2019 spirometry guidelines, a distinction is made between **acceptable and usable** measurements. Since not all patients may be able to meet the criteria for a technically acceptable FEV_1 and/or FVC during the manoeuvres of forced spirometry, the obtained values may still be clinically usable. Furthermore, the new guidelines uses different criteria for FEV_1 and FVC. For example: the FVC MUST meet 1 of 3 of the EOFE criteria to be acceptable, but does not need to meet 1 of 3 EOFE conditions to be usable. While FEV_1 does not require any of the EOFE criteria to be considered acceptable or usable.

If the patient should cough during the first second of expiration, this renders the FEV_1 of the trial as unacceptable and unusable, while the FVC on the other hand may be acceptable. Other causes for an unacceptable FVC may include glottis closure or early termination, such as inspiration or coming off the mouthpiece. If this occurs in the first second, the obtained values for FEV_1 are unacceptable as well as unusable.

Acceptability and Usability Criterion	Accep-tability	Usability	Accep-tability	Usability
	FEV_1	FEV_1	FVC	FVC
Must have BEV ≤ 5% of FVC or **100 mL**, whichever is greater	Yes	Yes	Yes	Yes
Must have no evidence of a faulty zero-flow setting**	Yes	Yes	Yes	Yes
Must have no cough in the first second of expiration*	Yes	Yes	No	No
Must have no glottic closure in the first second of expiration*	Yes	Yes	Yes	Yes
Must have no glottic closure after 1 s of expiration	No	No	Yes	No
Must achieve **one of three EOFE** indicators	No	No	Yes	No
Must have no evidence of obstructed mouthpiece/spirometer**	Yes	No	Yes	No
Must have no evidence of a leak**	Yes	No	Yes	No
VCIN – FVC must be ≤ 100 mL or 5% of FVC, whichever is greater	Yes	No	Yes	No

* For children aged 6 years or younger, must have at least 0.75 seconds of expiration without glottic closure or cough for acceptable or usable measurement of $FEV_{0.75}$.
** Can only be recognized by the operator and not by the SentrySuite software.

More changes to the criteria compared to the guidelines from 2005 concern the following:

- **Back-extrapolated volume (BEV):** The BEV is defined as the volume of gas that has already been expired from maximal lung volume to time 0, which stands at the beginning of each timed manoeuvre, and is included in the FEV_1 and FVC measurements. To ensure that the FEV_1 comes from a maximal effort, in the new ATS/ERS 2019 spirometry guidelines the BEV must be ≤ 5% of the FVC or 100 mL, whichever is greater. The 100-mL tolerance is a reduction from the 150-mL tolerance in the 2005 standards.
- **T PEF/T PEF 10-90% (in the guidelines referred to as rise time):** The T PEF provides insight to determine and characterize the speed or quickness at which maximal PEF is reached. PEF should be performed as close to time zero (moment of maximal inflation) as possible, and should occur with a sharp rise where very little time elapses between 10% to 90% of reaching top speed, also known as PEF. Measured in milliseconds (ms) it should be ≤ 150 ms. Where the T PEF measurement is > 150 ms, this is due to a sluggish start to expiration. While the flow-volume curve may still show a peak, it occurs later in expiration which can produce an erroneous FEV_1 value. However, it should be mentioned, patients with upper airway mechanical obstruction, can cause the T PEF to be in excess of 150 ms. Overlaying the series of Flow/Volume-Loop maneuvers can help determine if the high T PEF is due to effort or physiologic mechanical obstruction.
- **Difference FIVC (VCIN_F) to FVC:** The new ATS/ERS 2019 spirometry guidelines stress the importance of a maximal inspiration (measurement of Forced Inspiratory Volume Capacity (FIVC)) following the forced expiration. If the FIVC is greater than FVC, then the patient did not start the manoeuvre from TLC. That means if FIVC – FVC is > 100 mL or 5% of FVC, whichever is greater, than FVC and FEV_1 are not acceptable.

- **Repeatability criteria:** For subjects six years or younger only those manoeuvres where the difference between the two largest FEV_1 values and the two largest FVC values are ≤ 100 mL or 10% of the highest value, whichever is greater, are considered repeatable.

For subjects older than 6 years of age only those manoeuvres where the difference between the two largest FEV_1 values and the two largest FVC values are ≤ 150 mL are considered repeatable.

This is a change from the 2005 guidelines where there was no distinction with regard to age for repeatability, but rather only for an FVC value ≤ 1 litre.

Vyntus ONE with ultrasonic flow sensor technology to perform slow and forced spirometry, SB diffusion, N2-washout lung volumes, CPET and many more.

The software SentrySuite evaluates each trial, which makes it very easy for the operator to recognize if the FEV_1 and separately the FVC is unusable, usable or acceptable. SentrySuite offers two new quality parameters for the within-manoeuvres evaluation using ✓✓, ✓ and **x**:

Parameter short/ long name	Unusable	Usable	Acceptable
Q FEV_1 A19/Quality FEV_1 ATS 2019	x	✓	✓✓
Q FVC A19/Quality FVC ATS 2019	x	✓	✓✓

	%Chg...	Pred	Pred LL	Best	%(Best/Pred)	Tr 1	Tr 2	Tr 3	Tr 4	Tr 5
Q FVC A19				✓✓		✓✓	✓✓	✓✓	✓✓	
Q FEV1 A19				✓✓		✓✓	✓✓	x	✓✓	

New quality parameters for acceptability recognition within the SentrySuite software

The new guidelines stress the importance of the operator's ability to override the acceptability designation, since the operator may note for example a leak, a faulty zero-flow or an inadequate inspiration or expiration not detected by the software.

For this purpose, it is possible within SentrySuite to change the status of the two quality parameters for each trial within the Edit Mode. A little pen next to ✓✓, ✓ or **x** indicates manual change.

Edit mode tabular data

	%Chg...	Pred	Pred LL	Best	%(Best/Pred)	Tr	Tr	Tr	Tr
Best Ex/In									
Q FVC A19									
Q FEV1 A19									
FVC L	0	5.08	4.08	5.63	111	5.59	5.60	4.37	5.63

SentrySuite Edit Mode for forced spirometry with the possibilities to hide/unhide trials (in and ex separated), to select best curve (in and ex separated) and to edit the acceptability criteria for FVC and FEV_1.

Spirometry testing with Vyntus ONE

In addition to the quality parameters FET (forced expiratory time), VBEex (Back-extrapolated volume) and EOTV (End-of-test volume), two new quality parameters have been introduced:

- **T PEF (Time to Peak Expiratory Flow),** which describes the rise time from 10% to 90% of peak flow. (Long parameter name = T PEF 10-90)
- **VCIN-FVC**, which describes the difference between the forced inspiratory volume (VCIN_F) and FVC.

Review Mode tabular data

		%Chg...	Pred	Pred LL	Best	%(Best/Pred)	Tr 1	Tr 2	Tr 3	Tr 4	Tr 5	Tr 6	Tr 7	Tr 8	Tr 9	Tr 10	Z-Score
VC MAX	L	0	5.31	4.38	5.25	99	5.05	5.09	3.16	5.25							-0.10
FVC	L	0	5.08	4.08	5.25	103	5.05	5.09	4.89	5.25							0.27
FEV1	L	0	4.03	3.19	3.76	93	3.60	3.70	3.78	3.76							-0.52
FEV1%F	%	0	77.49	65.70	71.67	92	71.26	72.68	77.25	71.67							-0.81
PEF	L/s	0	9.37	7.38	10.49	112	10.11	10.20	9.55	10.49							0.92
MFEF	L/s	0	4.03	2.31	2.60	65	2.43	2.60	3.19	2.59							-1.37
FEF25	L/s	0	8.23	5.42	7.13	87	6.21	7.13	7.44	6.69							-0.65
FEF50	L/s	0	5.10	2.93	3.24	64	3.13	3.24	3.83	3.22							-1.41
FEF75	L/s	0	2.16	0.88	0.91	42	0.88	0.91	1.21	0.93							-1.61
VCIN_F	L	0	5.08	4.08	4.86	96	4.86	4.66	3.16	4.68							-0.38
PIF	L/s	0			7.58		7.42	6.64	7.04	7.58							
FIF50	L/s	0			7.26		7.26	6.48	6.99	7.51							
Quality																	
Grade FVC A19					C												
Grade FEV1 A19					A												
Q FVC A19					✔✔		✔✔	✔✔	✔✔	✔✔							
Q FEV1 A19					✔✔		✔✔	✔✔	✘	✔✔							
FET	sec	0			12.57		15.21	11.11	5.45	12.57							
T PEF	sec	0			0.06		0.04	0.06	0.09	0.05							
VBEex	L	0			0.16		0.08	0.16	0.21	0.10							
VBe%FV	%	0			2.99		1.57	3.08	4.26	1.86							
EOTV	L	0			0.024		0.015	0.024	0.092	0.020							
VCIN-FVC	L	0			«-0.39		«-0.20	«-0.43	«-1.74	«-0.57							
E A19 F		0			4		6	6	106	2							

New long parameter table for measurement program Forced Spirometry extended with columns “Pred LL” (Predicted Lower Limit of Normal) and Z-Score value plus a complete set of quality parameters.

Quality | Auto Interpretation | Interpretation/Comments

Type of quality check-ATS and ERS 2019

Quality of trial	Tr 1	Tr 2	Tr 3	Tr 4	Tr 5	Tr 6	Tr 7	Tr 8	Tr 9	Tr 10
Volume of back-extrapolation too large.			●							
No EOFE criteria found.			●							
Difference VC IN-FVC too large			●							

Tab “Quality” with detailed information for each trial referring acceptability and repeatablity according ATS/ERS 2019 guidelines.

- Compliant to the new ATS/ERS 2019 spirometry guidelines, an error code „E A19 F“ (Error FV ATS 2019), has been introduced. A more detailed description can be found within the Spirometry Online Manual of the SentrySuite software. Similarly, new detailed quality and reproducability notifications are displayed in the tab “Quality”.

New Grading for FEV_1 and FVC

During the course of spirometry updates for 2019, a new grading system was developed for assessing the degree of repeatability of technically acceptable maneuvers using letter grades A through F. While this new grading schema closely follows the grading developed by Hankinson and colleagues it has been expanded to include children below 6 years of age. The grading applies to the set of maneuvers (pre or post bronchodilator) rather than individual maneuvers and is applied independently to the FVC portion of the maneuver, as well as the FEV_1 portion of the maneuver. In contrast to the 2005 guidelines where intersession repeatability requirement was based on the measured FVC volume, this was removed for the 2019 guideline, instead repeatability requirement is replaced with a distinction between subjects greater than 6 years of age, and those subjects less than 6 years of age.

If only usable efforts for FVC and/or FEV_1 are obtained, the new grading schema designates those maneuvers as grade “U”. The grade “U” denotes

that while the effort for FVC and/or FEV_1 were not acceptable, at least 1 trial was "usable" and therefore standards of repeatability are not applicable. Keep in mind, grading, similar to acceptability and usability criteria, is applied independently to FVC and FEV_1, thus it is possible to have a grade "U" for FEV_1, and a grade "B" for FVC.

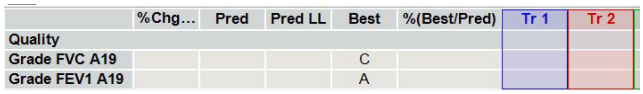
The new grading system offers the reviewer of data insight into the quality of the test session as well as confidence in interpretation of the results.

It's recognized that not all patients may be able to perform the manoeuvres and meet the criteria needed for grade A, but still be able to produce clinically usable results. This may apply, when the spirometry manoeuvres trigger the cough reflex, which can make it impossible for the patient to perform an acceptable manoeuvre. In cases graded with less than an A, the operator's skilled clinical judgment becomes a more important factor in evaluating the obtained measurement.

Grading within SentrySuite

The new gradings of the ATS/ERS 2019 spirometry guidelines have been implemented in SentrySuite accordingly. In SentrySuite 3.20, the grading for FVC and FEV_1 is visible as a bar graph within the SentrySuite Result Screen as well as the assigned letter grade found in the Best Column of the parameter table.

Grading bar graph within SentrySuite software



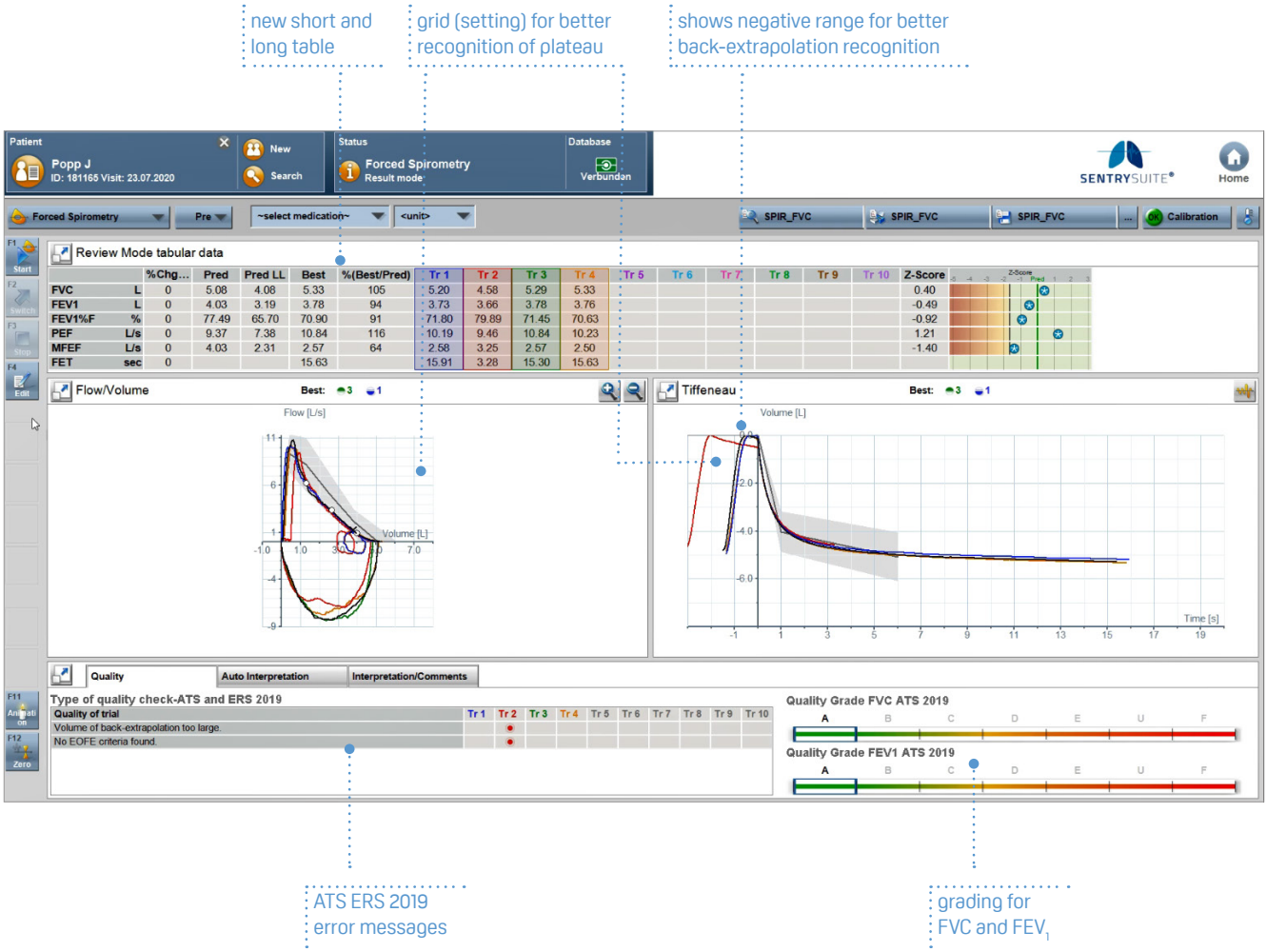
	%Chg...	Pred	Pred LL	Best	%(Best/Pred)	Tr 1	Tr 2
Quality							
Grade FVC A19				C			
Grade FEV1 A19				A			

Grading parameter for the Best column within SentrySuite software

Grading system for FEV_1 and FVC

Grades	Number of Measurements	Repeatability: Age > 6 yr	Repeatability: Age ≤ 6 yr
A	≥ 3 acceptable	Within 150 mL	Within 100 mL**
B	2 acceptable	Within 150 mL	Within 100 mL**
C	≥ 2 acceptable	Within 200 mL	Within 150 mL**
D	≥ 2 acceptable	Within 250 mL	Within 200 mL**
E	≥ 2 acceptable OR 1 acceptable	> 250 mL N/A	> 200 mL** N/A
U	0 acceptable and ≥ 1 usable	N/A	N/A
F	0 acceptable and 0 usable	N/A	N/A

** Or 10% of the highest value, whichever is greater



New SentrySuite result screen for forced spirometry according ATS/ERS 2019 spirometry guidelines

Calculation of the the BEST values

The best values of the various parameters are visible in the BEST column within the SentrySuite software according to the ATS/ERS 2019 spirometry guidelines. Values reported in the BEST column for FVC and FEV_1 are the largest values obtained from all acceptable trials. For this reason, it is not necessary that the best FVC and best FEV_1 come from the same trial. The reported best ratio of FEV_1/FVC in some cases is a composite of the values from 2 different trials. In cases where there are no acceptable efforts, the software searches remaining efforts and selects the largest FVC and FEV_1 values from usable efforts. As mentioned prior, the technician has the ability to over-ride software selection of BEST by simply using the Edit function (F4 icon) and manually selecting best loops as well as best data.

The PEF is another parameter to appear in the BEST column. Here the largest PEF of all accepted FEV_1 trials must be shown in the BEST column.

All other measured parameters are used from the trials with the largest sum of FEV_1 and FVC.

Definition of the BEST column

FEV_1	The largest FEV_1 from all trials with accepted FEV_1. Important note: In program spirometry the setting „Mix F/V parameters acc. to ATS“ needs to be checked.
FVC	The largest FVC from all trials with accepted FVC. Important note: In program spirometry the setting „Mix F/V parameters acc. to ATS“ needs to be checked.
FEV_1/FVC	Ratio of the best FEV_1 and the best FVC. Note: Best FVC and best FEV_1 may not necessarily come from the same trial.
VCIN_F	Largest inspiratory volume from all of the trials.
VCmax	Highest VC from all trials from slow and/or forced spirometry with accepted FVC (forced spirometry) and/or accepted VC (slow spirometry).
PEF	The largest PEF of all accepted FEV_1 trials. Important note: In program spirometry the setting „Mix PEF parameters acc. to ATS“ should be checked according ATS and ERS 2019 guidelines, otherwise the highest PEF/PIF of all trials would be used.
FET	The FET from the trial with the largest accepted FVC.
All other	All other measured parameters are used from the trial with the largest sum of FEV_1 and FVC. Important note: In program spirometry the setting „Best exhalation“ should be set to „FEV_1 + FVC“ and is normaly the standard.

New Reports

Already in alignment with the ATS/ERS Reporting Guidelines 2017, the SentrySuite Software offers two new spirometry reports incl. informative Z-Score graphic, curve graphics with „grid“ and grading.

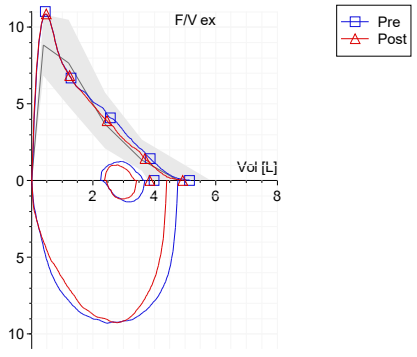
One for a single measurement (report name: SPIR_FVC_ATS2019) and one for a Pre/Post measurement (report name: SPIR_FVC_PREPOST_ATS2019).

Performing forced spirometry with Vyntus SPIRO

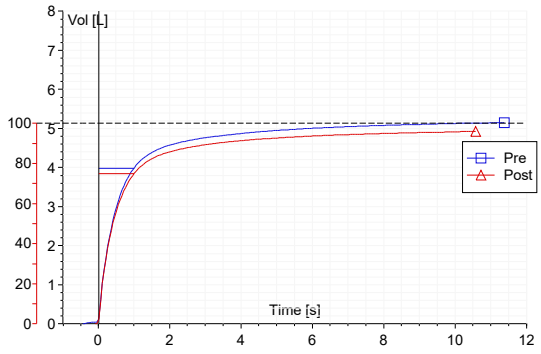
Vyaire Medical GmbH
D-97204 Hoechberg, Leibnizstrasse 7
Phone: +49 (931) 4972-0, Fax: +49 (931) 4972-423

Last Name:	TEST	Identification:	PFT123
First Name:	PFT	Age:	45 Years
		Height:	173 cm
Date of Birth:	01/01/1975	Weight:	83.9 kg
Gender:	male	BMI:	28 kg/m²
Smoking status:		Visit Date:	12.02.2020 17:52
Reason:			

Spirometry Flow-Volume



Flow-Volume Pre-Post

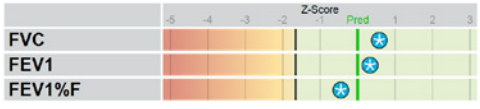


Pre - Post

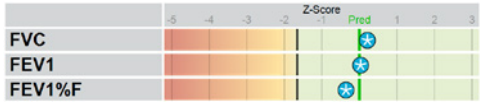
		Pre	Pred LL	Z-Score	%Pred	Post	Z-Score	%Pred	%Chng
FVC	L	5.14	3.77	0.58	107	4.91	0.21	103	-4
FEV1	L	3.98	3.01	0.33	104	3.84	0.03	100	-4
FEV1%F	%	77.49	69.59	-0.45		78.10	-0.35		1
VCIN_F	L	4.79	3.77	0.01	100	4.53	-0.42	95	-5
PEF	L/s	11.00	6.83	1.80	125	10.85	1.68	123	-1
MFEF	L/s	3.40	2.06	-0.24	93	3.30	-0.33	90	-3
FET	sec	11.39				10.57			
E A19 F		0				0			

Pre Bronchodilator

Post-Bronchodilator



Quality Grade FVC ATS 2019	A
Quality Grade FEV1 ATS 2019	A



Quality Grade FVC ATS 2019	A
Quality Grade FEV1 ATS 2019	A

Pred. Module: Stand DE#GLI

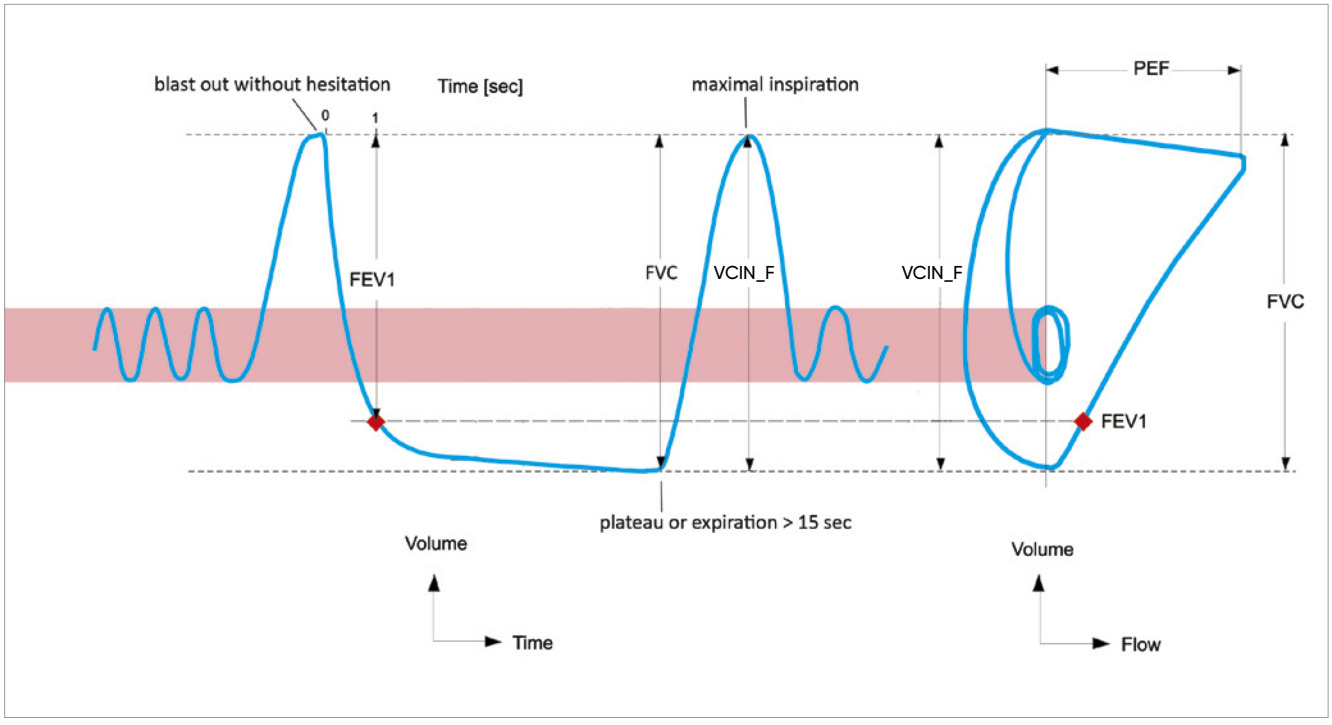
Comment

New report “SPIR_FVC_PREPOST_ATS2019”

2019 ATS/ERS Forced Spirometry workflow

In Summary – How to obtain high quality forced spirometry testing

- ✓ 1. Perform daily volume calibration (where appropriate) and verification using 3-Liter syringe
- ✓ 2. Check that patient uses nose clip and mouth is sealed around mouthpiece
- ✓ 3. Perform maximal inhalation and without hesitation a
- ✓ 4. "blast" of expiration till plateau or 15 seconds FET is reached
- ✓ 5. Perform maximal inhalation
- ✓ 6. Repeat this test at least three times or more until 3 acceptable and repeatable FEV_1 and FVC are reached. Striving for Grade A repeatability is key.
- ✓ 7. Add operator comments to the test



Spirogram and flow/volume-curve for the forced spirometry manoeuvre

Slow Spirometry

In the course of the updates to the ATS/ERS 2019 spirometry guidelines there also have been changes made concerning the slow spirometry:

New acceptability criteria for the slow spirometry

Compared to the forced spirometry, there is no differentiation between the obtained values other than "acceptable" or "unusable". The acceptability criteria depend on whether an ERV manoeuvre or an IC manoeuvre is performed.

The following criteria need to be met for acceptability according to the ATS/ERS 2019 spirometry guidelines:

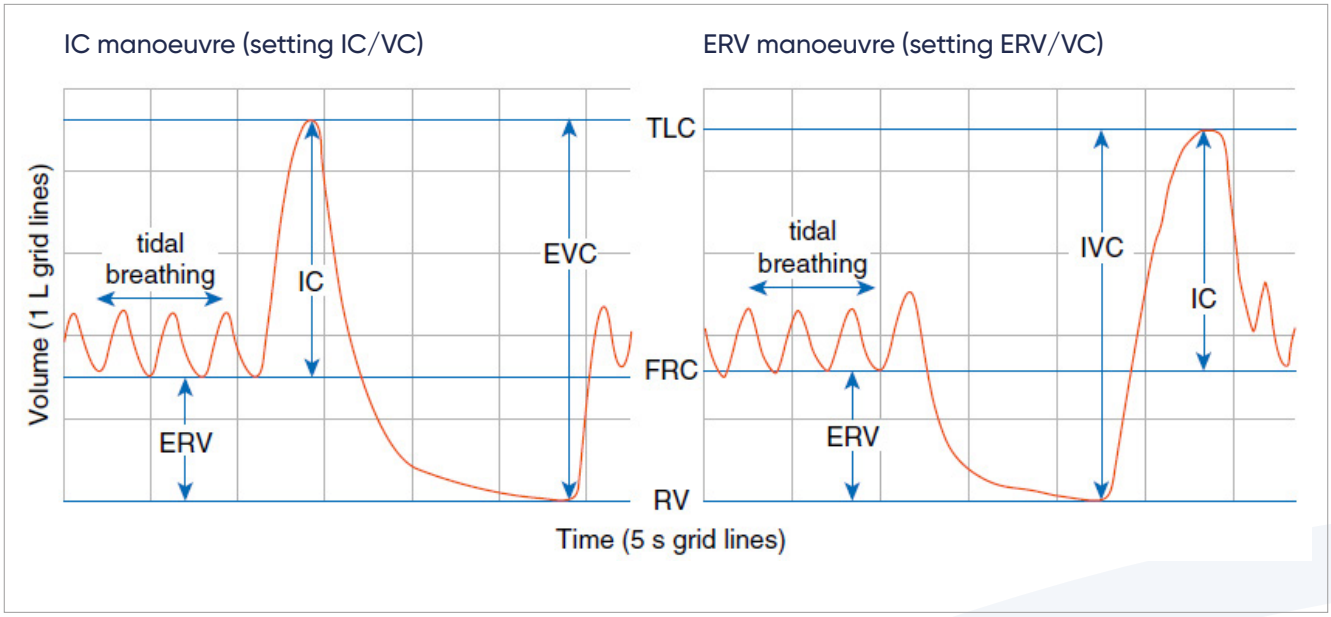
- **Acceptability of VC:**

To reach acceptability for VC (vital capacity) a complete expiration is necessary. The patient needs to achieve a plateau at the end of expiration, which is defined as the volume change of ≤ 25 mL in the last second of expiration. If the patient does not reach a plateau, the expiratory time needs to be at least 15 seconds for acceptance.

ERV maneuver: when performing the ERV maneuver, expiration to the plateau condition is required during the ERV maneuver (before the VCin) to be considered acceptable.

IC maneuver: when performing the IC maneuver, expiration to the plateau condition is required during the VCex maneuver (after the IC) to be considered acceptable.

Thereby it is less important to achieve a stable VT for an acceptable VC. As soon as the plateau is reached or the patient exhaled > 15 seconds a **double beep** should alert the operator.



Graham BK, Steenbruggen I, Miller MR. Standardization of Spirometry 2019 Update. Am J Respir Crit Care Med 200(8, e70-e88, 2019

- **Acceptability of VT:**

In order to measure an ERV (setting ERV/VC) or an IC correctly (setting IC/VC) as well as accurately calculate other sub-divisions of lung volumes, a stable tidal volume (VT) is essential. Stability is defined as having at least three tidal breaths with end-expiratory lung volume within 15% of the VT. As soon as the stability of VT has been reached a **single beep** should be heard or no later than 10 tidal breaths. After the single beep the ERV or the IC manoeuvre should be performed.

ERV manoeuvre: For acceptability VT needs to be stable and additionally a plateau or 15 seconds of expiration during ERV manoeuvre is necessary.

IC manoeuvre: For acceptability only VT needs to be stable.

According to the ATS/ERS 2019 spirometry guidelines the operator needs to have the ability to override the acceptability designation. In compliance, it is possible within SentrySuite, like in forced spirometry, to change the status of the two quality parameters in the Edit Mode.

Furthermore, a new error code "Error SVC ATS 2019" has been introduced to SentrySuite due to the updates and detailed quality alerts can be found in the tab "Quality". Find more information in the Spirometry Online Manual to the SentrySuite software.

New guidance during slow spirometry

If the patient does not reach the stability criterion for VT after ten breaths, the SentrySuite textual guidance will tell the operator to proceed to the ERV or IC manoeuvres. Otherwise a **single beep** alerts the operator when the VT is stable.

Acceptability criteria	VC IN VC EX	VT; ERV (ERV manoeuvre)	VT; IC (IV manoeuvre)
Stable VT	no	yes	yes
Plateau or expiration time ≥ 15 sec.	yes	yes	no

Each trial is evaluated automatically by SentrySuite software which makes it very easy for the operator to recognize if the measured VC and VT (ERV/IC) is acceptable or unusable. SentrySuite offers two new quality parameters for the within-manoeuvres evaluation using ✓✓ and **x**:

* slow volume tidal breathing

Parameter short/ long name	Unusable	Acceptable
Q SVC A19/Quality SVC ATS 2019	x	✓✓
Q SVT* A19/Quality SVT ATS 2019	x	✓✓

If the patient achieves a plateau at the end of expiration or when the patient has achieved an exhalation time of 15 seconds, the operator will hear a **double beep**.

- Grading
  There are no gradings for slow spirometry.

Performing spirometry with Vyntus SPIRO

Slow spirometry during the measurement within SentrySuite software

Calculation of the the BEST values

For the BEST column the largest VC from all accepted VC (parameter "Q SVC A19" shows ✓✓) is considered. Unusable VCs are not used for the BEST column. For the measured IC (IC-manoeuvre) or measured ERV (ERV-manoeuvre) the average of all trials with an accepted VT (parameter "Q SVT A19" shows ✓✓) is taken into account for the BEST column. VC MAX is the highest VC value from all trials from slow and/or forced spirometry with an accepted FVC or VC from forced spirometry or slow spirometry respectively.

Vyntus ONE

VC IN, VC EX	The largest VC from all trials with accepted VC (Parameter "Q SVC A19" shows "accepted" (✓✓).
IC ERV	The average of all trials with an accepted IC/ERV. (Parameter "Q SVT A19" shows "accepted" (✓✓).
VCmax	Highest VC from all trials from slow and/or forced spirometry with accepted FVC (forced spirometry) and/or accepted VC (slow spirometry).
All other sub-volumes	All other sub volumes measured parameters are calculated from BEST VC and BEST IC/ERV.

Vyntus BODY with ultrasonic flow sensor technology for slow and forced spirometry, body plethysmography, SB diffusion and many more.

Requirements

To work according to the newest ATS/ERS spirometry 2019 guidelines, you'll need:.

1. SentrySuite version 3.20 or higher needs to be installed
2. Within the settings of measurement program spirometry select **"Type of quality check"** to **"ATS and ERS 2019"**. As soon as "ATS and ERS 2019" is enabled the settings "Mix F/V parameter acc. to ATS" and "Mix PEF parameter acc. to ATS" will be enabled automatically.

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