**Checklist for Compliance with NLHEP Guidelines for Office Spirometers**

Note: Committee purpose and membership, conflict of interest, equipment testing process, and manufacturer notification are in the Spirometer Review Process (SRP) cover document, but key points are restated below.

**Definition of an Office Spirometer:** An office spirometer (DEVICE) is one which is marketed and sold to office-based physician practices (primary care and non-pulmonary subspecialties) in the United States. Spirometers intended for use almost exclusively within the hospital (pulmonary function laboratory, occupational health) or in research are not included in the Spirometer Review Process (SRP).

Spirometers manufactured for more than one type of use may meet the guidelines in the NLHEP document which supported the use of simple office-based spirometry use in the primary care setting (*Respiratory Care,* May 2000, and Ferguson, CHEST 2000; 117:1146-1161) *In order to meet the NLHEP SRP criteria, the DEVICE must have a PCP (primary care practice) mode and come from the factory in this mode (the default mode).* The DEVICE may have other modes which allow for other options and variables, but it is not acceptable for a user to be required to go through a configuration mode and change the configuration to make the spirometer become a DEVICE. The Checklist refers only to operation of the DEVICE when the "PCP mode" is selected.

REV07: While the October 2004 definition remains the preferred one, the revision as it relates to this definition is as follows:

> The DEVICE may come from the COMPANY in any mode, but the instructions must include a step-by-step process to reconfigure the DEVICE into the aforementioned "PCP mode." Once the reconfiguration is made, the DEVICE must stay in that mode and not be required to be reconfigured each time the DEVICE is turned on and off.

Office spirometers should allow maneuvers to stop after six seconds and measure and report the FEV6 as a substitute for the traditional FVC. The recently described FVC6 (Hankinson, *Chest* 2003; 124:1805) is slightly smaller than the FEV6 (by no more than 0.05 liters) only when volume spirometers are used, and then only when there is a leak or the exhaled air is cooling quickly. Therefore, the FVC6 equals the FEV6 for flow-sensing spirometers. The FEV6 is the highest volume exhaled during the first six seconds of the maneuver [not necessarily the volume measured at exactly 6.0 seconds]. Valid FEV6 measurements can be obtained from maneuvers which last two to six seconds **if** the end-of-test volume (EOTV) is less than 40 mL during the final half second (a relatively flat volume-time plateau was obtained). To make office spirometry reports easier to understand by PCPs, the DEVICE may measure FEV6 but label it as the FVC on displays and reports. A statement to that effect must then be included in the Operator's Manual.

**Spirometer Accuracy**: This SRP review does not relate to testing the short or long-term accuracy or repeatability of office spirometers, since ATS specifications are clearly established for this purpose, and waveform generator systems are widely available.

Office spirometers will be accepted for SRP review only after it has been verified that they have passed all ATS specifications for FEV1 and FVC (or FVC6) accuracy and repeatability for a diagnostic spirometer, as proven by using a BTPS waveform generator. FEV6 is the same as FVC6. A copy of the full waveform generator testing *report must* be provided for the exact model and software version being tested. A copy of the 510k pre-marketing approval letter from the FDA for the DEVICE being tested will also be required. Later versions of software for the same model will be accepted for testing if a list of changes with traceability analysis is included as required by the FDA

**Rationale and Format for Features on the Checklist:** Features on the Checklist are derived directly from current ATS/ERS (2005), AARC, and NLHEP guidelines. The Checklist is formatted according to the "path of workflow" for spirometry testing as defined by NCCLS document HS4-A (Application of the Quality System to Respiratory Services). This includes features that must be present pre-testing, during testing, and post-testing. All of the required features must be present in an office spirometer before it receives approval (passes). The optional features are encouraged, but are not needed to 'pass'. Each optional feature has been assigned a score range of 0-5. The REVIEWER will give a score within that range. The exact score is subjective. The highest possible feature score is 100. The individual and total score for the optional features will be reported to the COMPANY only, but the COMPANY may advertise their total feature score if they pass all of the required features.

**The Grading System for Each of the 20 Optional Features**

0 Feature not present in/with DEVICE
1 Feature present but poorly implemented
3 Feature implemented and useful
5 Feature implemented and adds substantially to quality of data or value of DEVICE

(REV07: 0 Feature not present in/with DEVICE
1 Feature present
2 Feature present and significantly enhances DEVICE

* If DEVICE has required feature, put an "X" in the Pass column

** For Optional Features, place the score (from 0 to 5) in the Pass column also

## Part 1: General Features

| Required Feature* | Optional Feature | Pass ** | Fail | Feature |
|---|---|---|---|---|
| X | | | | A. Equipment arrived complete and operational. |
| X | | | | B. ATS waveform report has been received and demonstrates accuracy and repeatability for FEV1 and FEV6 |
| X | | | | C. FDA 510K pre-market approval has been received. |

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| | X | | | D. Quality of the Operator's Manual: *The manual should match the software version. It can be in a printed format or viewed via an electronic/software version. Give a higher score for more of the following items in the manual:*<br>- steps for patient preparation<br>- equipment preparation<br>- patient instruction<br>- test performance steps<br>- acceptability/reproducibility criteria<br>- reference sets with valid age ranges<br>- interpretation methodology<br>- resource list including websites<br>- equipment troubleshooting<br>- equipment cleaning and maintenance<br>- index, table of contents, glossary |
| X | | | | E. Educational materials clearly describe correct spirometry performance and common performance errors. |
| | X | | | F. Reduces cross-contamination potential (higher score for lower potential) |
| | X | | | G. Power considerations: batteries and their availability, duration before charging or battery replacement needed |
| | X | | | H. Warranty and exchange provisions (score apparent value) |
| | X | | | I. Case appearance and apparent durability |
| | X | | | J. Availability of customer service (reviewer attempts this.)(REV07: Company may be contacted anonymously to evaluate customer support effectiveness.<br>Is there a toll free customer service number? Y N<br>Is there a web site with customer service contact information? Y N<br>Does customer service respond within one business day? Y N |
| X | | | | K. NHANES III prediction equations are used and accurately calculated (within 2%) for various age, gender, and ethnic groups, such as:<br>8 year-old boy, 120cm tall, Caucasian (list target values)<br>10 year old girl, 150cm tall, Black<br>25 year old man, 6 foot 6 inches tall, Caucasian<br>45 year old woman, 5 foot 6 inches tall, Hispanic<br>75 year old man, 6 feet tall, Black<br>65 year old woman, 5 feet tall, Caucasian<br>(See Appendix 1) |

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| | X | | | L. Supplementary equations provided for ages 5, 6, and 7 |
| | X | | | M. Additional reference authors are available, or the user may enter their own reference equations as desired. |

**Reviewer Comments on Part 1**:

## Part 2: Pre-Test Features

| Required Feature | Optional Feature | Pass | Fail | Feature |
|---|---|---|---|---|
| X | | | | A. Device is configured to "PCP" mode as the default setting as it comes from the manufacturer. (REV07: or can be easily configured to "PCP" mode following step-by-step instructions on a laminated card. If DEVICE is reconfigured to PCP mode by the end-user, the PCP mode must be persistent after power is turned off and the DEVICE is then turned on again.) |
| | X | | | B. The operator's manual specifies device accuracy limits for temperature and altitude. |
| X | | | | REV07 [additional item added to checklist]<br>C. If the Barometric Pressure is not used in calculating the BTPS correction factor, the range of barometric pressures over which the BTPS correction is valid must be published by the manufacturer. |
| X | | | | D. Temperature is measured automatically when needed to convert results to BTPS, to an accuracy of ± 1% C° (REV07: or the user is prompted to enter ambient temperature.) |
| X | | | | E. The operator's manual explains calibration checks. |
| | X | | | F. The calibration checks are easy to perform. |
| | X | | | G. A method of checking accuracy, such as a calibration syringe, is included. (Lower cost = higher rating) |

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| | X | | | H. Ease of data entry for height, age, gender, and race |
| X | | | | I. Calibration check displays PASS or FAIL (2.895 to 3.105L) |
| X | | | | J. The operator's manual includes appropriate instructions for troubleshooting FAILED calibration checks |
| | X | | | K. Issue a warning if acceptable daily calibration check has not been performed |

**Note: "C" has been added, which re-labels all items that follow it in this section.**

**Reviewer Comments on Part 2:**

## Part 3: Testing Session Features

| Required Feature | Optional Feature | Pass | Fail | Feature |
|---|---|---|---|---|
| | X | | | A. A flow-volume curve or volume-time curve is displayed (or quickly printed) after each maneuver. |
| | X | | | B. *During* FEV6 maneuvers, information is presented to help identify maneuver errors or prompt good performance (such as F-V or V-T displays, bar graphs, or audio signals). |
| X<br>X<br>X<br>X<br>X<br>X | | | | C. Displays maneuver acceptability/reproducibility messages (perform poor maneuvers to check each of these, variations on the exact message are acceptable):<br>- If BEV >150 mL, displays "don't hesitate"<br>- If FET <6.0 sec and EOTV >40 mL (invalid FEV6), displays "blow out longer"<br>- If PEF match >1.0 L/s, displays "blast out harder"<br>- If FEV6 match >150 mL, displays "deeper breath"<br>- Only one error message is displayed (priority listed above).<br>- After 2 acceptable maneuvers match, "good test session." |

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| X | | | | If PEFT >120 msec, displays “blast out faster” |
| X | | | | D. An appropriate test session quality (A-F) grade is displayed after each maneuver (during both pre and post BD testing). |

**Reviewer Comments on Part 3**

## Part 4: Post-Testing Features

| Required Feature | Optional Feature | Pass | Fail | Feature |
|---|---|---|---|---|
| | X | | | A. Convenient report printing, such as on 8.5 by 11 inch paper, non-thermal, standard PC printer, etc. |
| | X | | | B. The reference equation source is printed on the reports. |
| X | | | | C. **Only** the following parameters are reported:<br>FEV1 in liters with only one decimal place (i.e., 3.6)<br>FEV1 percent predicted, reported as an integer (i.e., 72%)<br>FEV6 in liters with only one decimal place (i.e., 5.3)<br>FEV6 percent predicted, reported as an integer (i.e., 106%)<br>FEV1/FEV6 reported as a percentage (i.e., 65%)<br>FEV1 and FEV6 are automatically BTPS corrected<br>(REV07: DEVICE may display other parameters but must be able to be reconfigured into “PCP” mode following step-by-step instructions on a laminated card.) |
| X | | | | D. Variables with a measured value below the LLN are indicated (e.g. highlighted, different color, asterisk) |
| X | | | | E. A QC grade (A-F) is determined and reported for both pre and post-bronchodilator test sessions. |
| X | | | | F. Post-BD FEV1 and FEV6 results are compared to the pre-BD results only if the QC grades for both pre and post-BD test sessions are A, B, or C. |
| X | | | | G. The percent change from baseline and the post-BD percent predicted values are reported for FEV1 and FEV6. Changes in other variables (including the ratio) should not be reported.. |

| | | | | |
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| | X | | | H. The best F-V or V-T curve is printed on the report and meets ATS size and aspect ratios. Color or dots/dashes are used to differentiate the curves for each maneuver. |
| X | | | | I. An interpretation is displayed and printed only if the test session QC grade is A, B, or C. If the quality grade is D or F and the results are within normal limits, the interpretation states, "normal, but the reported FEV1 and FVC should not be used for comparisons with previous or subsequent tests." |
| X | | | | J. Interpretation states "airway obstruction" when the FEV1/ FEV6 is below the LLN. |
| X | | | | K. The severity of impairment (mild, moderate, severe, etc) is categorized using the FEV1 percent predicted, according to published guidelines. |
| X | | | | L. If FEV1/ FEV6 is above the LLN, but the FVC6 is below the LLN, the interpretation states that patient has a "low vital capacity, perhaps due to restriction of lung volumes". |
| X | | | | M. A "significant" BD response is interpreted when either the FEV1 or the FEV6 improved by at least 12% and 0.20 liters. |
| | X<br><br><br>X | | | Results from maneuvers are stored and exported in digital format. A higher score will be given for storing the 3 best (or all maneuvers); using the 2004 ATS-ERS format; and MS Access or another widely-used database format is utilized.<br>Windows based database software is included with every system, and is easy to use (good quality) |

**Reviewer Comment on Part 4:**

**Note: The Appendix and references on the next page have been added to support the contents of this document.**

## Appendix 1: Predicted values (lower limits) of normal for selected patients

| Subject | Height | Race | $FEV_1$ | $FEV_6$ | $FEV_1/FEV_6$ |
|---|---|---|---|---|---|
| 8 year-old boy | 120 cm | Caucasian | 1.24 (0.88) | 1.44 (1.03) | 86 (77) |
| 10 year old girl | 150 cm | Black | 2.06 (1.54) | 2.33 (1.73) | 90 (80) |
| 25 year old man | 6 ft 6 inches | Caucasian | 5.65 (4.68) | 6.90 (5.77) | 84 (75) |
| 45 year old woman | 5 ft 6 inches | Hispanic | 3.11 (2.47) | 3.71 (2.97) | 84 (76) |
| 75 year old man | 6 feet | Black | 3.02 (2.14) | 3.85 (2.87) | 79 (69) |
| 65 year old woman | 5 feet | Caucasian | 2.05 (1.54) | 2.57 (1.98) | 80 (71) |

## Other references related to the Spirometer Review Process documents:


Bailey WC et al: Strategies for Preserving Lung Health and Preventing COPD and Associated Diseases: The National Lung Health Education Program: RespCare 1998;43:185-216.

Hankinson JL, Odencrantz JR, Fedan KB: Spirometric reference values from a sample of the general US population. Am J Resp Crit Care Med 1999:159;179-187

Ferguson GT, Enright P, Buist AS, Higgins MW: Office Spirometry for Lung Health Assessment in Adults. A consensus statement from the National Lung Health Education Program. Chest 2000; 117:1146-1161.

Miller MR, Hankinson J, Brusasco V, Burgos F, et al: Standardisation of spirometry. Eur Respir J 2005; 26:319-338

Pelligrino R, Viegi G, Brusasco V, Crapo RO, et al: Interpretative strategies for lung function tests. Eur Respir J 2005;26:948-968

ATS-ERS 2005 Standards for Spirometry web site:
www.thoracic.org and then to Education Statements/Guidelines and scroll to ATS/ERS Standardization of Lung Function Testing: Standardization of Spirometry