Low-cost, Open-source Spirometer

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***Background and Problem Statement*:** Spirometers are used to diagnose many pulmonary diseases including chronic respiratory diseases that affect approximately 500 million people worldwide. Many of these people do not have access to a spirometer because current models are expensive and operation requires a trained technician to administer the procedure. The purpose of this project is to develop a low-cost spirometer usable without the aid of a trained technician. The project includes the physical design of the spirometer, software development to display and analyze results, and designing a universal tool to provide audiovisual coaching on the tests.

Client requirements

- Interface spirometer with a computer via USB cable
- Affordable for use in emerging countries
- Handheld and durable
- Standardized audio/visual respiration coaching for patient
- Easy to disinfect
- Minimize calibration
- Simple and universal instructions for operation
- Graphically display results of FVC maneuver
    - FEV
    - FEV1
    - FEV1/FEV
    - FEV6
    - PEF
    - $FEF_{25\%-75\%}$
    - Time zero determined by back-extrapolation
- Monitor and evaluate the quality of the maneuver
- Provide feedback to the subject about their performance after each test
- Carry out some rudimentary analysis and interpretation of results

Design requirements:

1. Physical and Operational Characteristics

a. *Performance requirements*

i. Spirometer: Capable of continually measuring air flows between 0 and 14 L/sec for at least 15 seconds and recording air volumes of at least 8 L. The body should facilitate laminar air flow, and thus a linear flow/pressure relationship should be measured. The total resistance of the spirometer should be less than 0.15 kPa/L·sec at all flows between 0 and 14 L/s. Device will need to withstand these pressures and air flows multiple times daily and still be able to function accurately. Spirometer must still

function accurately after it or any accessories have been subjected to drop testing mandated by IEC 60601-1, pp 115-117. The handle must be able to withstand a force equal to 4 times the weight of the main body of the spirometer. If the spirometer is to be disassembled, markings should be clear to ensure correct reassembly or it should be impossible to assemble incorrectly.

ii. Hardware/software interface: Capable of sending pressure and temperature data each with 10 bit resolution at 100 Hz over USB. Should have duplex communication with the computer.

iii. Software: Should display plots of flow vs. volume and volume vs. time on the laptop screen preferably in real time, as well as display data numerically. Measurement display should be accurate to 0.01 L (L/s for flow). Software should be open source and capable of running on Linux-based platforms. The patient's name, age, gender, smoking status, height and weight must be stored by the computer. In addition, environmental data such as temperature, humidity, date, testing site and other information found in Table 8 of the American Thoracic Society (ATS) standards for accuracy and repeatability as per ATS*/ERS Standardisation of Spirometry*, 2005 update. Data from the measurements should be recorded in the standard format described in the standards for accuracy and repeatability section of *Standardisation of Spirometry,* 2005 update. If data is input in a measure other than the spirometry standard, the computer should convert the data to the appropriate units. The computer should monitor and evaluate the quality of the maneuver and instruct the patient when changes in the maneuver are necessary. Rudimentary analysis and interpretation should also be performed. Volume-time curves should be displayed with the aspect ratio of 1 L:1 sec, flow-time curve should have a ratio of 2 L/s to 1 L.

b. *Safety*: The spirometer should not pose a choking hazard and should contain no components that could physically injure the user. Standardized and automated audiovisual instruction and coaching- in appropriate language and at appropriate literacy level - should ensure that the patient is able to safely perform the test, and if so, safely guide and assist the patient and provider through the test with a maximum of eight repetitions as per *ATS/ERS Standardisation of Spirometry*, 2005 update. The spirometer should use an affordable disposable mouthpiece with a minimal lifespan (to minimize the likelihood of reuse) so that communicable diseases are not spread between users. Mouthpieces or mouthpiece packaging must be labeled "single patient use." All parts that come into contact with bodily tissues, fluids or gasses must be deemed biocompatible as relevant to their function. Appropriate biocompatibility will be defined according to the protocol defined in ISO 10993-1, *Biological Evaluation of Medical Devices*. All components intended for reuse that come into contact with the patient must be capable of being cleaned and disinfected or cleaned and sterilized. Instruction manual should specify what should be disinfected or cleaned.

c. *Accuracy and Reliability*:

i. *Spirometer* - The maximum error for volume readings must be <3% of the reading or .05 L, whichever is greater. Measurements must be repeatable enough such that when measuring a constant flow patterns, all readings fall within 3% or 0.05L of the mean of the readings, whichever is greater. Volume linearity error should not exceed 3% when measured at increments 0.4 to 0.6 L in size for the span of the measurement range (ISO 26782). Pressure vs. flow should fit a linear trendline with regression coefficient ≥ 0.98. Accuracy and reliability should be maintained with only initial factory-set calibration in varied temperature and humidity conditions. Mouthpiece should be designed such that there is no variability in their attachment to the spirometer, which potentially yields inconsistencies in the length of the spirometer.

ii. *Maneuver* - Repeatability of the spirometry maneuver should be graded by the system established by the ATS and described in *ATS/ERS Standardisation of Spirometry*, 2005 update. Standardized respiration coaching should ensure repeatable pulmonary measurements.

d. *Life in Service*: The unit will be used multiple times per day for a period of 10 years. Also, software should be capable of being easily updated to fix bugs and provide additional features.

e. *Shelf Life*: Unit should be able to withstand various modes of international transportation. Unit should maintain performance requirements with multiple daily disinfecting procedures.

f. *Operating Environment*: The unit should maintain accurate function between 17° and 35° C, in relative humidity from 30% to 75%, and in ambient pressure 85 to 106 kPa. Exhaled air is assumed to be at body temperature (37°C) and saturated with water vapor (100% humidity). The unit may be operated by a patient without technical training or supervision.

g. *Ergonomics*: The spirometer should be comfortable to use with either hand while sitting or standing. The mouthpiece should be comfortable to use for the duration of a full set of tests, at least 10 minutes. Audiovisual coaching tool should accommodate a range of languages and literacy. The device should be able to be used by everyone ages 8 and older.

h. *Size*: The unit is handheld and easily portable, measuring 10.2 cm (4 in) in length and 3.2 cm (1.25 in) in diameter. The handle should be small enough to be held by a hand with a 3.5 cm inside grip diameter.

i. *Weight*: The maximum weight for the unit is 500 grams (1.1 lb)

j. *Materials*: The chosen material for initial prototype is a PVC case with cordierite capillaries. The chosen materials are abuse-tolerant, easily manufactured on a mass scale, and water and heat resistant to deformity or breaking.

k. *Power*: Device must be powered via USB bus (maximum voltage 5 V, maximum current 100 mA).

l. *Aesthetics, Appearance, and Finish*: The material should look sleek yet not slip when held in the hands. The user interface should be professional and intuitive. There should be an option for entering information in metric or English units. Direction of flow must be marked. Name, address, manufacture trademark, and model identification number or serial number should be visible on the spirometer.

Any markings on the spirometer must remain legible after cleaning, disinfecting, or rubbing. Method of disposal should be labeled in packaging.

2. Production Characteristics

a. *Quantity*: One prototype whose design can be mass-produced and a version of software required to run the spirometer and display and interpret test results.
b. *Target Product Cost*: Less than $50, preferably around $20

3. Miscellaneous

a. *Standards and Specifications*: Unit should meet international standards for safety, specifically those of the World Health Organization (WHO) as per *Medical Device Regulations: Global overview and guiding principles* and should be compatible with a personal computer. Also, all operation information, such as that printed in manuals, in the motivational coaching software, in operation training software, and on the spirometer itself, must be conveyed in a universal fashion for multi-lingual understanding. An electronic copy of a user's manual should be included with the spirometer.
b. *Environmental impact*: Use, cleaning, and disposal of consumables should have minimal environmental impact.
c. *Customer*: Emerging nation healthcare practitioner
d. *Patient-related concerns*: Device mouthpiece should be replaced between uses
e. *Competition*: Most devices on the market are expensive:
    - SDI Diagnostics Spriolab II: $2395
    - SDI Diagnostics Astra 300 Touchscreen Spirometer: $1429
    - Microdirect spiro√ Spirometer: $195
    - MicroDirect Micro Spirometer: $351.55
    - MicroDirect SpiroUSB (with Spida5 software): $1419.55
    - The lowest cost spirometer was developed at the Indian Institute of Technology - Bombay and costs around $80.