

The development of a low-cost, open source spirometer

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Background: Chronic respiratory diseases affect over 500 million people worldwide, and up to 80% of the fatalities occur in low- and middle-income countries. Despite the importance of spirometry in diagnosis and management of respiratory disease, the high cost of equipment has significantly impeded its adoption in developing nations.

Objective: We assessed the technical feasibility of a low-cost spirometer and developed a functional prototype.

Methods: Prototypes with a variety of sensor and flow-tube arrangements, utilizing either a Venturi, Fleisch, or Lilly pneumotachometer, were developed and evaluated against American Thoracic Society and International Standards Organization standards, and assessed for reliability, affordability and ease of manufacture.

Results: Laboratory bench test results indicate that a Fleisch pneumotach-based design and single pressure sensor yielded the best balance of design criteria. A key feature is an internal capillary system to nearly linearize ($R^2 = 0.988$) the relationship between flow and pressure and maximizing the open area of the spirometer capillaries relative to wall thickness. Additionally, the open-source Java software can perform calculations for respiratory function assessment, display graphical results and provide patient motivation. Despite the high function of the design relative to its cost, the current embodiment does not meet American Thoracic Society standards for accuracy.

Conclusion: A spirometer capable of preliminary respiratory assessment can be manufactured for under \$100. This device would make spirometry more accessible to practitioners in low and

middle-income countries. Further development and human testing will improve the accuracy of the design to the standards of the American Thoracic Society.

Key Words: Spirometry, global health, chronic respiratory disease

Introduction

Chronic obstructive pulmonary disease (COPD) is currently the fourth greatest cause of death worldwide, and it is estimated that over 600 million are afflicted with the disease.¹ Spirometers, which are tools that measure respiratory air flows and volumes over time, are tools used to diagnose and monitor numerous lung disorders, including COPD. Unfortunately, health care providers in developing countries are unable to purchase spirometers because they frequently cost over \$1000. As a result, millions of people with COPD are not effectively monitored or treated.

Spirometry is also essential in the diagnosis and treatment of asthma, a chronic respiratory disease that affects an estimated 300 million people worldwide. The severity of asthma is especially prominent in low and lower-middle income countries, where approximately 80% of asthma fatalities occur.² The disproportionate amount of deaths in these countries is in no small part due to the lack of essential diagnostic and monitoring equipment available. Providing spirometric equipment at a price affordable to physicians practicing in low and lower-middle income countries will help address problems of under-diagnosis and under-treatment and raise the quality of care for millions of people with chronic respiratory disease. A team from IIT-Bombay has attempted to provide a low-cost spirometer to address this problem.³ However, this device uses expensive technology, such as Bluetooth capability, that unnecessarily increases the cost of the device. The

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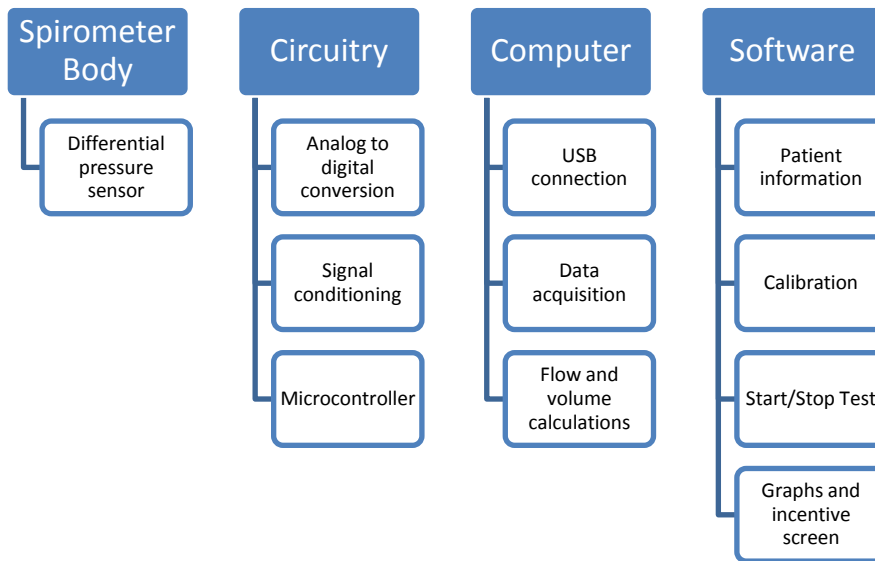


FIG 1. The user blows through the spirometer body which contains a differential pressure sensor. The sensor connects to the iLite chip, which performs analog to digital conversion and signal conditioning before sending data to a microcontroller. After receiving a start signal from the software, the microcontroller sends data to a computer via Universal Serial Bus (USB) where the software parses the data. Software also calibrates the spirometer, saves patient data, and displays graphs and the incentive screen.

absence of affordably-priced spirometers combined with an increasing prevalence of chronic respiratory diseases has created a massive demand for low-cost spirometry equipment.

To adequately perform lung function assessment, various pulmonary function indices should be measured including forced vital capacity (FVC), forced expiratory volume after 1 second (FEV1), peak expiratory flow (PEF), and forced expiratory volume after one second to forced vital capacity (FEV1/FVC) ratio⁴. Graphical displays of flow and volume data are known as spirograms, and their shape can be used by physicians to differentiate between lung abnormalities.⁵ Some low-cost devices currently on the market only measure one or two parameters such as PEF and do not provide all of the functions to detect mild diseases⁶. A low-cost spirometer that measures a variety of parameters and graphs data in real-time is necessary for thorough respiratory assessment.

METHODS

We developed a low-cost spirometer and accompanying software interface for respiratory assessment, depicted in Figure 1. The spirometer hardware functions as a Fleisch-type pneumotachometer which measures air flow by detecting a pressure drop across a system of internal capillaries. The analog signal output from the pressure sensor is transmitted to a ZMD31014 iLite signal conditioner which performs signal amplification and analog to digital conversion with 14-bit resolution. A microcontroller relays this data

via a Universal Serial Bus (USB) connection to a computer which converts pressure data to flow and integrates the signal to yield volume measurements. A Java-based graphical user interface can display the flow and volume data in real-time with an accompanying incentive animation. The Java-based software also allows calibration of the device using a standard 3-L syringe.

Hardware Design

A pneumotachometer is a device containing some resistive element that generates a pressure drop as fluid moves across the resistance. The pressure difference exerted by the fluid before and after the encountering the resistance is proportional to the velocity of the fluid. Common pneumotachs used in spirometry include the Fleisch-type, which uses a system of capillaries as the resistive element, and the Lilly-type, which uses a fine mesh screen for resistance. These models aim to linearize the relationship between air flow and the differential pressure to facilitate simple and accurate pressure to flow calculations. The linear relationship is realized by achieving laminar air flow, characterized by a Reynolds number (Re) less than 2000. Reynolds number is calculated according to

$$Re = \frac{\rho VL}{\mu}$$

where ρ is the fluid density, V is fluid velocity, L is the length traveled by the fluid, and μ is dynamic viscosity of the fluid. Venturi meters and fixed orifice

flow meters are also employed in spirometers, though these have a quadratic relationship between fluid flow and pressure.

We constructed various pneumotachometer configurations and evaluated them based on cost, linearity between air flow and differential pressure, ease of cleaning, and ease of manufacture. Linearity was considered highly important to ensure a single pressure sensor could accurately measure the differential pressure generated by air flows up to 14 L/s while maintaining adequate low flow sensitivity. Maintaining a low resistance to air flow was also important to prevent the design from impeding the patient's ability to generate his/her maximal air flow.

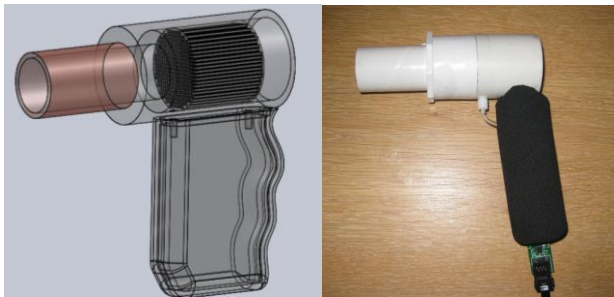


FIG 2: SolidWorks model and actual embodiment of low-cost spirometer design.

Based on these criteria, a Fleisch-type model with a system of capillaries 3.81 cm (1.5 in) long and 3.81 cm in diameter with a capillary density of 400 cells per square inch yielded the best results. We constructed Fleisch-type model (Figure 2) and assessed linearity by averaging ten seconds of pressure measurements from the spirometer at fixed

Pressure vs. Flow

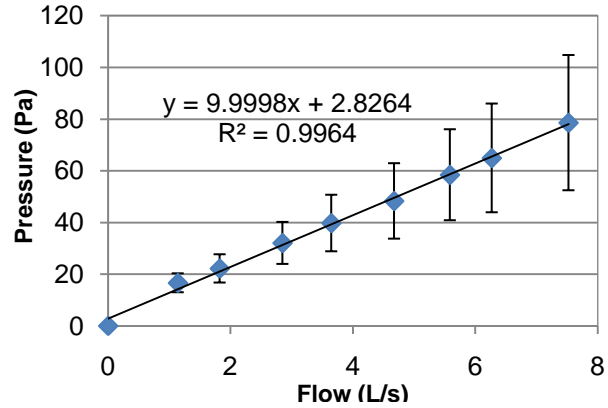


FIG 3: Graph depicting the average pressure values recorded by the pressure sensor (sample rate = 100 Hz) over a 10 second period at a fixed flow value.

air flows between 0 and 14 L/s. The pressure averages were plotted against the air flow and fit to a linear trend line. The linear regression coefficient for the Fleisch-type design was >0.98, as can be seen in Figure 3. The increasing variation at higher flow rates was a function of a turbulent air supply used for testing and not due to the sensor's stability at a given pressure, which was separately assessed (data not shown).

Software Design

The software package for the spirometer was programmed using Java to facilitate its use on any operating system without modifying the underlying code. The back end of the software performs data acquisition from the microcontroller and calculation of flow and volume. We used a low-pass, 4th order

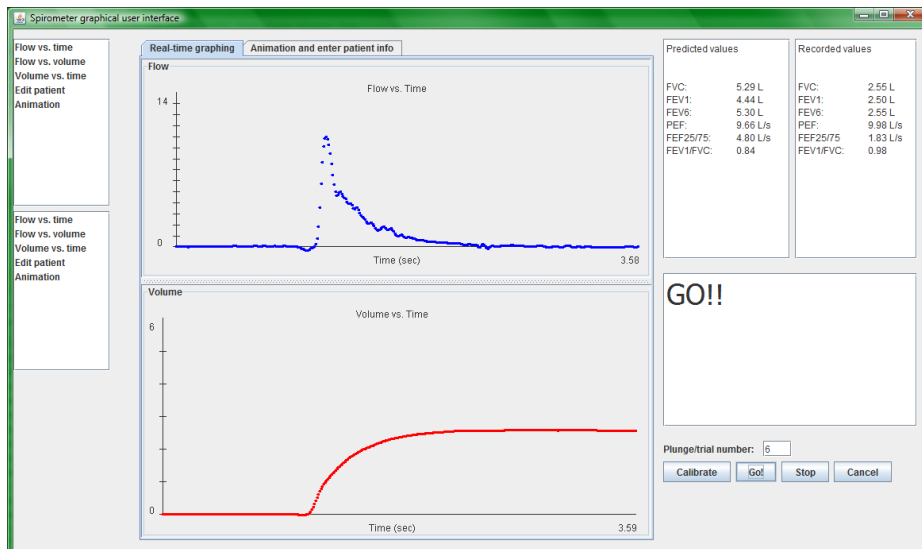


FIG 4: The graphical user interface displays real-time flow vs. time and volume vs. time graphs, an incentive animation, predictive and recorded spirometric parameters, and a screen to enter patient demographic information. Software also calibrates the spirometer and saves patient data to text files.

Butterworth digital filter to reduce background noise of flow data. The filter maintains a gain of 1 for frequencies up to 15 Hz, above which the signal is attenuated. This design follows the criteria set by the American Thoracic Society and should not affect the integrity of the data.

The graphical user interface is divided into two main screens, each possessing useful spirometry functions. The first screen allows for input of various patient demographic data such as age, height, sex, and race, which are necessary to establish expected pulmonary function indices established by Hankinson⁷ based on the National Health and Nutrition Examination Survey III.

The second screen allows the user to calibrate the spirometer using the standard 3-L syringe. The software contains an initial set of calibration coefficients, although a 3-L syringe should be plunged multiple times at a fast (peak flow >7 L/s), medium (peak flow >3.5 and <7 L/s) and slow (peak flow <3.5 L/s) speeds daily to update the calibration as recommended by the American Thoracic Society.⁸ After a desired number of calibration plunges, the user can click a “calibrate” button to update the coefficients used for flow and volume calculations.

The second screen also serves as the main testing screen viewed by the user as he is performing a test. Two real-time graphical displays are displayed in two frames within the test screen as shown in Figure 4. The user has the option of configuring the screen to show flow-time, volume-time or flow-volume time curves or the incentive animation in either of the two frames. A full list of functions the user may perform is shown in Table 1.

TABLE 1: List of functions available in the spirometer interface

Function	Description
Enter patient information and calculate spirometric parameters	Patient name, age, sex, race, height, ID, smoking status, asthma status, and COPD status are entered for spirometric parameter prediction and as useful information for the physician. Spirometric parameters calculated include FVC, FEV1, PEF, and the FEV1/FVC ratio.
Start recording spirometric maneuver or calibration plunge	Begins the data collection process and graphically displays graphs or incentive animation to accompany procedure.
Stop recording spirometric maneuver	Ends data collection process and displays calculated spirometric parameters next to recorded ones. The user is given the option to save or discard the trial.
Calibrate	Calculates a new set of coefficients used for flow and volume calculations based on the number of plunges the user has performed.

The incentive animation consists of a boat which users attempt to blow toward an island. Encouragement is provided by billowing sails and the motion of the boat toward the island. Following each maneuver, a pop-up window allows the user to accept or discard the maneuver if it was influenced by sub-maximal effort, coughing, taking a second breath or any other source of error. Test data is also saved in organized text files for future retrieval and analysis. Data acquisition is automatically stopped after one full second of flow measurements below 0.10 L/s.

Calibration Algorithms

The spirometer’s calibration procedure utilizes the mathematical methods described in Tang, et al.⁹ Briefly, pressure data from multiple plunges of a 3-L syringe are stored in a matrix where each row contains the pressure values recorded during a unique plunge stroke. Although the pressure-flow relationship is quite linear, Tang, et al. has shown that fitting a 3rd order polynomial function relating flow to pressure can improve the accuracy of calibration by allowing for small non-linearities. Thus, if p_t is the pressure at time t , then the corresponding flow F_t is given by:

$$F_t = b_1 p_t + b_2 p_t^2 + b_3 p_t^3$$

where b_1 , b_2 and b_3 are the constants referred to as the calibration coefficients. The volume V for each syringe stroke can be calculated using rectangular integration as

$$V = \sum F_t \times \frac{1}{f} = \frac{1}{f} \sum (b_1 p_t + b_2 p_t^2 + b_3 p_t^3)$$

where f is the frequency of the measurements in Hz. Using matrix notation, the volumes for the syringe plunges can be written as $Y = XB + E$ where Y is the array of volumes for each measurement, X is the matrix of pressure data summed for the duration of the measurement with columns in decreasing exponential order, B is the array of calibration coefficients, and E is the array of errors of each measurement. When using the syringe, the volume for each plunge is known to be 3 L, and one can estimate the calibration coefficients by assuming $E = 0$ for each plunge and using least squares regression to solve $B = (X'X)^{-1}X'Y$. By using pressure data from plunges at various speeds, B yields accurate coefficients for a third order polynomial to relate pressure measurements to units of air flow.

RESULTS

After constructing a prototype providing the maximal balance of design criteria described above, the software's interface design and calibration accuracy were independently evaluated. The interface design was assessed using a survey given to a respiratory technician highly familiar with spirometry equipment. The evaluation was designed to compare the functionality of the low-cost spirometer with other commercial devices and assess the value that additional features would add to the interface. Calibration accuracy was determined with data from 2 independent sets of 30 plunges using a Jones 3-L Calibration Syringe. The Jones syringe is different from other 3-L calibration syringes because it displays values for PEF, FVC, FEV1 and other indices for each plunge. The first set of thirty plunges, with 10 plunges each at slow, medium and fast flow rates, was used to calibrate the spirometer while the second set of plunges was used to assess how close flow and volume measurements were to the values recorded by the Jones calibration syringe.

Interface Design

After watching a short demonstration, a local respiratory technician provided feedback on the user interface. The technician had been performing pulmonary function testing for 5-10 years and had experience using 2-3 different commercial spirometers. The technician felt that it was "easy" to navigate the interface, enter patient data and start/stop a test. Furthermore, she felt the spirometry results were presented clearly. Additional value would be given to the software if it possessed the ability to overlay multiple curves, and incorporating a "ghost" version of the boat at the end of a maneuver would encourage the user to beat that attempt on future trials.

Calibration Accuracy

The volumes calculated for each of the thirty plunges is shown below in Figure 5. All plunges were from a calibrated 3-L syringe, thus a calculated value closer to 3-L demonstrates a more accurate calculation. The mean value of the thirty calculations was 3.04 ± 0.2588 L.

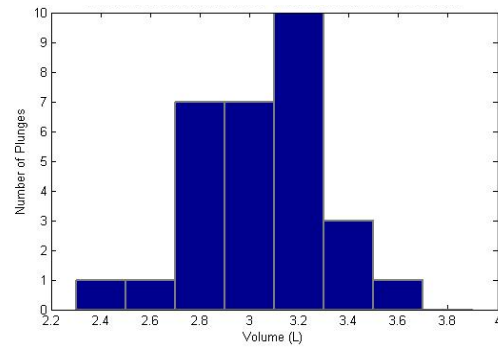


FIG 5: The calculated volumes from thirty plunges of a 3-L syringe are plotted in a histogram. The number of plunges at 0.2 L intervals from 2.3 to 3.7 L is shown.

The calculated peak expiratory flow (PEF) rates were also compared to the values measured by the Jones syringe. A plot of the values calculated by our spirometer vs. the values displayed on the Jones syringe is displayed in Figure 6. Because both values should ideally be the same, more accurate calculations are those closer to the line $y=x$.

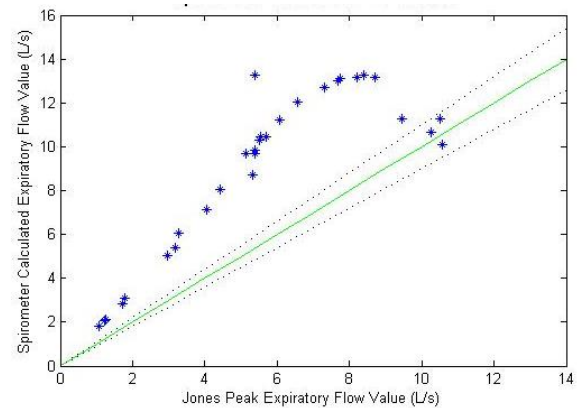


FIG 6: The peak expiratory flow (PEF) values calculated by the spirometer plotted against the values output by the Jones syringe. The solid green line represents the actual values the calculations should achieve, dotted lines represent $\pm 10\%$ of the Jones syringe values.

Finally, the forced expiratory volume after 1 second (FEV1), which is a common measure of respiratory function, was compared between the Jones syringe and the low-cost spirometer. The plot of FEV1 values calculated by the spirometer vs. the values output by the Jones syringe is shown in Figure 7. Similar to the graph for peak expiratory flow, a point closer to the line $y = x$ indicates a more accurate calculation.

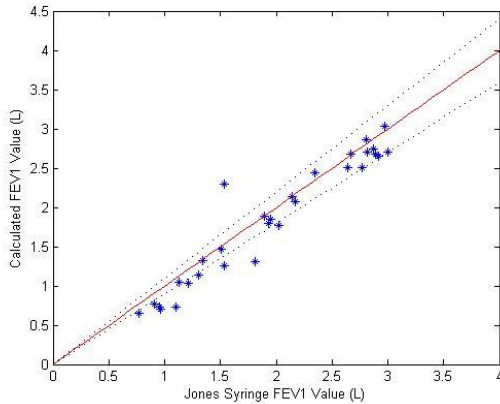


FIG 7: The forced expiratory volumes after 1 second (FEV1) values calculated by the spirometer plotted against the values output by the Jones syringe. The solid red line represents the actual values the calculations should achieve, dotted lines represent $\pm 10\%$ of the Jones syringe values.

DISCUSSION

The low-cost, open-source spirometer described above fulfills its intended purpose by 1) measuring respiratory air flow and volume data for up to 8 seconds 2) providing a graphical user interface to display the data and calculate pulmonary function test parameters 3) including a method to calibrate the spirometer using the industry standard 3 L syringe 4) providing an incentive animation to encourage maximal user effort and 5) maintaining low materials and development costs.

Performance

The low-cost spirometer measures lung flows and volumes to a sufficient accuracy to serve as a preliminary screening for respiratory disease. Furthermore, the ability to visualize the shape of the flow and volume data allows a trained respiratory technician to make an informed, qualitative assessment of the patient's lung function. Although the accuracy of the current embodiment is not able to meet clinical accuracy standards, the device shows the potential of a Fleisch-type pneumotach utilizing a single pressure sensor to function as a basic spirometer with minimal calibration. With professional manufacturing, such a design could yield a device capable of meeting ATS standards without a significant increase in price.

Much of the value of the current package is due to the software since it allows for visualization, analysis and interpretation of the respiratory data. By providing quantitative comparison of a number of pulmonary function indices against the established NHANES predicted values, the technician can quickly become aware of a potential problem. When the numeric values are combined with a qualitative assessment of the flow and volume curves, a

thorough analysis of the user's pulmonary function can be established. By encouraging maximal effort from the user through an incentive animation, the software provides a more standardized experience between users. The combined function of all the described features give the device considerable value when considering the end cost is under \$100. Moreover, open-source availability of the software package will allow programmers and others familiar with spirometry to improve and add on to the current feature list.

Although the device provides many functions that no other similarly-priced device currently offers, there are notable limitations to its use. As noted above, the design in its current embodiment does not meet ATS standards for accuracy and thus could not form the sole basis for any respiratory diagnosis. In this form, 28 out of 30 plunges were within 0.5 L of 3 L, but only 19 out of 30 had FEV1 calculations within 10% of the accepted value. The accuracy is likely limited by the current hardware configuration. By properly placing all circuitry components on one well-designed printed circuit board, and by professionally manufacturing the spirometer body, the accuracy of the design would improve significantly.

Future Work

Additional improvements to the design could be made in a few areas, especially in the hardware layout and construction. Currently, not all of the circuitry components are connected as seamlessly as they would be on a printed circuit board. Connecting the components via board traces and placing them all on a single board would significantly reduce the noise cause by electrical interference. If the spirometer body were to be manufactured as a single piece, or as a set of pieces with well-designed connections, the design would support a more homogenous air profile. The combination of these two refinements would greatly reduce the variability between measurements.

Although the function of the design was assessed by multiple criteria, no human subject testing has yet been completed with this hardware or software. After refining the hardware construction, future studies should be conducted with human subjects to evaluate the device's ergonomics and safety. Additionally, human testing would give a better indication of the incentives screen's capability to motivate the user to maximal effort.

Cost and Global Utility

The significance of the current design is the high number of functions it achieves while maintaining a comparatively low cost. The significant

reduction in cost allows the device to potentially be implemented in many environments throughout the world that have never had the chance for any kind of pulmonary assessment.

A potential means of implementation for our design would be to incorporate it into the new National Heart, Lung and Blood Institute (NHLBI) Centers of Excellence which are aiming to perform research on chronic diseases in numerous locations worldwide¹⁰. As described previously, spirometers are key tools for diagnosing and monitoring chronic respiratory diseases such as COPD and asthma. Recently, the Global Alliance for Chronic Disease, of which the NHLBI was a founding member, came out with specific plans for combating chronic disease worldwide. One of these plans was the creation of a “toolkit” to expand chronic disease monitoring. Our spirometer design would fit ideally into this toolkit due to its ability to work as a frontline assessment of chronic respiratory disease with a minimal cost.

CONCLUSION

We have developed a low-cost spirometer with associated open-source software suitable for the preliminary assessment of pulmonary function. The device is capable of measuring respiratory flows and volumes which are displayed in real-time on a graphical user interface. The software is capable of calculating the expected pulmonary test values based on user input for a comparison to the values achieved during a test, as well as encouraging maximal effort through an incentive animation. Although the device does not currently meet ATS standards, it possesses more features than any other similarly priced spirometry instrument and has the potential to become more accurate with more refined manufacturing methods.

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