



HAL
open science

DEVELOPMENT OF A CALIBRATION TOOL FOR INCUBATORS FOR NEONATAL PATIENTS IN THE CITY OF MANAUS (BRAZIL, 2022)

Ricardo Souza de Lima Junior, Samuel Agostinho Ferreira, Newton Lima,
Newton Silva de Lima

► **To cite this version:**

Ricardo Souza de Lima Junior, Samuel Agostinho Ferreira, Newton Lima, Newton Silva de Lima. DEVELOPMENT OF A CALIBRATION TOOL FOR INCUBATORS FOR NEONATAL PATIENTS IN THE CITY OF MANAUS (BRAZIL, 2022). XIII Mostra Científica - ULBRA Manaus | XIX Semana Nacional de Ciência Tecnologia & Inovação, 2022, Oct 2022, Manaus, Brazil. hal-03908757

HAL Id: hal-03908757

<https://hal.science/hal-03908757v1>

Submitted on 20 Dec 2022

HAL is a multi-disciplinary open access archive for the deposit and dissemination of scientific research documents, whether they are published or not. The documents may come from teaching and research institutions in France or abroad, or from public or private research centers.

L'archive ouverte pluridisciplinaire **HAL**, est destinée au dépôt et à la diffusion de documents scientifiques de niveau recherche, publiés ou non, émanant des établissements d'enseignement et de recherche français ou étrangers, des laboratoires publics ou privés.

**DEVELOPMENT OF A CALIBRATION TOOL FOR INCUBATORS FOR NEONATAL
PATIENTS IN THE CITY OF MANAUS
(BRAZIL, 2022)**

Ricardo Souza de Lima Junior¹

Samuel Agostinho Ferreira²

Newton Silva de Lima³

Abstract

In neonatology, the vulnerability of prematurely born patients is high and for this reason they require special care to ensure the evolution of the clinical picture. Thus, the use of neonatal incubators is primordial for the maintenance of their lives, considering that they create an ideal environment, thus enabling the self-regulation of body heat. However, their use must respect principles that ensure their functionality, for this the Brazilian Technical Standard NBR 15943-2011 determines the guidelines to be adopted by health establishments regarding the management of their technologies, because through these programs it is possible to ensure the reliability of the use of this equipment. To this end, the performance of calibration tests is a mandatory factor, since this procedure certifies the veracity of the parameters offered by this equipment during its use. This procedure is done by performing a set of standardized steps with the help of an analyzer built to perform specific functions, certifying the usability of the equipment through the analysis and comparison of acquired data. However, the calibration instruments available in the market are expensive and sometimes their availability is low, which can compromise the execution of this type of service in hospitals. Thus, in this work, we will approach the development of a low cost calibration instrument capable of measuring temperature, humidity and noise, using affordable materials and with accuracy values within the acceptable parameters of variation for the calibration of such equipment standardized by NBR IEC 60601-2-19.

Keywords: NBR 17025, temperature, humidity, noise.

¹ Electrical Engineering Academic, CEULM | ULBRA, ricardolima@rede.ulbra.br;

² Electrical Engineering Academic, CEULM | ULBRA, sam.ago.fer@rede.ulbra.br;

³ Professor PhD, CEULM | ULBRA, newtonulbra@gmail.com

Introduction

In neonatology, the importance of caring for prematurely born patients is essential, because in this period their vulnerability is high and the health of these individuals can be compromised by biological and environmental risks. Moreover, this type of patient has difficulty in body regulation and may lose heat through evaporation, radiation, convection and conduction (MINISTRY OF HEALTH, 2011). Thus, it is necessary to define strategies that minimize the impacts caused by this condition.

The use of hospital medical equipment for the treatment of patients is widespread in society in general. Its role is essential for the patient's evolution, considering that sometimes it performs functions that cannot be performed by human beings. Thus, the use of neonatal incubators is indispensable for the treatment of neonate patients, as their main function is to provide the newborn with a thermo-neutral environment by controlling the temperature and relative humidity of the air, in order to ensure the minimal production of body heat by the patient (IAIONE, 1999).

However, the use of this equipment must respect principles to ensure the reliability of the supplied parameters. For this, hospitals must have a management of the technologies present in their technological park to ensure the traceability, quality, efficacy, effectiveness, safety and performance, as stated by the National Health Surveillance Agency (2010).

Thus, given the need to obtain consistent results and check whether the information provided by a hospital medical device is cohesive, the calibration tests are of paramount importance to provide the proper functioning of such equipment. Moreover, calibration ensures the quality and credibility of patient care.

According to the International Metrology Vocabulary (2012), the definition of calibration is a set of steps that establishes, under specified conditions, a relationship between the values and measurement uncertainties provided by standards, using this information to establish a relationship in order to obtain measurement results from an indication.

In Brazil, the NBR IEC 60601-2-19 standard deals with the general provisions for the performance and operation of neonatal incubators and determines that this equipment must undergo periodic maintenance, stressing the importance of performing annually or whenever necessary calibration tests and electrical safety

analysis. To perform these services, equipment called analyzers are used, whose purpose is to perform specific activities according to the purpose of the equipment submitted to the procedures.

Currently, the analyzers present in the market are imported and have a high price, making it difficult to purchase them; moreover, their cost-benefit ratio is low, since these analyzers have outdated technology and complex operation.

As a result of the covid-19 pandemic and the increase in the production of electronic equipment, silicon (ore used in the production of semiconductor components and indispensable for making electronic boards) became scarce. Because of this, the creation of alternative devices using accessible technologies has become widespread. With this, it was observed that neonatal incubators provide physical quantities that can be measured by low-cost sensors on the market.

Based on this principle, followed by the question: "is it possible to create a calibration instrument for neonatal incubators using affordable resources available on the market?", this paper was developed based on the following objective: To develop a low-cost calibration device for measuring physical quantities provided by an incubator for neonatal patients, which is able to perform the sensing and statistical treatment of the data collected from the equipment:

- Measuring physical quantities such as: temperature, humidity and noise;
- To be low cost, easy to handle, and reliable;
- Being able to perform the statistical treatment of the collected parameters;
- Issue detailed reports and reports of the parameters provided by the equipment being measured.

Therefore, the development of a calibration instrument using accessible and low cost resources is not new, especially for incubators, however, with the technologies present in the market and the accessibility of these items, the evolution of the devices has been facilitated, integrating new ways of performing already consolidated tasks in a simplified, efficient and effective manner. Throughout this article, the construction of the proposed device and its integration with new technologies will be described.

This project was submitted to the Research Ethics Committee of CEULM/ULBRA, through Platform Brazil (CONEP).

Materials and Methods

The project was developed in three stages, arranged as follows: planning, construction and assembly of the prototype, and functional tests and direct comparisons of the results.

1. Planning

During the planning stage, the physical quantities provided by the equipment to be tested were taken into consideration. Thus, it was observed that neonatal incubators, in general, have as their main functions the control of temperature, humidity and oxygen. However, due to the hot air circulation system generated by the resistance, a characteristic noise inside the incubator that needs to be measured is noticeable, since the Brazilian standard NBR IEC 60601-2-19:2014 "Electromedical equipment - Particular requirements for basic safety and essential performance of incubators for newborns" establishes that the maximum sound level inside incubators in normal operation mode should be 60.0 dB. Therefore, the construction of the calibration procedure was focused on the parameters found in this type of equipment, with the exception of oxygen. Thus, the sensors to be used to build the prototype were selected to measure temperature, humidity and noise.

The prototype construction was focused on the use of accessible and low-cost tools, aiming to guarantee the same reliability in relation to the equipment already on the market. That said, the operating principle of the instrument developed was divided into stages, structured as follows: sensing, processing, treatment, and reporting.

Figure 1: Process flowchart.



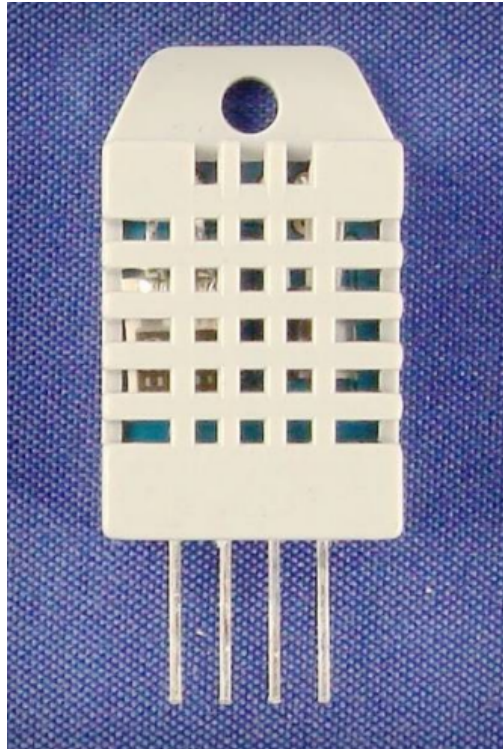
Source: Authors, 2022.

Sensing

The sensing stage will be performed through the use of sensors that will acquire the data provided by the measured equipment:

Temperature and humidity sensor DHT22:

Figure 2: DHT22 sensor.

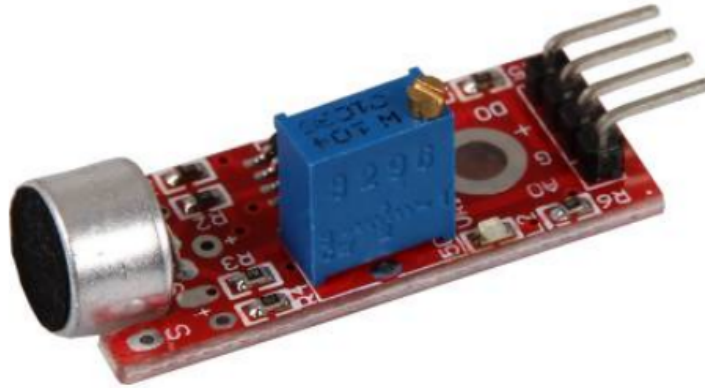


Model	DHT22
Power supply	3.3-6V DC
Output signal	digital signal via single-bus
Sensing element	Polymer capacitor
Operating range	humidity 0-100%RH; temperature -40~80Celsius
Accuracy	humidity +2%RH(Max +.5%RH); temperature <+-.0.5Celsius
Resolution or sensitivity	humidity 0.1%RH; temperature 0.1Celsius
Repeatability	humidity +-1%RH; temperature +-0.2Celsius
Humidity hysteresis	+-.0.3%RH
Long-term Stability	+-.0.5%RH/year
Sensing period	Average: 2s
Interchangeability	fully interchangeable
Dimensions	small size 14*18*5.5mm; big size 22*28*5mm

Source: Datasheet DHT22, 2017.

Noise Sensor KY037

Figure 3: Noise sensor KY-037.



Technical data / Short description

Digital Out: You can use a potentiometer to configure an extreme value for the sonic. If the value exceeds the extreme value, it will send a signal via digital out.

Analog Out: Direct microphone signal as voltage value

LED1: Shows that the sensor is supplied with voltage

LED2: Shows that a magnetic field was detected

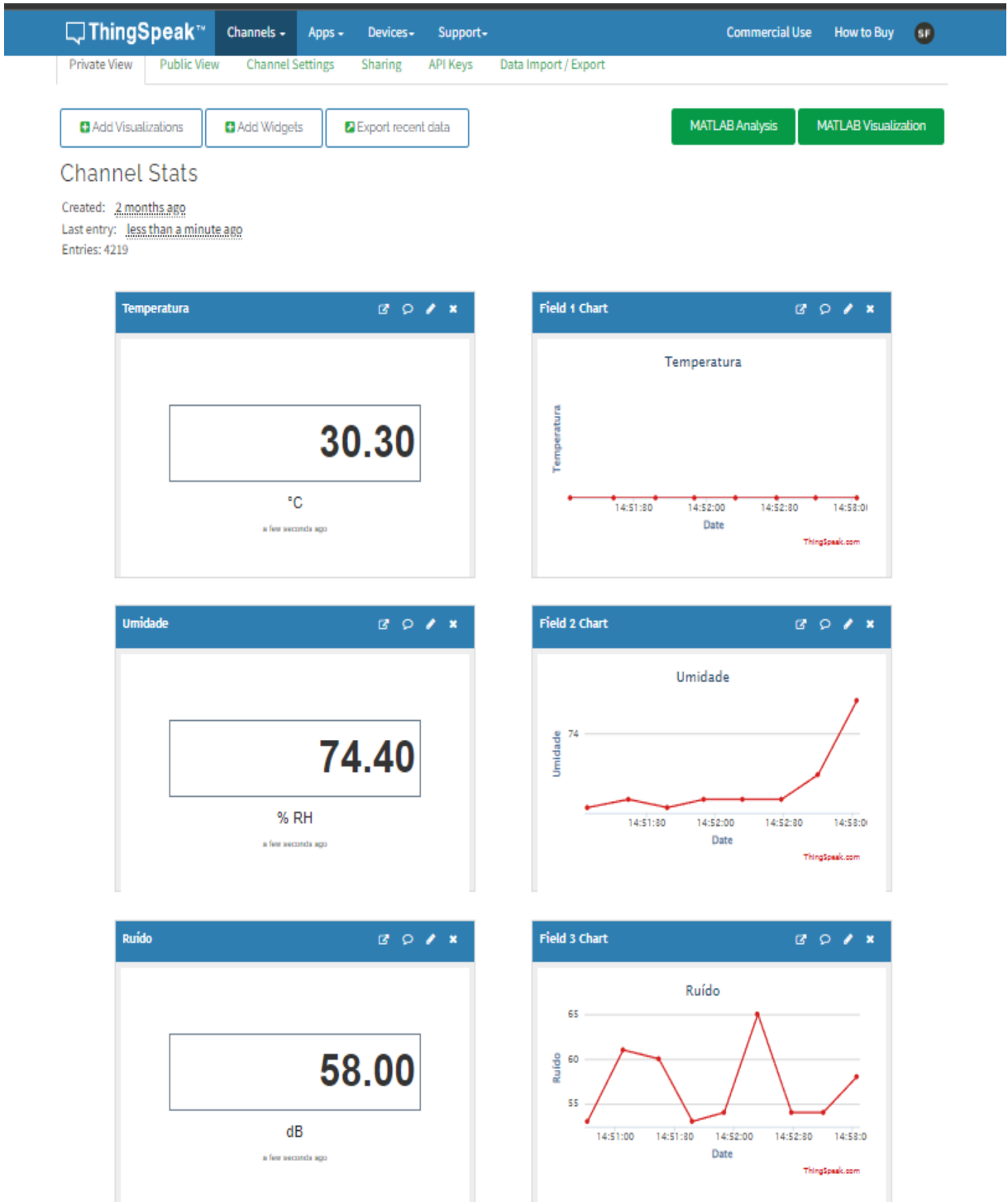
Source: Datasheet Ky-037, 2020.

Processing

For the processing of this data acquired by the sensing stage we used a programmable board called ESP 32, which has the possibility of integrating its functionality via wifi and currently has high accuracy compared to competing embedded. This data will be sent to the MATLAB platform through an MQTT server located in a domain that also belongs to mathworks, via internet connection.

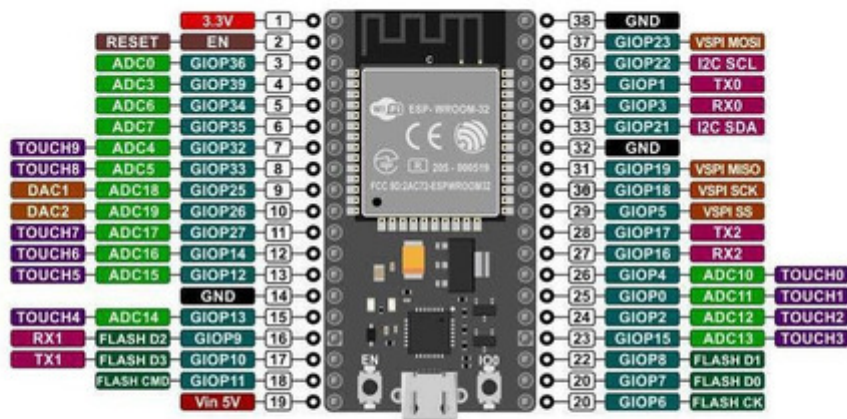
Server Mqtt - ThingSpeak

Figure 4: Interface ThingSpeak.



Source: Authors, 2022.

Figure 5: ESP-32 Module.



Model	ESP-WROOM-32
Power Supply	2,7 a 3,6 VDC
Output Signal	Analog and Digital (including PWM)
Processor	Xtensa 32-Bit LX6 Dual Core
WiFi	802.11 b/g/n: 2.4 a 2.5 GHz
Resolution	32-Bit of access and 4Mb
Interfaces	UART, SPI, SDIO, I2C, I2S, IR, PWM;
Support	Arduino IDE, Lua e MicroPython, Code C basic;

Source: Datasheet ESP-Wroom-32, 2020.

Treatment

The treatment of the data provided by the ESP 32 will be processed by a firmware developed in the Matlab platform, which will be responsible for the integration of the user interface and statistical treatment of the collected data. In this way, the operator will be able to visualize the execution of the procedure.

Report

At the end of the calibration procedure, a report will be developed to show the events observed during the calibration test, thus classifying the equipment's suitability for use. In addition, it will contain information related to the identification of the equipment, customer, and service provider, thus constituting a standardized report that can be traced later.

Figure 6: Interface App Designer.



Source: Authors, 2022.

2. Building and assembling the prototype

The prototype assembly was divided into two parts where the firmware was developed to perform the programming, control, and distribution of the data, and the hardware, responsible for the acquisition and processing of the obtained data.

The hardware consists of a logic board responsible for processing the data obtained through sensors that will be strategically positioned inside the incubator. The processing of this data is performed by programming based on some internal conversion calculations of the board used. The ESP-32 was chosen because of its resolution in receiving data that is more accurate than other competitors, thus avoiding a percentage of error when collecting these data from the physical environment.

Therefore, the data collected during the measurement will be forwarded to a MQTT server, which will only have the function of allocating and making available the data provided by the ESP. The data will be statistically treated by Matlab software.

To build the application responsible for the interface and data processing, the app designer was used, MATLAB's graphical customization tool, which allowed the construction of a customized interface according to the needs of the calibration procedures. The graphical interface was built in a simplified way aiming at an easy understanding for those who operate it, thus allowing the initialization of the

calibration procedure steps, which can be executed according to the predefined programming in the equipment under test. With this, the information collected by the hardware will be processed by a statistical calculation, where the standard deviation, measurement uncertainty and k factor will be verified, in order to make sure that the equipment's operation is within what is expected for its error margin, thus ensuring its suitability for use.

The calibration test will be divided according to the programming of the temperature in the incubator designed to be collected every 5 min at a frequency of three times for each sample. The temperatures used in the programming are: 30°C, 35°C, and 39°C.

3. Functional tests and direct comparisons of results

During this step, it was necessary to perform a series of tests to ensure the full operation of the flowchart already established (sensing, processing, treatment and reporting), where the verification of the operation of the sensors was performed as well as the veracity of the measured values, the ESP connection with the wifi network and sending packets to the MQTT server, after this verification and from there the data could already be monitored. The next test was the connection to the MATLAB platform and the integration of the obtained values with the statistical treatment code to be visualized via the user interface application. Therefore, after ensuring the full operation of the system, the calibration tests could be performed.

Initially in the prototyping phase, it was necessary to build an environment where it would be possible to simulate an incubator, so an adiabatic environment was built with cardboard box material for the casing, Styrofoam for thermal insulation, and reflective tape to ensure that the internal environment was as isolated as possible from the external environment, where we could have a fixed temperature value to be verified the variation of the sensor. However, during the execution of the tests, inconsistencies were observed in the values offered for measurement, indicating variation in the values obtained.

Thus, there was the need to perform the tests with consistent values so that the validation of the developed analyzer's operation could be concluded. For this, the Fanem IT-158/TS neonatal transport incubator provided by the clinical engineering of the Balbina Mestrinho State Maternity was used. This equipment in question is out of

circulation due to compromised structures, thus not being used by the medical staff of this hospital unit.

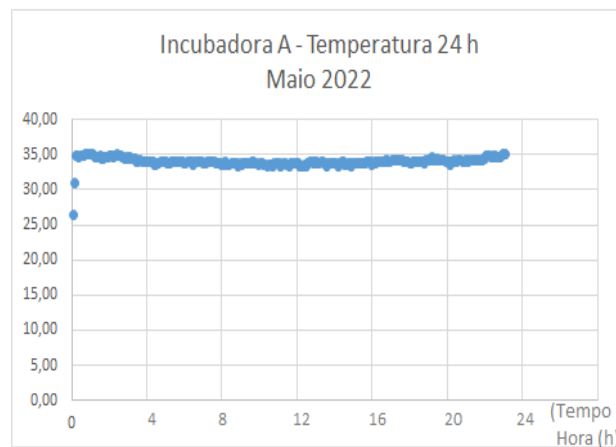
During the calibration test, a device to check temperature and humidity called Thermohygrometer was used to help compare the values obtained by the analyzer, thus making it possible to check the linearity and accuracy of the data obtained.

Then, the calibration test was performed for 24 hours in order to check the full operation of the equipment under test. During the verification it was possible to notice a variation in the values shown in the incubator in relation to the values measured by the analyzer and the thermohygrometer, thus indicating the need for intervention in the equipment measured, through corrective maintenance.

The data obtained by the analyzer and the hygrometer were similar throughout the procedure, presenting minimal variations between 0.10°C and 0.20°C .

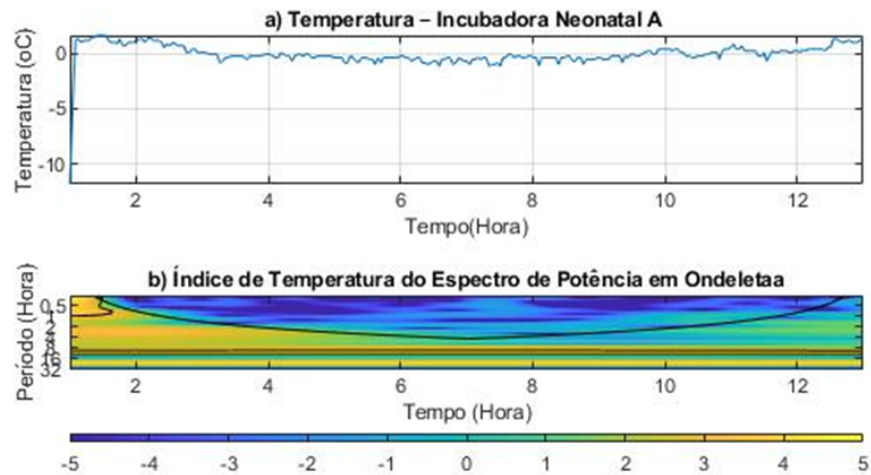
Simulation in Incubator A (temperature parameters)

Graph 1. 24h data - Temperature.



After the simulation of the calibration test was completed, a Wavelet (Wavelet Graph) was performed with the data obtained, so that it is possible to highlight the consistency of the measurements during the procedure.

Graph 2. Temperature - Wavelet Transform



Final Considerations

During this article, the development of a calibration instrument for neonatal incubators was presented, which had as objectives the creation of a low cost and simplified usability analyzer that would ensure the same quality and safety as the equipment already on the market. As shown in the results, the developed instrument has the ability to accurately measure measurable physical quantities such as humidity, temperature and noise, and is able to perform statistical treatments with the data collected by it, ensuring the reliability of the parameters delivered by the equipment under test. In addition, the MATLAB platform enabled the integration of new resources, which allowed communication via the internet, not requiring the connection of cables for data transmission, being sent via MQTT server.

The development of calibration instruments for neonatal incubators is not a new subject and it is possible to find several projects with the same objective, however, with technological advances it is possible to integrate new technologies present in the market, thus bringing innovation to this type of procedure. The results obtained during the testing phase open possibilities for changes in the way that the collection of this data is carried out for the expected purpose, in order to speed up the existing process, with currently available technology. Therefore, the performance obtained during the testing phase proved satisfactory, considering that the proposed objectives were met.

References

ALBUQUERQUE, A. A. M. et al. Sistema Automático de Avaliação de Desempenho de Incubadoras Neonatais, segundo a norma NBR IEC 60.601-2-19. In: **ANAIS DO XXIII CONGRESSO BRASILEIRO DE ENGENHARIA BIOMÉDICA (CBEB)**. [S.l.: s.n.], 2012.

ALEXANDRINO, J.C. et al. Desenvolvimento de um analisador de incubadoras neonatais. **Revista Brasileira de Engenharia Biomédica**, Rio de Janeiro, v. 27, n. 3, p. 194-207, 2011.

AMERICAN ACADEMY OF PEDIATRICS. **Follow-up Care of High-Risk Infants**. Pediatrics, [S.l.], v. 114, p. 1377-1397, 2004.

ASSOCIAÇÃO BRASILEIRA DE NORMAS TÉCNICAS. **NBR ISO/IEC 17025: Requisitos gerais para a competência de laboratórios de ensaio e calibração**. 2017.

BERTOLETI, Pedro. **Projetos com ESP32 e LORA**. 1. ed. São Paulo: Instituto Newton C. Braga. 2019.

CAMPOS, Carlos A. B. **Calibração de equipamentos**. Instituto de medidas do Estado do Paraná. Curitiba, PR, jun. 2014. Apresentação em Slideshare. 77 slides, color. Available at: https://www.saude.pr.gov.br/sites/default/arquivos_restritos/files/documento/2020-05/apresentacao_calibracao_de Equipamentos_2014.pdf. Accessed on: 11 out. 2021

CHAPMAN, Stephen J. **Programação em MATLAB para Engenheiros**. Technical translation Flávio Correa da Silva. 2. ed. São Paulo: Pioneira Thomson Learning. 2003.

COSTA, Enilson J. L. **Análise crítica de incubadoras neonatais a partir de medições de parâmetros dos ambientes interno e externo**. 2009. 192 f. Tese (Doutorado em Engenharia Mecânica) - Universidade Federal da Paraíba, João Pessoa, 2009.

ESP32 Technical Reference Manual. **Espressif Systems**. 2022.

GONCALVES, Veronica Lima. **Avaliação do desempenho metrológico de incubadoras neonatais em hospital público de grande porte e alta complexidade utilizando sistema de coleta automatizado**. 2018. 135 f. Dissertação (Mestrado em Ciências) - Universidade Federal de Uberlândia, Uberlândia, 2018.

IAIONE, F. **Desenvolvimento de um Equipamento Eletrônico para o Ensaio de Incubadoras Infantis**. Dissertação (Mestrado em Engenharia Elétrica) – Universidade Federal de Santa Catarina, Santa Catarina, 1999.

KOBAYOSHI, Marcelo. **Calibração de instrumentos de medição**. São Paulo: Editora Senai-SP, 2012.

KY-037 Microphone sensor module (high sensitivity). **JOY-IT Time for more**. 2021.

LIU, Thomas. **Digital-output relative humidity & temperature sensor/module DHT22 (DHT22 also named as AM2302)**. Aosong Electronics Co.,Ltd. China, Guangdong Province, Guangzhou, Baiyun. 2018.

MINISTÉRIO DA SAÚDE. **Atenção à saúde do recém-nascido - Guia para os profissionais de saúde: Cuidados Gerais**. 2. ed. Brasília: Ministério da Saúde, 2014. v.4: il.

MINISTÉRIO DA SAÚDE. **Atenção à saúde do recém-nascido - Guia para os profissionais de saúde: Cuidados com o recém-nascido pré-termo**. 1. ed. Brasília: Ministério da Saúde, 2011. v. 4.: il. – (Série A. Normas e Manuais Técnicas).

MINISTÉRIO DA SAÚDE. **Equipamentos Médico-Hospitalares e o Gerenciamento da Manutenção: capacitação a distância**. Ministério da Saúde, Secretaria de Gestão de Investimentos em Saúde, Projeto REFORSUS. – Brasília, DF: Ministério da Saúde, 2002. 709 p.: il. (Série F. Comunicação e Educação em Saúde).

MINISTÉRIO DA SAÚDE. AGÊNCIA NACIONAL DE VIGILÂNCIA SANITÁRIA (ANVISA). **Resolução da Diretoria Colegiada – RDC nº 2, de 25 de janeiro de 2010, dispõe sobre o gerenciamento de tecnologias em saúde em estabelecimentos de saúde**. Diário Oficial da União, Poder Executivo, Brasília, DF, 25 de janeiro de 2010.

VOCABULÁRIO INTERNACIONAL DE METROLOGIA. **Conceitos fundamentais e gerais e termos associados (VIM 2012)**. Duque de Caxias, RJ: INMETRO, 2012. 94 p.