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RESEARCH ARTICLE

AN INTEGRATIVE DESIGN APPROACH FOR ADAPTING OPEN-SOURCE MEDICAL DEVICES TO RESOURCE-LIMITED SETTINGS: DESIGN, LOCAL MANUFACTURE AND TECHNICAL EVALUATION OF THE LAAFI-RESPIR VENTILATOR IN BURKINA FASO

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Abstract

In low-income countries, many medical devices sit unused or out of service because local manufacturing, maintenance and energy conditions were not considered at the design stage. The open-source ventilators produced during the COVID - 19 pandemic rely on components that are rarely available in Sahelian countries. This study proposes and tests a design approach that adapts an existing open-source solution to the local context. A six-step approach, in which contextualization is carried out during functional analysis through the network of local manufacturing and maintenance actors, was applied to LAAFI-RESPIR, a bag-valve mechanical ventilator built at IRSAT (Burkina Faso). Five open-source projects were scored on five criteria. Bench tests measured the volume delivered by five cams over ten cycles each and the respiratory rate over controller settings of 40 to 80%. Bias, repeatability and equivalence with the MHRA tolerance (two one-sided tests) were analyzed, and the prototype was compared with the MHRA specification. OxyGEN was selected (13 of 15 points). Functional analysis added eleven constraint functions covering maintenance, local manufacturing, energy, safety and mobility.

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About 90% of the prototype is made from locally available materials; it runs on grid power, a photovoltaic module or a battery (3 h measured autonomy), is assembled with two open-end wrenches and uses fifteen hand-changeable cams. The rate was adjustable from 12 to 45 breaths/min, linear with the setting ($R^2 = 0.993$). Tidal volumes of 419 to 645 ml for nominal cams of 450 to 650 ml showed a systematic negative bias (−9.1% to −0.7%) with high repeatability (coefficient of variation ≤ 0.91%) and stayed within the MHRA tolerance of ±(4 ml + 15%) (equivalence, $p < 0.001$). Positive end-expiratory pressure, FiO_2 control and alarms are missing. **Conclusion:** The approach makes it possible to design an emergency medical device for local manufacture and maintenance without degrading its ventilation function. Because the safety functions are not yet present, the prototype is a bench demonstrator and is not suitable for clinical use; these functions must be added and verified before preclinical trials.

Introduction:-

West African countries have some of the lowest critical care capacities in the world. An estimate covering 54 African countries reported an average of 3.1 intensive care beds and 0.97 ventilators per 100,000 inhabitants, with West Africa having the fewest intensive care beds (Craig et al., 2020). Availability is a further problem: 30 to 40% of medical equipment in low-resource countries is out of service (Perry & Malkin, 2011; Samenjo et al., 2023), mostly because it was designed in and for industrialized countries, without regard to local spare-parts supply, maintenance skills or the quality of the electricity supply (Malkin, 2007; World Health Organization [WHO], 2011). Free (2004) showed that the adoption of a health technology depends as much on cultural, economic and infrastructural factors as on its technical performance, and Samenjo et al. (2023) found that durability, maintenance and repair principles are only beginning to enter the design of medical devices for sub-Saharan Africa. This diagnosis is mostly framed in terms of procurement and maintenance policy; few studies offer an operational method that turns these constraints into design requirements.

The COVID-19 pandemic made the problem acute and led to the development, worldwide, of low-cost open-source ventilators whose plans are freely distributed (Pearce, 2020). Open-source hardware has become a route to low-cost scientific and medical technologies (Pearce, 2012; Weber, 2004), although its use in medicine raises questions of reliability, safety and regulatory compliance (Niezen et al., 2016). Many of these ventilators automate a self-inflating bag-valve-mask (BVM) resuscitator, a principle proposed as early as 2010 (Al Husseini et al., 2010). Petsiuk et al. (2020) described a 3D-printable ventilator costing less than 170 dollars, validated on an artificial lung, and Fang et al. (2020) built a pneumatically driven enclosure around a standard BVM. Among the best-documented projects are OxyGEN, in which a lever driven by interchangeable cams sets the volume and the inspiration-to-expiration (I:E) ratio (Protofy.xyz, 2020); MUR, which uses a compressor and standard valves (MUR Project, 2020); MIT's E-Vent, which compresses a BVM with a motor (MIT Emergency Ventilator Project, 2020); OpenBreath, built with low-cost standard components (OpenBreath, 2020); and MakAir, a pressure-controlled ventilator with dedicated electronics and pneumatics (MakAir, 2020). These projects aimed at fast production in industrialized countries with working supply chains. Local maintainability, manufacture with basic workshop means and energy autonomy during power cuts were not among their design criteria, and their components, materials and processes are rarely available in Burkina Faso.

Since concurrent engineering (Sohlenius, 1992), design science has developed approaches that bring life-cycle viewpoints into early design: design for cost (Pahl et al., 2007), assembly (Boothroyd et al., 2010), manufacture (Stoll, 1988) and reliability (Ireson & Coombs, 1988), grouped as design for X (DfX) and built into design support systems (Huang et al., 2000; Kuo et al., 2001), followed by ecodesign (Rossi et al., 2016), now regulated in Europe (European Union, 2024). In West Africa, Marouzé (1999) proposed the CESAM method to steer the technological trajectory of equipment, Godjo et al. (2006) added participatory design, and Nzié (2006) and Azouma and Giroux (2009) formalized the integration of maintenance into design. Bationo (2007) and Bationo et al. (2009) showed that maintenance relies on a sociotechnical network of local actors (manufacturers, repairers, suppliers) that must be represented from the start of design, and the preliminary maintenance criteria analysis tool puts this into practice (Bationo &Boujut, 2022). Bagnaba and Bationo (2024) identified obstacles to the use of these methods by West African equipment manufacturers: complexity, lack of training and poor fit with available resources. Two recent frameworks respond to them. Design for the Maintenance of Sociotechnical Networks (DFMSN) formalizes the maintenance network of a piece of equipment and proposes design rules and indicators for service life, procurement lead time and parts cost; its application to a two-wheel tractor in Burkina Faso added rules on functional simplification, local procurement, manufacturability, autonomous maintenance and documentation (Bationo et al., 2026). The frugal and endogenous design approach (FEDA) starts from the resources, know-how and actors available in the region (Bagnaba& Bationo, 2026). Soulama et al. (2024) also showed, on a locally designed forced-

convection dryer, the value of quantitative performance evaluation for validating context-adapted design choices. These methods deal with agricultural and food-processing equipment. They have not been applied to medical devices, whose safety and performance requirements are standardized, and they do not explain how to adapt an existing solution designed elsewhere.

Frugal innovation seeks solutions that cost much less, focus on essential functions and perform well enough for underserved users (Radjou et al., 2013; Weyrauch &Herstatt, 2016). Tran and Ravaud (2016) showed its potential in medicine, provided that cost reduction does not compromise safety; Chakravarty (2022) described frugal medical devices developed by South African manufacturers; and Dabić et al. (2022) called for better evaluation of the performance of frugal innovations, whose design process is rarely formalized. For ventilators, that evaluation has clear reference points. Critical care ventilators fall under ISO 80601-2-12 (International Organization for Standardization [ISO], 2020), ventilatory support equipment under ISO 80601-2-80 (ISO, 2018), and alarm systems under IEC 60601-1-8 (International Electrotechnical Commission [IEC], 2006). In 2020, the UK Medicines and Healthcare products Regulatory Agency (MHRA) published a minimum specification for rapidly manufactured ventilator systems (RMVS). It requires, among other things, a rate adjustable from 10 to 30 breaths/min, a default I:E ratio of 1:2 (optionally 1:1 to 1:3), positive end-expiratory pressure (PEEP) of 5 to 20 cmH_2O, a backup battery of at least 20 minutes, alarms for power failure, disconnection, pressure and volume, and a volume accuracy of ±(4 ml + 15%) (Medicines and Healthcare products Regulatory Agency [MHRA], 2020). This specification is the comparison baseline for the present study.

Table 1 summarizes this review and the three gaps it reveals: (G1) design methods adapted to the African context do not deal with the adaptation of existing open-source solutions; (G2) open-source ventilators are not designed to be manufactured, maintained and powered in Sahelian countries; and (G3) prototypes from frugal approaches are rarely evaluated statistically against an international specification.

Table 1:- Positioning of the study relative to the literature.

Research stream	Contribution	Gap for the Burkinabe context	Response of this study
Medical devices in resource-limited settings	Diagnosis of non-functionality	Few operational design methods	Local constraints translated into functions and criteria
West African design methods (CESAM, sociotechnical network, DFMSN, FEDA)	Integration of the user, maintenance, the actor network and endogenous resources	Agricultural and food-processing equipment; no regulated medical devices	Adaptation of an open-source solution for a medical device
Open-source ventilators	Simple principles, free plans	Components not available locally; energy not addressed	Local manufacture, maintenance with two wrenches, hybrid energy
Frugal innovation	Low-cost solutions	Process rarely formalized; performance rarely evaluated	Six-step approach; statistical evaluation
Standards and specifications (ISO, IEC, MHRA)	Performance and safety requirements	Rarely applied to frugal prototypes	Conformity matrix, safety analysis and roadmap

The research problem of this article is therefore: how can the design process build local manufacturing, maintenance and energy constraints into the adaptation of an open-source medical device without compromising its technical performance? Three research questions follow. (RQ1) What procedure allows an open-source solution to be selected and then contextualized in a traceable way? (RQ2) Which functions must be added to the original principle for the equipment to be manufactured and maintained locally? (RQ3) How does the resulting prototype compare with the international requirements for emergency ventilators, including their safety requirements?

We address these questions through the design, manufacture and technical evaluation of a positive-pressure mechanical ventilator, LAAFI-RESPIR (*laafi* means "health" in Mooré), built at IRSAT. The contributions are: (i) a six-step design approach for integrating open-source solutions, in which contextualization takes place during functional analysis; (ii) a functional analysis extended with maintenance, manufacturing, energy, safety and mobility functions; (iii) a working bench prototype made with about 90% local materials and powered by hybrid energy; and (iv) a statistical evaluation of performance against the MHRA specification, with a cam calibration law and a conformity and safety analysis that guides further development. The prototype is a research demonstrator: it does not yet include PEEP, FiO_2 control or alarms, and it has not been used on patients (see "Safety limitations and intended use").

Materials and Methods:-

Research design:-

The work follows a design-science research approach based on a case study: a design approach is proposed, applied to a real case and evaluated through the performance of the resulting artifact. The case is the design of the LAAFI-RESPIR ventilator at IRSAT, Ouagadougou, between March and August 2020, during the COVID-19 pandemic. The work was the subject of a professional master's thesis in industrial engineering (Bagnaba, 2020). This article takes up its design and test data, analyzes them statistically and places them against the literature and international requirements.

Team, equipment and instruments:-

The multidisciplinary team brought together skills in industrial engineering, electronic and biomedical engineering, mechanical engineering and electrical engineering. Table 2 lists the resources used.

Table 2:- Team, equipment and measuring instruments.

Category	Item	Characteristics and use
Human resources	Multidisciplinary team	1 PhD in industrial engineering, 1 electronics engineer, 2 industrial engineering students, 4 general mechanics technicians
Software	SolidWorks	3D modeling of the prototype
	MATLAB	Generation of cam profiles from the OxyGEN model
Manufacturing	IRSAT general mechanics workshop	Lathe, milling machine, drill, welding station
	3D printer	Cam clamps and position sensor holders
	CNC cutting	Cutting of the Plexiglas cams
Reference	Reproduced OxyGEN open-source mock-up	Understanding the principle, first trials
Measurement	CITREX H5 gas flow analyzer (IMT Analytics, Switzerland)	Bidirectional measurement of flow, pressure and volume; manufacturer's volume accuracy ±2% of reading
	SmartLung 2000 test lung	Load for the volume tests
	Pressure gauge	Maximum pressure in the pneumatic circuit
	Stopwatch	Respiratory rate measurement
	Multimeter	Checking of the electrical wiring

Integrative design approach for open-source solutions:-
The proposed approach has six steps and an iteration loop (Figure 1).

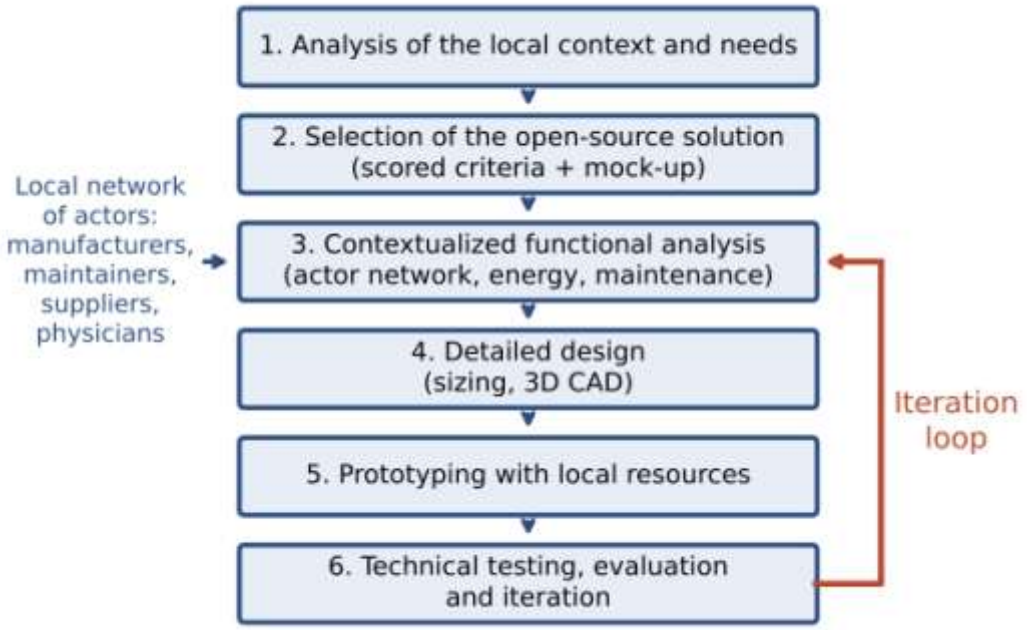


Figure 1:- Six-step integrative design approach for open-source solutions. The local network of actors (manufacturers, maintainers, suppliers, physicians) takes part in the functional analysis, where the solution is contextualized.

1. **Analysis of the local context and needs.** Study of the conditions of use (infrastructure, energy, medical practice), then definition of the requirements with stakeholders.
2. **Selection of the open-source solution.** Comparison of existing solutions against criteria derived from the needs, then reproduction of a mock-up of the main function with local materials to check feasibility and anticipate manufacturing problems.
3. **Contextualized functional analysis.** Identification of the service functions from the external environment, explicitly including the local manufacturing and maintenance actors (manufacturers, maintainers, technicians, physicians, component suppliers), followed by the functional specification and the choice of technological solutions according to what this network can supply. The solution is contextualized at this step.
4. **Detailed design.** Sizing and 3D modeling.
5. **Prototyping.** Manufacture of a working prototype using local resources wherever possible.
6. **Testing, evaluation and iteration.** Technical tests, performance evaluation and, if needed, a return to the functional analysis.

Selection criteria for the open-source solution:-
Five criteria, each scored from 1 to 3, were used to compare the projects (Table 3). They were set during the design phase (Bagnaba, 2020) and reflect the conditions for local reproducibility identified for small-business equipment in Burkina Faso (Bationo, 2007) and the DFMSN principles of local procurement and manufacturability (Bationo et al., 2026). Documentation determines whether a local team can reproduce and modify the equipment without the original designer. Hardware simplicity reflects compatibility with the skills and conventional machine tools of local workshops. Local availability of hardware governs both manufacture and future maintenance. Parameter display and adjustment reflect fitness for clinical use. Manufacturing cost governs affordability for health facilities. The criteria are unweighted, so each carries the same importance.

Table 3:- Scoring grid for the open-source solution selection criteria.

Criterion	Score 1	Score 2	Score 3
Detailed documentation	A few documents	Documentation available	Very detailed documentation
Hardware simplicity	Very complex hardware	Complex hardware	Simple hardware
Local availability of hardware	Not available locally	Less than 50% available locally	More than 50% available locally
Parameter display and adjustment	Less than 50% of parameters visible and adjustable	Less than 75% visible and adjustable	All parameters visible and adjustable
Manufacturing cost (CFA francs)	More than 2,000,000	1,000,000 to 2,000,000	Less than 1,000,000

Functional analysis:-

The functional analysis follows standard NF X 50-151: interactor diagram ("octopus" diagram), functional specification and FAST diagram. What sets it apart is that the local manufacturing and maintenance actors and the available energy sources are included among the elements of the external environment, so that the corresponding constraint functions are formulated and quantified in the same way as the medical functions.

Technical test protocol:-

All tests were bench tests without patients:-

- **Delivered volume.** Five cams with nominal volumes of 450, 500, 550, 600 and 650 ml (I:E ratio of 1:2) were tested. For each cam, the insufflated volume was measured over ten consecutive cycles with a CITREX H5 flow analyzer, the ventilator being connected to a SmartLung 2000 test lung.
- **Respiratory rate.** The controller setting was varied from 40 to 80% in 5% steps, and the number of cycles per minute was measured with a stopwatch.
- **Functional tests.** Operation on grid power and on a photovoltaic module, continuous operation for 24 hours, battery autonomy, indicator lights, pressure gauge, controller and emergency stop button.
- **Clinical demonstration.** The prototype was presented at Yalgado Ouédraogo University Hospital (CHU-YO) to anesthesiologists and intensivists from the Burkina Society of Anesthesia, Intensive Care and Emergency Medicine (SARMUB). It was not used on patients.

Statistical analysis and conformity assessment:-

For each cam we calculated the mean, standard deviation, coefficient of variation (CV), bias relative to the nominal value and 95% confidence interval of the mean. A one-sample Student's *t*-test tested the hypothesis of zero bias. Because a statistically significant difference is not necessarily clinically relevant, we also tested equivalence with the two one-sided tests procedure (TOST), using the MHRA tolerance of ±(4 ml + 15% of the value) as the margin. A linear regression between nominal and measured volume gave a calibration law for the cams, and a second linear regression related the controller setting to the respiratory rate. Calculations were done in Python (NumPy, SciPy). Finally, a conformity matrix compared the prototype with the requirements of the MHRA (2020) specification, classifying each requirement as met, partially met, not met or not evaluated.

Results:-

Selection of the open-source solution:-

Table 4 and Figure 2 compare the five projects. OxyGEN scored highest (13 of 15) thanks to very detailed documentation, simple hardware that is mostly available locally and a low manufacturing cost. Its weak point is parameter display. OpenBreath (10/15) has a better interface but relies on components not available locally. MakAir and E-Vent (7/15) were penalized by the complexity of their hardware and their cost.

Table 4:- Comparison of open-source ventilator projects.

Project	Documentation	Simplicity	Local availability	Display and adjustment	Cost	Total	Rank
OxyGEN	3	3	3	1	3	**13**	**1**
OpenBreath	3	2	1	3	1	10	2
MUR	2	2	1	2	2	9	3
E-Vent (MIT)	2	1	1	2	1	7	4
MakAir	1	1	1	3	1	7	4

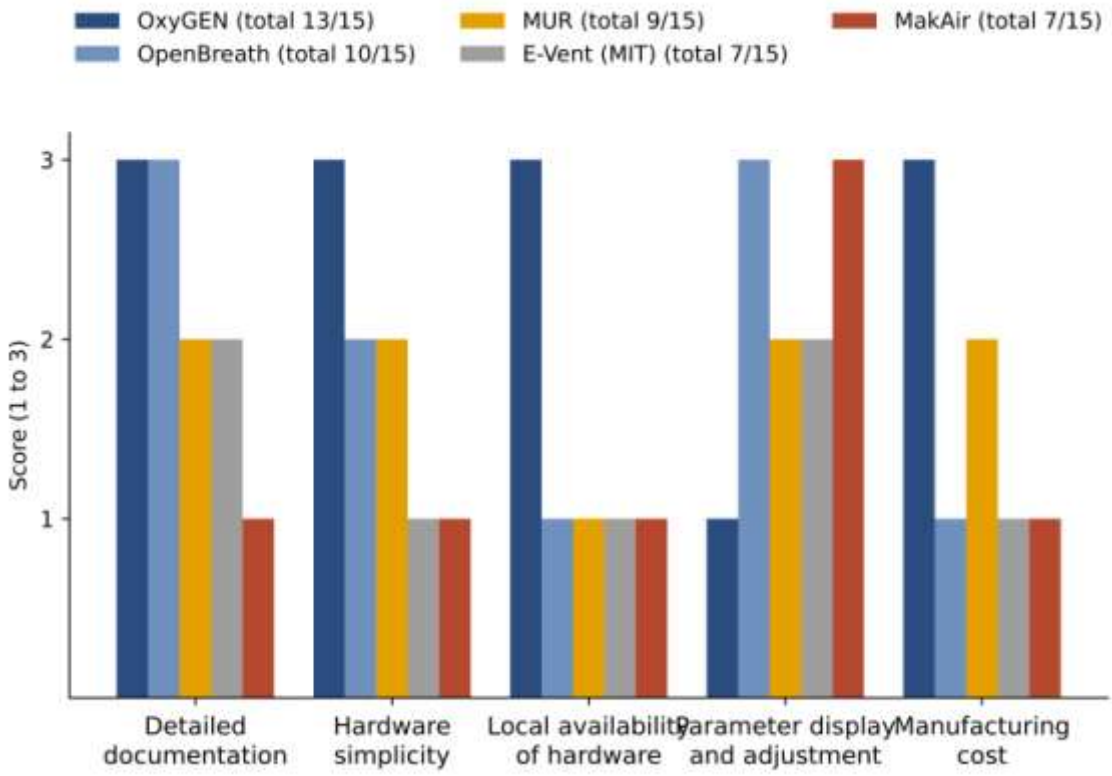


Figure 2:- Scores of the five open-source projects on the selection criteria. OxyGEN leads on four of the five criteria; its weakness in parameter display shaped the functions added during the functional analysis.

OxyGEN's weak score for display led directly to the addition of a controller with a display and of indicator lights during the functional analysis (see "Contextualized functional analysis"). The selected project was thus a starting point that the functional analysis had to complete.

Reproduction of the open-source mock-up:-

A mock-up based on the OxyGEN principle was built with local materials (Figure 3): a DC motor drives a cam that moves a lever, which compresses the self-inflating bag. This step confirmed technical feasibility with local means and revealed four shortcomings: changing a cam required a 13 mm open-end wrench; the rate was set without any display; no information on operating status was given; and the device could only run on grid power.



Figure 3:- Mock-up reproducing the OxyGEN principle with local materials (cam-driven lever compressing a self-inflating bag).

Contextualized functional analysis:-

Besides the patient, the ambient air and the physician, the interactor diagram (Figure 4) includes elements of the external environment that standard ventilator analyses leave out: the local manufacturer, the maintainer, local component suppliers, the power grid and solar energy. The result is one main function and twelve constraint functions (Table 5). Eleven of them (FC2 to FC12) do not exist in the OxyGEN project; they are the new functions of LAAFI-RESPIR.

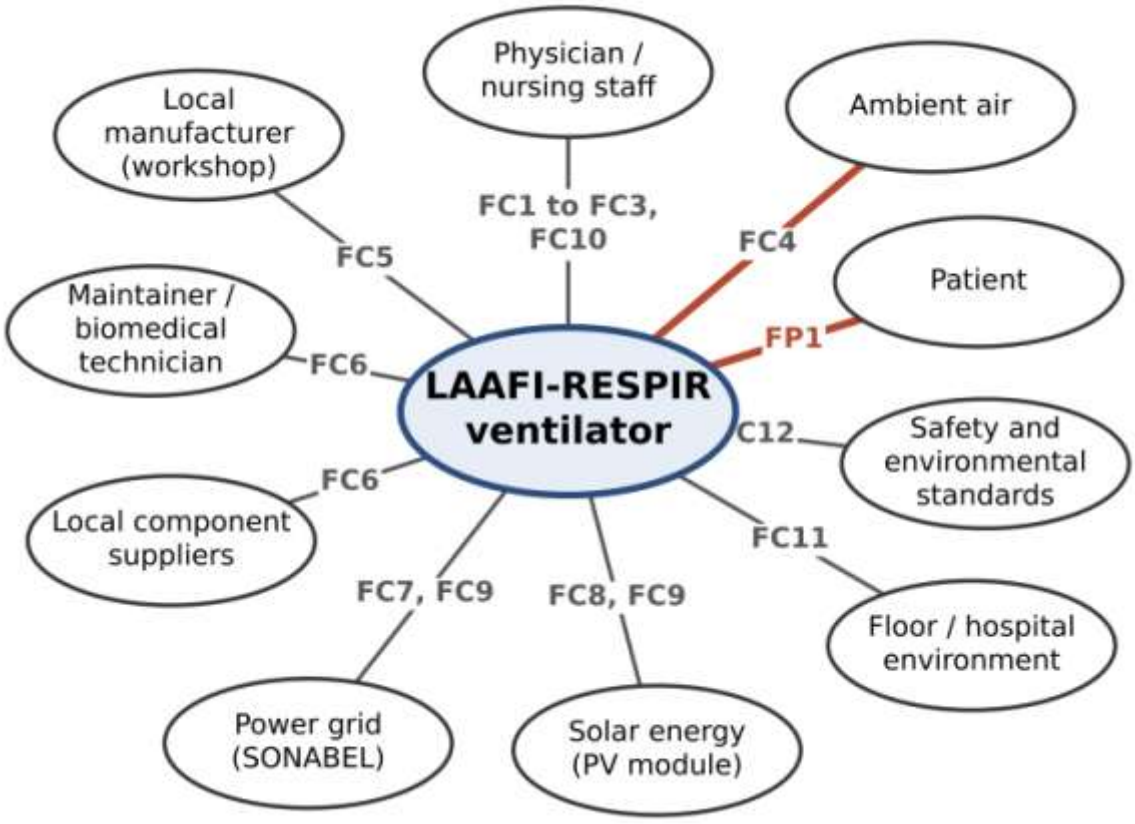


Figure 4:- Interactor ("octopus") diagram of the LAAFI-RESPIR ventilator. FP1: main function. Constraint functions FC5 to FC9 represent the integration of the local manufacturing, maintenance and energy network.

Table 5:- Functional specification of the LAAFI-RESPIR ventilator.

Function	Criterion	Level	Flexibility
FP1: Assist the patient's breathing using ambient air	Tidal volume delivered	450 to 650 ml/cycle (5 cams)	±(4 ml + 15%)
	Maximum circuit pressure	20 cmH_2O	None
FC1: Adapt the volume and I:E ratio to the patient without tools	I:E ratio	1:1, 1:2, 1:3	None
	Number of cams	15 (5 volumes × 3 ratios)	None
	Cam clamp tightening torque	11 N·m	None
	Patient classes	Children (0 to 14 years), youth (15 to 24), adults (25 to 64), older adults (65 and over)	None
FC2: Set the respiratory rate	Rate	12 to 45 breaths/min (initial target: 12 to 60)	None
FC3: Inform the caregiver of the operating status	Indicator lights	2 (power on, cam rotation)	None
FC4: Protect the patient from ambient air	Antibacterial filtration	99.99% of bacteria and viruses	None
	Oxygen content of ambient air / enrichment	21%; connection to an oxygen outlet	±1%
FC5: Be manufactured with local means	Share of locally available materials	≥ 90%	n/a
	Processes	Conventional machine tools, welding, 3D printing, laser cutting	n/a
FC6: Be maintained by local technicians	Assembly and disassembly tools	2 open-end wrenches (10 and 13 mm)	None
	Components	Standard (608ZZ bearing, M6 and M8 fasteners)	n/a
FC7: Run on the power grid	Voltage	230 V / 50 Hz	±10%
FC8: Run on solar energy	Module voltage / power	12 V / 100 W	±10%
FC9: Keep running during power cuts	Battery autonomy	3 h	±10%
FC10: Stop immediately in an emergency	Emergency stop button	1 (250 V, 10 A)	None
FC11: Move and stay stable on different floors	Casters	4 (solid rubber, Ø 50 mm)	None
	Handle (L × W × H)	128 × 35 × 12 mm	±15%
FC12: Comply with safety and environmental standards	Noise level	25 dB	+5%
	Pollution and degradation	None	None

Four remarks apply to these criteria. First, the medical criteria (volume, I:E ratio, rate) come from clinical practice and from the open-source projects. The volume range of 450 to 650 ml covers adults but not children, even though FC1 lists a "children" class. Second, the manufacturing and maintenance criteria (FC5, FC6) are quantified and verifiable: share of local materials, tools limited to two wrenches, standard components. They turn general intentions such as "make maintenance easier" into design requirements that can be checked. Third, the energy criteria (FC7 to FC9) reflect frequent power cuts: the equipment must be able to run without the grid. Fourth, the rate range for FC2

was first set at 12 to 60 breaths/min. Bench tests over the controller settings used (40 to 80%) gave 12 to 45 breaths/min (see "Technical performance"), and the specification was revised to this measured range. It covers the 12 to 30 breaths/min used in adult ventilation but not the 10 to 12 breaths/min lower end of the MHRA range (Table 8).

The FAST diagram (Figure 5) translates these functions into technological solutions.

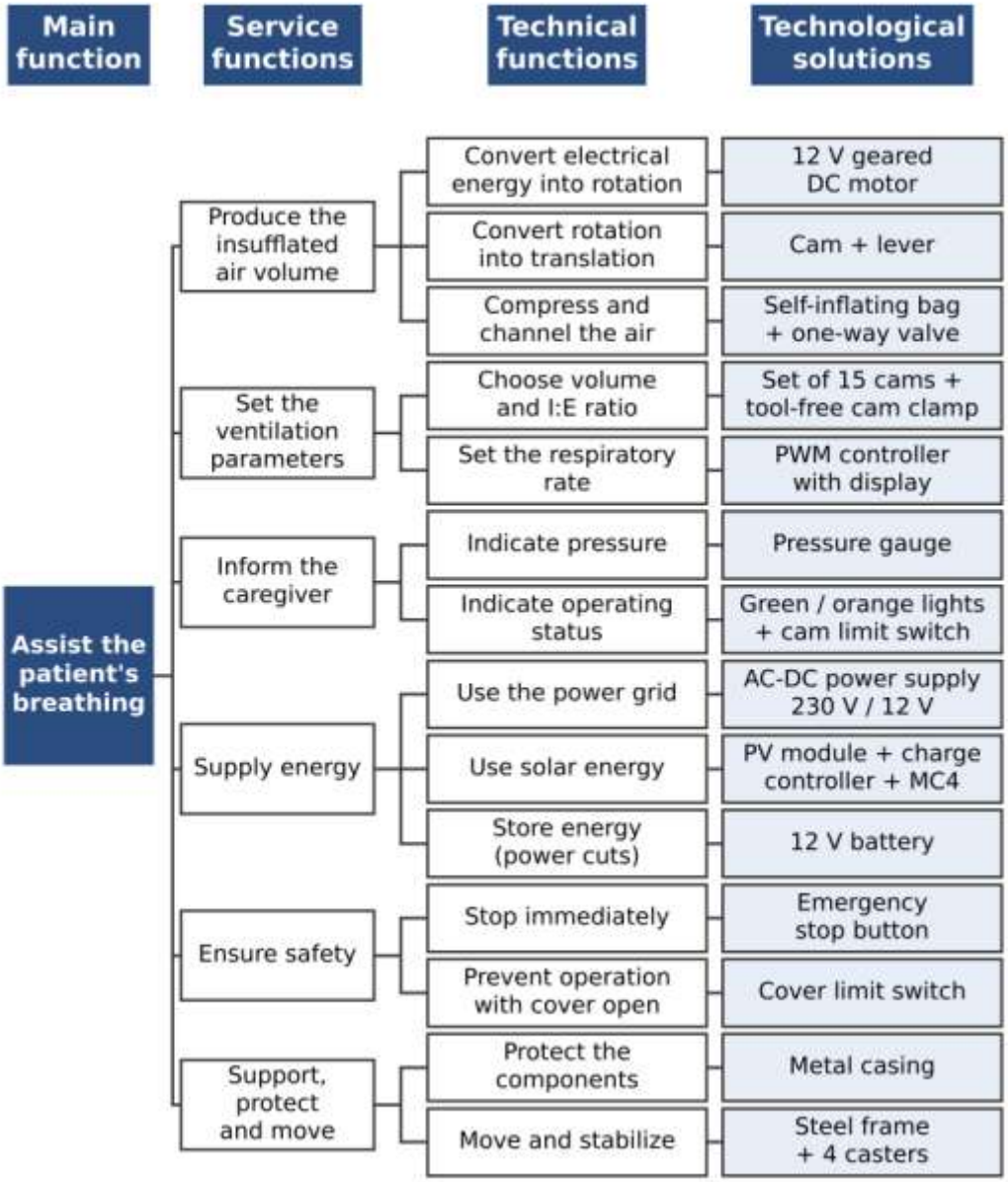


Figure 5:- FAST diagram of the LAAFI-RESPIR ventilator, from the main function to the technological solutions.

Detailed design and prototype:-

3D modeling (Figure 6) was used to check overall dimensions, access to components and assembly before manufacture. The prototype (Figure 7) consists of the following subassemblies. Figure 6 shows the three main subassemblies of the body (shell, mechanical drive and pneumatic circuit), and Figure 7 locates the controls described below: PWM controller, indicator lights, emergency stop button, pressure gauge, battery charge controller, air outlet and casters.

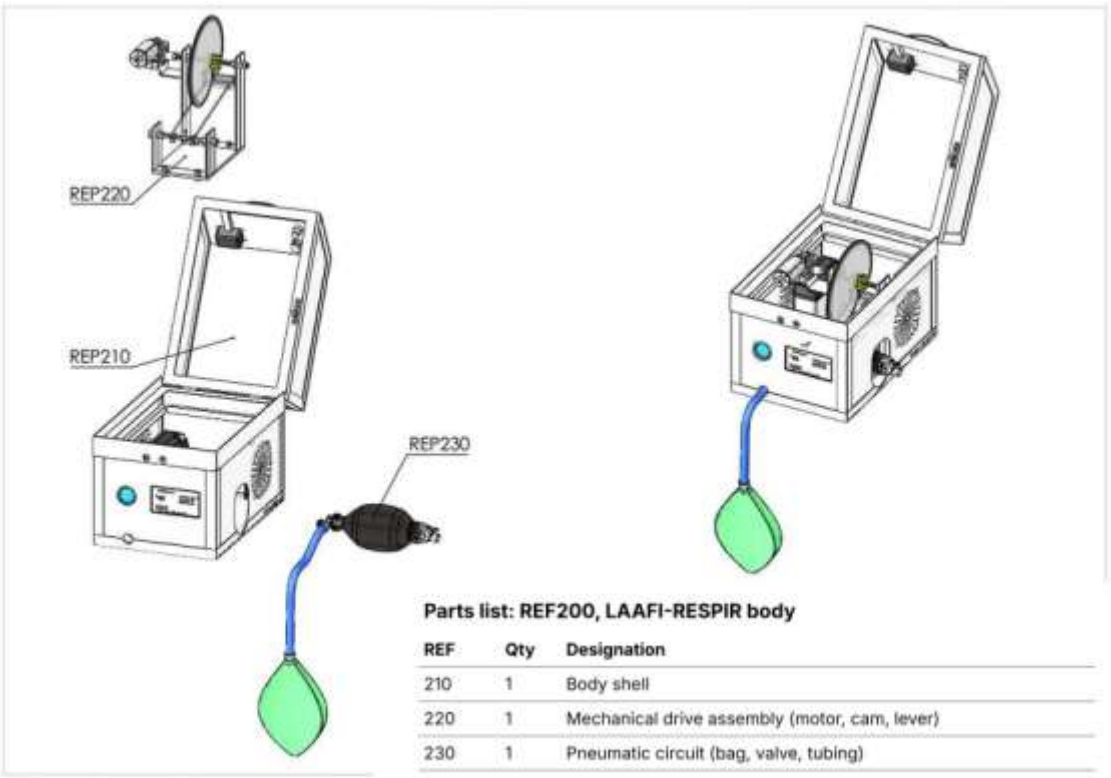


Figure 6:- 3D model of the prototype (SolidWorks): exploded view of the body (left) and assembled view (right).

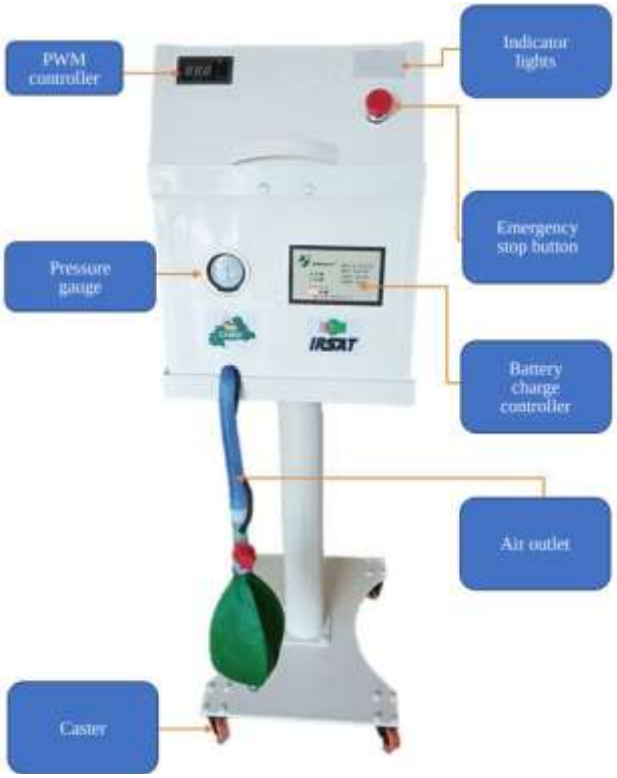


Figure 7:- LAAFI-RESPIR ventilator prototype built at IRSAT, with its controls and interfaces labeled.

Ventilation mechanism. A DC motor drives a cam that moves a lever. The lever compresses a self-inflating bag, whose air is directed to the patient through a one-way valve. An optional connection to an oxygen outlet allows the insufflated air to be enriched.
Cams. The cam profiles were derived from the geometric model of the OxyGEN project implemented in MATLAB (Bagnaba, 2020). Varying the lever stroke gave five volumes (450 to 650 ml) and three I:E ratios, for a total of fifteen laser-cut cams. A 3D-printed cam clamp lets them be changed by hand, whereas the mock-up required a 13 mm wrench.
Drive and control. The motor is a geared DC motor (Table 6). A pulse-width modulation (PWM) voltage controller with a display sets the rotation speed, and hence the respiratory rate, as a percentage of the supply voltage.

Table 6:- Technical characteristics of the main components.

Component	Characteristic	Value
Geared DC motor	Voltage / rated current / max. current	12 V / 2.5 A / 12 A
	Power	35 W
	Rated speed / rated torque	30 to 50 rpm / 4 N·m
	Reduction ratio / protection / mass	1/63 / IP40 / 1.3 kg
PWM controller with display	Voltage / rated current / peak current	5 to 30 V DC / 5 A / 15 A
	Power / switching frequency	150 W / 1 to 99 kHz
	Duty-cycle accuracy	1%
Solar charge controller	Input voltage / output voltage / max. current	16 to 20 V DC / 13.8 V DC / 15 A
Battery	Voltage / capacity	12 V / 18 Ah
Mains power supply	Conversion	230 V AC to 12 V DC

Energy. Three sources are possible: the grid through a 230 V AC / 12 V DC power supply, a 100 W photovoltaic module connected by MC4 connectors to a charge controller, and a 12 V battery. The battery was sized for three hours of operation. The energy required is 35 W × 3 h = 105 Wh, giving a capacity C = (105 × 1) / (0.5 × 12) = 17.5 Ah for a 50% depth of discharge, rounded up to 18 Ah.
Safety and information. An emergency stop button cuts the power immediately. A limit switch prevents operation with the cover open. A green light shows that the device is powered, and an orange light flashes each time the bag is released, confirming that the cam is turning. A pressure gauge displays the circuit pressure.
Structure and mobility. The components are protected by a metal casing mounted on a mast and a base with four solid rubber casters suited to smooth and uneven floors. The whole unit is assembled and disassembled with two open-end wrenches (10 and 13 mm).
Planned preventive maintenance. The battery is replaced every two years, the cams and worn mechanical parts every three years, and the self-inflating bag according to its manufacturer's recommendations. Almost all spare parts (fasteners, bearings, cables, switches, battery, car windscreen-wiper type motor) can be bought on the local market, which is the basis for the estimate of about 90% local materials.

Technical performance:-
Respiratory rate. The rate ranged from 12 breaths/min at a 40% setting to 45 breaths/min at 80% (Figure 8). The relationship is linear: RR = 0.783 u − 17.9 (R^2 = 0.993; root mean square error 0.85 breaths/min). It gives the caregiver a setting law that can be used directly: 20 breaths/min is obtained at u ≈ 48% and 30 breaths/min at u ≈ 61%. The 12 to 30 breaths/min range commonly used in adult ventilation is fully covered.

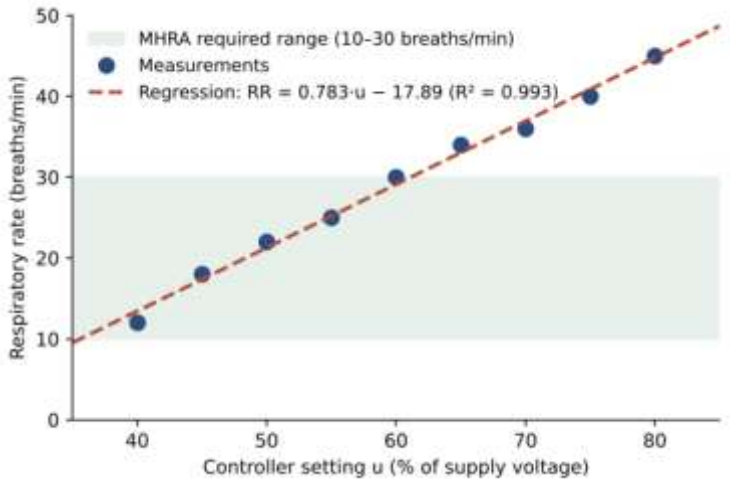


Figure 8:- Respiratory rate as a function of the controller setting. The shaded band is the range required by the MHRA specification (10 to 30 breaths/min).

Delivered volume. Table 7 and Figure 9 present the measured volumes.

Table 7:- Volumes delivered per cam (10 cycles per cam).

Nominal cam (ml)	Mean (ml)	SD (ml)	CV (%)	Bias (ml)	Bias (%)	95% CI of mean (ml)	Min to max (ml)	MHRA tolerance (ml)
450	418.9	0.99	0.24	−31.1	−6.9	[418.2; 419.6]	417 to 420	[378.5; 521.5]
500	454.7	4.14	0.91	−45.3	−9.1	[451.7; 457.7]	450 to 463	[421.0; 579.0]
550	525.6	1.78	0.34	−24.4	−4.4	[524.3; 526.9]	523 to 528	[463.5; 636.5]
600	575.4	2.67	0.46	−24.6	−4.1	[573.5; 577.3]	571 to 579	[506.0; 694.0]
650	645.4	2.01	0.31	−4.6	−0.7	[644.0; 646.8]	643 to 650	[548.5; 751.5]

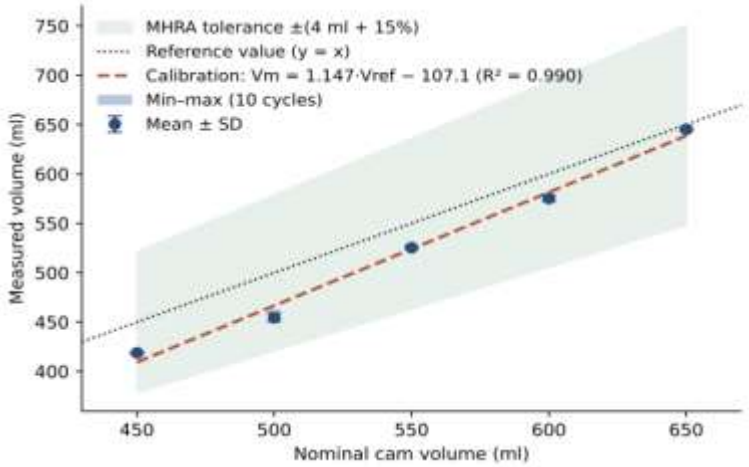


Figure 9:- Measured volumes as a function of nominal cam volume (mean ± SD and range over 10 cycles), compared with the reference value and the MHRA tolerance, with the calibration line.

Repeatability was high: the CV did not exceed 0.91%, and the range between extreme values was at most 13 ml. The bias was systematic and negative: every mean was below the nominal value, from −9.1% (500 ml cam) to −0.7% (650 ml cam), and the bias was statistically significant for all five cams (*t*-test, $p < 10^{-4}$). The volumes nonetheless remained clinically acceptable under the specification: every individual measurement fell within the ±(4 ml + 15%) tolerance, and equivalence with the nominal value was shown for all five cams (TOST, $p < 0.001$). The relationship between nominal and measured volume is linear ($V_m = 1.147\ V_{ref} - 107.1$; $R^2 = 0.990$). This gives a calibration law: to deliver 450 ml, the cam must be sized for a nominal volume of about 486 ml, and for 400 ml, about 442 ml.

Functional tests:- The prototype ran on grid power, on the photovoltaic module and on the battery, and ran continuously for 24 hours. The indicator lights, pressure gauge, controller and emergency stop button worked as specified. With an 18 Ah battery discharged to 50%, the measured autonomy was 3 h at an average consumption of 35 W.

Conformity with international requirements:-
Table 8 compares the prototype with the MHRA (2020) specification, used here as the reference for an emergency ventilator.

Table 8:- Conformity matrix of the prototype against the MHRA specification for rapidly manufactured ventilators.

MHRA requirement (RMVS)	LAAFI-RESPIR	Status
Volume-controlled mandatory ventilation	Volume set by the cam, cyclic insufflation	Met
Rate of 10 to 30 breaths/min	12 to 45 breaths/min (measured minimum: 12)	Partially met (10 to 12 not reached)
Default I:E ratio of 1:2, optionally 1:1 to 1:3	1:1, 1:2, 1:3 through the cam set	Met
Volume of 400 ml ± 10 ml; optionally 250 to 600 ml	419 to 645 ml; no 400 ml cam	Partially met (calibration to correct)
Volume accuracy ±(4 ml + 15%)	All measurements within tolerance	Met
PEEP of 5 to 20 cmH_2O	Not provided	Not met
FiO_2 control (50 to 60% and 90 to 100%)	Oxygen connection without FiO_2 adjustment	Not met
Pressure limit and relief valve at 80 cmH_2O	Pressure gauge; bag valve	Partially met
Backup battery ≥ 20 min	18 Ah; measured autonomy 3 h at 35 W; solar power	Met
Alarms: power failure, disconnection, pressure, volume	Status lights only	Not met
Display of settings and pressure	Setting in %, pressure on gauge	Partially met
Continuous operation for 14 days	24 h tested	Partially met
Circuit leak-tightness, internal temperature, IP22 protection	Not measured	Not evaluated

Of the twelve requirements evaluated, four are met, five partially met and three not met; three safety aspects remain to be measured. The gaps concern monitoring and advanced functions (alarms, PEEP, FiO_2). The ventilation function itself meets the requirements. These missing functions are the main safety limitations of the prototype and are discussed in "Safety limitations and intended use".

Clinician feedback:-
The demonstration at CHU-YO produced five suggestions for improvement (Bagnaba, 2020): check by spirometry the volumes actually delivered by the bag and their match with the cams; provide very small volumes (50 ml or less)

for pediatrics; set the rate directly rather than as a percentage of voltage; control the delivered oxygen fraction (FiO_2); and reduce the risk of CO_2 rebreathing, caused by the shared inspiratory and expiratory path, by placing a one-way valve as close as possible to the patient. A group of clinicians (anesthesia and intensive care, physiology) was formed to support the team toward preclinical trials.

Discussion:-

Answer to the research problem: contextualization during functional analysis:-

For RQ1, the six-step approach makes the choice of solution traceable (explicit, scored criteria) and validates it by reproducing a mock-up before any design investment. Building the mock-up first works much like an intermediate design object: it lets the local team learn the principle, measure the gap between the original solution and the means available, and identify the shortcomings to correct (see "Reproduction of the open-source mock-up").

For RQ2, the main finding is that contextualization takes place during functional analysis. By placing the local manufacturer, the maintainer, suppliers and energy sources in the external environment, the analysis produced eleven constraint functions absent from OxyGEN, each with quantified criteria. This shift is the methodological contribution of the study. It extends work on the sociotechnical maintenance network (Bationo et al., 2009; Bationo &Boujut, 2022) and on DFMSN (Bationo et al., 2026) by showing that these tools can transform an existing solution as well as design new equipment. Constraint functions FC5 and FC6 translate the DFMSN rules on local procurement, manufacturability and autonomous maintenance directly into quantified requirements, and extend their scope from agricultural equipment to medical devices. The approach can also be read as a variant of the frugal and endogenous design approach (Bagnaba& Bationo, 2026) for cases where the starting point is an external technical solution rather than a blank-slate need, which widens its field of application.

For RQ3, the prototype delivers repeatable volumes that are equivalent to the nominal values within the MHRA tolerance, and it covers the usual rate range. Local manufacture did not compromise the performance of the main function.

Safety limitations and intended use:-

A ventilator is a life-support device, and LAAFI-RESPIR still lacks three functions that such a device needs. Without PEEP, airway pressure returns to atmospheric pressure at the end of each expiration; in patients with acute respiratory failure, including COVID-19 pneumonia, this favors alveolar collapse and worsens oxygenation, which is why the MHRA specification requires an adjustable PEEP of 5 to 20 cmH_2O. The oxygen fraction is not controlled either: it depends on the oxygen flow added to the bag and can be neither set nor known, so the caregiver cannot titrate oxygen to correct hypoxemia or avoid prolonged exposure to high concentrations. There are also no alarms, so a circuit disconnection, a power failure, a motor stop or an overpressure would go unnoticed unless a caregiver watched the device continuously; for a ventilator-dependent patient such an event can be fatal within minutes, which is why IEC 60601-1-8 (IEC, 2006) and the MHRA specification make these alarms mandatory. Pressure is currently limited only by the valve of the bag and shown on an analog gauge, with no automatic cut-off, and the shared inspiratory and expiratory path noted by the clinicians (see "Clinician feedback") exposes the patient to CO_2 rebreathing.

For these reasons, the prototype in its current state is a bench demonstrator of the design approach and must not be used on patients. The bench results support the mechanical design and the local-manufacturing approach, but clinical safety has yet to be shown. The intended use after the next iteration is that of an emergency and transport ventilator (see "From gaps in conformity to a clinical roadmap"). Any use on patients will require the functions listed above, verification against ISO 80601-2-80 (ISO, 2018) and IEC 60601-1-8, preclinical trials and authorization from the national regulatory authority.

Volumetric performance: a correctable bias:-

The systematic negative bias follows from the mechanism. The insufflated volume depends on the lever stroke, but also on the elasticity of the bag, leaks at the valves and the compliance of the circuit. These losses increase with pressure and reduce the effective volume. This is a known limitation of bag-based ventilators (Fang et al., 2020; Petsiuk et al., 2020), which projects in industrialized countries compensate for with flow sensors and closed-loop control. The calibration law obtained here ($R^2 = 0.990$) offers a frugal alternative: resize the cams to offset the bias, with no added electronics. As with other equipment designed locally in Burkina Faso (Soulama et al., 2024), the quantitative evaluation showed how the prototype behaves and how to correct it. The larger deviation of the 500 ml cam (−9.1%, CV of 0.91%) also points to a defect specific to that cam, which needs checking.

The bias is statistically certain, yet the volumes stay within the international tolerance and are highly repeatable. Repeatability matters clinically because a stable bias can be corrected, while scatter cannot.

Frugality and maintainability:-
LAAFI-RESPIR has the three characteristics of frugal innovation: a large cost reduction, a focus on essential functions and adequate performance (Weyrauch &Herstatt, 2016). Its frugality comes mainly from choices aimed at maintenance: standard components, assembly with two wrenches, cams that can be swapped by hand, and a car-type motor available locally. These choices bring the DFMSN rules on manufacturability, local procurement and autonomous maintenance (Bationo et al., 2026) into the medical field. They address the causes of medical equipment non-functionality identified by Perry and Malkin (2011) and Malkin (2007), and they apply the durability, maintenance and repair principles that Samenjo et al. (2023) found to be rare in the design of medical devices for sub-Saharan Africa. The open-source ventilators of 2020 were designed for fast production in countries with working supply chains (Pearce, 2020), whereas LAAFI-RESPIR is designed to be repaired where it is used.

Energy as a design function:-
The hybrid power supply (grid, solar, battery) sets LAAFI-RESPIR apart from the open-source projects studied, all of which assume a reliable grid. The MHRA specification requires only 20 minutes of battery power, a figure suited to British hospitals. Where power cuts are frequent and some health centers have no electricity, three hours of autonomy and solar recharging are conditions for the device to be available at all. This choice is consistent with work that treats energy as a design constraint in its own right for equipment intended for Burkina Faso (Soulama et al., 2024).

From gaps in conformity to a clinical roadmap:-
The conformity matrix shows that the gaps concern monitoring (alarms, volume display) and advanced functions (PEEP, FiO_2), in line with general findings on open-source medical hardware (Niezen et al., 2016). These gaps, together with the clinicians' feedback, define the roadmap for the next iteration: (i) a PEEP valve and a one-way valve close to the patient, both standard components of resuscitation bags; (ii) power failure, disconnection and overpressure alarms compliant with IEC 60601-1-8 (IEC, 2006), which can be built with a pressure sensor and a low-cost microcontroller; (iii) direct setting in breaths per minute, based on the setting law established here; and (iv) resizing of the cams according to the calibration law. Full compliance with ISO 80601-2-12 (ISO, 2020) remains a long-term goal. In the short term, the most realistic position is that of an emergency and transport ventilator under ISO 80601-2-80 (ISO, 2018).

Contribution of the study:-
On the methodological side, the study proposes a design approach for integrating open-source solutions that can be transferred to other medical devices (oxygen concentrators, syringe pumps, suction units) and to other equipment. It pinpoints the step where contextualization happens, namely the functional analysis extended to the local network of actors, which meets the need for simple, operational methods expressed by West African equipment manufacturers (Bagnaba& Bationo, 2024). It adds a new entry point, the adaptation of an open-source solution, to DFMSN (Bationo et al., 2026) and to the frugal and endogenous design approach (Bagnaba& Bationo, 2026).

On the technological side, LAAFI-RESPIR is, to our knowledge, one of the first ventilators designed and built in Burkina Faso, and the only one of the projects compared to include solar power and a battery sized for power cuts. The statistical evaluation (repeatability, bias, equivalence with the MHRA specification, calibration and setting laws) goes further than the qualitative tests usually reported for frugal prototypes and responds to the call for better performance evaluation of frugal innovations (Dabić et al., 2022). Finally, a device manufactured and maintained locally reduces dependence on imports, creates business for local workshops and suppliers and, when solar-powered, can be deployed in health centers without electricity.

Limitations:-
The main limitation is clinical: the prototype has no PEEP, FiO_2 control or alarms (see "Safety limitations and intended use"), so its safety for patients has not been shown. The tests were run on the bench, without documented control of test-lung compliance and resistance, and without patients. The rate was measured with a stopwatch, with a single measurement per setting. The criteria for selecting the open-source solution were not weighted, and the scores were assigned by the design team. Circuit leak-tightness and internal temperature were not quantified, and battery autonomy was measured in a single test. Finally, the 90% share of local materials is an estimate that still has to be documented with a bill of materials.

Conclusion:-

This article proposed and tested an integrative design approach for adapting open-source solutions to medical devices in resource-limited settings, applied to the LAAFI-RESPIR ventilator. The six-step approach makes the choice of an open-source solution traceable, validates it by building a mock-up, and carries out contextualization during functional analysis by including the local manufacturing and maintenance actors and the available energy sources. Applied to OxyGEN, it added eleven constraint functions and produced a prototype made with about 90% local materials, maintainable with two wrenches and powered by the grid, solar energy or a battery.

The tests show that this contextualization did not compromise the main function. The rate is linearly adjustable from 12 to 45 breaths/min, and the delivered volumes, which are highly repeatable, stay within the international tolerance despite a systematic bias that the calibration law can correct. The conformity analysis locates the gaps in monitoring and advanced functions and sets out the roadmap toward preclinical trials. Until PEEP, FiO_2 control and alarms have been added and verified, LAAFI-RESPIR remains a bench demonstrator that must not be used on patients.

Local manufacture can bring income to national workshops and suppliers and reduce the import bill for medical devices, and solar power cuts the use of generators and their emissions. A ventilator that can be repaired on site could strengthen the equipment of regional hospitals and outlying health centers.

Future work will (1) add the missing functions (alarms, PEEP valve, one-way valve close to the patient, FiO_2 adjustment, direct rate display); (2) resize the cams according to the calibration law and develop pediatric cams; (3) run a test campaign following the MHRA protocol on a test lung with controlled compliance and resistance, measuring leak-tightness, repeated autonomy tests and temperature; (4) conduct preclinical and then clinical trials with the team at Yalgado Ouédraogo University Hospital within the national regulatory framework; (5) document the bill of materials and the full manufacturing cost; and (6) apply the approach to other essential medical devices and combine it with the frugal and endogenous design approach and DFMSN in a common methodological framework for local equipment manufacturers.

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Conflicts of interest:-The authors declare no conflict of interest.

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