Code number:

Title of the study: Validation of the performance of the COBOX solution for measuring heart rate (HR) and respiratory rate (RR).

Study Sponsor : Quantiq.io

Local investigators: Laure Abensur Vuillaume (Principal Investigator, CHR Metz-Thionville).

Co-investigators: Cedric Gil Jardine (Bordeaux University Hospital), Arnaud Depil-Duval (Saint-Joseph Hospital), Aurélie Roger (Bel-Air Hospital) .

Information essential to your decision to participate

Introduction

You are invited to participate in a clinical study intended to:

- Evaluate and validate the performance of the heart rate (HR) measurement taken or measured by the COBOX medical device when it is used by a healthcare professional in real conditions of use compared to the measurement carried out by applying the reference processes measurement via a CE marked device.
- Evaluate the performance of the measurement of respiratory rate (RR) measured by the COBOX medical device compared to a measurement performed by a manual counting reference method.
- Establish and verify the clinical safety of COBOX and detect any adverse side effects under normal conditions of use of the device and assess whether these constitute an acceptable risk in relation to the expected benefits of the device concerned.
- Evaluate the medico-economic and organizational gains generated by the use of the COBOX solution compared to reference measurement practices in the investigating centers.

Before you agree to take part in this study, we invite you to find out what this entails in terms of organization, advantages and possible risks, so that you can make an informed decision. This is called **giving informed consent** .

Please read these few pages of information carefully and ask any questions you wish to the investigator or the person representing him. This document consists of 3 parts: 1) information essential to your decision-making, 2) your written consent and 3) additional information (appendices) which detail certain parts of the basic information.

If you participate in this research, you should know that:

This clinical study is implemented after evaluation by the Sud-East VI personal protection committee.
Your participation is voluntary and must remain free of any constraint. It requires the electronic signature of a document expressing your consent. Even after having signed it, you can stop participating by informing the investigating doctor or his representative. Your decision not to or no longer to participate in the study will have no impact on the quality of your care or on your relationship with the investigator.
You will not be charged any fees for taking FC and FR specific to this study.
The data collected on this occasion is confidential and your anonymity is guaranteed when the results are published.
Insurance has been taken out in case you suffer any damage related to your participation in this research.

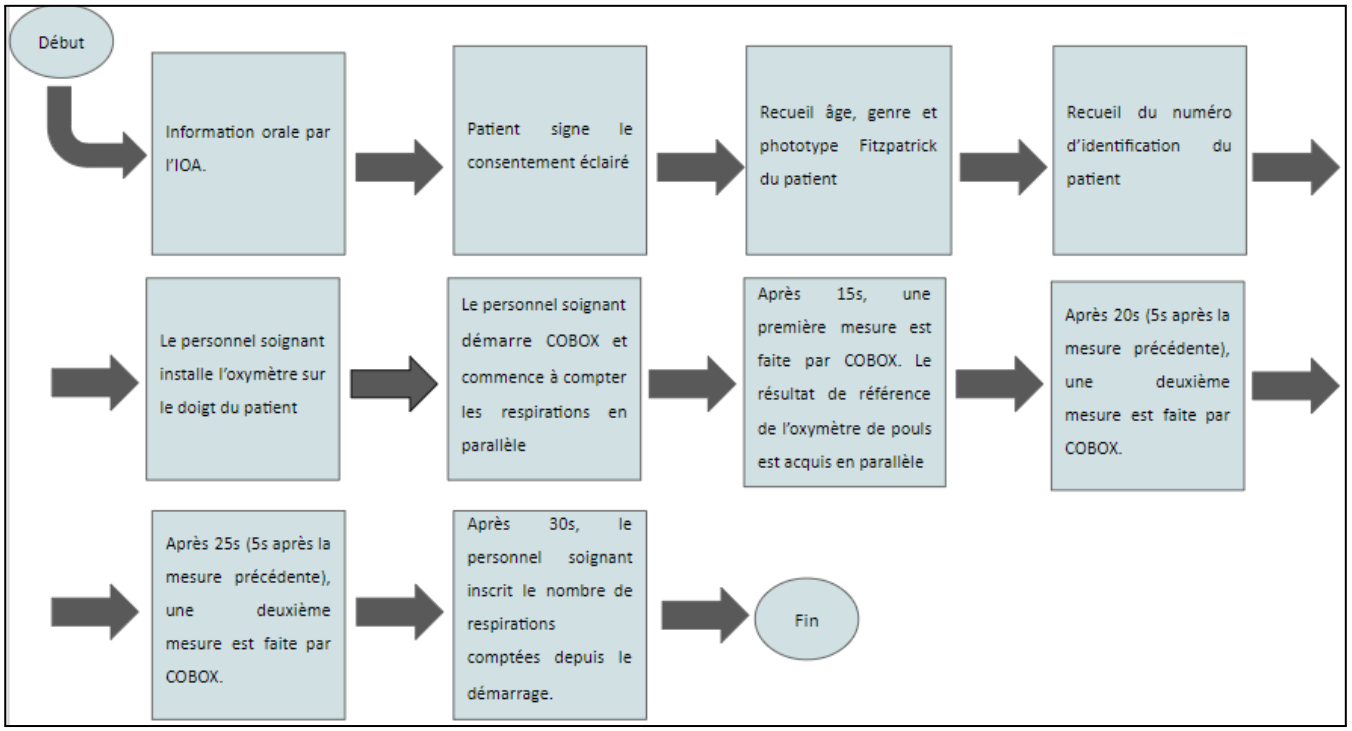
Code number:

You can always contact the investigator or a member of his team if you need additional information.

Additional information on your “Clinical Study Participant Rights” is provided in the appendix.

Description of the study

There are no modifications concerning the care, the usual circuit of the patients is not modified. The COBOX tool is used by the healthcare professional concurrently with his usual collection of input parameters. The scheme is as follows:



Data collected:

The data will include:
The taking of FC and FR by a health professional at the time of admission to the emergency room.
The taking of HR and FR by the COBOX tool at the time of admission to the emergency room.
Personal data: Collection of age, gender and Fitzpatrick phototype of the patient. They are strictly and obviously necessary for the conduct of the study so they are recorded and kept. These data are aimed at research to improve the preclinical and clinical performance of our Product. The data communicated is transmitted to the sole company Quantiq.io; we do not sell or transfer any data concerning you to third-party companies.

In addition, once the data is taken by the nurse, an identification number is assigned to you, which means that your identity will be replaced by an identification code in the study. The investigator and his team will therefore be the only ones able to make the link between the data transmitted throughout the duration of the study and your medical file.

Code number:

The personal data transmitted will not contain any combination of elements that could nevertheless allow you to be identified.

For more information, please refer to Annex 1 of this document

Risks and disadvantages

No associated risk has been identified. The data collected for the evaluation will be observational and the information provided by COBOX will not be used in clinical decision-making.
The Cobox application poses no risk to the patient.
There are no direct or indirect adverse effects for the patient identified to date.

If you participate in this research, we ask that you:

To cooperate fully in the smooth running of this research.

Contact

If you need additional information, but also in the event of a problem or concern, you can contact the investigator Dr. Laure Abensur Vuillaume or a member of her research team (GOETZ, Christophe, Medical Manager) at following phone: +33 6 81 34 13 67

If you have any questions relating to your rights as a participant in a clinical study, you can contact the patient rights ombudsman of your institution via the telephone number: telephone details:

- CHR Metz-Thionville: Dr. Laure ABENSUR VUILLAUME +33 6 81 34 13 67
- Bel-Air Hospital: Dr. Aurélie ROGER +33 3 82 55 82 55
- CHU Bordeaux: Dr. Cédric GIL JARDINE +33 6 85 98 65 10
- Saint-Joseph Hospital: Dr. Arnaud DEPIL-DUVAL +33 611605075

If necessary, the latter can put you in contact with the Ethics Review Committee of the Metz-Thionville CHR (CRETH).

Code number:

Informed consent

Participant:

I declare that I have been informed about the nature of the study, its purpose, duration, possible side effects and what is expected of me. I have read the information document and the appendices to this document.

I had the opportunity to ask all the questions that came to my mind and I got a satisfactory answer to my questions.

I understand that my participation in this study is voluntary and that I am free to end my participation in this study without this changing my relationship with the investigator / the therapeutic team in charge of my health.

I understand that data concerning me will be collected throughout my participation in this study and that the investigator and the sponsor guarantee the confidentiality of this data.

I consent to the processing of my personal data in the manner described in the section dealing with confidentiality guarantees (appendix 1).

Please tick the box:

▢ I accept that the research data collected for the purposes of this study may be further processed provided that this processing is limited to the context of the present study and subject to the approval of an ethics committee and a committee for the protection of persons;

▢ I refuse to allow the research data collected for the purposes of this study to be further processed provided that this processing is limited to the context of the present study and subject to the approval of an ethics committee and a committee for the protection of persons;

I have received a copy of the Participant Information and Informed Consent.

Last name, first name, date and signature of the participant

[If a witness / interpreter is present.] **Witness / Interpreter**

I was present during the entire process of informing the volunteer and I confirm that the information on the objectives and procedures of the study has been provided in an adequate manner, that the participant (or his legal representative) understood the study and that consent to participate in the study was freely given.

Last name, first name, qualification, date and signature of the witness / interpreter:

Investigating Doctor

I, the undersigned Investigator, confirm that I have provided the necessary information about the study orally and that I have provided a copy of the information document to the participant.

Code number:

I confirm that no pressure was exerted for the patient to agree to participate in the study and that I am ready to answer any additional questions, if necessary.

I confirm that I work in accordance with the ethical principles set out in the “Declaration of Helsinki”, in the “Good Clinical Practices” and in the law relating to experiments on the human person.

Surname, first name, date and signature of the investigator

Code number:

Validation of the performance of the COBOX solution for measuring heart rate and respiratory rate

Annex 1 "Protection of personal data"

In accordance with the Data Protection Act of January 6, 1978 amended by the law of June 20, 2018, and in accordance with the General Data Protection Regulations of April 27, 2016, you expressly consent to the identifying data you provide being recorded. Among the identifying data, only the data strictly and obviously necessary for the conduct of the study are recorded and kept. These data are aimed at research to improve the preclinical and clinical performance of our Product. The data communicated is transmitted to the sole company Quantiq.io; we do not sell or transfer any data concerning you to third-party companies.

On our website, detailed information on the exercise of your rights is available.

In its capacity as data controller, within the meaning of art. 4, 7) of the GDPR, Quantiq.io undertakes to comply with the European and national data protection framework, as resulting from the GDPR (art. 5 and following, art. 24 and following) and from the law information technology and freedoms (art. 57 et seq.). It observes all of the following general and specific rights and obligations:

1. Patient rights

The information collected by the application is recorded in a computerized file designed by Quantiq.io, responsible for processing, for the purposes of conducting research and studies in the field of health, evaluating and analyzing practices or care or prevention activities, as follows: 1) validate the measurement algorithms by collecting prospective data from subjects, intended for a solution intended to be certified as a Medical Device (CE Marking & Food and Drugs Agency [FDA]) for the year 2022; 2) improving algorithms through iterative use of data; 3) developing and designing new algorithms based on the subsequent processing of these same data. The data collected is personal data, including health data – physiological measurements – that are not identifiable, anonymized and hashed during their recording.

In accordance with the Data Protection Act of Jan. 6, 1978 amended by the law of June 20, 2018, and in accordance with Articles 6 and 9 of the General Data Protection Regulations of April 27, 2016, you expressly consent that the identifying data that you provide are recorded, and you consent to the health data strictly and obviously necessary for the operation of the application being recorded. The data communicated is transmitted only to Quantiq.io and its subcontractors; we do not sell or transfer any data concerning you to third-party companies. They are recorded on servers established on the territory of the European Union.

Once anonymized, these data are kept for 15 years to allow population monitoring and the improvement of *remote patient monitoring (RPM)* . In no way are anonymized data re-identified, either by individualization (allowing you to be isolated, as an individual, in the data set), or by correlation (by linking separate data sets concerning you), or by inference (by deduction from new information collected about you).

You have rights enforceable against Quantiq.io: you can exercise your rights of interrogation, access and verification, right of rectification, right to erasure, right of opposition, right to receive a copy

Code number:

(right to portability), and right of limitation directly on our website www.quantiq.io , or with the Data Protection Officer (address below).

Right of interrogation, access and verification: You have the right to know what information the administrations, public or private bodies and commercial companies hold about you in their files. For our company, you can ask us directly what categories of data we collect about you, what processing we apply and what purposes are pursued, the recipients or categories of recipients who have been able to access the data, their retention period or the criteria that determine this duration, the existence of automated decision-making, including the underlying logic, the importance and consequences of such a decision for you, and the reasons why we do not transfer your data to a country third party (non-EU member) or to an international organization;

Right of rectification *:* you have the right to request the rectification of erroneous, inaccurate or incomplete information concerning you

Right to erasure *:* you have the right to ask us to delete the data concerning you, in particular if you withdraw your consent to the use of your data or if you believe that this data must be erased to comply with a legal obligation. , or if you have objected to the processing of your data. To better satisfy your request, we ask you, in accordance with the law, to explain to us very precisely what data you wish to see erased. ;

Right of objection : You can object to your data being used by Quantiq.io for a specific purpose. You must put forward " *reasons relating to your particular situation* ", which we will take into due account. Please note that compelling reasons related to the proper functioning of our algorithm (and the vital interests attached thereto for patients) may constitute a legitimate and compelling interest in the continuation of processing (Art. 21 §2 GDPR), under warranty anonymization (Art. 35 GDPR);

Right to receive a copy (right to portability) : You have the right to recover some of your data in a machine-readable format. These rights relate to information that you have declared (for example your contact details), or data drawn from your activity (for example those drawn from a *quantified self*), but not the data derived, calculated or inferred from the information that you have provided. We will take this into account in examining your possible request to provide you with those to which you are entitled in a structured, commonly used or machine-readable format". You can use this data for strictly personal use, to transmit it to another online service, or for any other legal use that suits you.

Right to limitation : This right complements the exercise of other rights under the GDPR; it is not for isolated use but complementary to your right to interrogation, access and verification and your right to rectification. If you dispute the accuracy of the data used by Quantiq.io or object to the processing of your data, the law (Art. 18 GDPR) authorizes Quantiq.io to carry out a verification or review of your request during a certain delay. During this period, you have the possibility to ask Quantiq.io to freeze the use of your data. Concretely, Quantiq.io will then refuse to use the data but will have to keep them.

Code number:

To guarantee your rights, our subcontractors guarantee a level of protection at least equivalent to that guaranteed by Quantiq.io. Please note that, to prevent identity theft, we may ask you to provide proof of your identity at the time you submit this request.

Consult the cnil.fr website or our website www.quantiq.io for more information on your rights. To exercise these rights or for any questions about the processing of your data in this system, you can contact our data protection officer: Mr. **Nicolas Desrumaux (DMH)** , 12 Bis Rue Louise Michel - 92300 Levallois-Perret or write to us to dpo@dmh-aphp.fr . If you believe, after contacting us, that your "Data Protection" rights are not respected, you can file a complaint with the CNIL.

To guarantee your rights, our subcontractors guarantee a level of protection at least equivalent to that guaranteed by Quantiq.io.

Consult the cnil.fr website or our website www.quantiq.io for more information on your rights. To exercise these rights or for any questions about the processing of your data in this system, you can contact our data protection officer: Mr. **Nicolas Desrumaux (DMH)** , 12 Bis Rue Louise Michel - 92300 Levallois-Perret or write to us to dpo@dmh-aphp.fr . If you believe, after contacting us, that your "Data Protection" rights are not respected, you can file a complaint with the CNIL.

2. ***General obligations of Quantiq.io***

- respect and ensure respect for the general principles and specific rules of the GDPR throughout the operation of the service: we carry out the preliminary formalities, inform the control and regulatory authorities, follow their recommendations and opinions, keep a register of processing operations, continuously ensure that the compliance of processing with the European and national framework, and make all the parties involved responsible for respecting the rights of individuals;

- guarantee the complete and preliminary information of the people: we undertake to guarantee clear, complete and accessible information prior to the collection of your consent, to respect your right of interrogation and access, your right of rectification, your right to erasure, your right to oppose, your right to copy, either directly with due diligence and impartiality, or indirectly through the investigating doctor or a doctor that you (or your legal representatives) will have appointed;

- guarantee data protection from the design of the Quantiq.io solution and data protection by default;

3. ***Specific obligations of Quantiq.io***

Upon simple request from you, we will endeavor to provide you, as soon as possible:

- an explanation of the nature, scope, context and purposes of the collection and processing of personal data concerning you;

- a statement of the requests presented by Quantiq.io to the Commission Nationale Informatique et Libertés, with regard to the processing authorizations required, and the appropriate notices;

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- a summary of the documented instructions provided to the people who collaborated on this project.

Additionally, in order to maintain a high level of compliance and accountability, we are committed to:

- contribute to the constant improvement of data protection within our artificial intelligence engine Quantiq.io;

- declare to the CNIL and our Data Protection Officer the processing of personal data that we carry out, provide them with any useful and necessary information to demonstrate our compliance with applicable legislation, and keep its data processing register up to date. We have appointed a Data Protection Officer for this purpose (see below);

- adopt the appropriate technical and organizational measures to guarantee the full effectiveness of the right to the protection of personal data, and follow the legal developments on this point;

- not to transfer the data outside the territory of the European Union;

- observe the recommendations and follow the data processing implementation guidelines provided by our Data Protection Officer, as well as documented instructions such as the DPIA, unless otherwise required by law or regulation;

Final Obligations of Quantiq.io

Finally, Quantiq.io also undertakes, in accordance with art. 28 of the GDPR, to comply with the following obligations:

- not to allow one of our possible subcontractors to hire a second subcontractor for the data, without demonstrating that the latter protects computer rights and freedoms with a level at least equivalent to European standards, and without our prior written consent;

- ensure the integrity, confidentiality and security of the data and their processing process;

- assist our Data Protection Officer to follow up on any request made by a person, in accordance with their rights, to preserve data security;

- collaborate in any audits and inspections carried out by the CNIL or the Data Protection Officer on our processing of personal data;

- in the event of a violation of the confidentiality, integrity or security of the data, and in particular in the event of unauthorized access by third parties, Quantiq.io undertakes to immediately inform the person concerned, as well as the competent authorities, and in particular the CNIL, by means of relevant documentation.

Quantiq.io uses logical and physical security measures, including protection software (anti-malware and firewalls), to guarantee the integrity, security, availability, confidentiality and use of your data. in accordance with the sole purposes set out. We decline all responsibility in the event of intrusion into our databases by acts of cybercrime, whether of human origin or not.

The www.quantiq.io website is registered with the Commission Nationale Informatique et Libertés.

Code number:

Consult the cnil.fr website for more information on your rights. To exercise these rights or for any questions about the processing of your data in this system, you can contact our data protection officer: Mr. **Nicolas Desrumaux (DMH)** , 12 Bis Rue Louise Michel - 92300 Levallois-Perret or write to us to dpo@dmh-aphp.fr .

If you believe, after contacting us, that your "Data Protection" rights are not respected, you can file a complaint with the CNIL.

Code number:

Annex 2 "Other rights and protection of the participant"

Committee for the Protection of Persons

The Human Protection Committees have the task of protecting the people who take part in a clinical study. They ensure that your rights as a patient and as a participant in a clinical study are respected, that in the light of current knowledge, the balance between risks and benefits remains favorable to the participants, that the study is scientifically relevant and ethics.

Under no circumstances should you take the favorable opinion of the Committee for the Protection of Persons as an incentive to participate in this study.

Voluntary participation and costs associated with your participation

Before signing, do not hesitate to ask any questions you deem useful. Take the time to talk to someone you trust if you wish.

Your participation in the study is voluntary and must remain free of any constraint: this means that you have the right not to participate or to withdraw without justification, even if you had previously agreed to participate. Your decision will in no way modify your relations with the investigating doctor and/or the continuation of your therapeutic care.

If you agree to participate in this study, you sign the informed consent form. The investigating doctor will also sign this form and thus confirm that he has provided you with the necessary information about the study. You will receive the copy intended for you.

If you decide to participate in this study, this will not entail any costs for you or your insurer. Taking measurements: respiratory rate and heart rate are the responsibility of the promoter.

You may only be charged the usual treatment costs for your clinical situation.

Privacy Guarantee

Your participation in the study means that you accept that the investigating doctor collects data concerning you and uses them for research purposes.

You have the right to ask the investigator what data is collected about you and how useful it is for the study. You have a right of access to this data and the right to make corrections to it in the event that it is incorrect [1].

The investigator has a duty of confidentiality with regard to the data collected. This means that he undertakes not only never to divulge your name within the framework of a publication or a conference but also that he will code (that your identity will be replaced by an identification code in the study) your data before transmitting them to the manager of the database collected (Quantiq.io, Promoter of the study, establishment located at 4 ALL JACQUES PREVERT 92500 RUEIL-MALMAISON) . The investigator and his team will therefore be the only ones able to make the link between the data transmitted throughout the duration of the study and your medical file [2].

For the research data manager designated by the sponsor, the data transmitted does not allow you to be identified. The latter is responsible for collecting the data collected by all the investigators

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1 These rights are guaranteed to you by the law of January 6, 1978 (amended by the law of June 20, 2018) according to the General Data Protection Regulations of 2016.

2 Integrity in scientific research presupposes that the results of research can be verified, even after the results have been published. It is recommended that the link between the research data and the identity of the participant be kept for at least 5 years after the publication of the results. For clinical trials (drug studies), the law requires that this link be kept for 20 years.

Code number:

participating in the research, their processing and their protection in accordance with the requirements of the GDPR (2016) and the Data Protection Act (1978, revised in 2018) .
The personal data transmitted will not contain any combination of elements that could nevertheless allow you to be identified [3].

To check the quality of the study, your medical file may be examined by third parties (ethics committee, study sponsor, external auditors). In any event, this could only be done under the responsibility of the investigator or one of his collaborators and by persons subject to the obligation of professional secrecy.

The promoter will use the data collected within the framework of the study in which you are participating but also wishes to be able to use them within the framework of other research carried out in the same context (example: using your data as a control group).

If you withdraw your consent to participate in the study, in order to guarantee the validity of the research, the data coded up to the moment of your interruption will be retained. No new data may be transmitted to the Promoter.

Insurance

Any participation in a clinical study involves a risk, however minimal it may be. The Promoter assumes, even in the absence of fault, the responsibility for the damage caused to the participant (or to his beneficiaries) and linked directly or indirectly to the experiments carried out. The Promoter has taken out an insurance contract for [4]this liability (CNA/HARDY, HCCG019-10476419).

[3] The database containing the results of the study will therefore not contain any association of elements such as your initials, your gender and your full date of birth (dd/mm/yyyy).

[4] In accordance with the French law relating to experiments on the human person.