Acronym	CHILDMELODY	
Title	Crossover comparison of the efficacy and tolerance of telerobotic vs standard ultrasound exam in children	
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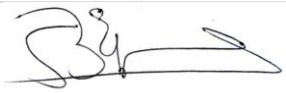
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1 Signature page of the protocol

Acronym	CHILDMELODY
Title	Crossover comparison of the efficacy and tolerance of telerobotic vs standard ultrasound exam in children
ID-RCB Number	2020-A03185-34

Promotor		
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	Made at	Créteil
	Made on:	
	Signature :	

Coordinating investigator		
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	Made at	Creteil
	Made on:	30/07/2021
	Signature :	

2 List of participating centres and stakeholders

N°	Centre	Principal investigator	Type of ultrasound	Sonographers
1	CHIC 40 avenue de Verdun 94000 CRETEIL	Pr Ralph EPAUD	Abdominal	Dr Mylène MABILLE Dr Francesco CUCCIOLI
			Thoracic	Dr Céline DELESTRAIN Dr Fouad MADHI Dr Aline MALTERRE
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2	CHIV 40 Allée de la Source, 94190 Villeneuve-Saint-Georges	Dr Emilie GEORGET	Abdominal	Dr Jean-Marc LAURENT Dr Claire JOURDAIN

3 List of abbreviations

ANSM	Agence Nationale de Sécurité des Médicaments et produits de santé
AMM	Autorisation de Mise sur le Marché
CPP	Comité de Protection des Personnes
CNIL	Commission Nationale de l'Informatique et des Libertés
CRF	Case Report Form
SAE	Severe adverse effect

4 Project summary

1) General characteristics	
Acronym	CHILDMELODY
Title	Crossover comparison of the efficacy and tolerance of telerobotic vs standard ultrasound exam in children
Coordinating investigator	Ralph Epaud
ID-RCB number	2020-A03185-34
ClinicalTrials number	ongoing
Sponsor	Centre Hospitalier Intercommunal de Créteil
2) Regulatory	
Study category	Interventional medical device research (RIPH1)
Number of study centers	2 centers
Methodology	Open labelled non-randomised multicenter study
Investigational product	- Ultrasonograph model TE7 from Mindray with a telerobotic arm (Melody System) - Ultrasonograph model TE7 from Mindray (comparator system)
3) Research design	
Population	Children aged of 1 to 10 years with a prescription of cardiac, abdominal or thoracic ultrasound exam
Background and rational for conducting this study	Facing Covid-19, children seem to have milder clinical symptoms than to adults (as has been reported for SARS-CoV and MERS-CoV infections). Nonetheless, some children presented with Kawasaki Disease (KD) and myocarditis with inflammatory parameters and required for some of the paediatric intensive care unit (PICU). More than 300 children have been hospitalized in Paris area from march to June 2020. Among them, we reported a series of 192 patients hospitalized in the suburbs of Paris. The CHIC identified 14 (7.3%) children with KD, or "Kawasaki-like" disease, and 8 (4.2%) with myocarditis. Of the 24 children admitted to a PICU, 13 had myocarditis or hemodynamic instability with KD (one child had KD with myocarditis), and 11 were admitted for symptoms related to Covid-19. In children with Covid-19, the diagnosis of KD and pneumonia should be made very quickly. However, the regional hospitals surrounding Paris don't have the required expertise. The use of MELODY allows the paediatric team to quickly carry out the necessary examinations while avoiding the movement of patients and the risk of contamination. The MELODY remote system developed by the company AdEchoTech is a CE-marked telemedicine technique, allowing an expert to perform an ultrasound scan on a distant patient (several hundred/thousands of kms). The Melody system makes it possible to optimize ultrasound expertise resources wherever they are located (all specialties combined) On the "patient" site, a dedicated room will be created close to the units devoted to the Covid-19 patient, easy to decontaminate and containing the robot. This tool will also permit to face of the challenge of fighting the Covid 19 virus by allowing equipped places to establish additional barrier to the spread of the virus.

	The feasibility of the clinical use of telerobotic sonography has been demonstrated in adults for abdominal, cardiac and prenatal exam. Thus, the aim of this study is to assess the feasibility of this system in children.
Expected benefits	Demonstrating telerobotic sonography is non-inferior to standard sonography in children. The use of telerobotic sonography may improve children and caregiver's safety in the context of COVID-19.
Sample size	40
Primary objective	To assess the concordance of telerobotic vs. conventional sonography results in children.
Main outcome	Concordance of the examination conclusion (normal or abnormal) between telerobotic and conventional ultrasound examinations
Secondary objectives	- To determine the feasibility of the telerobotic ultrasound at different ages - To compare the abnormalities described for each procedure in case of pathologic conventional ultrasound examination - To describe discordant results of conventional and telerobotic ultrasound examinations - To assess adverse events - To assess parent satisfaction - To assess medical staff satisfaction - To compare the duration of the examination for the 2 procedures
Secondary outcomes	- Age of patients with telerobotic ultrasound - Conventional and telerobotic ultrasound examinations results - Parent satisfaction questionner - Medical assistant and sonographer satisfaction questionner - Examination time
Inclusion criteria	- Patient from 1 year to 10 years - Patient requiring an ultrasound exam (thoracic, abdominal or cardiac) - French social security affiliation
Non-inclusion criteria	- Obesity defined by a BMI greater than 30 - Open wound making it impossible to carry out an ultrasound scan - Algetic patient - Instability of vital functions - Impossible to remain in a seated position - Refusal to participate in the study
4) Study plan	
Brief patient circuit	The study will be presented to patients who meet the eligibility criteria. The patient will be included after approval of the study by the child from 3 years old and his legal representatives and signature of the consent, Children will be initially scanned with a telerobotic ultrasound system. Within 3 hours after the telerobotic examination, patients will be scanned by a different sonographer with similar experience and qualifications

	using the conventional ultrasound, who will be blinded to the findings of the telerobotic examination. Based on the referring clinician's initial request, examinations included ultrasound examination based on the radiologist, cardiologist and pulmonologist clinical practice guideline. After completion of both exams, parents and children > 4 yo completed a survey based on that of Adams et al (1, 2) regarding their experience with the telerobotic examination. Similarly, sonographers and Patient site assistants will be asked to indicate their experience.	
Schedule of the study	Inclusion period	8 months
	Period of participation (treatment + follow-up)	1 day
	Overall duration	8 months
	Estimated starting date of study	01/02/2021

5 Background and rationale for conducting this study

5.1 Description of pathology

The discovery of a new form of pneumonia in early December 2019 in Wuhan, Hubei Province, followed by the rapid spread of the disease in China and across all continents, led to the most serious health crisis in the modern world for more than a century. Covid-19 results from the infection with the severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2), a virus that is one of the six coronaviruses already known to infect humans. Four of these (HCoV-NL63, HCoV-229E, HCoVOC43 and HKU1) usually caused mild common cold-type symptoms in immunocompetent people whereas the two others, the severe acute respiratory syndrome coronavirus (SARS-CoV) and the Middle East respiratory syndrome coronavirus (MERS-CoV) were responsible of severe pandemics in the past two decades (3) SARS-CoV-2 is responsible for an ongoing global pandemic, leading to 4.2 million cases and 286,613 deaths as of 12 May 2020, with France among the main affected countries, with 26,646 deaths to date (4). The first three Covid-19 cases identified in France were reported on 24 January 2020 in travellers returning from Wuhan, China (5). On March 2020, the incidence of Covid-19 began to rapidly escalate in France. By March 23, France had the second highest number of Covid-19 infections and the greatest number of deaths in Europe, which led the French health authorities to initiate a lockdown from 17 March 2020.

Children are less commonly affected by SARS-CoV-2. The Chinese Centres for Disease Control and Prevention stated that, of the 72,314 cases reported as of 11 February 2020, only 1.3% were in individuals less than 19 years old [4]. Early reports from China, Italy, and the United States indicated that SARS-CoV-2 causes illness of varying degrees, with females and children underrepresented among cases, especially among severe and fatal cases (6-8). Children seem to have milder clinical symptoms than adults (6-8) (as has been reported for SARS-CoV and MERS-CoV infections) (9).

In France, our group published a prospective multicentre study of children hospitalized in paediatric departments of Paris suburb hospitals identified 192 children with confirmed or highly suspected SARS-CoV-2 infection (10). Most cases showed mild or moderate clinical expression; Fever was recorded in 147 (76.6%) children and considered poorly tolerated in 29 (15.1%). The symptoms ranged from rhinorrhoea (34.4%) and gastrointestinal (35.5%) to respiratory distress (25%). Only 10 (5.2%) children had anosmia and five (2.6%) had chest pain. One-eighth of children were admitted to paediatric intensive care unit and 3 died(10). Moreover, a press release from the paediatric societies dated April 29, 2020, warned of a resurgence of Kawasaki (involves inflammation of the blood vessels, and includes symptoms such as red, swollen eyes, lips and mouth; swelling and reddening of the hands and feet; and swollen lymph nodes) and myocarditis in an inflammatory context, possibly related to Covid-19. In our study, we identified 14 (7.3%) children with Kawasaki Disease, or "Kawasaki-like" disease, and 8 (4.2%) with myocarditis. Of the 24 children admitted to a paediatric intensive care unit, 13 had myocarditis or hemodynamic instability with KD (one child had KD with myocarditis), and 11 were admitted for symptoms related to Covid-19 (10). Currently, diagnosis of Covid-19 require clinical assessment and

real-time reverse transcriptase polymerase chain reaction testing. Lund disease due to SARS-CoV-2 is often evaluated by an HRCT scan, which is the gold standard, but lung ultrasound is highly sensitive to detect and assess lung lesions in this infectious disease. The lung ultrasound findings are described firstly by Buensenso et al. in adulthood. They described diffuse pleural line abnormalities associated with small subpleural consolidations, areas of “white lung” with confluent B-lines mixed with spared areas. The lesions were diffuse and bilateral in the anterior and posterior zones. (11) Soldati et al. confirmed this aspect and reported that the interstitial syndrome was likely predominant in the intermediate stages of pneumonia, whereas consolidation was more frequent in the later ones (12). Most recently, an observational study of LUS in 10 SARS-CoV-2 infected children with a median age of 11 years confirmed the similarities with adults with vertical artifacts (70%), pleural irregularities (60%), areas of white lung (10%) and subpleural consolidations (10%)(11). (PMID: 32409232). Ultrasound makes it possible to quickly assess the lung conditions without ionizing radiation and without moving the patient to radiology unit. To monitor changes or resolution of lung damage, you can repeat the lung ultrasound as many times as necessary. The use of a remote lung ultrasound system, such as Melody, would limit the exposure and transmission of SARS-CoV-2 to caregivers and provide the ability to perform the ultrasound even in the absence of on-site ultrasound-trained personnel.Description of the Melody system

A clinic room (serving as the patient site/remote site) will be equipped with the MELODY patient system, Te7 ultrasound system. The following probes will be used:

- For abdominal ultrasound: convex probe C5-2s
- For thoracic ultrasound: linear probe L14-6Ns
- For cardiac ultrasound: SP5-1s and P7-3s probes

The MELODY system is a 3-degree-of-freedom robot designed to hold any standard ultrasound transducer and allows users to remotely control rotation, rocking, and tilting of the attached transducer. An adjacent room (serving as the sonographer site/central site) will be equipped with the MELODY Expert system, consisting of a mock transducer and an electronic control box. As sonographers manipulate the mock transducer in a manner similar to scanning conventionally, all fine movements of the mock transducer is reproduced by the scanning transducer at the patient site via the 3-degree-of-freedom robot. A touch screen monitor at the sonographer site displays the identical ultrasound system interface as that displays on the Te7. Sonographers control all settings such as gain and depth and added image annotations using either the touch screen monitor or mouse and keyboard.

A videoconferencing system enable communication between sonographers, patients, and patient site assistants. Gross placement of the robotic transducer holder and pressure of the transducer on the patient are adjusted by patient site assistants, who had no expertise in sonography, based on instructions from sonographers. A nondedicated Internet connection (50-Mbps download and 20-Mbps upload speeds where the system needs 2 Mbps download and 2 Mbps upload speeds) connects the

two sites, with separate data flows for the sonographic video data, ultrasound settings, robotic control, and videoconferencing system.

5.2 Summary of non-clinical and clinical trial results available and relevant to the biomedical research involved

Three international original studies have assessed the feasibility of the MELODY telerobotic system and compared it to conventional ultrasound exams (one for prenatal examinations and the 2 others for adults' cardiac and abdominal examinations (1, 2, 13).

The first one examined the feasibility of a telerobotic approach to remotely perform prenatal sonographic examinations in 30 participants. Intraclass correlations showed excellent agreement (>0.90) between telerobotic and conventional measurements of all 4 biometric parameters. Of 21 foetal structures included in the anatomic survey, 80% of the structures attempted across all patients were sufficiently visualized by the telerobotic system (range, 57%–100% per patient). Ninety-seven percent of patients strongly or somewhat agreed that they would be willing to have another telerobotic examination in the future(2).

In the second one, ultrasound exams were performed on 41 cardiac patients. The quality of the cardiac views obtained using tele-echocardiography was lower than that of reference echocardiography but generated similar measurements in 93%–100% of the cases. Bland–Altman plots and statistical comparison of tele- and reference echocardiography measures revealed no differences (p= 0.05). Of the 71 valve leaks or aortic stenoses present, 61 (86%) were detected using tele-echocardiography. These results indicate that tele-echocardiography provided reliable diagnoses and acceptable measurements in 86% and 93% of cases, respectively, with no false-positive diagnoses being reported (13)

The third one sought to assess the feasibility of performing adult abdominal examinations using the MELODY telerobotic ultrasound system in 18 patients prospectively. Ninety-two percent of organs visualized on conventional examinations were sufficiently visualized on telerobotic examinations. Five pathological findings were identified on both telerobotic and conventional examinations, 3 findings were identified using only conventional sonography, and 2 findings were identified using only telerobotic sonography. A paired sample t-test showed no significant difference between the 2 modalities in measurements of the liver, spleen, and diameter of the proximal aorta; however, telerobotic assessments overestimated distal aorta and common bile duct diameters and underestimated kidney lengths (P values < .05). All patients responded that they would be willing to have another telerobotic examination(1).

5.3 Research Rationale and Hypothesis

In children with Covid-19, the diagnosis of Kawasaki Disease (KD) and pneumonia should be made very quickly and require expertise in abdominal, thoracic and cardiac ultrasound expertise. However, the

regional hospitals surrounding Paris don't have the require expertise and need to send infected patient in reference hospital which increase the transfer of patients and the risk of contamination.

The " MELODY " remote system developed by the company AdEchoTech is a CE-marked telemedicine technique, allowing an expert to perform an ultrasound scan on a distant patient (several hundred/thousands of kms). The Melody system makes it possible to optimize ultrasound expertise resources wherever they are located (all specialties combined). Using the MELODY technics, the CHIC plan to provide cardiac/thoracic/abdominal Ultrasound expertise 24hs/24 to the paediatric emergency care units among the suburbs of Paris. On the "patient" site, a dedicated room will be created close to the units devoted to the Covid-19 patient, easy to decontaminate and containing the robot. Ultrasonography is a major first-line imaging examination, easy to implement, very relevant and often decisive but imposing in conventional practice a close proximity between the patient and the expert making the examination at high risk of contamination of one or the other in the current covid 19 epidemic situation. The Melody system makes it possible to optimize ultrasound expertise resources wherever they are located (all specialties combined) and eliminates the risk of exposure of experts on the one hand and patients on the other, allowing them to benefit from high-performance ultrasound expertise in their place of hospitalization.

In this context, we aimed to address the feasibility of the Melody remote control system for ultrasound probe to perform thoracic, abdominal and cardiac ultrasound in children and to compare it to conventional ultrasound exam

5.4 Description of the study population

Children from 1 to 10 years in the emergency room or during a scheduled visit and needing an ultrasound scan: cardiac, abdominal or thoracic.

5.5 Benefit/risk and ethical assessment

We aim to demonstrate the feasibility of the MELODY Telerobotic sonography as compared with standard exam. Using the Melody system in children will allow to perform quick diagnosis of pneumonia and Kawasaki disease (including cardiologic assessment) in all the suburbs hospital.

Moreover, this technic allows to perform abdominal sonography in infants which is crucial for intestinal invagination diagnosis. The melody system will bring the expertise of paediatric radiologist, cardiologist or pulmonologist who could not be available in all suburbs hospitals.

6 Research methodology

6.1 Methodology

Open-label, prospective, crossover non-randomized, controlled trial .

6.2 Research planning and justification

2 centres (CHI of Creteil and CHI Villeneuve-Saint-Georges) will participate to this study:

- 40 children are expected with an average inclusion rate of 8 patients per month.
- The duration of inclusions should be 8 months.
- The maximum duration of the research for the patient is 1 day.
- The end of the study is defined by the last visit of the last patient; this corresponds to the 1-day visit of the last patient included.
- The overall duration of the study will be 12 months.

7 Study objectives and outcomes

7.1 Primary objective

To assess the concordance of telerobotic vs. conventional sonography results in children.

7.2 Primary outcome

Concordance of the examination conclusion (normal or abnormal) between telerobotic and conventional ultrasound examinations.

7.3 Secondary objectives

- To determine the feasibility of the telerobotic ultrasound at different ages
- To compare the abnormalities described for each procedure in case of pathologic conventional ultrasound examination
- To describe discordant results of conventional and telerobotic ultrasound examinations
- To assess adverse events
- To assess parent satisfaction
- To assess medical staff satisfaction
- To compare the duration of the examination for the 2 procedures

7.4 Secondary outcomes

- Age of patients with telerobotic ultrasound
- Conventional and telerobotic ultrasound examinations results
- Parent satisfaction questionner
- Medical assistant and sonographer satisfaction questionner
- Examination time

8 Patient selection

8.1 Inclusion criteria

- Patient from 1 year to 10 years
- Patient requiring an ultrasound exam (thoracic, abdominal or cardiac)
- French social security affiliation

8.2 Exclusion (non-inclusion) criteria

- Obesity defined by a BMI greater than 30
- Open wound making it impossible to carry out an ultrasound scan
- Algetic patient
- Instability of vital functions
- Impossible to remain in a seated position
- Refusal to participate in the study

9 Study design

9.1 Study visits

9.1.1 Inclusion

The study will be explained and proposed by an investigator at the emergency room or during a scheduled visit. The information letter will be given to the legal representatives and the child from 3 years old. In case of acceptance, the legal representatives will be asked to sign the consent. In the emergency situation the signature of a single legal representative is required.

9.1.2 Ultrasound examination with the MELODY System

Child will be initially scanned using the telerobotic Melody system. The ultrasound machine used is the Te7 from Mindray allowing any type of ultrasound scan to be carried out. During the whole examination the operator will remain close to the child and will have to position the robotic arm according to the indications of the remote sonographer. During the examination the parent will remain at the child's side.

9.1.3 Classic ultrasound examination

The classic ultrasound will be performed immediately after the telerobotic ultrasound with a maximum delay of 3 hours between the 2 exams. After the telerobotic examination, patients will be scanned by a different sonographer with a similar experience and qualifications using a conventional ultrasound with the same ultrasound machine:TE7 from Mindray. The sonographer will be blinded to the findings of the telerobotic examination.

9.1.4 Procedure evaluation

Based on the referring clinician's initial request, examinations included ultrasound examination based on the radiologist, cardiologist and pulmonologist clinical practice guideline.

3 evaluation grids will be made according to the type of examination (cardiac, abdominal and thoracic). For each examination type, an image quality will be qualitatively scored from 1 (very poor) to 5 (excellent)

1) Abdominal

The following organs/ parts of the abdomen will be scanned:

- gallbladder and bile ducts
- liver
- Portal vein
- Spleen
- Pancreas
- Kidneys
- bladder

2) Cardiac

Standardised echocardiographic examination according to recommendations to assess:

- heart and vascular structures
- Ejection fraction and ventricular diastolic and systolic function
- Flow through all of the cardiac valves using colour doppler.

3) Thoracic

All parts of the lungs will be scanned. A visualization score for each elementary structure will be collected.
A total Lung aeration Score will also be calculated: the LUS score.

9.1.5 Patients site assistant survey

After completion of both exams, parents and children will complete a survey based on that of Adams et al (ref) regarding their experience with the telerobotic examination. Participants' parents will be asked to indicate their agreement with 4 statements using a 5-point Likert scale.

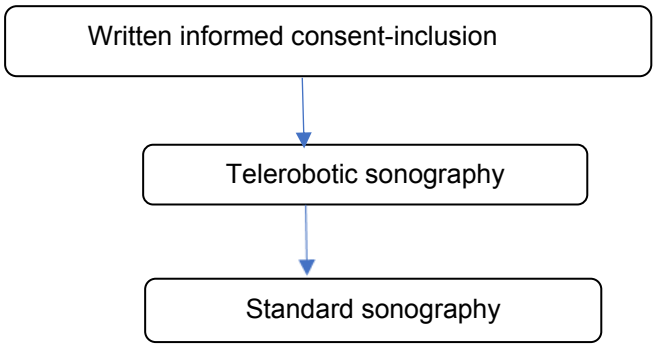
9.1.6 Sonographer survey

Sonographers will be asked to indicate their agreement with statements using a 5-point Likert scale after each telerobotic examination.

9.1.7 Non medical assistant survey

Patient site assistants will indicate their level of agreement with statements using a 5-point Likert scale after each telerobotic examination.

9.2 Study flow chart



9.3 Study plan

Visit	Screening (D0)	Inclusion (D0)
Informed consent	R	
Medical history	C	
Weight (kg)	C	
Height (cm)	C	
Standard sonography		C
Telerobotic sonography		R
Patient survey		R
Sonographer survey		R
Non-medical assistant survey		R

C: usual care
R: specific to the research

10 Investigational product

10.1 Telerobotic sonography: Melody system

Denomination MELODY Remote Control System for Ultrasound Probe	GMDN Code 37317	Category Telemedicine system
N° of software version MELODY_PCI_MCS 2.2.0 MELODY_PCI_SCS 2.1.0 MELODY_PCI_UIS 1.7.0 MELODY_ECI_UIS 1.7.0	Medical device class Class IIa (MDD 93/42/CEE and MDR EU 2017/745)	

The " MELODY " remote system developed by the company AdEchoTech is a CE-marked telemedicine technique, allowing an expert to perform an ultrasound scan on a distant patient (several hundreds/thousands of kms).

For this study, the 2 MELODY Remote Control System for Ultrasound Probe have the following serial number:

- 04-202010001 provide for CHI of Creteil
- 04-202010002 provide for CHI of Villeneuve-Saint-Georges

The Melody system makes it possible to optimize ultrasound expertise resources wherever they are located (all specialties combined) and eliminates the risk of exposure of experts on the one hand and patients on the other, allowing them to benefit from high-performance ultrasound expertise in their place of hospitalization. In the case of the current pandemic, the Melody solution, depending on the chosen configuration, will make it possible to eliminate the possible exposure of the patient or the expert to COVID-19.

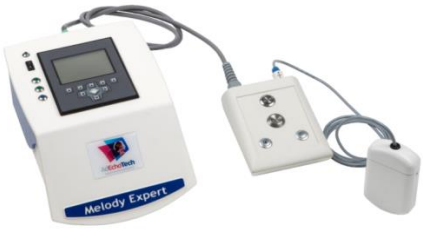
10.1.1 Medical device identification

The Telerobotic sonography involve the Melody system composed of the Melody Patient and of the Melody Expert 3 devices and the ultrasound machine: TE7 (described on section 10.2 p20)

- **The Melody Patient**



- **The Melody Expert**



- **The ultrasound machine TE7**



10.1.2 Use for the medical device

The MELODY system can be used on an adult population, female or male, for the following indications:

- fetal and abdominal imaging
- peripheral vessels

- pelvis
- urology
- cardiology

In the Childmelody study, the device will be use on a child population for the following indications:

- abdominal
- cardiology
- thoracic

10.1.3 How to use the device

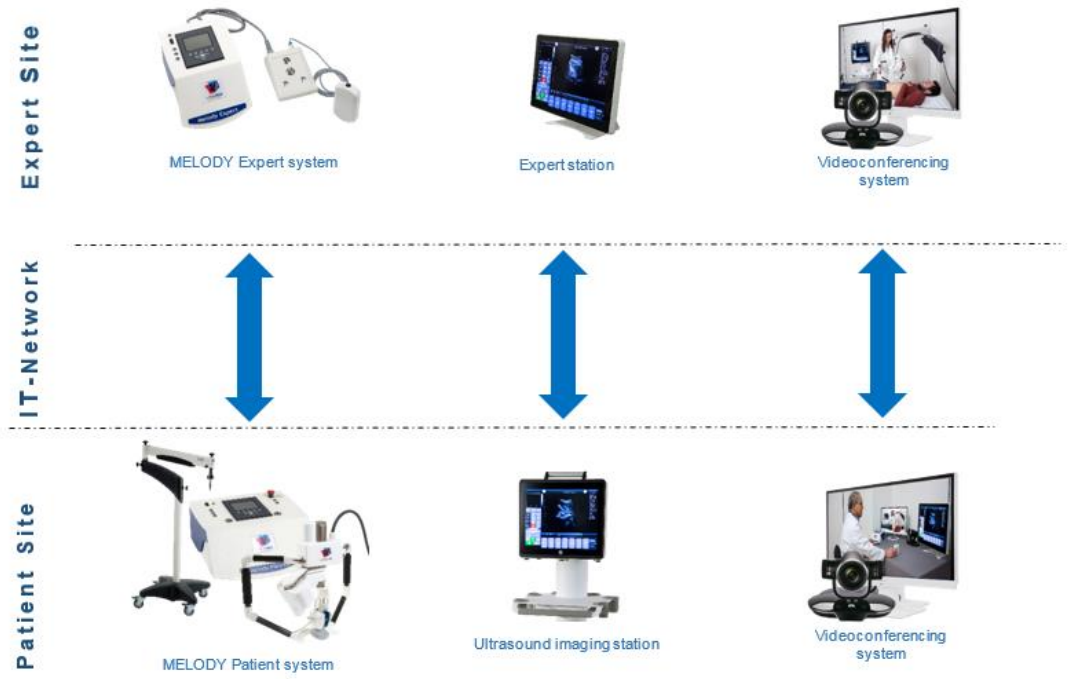
All medical staff involved in the study will be trained in its use.

On the "expert" site, the "dummy" probe, much like a standard abdominal ultrasound probe, allows a fast and ergonomic remote control of the robot. Thanks to the remote-control unit, the imaging expert keeps a total autonomy on the ultrasound image parameter setting (management of the gain, depth, change of the frequency, activation of the different ultrasound modes).

Videoconferencing allows the physician to see his patient and to dialogue with him.

On the "patient" site, a dedicated room will be created close to the units devoted to the covid patient. easy to decontaminate and containing the robot. A health professional who does not know ultrasound (general practitioner, manipulator, nurse...) assists the imaging doctor by positioning the robot on the patient. The MELODY solution then allows to reproduce all the movements of the imaging expert with precision. Video conferencing allows the patient to see his physician and to dialogue with him.

The solution transmits in real time the ultrasound image, the robot control and the videoconference.



10.1.4 Safety precautions

If the patient's skin has lesions (wounds, burns, etc.), the MELODY system must not be used on the injured areas.

10.2 Standard sonography

A standard sonography with the same ultrasound device (TE7 from Mindray) will be use as comparator.

Device	Model	Supplier name	Supplier's Addresse
Ultrasound imaging station	**Te7** 	MINDRAY	**MNDRAY** Mindray Medical France 1 Allée des Cerisiers 94035 CRETEIL Cedex, FRANCE

11 Concomitant and other treatments

There are no restrictions on the use of concomitant therapies for this study. In addition, the investigator may decide to implement treatments based on the results of the standard ultrasound scan, as would be the case in routine management.

12 Description of permanent or temporary withdrawal

12.1 Withdrawal of the informed consent

Patients are free to withdraw from the study at any time, without prejudice to further treatment.
A patient who withdraws consent will always be asked about the reason(s) and the presence of any adverse events (AE). The Investigator will follow up AEs outside of the clinical study.
If a patient withdraws from participation in the study, then his/her enrolment/randomisation code cannot be reused. Withdrawn patients will not be replaced.

12.2 Terminating part or all of the research

The study may be stopped if, in the judgment of the Sponsor, trial patients are placed at undue risk because of clinically significant findings that:

- meet individual stopping criteria or are otherwise considered significant
- are assessed as causally related to study drug,
- are not considered to be consistent with continuation of the study

Regardless of the reason for termination, all data available for the patient at the time of discontinuation of follow-up must be recorded in the CRF. All reasons for discontinuation of treatment must be documented.

13 Safety assessment

13.1 Protocol specificity

The use of the device will be done on supervision of the medical staff. The MELODY device use in this study is non-invasive and non-irradiating. None SAE is expected. This will allow monitoring of adverse events and adjustment of management if necessary.

13.2 Identified risks

In the current use of the Melody system in adults, two main residual risks have been identified :

- An impossibility to perform an examination due to a bad internet connection: the MELODY tele-echo solution has been optimized to operate with the lowest possible internet speed, which makes it possible to use it with ADSL, 3G+/4G or satellite networks.

- A delay in the diagnosis due to a difficulty in positioning the probe as requested by the expert: the patient's assistant is most often from a paramedical background and has knowledge of the human anatomy. In addition, he benefits from training from

AdEchoTech. Finally, according to the clinical studies conducted, the analysis time decreases with experience.

For children the following risks are identified:

- Difficulty in positioning the ultrasound probe because of the bulky base. One of the objectives of the study is to determine from which age group it is possible to use the device as it is today, and to design a base that would be adapted to the lower age group.
- A discomfort caused by the pressure exerted by the base or probe. The base is just placed on the part of the body to be examined by the assistant, there is no strong pressure exerted at this level. As for the probe, MELODY has been designed in such a way that it exerts a lower pressure than that of an expert. Studies have shown that this is sufficient to obtain the ultrasound images necessary for a diagnosis.
  Furthermore, MELODY is used in obstetrics, a medical field that is particularly sensitive to pressure.
- Injury, discomfort or difficulty performing the exam due to the child's agitation. The patient is never alone, a trained nursing staff (operator) is always present to hold the robot. The carrying foot of the probe robot supports the integrity of the robot's weight. In addition, the operator has full control of the robot's contact with the patient. In case of a restless patient, he can quickly move the robot away from the patient without constraint.
  It should be noted that the constraints are the same as in a conventional ultrasound scan.

13.3 Definitions

According to Article R1123-46 of the Public Health Code, Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices (MDR)

13.3.1 Adverse event (**article R. 1123-46 of the public health code)**

Any harmful event, unintended illness or injury, or untoward clinical sign, including an abnormal laboratory result, in participants, users, or others in a clinical investigation, whether or not related to the device under clinical investigation.

Note:
a. This definition includes expected events as well as unexpected events.
b. This definition includes events occurring in the course of a clinical investigation related to the investigational device, comparator, or procedures involved.
c. For users or others, the definition includes only events related to the use of the investigational device or comparators.

13.3.2 Adverse Reaction of a Medical Device under investigation

Adverse event related to the use of the medical device under investigation

Note 1 : This definition includes any adverse event resulting from inadequacies or inappropriateness in the instructions for use, deployment, implantation, installation and operation, or malfunction of the medical device under investigation.

Note 2: This definition includes any event resulting from an error in use or intentional misuse of the medical device under investigation.

Note 3: This includes the comparator if it is a medical device.

13.3.3 Device Defects (RDM article 2 (59))

Any defect in the identity, quality, durability, reliability, safety or performance of a device under investigation, including any malfunction, error in use or defect in the information provided by the manufacturer.
Quality Defect: Non-compliance with the specifications described in the CE marking/technical documentation or a deviation from Good Manufacturing Practices (GMP) / Good Distribution Practices (GDP), storage, labeling.

Durability failure: Failure to maintain performance during the life of the DM

Reliability Defect: Reliability is the probability that a primary part, device or complete equipment will be used without failure for a specified period of time, under specified operational conditions. (Reliability can be expressed as a duration that corresponds to the mean time between two successive failures).

Defect Performance: Failure of a device to achieve its intended purpose.

Malfunction: Failure of the medical device under investigation to perform in accordance with its intended use when used in accordance with the instructions, the clinical investigation plan or the investigator's brochure.

Error in use: An action by the user or lack of action by the user in using the medical device that results in an outcome different from that intended by the manufacturer or expected by the user.
Note 1: An error in use includes the inability of the user to perform a task.
Note 2: Usability errors may result from a mismatch between the characteristics of the user, the user interface, the task, or the user environment.
Note 3: Users may or may not know that a usability error has occurred.
Note 4: An unexpected physiological response from the patient is not considered in itself to be an error in use.
Note 5 to the article: Malfunction of a medical device that results in an unexpected outcome is not considered an error in use.

Defect in manufacturer's information : The manufacturer's information must enable the use of the device as intended by the manufacturer, ensure safe use, and meet applicable regulatory and normative requirements.

13.3.4 User (MDR Section 2 (37-38))

Any health care professional or layperson who uses a device.

13.3.5 Serious adverse event (RDM article2 (58))

Any adverse event that resulted in:

- death
- a serious deterioration in the health status of the participant that results in ::
  - a life-threatening illness or injury;
  - a permanent impairment of an anatomical structure or function;
  - hospitalization or prolongation of hospitalization of the patient;
  - medical or surgical intervention to prevent a life-threatening illness or injury or a permanent impairment of an anatomical structure or function
  - a chronic illness;
- Fetal suffering, fetal death, congenital physical or mental impairment or congenital malformation.

A planned hospitalization for a pre-existing condition or procedure required by the clinical investigation plan, without serious deterioration of health, is not considered a serious adverse event.

13.3.6 Serious Threat to Public Health (MDR Section 2 (66))

An event that may result in an imminent risk of death, serious deterioration of health, or serious illness that may require prompt corrective action, and that is likely to result in significant human morbidity or mortality, or that is unusual or unexpected at the time and place in question.

13.3.7 Serious Adverse Device Effect

An adverse device reaction that results in one of the consequences characteristic of a serious adverse event.

13.3.8 Serious Unexpected Adverse Reaction DM

A serious unexpected adverse event for a device is an event that, by its nature, incidence, severity, or outcome, has not been identified in the current risk assessment. Procedures associated with the use of a device should be addressed in the risk assessment, which determines whether or not procedure-related SAEs are unexpected serious adverse device reactions. SAEs related to procedures mandated by the clinical investigation plan but not with the use of the device should not be considered serious adverse device reactions.

13.3.9 Causality :

- **Unrelated**: causality with the DM, comparator, or procedures can be ruled out

- **Possible**: causality with the use of the DM, comparator, or trial procedures is weak but cannot be completely ruled out. Other causes are also possible (underlying or concomitant disease/clinical condition/effect of another treatment). Cases where the relationship cannot be assessed or no information has been obtained should also be classified as possible.

- **Probable**: the causal link to the use of the DM or comparator, or the relationship to the trial procedures, appears to be relevant and/or the event cannot be reasonably explained by another cause.

- Certain: the serious adverse event is related to the use of the DM, comparator, or trial procedures beyond reasonable doubt.

Intensity:

The intensity of adverse events will be determined as follows:
- mild (grade 1): no interference on the patient's daily activity ;
- moderate (grade 2): moderate interference on the patient's daily activity but still acceptable;
- severe (grade 3): significant interference on the patient's daily activity and unacceptable;
- life-threatening (grade 4);
- death (grade 5).

All life-threatening and fatal adverse events (grade 4 or higher) are considered serious and should be reported to the sponsor without delay

13.3.10 New facts (article R1123-46 of the public health code)

Any new data that may lead to a reassessment of the benefit/risk ratio of the research or of the product that is the subject of the research, to changes in the use of this product, in the conduct of the research, or in the documents relating to the research, or to the suspension or interruption or modification of the protocol of the research or similar research.

For trials involving the first administration or use of a health product in individuals without a medical condition: any serious adverse reaction.

13.4 Role of the investigator

13.4.1 The INVESTIGATOR'S role in the event of an adverse event or a new fact

Collection of undesirable events

Upon signing the consent form, the investigator is responsible for the collection of all adverse events and defects. He/she reports all serious and non-serious adverse events (biological and clinical AEs) as well as defects in the device (which could have led to a serious adverse event) that occur between the signing of the consent form and the end of the patient's participation or the end of the collection of adverse events, in the observation booklet.

These adverse events will be assessed at each visit during the study by questioning and during the clinical examination of the patient.

The following circumstances need not be collected:

- admission for a corporate or administrative reason,
- hospitalization for scheduled medical or surgical treatment prior to research,

The investigator should document the defect or event to the best of his or her ability, including, if possible, the medical diagnosis. The investigator should ensure that relevant follow-up information is provided to the sponsor as soon as possible.
The investigator should submit, in addition to the SAE/DD reporting form, copies of laboratory results or test reports or hospitalization reports documenting the serious adverse event, including relevant negative results, and should anonymize these documents and record the patient identification number.
The investigator should follow the patient who has experienced a SAE until resolution, stabilization at a level deemed medically acceptable by the investigator, or return to the previous state, even if the patient has discontinued the research procedure. Additional information regarding the evolution of the event, if not mentioned in the first report, will be sent to the sponsor by the investigator.

The investigator and the sponsor should independently assess the causal relationship between the serious adverse event, the investigative procedure of the MD and the associated treatments.

All serious adverse events for which the investigator or sponsor believes that a causal relationship can reasonably be considered are considered suspected serious adverse events.

The investigator should notify the sponsor of any new information that comes to his/her attention.

Reporting of serious adverse events (SAEs), adverse events of interest, DM defects and new facts.

The investigator reports each adverse event in terms of its severity and each defect in the device. The gradation of severity, if relevant, will be based on a predefined scale.

The investigator must notify the sponsor, without delay and no later than 3 calendar days from the day he/she becomes aware of it, of any serious adverse event (SAE), any adverse event of interest, or any defect in the DM occurring :

- from the date of the first investigative procedure performed
- during the entire duration of the patient's follow-up planned by the research,

Without time limit, if the investigator becomes aware of a serious adverse event, for which he suspects a causal link with the research, occurring after the end of the clinical trial in a participant he has treated, he must inform the sponsor without delay.

13.4.2 Procedures for notifying the sponsor

The initial notification of a serious adverse event is the subject of a written report signed by the investigator, using a special form for notification of serious adverse events specific to the clinical investigation.

Each item of this document must be completed by the investigator to enable the sponsor to carry out a relevant analysis.

The initial notification of a serious adverse event to the sponsor should be followed rapidly by a detailed written report(s) to monitor the progress of the case under vigilance or to complete the information.

The investigator will transmit, as far as possible, any document that may be useful to the sponsor (medical reports, biological results, results of complementary examinations, etc.). These documents must be made anonymous. In addition, they must be completed with the following information: acronym of the clinical investigation, number and initials of the participant.

Any serious adverse event will be followed up until its complete resolution (stabilization at a level deemed acceptable by the investigator or return to the previous state) even if the participant has left the clinical investigation.

Initial reporting, EvIG follow-up reports and any other documents are done by emailing the Clinical Research Center at crcvigilance@chicreteil.fr.

Summary table of the notification circuit by type of event

Type OF EVENT	Condition of notification	DEADLINE FOR REPORTING TO THE SPONSOR
Non-serious adverse event (by vigilance unit)	On the case report form	No immediate notification
Serious adverse event	Initial EvIG declaration form + Follow up if necessary	Notification to the sponsor without delay, as soon as it is known, and no later than 3 calendar days
New fact	Written report	Notification to the sponsor without delay

13.5 Sponsor's Responsibilities

13.5.1 13.5.1 Registration and evaluation of the sponsor

The sponsor records:

(a) any adverse event defined in the protocol as instrumental in evaluating the outcome of the clinical investigation.

b) any serious adverse event;

c) any defect in a DM that could have led to a serious adverse event in the absence of appropriate measures or intervention, or if the circumstances had been less favourable;

(d) any new evidence of an event referred to in (a) to (c).

The sponsor is responsible for the ongoing safety assessment of the investigational DM.

The sponsor must assess:

The causal relationship between the serious adverse event and the medical device and/or research procedures.

the unanticipated nature of the serious adverse events of the medical device

the expected or unexpected nature of the serious adverse events, Any serious adverse event whose nature, severity or evolution are not consistent with the information contained in the instruction leaflet or the instructions for use when the medical device is subject to CE marking

The evaluation of the expected/unexpected/unanticipated nature of a serious adverse reaction is carried out by the sponsor represented by its Vigilance sector on the basis of the information described below.

The sponsor records and analyses the New Facts.

13.5.2 Declaration to the competent authorities

In accordance with the European DM Regulation 2017/745, the sponsor must report to the competent authorities the following "reportable events":

(a) any serious adverse event that has a proven or reasonably foreseeable causal relationship with the device under investigation, the comparator device or the investigational procedure;

(b) any device defect that could have resulted in a serious adverse event in the absence of appropriate action or intervention, or in less favorable circumstances

(c) any new evidence of an event described in (a) and (b).

Only causality level 1 (i.e., "unrelated") is excluded from reporting

Reporting deadlines	**Type of "carry-over" events**

Type of "reportable" events "Without delay (immediately), and no later than 2 calendar days from the day on which the sponsor becomes aware of the reportable event or of new information concerning an event already reported.	All events resulting in death or imminent risk of death, serious injury or illness that require prompt corrective action for participants/patients, users, or others, or any new information about such cases. *This includes relevant and unexpected events when they become a potential public health hazard. It also includes the possibility of multiple deaths occurring at short intervals.*
Promptly (immediately), and no later than 7 calendar days from the day the Sponsor becomes aware of the reportable event or new information regarding a previously reported event.	Other "carry-over" events or any new information/updates regarding them.

The sponsor declares to the ANSM the vigilance data mentioned above:
- in the form of a table such as the one presented in the appendix of the recommendation entitled "Investigation summary safety report form" (MDCG-2020-10/2) available at: https://ec.europa.eu/health/sites/health/files/md_sector/docs/md_mdcg_2020-10-2_guidance_safety_report_form_en.xlsx

This table will be updated and transmitted each time a reportable event or new information relating to a reportable event is to be reported. If necessary, more detailed information should be provided upon request by the ANSM.

Details on the content of the information mentioned in this table are provided in section 10 of recommendation MDCG-2020-10/1.
- by email to : EC.DM-COS@ansm.sante.fr
indicating the following in the subject line of the e-mail YYYYMMDD_EIG_N°IDRCB or N°EUDAMED

13.5.3 Description of expected SAE

Not serious adverse events are expected under the protocol.

13.5.4 Annual Safety Report

One year after the first inclusion, the Vigilance Unit prepares a safety report including :

- a list of the expected and unexpected serious adverse effects of the research.
- a concise and critical analysis of the safety of the research patients

- summary tables of all serious adverse events that have occurred in the trial concerned since the beginning of the research.

This report is sent to the ANSM and the CPP within 60 days following the anniversary date of the first inclusion.

13.5.5 Data Monitoring Committee

For this study, no Data Monitoring Committee will be set up for several reasons:

- The Melody system studied is non-invasive and non-irradiating (no radiation is released)
- The Melody system will be only used under the supervision of the medical staff
- The Melody system have the CE marking and is use according to its notice to make ultrasound. The difference with its CE marking is that it is used on children and that thoracic ultrasound will be done for one group (10 patients).

14 Statistical analyses

14.1 Sample size estimate

In this pilot study and in absence of prior data on telerobotic ultrasound examination in children, we'll plan to include 40 subjects: with 10 cardiac sonographies, 20 abdominal sonographies and 10 thoracic sonographies.

14.2 Analysis plan

Statistical analyses will be performed at the end of the inclusions. Qualitative variables will be described by percentages and quantitative variables by their mean and standard deviation or median and interquartile range. Concordance analyses will be performed by a Cohen Kappa. The results of the statistical tests will be given at the bilateral 5% threshold. No interim analysis is planned. A more detailed analysis plan will be drafted and submitted for validation by the steering committee before the analysis of the study.

15 Ethical conduct of the study

15.1 Legal obligations

The sponsor and the investigators undertake that this research will be carried out in accordance with the regulations in force, as well as in accordance with Good Clinical Practice (I.C.H. version in force) and the Declaration of Helsinki.

15.2 Regulatory Authority Approval

The National Agency for the Safety of Medicines (ANSM) authorized this trial on January 29th 2021.

15.3 Committee for the Protection (CPP) of Persons/Institutional Review Board(s)

This clinical study received a positive opinion from CPP Sud-Est III on January 19th 2021.

15.4 Computerized data – French National Commission for Information Technology and Civil Liberties (CNIL)

The data collected during the study will be kept in a computer file that complies with the French Data Protection Act “Informatique et Libertés” of 6 January 1978, amended in 2004 and the European Data Protection Regulation (DPR). The promoter has undertaken to comply with the reference methodology MR-001 concerning the processing of personal data.

15.5 Insurance

The Sponsor declares that it has taken out an insurance policy with SHAM, policy no. 102,760, guaranteeing, in accordance with the clauses provided for in the contract and within the limit of the fixed amounts, the financial consequences of its civil liability as it results from the application of article L 1121-10 of the Public Health Code.

16 Data management

16.1 Data Collected

The following data will be collected:

- General information: date of birth, sex, height, history
- Ultrasound results
- Average time to complete an exam
- Score of satisfaction of patient/legal representative and of medical staff
- Undesirable events

16.2 Data Capture

The data will be entered in an electronic case report form.
Patients will be identified by the first letter of their surname, first name and inclusion number.

16.3 Right of access and confidentiality

The investigators will make the documents and individual data strictly necessary for the monitoring, quality control and audit of the research available to persons having access to these documents in accordance with the legislative and regulatory provisions in force (Articles L.1121-3 and R.5121-13 of the Public Health Code).

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In accordance with the legislative provisions of the preceding Articles, persons with direct access to source data shall take all necessary precautions to ensure the confidentiality of information relating to investigational medicinal products, research, the persons involved and, in particular, their identity and the results obtained. These persons, like the investigators themselves, shall be subject to professional secrecy.

During or at the end of the research, the data collected on suitable patients and transmitted to the sponsor by the investigators (or any other specialist) shall be rendered anonymous. Under no circumstances should the names and addresses of the patients concerned be made clear.

Each patient will be assigned a confidential identification code.

The sponsor will ensure that each patient involved in the research has given written consent for access to individual data concerning him or her that is strictly necessary for the quality control of the research.

16.4 Archiving of study documents

The documents relating to this research are archived in accordance with Good Clinical Practice and the regulations in force for a period of 15 years following the end of the research by the doctors, the investigating centres and the sponsor.

16.5 Quality control and quality assurance

A clinical research associate mandated by the sponsor visits the investigator's center on a regular basis, when the research is set up, and several times during the research according to the sponsor's procedures. During these visits, the following elements will be reviewed:

- informed consent,
- compliance with the research protocol and the procedures defined therein,
- quality of data collected: completeness, accuracy, missing data, consistency of data with source documents (medical records, appointment books, original laboratory results, etc.).

All visits will be the subject of a monitoring report in the form of a written report. A monitoring report letter will be sent to the investigating team after each monitoring visit.

An audit may be carried out at any time by a Sponsor representative and independent of the persons responsible for the research. Its purpose is to ensure the quality of the research, the validity of its results and compliance with the law and regulations in force.

The investigators agree to comply with the sponsor's and the competent authority's requirements for an audit or inspection of the research. The audit may apply to all stages of the research, from protocol development to the publication of results and the classification of data used or generated in the research.

16.6 Data properties

The Sponsor (CHIC of Créteil) is the owner of the data.
The conditions for the transfer of all or part of the research database are decided by the research sponsor and require a written contract.

17 Publication rules

17.1 Scientific Communications

Analyses will be performed by Sponsor or its representatives.

Any written or oral communication of the results of the research must receive the prior agreement of the coordinating investigator and co-investigators and, where appropriate, of any committee established for the research.

The main results of this study will be published in an international peer-reviewed English-language journal.

17.2 Communication of results to participants

In accordance with law n°2002-303 of 4 March 2002, participants are informed, at their request, of the overall results of the research.

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