Clinical Investigation Protocol

for

Safety and useability of a novel **robot**-assisted echocardiographic examination.

The RUAT ECHO Study

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Study Title	Safety and useability of a novel robot-assisted echocardiographic examination.
Short Title	The RUAT ECHO Study
Sponsor(s)	Mr. Mathew Saliba CEO, RMI Oceania Pty. Ltd.
Funding Organisation	RMI Oceania Pty. Ltd.
Study Site	Royal Brisbane and Women's Hospital (RBWH) Cardiology Department Metro North Hospital and Health Service

1 General Information

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Data Management	Biointelect Pty Limited

2 Protocol Acceptance

2.1 Investigator

I have read this protocol entitled: Safety and useability of a novel robot-assisted echocardiographic examination.

I agree to conduct the study according to this protocol and to internationally accepted standards of ICH Good Clinical Practice and local regulations.

Investigator's Name: Title:

Investigator's Signature: Date:

2.2 Sponsor

Sponsor's Name: Title:

Sponsor's Signature: Date:

3 Study Synopsis

RMI Oceania (the legal manufacturer and sponsor) has developed an ultrasound imaging Robotic Ultrasound Assistance Tool 'RUAT' that has the capacity to provide robotic systems which can be integrated into a healthcare system's specific digital network. This robot functions as a collaborative 'ROBOT' or 'COBOT' where a human operator remote controls the arm for image acquisition. The RUAT can be deployed in any location (including regional and remote) and controlled remotely with the sonographer using a novel workstation-based control system.

This is a pilot "Safety and Useability" Clinical Investigation of the RUAT system to perform an echocardiographic examination.

Up to 30 participants (over a 2-month period) will be recruited from inpatients and outpatients of the Royal Brisbane and Women's Hospital who have already received a standard (manual) echocardiogram examination and deemed suitable based on willingness to undergo the RUAT Echo scan for research purposes and are able to consent and participate.

The primary objectives include to:

a. assess the **safety** of the RUAT echo.

b. assess the **useability (functionality)** of using the RUAT echo as intended to obtain echocardiogram images of clinically suitable quality for reporting by a cardiac sonographer.

4 Schedule of Assessments

	Visit Structure		
Procedure	Screening	Day of RUAT Echo	Safety Follow-up visit /End of Study[1] 72 hours post scan
Manual echo (prior to RUAT study)[2]	X		
Informed consent	X		
Review inclusion and exclusion criteria[3]	X		
Demographics	X		
Echocardiogram using RUAT ECHO		X	
Functional verification of RUAT ECHO		X	
Participant experience Surveys[4]		X	
Adverse events/Adverse device events	Continuous from informed consent signature to end of study		

[1] Safety Follow-up visit may be conducted by telephone call or onsite if inpatient, within 72 hours after the examination.
[2] As part of the selection criteria participant will have recently undergone a manually performed echocardiogram. Any bruising or soreness will be documented as part of the screening and consent, ruling ineligible if the discomfort is too severe.
[3] Participants must have undergone a clinical (manual) echocardiogram performed and reported as per usual clinical pathway **prior** to study entry. All clinical decisions will be made based on this echocardiogram.
[4] Participant survey to be completed on paper after the RUAT Echo with the support of the observing sonographer.

5 Background

Clinical ultrasound is a cornerstone of modern medical imaging. It is inexpensive, non-invasive, and has improved versatility in application with advancements in ultrasound technology and automation. Cardiac ultrasound or echocardiographic examination ('echo') for screening and monitoring, and in emergency settings, is an essential diagnostic modality in indicated patient populations. Two major limitations of ultrasound examination in clinical practice include access to such services for regional, rural and remote areas, and the high injury rate sustained by sonographers when performing these procedures.

Cardiovascular disease is the leading cause of death globally, with one Australian dying every 12 minutes due to cardiovascular disease. It is the leading cause of death for men and women in Queensland, with rural areas having a 25% higher morbidity and mortality at least partly due to reduced access to primary healthcare. Rural Australians die younger than those who live in major metropolitan areas. This is further hampered by rural locations of Australia having significantly smaller populations, which limits the capability to provide full Cardiology services (particularly Echocardiography). As a result, patients either must travel long distances to a metropolitan location to have the procedure performed, or they wait long periods for an outreach team to travel to their rural location.

There is a high risk of injury for sonographers that conduct these scans due to prolonged awkward postures being held for long periods of time. These injuries are not uncommon, with 80-95% of sonographers experiencing work-related pain, with 90% of those experiencing pain for more than half their career, and one in five sonographers sustaining a career ending work-related injury.[1]

Remote control operation of cardiac investigation equipment has evolved and is feasible for certain procedures. To date, remotely operated exercise stress testing and Holter monitoring equipment, have been trialed in rural Queensland[2]. This enables specialists located in metropolitan areas to conduct and report these remote examinations on a same day basis, enabling rural populations to access healthcare technologies and specialist healthcare staff normally only located in metropolitan areas. The use of technology to improve remote healthcare delivery has real potential to significantly reduce associated morbidity, mortality and healthcare financial burden. While standardised and comprehensive telemedicine is still in its infancy, technological improvements now permit expansion of telemedicine initiatives.

Recently, robotic arm systems have been suggested to have the capability and feasibility to hold and appropriately manipulate existing ultrasound probes for image acquisition on humans. For example:

(1) Medirob Ergo – ergonomic echocardiography which is a CE Class I medical device – Medirob is a medical robot that is an ergonomic aid for ultrasound examinations. Injuries in sonographers are prevented by letting the robot hold the ultrasound transducer during examinations. The control of the mechanical arm is intuitive and precise. Examinations done with a robot produce the same ultrasound images that you get from traditional examinations.
Website: https://www.medirob.com/en/

(2) Another predicate device considered which is available in global market is the AdEchoTech Melody robotic ultrasound device which is Class II under the U.S. Food and Drug Administration (FDA) – This is a robotic arm with 4 DoF that performs ultrasound exams on a patient located remotely. It manipulates a "dummy probe", like the real one, allowing the operator to control the robotic arm. The ultrasound image is displayed on a screen in real time. The expert can make the ultrasound machine settings from a distance.
Website: MELODY, a remote, robotic ultrasound solution (adechotech.com)

Similar devices not yet licensed, but with cardiac applications include:

(3) ReMeDi – A European product which requires an assistant to bring the ultrasound transducer to the patient's chest, then is remotely operated by an echocardiographer. The operator uses a foot pedal and custom-designed dummy transducer to manipulate the arm and utilizes force feedback to control the pressure.

Website: REMEDI – ACCREA Engineering

Commercially available systems with no cardiac application include:

(4) MGIUS-R3 Robotic Ultrasound System – developed in China. At the patient end, the robotic arm and patient probe are integrated into the ultrasound machine. The remote operator's console is custom designed and integrates the ultrasound keyboard, transducer, pressure pad and teleconferencing facilities.

Website: MGIUS-R3 robotic ultrasound system-MGI-Leading Life Science Innovation (mgi-tech.com)

In addition, other relevant technologies which have been evaluated for use in clinical ultrasound are displayed below; table from *von Haxthausen et al., 2021*[3]. (Refer to Investigational Brochure Section B.2 a).

RMI Oceania (the legal manufacturer and sponsor) have developed a robotic arm system platform which carries similar attributes to the above-described products: Robotic Ultrasound Assistance Tool 'RUAT'.

A key advantage of the RUAT is that it has the capacity to provide robotic systems which can be integrated into a healthcare system's specific digital network. This robot functions as a collaborative robot or 'COBOT' where a human operator remote controls the arm for image acquisition. This system can be deployed in any location (including regional or remote) and controlled remotely with the sonographer using a novel workstation-based control system. RMI Oceania is engaging with a Queensland Health quaternary hospital (RBWH -Cardiac Sciences) to validate and use this technology in a world-first program. This partnership includes exclusive 'first' access to the technology and will enable sonography staff to be trained to conduct robotic ultrasound.

Two clinical studies have been conducted previously: a proof-of-concept study (see Section 5.1) and the COBOT study (see Section 5.2).

5.1 Proof-of-Concept Testing

RMI Oceania conducted initial development and proof-of-concept testing with the Queensland University of Technology. Full details of this study are provided in the Investigator's Brochure in Section # B.4 a) 1.

Project Title	Tele-operated Robotic Ultrasound
HREC approval	Reference Number: 2000001111
HREC Category	Human - Negligible-Low Risk
Approval dates	28/3/2021 to 28/3/2021
Device	Franca Panda Robot
Subject population	Volunteers

Analysis of the proof-of-concept study (unpublished) allowed for iteration of the initial device. The decision analyses and proposed changes to the RUAT design and functionality are summarised in Table 1.

Table 1: Decision Analysis for Alternative Device considered.

Parameters Analysed	Franka Panda Device (POC)	RUAT Device	Conclusions
Whether the sonographer(s) would be able to perform scans using a probe mounted on robotic arm to clinical standards	3 sonographers involved in the study were all able to perform the echo scan using the POC system. Two sonographers scanned three volunteers and one of the researchers during the second training session, while the third sonographer scanned two volunteers and one researcher during the second training session	Overall, feasibility for performing the 11 separate assessments of cardiac structure and function (as part of full clinical echocardiography examination) via the COBOT system was high, in majority comparable to manual echocardiographic examinations. The conclusion was that remote robotic echocardiographic examination via commercially available ultrasound platform performed by briefly trained cardiac sonographers is feasible.	The feasibility of performing the cardiac scans increased with the changes done for the Robotic arms after the Jaco2 arm was selected and the training provided to the sonographers were effective
Evaluating the usability of the ultrasound images acquired from maneuvering the robotic arm	The feedback given by the sonographers about the image quality obtained were mixed: in most of the cases, the sonographers felt that the quality of the standard scans was significantly higher than the POC system scan; while in some cases, the image quality was considered of comparable quality and in a few cases, the image quality acquired with the POC was considered even higher than the one achieved via manual scan	The feasibility of the COBOT system for producing the 38 separate quantitative measurements of cardiac structure and function was also overall very high, again in majority comparable to manual echocardiographic examinations.	The images acquired through remote scans using a better developed maneuvering system improved the images acquired to a quality level similar to a manual scan
Identifying imaging and control pitfalls or possible delays introduced	The Butterfly US probe selected for this application was not suitable to train the sonographers and utilise the POC system for the data collection due to the probe overheating limiting the continuous scanning capabilities of the probe. Later a Philips US probe was used. Delays in the scanning procedure which were related instead to the POC system were caused on several occasions by the robotic arm, the computers and the Haptic Touch controller, which needed to be restarted •The robotic arm joints were overstressed, or an excessive pressure was applied on the robot	Robotic examination image acquisition efficiency was initially longer than image acquisition via traditional examination, however there was no difference in reporting time. A significant learning curve was identified regarding efficiency in image acquisition	Although there were delays seen in acquiring the images due to the different types of US probes used, the final combination of Jaco 2 arm and the chosen US probe has brought in significant improvements and acquisition timing similar to a manual scan

	while mounting the probe on the probe holder; •The cables connected to the Haptic Touch controller/screens/computers were stretched became disconnected from the corresponding device; •The system froze, and rebooting was needed for unknown reasons.		
Evaluating the efficiency of using the current system for a cardiac scan	The volunteer set-up was straightforward and did not cause any delays in the scanning procedure. However, compared to manual scans, the patient positioning during the scan can be more challenging. On several occasions, the sonographer had to communicate to the volunteer how to slightly change his position while scanning, whereas, during a manual scan, the sonographer can "change" the position of the scanned person directly. The time required to complete a full scan using the POC varied between 25 and 40 minutes (vs 15-20 minutes for a standard scan), while imaging a specific window typically required 5 to 10 minutes. Additional challenges faced by the sonographer that delayed the scanning procedure were related to the use of the Haptic touch controller The robotic arm joints were overstretched, especially in the subcostal view, due to the large inclination angles needed for the probe to image the desired anatomy. Inducing the volunteer to breathe in a specific way was more challenging for the sonographer while operating the POC system due to the sonographer having to be consciously aware of moving the robot arm which was not familiar to them compared to the familiarity of a standard manual scan.	A sonographer learning curve was identified via 1:1 block sub-cohort analysis, demonstrating that additional hands-on training time via simulator and on patients is required to ensure reasonable competency translating to high feasibility in robotic examination. Inter-operator reproducibility was reasonable for feasibility in both the major assessments, as well as in the individual measurements	The learnings derived from the changes done for both the system (robotic arms & trolleys) and the sonographers experience during the various phases of training and practical live scan have increased both the efficiency in the scanning operations and the accuracy of the images
End-user (Sonographer & Patient) evaluation to understand if the selected technology is well-received	Most volunteers expressed some discomfort with the robot in the subcostal position. The discomfort was due to the continuous pressure applied on the belly and/or the feeling of being "imprisoned" under the robotic arm. One volunteer reported discomfort in the apical position due to the pressure on the ribs. In general, some volunteers expressed some stress/fear while being scanned, but none of the	Under review	There have been continuous positive responses received from both the sonographers and the patients with respect to the remote scan experiences over the evolution of the different device combinations used

	volunteers was contrary to the future use of a fully automated system for this type of scan. In general, the system was well received by the sonographers, who provided some suggestions to further improve the system		

Elements Analysed	Franka Panda Device (POC)	RUAT Device	Conclusions
Controllers	A touch haptic controller and a Logitech F710 controller were connected to the POC system. Sonographers were trained on the touch controller as it provides haptic feedback with 6 degrees of freedom (DOF). However, during the volunteer scanning, it was clear that the touch controller was considered challenging to operate. Moreover, movements requiring both translation and rotation pose a challenge with the touch controller. Controllers, which allow operation with both hands, might be easier to use and may have less of an impact on the sonographer	Logitech F310 Controller has been used. The controller allows the sonographer to manipulate the position of the probe, by sending commands to the robotic arm via the two NUCs (next unit of computing, i.e., minicomputer). Wired controllers were chosen due to having a more reliable connection and not being reliant on batteries.	Use of the Logitech Controller (Gamepad) in combination has resulted in better arm maneuverability and more effective scanning using the RUAT device
Sonographers	Before volunteer scanning, three sonographers were trained for two days, including one scanning session practice on one of the researchers. The sonographers' hand/wrist movements while operating the robotic system differ significantly from standard manual scans. Therefore, a detailed training program needs to be developed to ensure sonographers can operate the system effectively	Following training phases were involved for sonographers with associated practice opportunities (Cardiology, RBWH; Objective a): 1.Virtual training using a custom workstation 2.Practical training with COBOT using a marker pen and paper 3.Practical training with COBOT using simulator 4.Practical training with COBOT Echo on human patient/participant	Sonographers have exhibited more confidence after having been provided with a more formal phased training approach and been able to better manipulate the probe using the RUAT device.
Remote Operation of the Robot	The sonographer operating the teleoperated ultrasound imaging robot connects to the remote robot via local LAN or WAN connection, unlocks the robot, asks the operator at the remote location to align the patient on the clinical bed, selects a scan window and then asks the nurse to move the robot end-effector onto the patient skin. The sonographer scans the patient using the haptic controller to manipulate the robot. Remote scanning will introduce its own set of challenges, such as the time delay through the network infrastructure. The web user interface needs to be further refined to automate specific	The RUAT system allows for a sonographer to remotely scan a patient, using the following functional sequence: 1.The sonographer selects a scanning window from the selection displayed on the RUAT interface. Doing so sends a command to the Jaco2 to: Move to the home position, then Move to an intermediate position (or set of intermediate positions). This helps ensure the path of the robot is unobstructed and then Move to the preset position for the scanning window, approximately 10cm away from the patient. 2. Once the Jaco2 has finished the automated movement to the preset position for the chosen scan window, the sonographer takes manual control (using the controller) to contact the patient. 3. After the sonographer has contacted the patient, they will adjust the probe's position	A significant improvement has been noticed in the RUAT remote scanning operation through the new set of window display and automated movements

	actions, provide the sonographer with messaging, and possible options aiming at improving remote scanning	while looking at the ultrasound image. This adjustment may include increasing the applied force, adjusting the angle relative to the body, or moving the probe along the surface of the body. 4.Once the sonographer has obtained the desired images, they will switch to velocity mode, and move the probe away from the body. 5.When a sufficient distance has been reached (minimum 10cm), the sonographer selects another scan window from the display and repeats the above process.	
Robot selected	A Franka Panda robot was used for the POC system. However, it will be necessary to test a range of robots to assess their capability, DOF (including their singularities), software capability, force and torque control, human safety, etc.	Kinova Jaco2 robotic arm over the Kuka MED7. The comparison between the two arms is as follows: •DOF of a robotic arm refers to the number of joints (composed of "wrists" and "elbows") available to help move the end effector. A minimum of 6 joints is required to ensure the arm can be manipulated completely in space (3 translational directions and 3 rotational directions), however a 6-DOF arm will have some areas within which joints begin to align and the solution becomes unstable. These locations are referred to as "singularities". Adding an additional joint (going from 6-DOF to 7-DOF) can reduce the level of instability and is generally preferred to ensure smooth movement of the end effector.	Through the availability of 6-DoF from using the Jaco2 arm, effective manipulations through multiple directions have enabled the sonographers to perform effective scans. A recommendation is made to consider the 7-DOF version of the Kinova robotic arm for future development to further extend the device capabilities
Trolley for Robot	During the volunteer scanning, it became apparent that a trolley is needed to enable covering the whole scanning area. Scanning overweight/obese or female patients might be a challenge for a small robot with a force capability of only 3kg.	The Trolley chosen for RUAT Device - provides a portable platform upon which to mount the robotic arm as well as the Screen & Camera Mount. The trolley provides enclosed storage for the Robot NUC and Transformer, and connection points for mains power, e-stops, and ethernet	The use of trolley has enabled the sonographer to increase the scan coverage and the scan area of the patient

5.2 COBOT Study

An additional feasibility, safety and clinical accuracy study was conducted on the near-final device in 2022 (study unpublished). The study design, aims and outcomes are summarised here and in more detail in the Investigator's Brochure at Section B.4 a).

Title: Feasibility and clinical accuracy of novel robot-assisted, remotely performed echocardiographic examination with artificial intelligence-driven image optimisation development.
Institution: Cardiology, Royal Brisbane & Women's Hospital.

The study aimed to evaluate for the COBOT Echo:

a) Feasibility of the cardiac sonographers remotely performing COBOT Echo (standard exam, assessments and measurements of cardiac structure and function) on selected patients/participants using standard manually performed Echo as reference. Sonographer learning curve and interobserver analyses are included as secondary analyses.

b) Accuracy of objective quantitative measures produced by the cardiac sonographer remotely performing COBOT Echo (standard exam assessments and measurements of cardiac structure and function) on selected patients/participants using standard manually performed Echo as reference.

c) Efficiency of the cardiac sonographer remotely performing COBOT Echo (standard exam assessments and measurements of cardiac structure and function).

Summary of findings:

Total cohort was n=78 (age 51±15yrs; 57% male; 63% patients). RUAT Echo and standard manually performed Echo were performed within 72 hours.

The feasibility of evaluating 11 pre-specified structures was comparable for RUAT (92±9%) and manually performed (99±1%) echo. The feasibility of undertaking 36 pre-specified measurements for RUAT (86±11%) and manually performed (97±7%) echo was reasonable, although perhaps slightly less for RUAT echo.

The study showed that remotely performed, RUAT cardiac ultrasound examinations are feasible and can be safely performed with acceptable accuracy for individual measurements within an acceptable timeframe (although image acquisition is longer compared with standard manually performed echo). Further investigation of diagnostic accuracy for identifying specific pathologies, with different patient characteristics, and a broader range of operators and testing in a real-world long-distance remote environment is warranted prior to broader implementation.

6 Cardiac Sonographer Training

Prior to the study, 3 senior cardiac sonographers have been recruited (through Cardiology, RBWH) and undertake relevant training to perform the RUAT Echo examinations for the study.

6.1 Unsupervised virtual training

The sonographer first engages in unsupervised training using a custom workstation. Sonographers undertake free virtual practice and complete a series of practical exercises using a custom workstation.

6.2 Partially supervised practical training with RUAT using a marker pen and paper

The next practice series allows sonographers to undertake free practice and complete a series of exercises with the RUAT directly.

6.3 Partially supervised practical training with RUAT using simulator

Sonographers then under partial supervision use a simulator to demonstrate their training. Prior to completion, a competency assessment is performed. Only sonographers that completed this competency assessment are permitted to perform scans on participants.

6.4 Fully supervised practical training with RUAT ECHO on a human participant

The first scan for each sonographer is performed under full supervision once a competency assessment has been completed.

7 Study Objectives

Study objectives and endpoints are presented in Table 2.

Table 2: Study objectives and endpoints

Objectives	Endpoints
Primary	
To assess the safety of RUAT Echo	Adverse events Serious adverse events Adverse device effect Serious adverse device effects
To assess the useability (functionality) of using the RUAT echo as intended to obtain echocardiogram images of clinically suitable quality for reporting by a cardiac sonographer.	Verification of functional requirements Participant experience

8 Study Design

This is a pilot "Safety and Useability" Clinical Investigation of the RUAT system to perform an echocardiographic examination.

Up to 30 adults male or female participants will be recruited over a two-month period from inpatients and outpatient departments of the Royal Brisbane and Women's Hospital. Participants will be eligible if they have already received a standard (manual) echocardiogram examination.

8.1 Length of Study

Participants will be recruited until 30 participants have been recruited, estimated time is approximately 3 months.

Participants will undergo a single RUAT ECHO, which takes approximately 30-60 minutes.

Participants will undergo a single safety follow-up contact up to 72 hours ~~18-24-hours~~ after the RUAT ECHO is performed, either in person if inpatient or by telephone call/telehealth if outpatient/discharged patient.

9 Participant Selection Criteria

To be eligible, participants must meet all of the inclusion criteria and none of the exclusion criteria.

9.1 Inclusion criteria:

- Male or female aged 18 years or older
- Inpatient or outpatient who has already received a routine (manual) echocardiogram that has been clinically reported.
- Is willing to participate.

- Provides written informed consent.

9.2 Exclusion criteria:

- Is pregnant.
- Has poor patient mobility or is acutely symptomatic.

10 Study Procedures

Up to 30 participants will be required. Recruited participants will be RBWH Cardiology inpatients or outpatients who have already received a routine (manual) clinically reportable echocardiogram.

Study procedures and their timing are summarised in Figure 1 and the SoA (Section 4). Protocol waivers or exemptions are not allowed. Adherence to the study design requirements, including those specified in the SoA, is essential and required for study conduct.

All screening evaluations must be completed and reviewed to confirm that potential participants meet all eligibility criteria. The investigator will maintain a screening log to record details of all participants screened and to confirm eligibility or record reasons for screening failure, as applicable.

10.1 Administrative and Screening Procedures

10.1.1 Screening and Recruitment

Prior to enrolment in the study, each participant will have already received a routine (manual) clinically reportable echocardiogram as an inpatient or outpatient.

Potential study participants will be selected based on inclusion and exclusion criteria, as above.

The potential study participant will be approached in person via a member of the study team (study coordinator or research staff as delegated by the principal investigator) while on the ward as an inpatient or in clinic as an outpatient. The study coordinator or research staff will provide details of the study (verbally and via the information sheet as part of the Participant Informed Consent Form 'PICF'), as outlined in Section 16.2.

At the time of informed consent potential study participants will be asked to disclose any bruising, soreness, or discomfort in the chest area that may impact safety outcomes that the RUAT study may have.

10.1.2 Demographics

Participant demographics including age, sex, height and weight, will be collected at time of consent or RUAT echo.

Gender, height and weight information support the safe and effective conduct of an ultrasound, and or the interpretation of RUAT functionality. i.e., there are some technical challenges and differences in scanning female patients compared to male patients regarding chest shape, and patients with a larger body surface area can result in access issues or poor image quality.

10.2 RUAT ECHO Scanning

Only trained and competent sonographers (see Section 6) will undertake RUAT ECHO. Sonographers will perform RUAT ECHO according to their training and the RUAT ECHO User Instructions.

The RUAT Echo will be performed with a cardiac sonographer in the examination room at a sonographer remote workstation but not at the bedside ('*Performing Sonographer*'). A second sonographer ('*Observing Sonographer*') shall be at the bedside and supervise the procedure. The *Performing Sonographer* must not have been involved in the participant's initial clinical assessment.

The RUAT system is connected via ethernet cable to the sonographer remote workstation and a wired gaming controller is used to operate the robotic system.

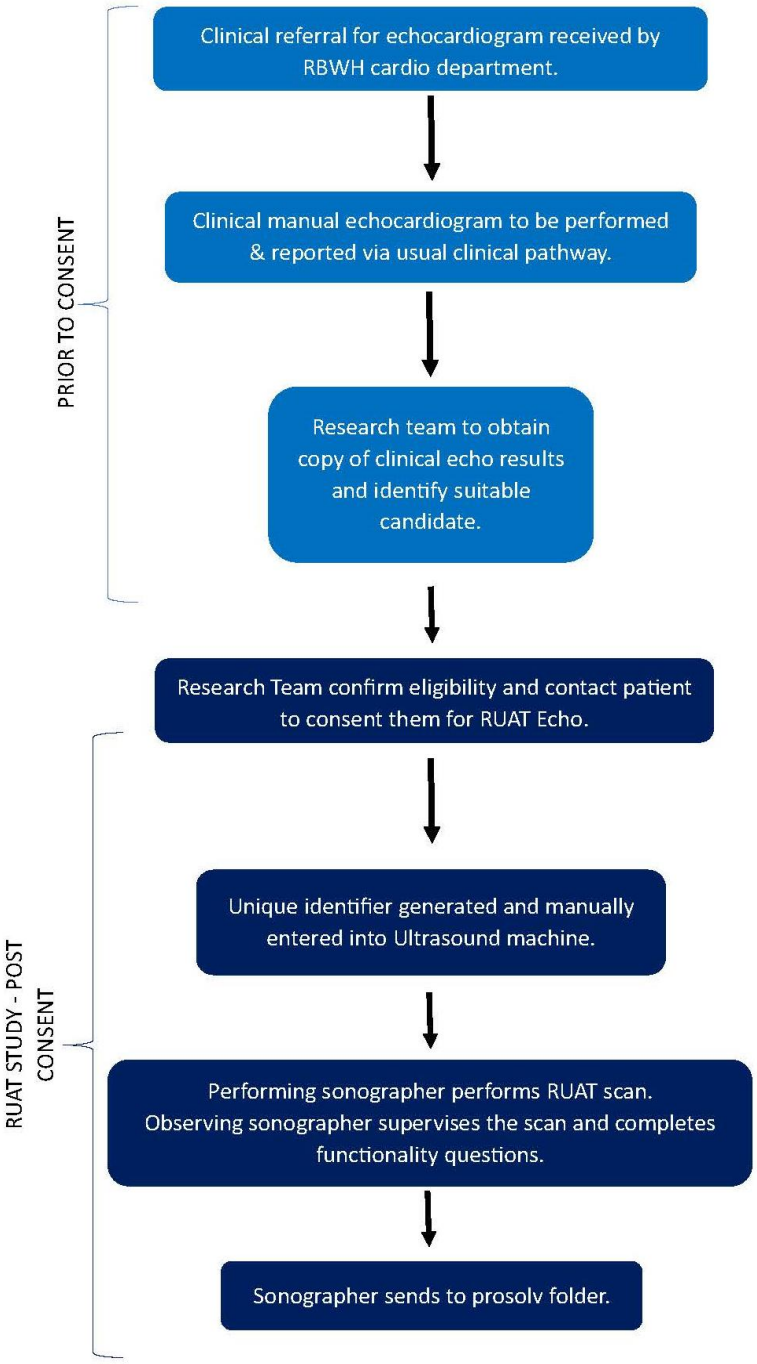

Figure 1: Scanning procedures

Cardiac sonographers will perform the RUAT Echo for up to 30 (total) recruited study participants. Although remotely performed in terms of the sonographer not holding the ultrasound probe in-hand (RUAT Echo exams), the *Performing Sonographer* will be physically co-located within the same room but not at the bedside of the study participant. This will provide patient and safety support for the procedure. The *Observing Sonographer* shall be at the bedside to supervise and verify that the RUAT performs as intended.

Results of RUAT-performed echocardiograms will not be used for clinical treatment since treatment decisions would have already been made from the initial (manual) echocardiogram as the standard of care.

The RUAT echocardiograms are only used to determine whether the images are of sufficient clinical quality to be reported on. In this regard 'clinical quality' refers to the images being classified as reportable by the sonographer.

At the end of the scan each study participant shall complete a RUAT experience survey.

10.2.1 Evaluation

10.2.1.1 Functional verification of RUAT ECHO

The *Observing Sonographer* will complete a functional verification checklist (see APPENDIX 1 - Functional Verification) to verify that the RUAT echo was performed as intended (as described in the Instruction Manual).

10.2.1.2 Participant Experience Survey

Study participants' feedback on their experience from start to end of the RUAT echo will be collected via a feedback survey delivered to the participant by the *Observing Sonographer* or *health practitioner observer* at the completion of the RUAT echo. Data will be collected on the ability to interact with the *Performing Sonographer*, probe pressure and their perceptions on the movement of the robotic arm with invitation for open commentary and to express a preference for the manual versus robotic RUAT method (see

APPENDIX 2 – Participant Experience Survey).

10.3 Adverse Events (AE), Adverse Device Events (ADE), Serious Adverse Events (SAE), Serious Adverse Device Event (SADE) and other Safety Reporting

The investigator and any qualified designees are responsible for detecting, documenting, and recording events that meet the definition of an AE/ADE or SAE and remain responsible for following up AEs that are serious, and considered related to the study intervention or study procedures.

To determine the safety of the RUAT echo, all AE/ADE/SAE/SADEs shall be recorded in the CRF and reported to the sponsor, ethics committee and TGA (if required) according to mandated timelines.

10.3.1 Definitions

The definitions applied for reporting adverse incidents for medical devices are those defined in ISO 14155:2020 Edition 3, July 2020.

Adverse Event (AE): Any undesirable clinical occurrence in a subject whether it is considered device related or not, that includes a clinical sign, symptom, or condition and/or an observation of an unintended technical performance or performance outcome of the device.

Adverse Device Event (ADE): A clinical sign, symptom or condition that is causally related to the presence of the device, or the performance of the device system.

An adverse event or an adverse device effect may be mild, moderate, or severe.

Serious Adverse Event (SAE): Any adverse medical occurrence that:

- Led to a death.
- Led to a serious deterioration in health of a patient user or other. This would include:
  - A life-threatening illness or injury.
  - A permanent impairment of body function or permanent damage to a body structure.
  - A condition requiring hospitalisation or prolongation of hospitalisation.
  - A condition requiring unnecessary medical or surgical intervention.
- Might have led to death or serious deterioration in health had suitable action or intervention not taken place. This includes:
  - Malfunction of a device such that it needs to be modified or temporarily/permanently taken out of service.
  - A factor (a deterioration in characteristics or performance) found on examination of the device.

Serious Adverse Device Event (SADE): A device-related serious adverse event.

Unanticipated Device Related Adverse Event: Any undesirable clinical occurrence in a subject considered device-related and not listed in the device technical manuals/Investigator's Brochure.

10.3.2 Time Period and Frequency for Collecting AE, ADE, SAE and SADE Information

All AEs, ADEs, SAE and SADEs will be collected from the signing of the patient informed consent form (PICF) until 72 hours post RUAT Echo, i.e., end of the study.

10.3.3 Method of Detecting AEs and SAEs

Care will be taken not to introduce bias when detecting AEs, ADEs, SAEs and/or SADEs. Open-ended and nonleading verbal questioning of the participant is the preferred method to inquire about AE/ADE occurrences.

10.3.4 Classification System

Investigators will be asked to assess the potential relationship of the adverse event to the ROBOT ECHO and/or to the procedure. For this study, each AE/ADE will be classified as device- or procedure-related. The following definitions will be used:

- Procedure-related: An adverse event that occurs due to the system application procedure. Commonly experienced events from an Echocardiogram include potential bruising, discomfort, focused pressure from the probe, lubricating gel may feel cold.
- Device Related: An adverse event that results from the presence or performance of the device or any other component of the system, for example if the RUAT robotic arm pushes too hard on the patient and fractures a rib.
- Unknown: If the adverse event cannot be determined to have a causal relationship with either the device or procedure, it will be classified as unknown.

The severity or intensity of each AE/ADE will be classified as per the below definitions:

- Mild: Patient is aware of event or symptom, but event/symptom is easily tolerated.
- Moderate: Patient experiences sufficient discomfort to interfere with or reduce their usual level of activity.
- Severe: Significant impairment of functioning; patient is unable to carry out usual activities.

10.3.5 Investigator Reporting Responsibilities

The Investigator must immediately report all SAEs or SADEs (within 24 hours from time of learning of the event) to the sponsor using the supplied SAE/SADE reporting forms. Initial reports should be followed by detailed written reports. The investigator will determine whether the event was device related.

All SAE/SADEs are also captured and reported using the same terminology on the SAE/SADE Form in the Case Report Forms.

SAE/SADEs are emailed to:

Biointelect Pty Ltd Urgent Attention Safety Reporting safety@biointelect.com

The Investigator must also notify their respective HREC/s of any serious adverse outcomes immediately or as specified by the HREC guidelines.

10.3.6 Sponsor Reporting Responsibilities

The sponsor must report serious and unexpected adverse device events which are fatal or life threatening to the TGA using the Medical Device Incident Report Form within 7 calendar days of first knowledge. Follow-up reports are required within an 8 additional calendar days.

Other serious unanticipated device related events need to be reported to the TGA within 15 calendar days of first knowledge by the sponsor.

Non-serious and anticipated device related adverse events and other adverse events are recorded on the Case Report Form as part of Good Clinical Practice. Any safety issues emerging from an analysis of these events need to be notified to the TGA and relevant HRECs.

11 Statistics

The analysis and reporting will be conducted on all data from all participants at the time the study ends.

The statistical analysis plan will be finalised prior to database lock, and it will include a more technical and detailed description of the statistical analyses described in this section. This section is a summary of the planned statistical analyses of the most important endpoints.

11.1 General Considerations

In general, data will be summarised descriptively. The number of participants tested and used in the final analysis will be summarised descriptively.

11.1.1 Decision Criteria

The primary objectives of the study are to:

- assess the **safety** of the RUAT echo.
- assess the **"useability" (functionality)** of using the RUAT echo as intended to obtain echocardiogram images of clinically suitable quality for reporting by a cardiac sonographer.

The **safety** of the RUAT Echo will be considered acceptable if there are no device related adverse effects.

RUAT Echo will be considered a **useable** method of performing echocardiograms if:

- Each functional verification criteria 1 through 11 (inclusive) performed "YES" at least 80% of the time an echocardiogram was performed by RUAT Echo, that is, pass functional verification (see APPENDIX 1 - Functional Verification).
- At least 80% of echocardiograms performed by RUAT Echo are considered of an adequate quality to provide a diagnostic assessment, that is, pass functional verification item #12 (see APPENDIX 1 - Functional Verification).
- At least 80% of participants report they are satisfied with undergoing RUAT Echo examination based on an average of the 4 subscales of the 10-point Likert scales from strongly disagree to strongly agree (see APPENDIX 2 – Participant Survey).

11.1.2 Multiplicity Adjustment

No adjustment for multiple comparisons is planned.

11.1.3 Impact of Intercurrent Events Strategies

Not applicable.

11.1.4 Handling of Missing Data

Missing data will not be imputed.

11.2 Analysis Sets

For the purposes of analysis, the following analysis sets are defined:

Participant Analysis Set	Description
Full analysis set (FAS)	All participants.
Safety analysis set (SAS)	All participants who are exposed to investigational medical device.

The full analysis set will be used to analyse endpoints related to the usability objectives and the safety analysis set will be used to analyse the endpoints and assessments related to safety.

All observed data will be used in the analysis.

11.3 Analyses Supporting Primary Objective(s)

11.3.1 Primary Endpoint(s)

The primary endpoints are as listed in Table 2.

11.3.1.1 Definition of endpoint(s)

Adverse events, adverse device effects, serious adverse events and serious adverse device effects are defined in Section 10.3.

11.3.2 Useability (functionality)

The RUAT Echo device will be deemed as being **sufficiently useable (functional)** (i.e., technically non-inferior) **if each of the 12 Functional Verification Criteria** (see APPENDIX 1 - Functional Verification) result in “YES” ≥80% of the time.

11.3.2.1 Main Analytical Approach

The proportion of RUAT echocardiograms deemed to be of sufficient quality will be summarised descriptively along with a 95% confidence interval.

Participant experience will be summarised descriptively.

Adverse events and serious adverse events will be coded using the Medical Dictionary for Regulatory Affairs and will be summarised by system organ class and preferred term by echocardiogram type (conventional vs RUAT Echo). No statistical comparisons between adverse events or serious adverse events by scan type are planned.

Adverse device effects will be coded using the FDA Medical Device Report (MDR) adverse event codes and will be summarised by Level 1 Term and Level 3 Term by echocardiogram type (conventional vs RUAT Echo).

11.3.2.2 Sensitivity Analysis

None planned.

11.3.2.3 Supplementary Analysis

None planned.

11.4 Other Analyses

None planned.

11.5 Interim Analysis

No formal interim analysis is planned.

11.6 Sample Size Determination

Approximately 30 participants will be recruited. A single-group design will be used to obtain a two-sided 95% confidence interval for a single proportion of the RUAT Echo images that are deemed of sufficient quality. The Exact (Clopper-Pearson) formula will be used to calculate the confidence interval. The sample proportion is assumed to be 80%. With a sample size of 30, the width of the associated confidence interval is 30.9% around the 80% (that is, from 61.4% to 92.3%).

Confidence interval widths were computed using PASS 2023, version 23.0.2.

12 Risk Analysis

The Investigator Brochure provides information regarding the robotic system and a more detailed risk analysis (Refer Investigator Brochure Section # B 5). The devices used in this study have no interventional aspect. There are no known health risks associated with diagnostic ultrasound technology.

A summary of identified risks associated with participation in this study include:

Risk: Study Participant discomfort due to pressing of ultrasound probe on chest (Robot-assisted Ultrasound Examination)

Mitigation: Participants will be informed of the potential for slight discomfort on the chest from pressing the ultrasound probe and that they can discontinue participation at any point if they find the pressure from the probe too uncomfortable to continue participation. The robot has an active pressure sensor with a limiter to prevent excess pressure being applied. The pressure limit is set to approximately 50% of the maximum pressure exerted by a human operator performing a standard ultrasound examination. A blue LED light on the sensor confirms pressure signals are actively being received and in the event of sensor failure, the pressure reading will drop to zero. Daily checks of the system include a manual test of the

pressure sensor which requires applying gentle pressure to the probe holder and the sonographer is to confirm that the force indicator moves on the computer display for every force limit level (1-5).

Risk: Operation of a robot arm

The RUAT holds and manipulates clinical and TGA approved ultrasound probes; the RUAT itself is controlled and always supervised by a human operator, and the supervising operator / attendant will always remain within 0.5m of the robot arm. The operator, the attendant and the patient all have an emergency stop button each within arm's reach which terminates the robot action within approximately 1 second.

Risk: Collection of confidential participant data

All collected data will be de-identified. All active and working data documents are secured with automated tracking logging to monitor all user access and activity.

13 Subject Completion and Discontinuation

13.1 Subject Replacement

It is anticipated that all subjects will complete the study. If a subject withdraws during the study after receiving RUAT echocardiogram, they will not be replaced.

13.2 Subject Withdrawals

Subjects will be withdrawn from the study if:

- Their consent is withdrawn.
- In the investigator's opinion, the subject's clinical condition necessitates withdrawal for safety reasons.
- They are unable to tolerate RUAT echocardiogram procedure.

Subjects will be advised that they may voluntarily withdraw from the study at any time, for any reason and they are not obligated to reveal the reason to the sponsor, and it will not affect their medical care. However, in such cases, appropriate efforts will be made by the sponsor to determine the reason for voluntary withdrawal from the study.

Subjects will be informed that should they withdraw from the study they should remain in the care of an appropriately experienced physician until the physician deems further follow-up unnecessary.

A Study Completion Form will be completed for all patients who withdraw from the study.

14 Study Termination

The sponsor, investigator, HREC or TGA reserves the right to terminate or suspend the study at any time, however, this will be discussed between the relevant parties beforehand.

If the sponsor determines that any unanticipated adverse device effect presents an unreasonable risk to patients, the investigation will be terminated as soon as possible. Termination shall occur no later than 5 working days after the sponsor makes this determination and no later than 15 working days after the sponsor first receives notice of the unanticipated adverse device effect. Ethics committee approval will be obtained prior to resuming a terminated investigation.

15 Study Monitoring and Data Management

15.1 Study Monitoring

The sponsor has appointed Biointelect (a Contract Research Organisation) to manage and monitor the study to assure them of the quality conduct of the study and to act as the contact between the investigational site and the sponsor.

Prior to commencement of the study, the monitor will conduct an initiation visit to ensure that all site staff are aware of their study responsibilities, and that the study needs to be conducted in accordance with the study agreement, HREC approval and applicable ICH GCP guidelines.

Throughout the study, the monitor will maintain written and oral communication with the Investigator and their staff regarding the ongoing compliance of the study.

All monitoring and project management will be undertaken in accordance with ICH GCP and ISO 14155 utilising relevant SOPs.

15.2 Access to Study Records

The investigational site/investigator will ensure that there is direct access to source data and any associated trial documents required for trial monitoring, audits, HREC review and regulatory inspection. In addition, the investigational site staff must make themselves available to the sponsor, study monitor, HREC or regulatory agency as required.

15.3 Source Document and Data Verification

The study monitor will visit the investigational site periodically (approximately every 6 weeks or as deemed necessary) in accordance with the study monitoring plan. They shall:

- Meet with the investigator and any applicable site staff to discuss ongoing study compliance and data accuracy.
- Review all source documentation to verify CRF entries.
- Review the investigational site file and regulatory documentation.
- Ensure, where possible that CRF entries are corrected on site [in the first instance] should discrepancies be noted.
- Collect copies of documents and completed CRFs.

15.4 Data Management

Basic patient/participant demographic data and echo images shall be collected. Subjects who participate in the study are coded with a specific clinical investigation identification number. All subjects are registered in a subject identification list (subject enrolment and identification list) that connects the subject's name and hospital record number with a clinical investigation identification number. All data will be registered, managed, and stored in a manner that enables correct reporting, interpretation, verification, and participant privacy in compliance to the Privacy Act 1988, which includes the Australian Privacy Principles (APPs).

All participant data relating to the study will be recorded on printed CRFs or transmitted to the sponsor or designee electronically (e.g., imaging data). The investigator or study coordinator is responsible for verifying that data entries are accurate and correct by physically or electronically signing the CRF.

The ultrasound data will not be used for purposes other than the assessment of quality to indicate that the RUAT echo functions as intended.

16 Regulatory Requirements

16.1 Human Research Ethics Committee (HREC) Approval

Before the study begins, written approval will be obtained by the relevant HREC responsible for the investigational site.

16.2 Subject Informed Consent

Once identified by the research team as suitable for study participation, each potential participant shall provide informed consent to undergo an additional echocardiogram which shall be conducted using a robotic arm (RUAT echo).

The potential study participant will be approached in person via a member of the study team (study coordinator or research staff as delegated by the principal investigator) while on the ward as an inpatient or in clinic as an outpatient. The study coordinator or research staff will provide details of the study (verbally and via the information sheet as part of the Participant Informed Consent Form 'PICF'), and then provide invitation for participation, free from coercion and pressure and with as much time as required for the potential participant to consider participating as well as the opportunity to ask questions.

It is the investigator's responsibility to ensure that each subject gives written informed consent to participate in the study prior to any study specific procedures at the time of screening. Each subject will be provided with a Patient Information and Consent Form. The investigator and/or assigned study coordinator will explain the nature of the study, its purpose, procedures, expected duration, and the potential benefits, risks and inconveniences in participation as outlined in the Participant Information Sheet. The subject will be given adequate time to decide whether they wish to participate and ask questions. On acceptance of participation, they will voluntarily sign and date (in their own handwriting) the information and consent form. The investigator and/or study nurse will also sign and date the same form. A signed and dated copy will be provided to the subject. The other copy will be maintained in the study file.

The subjects will be informed of their rights to privacy but will be made aware that the study data will be submitted to the sponsor and possibly to drug regulatory authorities for review and evaluation. They will be informed also that the study monitor may inspect their medical records to verify the accuracy and completeness of the study records and results.

The subjects will be informed of their right to withdraw from the study at any time without prejudice.

17 Insurance and Liability

17.1 Subject Compensation

The sponsor agrees to abide by the Medical Technology Association of Australia Guidelines for compensation for injury resulting from participation in a company sponsored clinical investigation.

17.2 Insurance Indemnity

The Sponsor will have in place Clinical Trial Insurance (with a $20m limit) and ensure that the investigational site/entity has in place Indemnity according to Medical Technology Association of Australia Form of Indemnity for Clinical Investigations.

17.3 Compliance with Good Clinical Practice

The clinical investigation will be conducted in accordance with the clinical investigation plan, the ethical principles of the Declaration of Helsinki, the principles of IS-EN ISO 14155:2020 and current national regulations governing this clinical investigation. This is to ensure the safety and integrity of the subjects and the quality of the data collected.

17.4 Archiving and Regulatory Inspection

The PI and sponsor will maintain the essential clinical investigation documents in the Sponsor Trial Master File and investigation site files archive. The sponsor shall keep all documentation for at least 15 years or as long as stipulated by the local institution.

18 Study Report

A clinical study report will be prepared and provided to the study investigator irrespective of whether the study terminates prematurely. A report may be used to support regulatory approval applications. The report will meet the standards of the ICH Guideline for Structure and Content of Clinical Study Reports.

19 Publication of Results

The clinical investigation will be registered in a publicly accessible database anzctr.org.au before the start of recruitment activities and the content will be updated throughout the conduct of the clinical investigation and the results entered at completion of the clinical investigation.

All information concerning the RUAT Echo study, operations, manufacturing, and clinical data which are not previously published are considered confidential by RMI Oceania Pty Ltd and shall remain the sole property of RMI Oceania Pty Ltd. Investigators must respect the confidentiality of data. The investigator should understand that the information developed in the clinical study will be used by RMI Oceania Pty Ltd in connection with the evaluation of the RUAT Echo system, and therefore may be disclosed as required to other clinical investigators, and to governmental agencies.

Should the investigators wish to publish, exhibit or lecture on the results of this study, the manuscript, exhibit, or presentation must be provided to RMI Oceania Pty Ltd at least 40 days prior to the intended use of the data as per the Clinical Investigation Research Agreement. For the avoidance of doubt, the investigator must receive written consent from RMI Oceania Pty Ltd prior to publication, exhibition, or disclosure of scientific and clinical data. This review by RMI Oceania Pty Ltd is not intended to curtail distribution of scientific and clinical data, but to identify and edit any company confidential information.

Authorship and publication manuscript composition will reflect joint-cooperation between multiple investigators, sites, RMI Oceania Pty Ltd personnel and delegates. Authorship will be established prior to writing any publications and adhere to NHMRC Authorship guide document R41C; Authorship: Guidance supporting the Australian. Code for the Responsible Conduct of Research, 2019.

20 Conflict of Interest Declarations

Conflicts of interest (COI) are defined as per Chapter 5.6 of the *National Statement on Ethical Conduct in Human Research (2023)* and the *Australian Code for the Responsible Conduct of Research (2018)* and are required to be disclosed in relation to researchers of the clinical study.

20.1 Investigator Declaration

Dr Adam Scott, Director of Cardiac Sciences, Cardiac Investigations Unit, Royal Brisbane Women's Hospital is a co-investigator of this study and declares a conflict of interest (COI). Dr Scott is a Director, and shareholder of the Sponsor company RMI Oceania Pty Ltd with financial and intellectual property interests.

Dr Scott has contributed intellectually to the design of both the medical device and the clinical trial.

To manage the COI Dr Scott **will not**:

- Be involved in identification of patient participants,
- Consent patients for the study,
- Conduct RUAT scans or manual echo scans,
- Interact with patient participants,
- Record or access clinical study data during the trial,
- Record or review safety events.

21 Sponsor and Investigator Obligations

21.1 Protocol Amendments

Neither the investigator nor the sponsor will modify or alter this protocol without the agreement of the other. All agreed protocol amendments will be clearly recorded on a protocol amendment form and will be signed and dated by the original protocol approving signatories. All protocol amendments will be submitted to the relevant institutional HREC for approval before implementation. The only exception will be when the amendment is necessary to eliminate an immediate hazard to the trial subjects. In this case, the necessary action will be taken first, with the relevant protocol amendment following shortly thereafter.

21.2 Protocol Deviations

Investigator(s) are not allowed to deviate from the CIP except if it is for the protection of the subject´s rights, safety, or well-being under emergency circumstances. All deviations shall be documented and reported to the sponsor, and the Ethics Committee as soon as possible. Deviations will be reviewed by the sponsor and reported to the appropriate regulatory bodies as required.

21.3 Investigator Responsibilities

The investigator must ensure that the study is conducted in accordance with the study protocol, study agreement, HREC approval and all appropriate regulatory guidelines including ICH GCP and ISO 14155.

21.3.1 Progress Reports

The investigator will submit, at intervals requested by the sponsor, a progress report on this investigation. These reports will be submitted both to the sponsor and to the investigator's Ethics Committee.

21.3.2 Withdrawal of Ethics Committee Approval

Should the Ethics Committee withdraw its approval, the investigator will notify the sponsor no later than five working days following such withdrawal.

21.3.3 Final Reports

Upon completion of the investigation, each investigator will contribute to submitting a final report on his/her part of the investigation within three months of completion of the investigation. This report will be submitted both to the sponsor and the investigator's Ethics Committee.

21.4 Sponsor Responsibilities

21.4.1 Reports

The sponsor, upon completion of the investigation, will prepare a comprehensive final report. These reports will be submitted to the investigator and the investigator's Ethics Committee.

21.4.2 Clinical Monitoring of the Study

The sponsor will monitor and ensure that this investigation is conducted in accordance with the signed investigator clinical study agreement and conditions imposed by the Ethics Committee, as well as other applicable regulations, including ICH GCP and ISO 14155.

22 References

1. Pallotta, O.J. and A. Roberts, *Musculoskeletal pain and injury in sonographers, causes and solutions.* Sonography, 2017. **4**(1): p. 5-12.
2. Scott, A.C., et al., *Cardiovascular Telemedicine Program in Rural Australia.* New England Journal of Medicine, 2020. **383**(9): p. 883-884.
3. von Haxthausen, F., et al., *Medical Robotics for Ultrasound Imaging: Current Systems and Future Trends.* Curr Robot Rep, 2021. **2**(1): p. 55-71.

23 Appendices

23.1 APPENDIX 1 - Functional Verification Checklist

#	Function	Performs as Intended (Y/N)
1	Did the Robotic Arm & cameras activate when turned on?	
2	Did the robotic arm move into home position when instructed?	

3	Did the robotic arm move into the preset positions correctly?	
4	Could the sonographer move the robotic arm onto the patient's chest from each preset position?	
5	Could the sonographer move the robotic arm from the end of the preset movement to the correct location on the patient's chest? (tests x,y, z axes).	
6	When in the correct location, could the robotic arm be instructed to the correct angulation so that an image could be acquired? (tests panning, tilting, rotation functionality).	
7	Did the force sensor work within its pressure range?	
8	Did the probe holder hold the probe correctly for the scan?	
9	Was there any restriction to the robotic arm movement caused by the cables? (wound around arm, caught in the bed, too short length from the US machine).	
10	Could the sonographer move the robot trolley as required during the scan?	
11	Did the patient telehealth screen provide adequate image and audio?	
12	Was the sonographer satisfied that the images could be used for reporting?	

23.2 APPENDIX 2 – Participant Experience Survey

Study Title:

Safety and useability of a novel robot-assisted echocardiographic examination – The RUAT ECHO Study – Medical Device Clinical Trial

Principal Investigator: Prof John Atherton

Director of Cardiology and Senior Staff Cardiologist,

Cardiology, Royal Brisbane and Women's Hospital

John.Atherton@health.qld.gov.au

Study Coordinator: Dr Kristyan Guppy-Coles

Research Fellow, Research Manager, Program Manager,

Cardiology, Royal Brisbane and Women's Hospital

Kristyan.Guppy-Coles@health.qld.gov.au

This survey has been provided to you as you have consented to participate in the **RUAT (ROBOT) ECHO study** and have undergone a robot cardiac ultrasound (also known as echocardiogram or 'echo'). The following statements for you to provide are to investigate patient experiences regarding the RUAT echo procedure.

Questions to be asked by research team (not the operating sonographer) to the patient.

Thank you for agreeing to participate in this study. Please respond to the questions below on a 10-point scale of your level of comfort with the procedure.

1. Were you comfortable (and lacking concern) with the speed of the automatic movements when the probe was not on your chest?									
On a scale of 1 to 10 with 1 being extremely uncomfortable and 10 being extremely comfortable where does your experience sit on this scale?									
1	2	3	4	5	6	7	8	9	10
2. When the sonographer was actively adjusting the probe on your chest, did you feel safe?									
On a scale of 1 to 10 with 1 feeling extremely unsafe and 10 feeling extremely safe where does your experience sit on this scale?									
1	2	3	4	5	6	7	8	9	10

3. Were you comfortable with the pressure applied by the robot to the chest?									
On a scale of 1 to 10 with 1 being extremely uncomfortable and 10 being extremely comfortable where does your experience sit on this scale?									
1	2	3	4	5	6	7	8	9	10
4. Could you clearly see the video of the sonographer?									
On a scale of 1 to 10 with 1 being unable to see the video at all and 10 being able to clearly see the video unobstructed where does your experience sit on this scale?									
1	2	3	4	5	6	7	8	9	10

5. Do you wish to receive by email a layperson summary of the clinical trial results?"

If yes, you understand that you are consenting to be contacted via email for the sole purpose of providing study results. Your information will not be used for any other purpose.

Please provide email if consenting: _____

- End of patient survey -