1 **TITLE:**

- 2 Design and Implementation of a Bespoke Robotic Manipulator for Extra-corporeal Ultrasound
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31 KEYWORDS:

- 32 Medical robot, robotic ultrasound, extra-corporeal ultrasound, robot design, mechanism design,
- 33 linkages and manipulators, robot safety, 3D-printing, rapid prototyping.
- 34

35 SUMMARY:

- 36 This paper introduces the design and implementation of a bespoke robotic manipulator for extra-
- 37 corporeal ultrasound examination. The system has five degrees-of-freedom with lightweight
- 38 joints made by 3D printing and a mechanical clutch for safety management.
- 39

40 **ABSTRACT:**

41 With the potential for high precision, dexterity, and repeatability, a self-tracked robotic system

42 can be employed to assist the acquisition of real-time ultrasound. However, limited numbers of 43 robots designed for extra-corporeal ultrasound have been successfully translated into clinical use. 44 In our study, we aim to build a bespoke robotic manipulator for extra-corporeal ultrasound 45 examination, which is lightweight and has a small footprint. The robot is formed of five specially-46 shaped links and custom-made joint mechanisms for probe manipulation to cover the necessary 47 range of motion with redundant degrees-of-freedom to ensure patient safety. The mechanical 48 safety is emphasized with a clutch mechanism to limit the force applied to patients. As a result 49 of the design, the total weight of the manipulator is less than 2 kg and the length of the 50 manipulator is about 25 cm. The design has been implemented, and simulation, phantom and 51 volunteer studies performed, to validate the range of motion, ability to make fine adjustments, 52 mechanical reliability, and safe operation of the clutch. This paper details the design and 53 implementation of the bespoke robotic ultrasound manipulator with the design and assembly 54 methods illustrated. Testing results to demonstrate the design features and clinical experience 55 of using the system are presented. It is concluded that the current proposed robotic manipulator 56 meets the requirements as a bespoke system for extra-corporeal ultrasound examination and has great potential to be translated into clinical use. 57

58

59 INTRODUCTION:

60 An extra-corporeal robotic ultrasound (US) system refers to the configuration in which a robotic system is utilized to hold and manipulate an US probe for external examinations, including use in 61 62 cardiac, vascular, obstetric, and general abdominal imaging¹. The use of such a robotic system is 63 motivated by the challenges of manually holding and manipulating a US probe: e.g. the challenge 64 of finding standard US views required by clinical imaging protocols and the risk of repetitive strain 65 injury²⁻⁴, and also by the needs of US screening programs: e.g. the requirement for experienced 66 sonographers to be on-site^{5,6}. With emphases on different functionalities and target anatomies, several robotic US systems, as reviewed in the works^{1,7,8}, have been introduced since the 1990s 67 to improve different aspects of US examination: e.g. long-distance tele-operation⁹⁻¹², as well as 68 robot-operator interaction and automatic control^{13,14}. In addition to the robotic US systems used 69 70 for diagnostic purpose, robotic high intensity focused ultrasound (HIFU) systems for treatment 71 purposes have been widely investigated as summarized in¹, with some of the recent works such as^{15,16} reported for the latest progress. 72

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74 Although several robotic US systems have been developed with relatively reliable technologies 75 for control and clinical operation, only a few of them have been successfully translated into clinical use, such as the commercially-available system from¹⁷. One possible reason is the low 76 77 level of acceptance for large-size industrial-looking robots working in a clinical environment, from 78 the point of view of both patients and sonographers. Additionally, for safety management, the 79 majority of the existing US robots rely on force sensors to monitor and control the applied 80 pressure to the US probe, while more fundamental mechanical safety mechanisms to limit the 81 force passively are usually not available. This may also cause concerns when translating into 82 clinical use as the safety of robot operation would be purely dependent on electrical systems and 83 software logic.

85 With the recent advancements of 3D printing techniques, specially-shaped plastic links with 86 custom-made joint mechanisms could provide a new opportunity for developing bespoke 87 medical robots. Carefully designed lightweight components with a compact appearance could 88 improve the clinical acceptance. Specifically for US examination, a bespoke medical robot aimed 89 to be translated into clinical use should be compact, with enough degrees-of-freedom (DOFs) and 90 range of motion to cover the region of interest of a scan; for example, the abdominal surface 91 including both the top and sides of the belly. Additionally, the robot should also incorporate the 92 ability to do fine adjustments of the US probe in a local area, when trying to optimize an US view. 93 This usually includes tilting movements of the probe within a certain range as suggested in^{18,19}. 94 To further address the safety concerns, it is expected that the system should have passive 95 mechanical safety features which are independent of electrical systems and software logic. 96 97 In this paper, we present the detailed design and assembly method of a 5-DOF dexterous robotic 98 manipulator, which is used as the key component of an extra-corporeal robotic US system. The 99 manipulator consists of several lightweight 3D-printable links, custom-made joint mechanisms, 100 and a built-in safety clutch. The specific arrangement of DOFs provides full flexibility for probe 101 adjustments, allowing easy and safe operation in a small area without colliding with the patient. 102 The proposed multi-DOF manipulator aims to work as the main component that is in contact with 103 patients and it can be simply attached to any conventional 3-DOF global positioning mechanism

- to form a complete US robot with fully active DOFs to perform an US scan.
- 105

106 **PROTOCOL**:

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Print all the links (L₀, L₁, L₂, L₃, and L₄) and the end-effector as shown in Figure 1 with ABS
 (acrylonitrile butadiene styrene) plastic, PLA (polylactic Acid) plastic, or Nylon using a 3D printing
 service. Use the STL files provided in the supplementary materials when printing.

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Note: changes in shape and scale of each part can be made based on the provided files. The innerprofile of the end-effector can be changed to fit different US probes.

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2. Print all the required additional components as shown in Figure 2 in Nylon using a 3D printing
 service. Refer to the material list for the required number of each component. Use the STL files
 provided in the supplementary materials when printing.

118

3. Polish all the printed plastic parts with polishing tools if necessary. Remove supportingmaterials left from 3D printing if necessary.

121

Note: some structures in the provided end-effector design are for a force sensor, which is not a part of the current reported protocol and will not be used for the assembly. The force sensor design concept has been reported in previous work²⁰, thus it is not covered in this paper.

125

126 3. Assembly of Joint 1 (J₁) based on Figure 3:

- 127
- 128 3.1. Place the four small geared stepper motors (with 20-teeth spur gears attached) into the

129 mounting cavities of L₀ and mount them with screws. 130 131 3.2. Place the two 37 mm O.D bearings into the bearing housings of L₀ and secure the 120-teeth 132 spur gear (Type A) onto the hexagon key of L_1 . 133 134 3.3. Insert the shaft on L_1 into the shaft hole on L_0 with the four small driving spur gears and the 135 large driven spur gear engaged and assemble the shaft collar to secure and retain the shaft. 136 137 4. Assembly of Joint 2 (J₂) based on Figure 4: 138 139 4.1 Place the four small geared stepper motors (with 20-teeth spur gears attached) into the 140 mounting cavities of L_1 and mount them with screws. 141 142 4.2. Attach the two 120-teeth spur gears (Type B) to the two 37 mm O.D bearings and position 143 them into the gear cavities of L₁, with the 120-teeth spur gear (Type B) engaged with the 20-teeth 144 spur gears mounted on the motors. 145 146 4.3. Insert the four ball-spring pairs into the clutch holes in L_2 with the two round clutch covers 147 pushing the spring into the clutch mechanism for pre-loading. 148 149 4.4. Insert the shaft (e.g. an M6 bolt with a nut) into the bores of L_1 and L_2 with the two joints 150 properly aligned and place the two 12 mm O.D bearings into the bearing housings of L₂. 151 152 5. Assembly of Joint 3 (J_3) based on **Figure 5**: 153 154 5.1. Place the two small geared stepper motors (with 20-teeth spur gears attached) into the 155 mounting cavities of L₂ and mount them with screws. 156 157 5.2. Place the 37 mm O.D bearing into the bearing housing of the 120-teeth spur gear (Type C) 158 and place the 32 mm O.D bearing into the bearing housing of L_3 . 159 160 5.3. Secure the large spur gear into the hexagon keyhole of L_3 (additional screws can be used if 161 necessary) and insert the shaft on L_2 into the bores on the large spur gear and L_3 , with the small 162 and the large spur gears engaged. Ensure the driven large spur gear rotates freely on the 37 mm 163 O.D bearing and L₃ rotates freely on the 32 mm O.D bearing. 164 165 6. Assembly of Joint 4 (J_4) based on Figure 6: 166 167 6.1. Place the two small geared stepper motors into the mounting cavities of L_3 and mount them with screws. Place the 8 mm O.D bearings into the bearing housings of L4. 168 169 6.2. Mount the 20-teeth long spur gear onto the two small stepper motors and insert the shaft 170 171 into the shaft hole of L_3 and L_4 after the two links are aligned (e.g. using an M5 bolt with a nut). 172 Ensure the built-in driven gear structure on L_4 mates with the 20-teeth long spur gear.

174 7. Assembly of Joint 5 (J₅) based on Figure 7:

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7.1. Place the two small geared stepper motors (with 18-teeth bevel gears attached) into the
mounting cavities of L₄ and mount them with screws.

178

7.2. Position the driving 144-teeth bevel gear onto the extrusion of L₄ with its bottom gear partengaged with the two driving small bevel gears.

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7.3. Insert the end-effector into the keyway of the large bevel gear and vertically position the
end-effector with the end-effector collar screwed onto it. Ensure the end-effector collar, rotating
on the top round surface of L₄, holds and positions the end-effector vertically.

185

186 **REPRESENTATIVE RESULTS:**

187 Following the protocol, the resulting system is a robotic manipulator with five specially-shaped 188 links (L₀ to L₄) and five revolute joints (J₁ to J₅) for moving, holding and locally tilting an US probe 189 (**Figure 8**). The top rotation joint (J_1) , with gear mechanisms actuated by four motors, can rotate 190 the following structures 360 degrees to allow the US probe to point towards different sides of the scanning area, such as the top, bottom, and sides of the abdomen. The main tilting joint (J₂), 191 192 with gear mechanisms actuated by four motors, is used to tilt down the probe to align with the 193 surface of the scanning area. As this joint is also crucial to the force management, a mechanical 194 clutch with balls, springs, and detent holes was incorporated. The last three orthogonal revolute 195 joints (J_3 , J_4 , and J_5), with gear mechanisms actuated by two motors each, are used to control the 196 tilting and axial rotation of the probe, allowing fine adjustments of the probe in a local area. The 197 last revolute joint J₅ also allows the mounting of an US probe in a specially-shaped end-effector. 198 The total weight and length of the proposed robotic manipulator, which is the only structure 199 usually on top of the patient's body, are less than 2 kg and 25 cm. The resulting design is such 200 that a large range of probe positions can be reached with only small movements of the remaining 201 global positioning mechanism when using the proposed robotic US manipulator. Considering just the proposed manipulator on its own, the probe can be rotated axially to any angle, tilted to 202 203 follow a surface angled between 0 and 110 degrees to the horizontal in any direction, and 204 positioned within a circle of diameter 360 mm. Additionally, the revolute joints J_3 and J_4 provide 205 a tilting angle in the range -180 to 180 degrees and -30 to 45 degrees, respectively in two 206 directions, which is used for local fine adjustments of the US probe. The ranges of movements 207 and tilting angles meet the required ranges for obtaining an ideal acoustic window for US 208 examinations as suggested in^{18,19}. The technical details of the proposed robotic manipulator are 209 summarized in Table 1 (Denavit-Hartenberg parameters and joint specifications) based on the 210 coordinate definitions shown in Figure 8. The estimated cost of the system is 500 GBP based on the current manufacturing method, components and materials. 211

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As an example used in this research, we employed a global positioning system which has a revolute joint (R_1) with a chain mechanism for rotating the complete arm and a two-bar armbased set of parallel link mechanisms (R_2 and R_3) with worm-gear drives (**Figure 9**). This 3-DOFs mechanism will work with the proposed 5-DOF manipulator to form a complete robotic US 217 system. Based on the proposed robotic manipulator and the example global positioning option 218 used for this research, Figure 10 shows a simulation example of the robot in positions around an 219 abdominal phantom, demonstrating that it is able to reach around both sides of the abdomen 220 and a range of positions on top. The design of the redundant joints in the system, particularly the 221 configurations of J₁ and J₂, allows tilting the probe to large angles with most of the mechanical 222 structures still staying away from the patient's body, as can be observed from Figure 10. 223 Consequently, with the last three joints $(J_3, J_4, and J_5)$ specified to rotate within limited ranges for 224 fine tilting adjustments, collision is avoided between the moving parts of the robot and the 225 patient's body.

226

227 With the electronics and the conventional stepper motor control system developed, experiments 228 have been performed to test the output force and validate the expected range of motion. The 229 current control unit is a box with microcontrollers, stepper motor drivers, power supply and 230 regulators, and other supporting electronic components included. The overall size of the control 231 box is 40 cm long, 23 cm wide and 12 cm deep. Based on the repeated testing of the system, the 232 maximum force that the robotic manipulator can currently exert is set to 27 N before the 233 mechanical safety clutch is triggered, specifying the output force range of the proposed system 234 to be 0 N to 27 N. With the configuration of the mechanical clutch, it was verified by repeated 235 testing that in the default position when the clutch is engaged, the balls are partially in the detent 236 holes of L_1 . Therefore the movements of the driven large spur gears actuate L_2 . However, when 237 excessive force is exerted at the end-effector, the clutch is disengaged with the balls moving out 238 of the detent holes of L₁.

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240 The range of motion of each joint reported in Table 1 was also repeatedly tested and validated. 241 The reliable working of the robotic manipulator over a long period of time has been extensively 242 tested on a fetal phantom and continuously verified with abdominal scans of internal healthy 243 volunteers (Figure 11). The study was approved by the local ethics committee. So far, 20 244 volunteer scans for general abdominal ultrasound examinations using the robotic manipulator 245 have been successfully performed with basic software control of the robot, mainly to evaluate 246 the reliability and feasibility of the mechanical design. It was concluded from the phantom and 247 volunteers studies that the current design of the robotic manipulator can reach the required 248 movement range at the required force, and provides enough fine adjustment, to obtain images 249 similar to the hand-held operation of the US probe for abdominal imaging. For all these scans, no 250 safety concerns or uncomfortable feelings were reported by the volunteers. The selection of 251 motors, mechanical ratios of mechanisms, and power levels, have been verified such that they 252 ensure the reliable movement of the probe on the patient's body, while at the same time 253 resulting in slippage if excessed forces are generated. Further details of this on-going volunteer 254 study and clinical evidence for the use of the robot will be presented separately.

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256 FIGURE AND TABLE LEGENDS:

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Figure 1: CAD drawing of all the links (L₀, L₁, L₂, L₃, and L₄) and the end-effector. The shape of each link is shown for reference when 3D printing using the provided STL files. The end-effector is illustrated with an US probe included in the assembly.

- 261
- Figure 2: CAD drawing of the required additional components. The shape of each component is shown for reference when 3D printing using the provided STL files. The components include spur and bevel gears in different sizes, shaft collar, clutch cover, and end-effector collar.
- Figure 3: Assembly instruction for J_1 . The required links, motors, gears, and bearings are shown with some structures changed to transparent to illustrate the assembly.
- 268

- Figure 4: Assembly instruction for J₂. The required links, motors, gears, ball-spring pairs, and
 bearings are shown with some structures changed to transparent to illustrate the assembly.
- Figure 5: Assembly instruction for J_3 . The required links, motors, gears, and bearings are shown with two perspective views to illustrate the assembly.
- Figure 6: Assembly instruction for J₄. The required links, motors, gears, and bearings are shown
 with the assembled J₄ mechanism indicated.
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- Figure 7: Assembly instruction for J₅. The required link and end-effector, motors, and gears are
 shown with some structures changed to transparent to illustrate the assembly.
- Figure 8: Summary of the proposed 5-DOF robotic manipulator with the end-effector holding
 an US probe. The coordinate definition of each joint and the overall size of the assembled
 manipulator are indicated.
- 284

Figure 9: CAD drawing of the example global positioning device. This arm-based device is used
to work with the proposed robotic manipulator for testing. The notations and the main
dimensions are shown in the drawing.

- Figure 10: Kinematic simulation of four different scanning postures around the phantom. This
 demonstrates an adequate range of motion for a typical abdominal US scan.
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- Figure 11: Implemented US robot using the described protocol. (a) The robotic manipulator with the example global positioning mechanism; (b) clinical use of the proposed robotic manipulator on a patient's abdominal area.
- 295
- 296Table 1: Technical details of the proposed robotic manipulator, including the Denavit-297Hartenberg parameters and the joint specifications.
- 298
- 299 **DISCUSSION:**

Unlike many other industrial robots that have been translated into medical applications, the proposed robotic manipulator described in the protocol was specifically designed for US examinations according to the clinical requirements for the range of motion, application of force, and safety management. The lightweight robotic manipulator itself has a wide range of movements sufficient for most extra-corporeal US scanning without the need for large 305 movements of the global positioning mechanism. As the closest mechanical structure to the 306 patient, the proposed links are also specially-shaped to be away from the patient. With most 307 DOFs embedded into a compact manipulator, robotic US scanning using this device can be done 308 in an intuitive way similar to human operation without the necessity of occupying a large space. Because of all these features, we expect the system produced following the protocol could gain 309 310 acceptance from the clinicians and patients, which is being validated with the on-going volunteer 311 study. With the proposed robotic manipulator, different conventional architectures for global 312 positioning can be used based on the particular requirement, such as a gantry or ceiling mounting 313 designs. An example global positioning device was used in this paper to enable the tests of the 314 proposed robotic manipulator.

315

316 The current protocol suggests that all the links can be printed using ABS or PLA plastics, or Nylon 317 based on the availability of the local 3D printing service, while using the Nylon prints is preferred 318 in general due to its material strength. Importantly as stated in the protocol, the additional 319 components, especially the gears, should be printed with Nylon or other strong materials to 320 ensure the reliability of the system. As new 3D printing materials are introduced, the use of 321 materials could be altered. The current protocol employs an end-effector specifically designed 322 for a particular US probe with the probe's 3D shape scanned by a CT imaging system to assist the 323 design of the inner profile of the end-effector. When the manipulator is used with other US 324 probes with different shapes, it is important to ensure that the inner profile of the end-effector 325 is re-designed to tightly mate with the outer profile of the US probe, in order to guarantee the 326 safe holding of the probe. The 3D shape and profile of the probe could also be obtained from 327 other types of 3D scanning. Additionally, it should be noted that some of the design details 328 described in the protocol, such as exact shapes and dimensions, shaft sizes, mounting keyways, 329 screws, and use of bearings, could be altered. For the same reason, some of the details are not 330 provided when it is obvious based on common knowledge of mechanical design.

331

332 The current design has a passive mechanical clutch which can be adjusted and used to limit the 333 maximum force applied to the patient. This is a safety feature that does not rely on any electrical 334 systems or software logic, which guarantees the fundamental safety for using the robot for US 335 examinations. The triggering point was set based on the range from our previous 336 measurements²¹ of the vertical force applied by human operators to the patients during normal 337 US scans as well as similar results reported from the existing literature¹⁸, both of which suggest 338 that the maximum vertical force usually does not exceed 20 N. This was treated as the 339 prerequisite that the trigger force of the clutch should be more than 20 N with some given 340 allowances. The amount of triggering force can be adjusted by changing the number of ball-spring 341 pairs, the spring constant, the size of the detent holes, and the pre-loading of the springs²². A 342 potential modification of the designed protocol for this is to change the numbers of cavities for 343 holding the ball-spring pairs in L₂. In practice when using the proposed system, the correct 344 working of the clutch can be easily verified by manually rotating the clutch joint and having the 345 clutch disengage and re-engage before any robotic US examination is performed. In the current 346 protocol, the safety clutch is only applied to J_2 as this joint is designed to align the probe with the 347 surface of the abdomen and can be directly used to limit the vertical force exerted on the patient 348 by the US probe. With a similar concept, a safety clutch can also be implemented for the J₁ spur

349 gear, which will ensure the safety of the J₁ rotational movement of the following structures. This 350 is not seen as an essential safety feature in the current protocol, but could be a potential 351 modification for a finalized version. The last three joints J₃, J₄, and J₅ are used for fine adjustments 352 of the probe's orientation. Kinematically, they are not used to generate any excessive force and 353 are not likely to collide with any obstacle. To minimize the size and weight of the proposed 354 manipulator, a safety mechanical clutch is not suggested for these three joints in any modification 355 of the protocol.

356

357 Following the proposed protocol to build the proposed manipulator for US examinations, the 358 same reliability of the mechanical system, the same ranges of motion, similar weights of the 359 whole manipulator, and a similar level of triggering force of the clutch are expected as are 360 reported in this paper. However, the repeatability and accuracy of the movements, as well as the 361 repeatability of the exact triggering force level of the mechanical clutch, would strongly depend 362 on the 3D-printing and assembly accuracy compared to the CAD design. This cannot be 363 guaranteed for the current prototype as a lab-based low-end 3D printing service was used for 364 manufacturing and the assembly was done manually for the purpose of preliminary prototyping. 365 It is expected that an industrial level of manufacturing and assembly following the design 366 protocol would result in good repeatability and high accuracy, although this is not our currently 367 our aim before the system is made into a final product for clinical trial. Testing of the performance 368 would also require a separate protocol, which includes kinematic modelling, a robotic control 369 method, motion tracking and calibration methods, and is thus not included in the current paper. 370 Similarly, the control precision and response of the proposed manipulator are determined by the 371 motor control method, robot control algorithm, and communication between the electronics of 372 the manipulator and the control interface. As these are beyond the aim of the current protocol 373 of introducing the new mechanical design and can be implemented using many existing 374 architectures, details are not provided in this paper.

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383 **DISCLOSURES:**

384 The authors have nothing to disclose.

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