

Scolifix: Integrated Wearable Solution for Remote Scoliosis Rehabilitation

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Abstract—Scoliosis is a complex three-dimensional spinal deformity characterized by lateral curvature and vertebral rotation, often requiring individualized therapeutic interventions to prevent progression or to improve posture. Personalized Schroth exercises allow prescription of patient specific Schroth exercises, and they are often used in scoliosis treatment. In traditional methods, exercise instructions are typically conveyed verbally or through printed materials, which often lead to misunderstandings or incomplete execution by the patient. Digitally prescribed patient-specific exercises allow exercise critical parameters such as direction, velocity, target angles, number of repetitions, and duration to keep at the desired position, specified in detail through an electronic platform. With its client-server architecture, an integrated wearable technology allows telemedicine in scoliosis rehabilitation. The exercise program is digitally transmitted to the patient's device in a standardized format via wearable technology, enabling clear and consistent follow-through. This technical approach ensures accurate delivery of the exercises and allows for a precisely personalized and monitored treatment protocol. Using telemedicine and wearable technology in Schroth exercise allows physicians to monitor patients remotely and provide remote prescriptions to patients if needed. This article defines such a wearable technology named Scolifix (the patent application: 2025/007293-2025-GE-356269) and explains the standards that it complies with.

Keywords—Wearable device, scoliosis, telemedicine.

I. INTRODUCTION

Scoliosis is a musculoskeletal disorder characterized by a sideways curvature of the spine, typically beginning during childhood or adolescence, and, if not noticed early, can gradually worsen over time. Normally, the spine should appear as a straight line when viewed from the front; however, in scoliosis, it curves to the right or left, taking on an "S" or "C" shape [1].

The symptoms of scoliosis often involve changes in body symmetry: shoulder height asymmetry, one-sided waist or back prominence, or more noticeable curvature of the spine when the patient bends forward. Occasionally, patients experience back or lower back pain related from their scoliosis. In more severe cases, the curved spine can compress the rib cage, leading to shortness of breath. Those symptoms cause not only cosmetic concerns but also physical discomfort [2].

The impact of scoliosis on quality of life can vary. Mild cases often do not cause significant health problems, but moderate to severe curvatures can lead to both physical and emotional challenges. Early diagnosis and treatment of scoliosis are critical during childhood to help prevent the condition from worsening [3].

There is no one-size-fits-all treatment: treatment for scoliosis is patient-specific, designed based on the degree of curvature, the patient's age, and the likelihood of progression. Regular checkups may be sufficient in mild scoliosis, whereas, for moderate cases, wearing a brace might be an option. The purpose of braces is to prevent the spine from curving further, especially when children are still growing. Physical therapy and targeted Schroth exercises also play a key role in managing scoliosis. These exercises aim to improve posture, strengthen the muscles around the spine, and promote muscular balance [4]. When conservative treatments are ineffective or with more severe cases, even a spinal fusion surgery may be necessary [5].

Physical therapy in scoliosis treatment focuses on preventing the curvature from worsening, improving posture, restoring muscular balance, and enhancing the patient's quality of life. These methods are personalized based on the type and degree of scoliosis that the patient is experiencing, and the patient's age. One of the most widely used rehabilitation techniques is the Schroth exercises. This 3D therapy includes targeted postures, breathing exercises, and muscle strengthening techniques specifically tailored to the individual's spinal curve.

The main goal of the Schroth therapy is to realign the spine in the opposite direction of the curve, reduce body asymmetry, increase lung capacity, and improve posture. Patients are trained on specific movements and positions based on the direction of their spinal curve. The exercises prescribed aim to counteract the rotation and lateral bending caused by their scoliosis. Training may also include rotational breathing in which the patient takes deep breaths into the compressed side of the rib cage, helping to expand the limited side and improve lung function. The therapy also helps patients become more aware of their bodies and learn how to maintain proper posture in daily life. Because Schroth therapy is customized for each patient, a unique program should be developed for each patient based on their scoliosis type and curvature. When done

consistently, Schroth exercises can slow the progression of the curve and, in some cases, even reduce it. Hence, for patients seeking non-surgical treatment options, Schroth exercises may offer a promising alternative [6].

However, implementing patient-specific Schroth exercises has some challenges. First of all, the exercises must be tailored to each individual. Every scoliosis case involves a different curvature pattern, rotation angle, and postural imbalance, which makes it difficult for patients to identify and perform the necessary positions independently. Moreover, since the exercises involve not just muscular work but also complex 3D breathing techniques, learning the correct breathing rhythm can be time-consuming and error-prone without professional guidance [7]. Maintaining consistency is another challenge: the exercises require discipline and routine that can be hard to achieve, especially for children and teens who may lack motivation or patience. Due to the technical complexity of some movements, doing Schroth exercises correctly at home may be difficult, and improper execution could reduce effectiveness or even worsen posture. For these reasons, traditionally, it is recommended that Schroth therapy initially be conducted under the supervision of an experienced physical therapist and then gradually transitioned to a home-based program as the patient gains confidence [8].

Because of these challenges, there is a growing need for a device that can assist patients in performing Schroth exercises correctly and independently when they are away from the clinic. Such a device could offer positioning support and guided instruction, helping patients follow their personalized therapy plans more effectively at home, which will bring in necessary motivation. Furthermore, having this device connected to physicians' systems will help physicians follow progress remotely and intervene on time if needed.

II. DEVICE DESIGN

Wearable telemedicine technology for Schroth exercise, i.e., Scolifix, has a client-server architecture and consists of three main components: two software components (with client and server architecture), and one wearable sensor module (Fig. 1). Scolifix is currently under patent review (Application - 2025/007293-2025-GE-356269).

A. Server module

The server module is a software designed as a multi-platform and multi-language application that also keeps an encrypted centralized patient database. The server module handles the following tasks:

- Provides the specialist doctor with CRUD services (create, read, update, and delete) on patient and exercise records.
- Respond to requests coming from the client module.
- CRUD services to patient-specific exercises, and push them to the client module.
- Maintain a history of exercise records and generate related reports.
- Allows data mirroring, backup, or restore if needed.

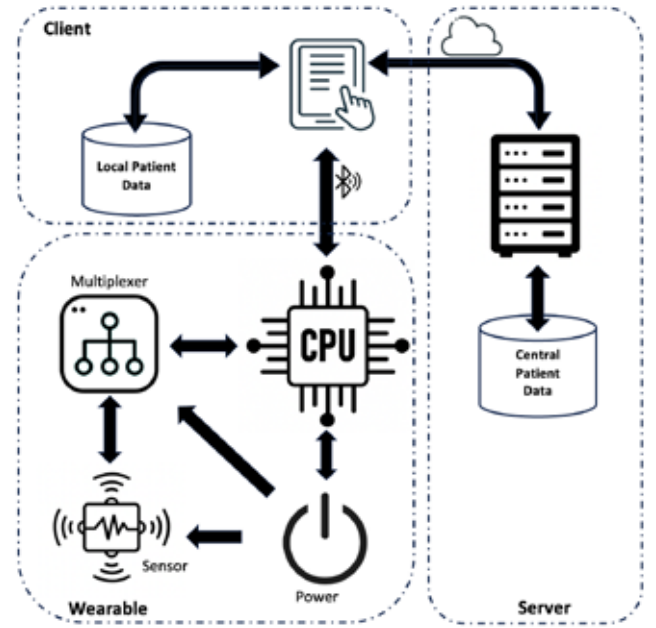


Fig. 1: Scolifix is a wearable telemedicine technology for Schroth exercise (the system architecture is under patent review - Application number: 2025/007293-2025-GE-356269).

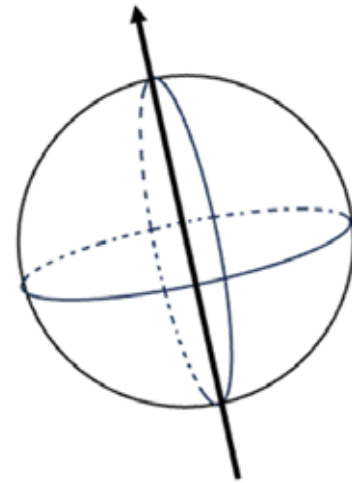


Fig. 2: Gimbal interface enables the client application to give visual directions on exercise. For each sensor, there is one gimbal, and with its colored visual alerts, the patient can see how the sensor and the attached anatomic point are moving. This visual real-time feedback allows the patient to complete exercises correctly.

- Push new firmware updates to client and wearable modules.
- Decode and encode industry-standard encrypted two way communication data to ensure secure communication with the client module.



B. Client module

The client module is a multi-platform application running on portable devices, such as iOS or Android. Also, it has an internal encrypted database to keep patient data assigned to devices. The client module handles the following tasks:

- Check for new firmware for the client and wearable modules, and push the updated firmware to the wearable sensor module.
- Receive patient-specific exercises created by the specialist from the server and update the locally stored patient exercise patterns.
- Keep a local copy of exercise definitions for the patient for offline operation, which is linked with the unique wearable identification number.
- Remind and initiate personalized exercises.
- Use the data received from the wearable module to monitor whether the patient is performing the prescribed exercises correctly, and notify the patient visually and audibly in real time. The target and real-time status of the IMUs are displayed using gimbal spheres (Fig. 2). The belts of the gimbal spheres turn red, yellow, or green depending on how close the real-time orientation matches the targets.
- Securely save the generated exercise records and push them to the server module encrypted. In case of a communication failure, retain data until communication is reestablished.
- Decode and encode industry-standard encrypted data to ensure secure communication with the server module.

C. Wearable module

The wearable module is a hardware platform with six sub-components: the central processing unit (CPU), channel multiplexer (MUX), the power unit, inertial measurement sensor units (IMUs), data cables, and a special adjustable garment to keep all these components securely in their prescribed anatomic locations. Wearable module has at least 8 IMUs, which can be increased to a maximum of 64 if needed, and increased number of IMUs allow high-resolution tracking for complex 3D movements. One of those IMUs is used as the geometric reference point for the others, and another is placed on the chest for breath monitoring. The properties and tasks of wearable unit are listed as follows:

- Equipped with a garment, made of flexible and washable fabric with pockets to keep all components (IMUs, power, CPU, and MUX) safely in their prescribed anatomic locations.
- Garment has flexible cable channels with hook-and-loop straps to secure connecting cables without restricting patient movements.
- Shielded data cables carry data between MUX and IMUs, and energy from the power unit to MUX and IMUs.
- IMUs continuously measure the direction, velocity, and acceleration of anatomical points.

- MUX allows communication between the CPU and IMUs.
- CPU selects the IMU channel, reads data, calculates relative acceleration, velocity, and direction with respect to the reference sensor, including breath volume and frequency.
- CPU keeps a unified device identifier (UID) which is also linked to the patient.
- CPU packs IMU data, includes time stamp and labels with UID, and wirelessly transfers to client module using Bluetooth technology.
- Power unit is equipped with a rechargeable battery, and its battery management circuitry allows safe charge, short circuit, and thermal protection of the battery.
- Power unit displays the battery charge level and energizes all electronic units of the wearable module.
- All components in contact with the patient are bio-compatible, and all electronic components have IP65 dust and water spill resistance.

III. DEVICE COMPLIANCE

The sensors, the client and server are expected to comply with Class IIb or relevant standards based on the intended market and categorized under four major headings:

- Medical device classification
- Quality and risk standards
- Wireless or telecommunication standards
- Data privacy and security standards

The standards are summarized in Tab. I for convenience.

A. Medical device classification

The wearable module will be actively influencing the treatment with real-time collected data, and later provide feedback to the patient as audio or visual feedback for scoliosis exercises, through the client module. Incorrect feedback could worsen scoliosis by improper posture reinforcement; therefore, the standards applicable to the device are Class IIb for EU (MDR2017/745) and Class II per 21 CFR 807.92 (510(k)) for US (FDA) with a predicate device category of 21 CFR 890.5050 or CFR 890.2000.

B. Quality and risk standards

For the EU market, to obtain the CE mark, ISO 13485 is mandatory. Similarly, ISO 14971 is needed for risk analysis and possible risk filing. Furthermore, the EU mandates a unified device identifier (UDI) per Article 27, Annex VI. FDA also recognizes ISO 14971 for risk assessment and requires UDI per 21 CFR 830. Possible software failures may result in medium injury; therefore, for the EU market, the IEC 62304 Class B standard will be applicable. Similarly, the audiovisual feedback through the user interface may affect patient safety, forcing IEC62366 compliance. The US also expects these standards to be met; furthermore, FDA Cybersecurity Guidance, including patchability and vulnerability monitoring, should be met.

TABLE I: Required medical device compliance summary, before marketing Scolifix in different regions

Region	Device Class	Software Class	UDI Requirement	Medical Standards	Data Privacy/Security	Wireless Standards
EU (MDR)	Class IIb	IEC 62304 Class B	Mandatory (MDR Art 27, EUDAMED)	MDR 2017/745 (Rule 13) ISO 13485 ISO 14971 EN 62366-1 EN 1041 (Labeling)	GDPR (Art. 32) ISO 27001 (cloud)	RED Directive ETSI EN 300 328 (BLE) EN 301 489 (EMC)
USA (FDA)	Class II	No formal class IEC 62304 used voluntarily	Mandatory (21 CFR 830, GUDID)	21 CFR 820 (QSR) FDA Cybersecurity Guidance (2023) ISO 13485 (MDSAP) ANSI/AAMI SW91	HIPAA (BAAs required) NIST SP 800-53 (cloud) UL 2900-1	FCC Part 15B (EMC) FCC Part 15C (Intentional radiators) Bluetooth SIG
UK (MHRA)	Class IIb	Class B	Planned (Mirrors EU, not enforced)	UK MDR 2002 BS EN 62304 BS EN 60601-1 (Safety)	UK GDPR NHS DSP Toolkit	UKCA (via RED compliance) BS EN 300 328
Canada	Class II	Class B	Voluntary (MDSAP alignment)	SOR/98-282 ISO 13485 (MDSAP) ISO 14971	PIPEDA PHIPA (Ontario)	ISED RSS-247 (BLE) CAN/CSA-C22.2 No. 60601-1
Australia	Class IIb	Class B	In development (Consultancy phase)	TGA Act 2002 ISO 13485 ISO 14971	Privacy Act 1988 (APP 8) OAIC Guidelines	ACMA RCM (BLE) AS/NZS 60601.1
Japan	Class II	IEC 62304 applied; class determined by risk (Class B)	Mandatory (PMDA, IMDRF-aligned)	PMD Act JIS Q 13485 JIS T 62304 JIS T 14971	APPI MHLW Cloud Guidelines	MIC Ordinance (BLE) JIS C 60601-1
China	Class II	Class B	Mandatory (NMPA database)	RSAMD (revised 2021) YY/T 0287 GB 9706.1 YY 0316	PIPL MLPS 2.0 (cybersecurity framework)	SRRC (BLE) GB 9706.1 (Safety)

C. Data privacy and security standards

Since the device processes and transmits real-time or offline health data, stricter safeguards apply. In the EU, GDPR and MDR compliance are expected. Furthermore, per Article 32 GDPR, pseudonymization of patient data is required. Since the data or server will most likely be hosted as a cloud/server structure, ISO 27001 will also be required. For the US, HIPAA security implementation (NIST SP 800-53; NIST SP 800-66) applies, and a Business Associate Agreement (BAA) is required if cloud providers are utilized for hosting and storing protected health information (PHI).

D. Wireless and Telecommunication standards

Due to the use of Bluetooth data communication in wearable devices and client applications, BLE Certification is needed (ETSI EN 300 328 / FCC Part 15). Furthermore, for the EU, per the RED Directive, a CE marking is required for radio equipment. For the US, FCC Part 15B (EMC) and 15C intentional radiators compliance are required.

IV. CONCLUSION

The device design has reached a mature stage, with its operational mechanism clearly defined and aligned with relevant international compliance standards. A physical prototype has not yet been entirely constructed; on the other hand, its detailed design documentation supports its technical feasibility and regulatory alignment. A patent application has been filed (2025/007293-2025-GE-356269) to secure the intellectual property of the Scolifix.

A comprehensive usability and clinical testing stage will be the critical future steps in evaluating the effectiveness and safety of the Scolifix. Clinical tests of Scolifix with patient populations or in real-world therapeutic contexts have not been started; so, the clinical relevance has not been assessed yet. However, despite this pending stage, with its comprehensive design, including non-invasive operation, user-specific therapeutic feedback, integration with digital health platforms, and remote monitoring and patient treatment by

the physician, Scolifix has promising features in telemedicine. Further studies will focus on prototype construction, followed by usability testing and clinical validation to support its translational readiness.

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