DE GRUYTER Current Directions in Biomedical Engineering 2025;11(1): 513-516

Yeqingqing Huang*, Moritz Spiller, Ludwig Wermke, Axel Boese, Nazila Esmaeili, Christian Hansen, and Alfredo Illanes

Development of a robotic test stand for testing vibroacoustic sensor units in needle insertion experiments

https://doi.org/10.1515/cdbme-2025-0230

Abstract: To ensure the quality of newly developed medical devices, rigorous testing is essential. Conventional manual testing is a time-consuming, costly, and non-standardized process. Therefore, automation and robotics play an important role. This work presents the development of an automated test stand utilizing a robot arm to conduct performance tests on vibroacoustic sensing units, serving as navigation devices for lumbar puncture. Following a series of tests, the results obtained from robotic testing are compared with those from manual testing, which serves as a reference method. Both testing methods show identical outcomes. However, robotic testing demonstrates significantly improved efficiency

Keywords: Automatic test stand, Performance test, Vibroacoustic sensing, Needle puncture

1 Introduction

A lumbar puncture is a diagnostic procedure used to identify various diseases, such as infections of the nervous system [1]. During the procedure, a spinal needle is inserted into the subarachnoid space [2]. The correct placement of the needle during the puncture poses a significant challenge for clinicians. Incorrect positioning can increase the risk of complications such as post-puncture headaches [3, 4]. Recently, vibroacoustic technology has been proposed in the literature as a method for obtaining haptic and navigational information from surgical instruments [5, 6], particularly needles. This technology enables accurate detection of needle position during the procedure, facilitating applications such as lumbar punctures [4].

Before newly developed medical devices can be introduced to the market in the European Economic Area (EEA), they must fullfill legal approval requirements as defined by the Medical Device Regulation (MDR) [7]. The MDR outlines safety and performance criteria. In order to prove that the products meet these requirements, producers are required to undergo a "conformity assessment procedure.", which involves rigorous performance testing [8, 9]. For small and medium-sized enterprises (SMEs), the documentation and human resource demands are a high additional expense [10]. For this reason, it is beneficial to automate the testing process in order to save time and costs. However, there is currently no particular automated test stand available for vibroacoustic sensing technology experiments.

The aim of this work is to design an automated test stand for testing the vibroacoustic response during robotic insertion of spine needles. To verify its functionality and demonstrate improved testing efficiency, a series of needle insertion tests were conducted in a foam testing material. Manual testing was also performed for comparison purposes.

2 Methods

2.1 Construction of automated test stand

The developed automated test stand involves a robot arm (Franka Emika Panda, München), which has 7 axes and therefore provides a high flexibility. The test stand also includes a personal computer (PC) serving as the master device, which controls the robot and manages the testing process, including the acquisition of vibroacoustic signals. The sensor unit to be tested is attached to the needle hub of the puncture needle, which is fixed to the robot's fingertip. The test material is positioned inside a plastic box, held in place between two box inserts (see Fig.1).

To facilitate the configuration of performance test parameters and manage the testing process, a Graphical User Interface (GUI) application was developed. The Python library

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***Corresponding author: Yeqingqing Huang,** Otto-von-Guericke University, 39120 Magdeburg, Germany, jocelynhuang1999@gmail.com
Moritz Spiller, Ludwig Wermke, SURAG Medical, Leipzig, Germany
Axel Boese, INKA - Innovation Laboratory for Image Guided Therapy, Otto-von-Guericke University, Magdeburg, Germany
Nazila Esmaeili, Center for Digital Surgery, Department of General, Visceral and Pediatric Surgery, University Medical Center, Göttingen, Germany
Christian Hansen, Alfredo Illanes, Research Campus STIMULATE, Otto von Guericke University, Magdeburg, Germany

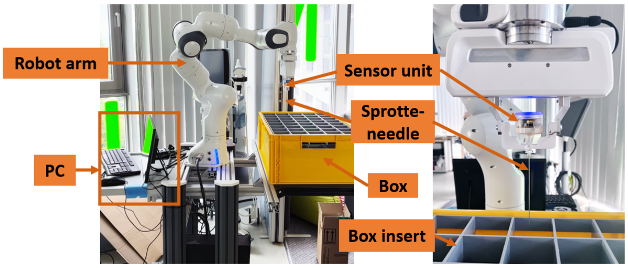

Fig. 1: Setup of the automatic test stand

"franky" was used for the robot programming [11]. The GUI was designed using "PyQt5", and the "Bleak" Python library was used to connect and communicate with the sensor unit via Bluetooth Low Energy (BLE) [12].

2.2 Robotic test workflow

Before starting the performance test, the robot first moves to the predefined start position. The needle hub is then fixed by closing the gripper. This process is controlled through the GUI. After clicking the button on the GUI, the connection to the sensor is automatically established. Several parameters for the test are configured using the GUI, e.g. the number of insertions, insertion velocity and insertion angle. By giving the length and width of the insertion area, the moving path of the robot is adjusted. Additionally, the test information such as the type of test material, type of needle, and sensor unit to be tested, should be provided. After giving all necessary information, the test can be started.

During the test, the needle is inserted by the robot into the test material according to the preconfigured settings. To prevent the test procedure from being affected by repeated punctures in the same area of the test material, and to avoid the needle touching the edges of the box insert, the robot was programmed to move along a predefined snake-like path throughout the test process (see Fig.2).

Once the end effector reaches the starting position, data transmission between the sensor unit and master device begins automatically, as programmed in the application. Data transmission stops after the needle has penetrated the test material. Thereafter, the end effector returns to its starting position again and moves to the next insertion position. The signals are detected by the sensor unit and saved as a single file for each insertion in a predefined folder.

After the required number of insertions has been achieved, the test is terminated. Then, the collected signals are processed in the background. The results and relevant test information are then documented automatically.

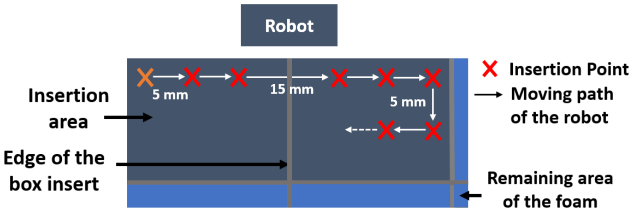

Fig. 2: Trajectory of the robot arm (Top view of the foam)

2.3 Experimental design

A series of robotic and manual tests were executed to evaluate the efficiency of the robotic test stand in performance testing. Two vibroacoustic sensor units (SURAG Medical GmbH, Leipzig) with different sensitivities were tested. The sensor unit 1 (S1) has a larger sensing element than the sensor unit 2 (S2), making it more sensitive to punctures. By comparing results from these two sensors, the ability of robotic test stand to detect varying sensor sensitivity levels was assessed. These sensors were attached to a Sprotte Spinal Needle (20G) and acquired with a sampling frequency of $16\,\mathrm{kHz}$ and $16\,\mathrm{bit}$ quantization.

During manual testing, the needle hub was held between the thumb and index finger. Throughout the experiments, the insertion angle was kept constant at 90° to the test material. A metronome with a predefined BPM [1] was used to maintain consistent insertion speed. Each insertion began on the first beat and fully penetrated the foam on the second. The robotic test followed the same procedure as described in section 2.2. The needle was inserted 50 times at slow speed and 50 times at fast speed for both test methods (manual and robotic) and each sensor unit. PUR foam with a thickness of $1.5\,\mathrm{mm}$ was used as the test material for all tests. Vibroacoustic signals were generated through the interaction between the needle and foam. These signals are transmitted through the needle shaft and then detected by the sensor unit.

To determine the time required for both manual and robotic testing, a timer was used during each test. The timing started at the beginning of the insertion process and ended when the test was completed.

2.4 Signal analysis methodology

As the needle penetrates the foam, each bubble breakage caused by the needle tip results in a transient vibroacoustic signal excitation. By detecting the peaks of each transient response and assessing their energy and signal-to-noise ratio (SNR), the performance of the tested sensor units can be eval-

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[1] BPM: Beats per minute

uated. Bubble breakage transient responses with higher energy and SNR correspond to higher sensitivity in sensing. To detect the peaks of the transient response, the signal must be processed.

Background noise for each signal is first filtered out. A relevant segment of the recorded signals is then selected, containing the signals when the needle penetrated the foam. In order to better extract peaks, a homomorphic envelope is applied, which captures maximum amplitude variations and enables highlighting key events. The detected peaks are used to quantify the recorded sensor signals through four quality parameters: average energy, average maximum and minimum signal values and the number of the excitations for each recorded signal. A high-quality sensor should detect all events with a high response.

3 Results and Discussion

3.1 Comparison of test duration

To assess test efficiency, a timer was used to measure the duration of each test (see section 2.3). As test duration is closely related to insertion velocity, the average insertion speed was calculated by dividing the foam thickness by the needle's penetration time, which was derived from the number of detected samples within a selected interval and the known sampling rate.

Tab. 1: Test duration

(a) Test duration for manual testing

Sensor unit (velocity)	Average insertion velocity ($\frac{mm}{s}$)	Test duration
S1 (35 BPM)	8,86	12min58s
S2 (35 BPM)	10,01	13min39s
S1 (70 BPM)	17,10	11min17s
S2 (70 BPM)	18,04	10min45s

(b) Test duration for robotic testing

Sensor unit (velocity)	Average insertion velocity ($\frac{mm}{s}$)	Test duration
S1 (15 $\frac{mm}{s}$)	15,09	20min55s
S2 (15 $\frac{mm}{s}$)	16,71	20min50s
S1 (25 $\frac{mm}{s}$)	25,2	13min12s
S2 (25 $\frac{mm}{s}$)	24,05	13min17s

As shown in Table 1, the average insertion velocity during manual testing is generally slower. However, the overall test duration is shorter compared to robotic testing.

There are two main reasons for the longer duration of robotic testing. The first is the frequent occurrence of communication errors, which interrupts the robot's movement. To deal with this error, an automatic error compensation mechanism was programmed. Whenever this error occurs, the robot repeats the puncture movement at the next insertion point. This error compensation mechanism is time-consuming.

Additionally, the robotic testing method itself could be a contributing factor. In manual testing, the operator can quickly withdraw the needle from the test material and move it to the next insertion point. In contrast, all robotic movements are executed at a constant and predefined speed.

Since performance testing with the robot is fully automated, the presence of an operator is not required throughout the process. In addition, the duration of robotic testing can be further reduced by addressing the aforementioned error. As a result, robotic testing can still be considered as an efficient and time-saving method.

3.2 Comparison of quality parameters

The results of four quality parameters from manual and robotic testing are statistically analysed using box plots. The medians from each box plot are shown in the table 2.

Tab. 2: Results of quality parameter

(a) Signal energy

	manual(S1)	robotic(S1)	manual(S2)	robotic(S2)
slow	$28 \cdot 10^3$	$42 \cdot 10^3$	$0,8 \cdot 10^3$	$0,18 \cdot 10^3$
fast	$30 \cdot 10^3$	$29 \cdot 10^3$	$0,54 \cdot 10^3$	$0,77 \cdot 10^3$

(b) Maximum signal values

	manual(S1)	robotic(S1)	manual(S2)	robotic(S2)
slow	70,64	77,51	3,44	2,69
fast	74,96	65,7	5,6	6,5

(c) Minimum signal values

	manual(S1)	robotic(S1)	manual(S2)	robotic(S2)
slow	52,5	77,24	4,76	3,17
fast	44,98	62,37	7,43	7,44

(d) Number of detected excitations

	manual(S1)	robotic(S1)	manual(S2)	robotic(S2)
slow	24	17	23	19
fast	23	14	20,5	14

The tests conducted with S1 have significantly higher signal energy in both test methods. This result is consistent with our expectations, since the S1 has a higher sensitivity (see section 2.3). In this case, the results from both test methods are consistent.

The maximum and minimum signal values represent the intensity of each detected excitation. A high signal value indicates a strong sensor response to the breaking of bubbles in the test material. Table 2b and 2c show the median values of average maximum and minimum signal values for each insertion action. The medians clearly illustrates that S1 consistently has higher signal values for both test methods. This result also meets our pre-test expectation.

Furthermore, the quality of the sensor unit can be evaluated by the number of detected excitations. Due to the higher sensitivity of S1, it was expected that more excitations would be detected during testing with this sensor. However, the results presented in Table 2d do not show a significant difference between the two sensor units. This may be explained by the fact that, although the S2 is less sensitive, it is still sufficiently capable of detecting bubble breaking. Thus, it is difficult to determine which sensor unit has better quality based on this parameter alone using both test methods.

According to the results presented above, the quality of the two sensor units can be identified through quality parameters (with the exception of the number of detected excitations) using both manual and robotic testing methods. In this regard, the results from both test methods found to be identical.

4 Conclusion

In this work, an automated test stand was developed using a robot arm to conduct performance testing of vibroacoustic sensor units. To verify the reliability and efficiency of the automatic test stand, a series of experiments were conducted, and the results were analyzed.

The full automation of robotic testing reduces significantly the operator's time involvement during performance evaluations. However, due to the longer test durations, it is necessary to address the frequently occurring error (see section 3.1). The Python library “franky” has recently been updated. The future experiments should be performed with this updated version.

The quality and performance of the sensor units are evaluated using quality parameters. Both robotic and manual testing yielded identical results. It is possible to assess the sensor quality and identify differences between two sensor units through both testing methods. Due to time limitations, only 50 insertions for each test were performed in this work, which provides an initial result. For future work, a larger number of insertions should be conducted in order to obtain more statistically reliable results.

In conclusion, the automated testing process significantly reduces the testing time and operator's workload. Therefore, the robotic test stand developed in this work shows to be more efficient and advantageous than manual performance testing for vibroacoustic sensor units.

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