

# Using Artificial Intelligence to Improve the Accuracy of a Wrist-Worn, Noninvasive Glucose Monitor: A Pilot Study

Journal of Diabetes Science and Technology I–8 © 2024 Diabetes Technology Society Article reuse guidelines: sagepub.com/journals-permissions DOI: 10.1177/19322968241252819

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#### **Abstract**

**Background:** Self-monitoring of glucose is important to the successful management of diabetes; however, existing monitoring methods require a degree of invasive measurement which can be unpleasant for users. This study investigates the accuracy of a noninvasive glucose monitoring system that analyses spectral variations in microwave signals.

**Methods:** An open-label, pilot design study was conducted with four cohorts (N = 5/cohort). In each session, a dial-resonating sensor (DRS) attached to the wrist automatically collected data every 60 seconds, with a novel artificial intelligence (AI) model converting signal resonance output to a glucose prediction. Plasma glucose was measured in venous blood samples every 5 minutes for Cohorts I to 3 and every I0 minutes for Cohort 4. Accuracy was evaluated by calculating the mean absolute relative difference (MARD) between the DRS and plasma glucose values.

**Results:** Accurate plasma glucose predictions were obtained across all four cohorts using a random sampling procedure applied to the full four-cohort data set, with an average MARD of 10.3%. A statistical analysis demonstrates the quality of these predictions, with a surveillance error grid (SEG) plot indicating no data pairs falling into the high-risk zones.

**Conclusions:** These findings show that MARD values approaching accuracies comparable to current commercial alternatives can be obtained from a multiparticipant pilot study with the application of Al. Microwave biosensors and Al models show promise for improving the accuracy and convenience of glucose monitoring systems for people with diabetes.

#### **Keywords**

blood glucose self-monitoring, diabetes mellitus, microwaves, noninvasive glucose monitoring, radio frequency, wearable electronic devices

#### Introduction

Self-monitoring of blood glucose (SMBG) is an important part of managing diabetes.<sup>1</sup> However, the invasiveness of standard finger-prick glucose tests, which must be taken several times a day, are a significant barrier to SMBG.<sup>2</sup> Systems for continuous glucose monitoring (CGM)—with wearable glucose sensors that provide continuous glucose readings from the interstitial fluid in the subcutaneous tissue—are therefore increasingly being used.<sup>3</sup> The continuous data from such CGM systems provide insight into glycemic patterns

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Mohamed Sabih Chaudhry, Afon Technology, Unit 670 Castlegate Business Park, Caldicot Road, Caldicot, Monmouthshire NP26 5AD, UK. Email: sabih.chaudhry@afontechnology.com throughout the day, improving glycemic control and increasing patient confidence in managing their diabetes. <sup>4</sup> Nevertheless, CGMs require the insertion of a subcutaneous sensor which can compromise skin integrity. <sup>5</sup> Interstitial glucose levels lag 5 to 10 minutes behind blood glucose levels, which may lead to underestimations of changes in glycemic levels, particularly during activities such as exercise. <sup>6</sup> There is thus great interest in the development of accurate, noninvasive, wearable devices for CGM. <sup>7,8</sup>

Many noninvasive glucose monitoring (NIGM) systems currently under investigation, such as photoacoustics<sup>9</sup> and near infra-red spectroscopy,<sup>10</sup> use expensive instrumentation and are subject to error from physiological and environmental variables.<sup>11</sup> Other methods such as transdermal or epidermal electrochemical sensors may still involve the use of microneedles,<sup>12</sup> or involve monitoring glucose in sweat which can also be problematic.<sup>13</sup>

Studies have shown that employing microwave technology is a promising area of development for such devices. Microwave-based approaches typically makes use of dielectric spectroscopy to measure changes in the dielectric property profile of biological tissue as blood glucose concentration fluctuates. These approaches generally focus on microwave frequencies within a 0.1 to 20 GHz range, although lower radio frequency methods can also use impedance spectroscopy where it can be more useful to represent changes in terms of resistances. A recent review investigated dielectric spectroscopic-based microwave techniques for measuring noninvasive blood glucose measurements.<sup>14</sup> Several studies have discussed resonance-based sensors for measuring glucose in the microwave spectrum. For example, one study has shown that a micro-resonator using a metal-insulator-semiconductor provided a reliable indicator of glucose levels. 15 Another reports promising tests of a highly sensitive resonator-based microwave biosensor for real-time blood glucose detection.<sup>16</sup> Radiofrequency-based biosensors have also undergone recent studies into real-time and continuous glucose detection.<sup>17</sup> Nevertheless, a similar signal-noise ratio, interference from nearby radio frequency devices, and difficulties differentiating between glucose and other biological components necessitates a need for increased sensitivity, accuracy, and stability in such sensors, some of which could be achieved through the implementation of artificial intelligence (AI) and machine-learning algorithms.

Here, we report on an open-label, pilot design study of a novel, noninvasive, wrist-worn device which analyses resonance shifts in the microwave spectrum using AI. Within the device, a dial-resonating sensor (DRS) uses a microwave sensor to measure bulk plasma glucose levels in the body, which are then converted to a glucose measurement. In a previous publication, an earlier version of the device was combined with a linear regression algorithm, achieving comparable absolute relative difference (ARD) results to the first models of commercially available minimally invasive products. <sup>18</sup> This study aims to build upon those obtained

accuracies; first, because of subsequent design improvements, and second, using machine-learning algorithms with which to make glucose predictions. No prior data were obtained for building an AI model, with only the data gathered from this clinical study used for training and testing any machine-learning algorithms once the study had concluded. It is expected that with large-scale trials involving a wider range of participants that sufficient data will be gathered with which to develop AI models capable of real-time predictions.

# **Methods**

## **Ethics Statement**

Ethics committee approval was obtained (WoS reC4, 21/WS/0139), with all participants providing written informed consent.

# Study Design

In this open-label, pilot design study, four cohorts (each comprising five participants) attended trials that were ≤seven days apart at the Joint Clinical Research Facility (JCRF) in Swansea, Wales. A total of four 2-hour sessions or two 8-hour sessions were organized for each participant from Cohorts 1 to 3 and Cohort 4, respectively. During each trial, DRS-derived measurements were recorded alongside plasma glucose levels measured using a YSI 2500 laboratory glucose analyzer. Glucose levels were not given by the DRS device in real time and were generated as part of the AI model once the clinical study had concluded. The Random Forest algorithm was applied to DRS sensor—reference glucose data pairs obtained from all subject trials once the clinical study had concluded. Statistical analysis was performed on the averaged predictions obtained from 50 individual Random Forest models, each of which used a Monte Carlo (MC) resampling procedure to separate subject data into a training and external test set. No major changes were made to the protocol during the study.

## **Participants**

To be included in the study, participants needed to have documented type 1 diabetes diagnosed before age 29 or have had documented type 2 diabetes for more than one year with negative glutamic acid decarboxylase antibody test results. They were also required to be aged 18 to 80 years and to have a body mass index of 18 to 35 kg/m². Potential participants were then excluded if they had another active implantable medical device (e.g., a pacemaker); were currently participating in another clinical trial for a pharmaceutical product; had a history of allergies to any materials used in the study; were females who were pregnant or lactating; had clinically significant abnormal values in clinical chemistry; had a

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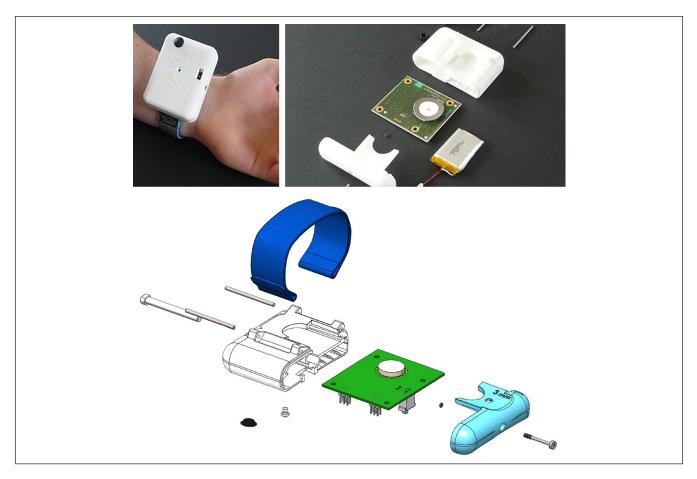


Figure 1. DRS device. Wearable device (left) and exploded view (right).

concurrent illness or condition that may interfere with blood glucose levels; have had an episode of diabetic ketoacidosis, hyperglycaemic hyperosmolar nonketotic coma, or severe hypoglycaemia within one month prior; were on pramlintide; had a wrist injury; or, had severe macrovascular disease. As this was a pilot study, a sample size calculation was not performed. Instead, the target was to recruit five participants to each cohort.

# **DRS** Device

The DRS device comprises a planar split ring resonator fabricated on the top layer of a multilayered printed circuit board (PCB). Other system components such as the oscillator, coupler, microcontroller unit (MCU), and detector are fabricated on the other side of the PCB to realize the wearable wrist-worn monitor (Figure 1). The DRS is designed to radiate high-frequency, low-power electromagnetic waves into the patient's wrist over a frequency band of 1 to 10 GHz. The electromagnetic signal transmitted into the wrist is susceptible to glucose-induced dielectric changes in the arteries, veins, and interstitial fluid. These dielectric changes result in a shift of the absorption spectrum of the electromagnetic

wave in the blood, which can then be algorithmically transformed into a prediction of the change in glucose concentration within blood.

# **Procedures**

After providing informed consent, screening for eligibility was conducted by a member of the clinical team at least seven days before the first trial visit. Patient details were reviewed by a clinical team member before approval to take part in the study was given. Upon admittance to the study, a second visit (Trial 1) was scheduled.

Participants attended each session after a minimum four-hour fast to ensure low plasma glucose levels were recorded at the start of each session. Eligibility was re-confirmed at the commencement of each session. Participants who displayed hypoglycaemic readings during a session were treated with carbohydrates before continuing the trial. At each visit, the patient had the DRS device strapped to the same wrist for calibration and a venous cannula inserted into the participants' arm. For a single patient trial, due to difficulty with inserting the cannula, the DRS device was strapped to the other wrist. Device operators were engineers who had been

Table 1. Patient Demographics for Cohorts 1, 2, 3, and 4.

Demographics	Cohort I	Cohort 2	Cohort 3	Cohort 4
Male/female ratio	3/2	4/I	2/3	(1)4/1
Age—mean	54.4	58.8	58.6	45.4
Age—standard	7.5	20.8	14.6	23.4
deviation				
Age—range	42-62	33-79	42-75	21-72

trained in usage of the DRS and on study procedures. Patients remained sitting or reclining on a bed throughout the trial period. Participants drank one 200 mL bottle of Ensure Plus to increase glucose levels (at T90 for Cohorts 1 and 2, T30 for Cohort 3, and T120 for Cohort 4), and were permitted comfort breaks as needed. Time was added for comfort breaks to ensure a full trial period was completed for each participant.

The first measurement from the DRS device was taken and recorded at time point 0 (T0). Within one minute, a blood sample was taken via a venous cannula for plasma glucose measurement. Thereafter, DRS measurements were automatically triggered at 60-second intervals, with blood samples for glucose measurements taken every five minutes throughout sessions involving Cohorts 1 to 3 and every 10 minutes for those with Cohort 4. Medical staff remained on hand to assist in case of any adverse reactions. At the end of the trial, participants were offered refreshments and discharged if their plasma glucose levels were acceptable. Trialing of each cohort took place over a period of approximately five to six weeks between July 2022 and June 2023.

# Data Analysis

An AI model was built using the Random Forest algorithm, which was chosen due to its better predictive accuracies and ability to limit overfitting than has been observed from other algorithms. 19 An MC resampling procedure was applied to the full 4-cohort data set, in which DRS measurement—reference glucose data pairs across all subject trials were randomly separated into a training and test set with a 70%/30% split. A Random Forest model was trained and evaluated on these respective data subsets. Model hyperparameters were optimized using the training set and an inner five-fold cross-validation loop, involving a full grid search of all possible parameter combinations. These hyperparameters included maximum tree depth, minimum samples required for an internal node split, minimum samples required at a leaf node, maximum features considered, and bootstrapping. Mean squared error was used as the criterion to measure split quality. The test set was treated as an external data set with which to validate model performance, and so was not seen by the algorithm during model training. A total of 50 MC resamples were performed using the process described above, resulting in 50 independent Random

Forest models built on different random subsets of the full four-cohort data set. Final model performance was evaluated using the averaged glucose predictions from all 50 independent models.

A statistical analysis of reference YSI glucose measurements against averaged glucose predictions was carried out to evaluate the final AI model performance. Statistics were also calculated from the averaged predictions from each fivefold cross validation (CV) performed on the training set for each MC resample. Several metrics were used in this analysis including the coefficient of determination  $(R^2)$ , root mean square deviation (RMSD), standard deviation of the error of prediction (SD), mean absolute error (bias), MARD, and median ARD. Accuracy of the DRS device was primarily determined by obtaining the MARD due to its common use in assessing the performance of glucose monitoring systems.<sup>20</sup> Surveillance error grids (SEGs) were used according to the methodology described by Klonoff et al,<sup>21</sup> to display the clinical risk of errors in the DRS-generated data. The color-coded zones shown within an SEG plot represent the risk levels, ranging from "none" (green) to "extreme" (brown), associated with inaccurate blood glucose measurements with respect to a reference value. These zones display the risk of mistreating a hyper or hypoglycaemic event and have become a common approach for describing the performance of blood glucose monitors.

# Results

## Sample Characteristics

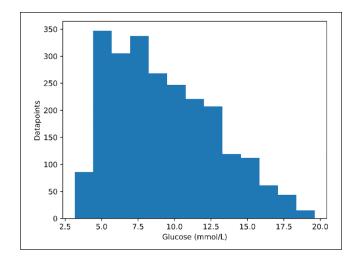
Each cohort included five participants, with one participant included in Cohorts 1 and 3 and another in Cohorts 1, 3, and 4. In each cohort, 60.0% of participants had type 1 diabetes and 40.0% had type 2 diabetes. Table 1 provides a breakdown of participant demographics across each cohort.

In total, there were 63 trials conducted across the 20 participants. Each trial had 31 to 50 glucose measurements taken with associated device readings. From a total of 2369 readings across all trials, YSI plasma glucose measurements ranging from 3.2 to 19.6 mmol/L were obtained, with a mean and median of 9.3 and 8.8 mmol/L, respectively. As DRS readings were recorded every 60 seconds, while YSI glucose measurements were taken every 5 or 10 minutes, data pairs were generated by matching data based on the closest collection times. Other methods of pairing sensor readings with reference glucose measurements, such as various averaging techniques, are currently being investigated for future studies but have not been applied here. Figure 2 gives the distribution of these reference glucose measurements.

## Accuracy

An average MARD of 10.3% was obtained from glucose predictions across all trials for Cohorts 1 to 4, with individual

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**Figure 2.** Distribution of reference glucose values measured using a YSI 2500 laboratory glucose analyzer.

MARDs of 10.3%, 10.1%, 9%, and 12.1% for Cohorts 1, 2, 3, and 4, respectively. Table 2 provides a breakdown of these results alongside the average median ARD and individual cohort median ARD values. The distribution of MARD values across trials is given in Figure 3, which shows a clustering of MARD values below 20% and a long-tailed distribution. A single MARD can be seen above 25% in Figure 3, which was likely the result of outliers recorded in several raw data features specific to that trial. A plot of reference glucose values against the average predictions across all test set data is given in Figure 4. For each reference-predicted glucose datapoint in Figure 4, an error bar shows the variability in that value across each MC resample for which it was in the test set. Additional statistical measures of the quality of these predictions are given here as well as in Figure 4: coefficient of determination  $(R^2)$ , RMSD, mean absolute error (bias), and standard deviation of the error of prediction (SD). Test set predictions across all 50 MC resamples gave measures of 0.87, 1.30, -0.01, 1.29, 10.26, and 7.36 for R<sup>2</sup>, RMSD, bias, SD, MARD, and median ARD, respectively. Averaged cross-validation statistics were also calculated with 0.85, 1.39, 0.01, 1.39, 11.16, and 8.27 for  $R^2$ , RMSD, bias, SD, MARD, and median ARD, respectively. All statistics were calculated from the averaged glucose predictions across all 50 MC resamples. Where applicable, statistics are given in mmol/L.

Surveillance error grid analysis (Figure 5) shows that the measurements obtained were primarily (89.4%, 10.3%) within the deep green (no risk) zone and the light green (slight, low risk) zone, with small numbers (0.2%) within the yellow zones (moderate risk). No measurements were in the orange (great risk) or red (extreme risk) zones. Table 3 highlights the percentage of each data pair within these risk factor ranges.

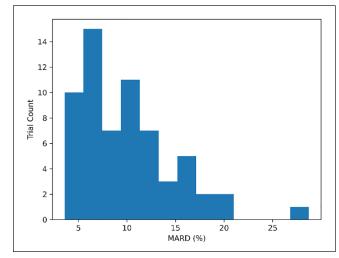
# Safety

There were no adverse events reported.

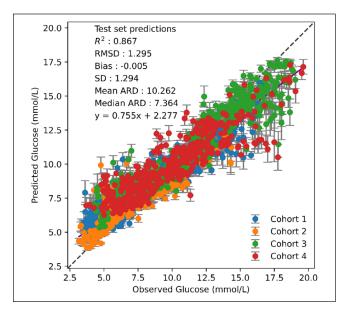
**Table 2.** Mean ARD and Median ARDs Calculated From the Averaged Test Set Predictions Across All Resamples for Cohorts 1, 2, 3, and 4.

Accuracy	Average%	Cohort I%	Cohort 2%	Cohort 3%	Cohort 4%
Mean ARD Median ARD	10.3 7.4	10.3 9.0	10.1	9.0 7.7	12.1

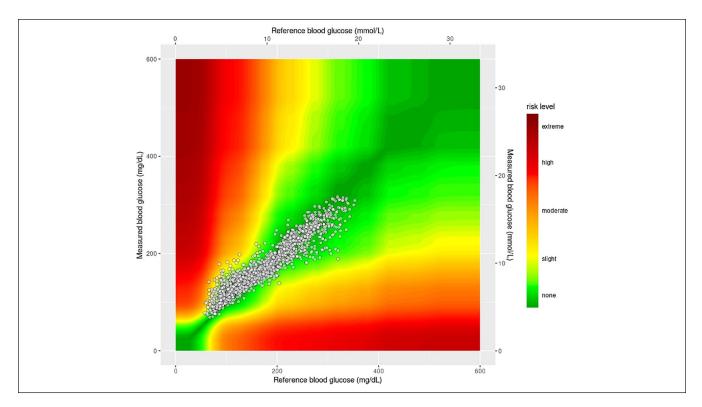
Abbreviations: ARD, absolute relative difference.



**Figure 3.** Distribution of MARD values across subject trials. Calculated values were obtained from reference glucose measurements and their corresponding averaged glucose predictions across all MC resamples.



**Figure 4.** Reference glucose measurements against the averaged glucose predictions taken across all MC resamples from the external test sets. Statistics are given for the averaged predictions and color coded by cohort. Error bars are shown for each measurement-prediction datapoint and give the variability of glucose predictions across each MC resample for which it is present in that test set. Abbreviations:  $R^2$ , coefficient of determination; RMSD, root mean square deviation; SD, standard deviation; ARD, absolute relative difference.



**Figure 5.** SEG for Cohorts I to 4. The color-coded grid represents the risk level associated with an error in a measured blood glucose value with respect to a reference value. Green indicates no risk, and brown indicates extreme risk.

Table 3. Percentage of Pairs in Each Risk Grade From SEG Plot.

Risk grade	Cohorts 1-4	Risk factor	
None	89.4%	0-0.5	
Slight	10.3%	>0.5-1.5	
Moderate	0.2%	>1.5-2.5	
High	N/A	>2.5-3.5	
Extreme	N/A	>3.5	

# **Discussion**

This study compared the accuracy of a non-invasive, wearable glucose measurement system using microwave resonance technology, to standard plasma glucose monitoring. Several prior studies have established the possibility for detecting plasma glucose levels. <sup>15,17,18,22</sup> The most recent of these studies demonstrated that a MARD of 28% could be obtained from subject-specific multiple regression models trained on DRS device measurements. <sup>18</sup> Here, it has been shown that the accuracy of the DRS device has been improved upon with a drop in MARD from 28% to the 10.3% obtained in this study. This reduction in MARD suggests that a combination of improvements to the DRS design, the use of a more complex algorithm, and a random sampling procedure applied to the full four-cohort data set has led to an increase in accuracy since previous device tests. Results also

suggest that the DRS device under consideration was capable of approaching a level of accuracy comparable to commercially available glucose monitoring systems when applied within this study. In general, a system with a MARD <10% is regarded to have good analytical performance.<sup>23</sup> Other commercially available CGM systems such as the Freestyle Libre (Abbott Diabetes Care, Witney, UK), Minimed Enlite (Medtronic, Dublin, Ireland), and Dexcom (Dexcom Inc., California, USA) have published MARDs of 11.4%,<sup>24</sup> 13.6%,<sup>25</sup> and 9.3%,<sup>26</sup> respectively.

Results also showed that no data pairs were in the highrisk categories of clinical error in SEG. The DRS device considered herein has the advantage of being noninvasive, which can be assumed to improve patient adherence to self-monitoring procedures,<sup>2</sup> thus leading to better health outcomes.<sup>27</sup>

A current limitation of this approach is that the AI model was built after all trial data had been collected, and not generated as data collection was occurring. It is expected that additional clinical trials involving a wider range of participants and longer test periods will result in valuable data with which to support the development of AI models capable of real-time predictions, as well as investigate other sampling procedures and calibration techniques.

The study is limited by the fact that accuracy of the device was assessed under the hands of trained engineers within a controlled environment and so may not reflect any settling period observed for an individual user with Quresh et al 7

diabetes under daily life conditions. Nevertheless, the controlled, lab-based nature of the study adds to the body of evidence supporting the use of AI and machine-learning to improve the accuracy of NIGM systems. The development of NIGM wearable systems that provide an accurate and sensitive glucose measurement are of great relevance, given the increasing popularity of CGM systems which are frequently replacing SMBG in a variety of therapeutic situations.<sup>20</sup>

#### **Conclusions**

This study demonstrates that a novel, noninvasive, wearable DRS device could estimate glucose levels in the body with reasonable accuracy compared with venous plasma glucose measurements. Future studies will continue to test the accuracy of subsequent iterations of the device as well as provide further data to improve the AI model.

#### **Abbreviations**

AI, artificial intelligence; ARD, absolute relative difference; CGM, continuous glucose monitoring; DRS, dial-resonating sensor; MARD, mean absolute relative difference; MC, Monte Carlo; MCU, micro-controller unit; NIGM, noninvasive glucose monitoring; PCB, printed circuit board; SD, standard deviation; SEG, surveillance error grid; SMBG, self-monitoring of blood glucose.

# **Acknowledgments**

The authors would like to thank the study participants. Dr Danielle Bodicoat and Dr. Sandra Garrido (independent consultants) provided writing assistance paid for by Afon Technology. Bodicoat and Garrido jointly produced the first draft based on previous submissions, the protocol, and Clinical Investigation Report, which was then critically reviewed and updated by the authors.

#### Author Contribution Statement

All persons who meet authorship criteria are listed as authors. All authors have participated sufficiently in the work to take public responsibility for the content, including participation in the concept, design analysis, writing or revision of the manuscript.

#### **Declaration of Conflicting Interests**

The author(s) declared the following potential conflicts of interest with respect to the research, authorship, and/or publication of this article: MRAQ, CH, DJF, BL, ICM, and JAMR are employees of Afon Technology, and MSC is the chief executive officer of Afon Technology.

#### **Funding**

The author(s) disclosed receipt of the following financial support for the research, authorship, and/or publication of this article: This work was supported by the Welsh Government's SMARTCymru program, backed by the EU's European Regional Development Fund (grant no. 2019/ED/054).

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