Research Square

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Diagnostic accuracy of a thermal microsensor for measuring wear time of removable extra-oral orthodontic appliances

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Abstract

Purpose

Adherence to orthodontic treatment with removable extra-oral appliances is a key factor influencing treatment outcomes. Objective compliance monitoring systems, such as the Theramon® microsensor, are increasingly used to assess wear time. The aim of this study was to evaluate the diagnostic accuracy of the Theramon® system in detecting wear time of removable extra-oral orthodontic appliances under controlled conditions and to identify the optimal temperature cut-off for maximizing detection accuracy in both winter and summer conditions.

Methods

A diagnostic accuracy study was conducted on a convenience sample of five healthy volunteers at the Department of XXXX. Two measurement sessions were performed, one in winter and one in summer. The Theramon® microsensor served as the index test. No independent reference standard was available; actual appliance wear time was determined using participant diaries, which were considered representative of true wear time. The optimal temperature cut-off was determined exploratorily during data analysis.

Results

During the winter session, the optimal temperature cut-off was 29.12°C, with a sensitivity of 0.990 (95% CI: 0.983–0.995) and specificity of 0.999 (95% CI: 0.998–0.999). In the summer session, the optimal cut-off was 32.25°C, with a sensitivity of 0.980 (95% CI: 0.971–0.986) and specificity of 0.971 (95% CI: 0.969–0.974). When data from both sessions were combined, a cut-off of 31°C was selected, resulting in a sensitivity of 0.984 (95% CI: 0.979–0.988) and specificity of 0.969 (95% CI: 0.967–0.971).

Conclusions

Under controlled conditions, the Theramon® microsensor demonstrated high diagnostic accuracy in monitoring wear time of removable extra-oral orthodontic appliances. These findings support its clinical use for objectively assessing patient adherence to devices such as the facial mask.

INTRODUCTION

Removable orthodontic appliances are widely used for the treatment of specific malocclusions. Their popularity is supported by several inherent advantages, including greater patient acceptability, lower invasiveness compared to fixed appliances, and generally lower costs [10, 13]. However, the success of treatment with removable devices depends on multiple factors, among which patient adherence to

prescribed wear protocols plays a pivotal role [5, 15]. Indeed, the literature reports that up to 92% of patients fail to comply with the recommended wear times, thereby compromising treatment outcome [18]. Factors such as age, sex, maturity level, motivation, personality traits, and the type of appliance can influence adherence [19]. Nevertheless, although these factors may provide useful general insights, they do not allow reliable prediction of compliance at the individual patient level [1, 2].

Various methods have been proposed to assess treatment adherence, including self-report questionnaires. However, these approaches have consistently proven unreliable, as patients tend to overestimate their actual wear time [3]. This limitation underscores the need for objective, clinically applicable systems to monitor compliance. The concept of objectively measuring patient cooperation dates back to the 1970s; however, technological constraints at that time prevented widespread implementation. Recent technological advances have enabled the development of electronic devices capable of recording wear time, among which the Theramon® system (MC Technology GmbH, Hargelsberg, Austria) is one of the most widely used [9, 17, 18].

To date, studies on Theramon® accuracy have largely focused on intra-oral appliances, mostly in vitro [9, 17, 19, 20]. In vivo studies present additional methodological challenges, including the difficulty of precisely controlling actual wear time and the potential influence of patient-related behavioral factors [4, 14, 17]. Importantly, no studies have evaluated the accuracy of the Theramon® system when applied to extra-oral orthodontic appliances. The only available evidence derives from the ophthalmology field [1, 8], where elevated ambient temperatures were shown to potentially affect measurement accuracy, emphasizing the need for investigations conducted under different seasonal and climatic conditions [1, 8].

Based on these considerations, the present study aims to evaluate the diagnostic accuracy of the Theramon® system in detecting wear time of removable extra-oral orthodontic appliances under controlled conditions, with particular focus on the facial mask. Additionally, the study seeks to identify the optimal temperature cut-off for the device to maximize detection accuracy in both summer and winter conditions.

MATERIALS AND METHODS

Study design

This study was designed as a prospective observational accuracy study. Data collection was prospectively planned before performing the Theramon® recording sessions. The study was conducted in accordance with STARD (Standards for Reporting Diagnostic Accuracy Studies) guidelines [6].

Participants

Five volunteers were enrolled in the study, including researchers involved in the project and their family members, all of whom provided informed consent to participate. After consultation with the Ethics

Committee of XXXX, and given the non-invasive nature of the experiment and the involvement of volunteers, formal ethical approval was not required.

The inclusion criteria were:

- reliability in accurately reporting data related to device usage;

- willingness to adhere to the measurement protocol, consisting of wearing the Theramon® device seven times during each experimental session.

Participants were recruited as a convenience sample, selected among individuals available to take part in the study. Data collection was carried out at the Department of XXXX, between January and September 2023.

Measurement Protocol

The study consisted of two experimental sessions, one conducted during winter and one during summer. In each session, every participant was provided with a Theramon® device, which was positioned in contact with the forehead using adhesive tape. Participants were instructed to wear the device for 10 consecutive hours on seven separate occasions per session.

Each participant maintained a detailed diary, recording the actual duration of device wear as well as the exact times at which the device was applied and removed. These diary records were considered representative of the true wear time. At the end of each session, the thermosensor was returned, and the recorded data were transferred to a computer using a Theramon® reading station and the manufacturer's dedicated software.

Test method

The index test evaluated in this study was the Theramon® system (MC Technology GmbH, Hargelsberg, Austria), a thermal microsensor designed to monitor the wear time of extra-oral orthodontic appliances. The device records skin-contact temperature at 15-minute intervals. By analyzing these temperature measurements, it is possible to determine whether the appliance is being worn and, consequently, to estimate patient adherence to the prescribed treatment.

No established reference standard exists for assessing adherence to removable extra-oral orthodontic appliances. In the present study, participants' diaries were used to define the presence or absence of the target condition (i.e., appliance worn or not worn). All volunteers were fully instructed and aware of the study objectives, supporting a high level of accuracy and reliability of the reference data.

A positive index test result corresponded to the appliance being worn, whereas a negative result corresponded to the appliance not being worn. The temperature threshold (cut-off) was not predefined

but was identified during data analysis using an exploratory approach. The cut-off value that maximized diagnostic accuracy was subsequently selected based on statistical criteria.

The Theramon® readout station was connected to a computer via USB, on which the manufacturer's dedicated software (MC Technology GmbH, Hargelsberg, Austria) was installed. Each microsensor was inserted into the readout station to enable data transfer. All temperature recordings stored in the sensor were downloaded using the Theramon® software. Each measurement was associated with a timestamp (date and time), allowing precise reconstruction of the device usage history. The data were subsequently exported in Excel format (Microsoft Corp., WA, USA). Wear-time data recorded in the participants' diaries were likewise digitized and organized in an Excel spreadsheet to enable direct comparison with the measurements recorded by the device.

Statistical Analysis

Descriptive statistical analyses were performed separately for the winter session, the summer session, and the combined dataset. For each dataset, mean, standard deviation, minimum, and maximum temperature values were calculated, distinguishing between periods when the device was worn and when it was not worn, as determined by the diary records.

An exploratory analysis was then conducted to identify the optimal temperature cut-off for discriminating between the two conditions (device worn vs. not worn) and to calibrate the system for potential clinical use. Cut-off values were determined separately for the winter session, the summer session, and the combined dataset.

The optimal cut-off value was identified by maximizing Youden's index (J), calculated as:

$$J = Sensitivity + Specificity - 1$$

For each dataset (winter, summer, and combined), receiver operating characteristic (ROC) curves, area under the curve (AUC) values, sensitivity, specificity, and contingency tables were generated for the temperature threshold that maximized Youden's index.

RESULTS

Participants

The study was conducted on five volunteers (four males and one female). The demographic characteristics of the participants were as follows: Subject 1, male, 60 years; Subject 2, male, 49 years; Subject 3, female, 18 years; Subject 4, male, 14 years; Subject 5, male, 57 years.

Measurements were carried out during two experimental sessions: a winter session (January 1 to February 7, 2023) and a summer session (August 1 to September 7, 2023). In XXXX, ambient temperatures during the winter period ranged from 0 to 17°C, while during the summer period they

ranged from 15 to 35°C (Consorzio Lamma – Laboratory for Environmental Monitoring and Modelling for Sustainable Development) [11].

No indeterminate results were observed, as the condition of interest (device worn or not worn) was clearly identifiable for each measurement based on the recorded temperature values and the information reported in the participants' diaries. No missing data occurred, as all temperature recordings were successfully retrieved from the sensors and all diaries were completed in full.

Descriptive Statistics

Descriptive statistics for the winter and summer sessions are reported in Tables 1 and 2, respectively. These include the number of measurements (N), mean temperature values, standard deviations, and minimum and maximum recorded temperatures.

Table 1
Descriptive statistics of the winter session data. Values are expressed as mean ± standard deviation (SD) [minimum–maximum]. Temperatures are reported in degrees Celsius (°C).

	device not worn		device worn	
Subject	N	Mean ± SD [min–max] (°C)	N	Mean ± SD [min–max] (°C)
1	3226	20.05 ± 1.49 [11.39; 33.56]	280	32.99 ± 1.29 [20.18; 35.52]
2	3239	18.79 ± 1.54 [11.17; 32.85]	280	32.46 ± 1.98 [13.77; 34.97]
3	2609	17.94 ± 0.90 [15.74; 32.83]	280	32.83 ± 1.20 [19.32; 35.25]
4	3247	17.97 ± 0.81 [13.20; 21.61]	280	32.48 ± 0.52 [31.09; 34.45]
5	3236	17.92 ± 0.95 [12.37; 32.43]	280	32.82 ± 1.67 [18.54; 34.43]
TOT	15557	18.56 ± 1.45 [11.17; 33.56]	1400	32.72 ± 1.43 [13.77; 35.52]

N: Number of temperature recordings; SD: Standard deviation of the recorded temperature; Min: Minimum recorded temperature; Max: Maximum recorded temperature; Tot: Total number of measurements.

Table 2
Descriptive statistics of the summer session data. Values are expressed as mean ± standard deviation (SD) [minimum–maximum]. Temperatures are reported in degrees Celsius (°C).

	device not worn		device worn	
Subject	N	Mean ± SD [min–max] (°C)	N	Mean ± SD [min–max] (°C)
1	3719	28.57 ± 3.04 [22.77; 37.73]	280	34.89 ± 0.46 [33.19; 36.26]
2	3615	27.41 ± 1.62 [22.61; 32.69]	320	33.85 ± 0.93 [29.27; 36.05]
3	3625	26.75 ± 1.24 [24.50; 34.86]	280	34.36 ± 1.21 [25.86; 35.83]
4	3625	26.74 ± 1.24 [24.56; 34.69]	280	34.12 ± 0.97 [25.81; 35.29]
5	3611	26.76 ± 1.23 [24.62; 34.48]	280	34.54 ± 0.92 [25.87; 35.57]
TOT	18195	27.25 ± 1.96 [11.17; 33.56]	1440	34.34 ± 1.00 [25.81; 36.26]

N: Number of temperature recordings; SD: Standard deviation of the recorded temperature; Min: Minimum recorded temperature; Max: Maximum recorded temperature; Tot: Total number of measurements.

During the summer session, a protocol deviation occurred because participant 2 wore the Theramon® device eight times instead of the planned seven, resulting in 320 temperature recordings rather than 280. Table 3 summarizes the descriptive statistics for the combined dataset.

Table 3
Descriptive statistics for the combined sessions. Values are expressed as mean ± standard deviation (SD) [minimum–maximum]. Temperatures are reported in degrees Celsius (°C).

	device not worn		device worn	
Subject	N	Mean ± SD [min–max] (°C)	N	Mean ± SD [min–max] (°C)
WS	15557	18.56 ± 1.45 [11.17; 33.56]	1400	32.72 ± 1.43 [13.77; 35.52]
SS	18195	27.25 ± 1.96 [22.61; 37.73]	1440	34.34 ± 1.00 [25.81; 36.26]
TOT	33752	23.25 ± 4.67 [11.17; 37.73]	2840	33.54 ± 1.47 [13.77; 36.26]

N: Number of temperature recordings; SD: Standard deviation of the recorded temperature; Min: Minimum recorded temperature; Max: Maximum recorded temperature; Tot: Total number of measurements; WS: Winter session; SS: Summer session.

Search for the Temperature Threshold Value

The search for a temperature threshold value to calibrate the Theramon® device was performed separately for the winter and summer sessions, as well as on the combined data. The choice of the threshold value was calculated by maximizing Youden's index.

Winter Session

Figure 1 shows the ROC curve. The X-axis represents the false positive rate (1 – specificity), while the Y-axis represents the true positive rate (sensitivity). The area under the curve (AUC) was 0.998 (95% CI: 0.997 to 0.998). The optimal cut-off point corresponds to a temperature of 29.12°C, where the difference between the true positive rate and the false positive rate is maximized.

Table 4 shows the contingency table comparing the data recorded by the Theramon® device with the reference provided by the participants' diaries, for the winter session. Based on these data, at the optimal cut-off the sensitivity was 0.990 (95% CI: 0.983 to 0.995) and the specificity was 0.999 (95% CI: 0.998 to 0.999).

Table 4
Contingency table with reference to the temperature value of 29.12°C in the winter session.

	Worn	Not worn	Total
>= 29.12°	1386	15	1401
< 29.12°	14	15542	15556
Total	1400	15557	16957

Summer Session

The ROC curve for the summer session is shown in Fig. 2 (right panel). The AUC was 0.984 (95% CI: 0.982–0.986). Youden's index was maximized at a temperature of 32.25°C, which was therefore identified as the optimal cut-off for the summer session.

Table 5 presents the contingency table for the summer session. At the optimal cut-off, sensitivity was 0.980 (95% CI: 0.971–0.986) and specificity was 0.971 (95% CI: 0.969–0.974).

Table 5
Contingency table with reference to the temperature value of 32.25°C in the summer session.

	Worn	Not worn	Total
>= 32.25°	1411	522	1933
< 32.25°	29	17673	17702
Total	1440	18195	19635

Combined sessions

The ROC curve for the combined data is shown in Fig. 3 (right panel). The AUC was 0.986 (95% CI: 0.985–0.987). Youden's index was maximized at a temperature of 31.13°C, which was identified as the optimal cut-off value for the combined dataset.

Table 6 reports the contingency table for the combined sessions. At this cut-off, sensitivity was 0.983 (95% CI: 0.978–0.988) and specificity was 0.972 (95% CI: 0.970–0.973).

Table 6
Contingency table with reference to the temperature value of 31.13°C in the combined session.

	Worn	Not worn	Total
>= 31.13°	2792	958	3750
< 31.13°	48	32794	32842
Total	2840	33752	36592

For practical clinical application, a temperature threshold of 31°C may be adopted, as it simplifies interpretation without substantially compromising diagnostic performance. At this cut-off, sensitivity remained high (0.984, 95% CI: 0.979–0.988), while specificity was also satisfactory (0.969, 95% CI: 0.967–0.971), corresponding to a low false-positive rate (Table 7).

Table 7
Contingency table with reference to the temperature value of 31°C in the combined session.

	Worn	Not worn	Total
>= 31°	2795	1034	3829
< 31°	45	32718	32763
Total	2840	33752	36592

DISCUSSION

Removable orthodontic appliances are widely used in clinical practice; however, treatment success largely depends on patient compliance [5, 15, 16]. For this reason, the availability of objective monitoring tools is essential. The Theramon® system has been extensively investigated and validated for intra-oral appliances [5, 14, 17, 19]. To date, however, no studies have evaluated its diagnostic accuracy when applied to extra-oral orthodontic devices. The present study was therefore designed to explore the feasibility and reliability of the Theramon® system under simulated extra-oral conditions and to assess its potential applicability in this specific clinical context.

The limitations of the present investigation should be interpreted in light of its preliminary and exploratory nature. The study included a small number of participants recruited as a convenience sample, a choice that ensured strict adherence to the experimental protocol but limits the generalizability of the findings. Nevertheless, the use of repeated measurement sessions and multiple

recordings per participant partially compensated for the small sample size, allowing the collection of a substantial number of observations and enabling robust statistical analyses.

Another relevant limitation concerns the absence of an independent reference standard. Participants' diaries were used to define the "worn/not worn" condition, representing a pragmatic solution in an exploratory setting but not a true gold standard. Diary-based measures may be affected by recording errors or omissions; however, in the present study, the risk of such inaccuracies is likely minimal. All volunteers were fully informed about the study objectives, highly cooperative, and instructed to accurately record device usage, supporting the reliability of the reference data.

The temperature threshold used to discriminate between worn and non-worn conditions was empirically derived from the study data and should therefore be considered exploratory. This data-driven approach may lead to an overestimation of diagnostic accuracy, particularly in studies with limited sample sizes. Consequently, further investigations on independent and larger samples are required to validate the proposed cut-off values and to confirm the reproducibility of the results [7, 12].

Environmental conditions represent a critical factor when evaluating the performance of thermal sensors used in extra-oral applications. Previous studies in the ophthalmologic field have highlighted that high ambient temperatures, particularly above 33°C, may reduce the ability of the Theramon® sensor to clearly discriminate between worn and non-worn periods [8]. Abaza et al. [1], using Theramon® to monitor eyeglass wear time, reported mean percentage errors below 10% and accuracy levels ranging from 90% to 96%, suggesting that the system performs reliably under mild to moderate environmental conditions.

In the present study, measurements were conducted during two distinct seasonal periods, allowing an assessment of the influence of environmental temperature on device performance. Ambient temperatures ranged from 0 to 17°C during the winter session and from 15 to 35°C during the summer session [11]. This design allowed evaluation of Theramon® performance under different environmental temperature conditions.

Seasonal comparisons revealed differences in diagnostic performance and optimal cut-off values. During the winter session, the device showed excellent discrimination, with an AUC of 0.998, sensitivity of 0.990, specificity of 0.999, and an optimal cut-off of 29.12°C. These results indicate an almost complete separation between worn and non-worn measurements, with minimal misclassification. Most errors occurred during short transition periods when the device was being applied, likely reflecting the time required for the sensor to adapt to changes in temperature. This observation is consistent with previous reports [4, 8].

During the summer session, diagnostic performance remained high but slightly decreased, with an AUC of 0.984, sensitivity of 0.980, specificity of 0.971, and a higher optimal cut-off of 32.25°C. This reduction in discriminative ability is likely attributable to environmental factors such as higher ambient

temperatures, increased sweating, and sun exposure, which may reduce thermal contrast between the skin and the environment.

These findings indicate that the optimal temperature threshold is context-dependent. A threshold calibrated exclusively under winter conditions could underestimate actual wear time during summer, whereas a summer-calibrated threshold might overestimate wear time in colder environments.

Analysis of the combined dataset provided an overall assessment of Theramon® performance across seasons. The AUC remained high (0.986, 95% CI: 0.985–0.987), and the optimal cut-off of 31.13°C, derived from Youden's index, lay between the seasonal thresholds. This value represents a compromise that balances sensitivity and specificity under varying environmental conditions.

From a practical standpoint, adopting a rounded cut-off of 31°C appears reasonable. This approach simplifies clinical implementation and interpretation without substantially compromising diagnostic performance. At this threshold, sensitivity remained high (0.984, 95% CI: 0.979–0.988), while specificity was also satisfactory (0.969, 95% CI: 0.967–0.971).

Overall, although environmental conditions may influence sensor performance, the adoption of an appropriate temperature cut-off appears to be an effective strategy for maintaining high accuracy. This is particularly relevant given that extra-oral orthodontic appliances, such as facial masks, are typically worn in domestic environments, where extreme temperatures are uncommon. Nonetheless, patients should be provided with clear clinical instructions to preserve recording accuracy, including avoiding direct exposure of the device to heat sources such as intense sunlight or radiators and minimizing contact with wet skin or other factors that could interfere with sensor readings.

CONCLUSIONS

The Theramon® microsensor demonstrated high diagnostic accuracy in detecting the wear time of extra-oral orthodontic appliances, with slightly superior performance during winter conditions due to greater thermal contrast between the body and the environment. A temperature cut-off of 31°C proved to be an effective and pragmatic threshold for combined seasonal data, yielding a sensitivity of 98.4% and a specificity of 96.9%. This threshold allows reliable clinical use of the device across different seasons and geographic settings without the need for site-specific recalibration.

Declarations

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Data availability statement: The data that support the findings of this study are not openly available due to reasons of sensitivity and are available from the corresponding author upon reasonable request.

Authors' contributions: F.C. Writing - original draft and Data curation; M.N. Conceptualization, Methodology, Formal analysis, Writing - review & editing; M.L. Investigation and Data curation; M.C Investigation and Supervision; V.G. Investiogation and Project administration; L.F. Conceptualization, Methodology, Writing - review & editing

Ethics approval: Five volunteers were enrolled in the study, including researchers involved in the project and their family members, all of whom provided informed consent to participate. After consultation with the Ethics Committee of XXXX, and given the non-invasive nature of the experiment and the involvement of volunteers, formal ethical approval was not required.

Competing interests: The authors have no relevant financial or non-financial interests to disclose.

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Figures

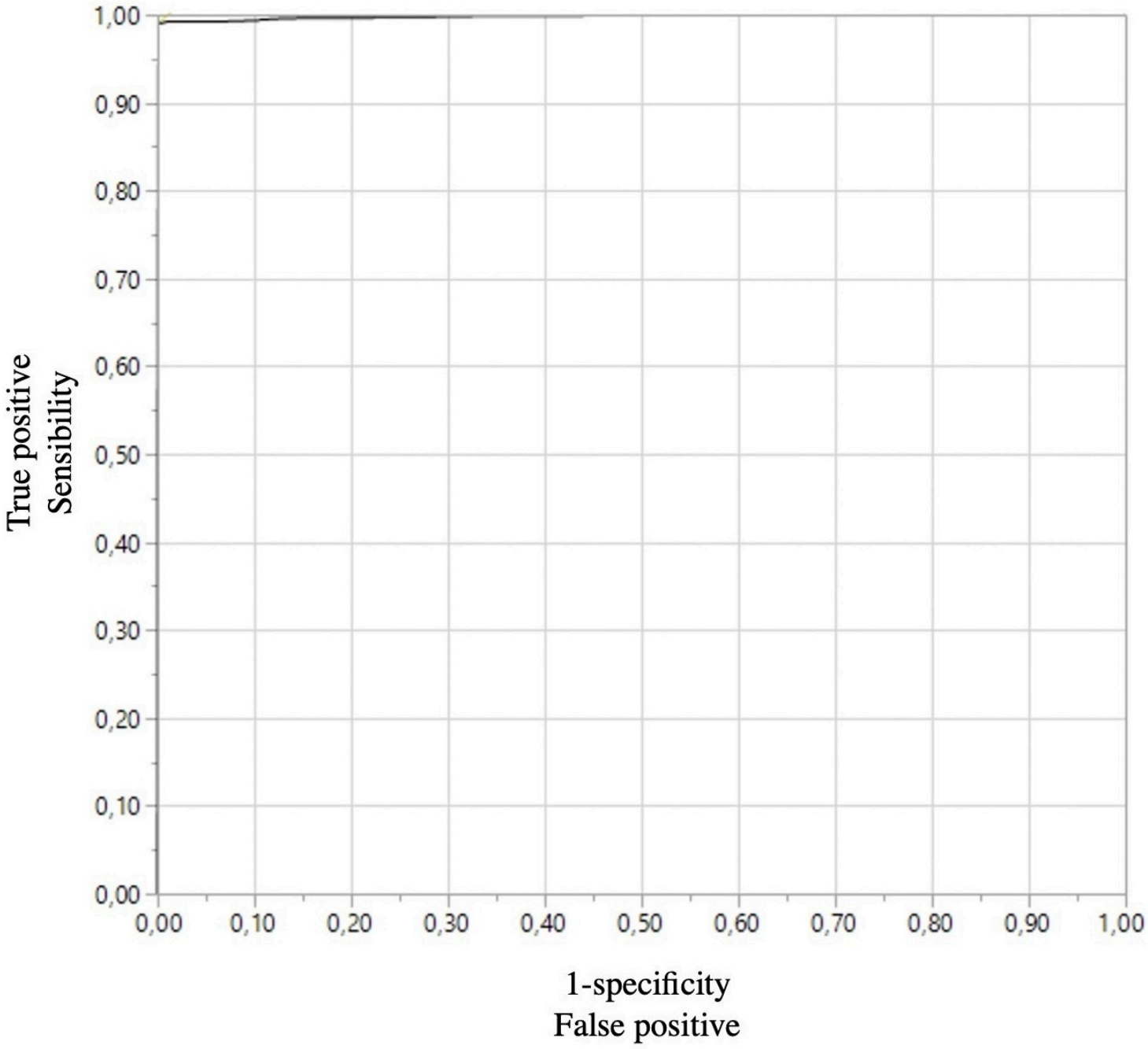


Figure 1

ROC curve for the winter session.

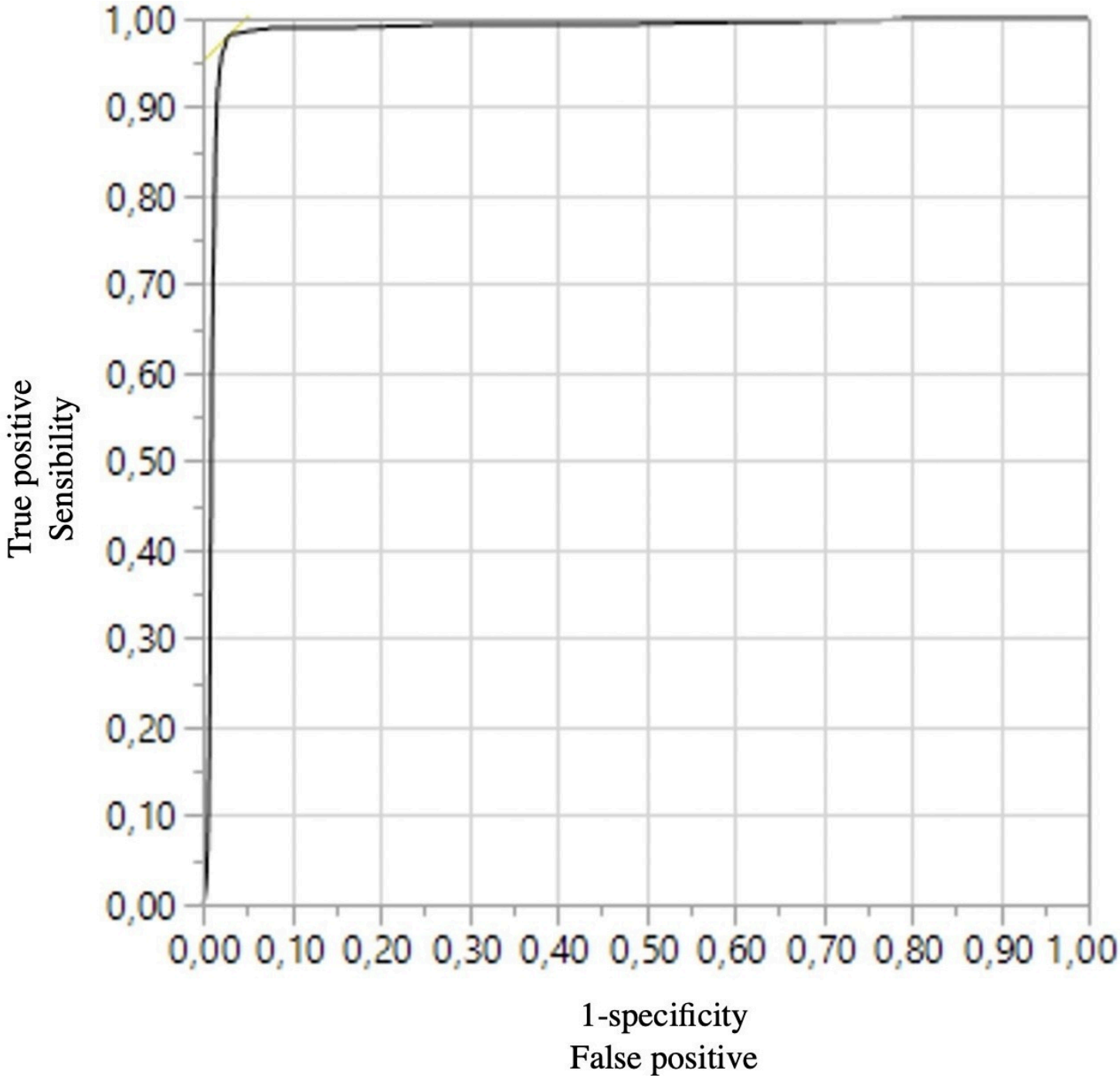


Figure 2

ROC curve for the summer session.

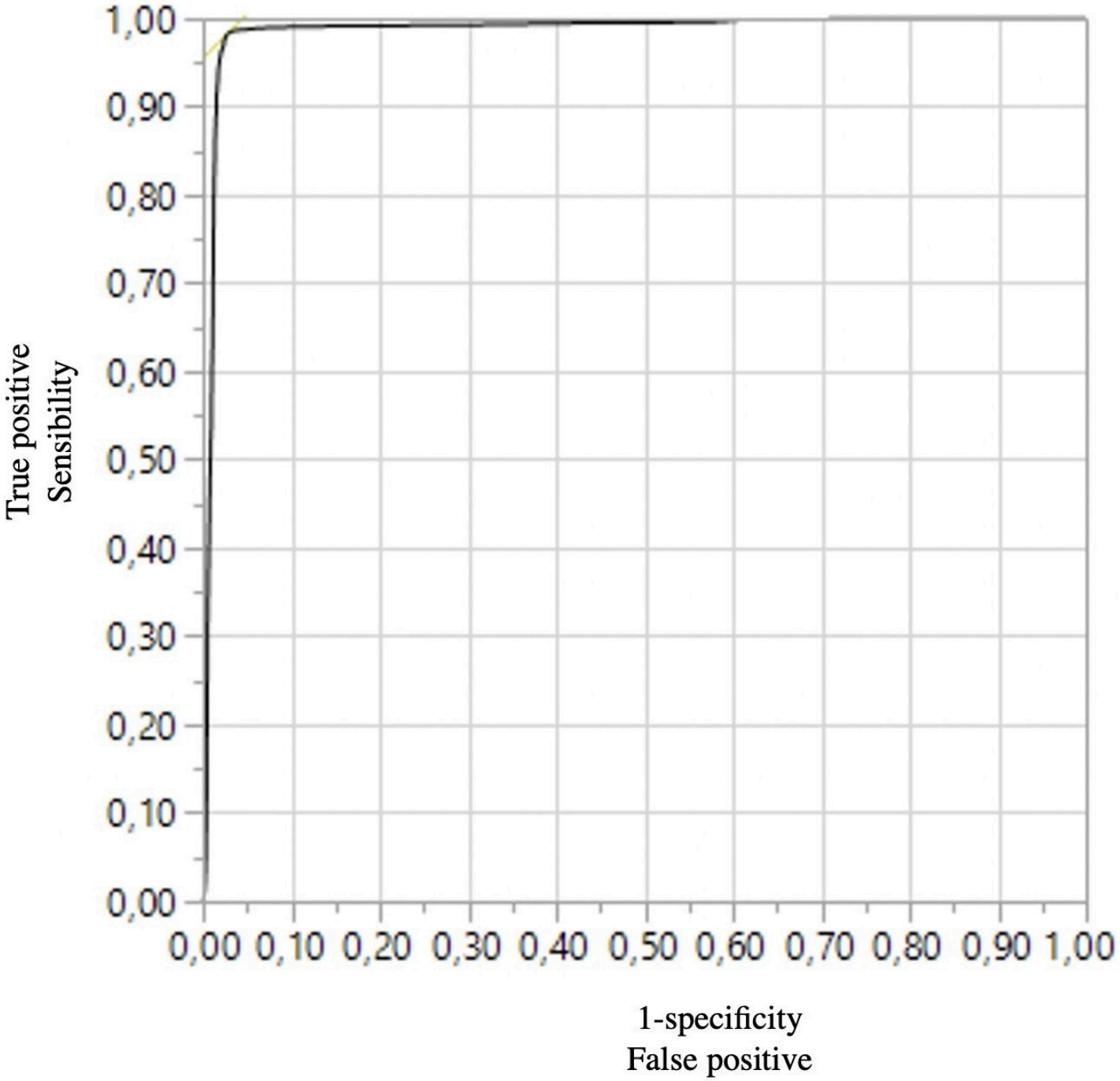


Figure 3

ROC curve for the combined sessions.