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Temporal Dynamics of Transdermal Alcohol Concentration Measured via New Generation
Wrist-Worn Biosensor

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In Press at Alcoholism: Clinical and Experimental Research

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Abstract

Background: The development of a transdermal alcohol biosensor could represent a tremendous advance towards curbing problematic drinking. But several factors limit the usefulness of extant transdermal technology, including relatively lengthy delays between blood alcohol concentration (BAC) and transdermal alcohol concentration (TAC), as well as the large/bulky designs of currently available transdermal sensors (e.g., ankle monitors). The current research examined the lag time between BAC and TAC using a prototype of BACtrack Skyn—a new-generation wrist-worn transdermal sensor featuring a compact design and smartphone integration. **Methods:** Participants (N=30) received either a dose of alcohol (target BAC .08%) or a non-alcoholic beverage in the laboratory while wearing both the AMS SCRAM ankle monitor and a Skyn prototype. Participants were monitored in the laboratory until breath alcohol concentration (BrAC) dropped below .025%. **Results:** Device failure rates for Skyn prototypes were relatively high (18%-38%) compared with non-prototype SCRAM devices (2%). Among participants with usable data, both Skyn and SCRAM-measured TAC showed strong correlations with BrAC, and both Skyn and SCRAM devices detected alcohol within 30-minutes of first alcohol-administration. Skyn-measured TAC peaked over 1-hour earlier than SCRAM-measured TAC (54 versus 120 minutes after peak BrAC, respectively), and time-series models suggested that, on average across all measured portions of the BrAC curve, Skyn-TAC lagged behind BrAC by 24 minutes, whereas SCRAM-TAC lagged behind BrAC by 69 minutes—all differences statistically significant at $p<.001$. **Conclusions:** Results provide preliminary evidence for the validity of a new-generation wrist-worn transdermal sensor under controlled laboratory conditions, and further suggest favorable properties of this sensor as they pertain to the latency of transdermal

51 alcohol detection. The prototype-version of Skyn employed here displayed a higher failure rate
52 compared with SCRAM and, in future, more reliable and robust Skyn prototypes will be required
53 suitable to field testing across diverse environmental conditions.

54 *Keywords:* Alcohol, biosensor, transdermal, BAC, measurement

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59 The development of a wearable alcohol biosensor could represent a key advance toward
60 helping people make informed decisions about their drinking and, potentially, toward curbing
61 alcohol-related morbidity and mortality. Devices for the objective quantification of behaviors
62 have long been of interest to researchers and consumers across health domains (e.g., fitbit for
63 exercise; Haynes & Yoshioka, 2007), but, due to alcohol’s neurocognitive effects and also
64 cultural conventions surrounding drinking, the need for a biosensor to measure alcohol
65 consumption has loomed particularly large. Specifically, drinking at more extreme levels is
66 associated with memory and cognitive disruptions that can impair awareness of the quantity of
67 alcohol consumed (Weissenborn & Duka, 2003; White, 2003). Further, standard drink sizes and
68 quantities can vary widely so that even the cognitively alert drinker may not always be aware of
69 the amount of alcohol she ingests (Barnett, Wei, & Czachowski, 2009; Kerr, Greenfield,
70 Tujague, & Brown, 2005; Kerr, Patterson, Koenen, & Greenfield, 2008). Finally, societal stigma
71 can accompany alcohol consumption for many individuals such that, even given an awareness of
72 their own drinking practices, some might be reluctant to share this information with others, thus
73 interfering with the identification of those in need of alcohol intervention as well as the
74 investigation of drinking behavior via research (Davis, Thake, & Vilhena, 2010; George,
75 Gournic, & McAfee, 1988; Zapolski, Pedersen, McCarthy, & Smith, 2014). A wearable alcohol
76 biosensor might serve health needs across a variety of domains, including aiding prevention of
77 alcohol-related disorders (Fairbairn & Kang, in press), improving outcomes in harm reduction
78 alcohol intervention programs (Barnett, 2015), reducing the number of alcohol-related motor
79 vehicle fatalities (Blincoe, Miller, Zaloshnja, & Lawrence, 2015), and refining outcome
80 assessment in alcohol research (Leffingwell et al., 2013).

81 Researchers have explored a variety of different methods for the continuous tracking of
82 drinking (Fairbairn & Kang, in press; Swift, 2003), but transdermal devices are currently those
83 with the firmest basis of empirical support for their viability as continuous alcohol biosensors.
84 Approximately 1% of alcohol consumed is diffused transdermally in the form of sweat and
85 insensible perspiration (Swift, 2003; Swift & Swette, 1992). Thus, similar to the manner in
86 which a breathalyzer estimates BAC by measuring the quantity of alcohol in expired air,
87 transdermal sensors might estimate BAC by examining alcohol in water vapor emitted from the
88 skin. Measured via a device that rests on the surface of the skin, transdermal assessment is
89 passive and unobtrusive. Correlations between transdermal alcohol concentration (TAC) and
90 blood alcohol concentration (BAC) tend to be strong (Giles et al., 1987; Luczak & Rosen, 2014;
91 Sakai, Mikulich-Gilbertson, Long, & Crowley, 2006). Yet, despite their promise, challenges
92 have emerged for transdermal monitors—including challenges associated with the available
93 devices themselves as well as those associated the data produced by these devices—and these
94 challenges have limited the widespread implementation of transdermal alcohol assessment within
95 research and also everyday drinking contexts.

96 Concerning challenges associated with the devices themselves, at the present time, the
97 only available transdermal monitors take the form of relatively large/bulky bracelets designed to
98 be worn around the ankle. Although previously some smaller wrist-worn transdermal devices
99 were accessible to researchers (e.g., the WrisTAS device)¹, at the current time, the Secure
100 Continuous Remote Alcohol Monitor (SCRAM) ankle bracelet is the only widely-available
101 wearable alcohol biosensor. SCRAM devices, which weigh about 6 oz and are approximately the

¹ One of the first transdermal devices developed was the WrisTAS, marketed by Giner Labs, which was worn around the wrist as a watch (Leffingwell et al., 2013). However, this device was only used for research purposes, to our knowledge, and has not been made available to researchers for several years now.

102 dimensions of a large deck of cards, are mainly designed as abstinence monitors for use with
103 criminal justice-involved populations (see Figure 1). Data from SCRAM has been examined in
104 several dozen studies (Fairbairn et al., 2018; Sirlanci et al., 2018; see Leffingwell et al., 2013 for
105 a review), and associations between SCRAM-measured TAC and BAC have been generally
106 estimated as strong. SCRAM employs fuel cell technology whereby alcohol molecules are
107 translated into a measurable electrical current at the sensor. The large size of these bracelets is
108 partially attributable to the nature of the specific fuel cell employed, which requires a pump to
109 promote the active flow of air across the sensor, a feature that also limits the TAC sampling
110 interval to a relatively extended 30 minutes (Wang, Fridberg, Leeman, Cook, & Porges, in
111 press). The size, ankle positioning, and relatively sparse data produced by these devices appear
112 to be well suited for their application as abstinence monitors with non-voluntary populations.
113 However, since wearing SCRAM devices can produce discomfort and embarrassment (Barnett,
114 Tidey, Murphy, Swift, & Colby, 2011), the usefulness of these ankle monitors for voluntary
115 populations (e.g., as health behavior trackers among large populations of consumers) is severely
116 limited.

117 In addition to challenges associated with the transdermal devices themselves, another
118 important challenge surrounds the nature of the data produced by these devices—in particular,
119 delays between the time that alcohol is ingested and when it can be detected transdermally. TAC
120 is believed to lag behind BAC by a substantial margin, with the extent of this lag being typically
121 estimated as lasting at least 1-hour (Fairbairn & Kang, in press; Leffingwell et al., 2013), and
122 potentially as long as 3-4 hours (Marques & McKnight, 2009). Note that several of the more
123 pressing proposed applications of transdermal alcohol biosensors would require real-time or near
124 real-time estimation of drinking (Fairbairn et al., 2018; Fairbairn & Kang, in press)—e.g.,

125 researchers aiming to map everyday alcohol use with associated antecedent and/or consequent
126 behaviors in real time. Of note, while it is clear that some delay exists between BAC and TAC,
127 the exact extent of this delay is currently unclear. In estimating this delay, researchers have
128 mainly employed SCRAM ankle monitors, and have further examined delays nearly exclusively
129 by examining the relative timing of TAC/BAC peaks (Sakai et al., 2006; Swift, Martin, Swette,
130 Laconti, & Kackley, 1992). Regarding the former of these issues, since the permeability of the
131 skin and also the density of sweat glands differs on different areas of the body, the relationship
132 between BAC and TAC also differs depending on where on the body TAC is assessed (Swift,
133 2000). Indeed, a review of the literature indicates that the notion that TAC lags behind BAC by a
134 factor of 2-4 hours is derived entirely from studies employing ankle monitors (Fairbairn, Rosen,
135 Luczak, & Venerable, in press; Marques & McKnight, 2009), whereas studies employing wrist
136 sensors (e.g., the early WrisTAS device) have estimated substantially smaller lag times (Swift et
137 al., 1992; see Table 1 for a literature review of studies examining TAC in relation to objectively
138 assessed BAC). In addition, a more nuanced operationalization of lag-time—encompassing
139 other portions of the BAC curve beyond TAC/BAC peak—could aid in informing our
140 understanding of the relative timing of TAC vs. BAC.

141 Recently, a new generation of wrist-worn devices has emerged that leverages advances in
142 electronics and wireless communication in order to substantially reduce the size and increase the
143 comfort/attractiveness of transdermal alcohol monitors (Wang et al., in press). One such device
144 is BACtrack Skyn™. Skyn is a small device that includes a transdermal alcohol biosensor,
145 rechargeable battery, and a companion smartphone application. Skyn is worn on the inside of the
146 wrist—a position selected to increase its sensitivity and decrease lag to detected alcohol.
147 Currently in the prototype phase, Skyn is designed to be comfortable, user friendly, and socially

148 acceptable, similar to a Fitbit or smartwatch (see Figure 1). Like SCRAM, Skyn uses fuel cell
149 technology in order to assess TAC. Unlike SCRAM, however, Skyn devices do not require a
150 pump to generate air flow across the sensor and instead rely on passive airflow—a feature that
151 reduces the size and dimensions of the device and also facilitates more rapid TAC sampling, with
152 current prototypes allowing for sampling as frequently as every 20 seconds (Wang et al., in
153 press). While the new generation of transdermal alcohol sensors hold promise for use in research
154 as well as for widespread health behavior monitoring, these devices have not been examined in
155 controlled studies and so the relation of readings produced by these devices to ingested alcohol is
156 unknown.

157 In the current study, we employ laboratory methods to directly compare data produced by
158 two transdermal alcohol monitors—the widely-researched SCRAM ankle monitor and the newer
159 wrist-worn Skyn device. This study focuses on an examination of TAC over time among
160 participants administered a single fixed dose of alcohol, although we also include a subsample of
161 participants administered no alcohol by way of control. We used breathalyzer readings to
162 validate TAC measures—chosen as a noninvasive measure with a strong and well characterized
163 relationship with BAC (Bendtsen, Hultberg, Carlsson, & Jones, 1999; Jones & Andersson, 1996,
164 2003; Ramchandani, Plawecki, Li, & O'Connor, 2009). In light of the identified challenges
165 surrounding delays in the detection of alcohol via transdermal monitors (Leffingwell et al.,
166 2013), the primary aim of this research is to examine and quantify lag times between ingested
167 alcohol and TAC, operationalized through a range of metrics intended to capture various
168 positions on the BAC curve.

169 Note that the restricted alcohol dosing procedures employed in this study are well-suited
170 to addressing our primary aim of examining comparative lag times across transdermal sensors

171 under controlled conditions, whereas the limited variation in BAC produced by these procedures
172 mean that they are less well suited to quantifying the magnitude of BAC-TAC correlations.
173 Nonetheless, given that no prior study has quantified BAC-TAC correlations using this newest
174 generation of transdermal sensors, we also include a preliminary examination of BAC-TAC
175 correlations for both Skyn and SCRAM as a supplemental analysis.

176 Method

177 ***Participants***

178 A total of 50 young social drinkers underwent experimental procedures. The final sample
179 of participants consisted of the 30 individuals for whom we were able to obtain breathalyzer,
180 SCRAM, and also Skyn readings for the experimental session (see later section on device
181 failures). This final sample of participants consisted of 25 participants assigned to the alcohol
182 condition and 5 participants assigned to the control condition. The average age of participants
183 was 22 years old (range, 21-28). Participants were 50% female (15 females and 15 males). Sixty
184 percent of participants identified as White, 23.3% as Asian, and 16.6% as multiracial (3.3%
185 African-American/Hispanic, 3.3% Hispanic/Asian, 3.3% White/Asian, 6.7% White/Hispanic).
186 Participants were required to be at least 21 years of age and no older than 30, to consume alcohol
187 regularly, and report being comfortable with the dose of alcohol administered in the study.
188 Exclusions included taking medications that might interact with alcohol, medical conditions for
189 which alcohol consumption was contraindicated, pregnancy in women, history of severe Alcohol
190 Use Disorder, or especially light drinking practices (see recommendations of the National
191 Advisory Council on Alcohol Abuse and Alcoholism, 1989 for alcohol-administration in human
192 subjects). On average, participants reported drinking alcohol on 10.13 days out of the past 30
193 (SD=4.73) and consuming an average of 4.90 drinks per occasion (SD=1.83).

194 ***Procedure***

195 Participants who successfully completed a phone screening were invited into the
196 laboratory for a beverage-administration session. All participants were required to abstain from
197 drinking alcohol for at least 12 hours prior to their laboratory session, and to refrain from eating
198 for 4 hours. Upon arriving in the laboratory, participants were breathalyzed (Intoximeters Alco-
199 Sensor IV) to ensure a 0.00 breath alcohol concentration (BrAC), and their weight and height
200 was assessed. Pregnancy was assessed in female participants via HCG urine test strip.
201 Participants were then given a light meal that was roughly adjusted for their weight.

202 Next, SCRAM monitors were positioned on the inside of participants' left ankles, worn
203 high up on the leg, snug against the calf. Skyn devices were positioned on the inside of
204 participants' left wrists. Both devices were then worn for a no-alcohol baseline period
205 (approximately 1 hour), during which baseline TAC readings were established and participants
206 completed questionnaires unrelated to the current study.

207 Participants were next administered their study beverages. Beverages were administered
208 in 3 equal parts over the course of 36 minutes, and participants were encouraged to consume
209 their beverages evenly over each of the three 12-minute intervals. Participants assigned to
210 receive alcohol received a dose intended to bring them up to the legal driving limit (.08%). The
211 precise amount of alcohol administered was adjusted for each individual's body water as
212 calculated based on formulas accounting for gender, height, age, and weight (Curtin & Fairchild,
213 2003; Watson, Watson, & Batt, 1981). Note that this dose of alcohol was originally chosen for
214 the purposes of the parent study investigating alcohol's effects on mood (e.g., Fairbairn et al.,
215 2018, 2015), but it also has utility for the proposed project, given potential applications of
216 wearable biosensors for determining driving safety. Control participants received an isovolumic

217 amount of a non-alcoholic beverage. Assignment to beverage condition was randomly
218 determined. Beverage intake was monitored via video to validate drink start time (see below) and
219 also to ensure even consumption across the 36-minute drink period.

220 Following beverage administration, participants in the alcohol condition provided
221 breathalyzer readings at approximately 30-minute intervals until they left the lab. During this
222 time period, participants engaged in a variety of study tasks, ranging from those requiring a
223 moderate amount of walking (e.g., between rooms in a lab) as well as those that were largely
224 stationary (e.g., speaking with another participant while seated). Participants in the control
225 condition were allowed to leave after study tasks were completed (3-4 hours after the end of
226 drinking). Participants administered alcohol were required to stay in the lab until their BrAC
227 dropped below .025%² and also their SCRAM TAC output registered at least one descending
228 value (generally between 5-7 hours post-drink—average BrAC among alcohol participants at
229 discharge .019%).

230 *Data Processing and Analysis*

231 Skyn data was transmitted via Bluetooth from Skyn devices to BACtrack's custom
232 smartphone application, which was installed on our lab's ipod touch devices. The application
233 displays TAC readings in graphical form, and the raw data files can be exported in the form of
234 csv files via this application or BACtrack's internet-based data storage system. SCRAM data was
235 extracted using direct connect software and downloaded from SCRAMnet, a cloud-based server.

236 We analyzed latency of TAC values relative to the onset of drinking and BrAC curves
237 using the following three metrics: 1) latency to first transdermally detected alcohol; 2) time

² In the current study, given the relatively substantial dose of alcohol administered, it was not feasible to keep participants in the lab until their BAC reached 0.00. Note that, including the pre-drink baseline, visits often lasted as long as 9 hours. Using the current procedures, we were able to capture the majority of the descending limb of the BAC curve.

238 elapsed between peak BrAC and peak TAC; and 3) latency to maximal cross-correlation across
239 TAC and BrAC curves. As an examination of these latency metrics among control participants
240 would not have been meaningful and, in some cases, would have been impossible (e.g., latency
241 to peak BrAC where BrAC values consist of all 0s), only participants assigned to the alcohol
242 condition were included in latency analyses. Note that data produced by SCRAM is standardized
243 such that it includes a natural zero starting value. In contrast, data produced by the Skyn
244 prototypes used in this study featured no standardized zero point, with baseline values varying
245 across Skyn files. With respect to time to first transdermally detected alcohol, for SCRAM TAC,
246 this was operationalized as the time elapsed from the very beginning of the participant drink
247 period to time of first non-zero SCRAM reading.³ For Skyn TAC (files with no natural zero
248 point—see above), latency to first transdermally detected alcohol was operationalized via a
249 function that systematically tests each point in a series and automatically detects points of change
250 in the trend using a formula that minimizes the sum of the residual error and applies a penalty for
251 each change (MATLAB changepoint function; Killick, Fearnhead, & Eckley, 2012). Finally,
252 with respect to cross-correlations, these analyses were conducted at the level of the participant
253 and specifically targeted those assigned to receive alcohol (see below). In particular, cross-
254 correlation coefficients indexed the correlation between an individual's BrAC with that
255 individual's TAC (either Skyn or SCRAM) at various lag times (or latencies) over the course of
256 the session.⁴ Since the sampling intervals for BrAC and SCRAM TAC were relatively sparse

³ Note Alcohol Monitoring Systems (AMS) itself uses a much higher threshold (at least .02% TAC) when processing SCRAM data files in order to identify alcohol episodes. This relatively high TAC threshold is adopted in order to reduce the risk for false positives, which were not a concern in the current study.

⁴ Cross-correlation is a metric for assessing the similarity of two time series as a function of the level of displacement between the series. A cross-correlation analysis will produce the value of the correlation of two time series across multiple different “lags” or displacement levels—e.g., Skyn value at time t with BrAC at $t-1$, Skyn value at time t with BrAC at $t+1$, contemporaneous Skyn and BrAC, etc. The maximal cross-correlation—or the time lag at which the correlation between the two time series is at its peak—can be used to assess the level of displacement between the two time series.

257 (~30 minutes) when compared with Skyn (1 minute), BrAC and SCRAM data was interpolated
258 from sampled values such that a file with minute-level estimates of BrAC, SCRAM TAC, and
259 Skyn TAC was produced for each participant spanning the time period from the beginning of the
260 drink period to last BrAC reading (Fritsch & Carlson, 1980; Sidek & Khalil, 2013). Cross-
261 correlation analysis was applied to each participant file and the lag time that maximized the
262 value of the cross-correlation function between BrAC and TAC (both Skyn and SCRAM) was
263 recorded for each participant (Gottman, 1981). Paired t-tests were used to compare lag times for
264 Skyn TAC and SCRAM TAC.

265 The association between BrAC and transdermally detected alcohol was assessed using
266 the following three metrics: 1) Correlation in peak BrAC and TAC values across participants; 2)
267 Correlation in area under the curve for BrAC and TAC across participants; 3) Maximal value of
268 cross-correlation between BrAC and TAC for each participant. For the purposes of calculating
269 peak and area under the curve values, Skyn data was centered and standardized by subtracting
270 the start value (reading taken at the initiation of the drink period) from all subsequent readings.
271 All participants (alcohol and control) were included in the analysis of peak values and area under
272 the curve—which examine variation between participants—whereas only participants in the
273 alcohol condition were included in cross-correlation analyses—which examine variation within
274 participants over time, and so variability at the within-subject level is required. Area under the
275 curve for BrAC, Skyn, and SCRAM data was calculated by summing all data points from the
276 beginning of the drink period to the last moment that a BrAC reading was taken. Pearson
277 correlation coefficients were used to examine associations between peak values and area under
278 the curve for BrAC and TAC. Maximum cross-correlations between BrAC data and TAC (see

279 above) were calculated for each participant and then Skyn and SCRAM correlations for each
280 participant were compared using paired t-tests.

281 Results

282 *Descriptive and Device Statistics:* Among those assigned to receive alcohol, average peak
283 BrAC was .08% ($SD=.01$; *Range* .06-.12). Five different Skyn prototype devices and 13 SCRAM
284 ankle monitors were used for this research. The five Skyn devices employed included 3 older
285 generation prototype devices (manufactured in 2016) and 2 newer generation prototype devices
286 with improved Bluetooth connectivity and other additional features (manufactured in 2018).
287 Among alcohol participants, over the course of the entire lab session, the average number of
288 BrAC readings collected per participant was 11 ($SD=1.6$), the average number of SCRAM TAC
289 readings was also 11 ($SD=1.4$), and the average number of Skyn TAC readings was 309
290 ($SD=44.3$).

291 In Figure 2, we provide visualizations of data from all alcohol (P1-P25) and control
292 participants (P26-30) during the laboratory session. In line with data produced in prior studies,
293 visual inspection of these data suggests that there exists variability in both Skyn and SCRAM
294 measured TAC that appears to be unconnected with alcohol consumption. Nonetheless, among
295 participants assigned to receive alcohol, TAC broadly mirrors the characteristic BAC curve,
296 ascending with alcohol ingestion and then descending with the passage of time following
297 ingestion.

298 *Device Failure Rate:* Note that Skyn devices used in this study were prototypes, and rates
299 of failure of both the devices and the accompanying smartphone application were relatively high.
300 A total of 9 Skyn files were either incomplete, blank, or unusable due to device failure (3 files
301 were completely blank for unknown reasons, 3 files consisted of an entirely flat line with no

302 oscillation, and 3 files were blank or severely truncated due to battery failure). An additional 10
303 Skyn files were lost during the initial stages of this project as our team learned to work with
304 these delicate prototypes.⁵ In contrast, SCRAM devices, which are not in the prototype phase,
305 produced only one unusable (flat line) file within the conduct of this research. In sum, failure
306 rates for Skyn prototypes ranged from 18%-38% (depending on metric), whereas the failure rate
307 for SCRAM was 2%. Data presented below reflects that derived from our final sample of
308 participants—individuals for whom we were able to obtain BrAC, SCRAM, and also Skyn data
309 (see methods section).

310 *TAC Latency:* With respect to latency to first detected alcohol, both Skyn TAC and
311 SCRAM TAC appeared to perform relatively well, detecting alcohol within 30 minutes of the
312 initiation of the drink period. Time to first detected alcohol via Skyn was 22.08 ($SD=12.38$)
313 minutes⁶ and was very similar for SCRAM at 22.52 ($SD=13.03$) minutes. The difference between
314 these values was non-significant, $t(24)=.14$, $p=.891$. See also Table 2.

315 BrAC readings reached their peak an average of 77.28 ($SD=30.34$) minutes after the start
316 of drinking. Skyn TAC readings peaked an average of 131.52 ($SD=32.90$) minutes after the start
317 of drinking (54 minutes after peak BrAC), and SCRAM TAC readings peaked an average of
318 197.20 ($SD=42.60$) minutes after the start of drinking (120 minutes after peak BrAC). The

⁵ The Bluetooth connection feature of the Skyn devices naturally disconnected from the accompanying smartphone application throughout the visit as participants moved from room to room. In order to reconnect and generate a datafile for some of these Skyn prototypes, it was necessary to first close and then re-open the accompanying smartphone application and also disconnect/reconnect the device from Bluetooth—a quirk we discovered only with trial and error after experiencing some data loss.

⁶ In addition to the MATLAB changepoint function, we also attempted this analysis using one additional operationalization—defining time to first detected alcohol as 10 consecutive Skyn readings above the initial baseline value. Using this alternative operationalization, the average time to first detected alcohol via Skyn was 17.72 minutes ($SD=11.51$). However, given that the choice of “10 values” was somewhat arbitrary, we present the automated MATLAB approach (above) for the purposes of final analyses.

319 difference in lag time between peak Skyn TAC and peak SCRAM TAC emerged as highly
320 significant: $M_{\text{diff}}=65.68$ minutes ($SD=51.27$), $t(24)=6.41$, $p<.001$.

321 Finally, when cross-correlation coefficients were examined, the average latency of
322 maximal cross-correlation between BrAC and Skyn TAC was 23.88 ($SD=26.11$) minutes. The
323 average latency of maximal cross-correlation between BrAC and SCRAM TAC was 68.56
324 ($SD=36.83$) minutes. The difference in lag time between peak Skyn TAC and peak SCRAM
325 TAC emerged as highly significant: $M_{\text{diff}}=44.68$ minutes ($SD=43.09$), $t(24)=5.18$, $p<.001$. Note
326 that these values reflect the average lag time across all portions of the BAC curve measured in
327 the current research—representing the majority, although not the entirety, of BAC/TAC curves
328 (see methods). See Table 3 for cross-correlation lag times presented at the level of the device.

329 *TAC-BrAC Associations:* Here we provide preliminary information concerning the
330 association between BrAC, Skyn TAC and SCRAM TAC when dosing range in the alcohol
331 condition is highly restricted (see above). Across all 30 participants, there was a strong and
332 significant positive correlation between peak BrAC and peak Skyn TAC values, $r=.77$, $n=30$,
333 $p<.001$. There was also a strong significant correlation between peak BrAC and peak SCRAM
334 TAC, $r=.56$, $n=30$, $p=.001$. Participants who reached a higher peak BrAC also had higher peak
335 TAC values, as measured using Skyn and also SCRAM. Concerning area under the curve, there
336 was a strong and significant positive correlation for BrAC and Skyn TAC, $r=.79$, $n=30$, $p<.001$,
337 as well as for BrAC and SCRAM TAC, $r=.60$, $n=30$, $p<.001$. Finally, in cross-correlation
338 analyses examining within-participant change over time among alcohol participants examined as
339 time series (see above), the average maximal cross-correlation between BrAC and Skyn TAC
340 was $.60$ ($SD=.15$). The average maximal cross-correlation between BrAC and SCRAM TAC was
341 $.51$ ($SD=.12$). The difference between these correlations emerged as statistically significant:

342 $M_{diff}=.09$ ($SD=.20$), $t(24)=2.38$, $p=.026$, with cross-correlations being higher for Skyn vs.
343 SCRAM. Note that results of analyses examining area under the curve and also cross-
344 correlations (although not peak values) should be interpreted with incomplete TAC/BAC
345 trajectories and also differential lag times for Skyn vs. SCRAM in mind. See Table 3 for cross-
346 correlations at the level of the device.

347 Discussion

348 Transdermal alcohol sensors represent a promising method for continuous, unobtrusive
349 measurement of alcohol consumption. But the measurement of alcohol consumption
350 transdermally has been associated with significant challenges, including those associated with
351 devices themselves as well as the delay in data produced by these devices. The current research
352 represents the first systematic examination of data produced via a new generation transdermal
353 device that features a compact, wrist-worn design, relatively rapid TAC sampling, and
354 smartphone connectivity. Specifically, using data derived from a controlled dosing context and
355 varied metrics for capturing TAC latency, we examined lag times between ingested alcohol and
356 transdermally detected alcohol among participants wearing both the SCRAM ankle monitor and
357 a prototype of the newer wrist-worn Skyn device. Both Skyn and SCRAM showed initial
358 temporal sensitivity to ingestion of a moderate dose of alcohol, detecting alcohol within 30
359 minutes of first consumption. As time progressed across the drinking episode, the wrist-worn
360 Skyn device emerged as generally faster in its response to alcohol ingestion compared with the
361 ankle-worn SCRAM. Specifically, TAC measured using Skyn reached its peak over an hour
362 prior to TAC measured using SCRAM (54 minutes after peak BrAC for Skyn vs. 120 minutes
363 after peak BrAC for SCRAM). On average, when all measured portions of the BAC curve were
364 considered via time-series models, Skyn lagged behind BrAC by approximately 24 minutes,

365 whereas the average lag between BAC and SCRAM was significantly longer at 69 minutes. In
366 other words, in time-series models, the lag time between Skyn and SCRAM emerged as nearly
367 double the duration of lag time between Skyn and actual BrAC. Finally, this study also provides
368 some information on the validity of the wrist-worn prototype in terms of dose-response—
369 although associations captured within this study should be considered preliminary (likely
370 dampened) due to the restricted dosing range as well as the slightly truncated TAC/BAC
371 trajectories captured in our lab session. Note that Skyn devices used in this study were
372 prototypes, and data captured with both Skyn and SCRAM devices demonstrated variability in
373 TAC that appeared to be unrelated to BrAC. Nonetheless, correlations between Skyn TAC and
374 BrAC captured within this study were large in magnitude and tended to exceed correlations
375 between BrAC and SCRAM TAC.

376 The lag time between ingested alcohol and transdermally detected alcohol is typically
377 estimated as being at least 1 hour in duration (Leffingwell et al., 2013), with some studies
378 estimating this delay as lasting up to 4 hours (Marques & McKnight, 2009). Note that these
379 lengthier delay estimates have been derived from studies employing the SCRAM ankle monitor,
380 and have further not typically examined lag times at points on the BAC curve beyond peak
381 values (Marques & McKnight, 2009; Sakai et al., 2006; Fairbairn & Kang, in press; See Table 1
382 for a review). The prolonged nature of such delays might preclude certain real-world applications
383 of transdermal alcohol sensors—e.g., a drinker wishing to assess his/her safety for operating a
384 motor vehicle. As with past research, data from the current study continued to provide evidence
385 for a delay in the transdermal detection of alcohol when compared with BrAC. However, here,
386 when examined across the entire sampling interval investigated in this research—which
387 encompassed the majority (although not the entirety) of the BAC curve—the average lag time

388 between Skyn-estimated TAC and BrAC was less than 30 minutes, significantly smaller than that
389 estimated via SCRAM. In the future, applications of advanced machine learning algorithms—
390 with the ability to predict future values based on sequences of current values—might ultimately
391 be applied to TAC data to further reduce the extent of this lag (Mandic & Chambers, 2001).

392 In addition to its implications for the understanding of lag times between BAC and TAC,
393 this research also contributes to the literature by providing preliminary information on the
394 validity of a relatively compact, wrist-worn sensor. To date, a barrier to the widespread
395 implementation of transdermal biosensors has been the relatively large/bulky nature of extant
396 transdermal devices. At the present time, the SCRAM ankle monitor is the only readily available
397 transdermal sensor. SCRAM, and similar devices, will likely continue to have an important place
398 in assessing drinking among criminal-justice involved populations and for some research and
399 clinical applications, and, at the current time, SCRAM remains the most reliable available
400 transdermal sensor. However, the relatively bulky design and ankle positioning of this device
401 limit its usefulness outside of specific clinical, criminal justice, and research applications and
402 preclude its implementation among broad populations of drinkers interested in tracking their
403 health behaviors. Thus, although approximately half of the world's population drinks alcohol
404 (WHO, 2014), with 27% of US adults reporting at least one episode of binge drinking in the past
405 month (SAMHSA, 2015), only a subsample of these individuals are served by current
406 transdermal technology. Note that the current study examined TAC data in response to a fixed
407 dose of alcohol, restricting the range of BACs and so likely leading to attenuated estimates of the
408 associations between TAC and BAC. Nonetheless, despite the fixed dosing procedures,
409 associations between Skyn TAC and BAC emerged as strong. Thus, by providing initial data for
410 the validity of a compact, wrist-worn sensor, the current study takes an important first step

411 towards providing an attractive, wearable device for everyday drinkers seeking to monitor their
412 alcohol consumption.

413 Although the current project represents an important first step to addressing specific
414 challenges associated with the transdermal detection of alcohol, many other key challenges lie
415 ahead before these devices are ready for real-world implementation. As noted above, similar to
416 data produced by prior studies (Leffingwell et al., 2013), data from the current study indicate that
417 the BAC-TAC correlation is strong, but yet this correlation is not a perfect one and so some
418 portion of the variation in TAC remains as yet unexplained. As it pertains to Skyn data, some of
419 this unexplained variability is likely attributable to the fact that the devices used in this study
420 were hand-assembled prototypes, and so this variability may diminish with device development
421 as prototypes improve and machine-made devices become available. It is also possible that some
422 of this unexplained variability may simply be a characteristic intrinsic to transdermal alcohol
423 measurement. Note that current Skyn prototypes collect data on not only TAC, but also include
424 temperature and accelerometer gauges—measures that may account for some portion of the
425 variability in the BAC-TAC relationship—and algorithms that incorporate information from all
426 of these gauges simultaneously may ultimately be able to provide a closer approximation of
427 exact BAC values. Further, the relationship between TAC and BAC is believed to vary
428 depending on both individual-level factors (e.g., the thickness of an individual's skin) as well as
429 situation-level factors (e.g., degree of ambient humidity). Note that it is possible that the extent
430 of variation in the BAC-TAC relationship has been over-estimated due to a tendency of prior
431 studies to rely on data from the SCRAM monitor, the ankle positioning of which might lead to
432 increased variation in the distance between sensor and skin (e.g., sliding from sitting snug
433 against the calf to hanging loosely around the ankle bone as participants walk)—a factor that has

434 been theorized to have an important impact on the BAC-TAC relationship (see Anderson &
435 Hlastala, 2006). Nonetheless, it will be critical to conduct research examining large and diverse
436 samples of participants, in addition to extensive research in real-world contexts featuring
437 fluctuation in ambient conditions, in order to further disentangle the relationship between TAC
438 and BAC. These future studies will also need to address the issue of potential “false positive”
439 TAC values produced by environmental alcohol, considering sensitivity and specificity as well
440 as the reliability of the Skyn over time and across devices. Relatedly, data from the current Skyn
441 prototype represents a raw value reflecting electrical current detected at the transdermal sensor
442 and has not been standardized to include a meaningful zero metric or reflect a scale comparable
443 to BAC. Thus, in the current study, we examine correlations between Skyn TAC and BAC,
444 rather than estimating the accuracy of measurements produced from the Skyn device. Skyn data
445 in the current study was standardized for each individual/device combination by subtracting out
446 the baseline value. Translating Skyn data into estimates along a standardized metric—and
447 accounting for factors that might lead to differential baseline values across different
448 device/individual combinations—is a task for future research.

449 Although the current study does suggest that the lag time between BAC and TAC
450 diminishes when TAC is measured using Skyn, the question of mechanism is unaddressed. The
451 extent to which this effect is explained by characteristics of the device (e.g., method of
452 measurement, sampling interval) or by the body positioning of the device (e.g., relative
453 distribution of sweat glands, permeability of skin) is left for future research to explore. It’s also
454 worth noting that the hand-assembled Skyn prototypes employed in this study yielded a
455 relatively high failure rate (18%-38% vs. 2% for SCRAM). More durable and reliable prototypes

456 will likely be required before extensive field testing is feasible. Thus, at the current time,
457 SCRAM is still the most reliable transdermal alcohol sensor.

458 Finally, note that participants in the current study left the laboratory once their BrAC had
459 descended below .025% and their TAC had also begun to descend (see methods). Thus, although
460 these methods did capture the majority of BAC and TAC curves for participants enrolled, these
461 curves were not complete. Thus, analyses presented here that might be impacted by such
462 incomplete curves—area under the curve calculations and also cross correlation analyses—
463 should be interpreted with these truncated curves in mind. Future research should examine
464 complete TAC/BAC curves when feasible.

465 *Conclusion*

466 A wearable alcohol biosensor has the potential to fill a tremendous public health gap.
467 The path towards developing such a biosensor has been lengthy and involved formidable
468 challenges. Recent devices have been developed that leverage advances in miniaturization and
469 electronics, and rigorous research of such devices, employing multiple methods and large human
470 samples, offer the possibility of at last producing a viable alcohol biosensor and, importantly,
471 clarifying its potential place in the arsenal of techniques aimed at better researching, preventing,
472 and treating alcohol use disorders.

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Table 1.
Studies examining validity of transdermal alcohol sensors using objective assessment techniques (BrAC/BAC)

Study	N	Type	Device	Locat	Alc Meas	Lag (min)	r's
Giles et al., 1987	19	Lab	Unspec	Palm	BAC	NR	.94-.99
Swift & Swette, 1992	15	Lab	WrisTAS	Arm	BrAC	30	.61-.96
Davidson, Camara, & Swift, 1997	12	Lab	Unspec	Arm	BrAC /BAC	NR	.52-.70
Dougherty et al., 2012	22	Lab	SCRAM	Ankle	BrAC	NR	.70-.99
Hill-Kapturczak et al., 2014	19	Lab	SCRAM	Ankle	BrAC	NR	NR
Hill-Kapturczak et al., 2015	21	Lab	SCRAM	Ankle	BrAC	129	.87
Wang, Fridberg, Leeman, Cook, & Porges, 2018	2	Lab	Skyn /Tally	Wrist	BrAC	75 /55	NR
Sakai et al., 2006	20	Lab	SCRAM	Ankle	BrAC	150	.49-.84
Fairbairn et al., 2018, in press	48	Lab/Amb	SCRAM	Ankle	BrAC	130	NR
Marques & McKnight, 2009	22	Lab/Amb	WrisTAS/ SCRAM	Wrist/ Ankle	BrAC	137/ 270	NR
Sakai et al., 2006	24	Amb	SCRAM	Ankle	BrAC	NR	NR
Luczak & Rosen, 2014	1	Lab/Amb	WrisTAS	Wrist	BrAC	NR	NR

The top section of this table lists studies conducted only in the laboratory, whereas the bottom section lists studies that included an ambulatory (field) assessment arm. Where a study contained both laboratory and ambulatory arms, but examined distinct groups of participants within these arms (e.g., Sakai et al., 2006), the study is listed under both sections of the table.

Note that, in the case of some of the studies listed above, data from the same sample were included in more than one publication (e.g., Fairbairn et al., 2018, in press). In such cases, only the citation for the parent (first) publication is listed in the table. Studies featuring devices that were not clearly “wearable” (e.g., Kamei et al., 1998) and also studies featuring sweat patches (e.g., Phillips, 1984) are not included.

Lab=laboratory study; Amb=Ambulatory study; Unspec =transdermal device not named; Locat=Body position of the transdermal device; Alc Meas=How BAC was measured in the study; BAC=Direct measure of BAC via blood or plasma; BrAC=Breathalyzer; Lag=time (in minutes) between peak BAC and peak TAC; NR=Not reported; r's=correlation coefficients between TAC and BAC

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Table 2.
Latency to Transdermal Detection of Alcohol

	Mean Minutes (SD)	Paired t-test (Skyn vs. SCRAM)
Latency to First Detection		
SCRAM TAC	22.52 (13.03)	
Skyn TAC	22.08 (12.38)	$t(24)=.14, p=.891$
Latency to Peak		
BrAC	77.28 (30.34)	
SCRAM TAC	197.20 (42.60)	
Skyn TAC	131.52 (32.90)	$t(24)=6.41, p<.001$
Max Cross-Correlation Lag		
BrAC and SCRAM TAC	68.56 (36.83)	
BrAC and Skyn TAC	23.88 (26.11)	$t(24)=5.18, p<.001$

SD=Standard deviation. TAC=Transdermal alcohol concentration. BrAC=Breath alcohol concentration.

All latency values above are calculated with respect to the beginning of the drink period for alcohol participants (N=25). Cross-correlations were calculated based on data collected from the beginning of the drink period until discharge, which occurred once BrAC had dropped below .025% and TAC had also begun to descend (average BrAC at discharge .019%)

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Table 3.
Device-Level Maximal Cross-Correlation Values and Lag Times between BrAC and TAC

Device-Level Cross-Correlations for Skyn			
Device ID	N	Mean Max Cross-Correlation (SD)	Mean Max Cross-Correlation Lag (SD)
7AB3	8	.66 (.16)	17.75 (10.98)
B6B3	2	.40 (.18)	32.50 (7.78)
18	3	.58 (.03)	22.00 (14.18)
9	2	.50 (.26)	16.50 (23.34)
0DB5	10	.62 (.12)	29.10 (38.98)

Device-Level Cross-Correlations for SCRAM			
24141	2	0.50 (0.05)	26 (31.11)
80002	1	0.42	57
114798	2	0.47 (0.01)	72 (11.31)
114888	4	0.43 (0.08)	67 (25.81)
115307	4	0.53 (0.16)	64.50 (24.37)
115411	1	0.69	48
115503	1	0.52	180
115887	1	0.57	93
117117	1	0.56	71
126571	1	0.61	118
127392	4	0.52 (0.21)	48.75 (33.08)
127453	1	0.50	49
127773	2	0.51 (0.06)	90.50 (41.72)

SD=Standard deviation. TAC=Transdermal alcohol concentration. BrAC=Breath alcohol concentration. N=Number of participants who wore this device. Mean Max Cross-Correlation Lag is presented in minutes. Devices worn by only one participant list no standard deviation.

Cross-correlations refer to within-subject correlations between TAC (measured either using Skyn or SCRAM devices) and BrAC for alcohol participants (N=25) measured over time during the course of the lab session. Cross-correlations were calculated based on data collected from the beginning of the drink period until discharge, which occurred once BrAC had dropped below .025% and TAC had also begun to descend (average BrAC at discharge .019%). Cross-correlations listed under Skyn devices represent associations between BrAC and Skyn-measured TAC, and cross-correlations listed under SCRAM devices represent associations between BrAC and SCRAM-measured TAC.

Of the Skyn devices listed above, 7AB3, B6B3, and 0DB5 represent older generation Skyn prototypes (2016), whereas devices 18 and 9 represent newer generation prototypes (2018).

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Figure 1. AMS SCRAM ankle bracelet (left) and BACtrack Skyn wrist monitor (right) displayed side-by side. The top panel displays these devices as worn on ankle/wrist, whereas the bottom panel displays them to scale. The approximate weight of the devices is 6oz (SCRAM) and 1oz (Skyn prototype), respectively.

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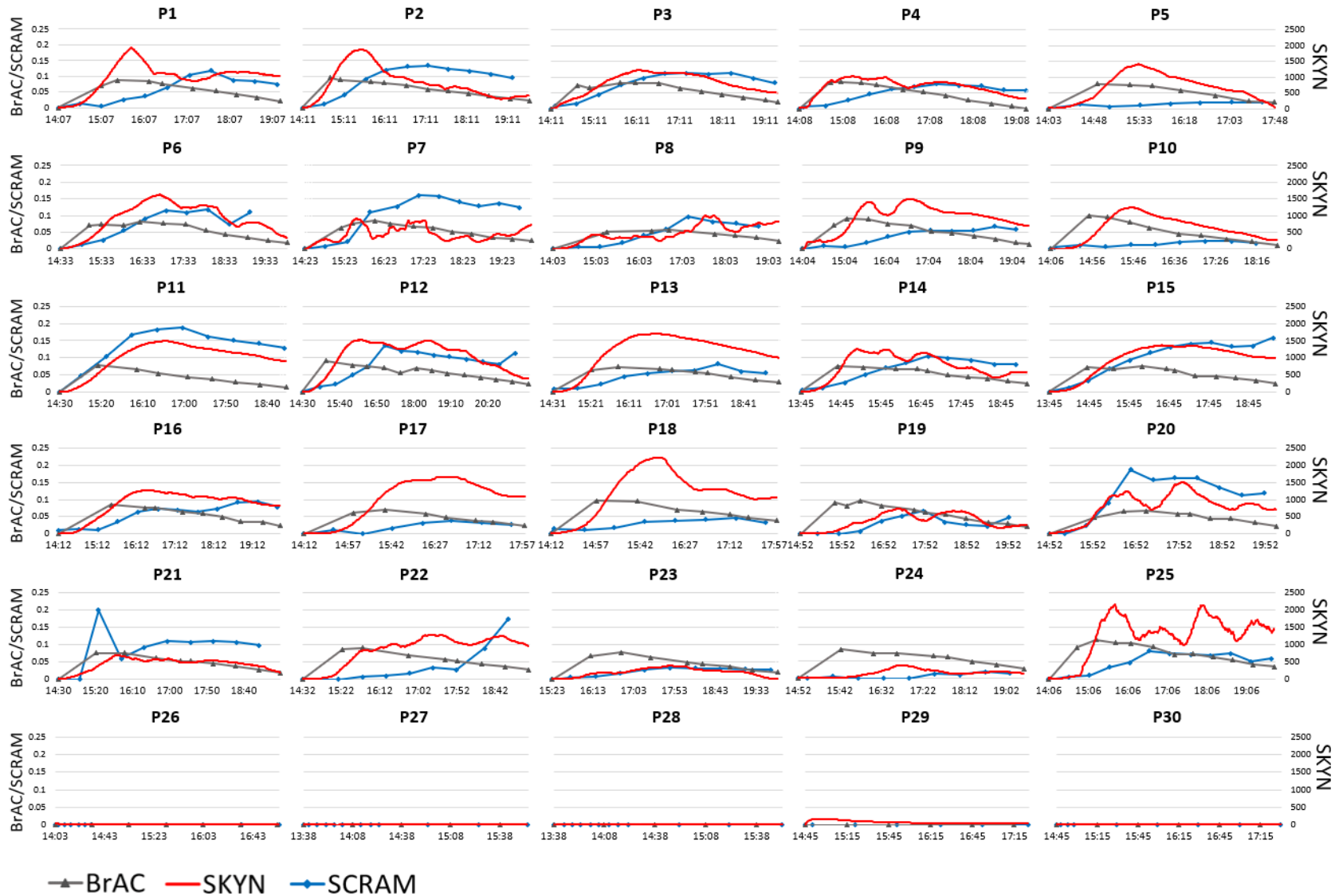


Figure 2. Skyn prototype, SCRAM, and BrAC data for each of the 25 participants assigned to receive alcohol (P1-P25) as well as the 5 no-alcohol control participants (P26-P30). Data reflects the entire period of assessment, beginning from the moment just prior to first alcohol consumption (beginning of the drink period) to the final BrAC reading. For this visualization of Skyn data, data was standardized by subtracting the lowest value for each participant file, and a 30-minute moving average window was also applied.