Reducing Opioid Related Deaths for individuals who are at high risk of death from overdose on release from prison and within the homeless hostels for drug users; an issue further complicated by the impacts of COVID-19.

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Abstract

Background: Deaths involving heroin, morphine and cocaine were the highest on record in Northern Ireland in 2019. Figures from the Northern Ireland Statistics and Research Agency (NISRA) indicate that 191 people died were recorded as drug related deaths in 2019 with just over half (95) males aged 25-44 (NISRA, 2020). Opioid users from the homeless population and those who are recently released from prison are considered high risk from an opioid overdose (REF).

Methods/Design: This feasibility study was designed to work co-productively with opioid users, to test the practicality of wearing a wearable device and to investigate whether the data captured on a Wearables device, designed to detect signs of a drug overdose, could be successfully transferred from the device to a backend cloud service. The study encompassed four focus groups in total, three with opioid users and one with workers.

Discussion: Qualitative data indicated that the target population would welcome such a device and provided a range of views and ideas regarding the refinement of the design. The provision of information regarding the specific functionality of the device was considered key and could be disseminated via front line services.

From the data obtained from the wearables devices, it was concluded that it was feasible to use a consumable wearable device for monitoring opioid users' biomarkers remotely. The data acquisition and transfer process would not be a barrier for future research.

Keywords: Opioid Overdose, Wearable Technology, co-production.

Section 1: Introduction

As drug deaths continue to rise across the four nations it is imperative that innovative interventions are sought, tested, and implemented to address the complex issue of drug related deaths (Black 2020). The urgency of the situation is compounded by the current global pandemic. The prison leaver subgroup and hostel population who are homeless are particularly vulnerable to opioid related deaths. For those who are just released from prison, it is a crucial time in which to intervene and prevent overdose related deaths (Bukten et al., 2019). The use of technology has been identified as a means of supporting and replacing traditional interventions with users of services in various contexts, for example, life-style choices, rehabilitation, and working with older people (Guo, 2016; Domingues et al., 2019; Wherton et al., 2019).

Presently, the scale of human costs associated with drug related death is creating an environment of despair and hopelessness for individuals, families, communities, and service providers. The complex issues associated with heroin use, related overdose deaths have been exacerbated by the current COVID-19 crisis, and it is anticipated the overdose deaths will increase over the next year.
Deaths involving heroin, morphine and cocaine were the highest on record in 2018-19 in Northern Ireland. New figures from the Northern Ireland Statistics and Research Agency (NISRA) show that 191 people died because of a drug overdose last year with just over half (95) men aged 25-44 (NISRA, 2020).

Information from the Street Injectors project, Extern (SISS) indicates that there has been a steady increase in the reported use of IV heroin alongside an increase in the use of IV Cocaine. There has also been more emphasis on opioids mixed with street manufactured benzodiazepines, which are highly potent and increase the chance of overdose deaths when used with opioids. To date there has been limited research in this area and figures suggest that an intervention is required to help reduce the number of fatalities amongst an ever-expanding opioid problem.

This feasibility study focuses on adapting wearable technologies to prevent loss of life in highly vulnerable and hard to reach populations. In particular, we aimed to refine the design of a wearables device that would specifically address these current concerns by monitoring a users' life signs and send an alert when a potential overdose is detected. We worked co-productively with opioid users and workers from a relevant frontline service to obtain their views and ideas regarding the design of the technology and also to test the feasibility of wearing such a device. To date, no research of this nature has been done and so working co-productively with service users was deemed as crucial.

Section 2: Methodology

This section sets out the main research questions and objectives for the study and outlines the study design and methodology.

2.1 Research questions and objectives

The study sought to address five key research questions:

(i) What are the views and ideas of prison populations and homeless hostel occupants with opioid disorders regarding the feasibility of the wearable device?

(ii) What is the lived experience of homeless hostel dwellers with opioid disorders regarding the acceptability of the mobile technology?

(iii) What are the views and experiences of Extern workers regarding the protocol in a general overdose situation and perceptions of the wearable devices?

(iv) What is needed (if anything) to improve/ refine the mobile technology?

(v) Can the data from the wearables device successfully transferred to a secure server?

In doing this, the study had the following core objectives:

(i) To work co-productively with individuals in prison and service users in a homeless hostel who have opioid disorders.

(ii) To test the acceptability and practicality of wearing a wearable device.

(iii) To obtain an overview of the experiences of workers as to what the protocol is within their service in a general overdose situation and their views on the service users wearing a device.

(iv) To refine the wearables in view of the results from the co –production work with opioid users in prison and in a homeless hostel based in Belfast.

(v) To assess whether the data recorded on the device can be successfully transferred from the device to a backend service in the cloud.

2.2 Study Design

Reflecting the main research questions and objectives for the study, the research consisted of two phases:

2.2.1 Co-production Phase

The team undertook co-production work with a group of previously active opioid users in two local prisons and in a voluntary sector homeless hostel for people who use drugs (PWUD).

The study design encompassed the use of four focus groups in total. Two were conducted face-to-face in a prison setting with prisoners; one in Hydebank College and one in HMP Maghaberry whilst another was carried out face-to-face with service users who reside in a homeless hostel in Belfast. The number of participants ranged from two – seven for each of the focus groups with all having had some experience of using heroin as well as other prescription and illegal drugs.

A fourth focus group was conducted remotely via Zoom with staff from Extern Street Injectors Support Service (SISS) in order to ascertain views regarding the practicality of service users using the wearables device as well as their views and experiences regarding the protocol within the hostel regarding a general overdose situation.

Throughout the co-production phase, the research team members reviewed and revised the co-produced ideas and considered points raised by participants (during the focus groups) regarding the feasibility, practicality, and acceptability of wearing the device to inform the evaluation process. It was crucial to engage with individuals in the prison and in the homeless hostel in order to gain trust and give participants ownership of the concept of the wearables to preserve life in a potential overdose situation.

2.2.2 Wearables Phase

We assessed the feasibility of 'wearing' the device within a sample of the homeless population. The individuals were asked to wear the device whilst in the homeless shelter (for participant protection) whilst under the supervision of the researchers.

The vulnerable client group was considered under the Capacity guidance within the Mental Health Capacity Act (2016). Prior to each participant wearing the wristband for the designated 1.5 – 2-hour period, staff checked that the participant was still willing to wear the band and that informed consent was not marred by lack of capacity. If the Extern worker or the researcher collecting the data had any concerns about the person's ability to consent to participate then they would not proceed with the request. In addition, issues of capacity and consent were routinely considered by the workers and researchers involved and so they were able to identify any concerns about impaired mental capacity. The device was not used to prevent loss of life in this study. It was simply to gauge the service users' views of the

practicality of wearing the device and to assess the reliability of the transfer of data to a secure backend cloud serve service.
Data was collected for 6 evening sessions between 10.11.21 – 29.11.21. Participants were asked to wear the device in the communal area between 6pm -7.30pm during which time readings were taken from the device and stored on the individual wearables.

2.3 Focus groups

In relation to carrying out the focus groups, two experienced researchers undertook the focus groups with opioid users and workers. Two of the focus groups with opioid users were conducted inside a prison setting and prior security clearance for the researchers had to be negotiated with the Northern Ireland Prison Service. Three out of the four focus groups were digitally recorded and transcribed and NVivo was used to assist the organisation and coding of data. One focus group was not recorded due to the researchers not being granted clearance from prison security to use a voice recorder. In this occasion, detailed notes were taken by the researchers.

2.4 Settings and Locations of data collection

Data was gathered via focus groups, three of which were conducted face-to-face in meeting rooms in Hydebank College, HMP Maghaberry and Extern Ormeau Centre in Belfast. The staff focus group was conducted remotely via video conferencing software, Zoom.

2.5 Eligibility

Participants were eligible for the study if they were highly vulnerable, had a history of opioid use, were 18 years or older, currently resided in one of the prisons in Northern Ireland or in the homeless hostel in Belfast and had capacity to consent. Individuals were excluded if they did not meet any of the inclusion criteria and/ or if they were unable to speak sufficient English to take part.

2.6 Recruitment and informed consent

As this study recruited from vulnerable hard to reach populations, recruitment was assisted by the appropriate substance use support services.

Recruitment to the prisoner focus groups (Hydebank College and HMP Maghaberry) was coordinated by Alcohol and Drugs: Empowering People Through Therapy (ADEPT). AD: EPT is a local community sector organisation that has been contracted to work with people who have identified drug use issues in prison. Staff asked individuals who were currently engaged with the service within the prison setting, if they would be willing to take part in the study to and provided some information about what the study involved.

The sample of hostel dwellers were recruited via the assistance of Extern who have management responsibility for the workers employed in the unit situated in Belfast. Staff from the hostel asked residents (who met the inclusion criteria) if they were willing to take part in the study and if so, briefly explained the study and what their participation would involve.

Extern workers from the Street Injectors Support Service (SISS) were recruited to participate in a focus group via the manager of the need exchange service in Belfast. Prior to the commencement of the study, Extern had agreed to full participation in the research. The research team provided an email invitation to the manager to send out to staff. Participant Information Sheets (PIS) and consent documentation were also sent along with the invitation email. Those staff who wished to take part were contacted by the research team one week prior to the focus group to answer any questions regarding the study. Staff were assured that participation was not compulsory, and all participants were given one week to consider whether they wished to take part in the interview.

Informed consent was sought at the beginning of each focus group by the researchers and each participant was asked to provide written consent after the PIS was read aloud to the group and all questions relating to the study were answered by the research team. Each participant was also given a copy of the PIS which included the contact names and numbers of the research team. Participants were aware that they could withdraw from the study at any time up until the point of data analysis

2.7 Participants

The study sought to recruit 20 individuals with opioid disorders and 5 workers the co-production phase, and 10 service users from a homeless hostel for the wearables phase.

In the end, sixteen participants who had opioid disorders were recruited to take part in the co-production phase; twelve from the prison population and four service users from the homeless hostel, nine of which were female. Their ages ranged between 22-43 years with a mean age of 29 years. Four Extern workers were also recruited (2 of which were female).

In the wearables phase, there were six participants in the hostel (2 female) with an age range of 24-53 years.

2.8 Sampling strategy

A purposive sampling technique was employed in relation to the identification of the prisoners and the service users who resided in the homeless hostel with specialist provision for injecting drug users. The same method was used to select the sample (n=4) of Extern workers.

2.9 Ethics

Ethical approval for the study was secured from HSC Office for Research Ethics Committees Northern Ireland (ORECNI) A on 2nd July 2021 (REC reference number: 21/NI/0089).

2.10 Analyses

All data was held securely on password protected computers to protect against unauthorised access.

Focus groups were transcribed verbatim and anonymised through the removal of potential identifiers. The transcripts were uploaded to NVivo 12 for thematic analysis. This facilitated the organisation of the data and the coding of the data into themes. All personal identifiers were removed from focus group transcripts prior to analysis to ensure that participants could not be identified, and the audio files immediately destroyed. Two members of the research team coded the qualitative data. From the codes, a series of broader themes was identified, and these form the overview of the qualitative findings.

Data from the wearables was transferred directly to a secure private server in the cloud and was monitored intermittently by Dr Li Guo at Manchester Metropolitan University. The transferrable data containing the two output readings (SPo2 and heart rate) did not contain any personal identifiers. The data was anonymous and was not monitored in real time. After the completion of data collection, the data was downloaded from the server and analysed using Python (local analysis toolkit).

Section 3: Findings

This section reports the findings from the feasibility study. As noted in section 2, there were two phases to the data collection process.

3.1 Qualitative findings from the co-production phase

We conducted three focus groups with service users, one in Hydebank College, one in HMP Maghaberry and another in a homeless hostel in Belfast, with specialist provision for injecting drug users, each lasting approximately 30 minutes. The purpose of this qualitative component was to provide information on the views and experiences of opioid users regarding the acceptability and feasibility of wearing the device to preserve life in a potential overdose situation and to capture any ideas of how best to improve the design. In total, there were 16 participants who took part in the three focus groups for opioid users. Below are the findings from the focus group with opioid users:

3.1.1 Views and experiences of opioid users

First reactions

The initial reaction was positive**.** All participants expressed an interest in the wearables technology when it was presented to them and agreed, that in principle, such a device would be extremely beneficial to help reduce the risk of overdose within the active drug using community. Almost three-quarters of those users taking part (11 out of 16) had at least one personal experience of overdosing whilst injecting heroin and had been administered Naloxone on at least one occasion thus further emphasising the need for such a device within the target population. The views, experiences and ideas of the service users are outlined in detail below:

Challenges and aids of the of the design

Participants were asked what factors helped or hindered the design of this proposed device and their decision to wear it, if it were readily available to them.

(i) GPS tracking

The most common concern and biggest fear noted by the service users was that of GPS tracking. All respondents (n=16) were concerned about the GPS system within the device and it's potential to track their everyday movements. All were keen to seek clarification regarding the particulars of the GPS system, for example, when this would be activated on the device, how, for what duration and exactly what information was captured by the technology:

> *"I just wouldn't like the tracker, I don't know…I think that's dangerous… would it be tracking you all the time or just when you have an overdose?... we're always gettin' into trouble, up to all f**king sorts on a daily basis, you wouldn't want anyone to know what you're doin, or where ya are like… do ya know what I mean?"* (Service user 3, female).

Participants concerns centred around the fact that they would go to meet their dealers on a regular basis, to purchase drugs, in certain parts of the city and did not want their whereabouts being tracked due to the illegal nature of their activity. Three (out of 16) voiced significant concerns about wearing the device when using drugs at specific locations, for example, at their dealer's house. They feared that the GPS might be triggered when taking a 'hit' at such a location as this would attract unwanted attention to the dealer's location. In such circumstances, they explained that they would be likely to remove the device before injecting:

> "*What if I'm lying up in my drug dealer's flat and I've took a hit, and the thing goes off and then all these ambulances arrive, do you know what I mean? And then I'm in shit and everybody's in shit…. Like the ambulances will report that 'til the police and people will think I'm a rat for getting the peelers…there's people that have been left to die for less, pulled up the street of the drug dealers' house and left in the street or in public toilets or somewhere like that"* (service user 1, female).

The facilitators explained that the GPS tracking would only be active if an individual's blood oxygen saturation levels dropped below 90 percent and that this SpO2 level, as well as a decreased heart rate is considered abnormal and required immediate medical attention. The participants were assured that future versions of the wearable would utilise the life sign indicators on the wristband to trigger the activation of the GPS. The device would then be able to identify the location of the user at that particular time point only and share this location with Northern Ireland Ambulance Service (NIAS) so as they could issue a rapid response vehicle. This significant and understandable fear of the GPS locator highlighted that the provision of accurate information regarding this function in particular was paramount in users wearing the device.

(ii) Size of wristband

It was noted by over half of respondents, that the wrist size of active opioid users is usually significantly smaller than the average person due to poor diet and sustained drug use. It was therefore agreed by the respondents that the wristband of the device should be designed accordingly to ensure the best fit possible:

> *"Like most of us, by the time we get really bad…our wrists are smaller, like when I'm strung out, I'm only 6 or 7 stone like, you should make the strap out of elastic or whatever if you say it has to stay close to your arm…"* (service user 5, female).

One suggestion was to have a 'snap band' as a strap or alternatively make it more flexible by using elastic. One respondent however, warned not to make the strap of the device a rubber band as users might be inclined to use this as a tourniquet when injecting.

(iii) Linkage to Northern Ireland Ambulance Service (NIAS)

A significant number (14 out of 16) raised concerns regarding the NIAS response to an overdose situation and feared that this would attract unwanted attention from the police. They were unsure if they would want to take the risk of attracting attention from authorities for fear of the consequences such as getting 'nicked' or a return to prison if out on licence/ drug ban.

On the other hand, the linkage to NIAS was perceived to be essential by the majority as it would ensure that medical assistance would arrive in the quickest possible time:

> *"I think it would be useful to link it up to the ambulance service as you've like only got so much time before ya pass like but not if was linked up to the police…. I think it should be linked up to ambulance and have an alarm as well"* (Service user 6).

(iv) Alarm

Participants also agreed that the device should also have an alarm which was activated in an overdose situation so as to alert peers and/ or passers-by to administer Naloxone which would be carried by the user. The alarm would consist of a loud tone as well as a voice message to administer Naloxone:

> *" Like, what if you were down an alley somewhere havin' a hit, like I'll give an example, if someone was down at the [specific location] in Belfast and there's no-one around ye know, but if someone was to walk past and that thing had an alarm, it could either be a really loud sound or a voice stating that, 'I have Naloxone on my person, please administer the Naloxone, I am an opioid user…' if you're on your own and you've overdosed, somebody needs to find ye like..."* (Service user 7, female).

One respondent, who had personally experienced a number of opioid overdoses suggested that the device should also provide the user with a warning alarm when it detects early signs of potential overdose.

Almost all (14 out of 16) felt that an alarm on the device would be extremely useful to alert them if one of their peers was experiencing an overdose:

> *"I think it would be really good if say you were with one of your friends and they went over and we it was able to alert you as well and you had Naloxone and they didn't...* (service user 10, male).

(V) 'Cancel' button on device

One respondent spoke of how during her own experiences of injecting heroin, he had recovered from a near overdose situation several times and did not require any intervention. Thus, he suggested that a button on the device to cancel an activation of a response from NIAS would be beneficial, not only for users but for the already overburdened ambulance service:

> *"Do ya know the way some people are that close to overdose, but they come back? Like would there be a lot of false alarms? By the time the ambulance receives the alert and arrives and you're alright and then you could've ended up getting nicked…. Something to send a message that it was a false alarm would be good…like otherwise we would be wasting a lot of ambulances' times, like we would be up and gone by the time they get there and there probably, and there could be someone else that might really need it [ambulance]...like maybe it could be cancelled if our heartbeat returned to normal again for at least one minute… like it could maybe send a direct message, 'crisis averted'"* (service user 12, male).

(Vi) Appearance of Wearables device

All respondents were in agreement that the device should not have a resale value. It should be as discreet as possible and should resemble a plain wristband rather than a watch with an interface. The purpose and function of the device should not be obvious to others they felt most users did not want relatives/ friends to know that they were using heroin. The general consensus was that it should appear as a thin black strap. It was also noted that the device would need to be waterproof as the target population would often be sleeping outdoors in all weathers.

It was noted throughout all three service user focus groups that the Withings ScanWatch device was unsuitable as it required the user to place their hand over the screen in order to obtain a reading of SPo2 in a potential overdose situation. It was agreed that the user would be unable to perform this action due to deteriorating health state and it was unanimously agreed by participants that it would be necessary for both the readings for heart rate and SPo2 to be monitored automatically by the device without any intervention from the user.

(Vii) Sense of safety

It was discussed as to whether the participants felt that by wearing the device, it would provide them with a sense of safety (in that it would reduce the risk of dying from an overdose) and thus result in them 'using' more. The general view was that they did not use more when carrying Naloxone on their person and so did not perceive the wearing of the device to result in an increase in use.

"Nah you're gonna use what you're gonna use anyway as you've got Naloxone, users carry Naloxone, ya don't use more if you've got that so why would ya use more with one of them on your wrist?." (Service user 14, male).

(Viii) Poly drug use

Two service users raised the question as to whether the device would be able to detect a potential overdose when under the influence of any drug or was it just specifically designed to reduce the risk of a heroin overdose. All participants stated they often used other substances alongside heroin, the main ones being cocaine, Pregabalin (Lyrica) and /or Diazepam 10mg (Blues). Over half (10 out of 16) considered the mixture of Pregabalin and/ or diazepam along with heroin to be the trigger for an overdose. One respondent described the consequences of her using all three drugs simultaneously:

"I took Blues, Pregabalin and heroin together and I collapsed… and the blood circulation stopped runnin' through my hand and now it doesn't work properly…I can't move some of my fingers, they're stuck like that, stiff and I can't really move them…" (service user, 4 female).

"Most of us who use heroin ye know, like coke goes side by side with it and tablets...ya know, those three things, we all do them… like we're all proper junkies" (service user 5, female).

It was explained by the facilitators that the device was designed to detect a drop in the blood oxygen saturation levels and heart rate which would be the indicator of an overdose from any substance or mixture of drugs and that this would therefore still be of benefit to polydrug users.

One participant noted that the device would be useful for anyone going on a night out to wear as it could potentially alert them if they had been 'spiked' as drinks 'spiking' has been on the increase during the last 12 months across the UK.

Administration of Naloxone

(i) Fear of ruining hit

There were concerns that someone could be administered Naloxone when not actually in an opioid overdose situation. Around half (9 out of 16) reported previously feeling frustrated after being administered Naloxone as it ruined their 'hit'. One participant raised the concern that some users might be afraid to wear the device when taking a hit for fear of activating a response and being administered Naloxone:

"Like what if you're too scared to wear that on your wrist when you're taking a hit in case it sends a signal and so you would just take it off before…like when you're strung out, ya don't care about anything but your hit, ya don't care about yourself. Ya don't care if ya live or die when you're strung out…like before ya know it, the ambulance and cops would be there and

you'd end up getting done for gear and for bein' somewhere you're not meant to be…l" (service user 4, female).

(ii) 'False Alarm'

A small number (3) also expressed concerns about being given Naloxone whenever they hadn't taken any opiates:

> *"There was a fella once who overdosed on Spice and Pregabalin, he was getting on all 'creepy' on the spice or whatever, and some worker from [frontline service] came over and was gonna hit him with Naloxone and I shouts, don't hit him with that, he's not on opiates!"* (Service user 10, male).

The facilitators reassured the participants that if a person was given Naloxone and hadn't used opiates, it wouldn't do anything to them would not cause them any harm.

Benefits versus risks

(i) Unsafe environment

Others(n=3) described their own experiences of having overdosed and why ultimately, they felt that the benefits of the device outweighed the risks:

> *I'll tell you why this is a brilliant idea, cause if everyone panics and runs off and is willing to leave ya, at least the device will alert someone that you're in trouble…my friend, who overdosed there in the public toilets, if she had one of them on her, someone could've tended to her but now she's dead…."* (Service user 11, female).

> *If it wasn't for a young fella, I would've OD'ed down the (specific location)….In an abandoned building and there was about ten of us there, they robbed me, they left me, they punched me, they stuck their hand down me pants and took drugs out of me, they robbed me and left me there and only for the young fella coming in…he saw me blue and got help…otherwise I'd be gone…* (service user 6, female).

(ii) Unpredictability of peers

The fact that the users could not always depend on their peers to help them should they overdose was the main reason why they considered the device to be particularly beneficial. Education and information regarding Naloxone and the fact that it can be used to help people in an overdose situation and significantly reduce the need for the police intervention was deemed as vital:

> *The main reason why people leave is because they don't want the police to come, so when people finally understand that by administering Naloxone, the police aren't gonna come because they're bringing the person back…..then they're gunna use it,*

people don't seem to understand that yet…the only reason they run is because they've got warrants or because they don't wanted lifted or whatever…that's why you're better off to have one a them on your arm….so as you have a better chance of getting help" (service user 3, female).

(iii) Lone injecting

The wearables device was considered by all respondents to be most advantageous to those who tend to 'shoot up' alone at home or elsewhere:

"If you're on your own and you overdose somewhere in a flat or outside somewhere and nobody knows where ya are, like, then it would be good so as someone could find ya…I think it would be great for someone on their own…." (Service user 3, female).

3.1.2 Views and ideas of workers

A focus group was also conducted (remotely) with staff (n=4) from Extern Street Injectors Support Service (SISS) to ascertain the views of workers regarding the feasibility of the wearables device and to obtain an overview of what the protocol is in a general overdose situation.

Harm reduction level

Overall, the staff from Extern Street Injectors Support Service considered the device to be a good idea in principle which would be beneficial in terms of harm reduction as it would help to reduce the number of deaths within the target population. They did however have some concerns regarding the practicalities of the design and the use of such a wearables device within the drug using community. These are outlined in detail below.

Design and functions of wearables device

(i) Resale value

It was reiterated by staff that the device should not have a resale value otherwise it would be sold on or stolen. The workers noted that due to the chaotic lifestyle of some users that they would also have concerns as to whether they would lose the device and would have to be issued with a new supply on a regular basis.

(ii) GPS tracking

All workers envisaged concerns and fears from users that authorities could potentially tap into the GPS system on the device and track their whereabouts on a daily basis and see the

locations in which they go to meet their dealers and buy drugs. They also anticipated that the dealers might have concerns and paranoia regarding their clients wearing the technology, which in turn, they feared could put the users at risk. All workers agreed that rumours can circulate quickly within the drug using community and so if one person were to say that the device can track the user on a regular basis, this speculation would likely spread quickly throughout the drug using community and dealers.

It was thus suggested by the SISS workers that the provision of honest and open information as to how the device would function is vital and could be relayed to their service users via their workers and other relevant frontline services so as to minimise the risk any such rumours and misinformation.

(iii) Linkage with Northern Ireland Ambulance Service

From the workers experience, service users have had the chance to build up trust and rapport with the SISS team and on previous occasions did not respond well to the arrival of paramedics. One respondent reported that in the majority of times, when they have administered Naloxone in an overdose situation, and paramedics have arrived that the user has not allowed the paramedics to work on them as they felt that it was an intrusion.

> *"They really do take offence... you know, when we bring them round with Naloxone, the majority of them will not let the paramedics work on them because they just don't want that intrusion* (Worker 1, female).

However, it was agreed overall, that the alert from the device regarding a potential overdose was vital as the administration of Naloxone was the most important thing. They all therefore agreed that it would still be beneficial to alert the ambulance service as ultimately, they explained, it is up to the user as to whether or not they wish to be taken to hospital in the ambulance.

> *"The main thing is getting an alert to a possible overdose and getting Naloxone into them and it's their decision ultimately as to whether they want to go to hospital or not, if they don't want to, and they're ok, well then their lives will still have technically been saved by the device and the Naloxone and yes it might wear off but there are other services in town, including ourselves that can monitor that"* (Worker 2, female).

(iv) Detection of specific substance

One suggestion was whether the device could be modified in such a way in order to detect what type of substance the user had taken to cause the overdose, for example, whether its benzodiazepines or heroin. They felt that this would be of great advantage as they also see a significant number of overdoses due to benzodiazepine and would know whether or not to administer Naloxone.

Extern protocol in an overdose situation

The Extern SISS protocol in an overdose situation at present is to phone and ambulance, administer naloxone, and then do CPR. They stated that they would administer Naloxone in small doses so as the user would not go into straight withdrawal. They stated that as much as eighty percent of users in an overdose situation would refuse to be taken to hospital in the ambulance after being administered Naloxone. Two of the workers stated that the main reason for the user refusing to be taken to hospital is because of fear of friends or family discovering they use heroin. It was emphasised that this applies more so to 'stable' users.

Alert multiple sources

It was agreed by all workers that it would be of benefit to send an alert from the device to Extern and perhaps to a nominated friend of the user. This would ensure that the user would receive a quick response from whoever is within the closest proximity. The workers pointed out that as they are based in the city centre and travel on bicycles, that their response time would likely be quicker than the ambulance service and that they would be able to administer Naloxone ahead of the arrival of the emergency services.

Buy-in from paramedics

Two workers also highlighted that it would be important to ensure that paramedics were willing to venture down dark alleyways without police assistance in order to potentially reach users who have overdosed. They stressed that this was something that their team was used to doing on a daily basis but not everyone would be willing to take those risks, especially in the dark.

Ambivalence of drug users

All staff expressed concern that some users may remove the device when injecting as they would not want to potentially ruin their hit with the administration of Naloxone. Workers stated that a significant number of their service users were not concerned as to whether they live or die, instead, to them, their hit is paramount, regardless of the consequences.

> *Some them wouldn't even take Naloxone off us, they're like 'I'm not gonna overdose, I'm not gonna overdose' and then we would give it to somebody who is with them but the majority of them doesn't want you to inject them with Naloxone, so it's like that mind set where they'll think, 'well I've a device on me, that's maybe going to send a thing saying I need an injection of Naloxone, I'm gonna take it off"* (Worker 1, female).

Potential of wearable to increase risk of overdose

One worker described how she felt that the device had the potential to perhaps increase the risk of overdose:

> *"I think it could also increase the risk, if say, someone was sitting in the exchange, they were heavily under the influence, their alarm goes off, they're supposed to be hit with Naloxone but we know that if they're hit with Naloxone, they would go get up, get another hit, go over within minutes and then be found dead somewhere essentially whereas if they were in the safety of the exchange or somewhere else more appropriate they could still be monitored and be ok.."* (Worker 3, male).

Opportunity for buy-in

It was suggested by one worker that a good time in which to secure buy-in from the user and offer them the wearables device could be just after they have been administered naloxone. They might be more likely to wear it after such an occasion as it may facilitate the timely administration of naloxone and thus lessen the need for them to be taken to hospital.

3.2 Wearables phase - findings

3.2.1 The Choice of the Data Collection Device

For this feasibility phase of the research, the Withings Scanwatch was chosen as the data collection device based on the several considerations:

1. We aimed to collect both heart rate and oxygen saturation (SPo2) readings from opioid users with full control of the data and this device purported to provide this function.
2. Both heart rate and SPo2 data could be collected by the device and synchronised to a cloud service in real-time.
3. Both heart rate and SPo2 data would be stored and could easily be accessible to use for later analysis.

After a thorough survey of the consumer wearable products/services available in the current markets (Apple Watch, Samsung Watch, Fitbit, Garmin, Huawei and Withings), the Withings Scanwatch was the only product that met all the above requirements. Most devices from the other brands did not provide full control of the SPo2 measurement (SPo2 measurement with other devices was triggered only during the night, while a user is sleeping). Huawei band 2, on the other hand, although provides 24/7 SPo2 and heart rate measurement, does not provide data export API out of its ecosystem.

3.2.2 The Data Collection Process

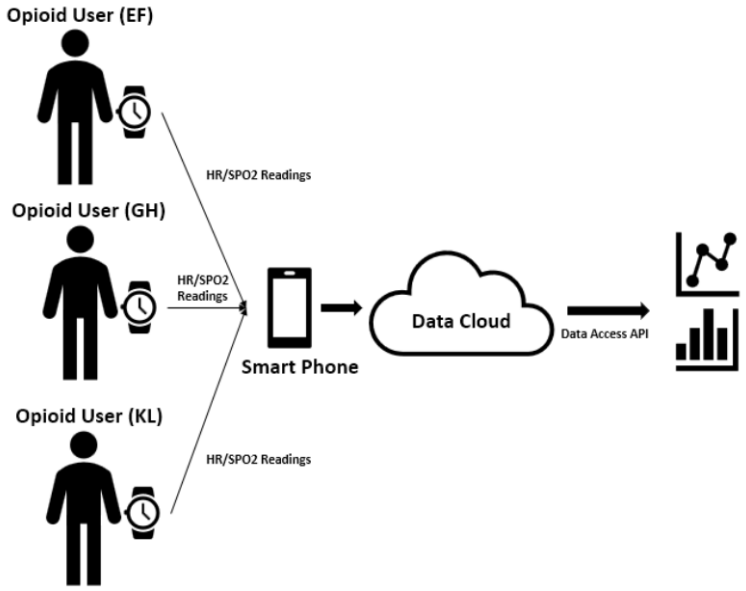

Figure 1: The Data Collection Process and the System Architecture

As shown in Figure 1, during the feasibility study, all the users were required to wear a Scanwatch under a shared Withings Health 10mate account. Although not having their separate accounts created, each user's data was tagged and could be identified by his/her Scanwatch serial ID. In this way, all users' data was managed by a single account, hence making the subsequent data sharing process much easier and controllable.

The Scanwatch regularly and automatically (each minute) measured the users' heart rate without requiring any user inputs. While for the oxygen saturation readings, users did need to manually trigger the Spo2 measuring mode and hold the watch for 30 seconds to make sure a valid Spo2 reading is generated. This was not considered a major drawback at this stage of the research as the aim was to test feasibility of the transferability of data to a secure server. Thus, the need to manually trigger the Spo2 reading was not an issue as the device was not being used for real time detection of an overdose situation in this feasibility stage of the research.

Both measured data were then synchronised through Bluetooth from the watch to a smartphone device that acted as a hub and transferred all the watch data to the backend data cloud service. Through the data access API provided by the data cloud service, our data analyst was able retrieve those data and perform local data exploration and analysis.

3.2.3 The Initial Data Exploration

After all the data was retrieved for the feasibility study, an initial data exploration study was conducted with a local analysis tool kit (Python). The plots (see appendices) show both heart rate (blue bar) and SPo2 readings (red bar) for each user (EF, GH, KL) on different dates and times throughout the data collection phase.

From those plots, we are confident to conclude that it is feasible to use a consumable wearable device for monitoring opioid users' biomarkers remotely. The data acquisition and transfer process will not be a barrier for such studies going forward.

Section 4: Summary and Conclusions

The key findings of the feasibility are discussed below, followed by some conclusions and recommendations.

4.1 Key Findings

This present study sought to refine the design of a wearables device for opioid users to detect a potential overdose situation and to test the transferability of data from the device to a backend service on the cloud. In order to test the feasibility of the device in the target population we worked co-productively with individuals in prison and service users in a homeless hostel who had opioid disorders.

4.1.1 Co-production with opioid users

The study captured the views of opioid users regarding the acceptability and practicality of wearing such a device within the drug using community to detect the signs of an overdose. Those who took part offered important insight into the potential benefits and risks associated with wearing the technology within the drug using community as well as a vision of what the device should look like and how it should function in order for it to succeed.

It was concluded by the vast majority of users that the benefits of such a wearables device significantly outweighed the risks. They seemed keen to avail of the technology as soon as it was fully developed. It was agreed that information about the wearables device and how it worked needed to be readily accessible and distributed clearly to users via frontline services such as Extern; this was considered as key, particularly in relation to the GPS function. It was clear from the findings that users were keen to know exactly how the device would work before they would want to wear it. There were concerns for example, that smoking a joint might cause a sufficient drop in SPo2 which might activate an alert from the device. Education regarding how the alert would be triggered by the device was therefore crucial in order to secure buy-in and trust from the target population.

Other ideas related to the size and flexibility of strap, the appearance of the device and the need for this to be discreet, perhaps resembling a small wristband and the importance of having an alarm to alert passers-by as well as being linked in with NIAS.

When asked about how to best distribute the device to the target population, the consensus was that distribution should take place from the needle exchange facility. Users suggested that the device could be readily available within this city centre facility and that they could collect one when in collecting their ‘works’ (clean needle packs and Naloxone).

4.1.2 Co-production with workers from relevant front-line service

Overall, SISS workers agreed that the device would be of great benefit in principle to users, particularly in terms of harm reduction. They did, however, share their views and ideas regarding the further refinement of the device for future development. Key points raised by staff included the importance of education and availability of information regarding the functioning of the device, the importance of alerting others as well as the ambulance service to ensure best response time and administration of Naloxone. They felt that their service could play a pivot role in the initiative, in particular, in the dissemination of information regarding the technology and distribution of the device itself within the drug community; as well as in responding to an alert of a potential overdose situation in the quickest time in order to administer Naloxone.

4.2 Wearables phase – transferability of data from device to secure server

Physical metrics are routinely used in medicine to determine the safety of patients. Early warning score define the degree of illness a patient is suffering. The heart rate and oxygen saturations are basic metrics and can be used in conjunction with other parameters to determine the acuity of illness and also as a trigger for an intervention such as the administration of Naloxone. It was therefore considered essential that the wearables device that was used in this feasibility study could capture both blood oxygen saturation levels and heart rate. It was concluded that the blood oxygen saturation levels and heart rate measured by the ScanWatch device had been successfully recorded and transferred to the secure cloud service which could easily be accessed by the research team. This is novel and suggests the possible use of wearable devices to provide a safety profile for patients who use drugs and is in keeping with a successful proof of concept.

As this study sought to assess whether the data (SPo2 and heart rate) recorded on the device could be successfully transferred from the device to a backend cloud service and was not testing the device in a real time overdose situation with individuals who had taken opioids the manual recording of SPo2 readings using the Withings ScanWatch was not a significant issue.

Despite this, the researchers noted a number of shortfalls with using the Withings Scanwatch as the data collection device in general. The SPo2 reading was difficult to capture, and the readings were often inconclusive (see plots in appendix 1-3). If there was even a slight movement from the participant, the reading was deemed to be inconclusive. In addition, if the users' hands and wrists were cold, the device failed to capture oxygen saturation levels as this resulted in a low pulsatile signal. It is quite common for users who inject to have circulatory issues which may, however, explain this issue. There were also a significant number of occasions during data collection in which the SPo2 readings were below average

(between 83-93 percent). Normal pulse oximeter readings usually range from 95 to 100 percent.

These findings from both phases will inform the future design of the wearables device so as it will be fit for purpose within the drug using community without presenting any risk or harm to the user.

4.3 Limitations

The sample size was small and not representative of the target population in general. This was partly due to the pandemic and Covid restrictions and also the complexity of recruiting those from within the prison and homeless population.

4.4 Recommendations

On the basis of these findings, future research could focus on the development, refinement, and piloting of a wearables device fit for purpose within the drug using community. The aim of this initiative would be to significantly reduce the number of deaths due to drugs overdose within the general drug using population.

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Appendices

Appendix 1:

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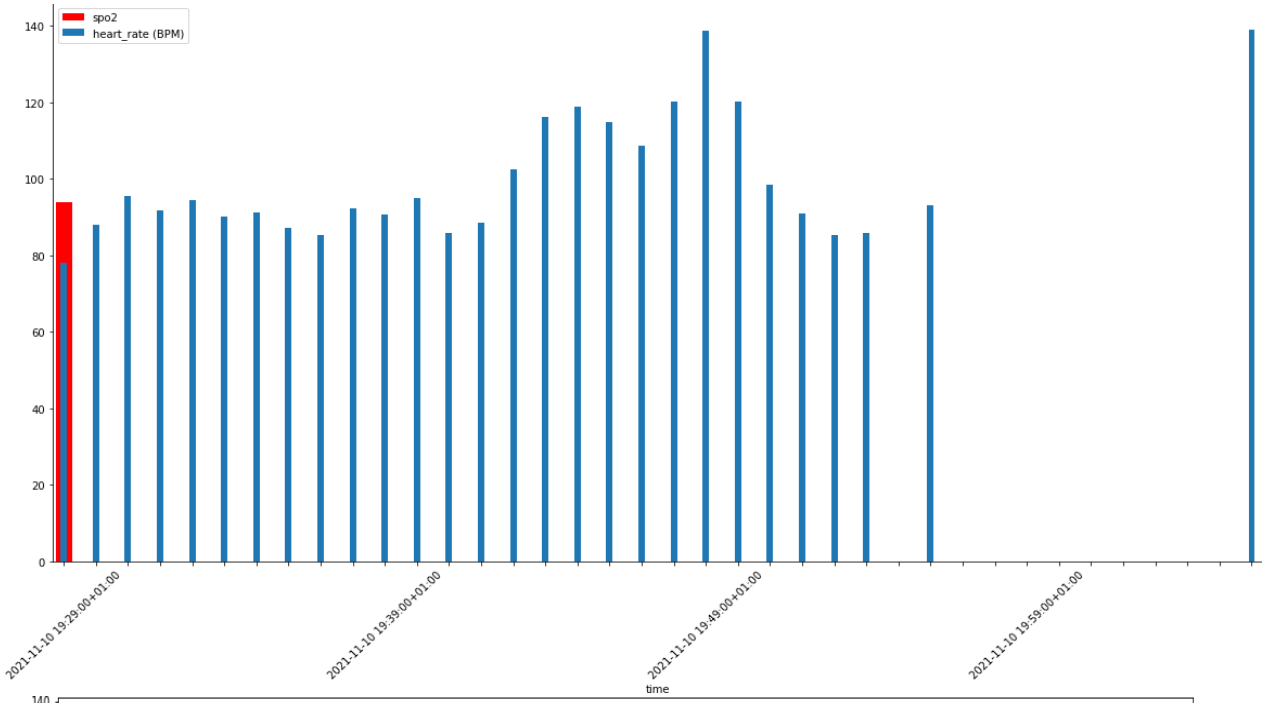

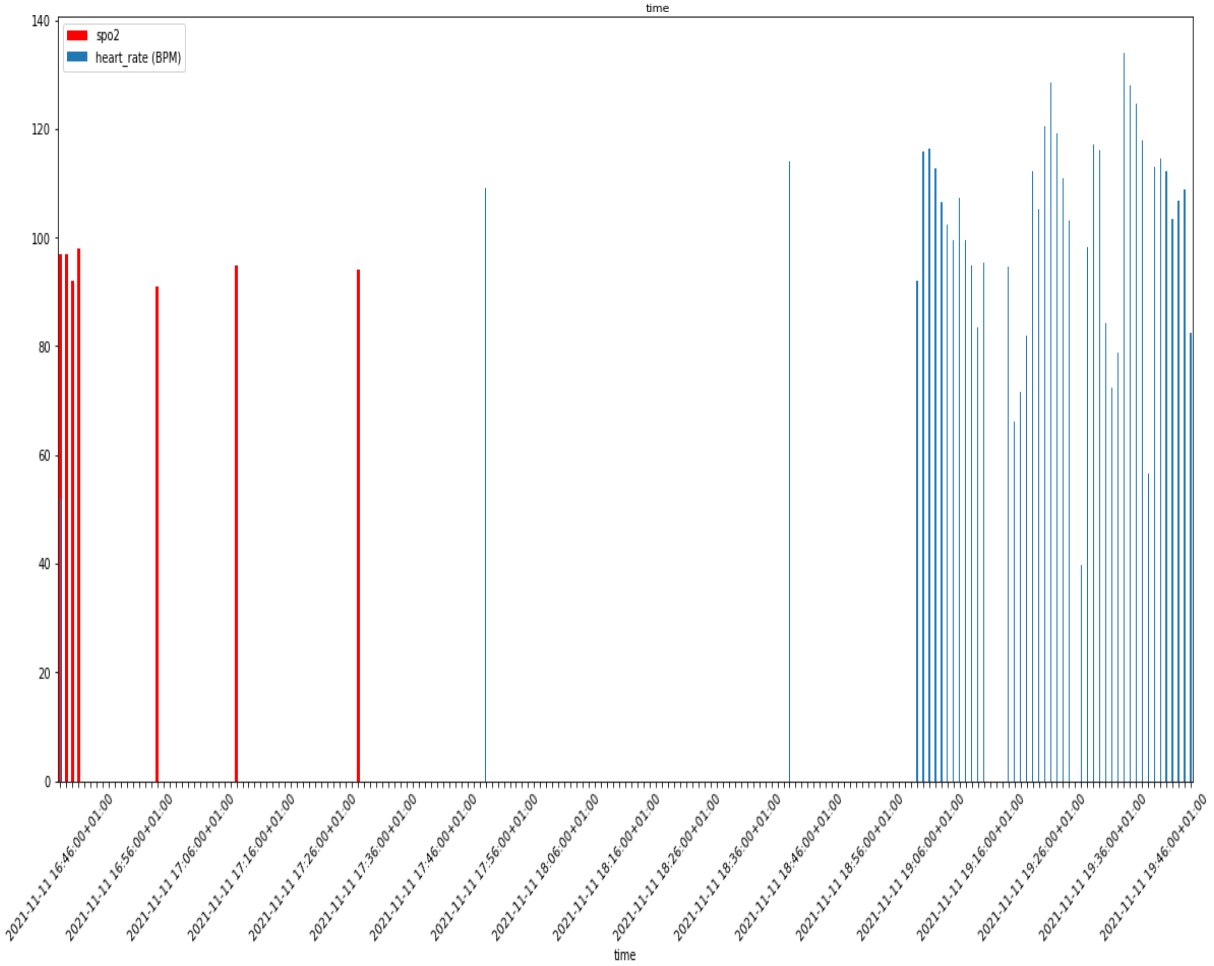

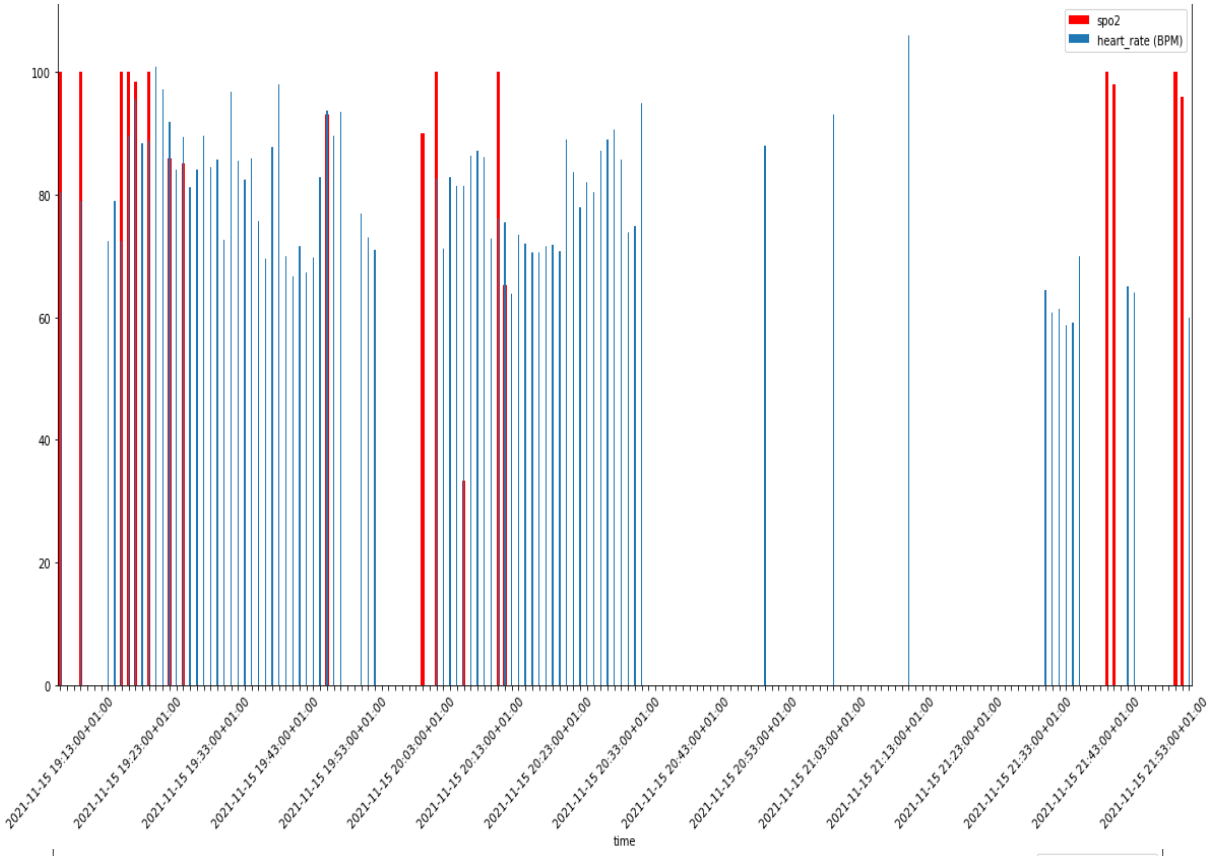
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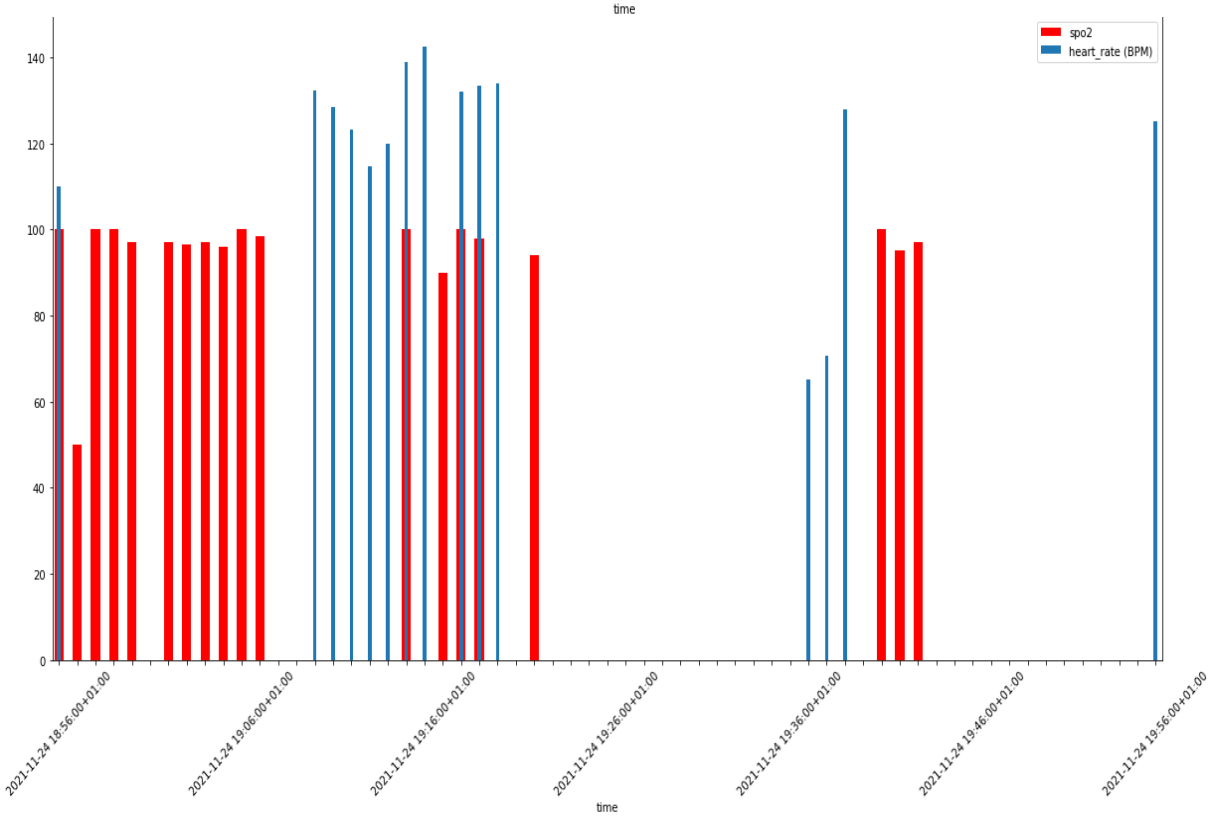
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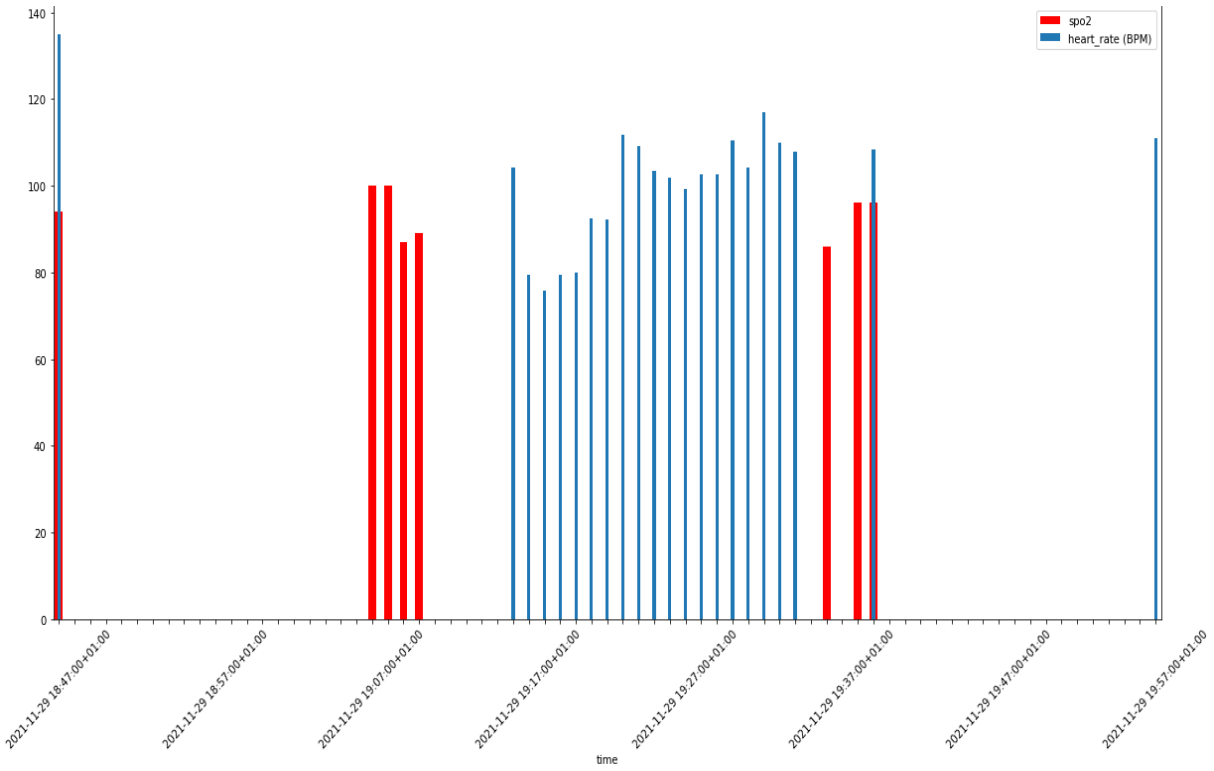
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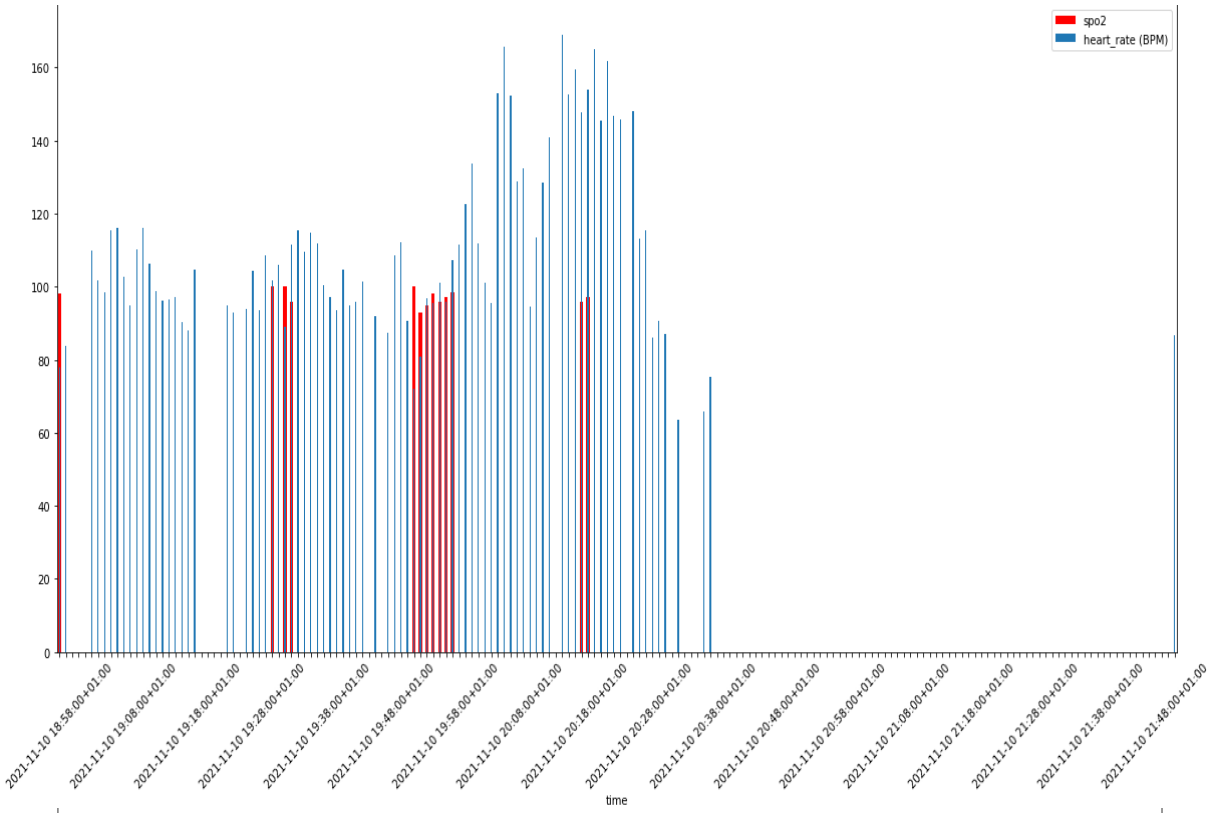

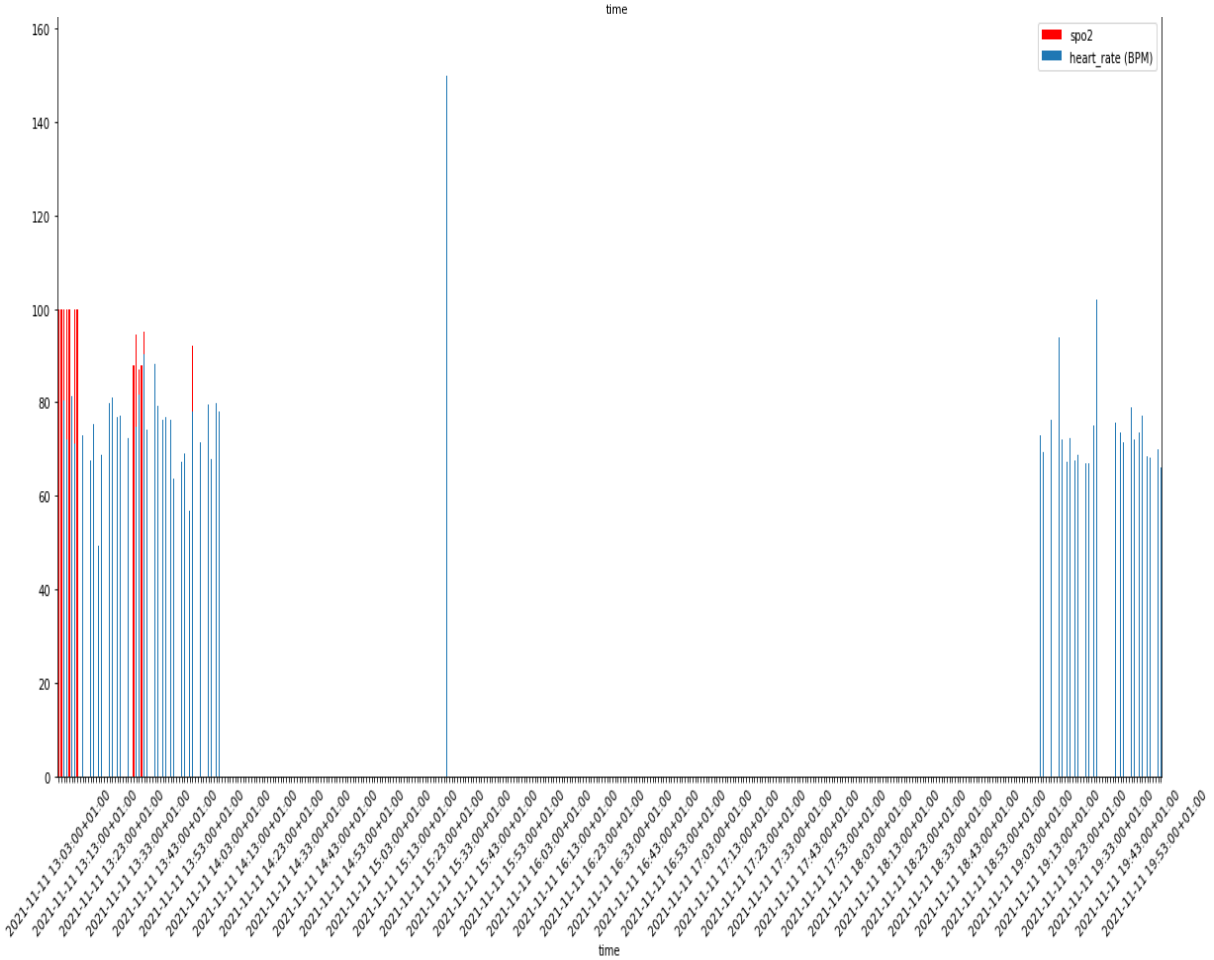

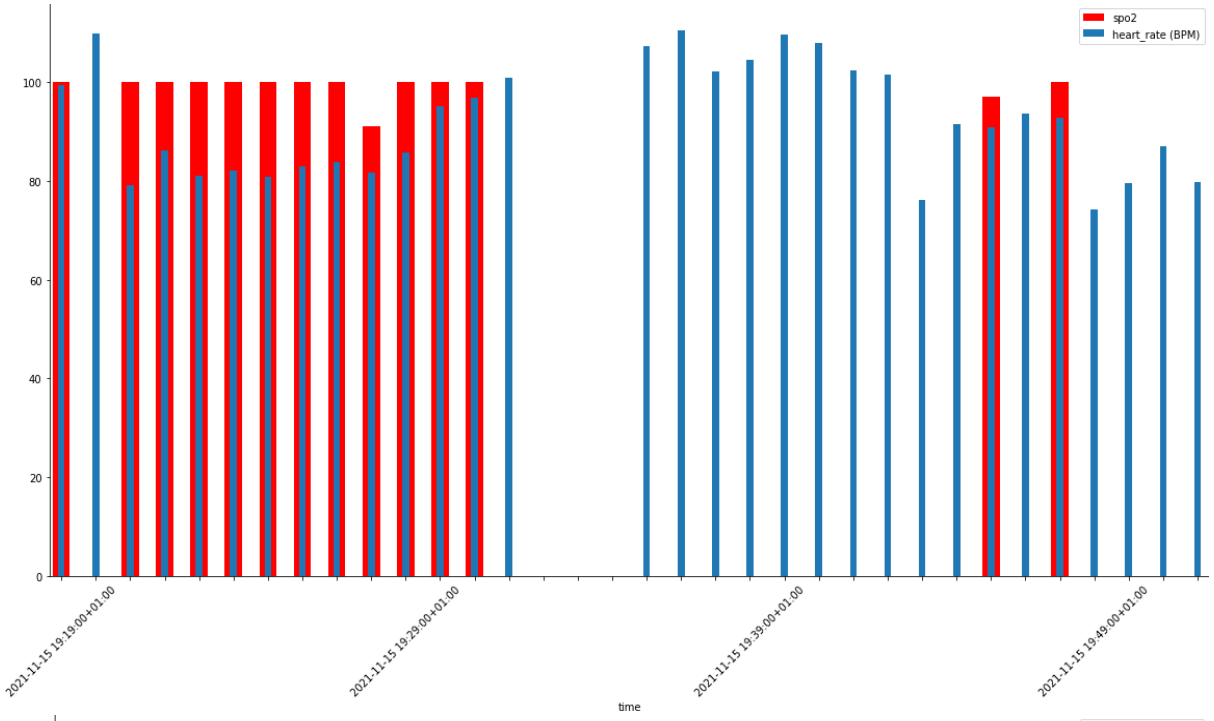
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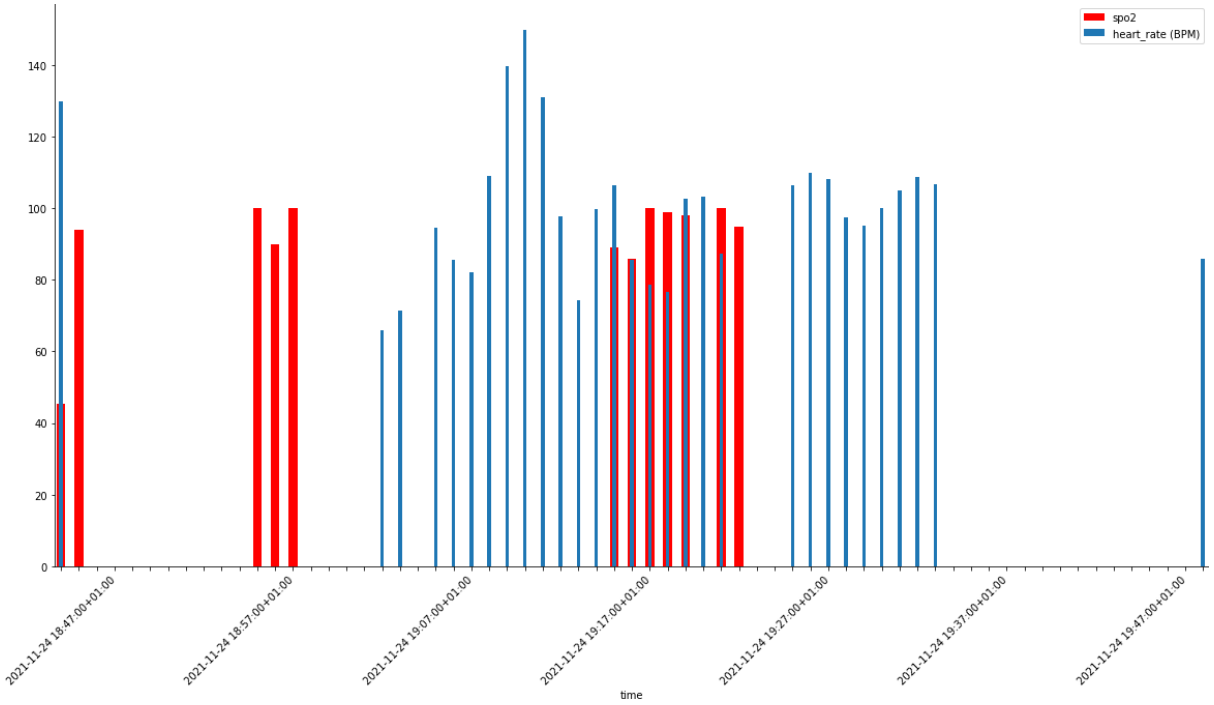
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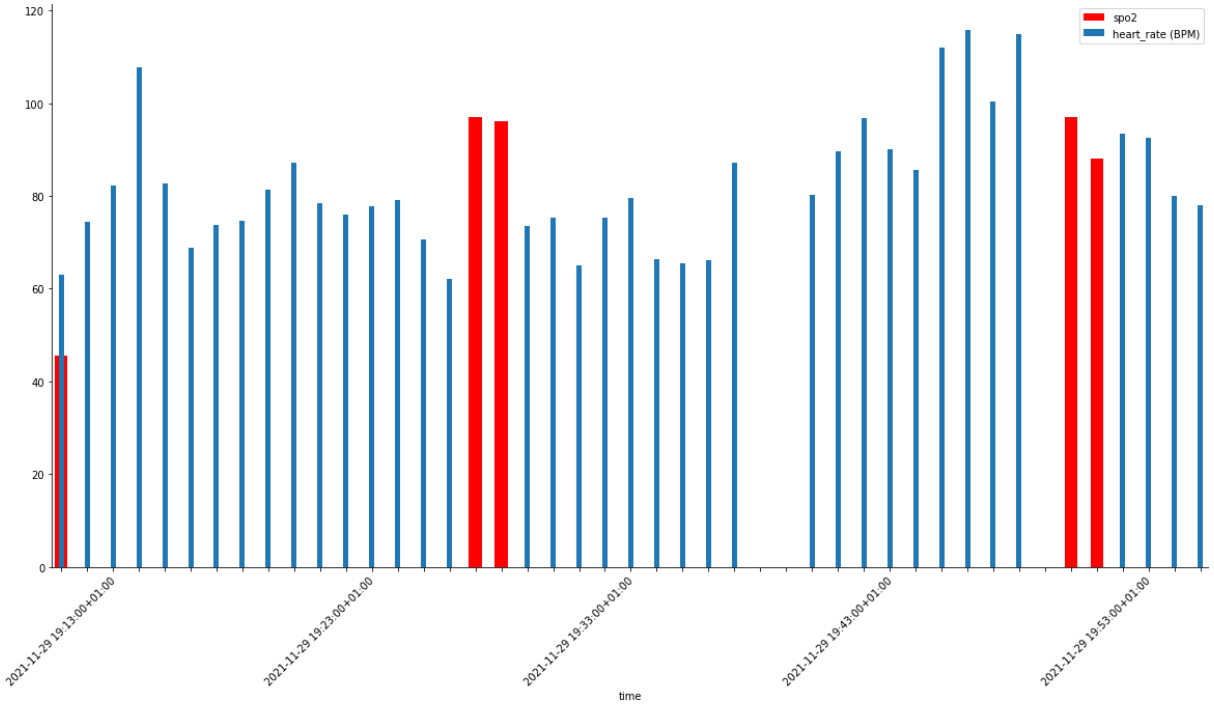
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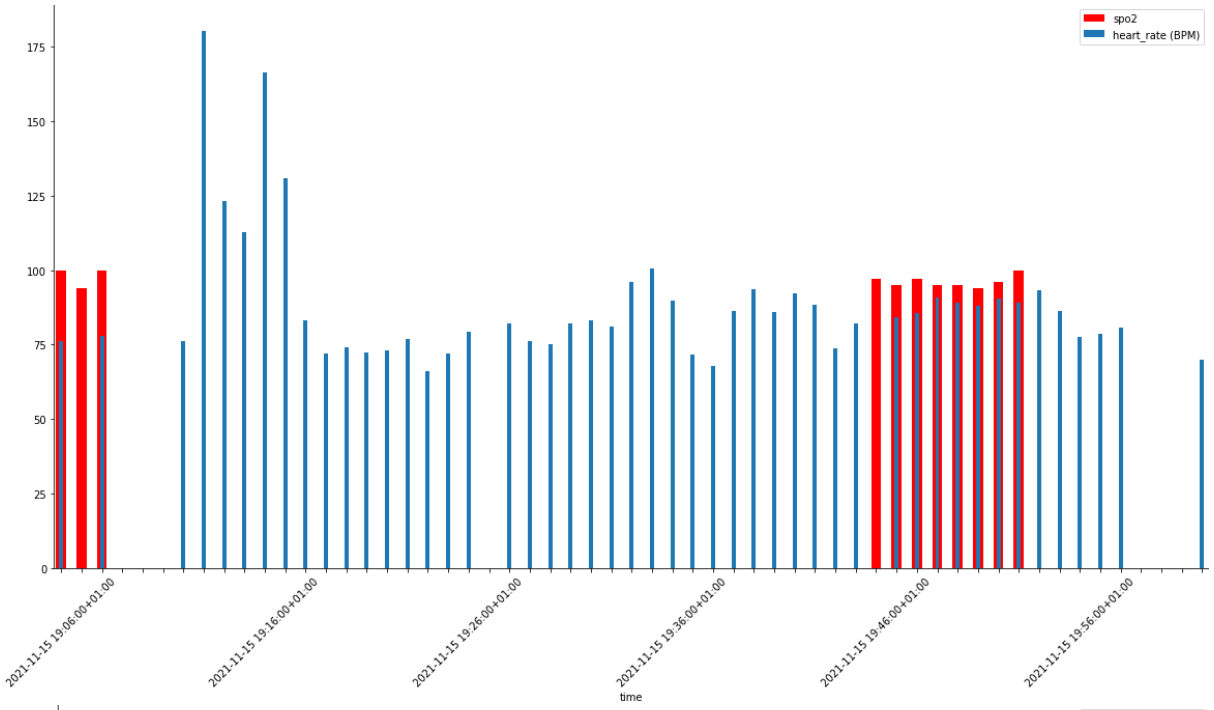

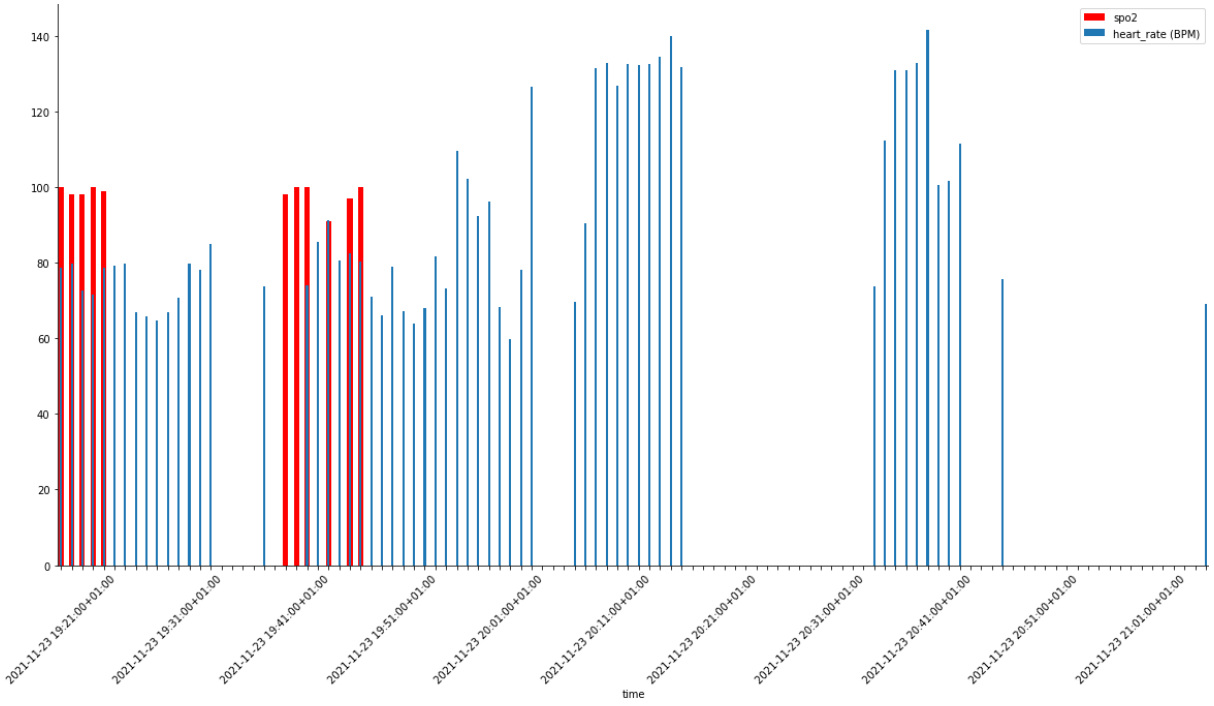

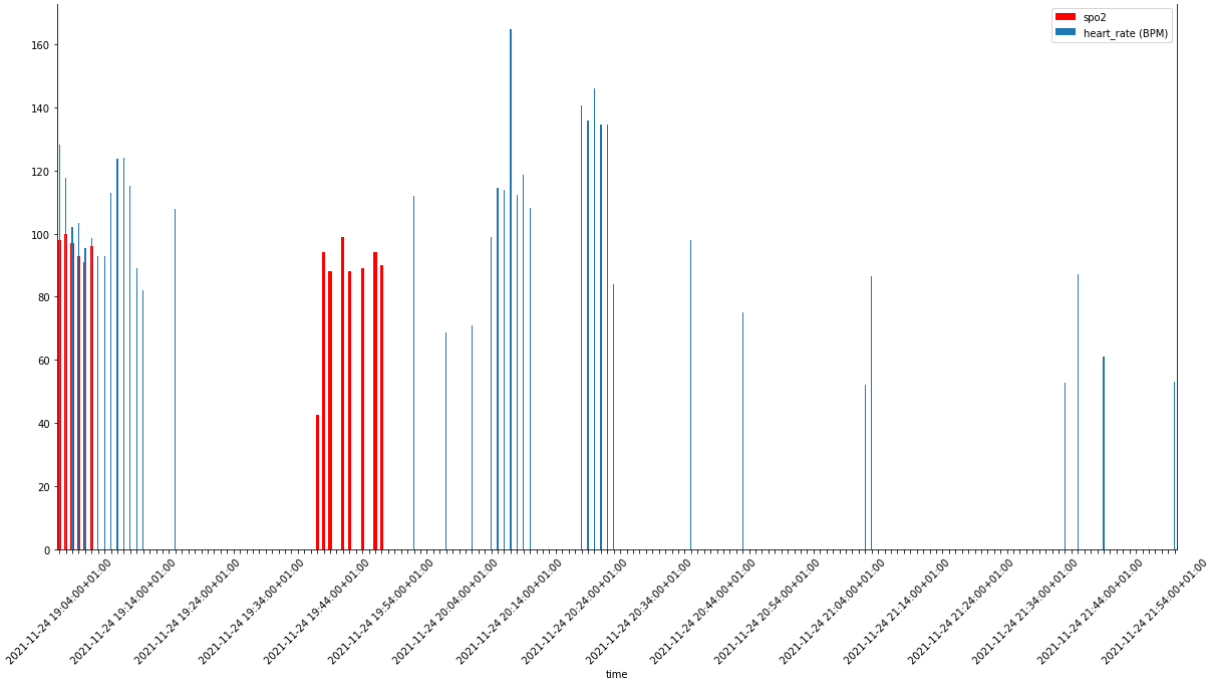
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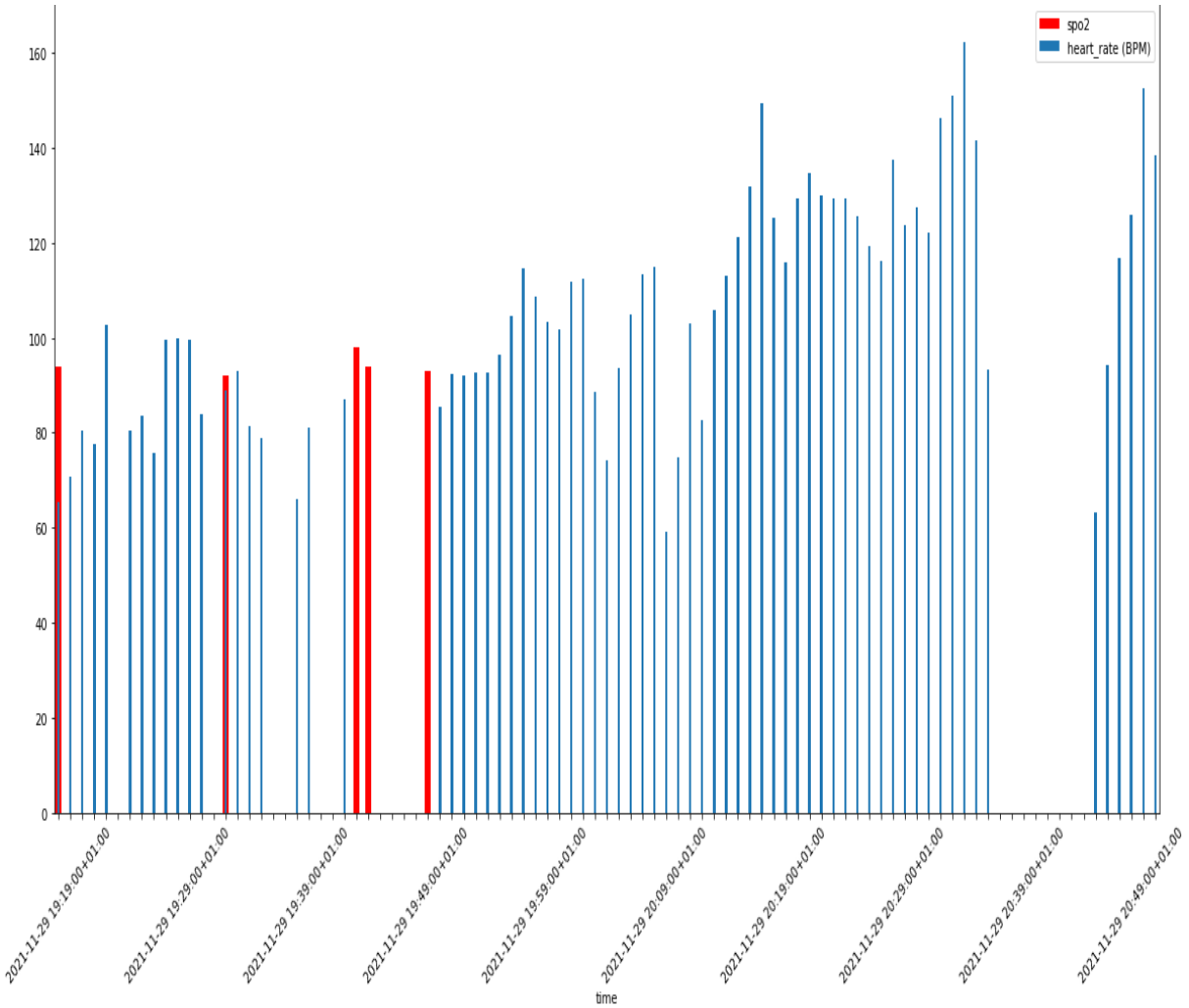
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