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SMARTCAP VALIDATION

Independent assessment from Universidad de Chile

Further to the independent assessment of SmartCap performed by Monash University Accident Research Centre, Austin Health Department of Respiratory & Sleep Medicine and the Institute for Breathing & Sleep, a validation of the SmartCap Fatigue Monitoring technology has been completed by researchers in the Faculty of Medicine at the University of Chile.

EdanSafe provided de-identified SmartCap data to Universidad de Chile researchers for the purposes of an independent assessment. In particular, the researchers focussed on identifying the extent to which the signals detected by SmartCap headwear matched clinical EEG, and also determining whether large data sets captured in a field setting reflected the circadian patterns expected.

I'm pleased to let you know that the study achieved both of these objectives. To paraphrase the findings:

- The SmartCap utilises signals that reliably represent EEG; and
- The SmartCap data, when analysed by time of day, adequately reflects the expected circadian patterns.

Attached to this letter is a translation of the full report.

Kind Regards,

Daniel Bongers

Project: Evaluation of "SmartCap" tecnology designed to monitor *on-line* the fatigue level of workers.

Applicant: División Ministro Hales (DMH), Codelco.

Investigator: Sleep and Chronobiology Laboratory, Department of Physiology and Biophysics, School of Medicine. University of Chile.

Progress Status: Completed.

Introduction:

Fatigue and accidents in the operational environment.

In the operational environment scenario where the operating system is highly dependent on human performance, fatigue should be defined as a propensity to degrade performance. From this perspective, fatigue can be seen as an indicator of baseline risk for the occurrence of errors and accidents.

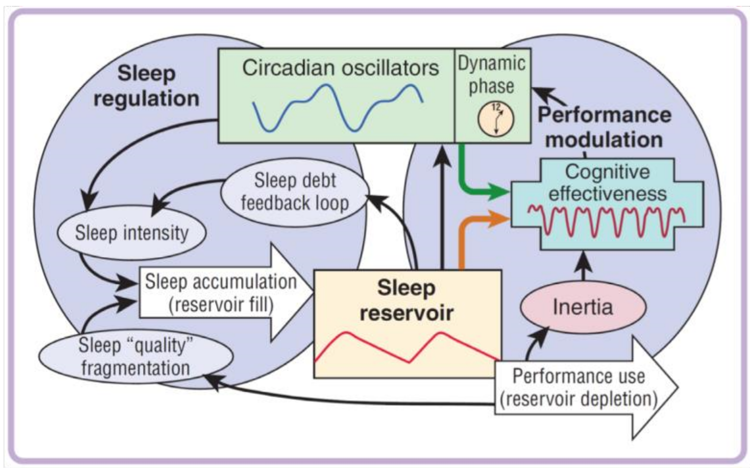
Current evidence shows that it is not predictable, moment-to-moment, if a particular action in a context of fatigue will be conducive to error. This suggests that the occurrence of accidents in the operational environment of fatigue, is a stochastic phenomenon. Studies in subjects undergoing sleep deprivation led to theorize that this hazardous yield variability arises from a condition of persistent instability in vigilance. That is, a configuration of high homeostatic sleep pressure, resulting in a rapid and uncontrollable transition to sleep, to which the subject resists making an increasing effort to achieve compensatory yield. Thus, the timely occurrence of an error arises from a brain state of effective transition to sleep for a short time, whilst vigilance is maintained with effort. Thus emerges a possible explanation of why a person deprived of sleep, prone to fatigue thus could not be fully alert to a decrease in performance, as he is unable to perceive any errors or omissions. This realises the usual discrepancy between self-perceived fatigue and reduced performance objective.

It is emphasised that the association between fatigue and accidents involves the coincidence in a period of reduced attention, high cognitive demands and significant consequences in the case when an error occurs.

Biological determinants of fatigue and strategies developed for prediction.

The magnitude of fatigue results from the interplay of multiple factors, namely time awake, circadian phase and workload (time on a specific task, complexity and intensity of the task).

In the context of increasing efforts to optimise fatigue risk control in the operational environment, there are various mathematical models to anticipate the occurrence of fatigue and proactively intervene in the course of that process. The vast majority of these models comprise three main components in the modulation of alertness and performance: circadian fluctuation of alertness and sleep propensity; homeostatic modulation of sleep-wake cycle (time awake, the time spent sleeping, and accumulated sleep debt); and sleep inertia (depends on the depth of sleep upon awakening. This dissipates exponentially from the time of awakening).



Modelo de los Tres Procesos representado esquemáticamente.
Figura obtenida de: Steven R. Hursh and Hans P.A. Van Dongen. Fatigue and Performance Modeling. En Meir H. Kryger Thomas Roth William C. Dement. *Principles and Practice ofSleep Medicine.* Elsevier Saunders. St Louis, Missouri. p: 745-752. 2011

Model of Three Processes represented schematically

The major limitation of these mathematical models lies in the failure to consider the inter-individual differences and the effect on the level of fatigue and the likelihood of an error due to sleep loss and circadian timing (vulnerabilities: larks verses owls, basal sleep requirements, experience in the specific task). Consequently, the most applicability is in predicting large-scale projects, thus providing a pattern that guides the planning of working hours. The value of these models becomes questionable for the individual case. It is in this context that SmartCap emerges as an innovative technology, while claiming to be able to report from moment to moment, and in a discrete numerical scale, the status of a particular users fatigue based on electroencephalographic criteria.

Properties promised by Smartcap technology.

1.- Ability to capture in the field electroencephalographic signals of sufficient quality to proceed with analysis.

2.- Determining a level of fatigue, second by second, given a window of 12 seconds into discrete categories that represent a growing state of fatigue (2, 3, 3+ and 4). This scale is presented as universal, therefore claims to have the same meaning for any subject and in any situation.

3.- Alarm generation for the states 3+ and 4. It assures that these alarms have high sensitivity and specificity.

4.- Generation of a database that stores the history of temporal records of all operators monitored.

Brief overview regarding EEG and its application in the analysis of fatigue and sleepiness.

Electroencephalography (EEG) is a technique that reports the electrical brain activity noninvasively. Discovered by Hans Berger in 1924, it represents a mature technology with 90 years of evolution. In classical EEG, a variable number of metal electrodes are divided into different positions on the scalp, using conductive paste or gel to reduce the resistance between the electrode and the skin. The spatial deployment of electrodes is to obtain information from the frontal, parietal, temporal and occipital lobes of both hemispheres of the brain.

Different types of analysis on voltage fluctuations in the various channels of EEG in both time series and in the frequency domain, report valuable information primarily for medical and scientific research applications. However, from the long evolution of this technology, researchers have found applications in other areas like psychology, social sciences and engineering (mainly in the area of "brain computer interface").

In the last decade, a dramatic reduction in size, weight and cost of EEG instrumentation, plus the possibility of wireless communication with other digital systems, has opened the possibility to further extend applications, reaching unsuspected areas, allowing even entry to homes, for entertainment, biofeedback, support learning and memory training (examples: emotiv.com, neurosky.com). At present there is an explosion of activity, experimentation and product development around this technology area.

EEG and fatigue analysis.

The proposed solutions throughout history for detecting fatigue levels presented vast difficulties that are not entirely resolved today. The technological approach to the problem has been aimed at creating a " drowsiness algorithm", able to discriminate the different steps in the spectrum transition from wakefulness to sleep. The variables used in the different algorithms have included eye movement, blink rate and, of course, the EEG. Most of these works have achieved only relative effectiveness in detecting fatigue and progressive loss in the ability to stay alert.

The inter-individual differences are the major confusion factor in the development of any algorithm that is based on the use of EEG for detecting fatigue and drowsiness, they do not escape the problem of predictive models, as I previously emphasised. The task becomes complex due to multiple physical and psychological variables that are operating at one time and specific individual on a given biological determinants known baseline. Another group of methodological and technical difficulties arising from the transfer order electroencephalogram from controlled laboratory conditions is the operational environment, including: the data reduction resulting from modifying a standard EEG arrangement, addressing the entire brain surface topography, a simplified EEG arrangement; the need to use dry electrodes (no conductive gel); distance limitations in signal receiving devices; transient loss of the signal, preventing continuous records; and lack of adherance of human resources.

Challenges facing Smartcap.

- Offer conditions for reliable recording in the operational environment.

- as an indicator of fatigue, a final common pathway for the integration of multiple variables, must address fatigue as a function of all the same underlying processes. Begs the question: is the discrete numerical scale that displays Smartcap evaluated as multidimensional fatigue or phenomenon, is it constructed from a subset of all variables involved? The immediate implication of this question involves the EEG and its ability to reflect fatigue as a continuous, progressive and multi-determined phenomenon.

-SmartCap must deal with inter-individual variations in relation to the determinants of fatigue and performance: the discrete numerical scale that Smartcap displays is applicable to all individuals? An affirmative answer would imply that it is possible to make a direct and universal behavioral translation for specific electroencephalographic markers.

Methods.

Data Collection.

- **Methodology of sleep deprivation.**

To have a wide range of experimental conditions on the homeostatic pressure for sleep, volunteers were subjected to different physiological states, based on the following criteria: the time of day the test is taken, the time from the last sleep, and the number of hours of sleep. The subjects were divided into two groups: (A) those who slept normally (minimum of 7 hours, having gone to sleep later than midnight) and (B) sleep deprived (having slept a maximum of 4 hours between 02:00 to 06:00). The recordings were made at two times during the day after the night of controlled sleep: from 09:00 to 11:00; or between 18:00 and 20:00.

- **Enrollment conditions.**

In all cases, recording occurred in parallel with medical standards electroencephalography (Alice PDx) and the data reported by Smartcap. While the subject was enrolled, he performed an attentional task of visual recognition: a 42-inch LED display (1920x1080) located at 1m from the subject, 150 crosses inscribed in a circle (shown in Figure 4) of gray (RGB (64,64,64)), were presented randomly positioned on a black background (RGB (0,0,0)). One figure, over a period of 3 seconds changes progressively towards a bright green color (RGB (0,255,0)). The time when the colour transition starts is set by a random Poisson distribution (average 10 seconds) to make it unpredictable. When the subject recognises figure distinguished from the others, must click within the circle. The system records the time difference between the start of the color transition and a valid click, as a record of attentional performance.

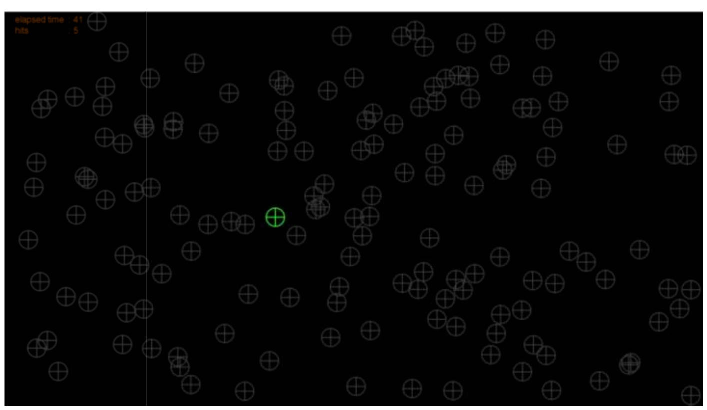


***Figure 1. Screenshot of attentional task*.**

Protocol 1.

15 subjects (age = 34.8 ± 9.3 years, of both sexes), 8 in group A and 7 in group B, were recorded in parallel and for a time of 20 minutes, a standard EEG (Alice PDx) and SmartCap EEG, while performing attentional task as described. A special version of Smartcap (provided by EdanSafe), capable of delivering via Bluetooth raw EEG data was used for this purpose. The objective of this protocol was to verify the technical quality of the raw data that is then subjected to analysis algorithms by Smartcap. All the records of this protocol were performed in AM hours.

Protocol 2.

Statistical analysis of logs obtained from a pilot study conducted in DMH, and from study a mining company in Australia. Language and programming environment R (www.rproject.org) was used for this purpose. The objective of this protocol was to analyze the correlation between the state of fatigue reported by Smartcap and biological determinants of health.

Results.

Protocol Development 1.

- **Description of SmartCap instrumentation.**

General aspects of the Smartcap instrumentation were analysed. First, it was verified that the system uses thread as dry electrical contact between the instrument and the skin of the user's forehead.

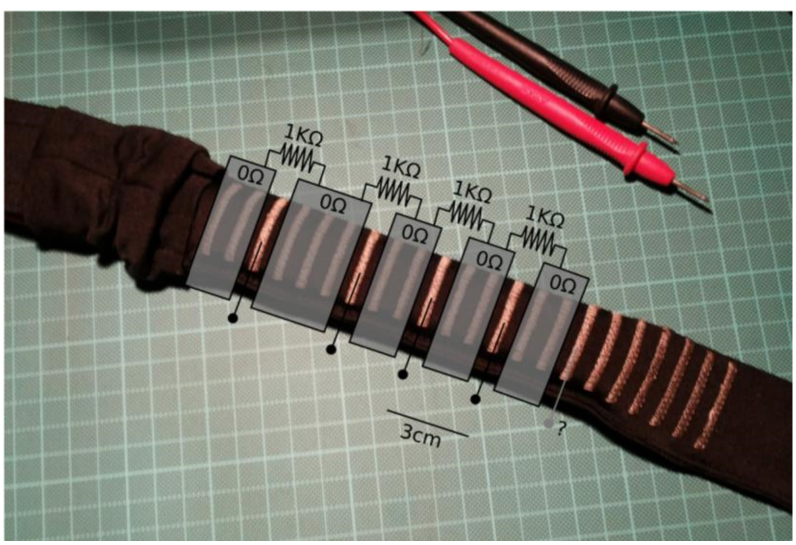


***Figure 2. Stitching thread in the Smartcap band and their conductivity relationship*.**

In figure 2 Smartcap Band and stitching thread is displayed. The thread used is high quality, providing a low electrical resistance, comparable to a metallic conductor. Several of these neighboring seams are shorted (gray boxes) and connected together with a resistance of about 1k. Among these groups are electrically isolated four-seam most likely corresponding to the electrodes whose derivations produce left and right channel EEG Smartcap. Delocalised interconnected and spatially, seams are probably an electrical reference. The band is connected (Figure 3) with ease to the processing unit (Figure 4) of Smartcap.

Figura 3. The band has a receptacle connector (16 pins) for the Smartcap processing unit.

Figure 4. Smartcap processing unit that encapsulates CPU, battery and Bluetooth communication module.

The Smartcap processes EEG signal, determining the level of user fatigue as a numerical category. It may also report various conditions of instrumental error or inability to determine a state of fatigue uncertainty of the algorithm.

- **Comparison of EEG signal provided by Smartcap and a standard EEG.**

The special version of Smartcap, delivering raw EEG signal wirelessly displays two channels at a rate of 256 samples per second. In figure 5 a 30 second portion of recorded Smartcap synchronised with a front channel

PDX Alice (200 Hz) is shown. It can be appreciated that Smartcap strongly filtered low frequency artifacts, such as flicker of the eye. Four flashes of similar amplitude are indicated with arrows on both records. Note how small they are in the register of Smartcap when compared with high and mid-frequency components.

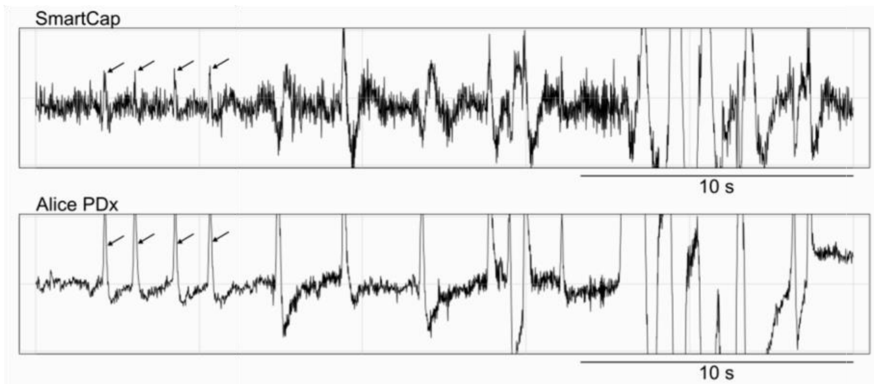


Figure 5. Synchronised 30 s record of Smartcap and a front channel Alice PDx.

The spectral analysis of segments corresponding to the same log shown in Figure 5, is displayed in Figure 6. It may be evident that the Smartcap filter attenuates low frequencies about 2 Hz (indicated by arrows)

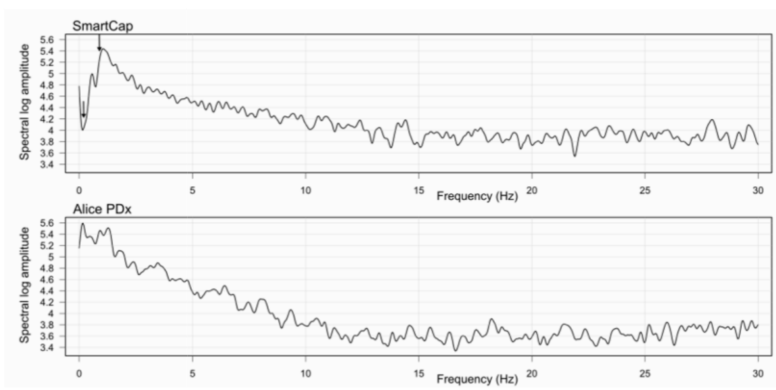


Figure 6. Spectral analysis of the same logarithmic scale segments shown in Figure 5.

Additionally, spectrograms were constructed for both logs (Smartcap / AlicePDx). Differences in both instrumentation filters, evidenced in Figure 6, are not a problem to verify that the overall spectral fluctuations over time are similar. For the case shown in Figure 7, it can be seen that the overall structure of the spectrum is the same in both cases, with lower spectral power in the central area (blue). More locally, the maximum spectral powers in the beta band, indicated by the labels A and B, are conserved in both spectra. The same applies to the decrease in power in theta band (labeled C).

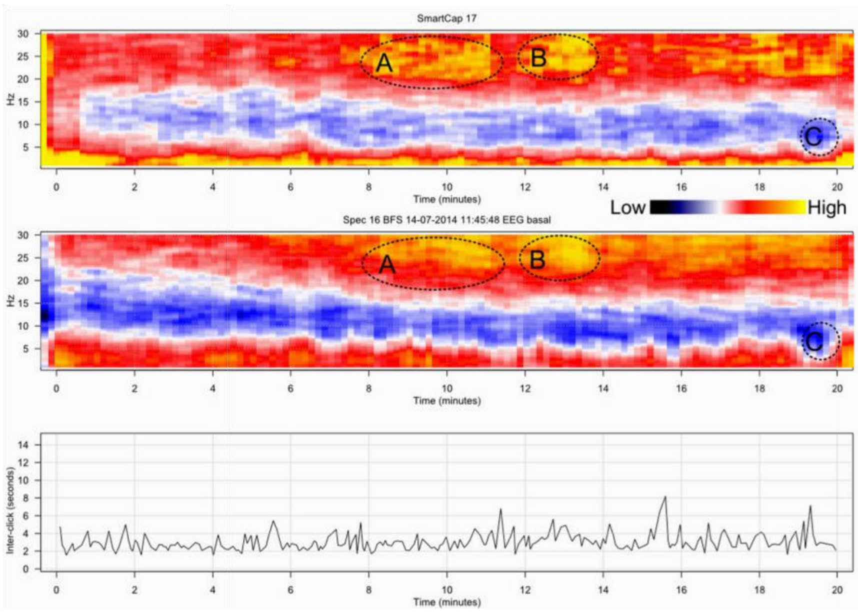


Figure 7. Spectrograms parallel records 20 minutes of Smartcap (above) and a front channel Alice PDx (center). Bottom panel corresponds to time related to attentional task.

The set of data provided by Smartcap was explored semi-quantitatively with respect to their behavior in the light of the main biological determinants considered in models predictive of fatigue. To this effect we considered only data from 17 records deemed valid for analysis.

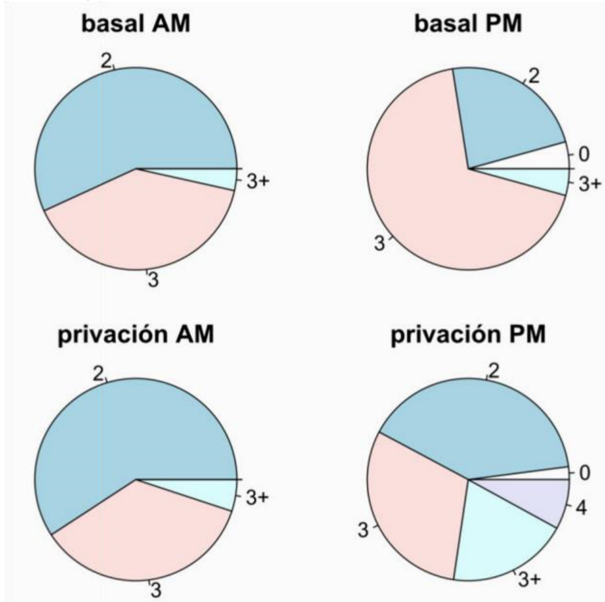


Figure 8. Distribution of states of fatigue reported by Smartcap as sleep debt (basal or deprived of sleep) and circadian phase (AM or PM).

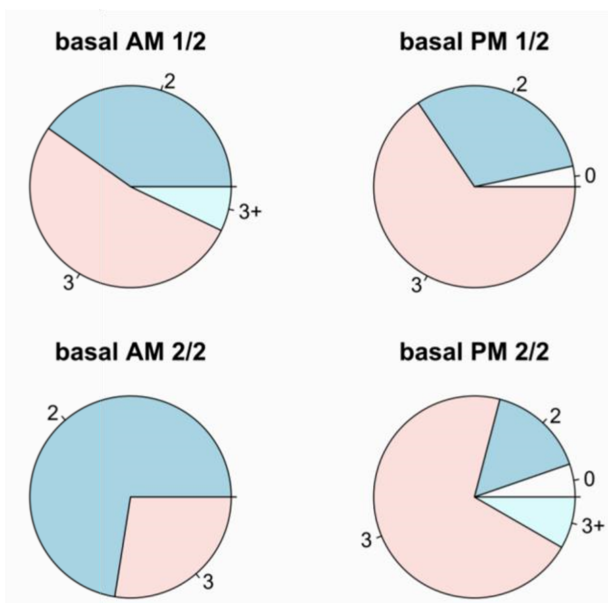


Figure 9. Distribution of states of fatigue reported by Smartcap as circadian phase (AM or PM) and time in the attentional task (first or second half). All data come from subjects without sleep deprivation.

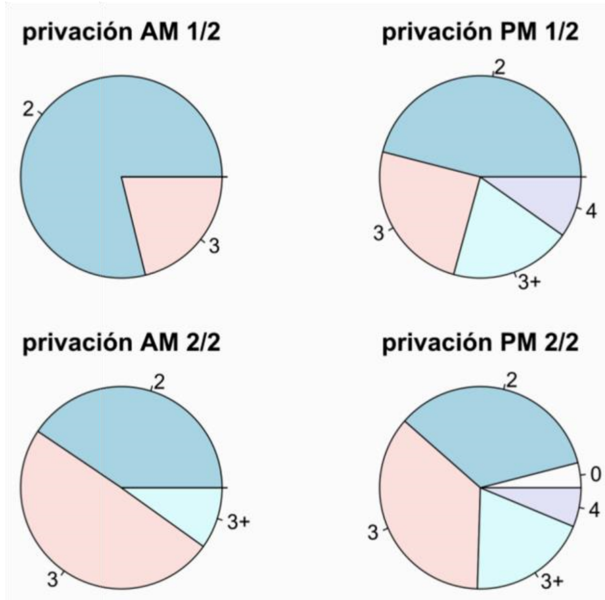


Figure 10. Distribution of states of fatigue reported by Smartcap as circadian phase (AM or PM) and time in the attentional task (first or second half). All data come from subjects with sleep deprivation.

Protocol Development 2.

- **Exploring fatigue levels reported by Smartcap in mining DMH (pilot study) and their relationship to circadian phase (day shift or night shift) and time shift.**

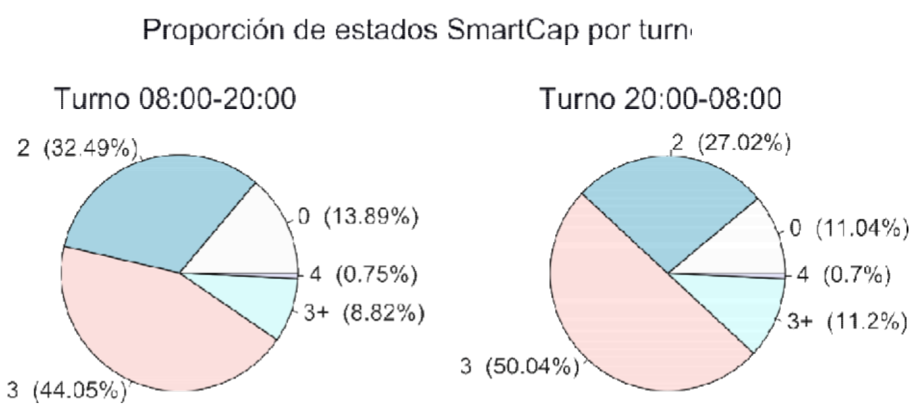


Figure 11. Distribution of states of fatigue reported by Smartcap as circadian phase (day shift or night shift).

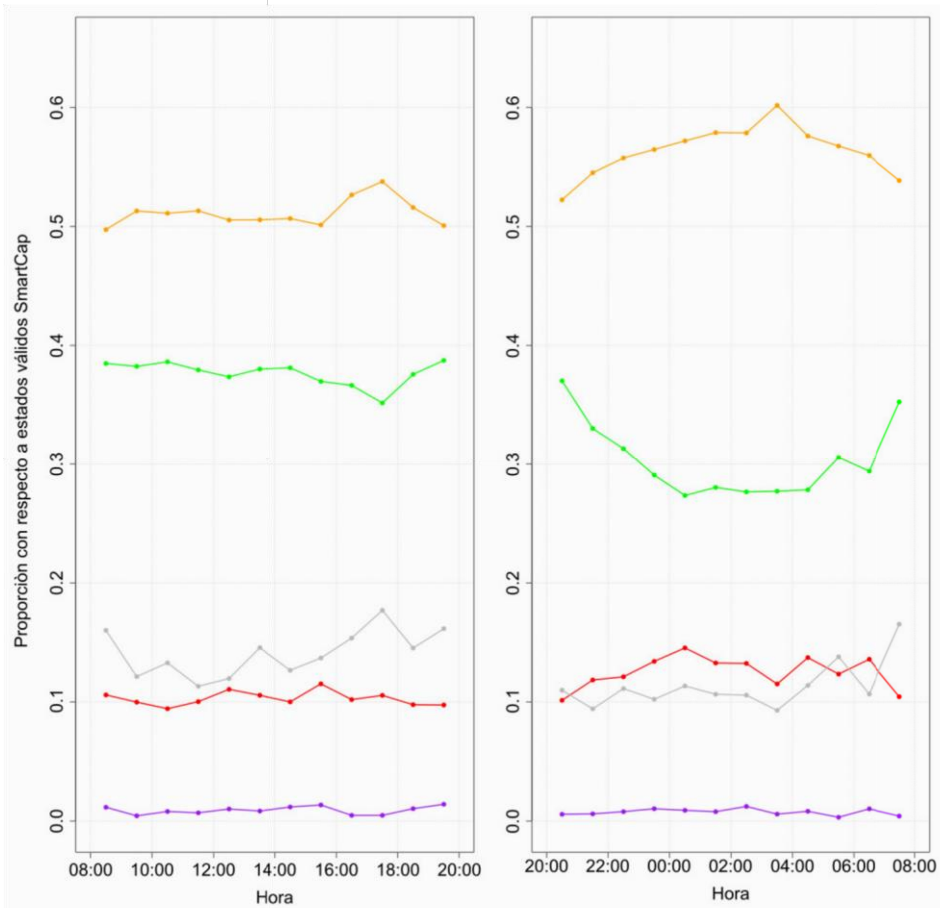


Figure 12. Time course of the distribution of states of fatigue (hourly) reported by Smartcap for each circadian phase (day shift or night shift). Green: 2; Yellow: 3; Red: 3+; Purple: 4; Gray: 0. Except for state 0, the values correspond to the ratio of valid states.

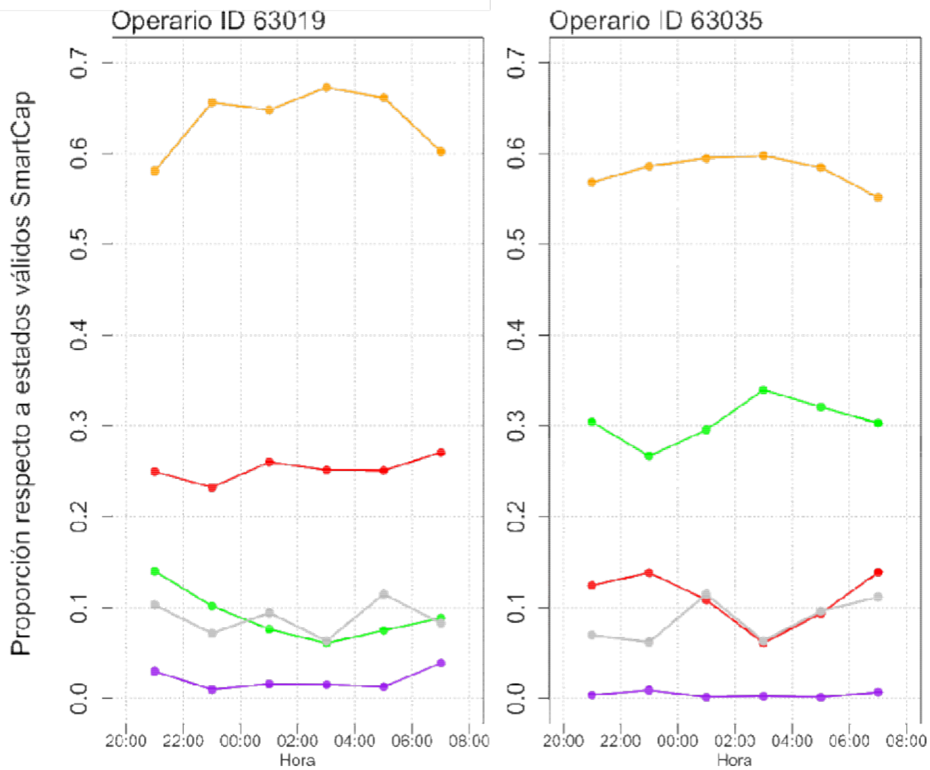


Figure 13. Time course of the distribution of states of fatigue (every two hours) Smartcap reported by two operators working in night shift. Green: 2; Yellow: 3; Red: 3+; Purple: 4; Gray: 0. Except for state 0, the values correspond to the ratio to valid states.

- **Exploring fatigue levels reported by Smartcap at Rio Tinto and its relation to circadian phase (day shift or night shift) and time shift.**

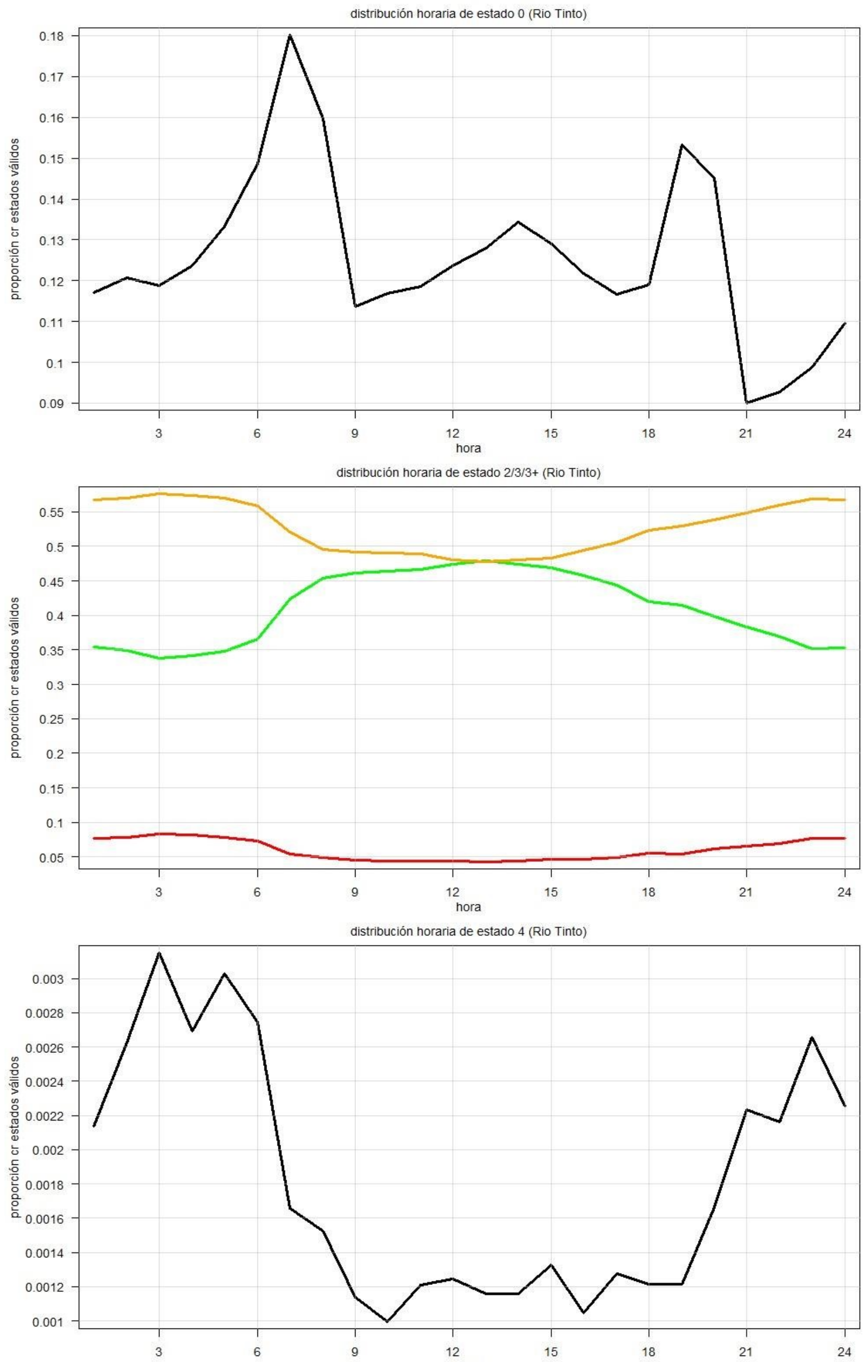


Figure 14. Time course of the distribution of states of fatigue reported by Smartcap in 24 hours.
Upper panel: distribution of state 0 with respect to all states reported by Smartcap. Central panel: distribution of states 2 (green), 3 (yellow) and 3+ (red), only with respect to valid states. Bottom panel: distribution of state 4, only with respect to valid states.

- **Effect of the confusion of states in the proportion of failures and false alarms.**

Smartcap operates as an automatic classifier of fatigue level of an operator based on features derived from the EEG. From the point of view of risk management, fatigue categories most relevant are those that generate an alert that could involve an intervention in the task (eg. Removal of operator). As in any classification system, there may be errors in detecting these categories: false negatives (the system fails to generate an alert conditions was necessary) and false positives (the system generates an alert when it was not necessary). The standard way to quantify the discriminatory power of a rating system is determining its sensitivity (rate of true positives correctly identified. A higher sensitivity, fewer false negatives) and specificity (true negative rate properly discarded. A greater specificity, fewer false positives).

In general it is not possible to optimize the sensitivity and specificity simultaneously, so one should choose a balance. In practice, seeking a very high sensitivity can be at the cost of a mediocre specificity, which would result in too many false alerts, hindering the continuity of the task, deteriorating confidence in the system diagnostics and, therefore, making it alerts less effective. This is especially the case if you expect the alert condition is unlikely. For example, if the sensitivity is 100%, the specificity is 90% and the probability of occurrence of an alert condition is 5%, the probability of a false alarm is 9.5% while the probability of a true alarm is 5% (about 2 of 3 alarms would be false). If the probability of occurrence of an alert condition reduces to 1%, only 1 in 10 alarms would be true.

The relevance of an alert can be determined taking into account failures in an attentional task such as the OSLER test, as was performed in assessing Smartcap by Monash University. The most extreme case studied in this assessment relates to 4 or more successive failures, corresponding to at least 12 seconds unanswered by the subject submitted to the OSLER test. This condition almost certainly corresponds to a period of sleep that would be high risk in the field. The condition occurs in 6.25% of the data studied. Smartcap results are: 100% sensitivity and specificity in 74.04% cutoff > = 3.683333; 94.74% sensitivity and 82.11% specificity in the cutoff > = 4. In the former case 80% would be potentially false alarms generated, and in the second case, 74%. Note that these results are not directly transferable to Smartcap as it operates in the field. The cutoff mentioned corresponds to the evaluation result of averaging the Smartcap along one minute and found an additional state "5" corresponding to said sleep, and does not refer to the "3+". In addition, the actual outcome of Smartcap is quantized into discrete states that are determined through a process of integration at two levels. To illustrate the relationship between the instantaneous state and the integrated state, simplified stochastic simulation was developed considering a single competition between two neighboring states.

The result is a sigmoid relationship can be seen in the following figure.

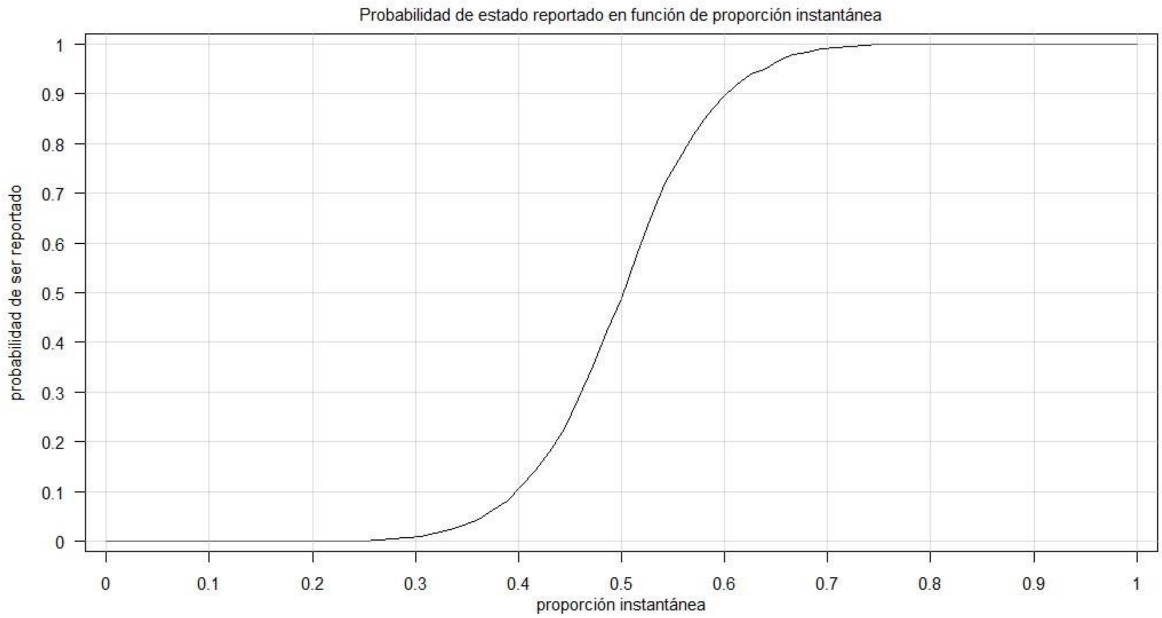


Figure 15. Relationship between ratio of instantaneous occurrence of a state and integrated reporting

The cutoff > = 3.683333, assuming states 3 and 4 correspond to the abscissa and deliver 683,333 with probability close to 1 the result "4". In practice, the quantization of the result becomes less controllable sensitivity and specificity. However, it is important that the measurement of specificity could yield a much higher value when you consider that an alarm condition reported not necessarily indicate the occurrence of a simultaneous attentional failure, but the propensity for such failure is briefly present.

Discussion:

Smartcap proved to be highly reliable with respect to the capture of electroencephalographic signal. During data acquisition, were few instances in which it was necessary to stop registration to rearrange the headband and re-establish the capture of EEG. With regard to the characteristics of the acquisition, we can conclude that Smartcap filtered low frequency components (about low 2 Hz), allowing to rule out the high rate engine artifact (eg eye blinking) and electrical activity of the muscles of the forehead (EMG), which is observed in raw front bypass.

The dataset provided by Smartcap under controlled experimental conditions, realised a dynamic that keeps consistency with major biological determinants of fatigue: the record in basal conditions and PM hours, found most represented by 3 and 3+ with respect the AM registry and under the same experimental conditions (effect of circadian phase and homeostatic sleep pressure). Under experimental conditions of sleep deprivation, PM schedule recording presented emergence of state 4, and an increased incidence of 3+ with respect thereto in AM (effect of circadian phase stepping joined homeostatic pressure for sleep, as sleep debt) schedule.

Fatigue as a function of elapsed time in a specific task, dividing the records evaluated in two halves.

In basal conditions and PM hours, it is observed an increase in the proportion of 3+ in the second half of the attentional task, with respect to the same point in the first half of the attentional task. Despite being predicted, it failed to observe the additive effect of sleep debt over time in attentional task circadian phase, so that no difference in the proportion of 3+ and 4 when comparing the first and second half of registration sleep restriction conditions and PM hours. The experimental design makes it impossible to consider these findings as conclusive, although they allowed an exploration of the behavior and data consistency.

The relationship between fatigue levels reported by Smartcap, circadian phase and time specific task could be analysed with a greater number of records due to available databases provided by DMH and Rio Tinto. In the case of DMH data, particularly on the night shift, you can see the additive effect of different biological determinants that are acting on fatigue: from the start of the shift a decreasing trend in the proportion of state 2 with subsequent rise in the final portion of the shift (possible effect of circadian modulation of alertness); the ratio of state 3 is an approximately reciprocal to state 2 course with initial climb, plateau, and finally fall in the latter portion of the shift; 3+ state ratio also shows a rising trend with subsequent initial plateau. State 4 is poorly represented in this dataset. State 2 occupied a ratio to the total valid states clearly lower when comparing the night shift to day; situation is reversed in the case of states 3 and 3+. Data provided by Rio Tinto mining reinforce the same findings. In this case, the state 4 was plotted individually, verifying that during the night the ratio to the total valid states is actually higher. This is consistent with the time at which the circadian modulation of alertness is at its lowest level.

Smartcap performance as a universal indicator fatigue became more equivocal to proceed with individual exploration of each of the 17 records obtained under controlled laboratory conditions, and considered valid for analysis. Interindividual variability consistent with those reported in the literature is observed. The incidence of electroencephalographic markers suggestive of sleep-wake transition, have variable reflection in the state of fatigue indicated by Smartcap. This variability also seems to manifest on data provided by DMH. In Figure 13, the dynamics of the states of Smartcap for two night-shift workers compared. While the curves realize similar trends, possibly reflecting the circadian fluctuation in alertness, both 2 and 3+ states have clearly disparate proportions in either worker. If indeed a worker shift after shift is less able to perform, or, if this applies only to phenotypic variations in their electroencephalographic manifestations it is not possible to conclude yet.

With respect to the ability of SmartCap to detect the process of transitioning to sleep, it is necessary to emphasize that fatigue and drowsiness, although colloquially used interchangeably in this context should be understood as two different concepts, but closely related. Drowsiness is the propensity to sleep and decreased alertness, therefore it is an engine of fatigue and is entirely modulated by the determinants described in the prediction model of the latter. There are two strategic directions to quantify the magnitude of sleepiness: through polysomnographic analysis, measuring the latency to achieve sleep, without any effort to maintain wakefulness (Multiple Sleep Latency Test, MSLT) or to the continuing effort to preserve (Maintaining Wakefulness Test, MWT); and behavioral observation, standardized tests designed to reveal the performance degradation (eg Psychomotor Vigilance Test, PVT, and Oxford Sleep Resistance Test, Test OSLER), ie, showing fatigue. We conclude then that sleepiness realises the physical and cognitive phenomena reflected behaviorally as fatigue. Therefore, the potential for desensitisation of SmartCap to account for transition to sleep, should be regarded as a failure in its capacity to detect the drowsiness dimensions of the fatigue process.

Perhaps the most important aspect of an interactive tool for risk management that allows to control reactive behavior incidents factors. In this regard it is essential that a defined course of action against alarm levels, something that is not formalised in Smartcap technology. The technical difficulty for this purpose depends on balancing sensitivity and specificity properly. If the specificity does not reach high enough levels, it can generate too many false alarms for the practical implementation of a scheme for management.

Conclusions:

- Smartcap instrumentation produced a reliable signal under laboratory conditions EEG.
- It is important to note that EEG obtained from frontal electrodes is susceptible to artifacts generated by contractions of facial muscles (particularly problematic example chewing gum because it produces a sustained artifact).
- The field data show that the stability problems of the signal (most of the conditions under which Smartcap reports "0") occur with a frequency lower than 20%, in the sample of DMH, also with Rio Tinto.
- The Consolidated Statistical Time fatigue levels that Smartcap delivers adequately reflects the dynamics of biological determinants that modulate fatigue.

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