Sleep Physiology and Monitoring

Survey

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Medical burden of sleep disorder

- Approximately 13.6 ± 0.6 million adults been diagnosed of sleep disorder (ICD G47.x, 2018)
- Sleep disorder is associated with higher rates of health care utilization and expenditures
- Overall incremental health care costs represents approximately $94.9 billion

Huyett P. J Clin Sleep Med. 2021

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Highlight

Survey

- Sleep characteristic across the lifespan
- Sleep monitoring
- Circadian and chronotype
  - Non-pharmacologic and non-mechanical managem
- Data-driven revolution in sleep science
- Sleep technology

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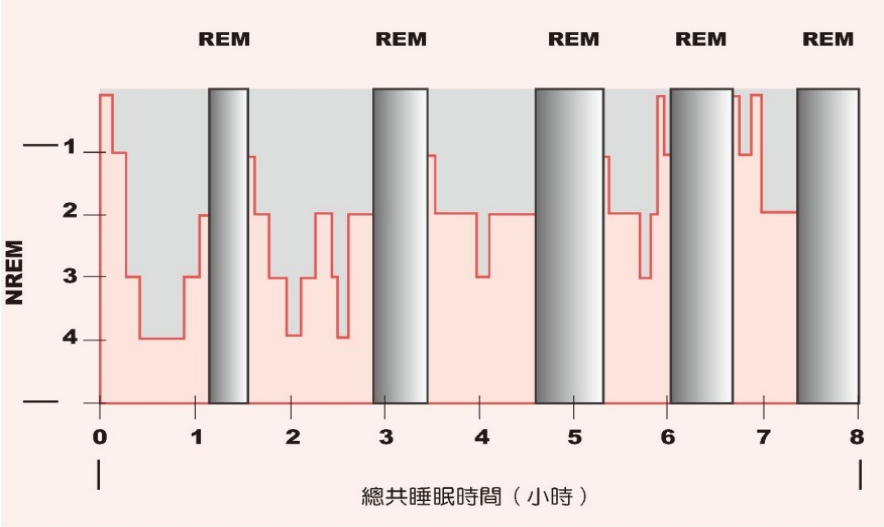
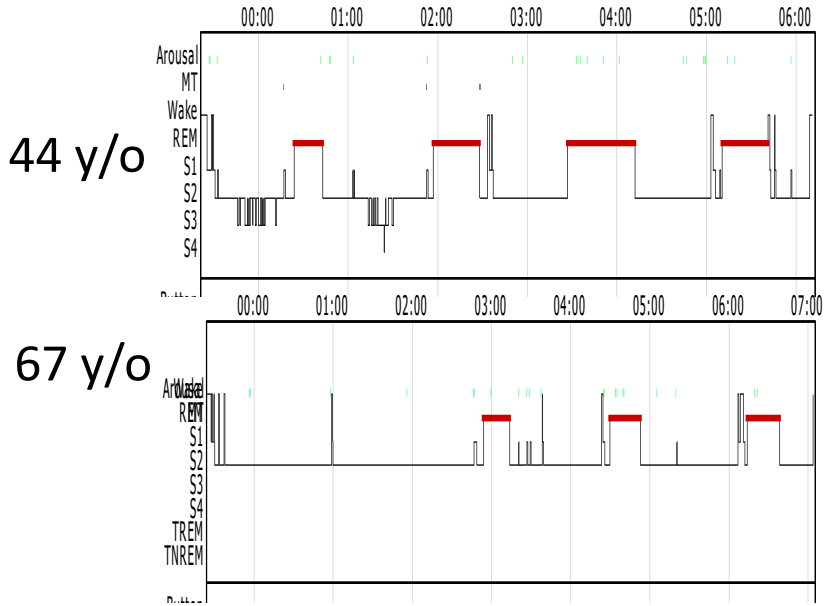
Physiology of sleep

- 一個睡眠週期約90分鐘，一個晚上有4~5個週期，睡眠週期分為非快速動眼期 (NREM)跟快速動眼期 (REM)
- 深睡期(SWS)為身體休息與內分泌激素分泌，如生長激素
- 夢境與日間學 整合成記憶 則發生在快速動眼期

Sleep stage hypnogram





Borbély Hum Neurobiol. 1982;1(3):195

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Sleep stage across lifespan

週期	兒童	年輕人	老年人
Wake 清醒比例 (%)	<	5	>
REM 快速動眼期比例 (%)	=	20-25	=
NREM非快速動眼期比例 (%)			
N1 1	<	2-5	>
N2 2	=	45-55	>
3 SWS	>	3-8	<
4 SWS	>	10-15	0
總共睡眠時間	10-12	8-10	6-8

Function of sleep: memory

- Sleep promotes consolidation of memory learned before sleep and acquisition of new memories learned after sleep
- Slow wave sleep (SWS) and REM were beneficial for declarative and procedure memories, respectively
- Recently, REM has been reported to facilitate the verbal learning by consolidation of language-related learning
  - REM and SWS deprivation adversely affected explicit verbal recall.
  - REM is associated with verbal function in Down syndrome children

Mednick S Nat Neurosci. 2003; Rauchs G. J Sleep Res. 2005; Casey SJ *Neuropsychology.* 2016; Spano G. *Proc Natl Acad Sci* 2018, Lee NC Journal Formosa Medical Asociation 2020

Sleep duration across lifespan: short sleep duration is harmful

Survey 1-2

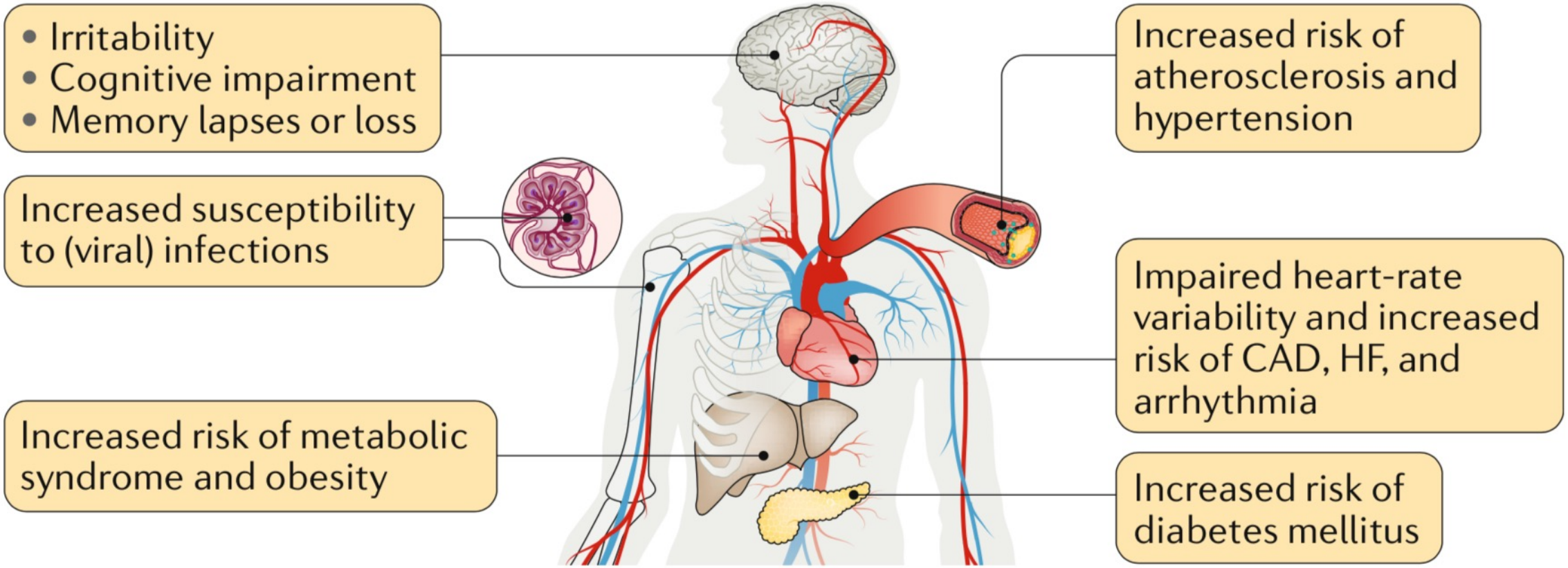


Fig. 3 | **General effects of short sleep duration on different organs and systems.** Short

Hirshkowitz M. National Sleep Foundation 2015; Tobaldini E. Nature Reviews Cardiology 2019

Measurement of sleep

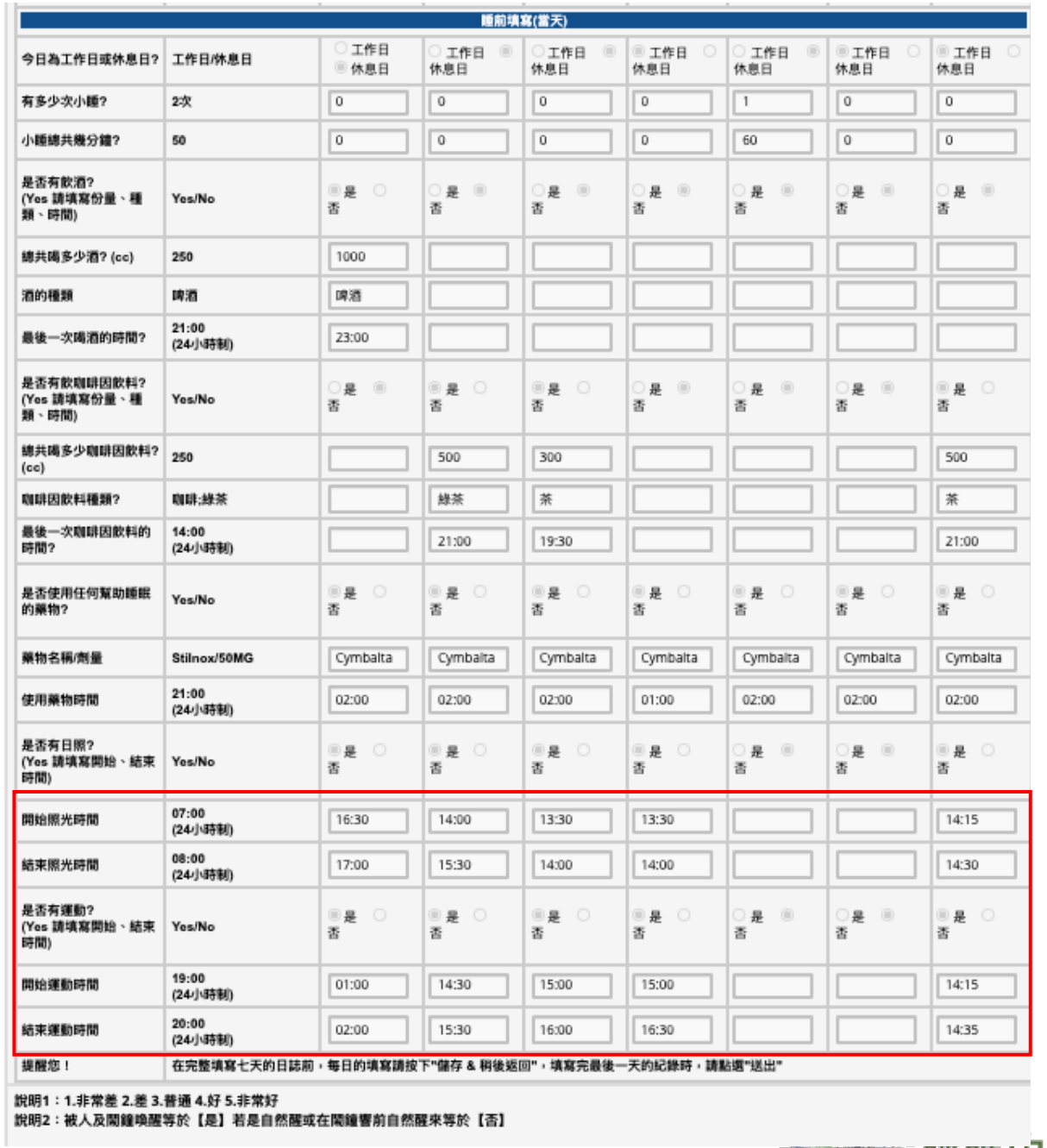
- Subjective
  - Habitual sleep pattern: sleep log
  - Sleep quality:
    - Pittsburgh Sleep Quality Index (PSQI) (PSQI>5 poor quality)
    - Visual analog scale
- Objective
  - Polysomnography (PSG)
  - Actiwatch
  - Single lead EEG

Sleep log: self report habitual sleep pattern
早上填寫前一晚

早上填寫(前一晚)	範例	第一天	第二天	第三天	第四天	第五天	第六天	第七天
提醒您！	在完整填寫七天的日誌前，每日的填寫請按下"儲存 & 稍後返回"，填寫完最後一天的紀錄時，請點選"送出"							
日 期	01-02-2019 (MM-DD-YYYY)	04-30-202'	05-01-2021	05-02-202'	05-03-202'	05-04-2021	05-05-202'	05-06-2021
星期幾	星期一	星期五	星期六	星期日	星期一	星期二	星期三	星期四
就寢時間(躺上床的時間)	22:15 (24小時制)	01:20	04:20	04:50	03:30	05:30	04:20	05:00
嘗試入睡時間	23:30 (24小時制)	01:22	11:00	05:00	03:35	05:35	04:30	05:05
睡著所需時間	45分鐘	1	0	3	5	10	10	5
醒來的次數(最後醒來不算)	3	1	1	0	0	1	1	3
總計醒來的時間(最後醒來不算)	60分鐘	2	2	0	0	2	2	5
最後醒來時間	6:35AM	09:50	11:00	13:00	12:00	13:00	13:00	12:45
起床時間	7:20Am	10:00	11:05	13:05	12:05	13:05	13:05	12:50
自覺睡眠品質如何?	4 (請見下方說明1)	3	3	3	3	3	3	3
備註	感冒							
今日是否被鬧鐘喚醒?	Yes/No (請見下方說明2)	○是 ◉否	◉是 ○否	◉是 ○否	○是 ◉否	○是 ◉否	◉是 ○否	○是 ◉否
睡前填寫(當天)								

Sleep log: self report habitual sleep pattern
睡前填寫當天

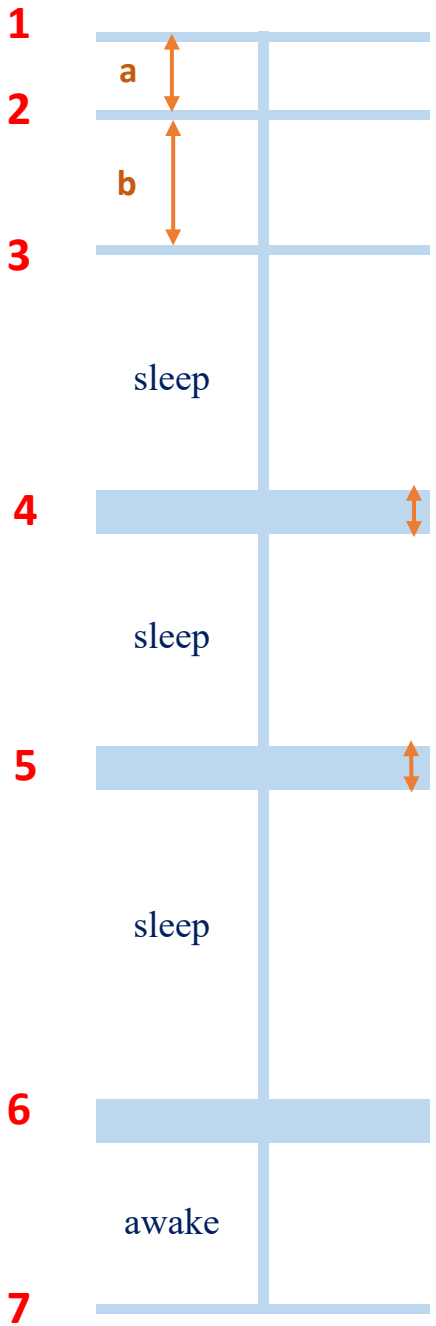
- Parameter
  - Time in bed (TIB)
  - Time to try to fall asleep
  - Latency of sleep onset (LSO)
  - Wake after sleep onset (WASO)
  - Sleep hour
  - Sleep quality
  - Sleep efficiency= sleep hour/TIB



睡前填寫(當天)

今日為工作日或休息日?	工作日/休息日	○工作日 ◉休息日	○工作日 休息日	○工作日 休息日	○工作日 休息日	○工作日 休息日	◉工作日 ○休息日	◉工作日 ○休息日
有多少次小睡?	2次	0	0	0	0	1	0	0
小睡總共幾分鐘?	50	0	0	0	0	60	0	0
是否有飲酒? (Yes 請填寫份量、種類、時間)	Yes/No	◉是 ○否	◉是 ○否	○是 ◉否	○是 ◉否	◉是 ○否	◉是 ○否	◉是 ○否
總共喝多少酒? (cc)	250	1000						
酒的種類	啤酒	啤酒						
最後一次喝酒的時間?	21:00 (24小時制)	23:00						
是否有飲咖啡因飲料? (Yes 請填寫份量、種類、時間)	Yes/No	○是 ◉否	◉是 ○否	◉是 ○否	○是 ◉否	◉是 ○否	◉是 ○否	◉是 ○否
總共喝多少咖啡因飲料? (cc)	250		500	300				500
咖啡因飲料種類?	咖啡;綠茶		綠茶	茶				茶
最後一次咖啡因飲料的時間?	14:00 (24小時制)		21:00	19:30				21:00
是否使用任何幫助睡眠的藥物?	Yes/No	◉是 ○否	◉是 ○否	◉是 ○否	○是 ◉否	◉是 ○否	◉是 ○否	◉是 ○否
藥物名稱/劑量	Stilnox/50MG	Cymbalta	Cymbalta	Cymbalta	Cymbalta	Cymbalta	Cymbalta	Cymbalta
使用藥物時間	21:00 (24小時制)	02:00	02:00	02:00	01:00	02:00	02:00	02:00
是否有日照? (Yes 請填寫開始、結束時間)	Yes/No	◉是 ○否	◉是 ○否	◉是 ○否	◉是 ○否	○是 ◉否	◉是 ○否	◉是 ○否
開始照光時間	07:00 (24小時制)	16:30	14:00	13:30	13:30			14:15
結束照光時間	08:00 (24小時制)	17:00	15:30	14:00	14:00			14:30
是否有運動? (Yes 請填寫開始、結束時間)	Yes/No	◉是 ○否	◉是 ○否	◉是 ○否	◉是 ○否	○是 ◉否	◉是 ○否	◉是 ○否
開始運動時間	19:00 (24小時制)	01:00	14:30	15:00	15:00			14:15
結束運動時間	20:00 (24小時制)	02:00	15:30	16:00	16:30			14:35
提醒您！	在完整填寫七天的日誌前，每日的填寫請按下"儲存 & 稍後返回"，填寫完最後一天的紀錄時，請點選"送出"							

說明1：1.非常差 2.差 3.普通 4.好 5.非常好
說明2：被人及鬧鐘喚醒等於【是】若是自然醒或在鬧鐘響前自然醒來等於【否】



Time to get on bed

Time to try to fall sleep

Onset latency

Awake 1

Awake 2

Last awake

Time to get off bed

Actiwatch: 1st Rest epoch

Actiwatch: Rest-S 後1st Rest epoch

Actiwatch: Rest 後1st Active epoch

Sleep log

① Time in bed (TIB) = 7 – 1

② Onset latency = b

③ Sleep onset = 3

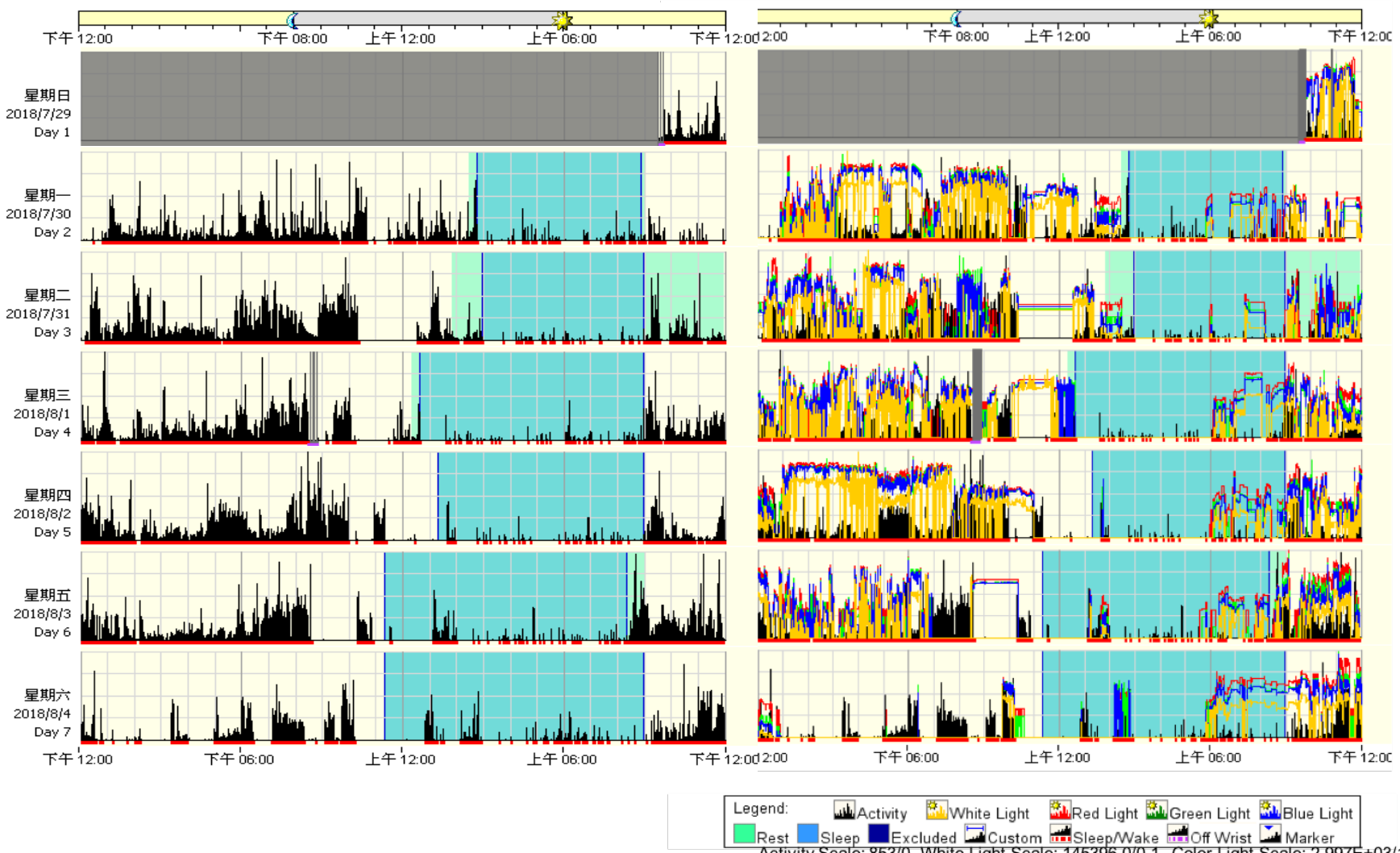
④ Sleep period = 6 - 3

⑤ Frequency of awake = 2

⑥ WASO = c + d

⑦ Total sleep time = 6 – 2 – b – c – d

Actiwatch: objective measurement of sleep-pattern



	Avg
Time in Bed (hr)	8:19:17
Total Sleep Time (hr)	6:44:38
Onset Latency (min)	14.43
Sleep Efficiency (%)	81.85
WASO (min)	40.07
#Awak.	41.29

Smith MT. J Clin Sleep Med. 2018

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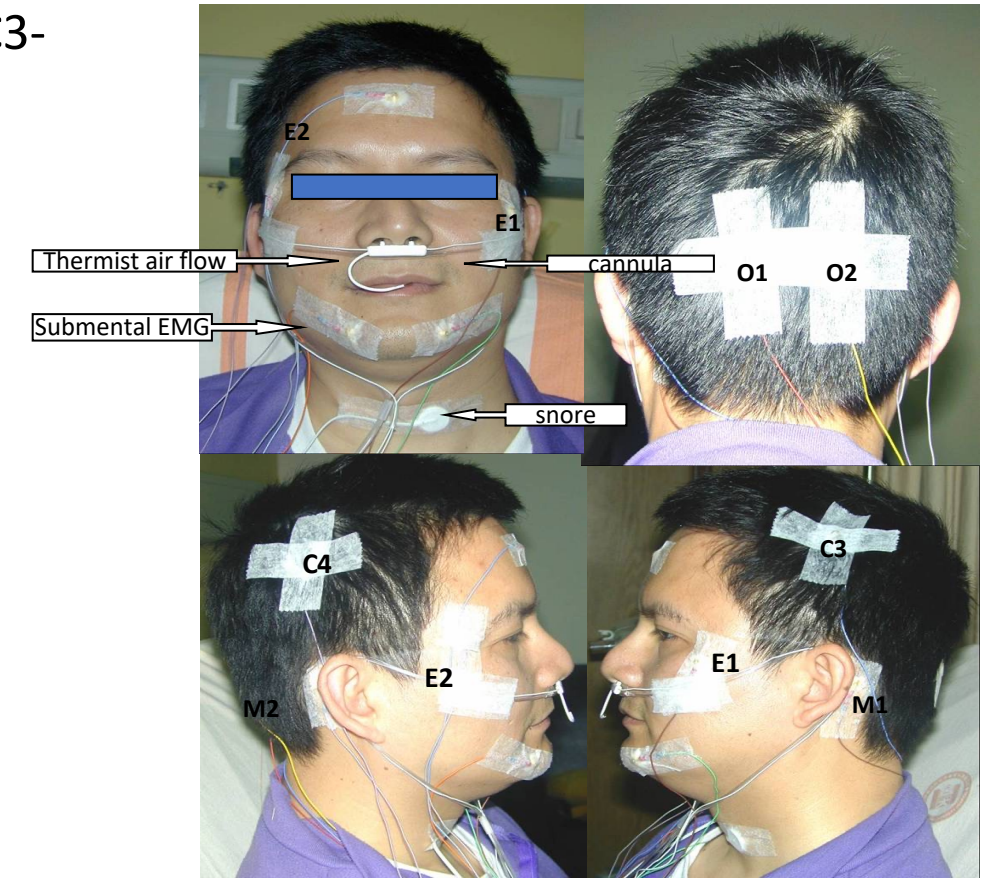
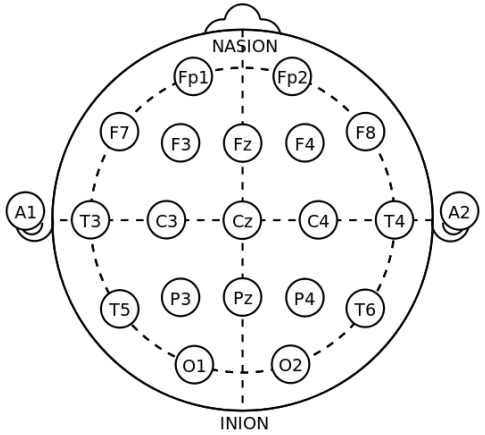
Polysomnography: montage

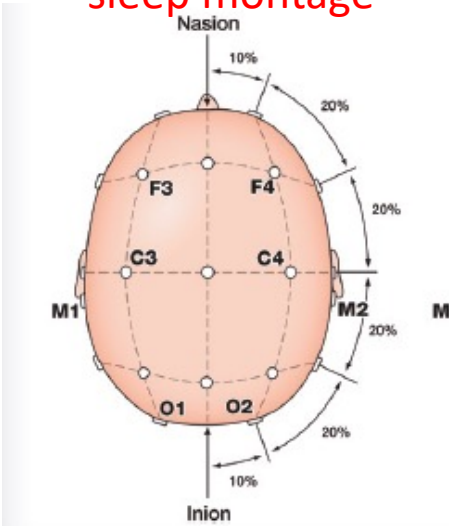
- 6 EEG: F4-M1, C4-M1, O2-M1, F3-M2, C3-M2, O1-M2
- 2 EOG: E1-M2, E2-M2
- EMG: submental (3), leg (2), arm (2)



seizure montage

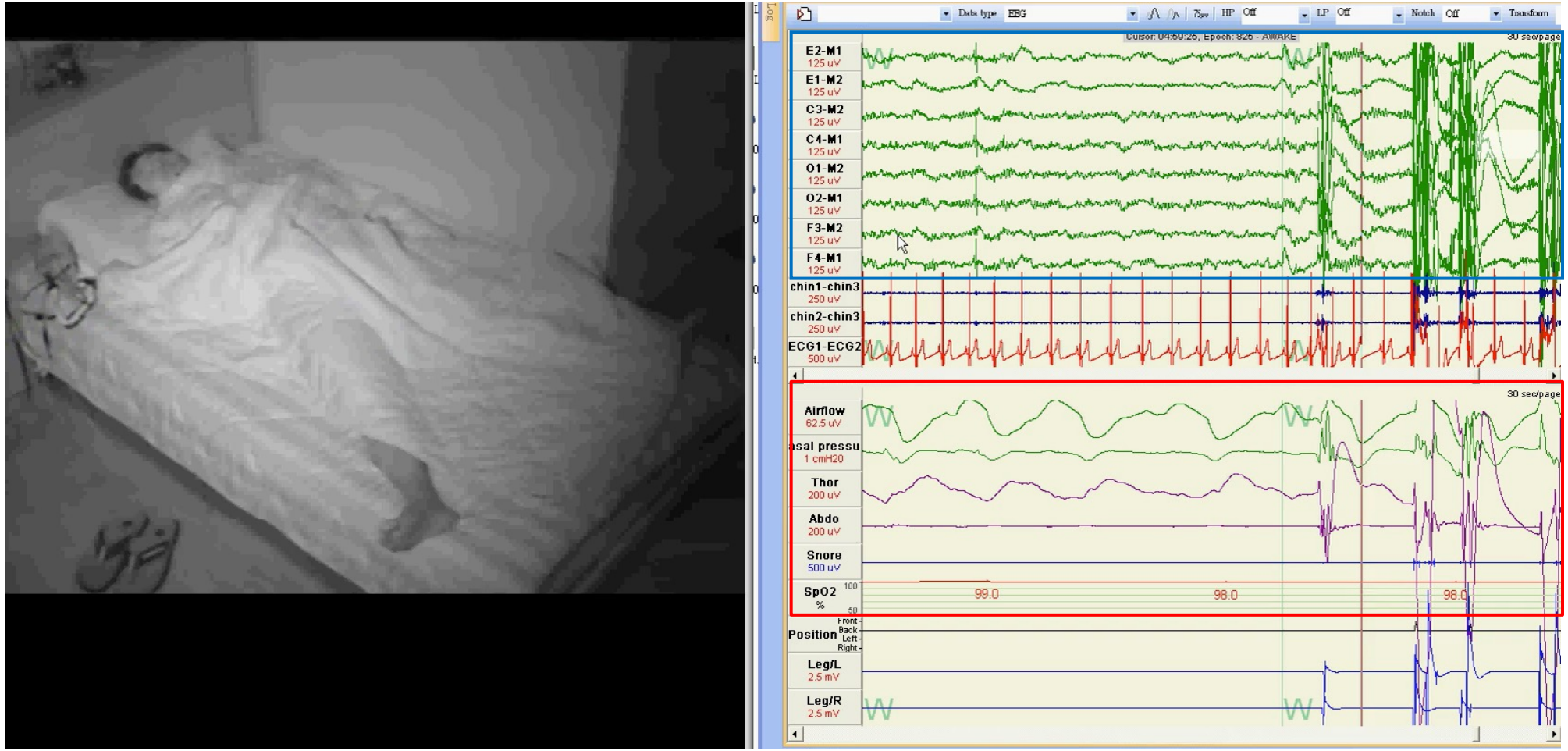


sleep montage



Berry RB. The AASM Manual for the Scoring of Sleep and Associated Events: Rules, Terminology and Technical Speci cations. Version 2.4

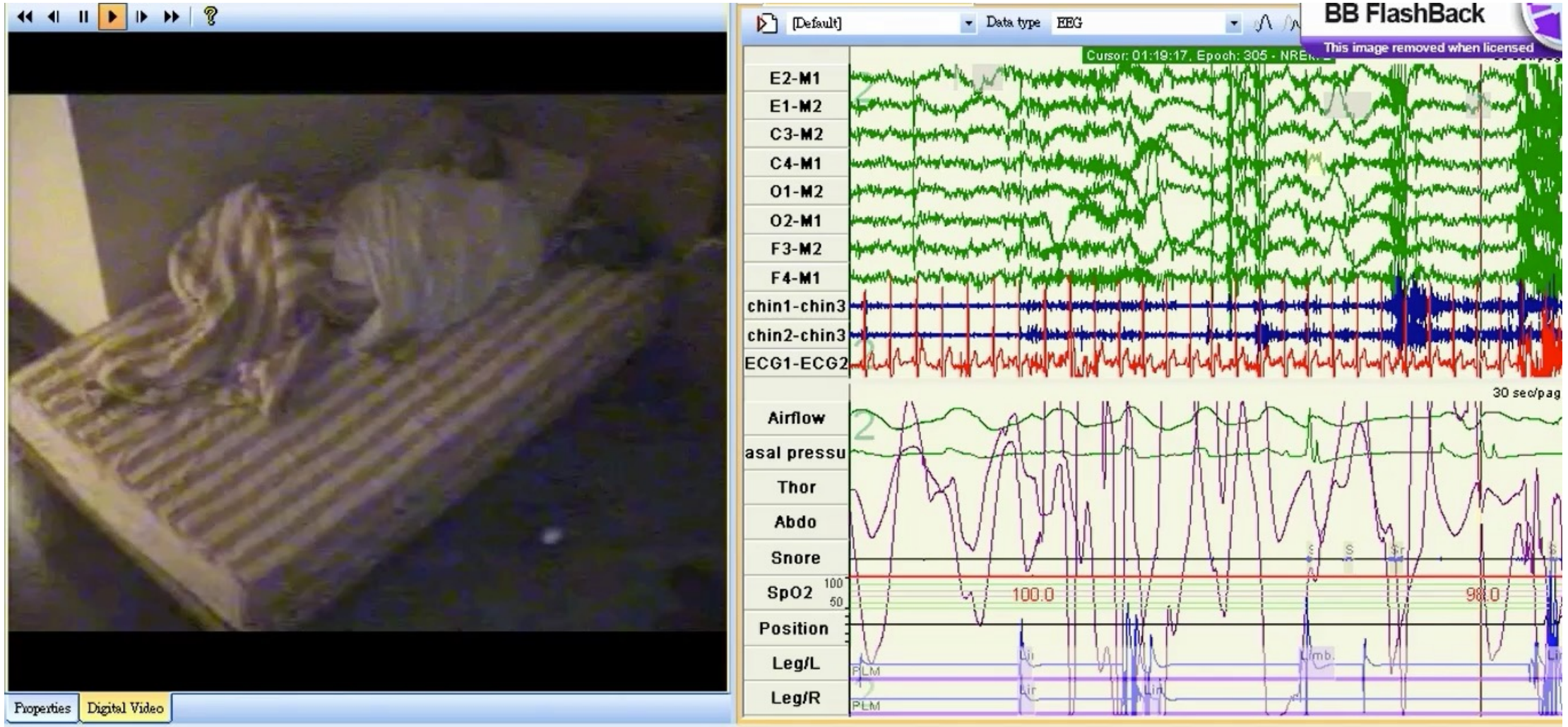
Video polysomnography: propriospinal myoclonus



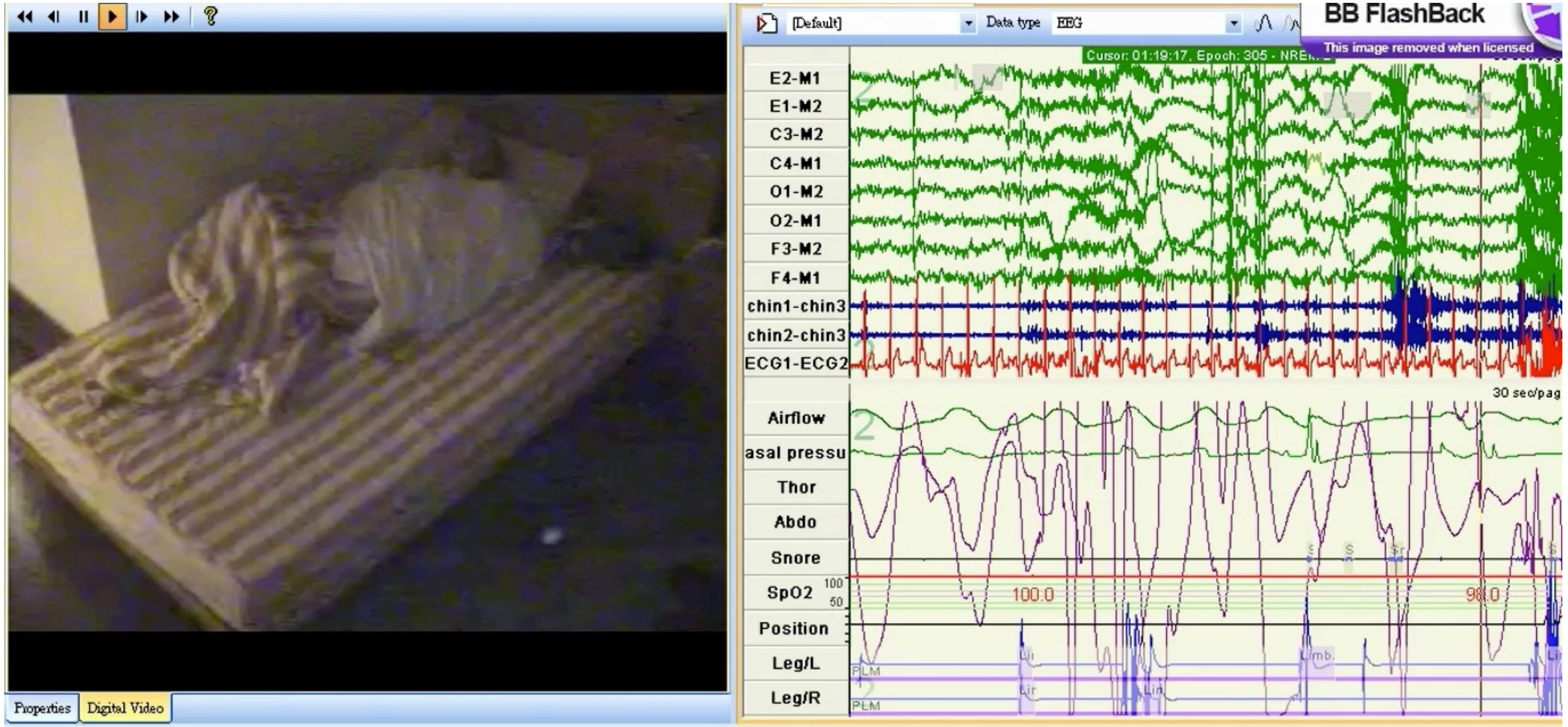
EEG

breathing event

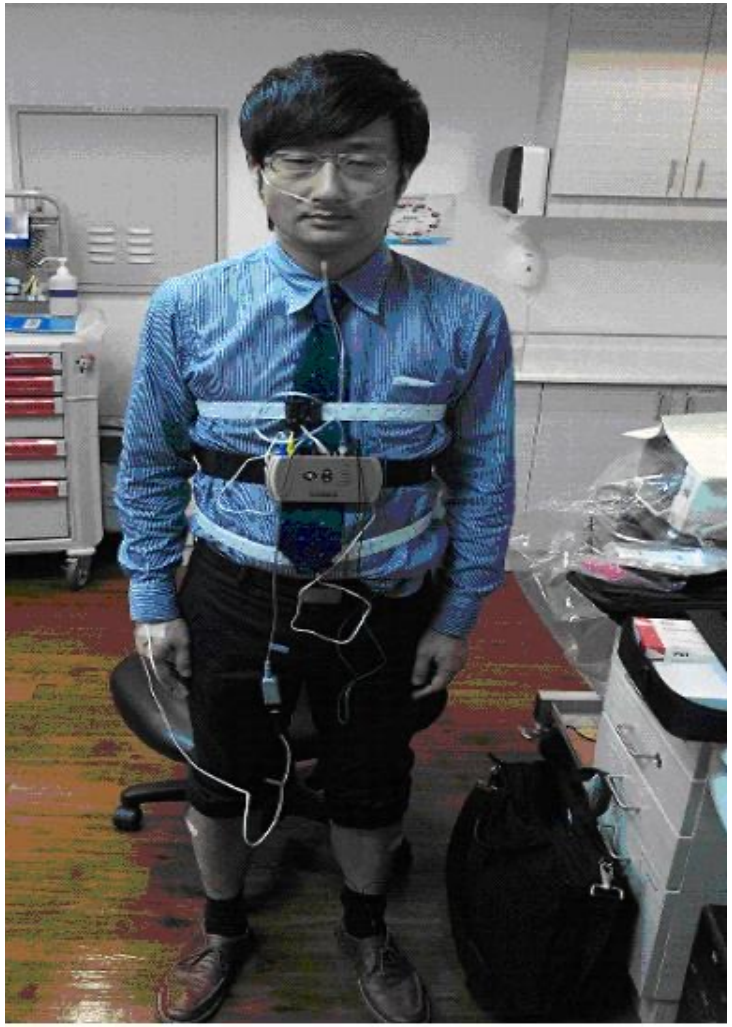
Video polysomnography: Confusional arousal



Video polysomnography: Confusional arousal



Home sleep testing (HST) for diagnosis of OSA



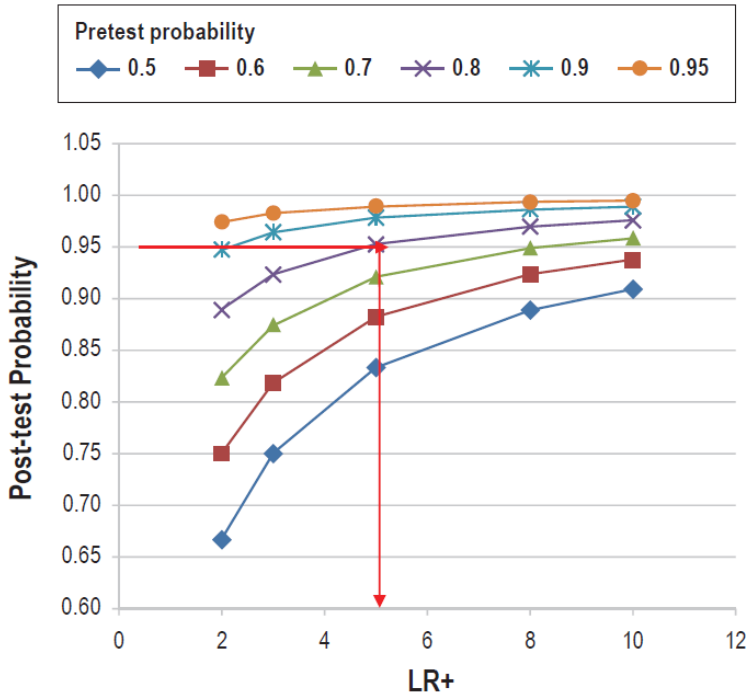
- Portable monitor (PM) classification
  - Type 2: ≥ 7 channel
  - Type 3: ≥ 4 channel including ventilation, HR or ECG, and SpO_2
  - Type 4: 1 or 2 channel
- PM not appropriate for patients
  - Comorbidity: moderate-severe pulmonary disease, NMD, or CHF
  - Sleep disorders: CSA, PLM, insomnia, parasomnia, circadian rhythm disorders, narcolepsy

Collop NA J Clin Sleep Med 2007

Out-Of-Center testing: SCOPER classification

- SCOPER: Sleep, Cardiovascular, Oximetry, Position, Effort, and Respiratory
- Criteria for clinically practice: LR+ ≥ 5; Sensitivity≥0.825; In-lab AHI ≥ 5/hr

Sleep	Cardiovascular	Oximetry	Position	Effort	Respiratory
S_1 – Sleep by 3 EEG channels* with EOG and chin EMG	C_1 – more than 1 ECG lead – can derive events	O_1 – Oximetry (finger or ear) with recommended sampling	P_1 – Video or visual position measurement	E_1 – 2 RIP belts	R_1 – Nasal pressure and thermal device
S_2 – Sleep by less than 3 EEG* with or without EOG or chin EMG	C_2 – Peripheral arterial tonometry	O_{1x} – Oximetry (finger or ear) without recommended sampling (per Scoring Manual) or not described	P_2 – Non-visual position measurement	E_2 – 1 RIP belt	R_2 – Nasal pressure
S_3 – Sleep surrogate: e.g. actigraphy	C_3 – Standard ECG measure (1 lead)	O_2 – Oximetry with alternative site (e.g. forehead)		E_3 – Derived effort (e.g. forehead versus pressure, FVP)	R_3 – Thermal device
S_4 – Other sleep measure	C_4 – Derived pulse (typically from oximetry)	O_3 – Other oximetry		E_4 – Other effort measure (including piezo belts)	R_4 – End-Tidal CO_2 ($ETCO_2$)
	C_5 – Other cardiac measure				R_5 – Other respiratory measure



Collop NA. J Clin Sleep Med 2011

Collop NA. J Clin Sleep Med 2011

OSA Devices for Out-Of-Center Testing

$$AHI^{ns} = \frac{[\text{all PSG determined respiratory events (apneas, hypopneas using other definitions, RERAs)}]}{\text{Total sleep time (h)}}$$

$$AHI^{ns} = \frac{[\text{all PSG determined respiratory events (apneas, hypopneas using other definitions, RERAs)}]}{\text{Total sleep time (h)}}$$

$$REI = \frac{[\text{apneas} + \text{hypopneas}]}{\text{Total sleep or recording time (h)}}$$

1. $odds_{pre} = probability_{pre}/(1\text{-}probability_{pre})$
2. $odds_{post} = odds_{pre} \times LR+$
3. $probability_{post} = odds_{post}/(1+odds_{post})$

OSA Devices for Out-Of-Center Testing Categorized by SCOPER

Device Name	Sleep	Cardiac	Oximetry	Position	Effort	Respiratory
ApneaLink (Ng 2009)	0	4	1x	0	0	2
Apnoescreen I (Golpe 2002)	3	4	1x	2	0	3
Apnoescreen II (Garcia-Diaz 2007)	3	3	1x	2	4	3
ARES (Westbrook 2005)	3	4	2	2	0	5
ARES (Ayappa 2008, To 2009)	3	4	2	2	3	2
Compumedics PS-2 (Iber 2004)	2	3	1x	0	1	3
Embletta PDS (Ng 2010)	0	4	1x	2	1	2
Embletta (Dingli 2003)	0	0	1x	2	4	2
Morpheux Hx software with standard hospital signals (Amir 2010)	4	3	1x	0	4	4
Northeast Monitoring Holter-oximeter (Heneghan 2008)	0	3	1x	0	0	0
Novasom QSG/Bedbugg/Silent Night (Reichert 2003)	0	4	1x	0	x	5
Novasom QSG/Bedbugg/Silent Night (Claman 2001)	0	4	1x	0	4	5
Remmers/SnoreSat (Jobin 2007)	0	0	1x	2	0	5
Siesta (Campbell 2010)	2	3	1x	2	4	1
SNAP (Michaelson 2006)	0	4	1x	0	0	5
SNAP (Su 2004)	0	4	1x	0	x	5
Somté/Morpheus (Takama 2010)	0	4	1x	0	x	3
Stardust II (Yin 2006, Santos-Silva 2009)	0	4	1x	2	4	2
WatchPAT (Bar 2003)	0	2	1x	2	0	0
WatchPAT (Ayas 2003, Pittman 2004, Pittman 2006, Zou 2006, Pang 2007, Choi 2010)	3	2	1x	2	0	0

Sleep tracking

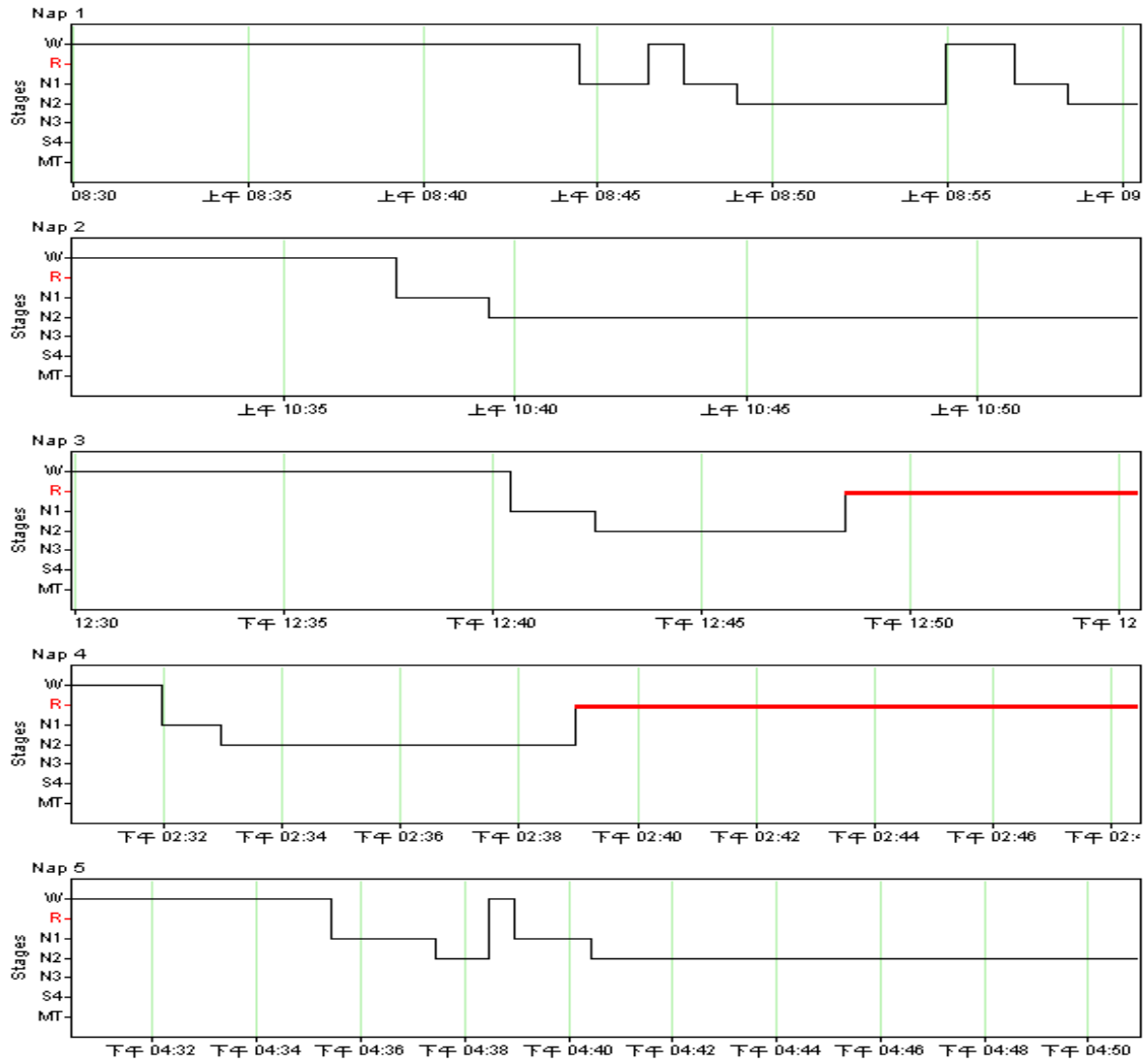
Company - Product	Innovative Sleep Solutions, LLC - SleepTracker	Fitbit Inc. - One™	Fitbit Inc. - Flex™
			
Launch Year	2007	2012	2013
Used Signal	Actigraphy	Actigraphy and altimeter	Actigraphy
Provided Data	Sleep stages, sleep hours, sleep efficiency	Steps taken, calories burned, distance traveled, stairs climbed, sleep hours, sleep efficiency	Steps taken, calories burned, distance traveled, activity minutes, sleep hours, sleep efficiency
Features	Analyze sleep pattern, smart alarm, track sleep efficiency	Set goals, silent alarms, track sleep efficiency, playable with other apps	Set goals with feedback of LED score, silent alarms, track sleep efficiency, playable with other apps

Comparison of sleep Tracking with PSG

- PSG vs wristband (UP) vs smartphone application (MotionX 24/7) vs actigraphy (Actiwatch2) in pediatrics with SDB
  - N=78, 65% male, 8.4±4.0 y/o
  - Outcome: sleep onset latency (SOL), total sleep time (TST), wake after sleep onset (WASO), and sleep efficiency (SE)
  - Result
    - No differences in mean TST, WASO, or SE between PSG and actigraphy or PSG and UP
    - Actigraphy overestimated SOL (21 min). MotionX 24/7 underestimated SOL (12 min) and WASO (63 min), and overestimated TST (106 min) and SE (17%)
    - UP showed good sensitivity (0.92) and accuracy (0.86) but poor specificity (0.66)

Toon E. J Clin Sleep Med 2015

Multiple Sleep Latency Test (MSLT)



ated for assessment of

min : significant sleepiness, >10

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Maintenance Of Wakefulness Test (MWT)

- Measuring ability to stay wake
- MWT doesn’t correlate with the average sleep latency of MSLT
- Procedure
  - 4-trial of 20-40 min
  - Average sleep latency
    - Normal: 35.2 min for 40-min test and 18.7 min for 20-min test
    - Narcolepsy: sleep latency around 10 min

Agreement between self-report and PSG sleep hour is higher in elderly

N=7491	Self-report sleep hour (h)																	
	All		<65 y/o		≥65 y/o		male		female		male<65		male ≥65		female<65		female ≥65	
PSG sleep hour (h)	<5	≥5 and <6	<5	≥5 and <6	<5	≥5 and <6	<5	≥5 and <6	<5	≥5 and <6	<5	≥5 and <6	<5	≥5 and <6	<5	≥5 and <6	<5	≥5 and <6
<5	184	346	128	265	56	81	133	251	51	95	96	195	37	56	32	70	19	25
≥5 and <6	232	530	198	472	34	58	144	374	88	156	125	333	19	41	73	139	15	17
≥6	106	288	93	272	13	16	71	211	35	77	61	200	10	11	32	72	3	5
Agreement in <6h (%)	76.6		74.4		88.8		76.2		77.7		74.2		87.9		75.1		90.5	
Agreement in <5h (%)	35.2		30.5		54.4		38.2		29.3		34.0		56.1		23.4		51.4	

Chang SF , thesis 2021

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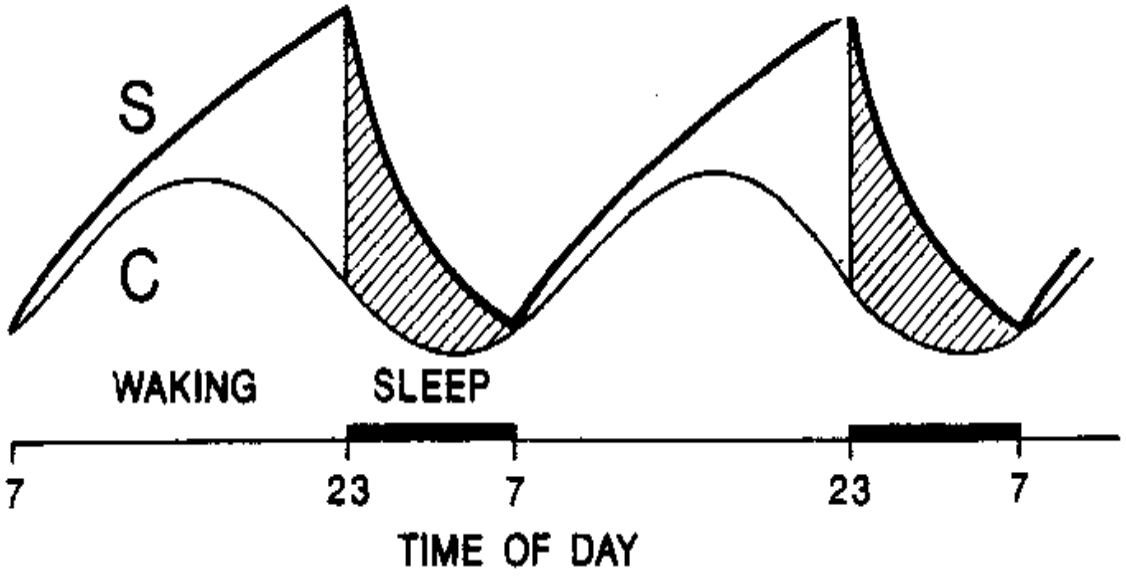
Circadian and chronotype

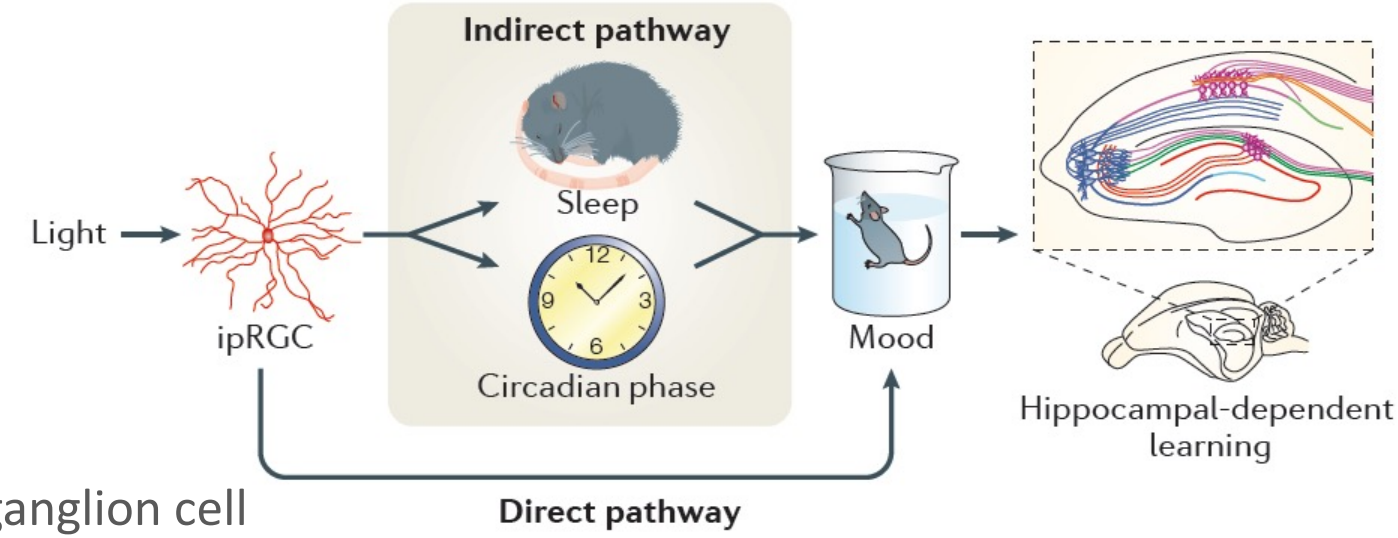


S: sleep driving; C: circadian

- Circadian biomarker
  - Melatonin
  - Cortisol
  - Thyroid stimulating hormone
  - Core temperature
  - Urine output
- Intrinsic clock: free running, 24-25 hr
- Chronotype
  - Entrainment vs detrainment

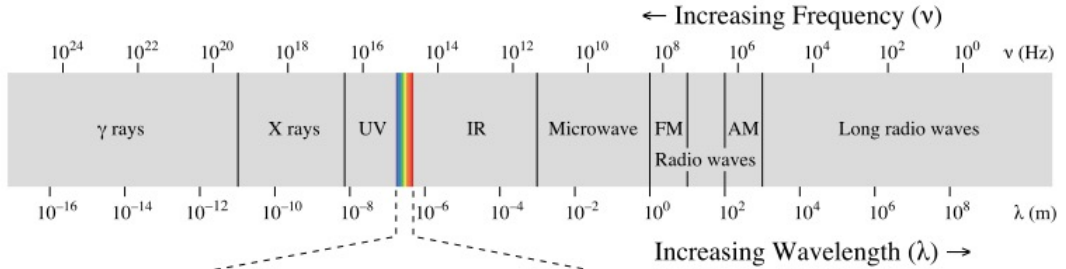
Borbély Hum Neurobiol 1982

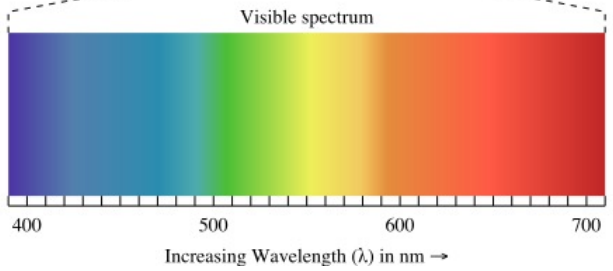
Influences of light on sleep and circadian



ipRGC (M1-5)

non-image forming ganglion cell



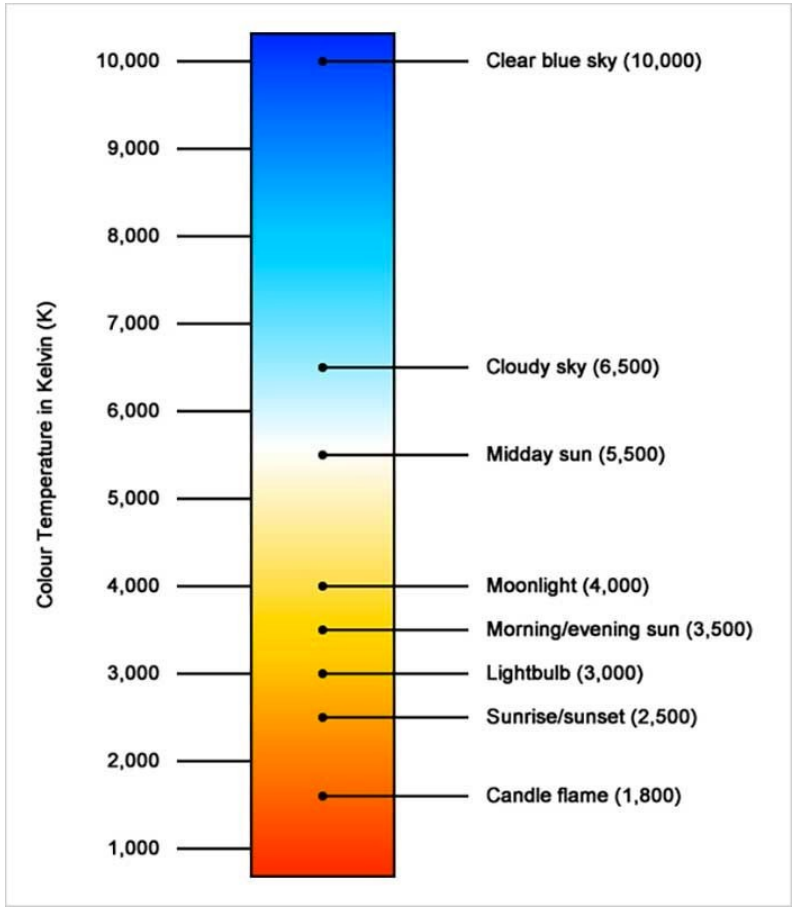


Blue light wavelength 460-480 nm

LeGates TA. Nature 2014

Luminance and color temperature

Iluminance (lux)	Surfaces illuminated by
0.002	Moonless clear night sky with airglow
0.05–0.3	Full moon on a clear night
50	Family living room lights
80	Toilet lighting
100	Very dark overcast day
320–500	Office lighting
400	Sunrise or sunset on a clear day.
1000	Typical TV studio lighting
10,000–25,000	Full daylight (not direct sun)
32,000–100,000	Direct sunlight

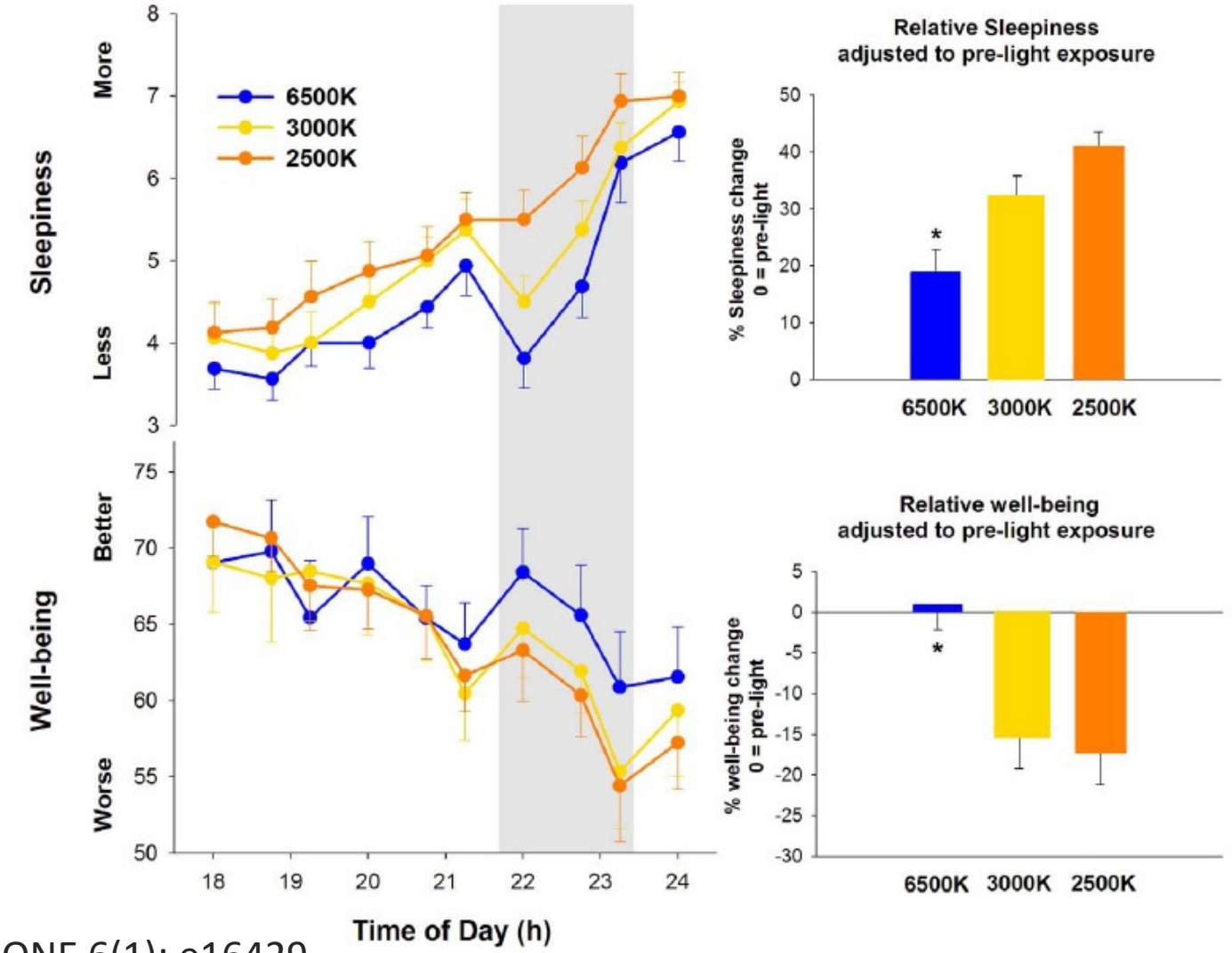


LeGates TA. Nature 2014

Effect of light on sleepiness and well-being

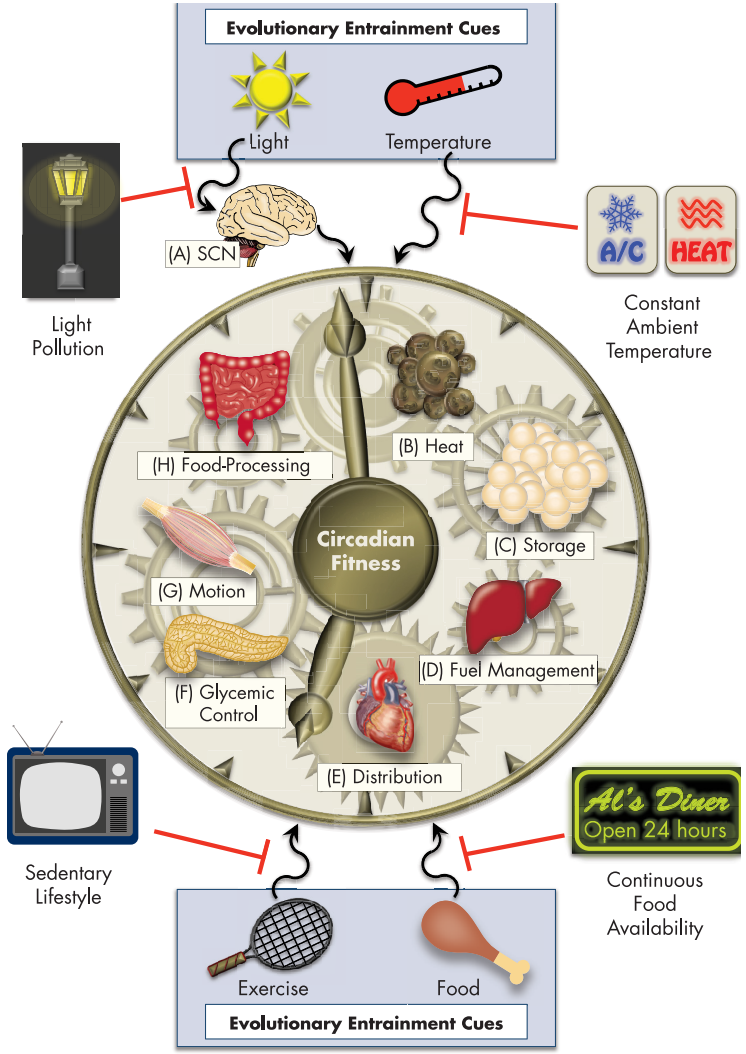
嗜睡程度

精神好

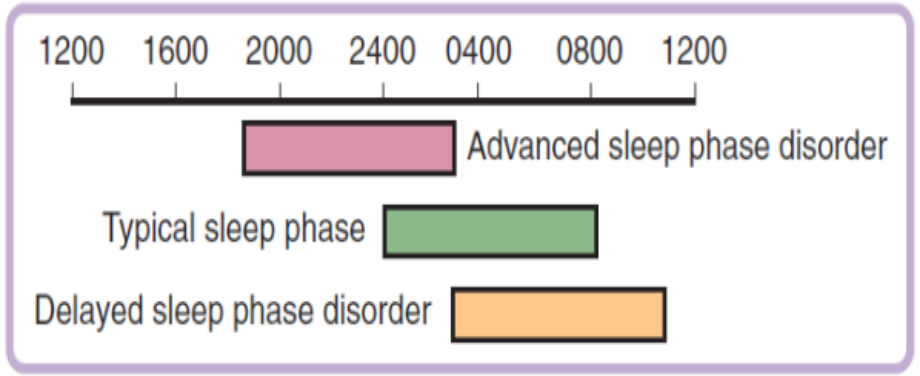


Chellappa SL. PLoS ONE 6(1): e16429

Environmental impact on chronotype: diet and exercise



- Early evening exercise forward body clock
- Alcohol
- Phase advances vs phase delays



Gerhart-Hines Endocrine Review 2015

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Chronobiologic monitoring techniques

- Subjective
  - Munich ChronoType Questionnaire (MCTQ)
- Objective
  - 3 -14 day actiwatch (5 weekday+2 weekend)
  - Salivary or plasma melatonin
    - Dim light melatonin onset (DLMO) and offset: evening rise in blood levels of melatonin. approximately 10.75 hours before wakeup time.
- Chronotype: morning type, evening type, intermediate

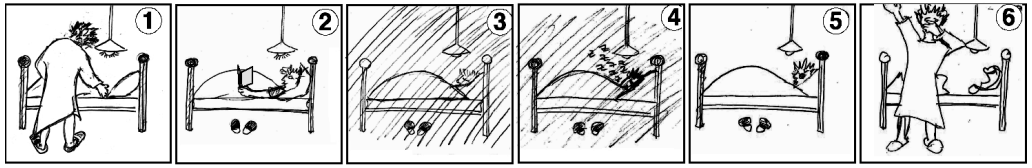
Smith MT. J Clin Sleep Med. 2018

Assessment of chronotype: MCTQ

Survey 3-5

- Munich ChronoType Questionnaire (MCTQ)
  - Shift vs no shift

How to fill out the Munich ChronoType Questionnaire:



- Midsleep
  - Bedtime + sleep onset + sleep duration/2
    - Weekday: W1-4, W7 night (MSF); free day: W5-6 night (MSW)
- Social jet lag= midsleep time on free day (MSF)- midsleep time on work day (MSW)

Roenneberg T. Journal of Biological Rhythm 2003; Juda M. Journal of Biological Rhythm 2013; Cheng WJ. Chronobiology International 2017.

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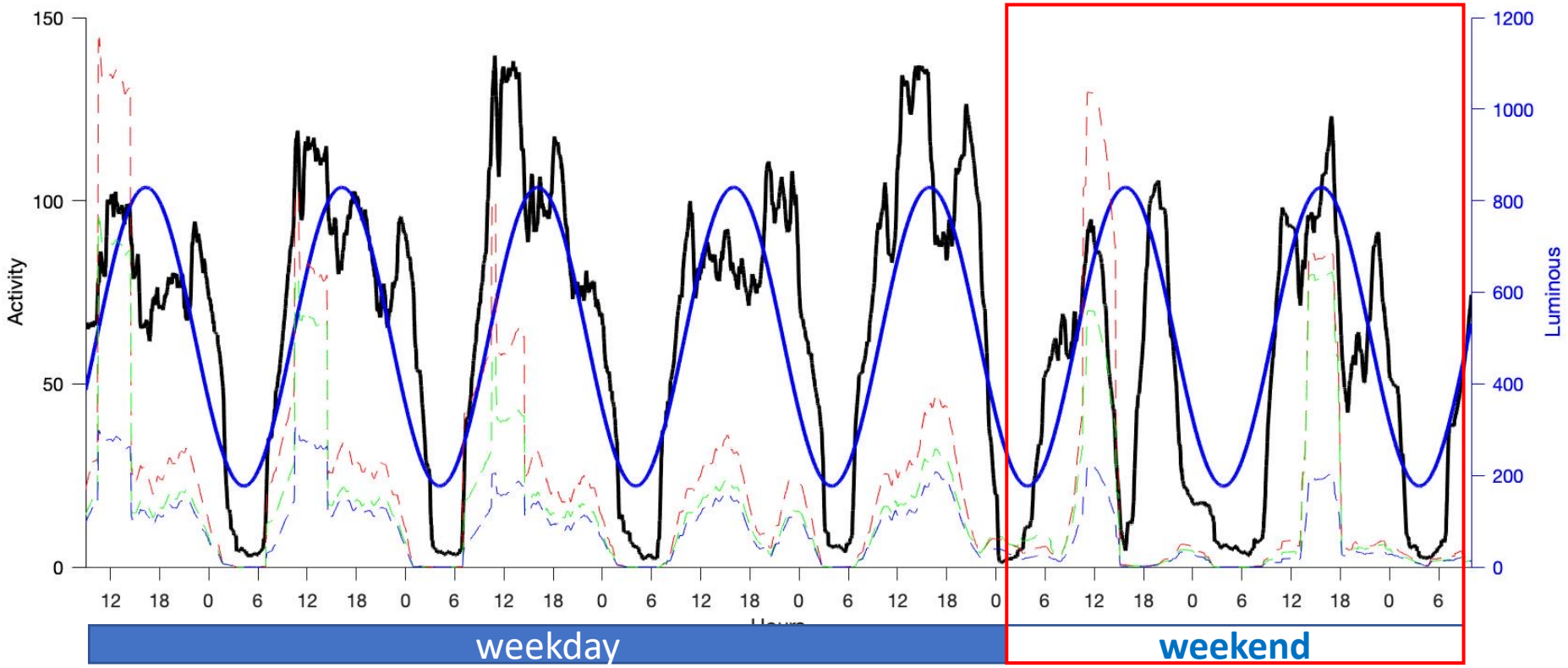
Detection of circadian rhythm with Actiwatch

activity count
model fit
RGB



The phase of clock is different during the weekday and weekend

Lee PL. Unpublished data

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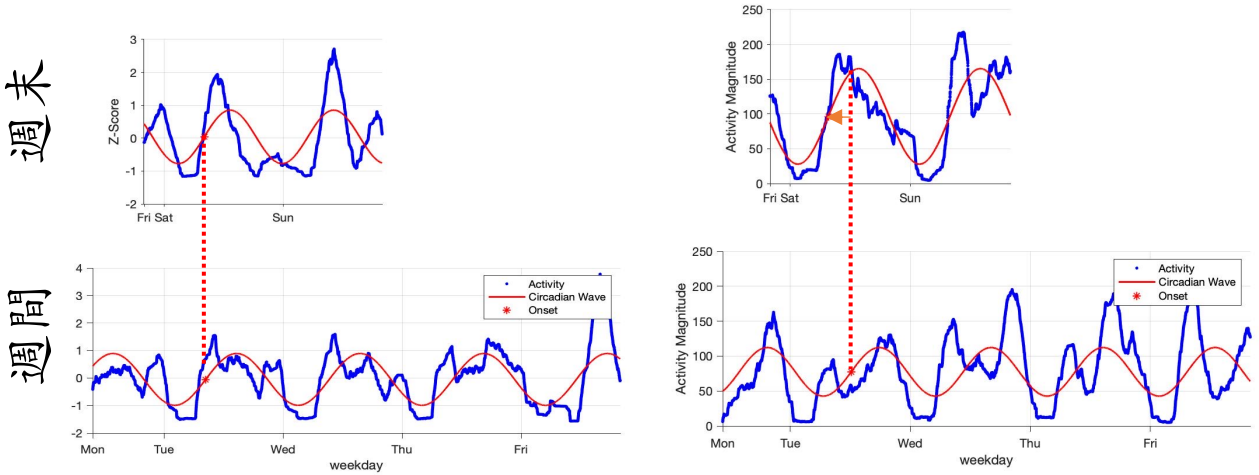
偵測:生理時鐘指數推估其他生理數值

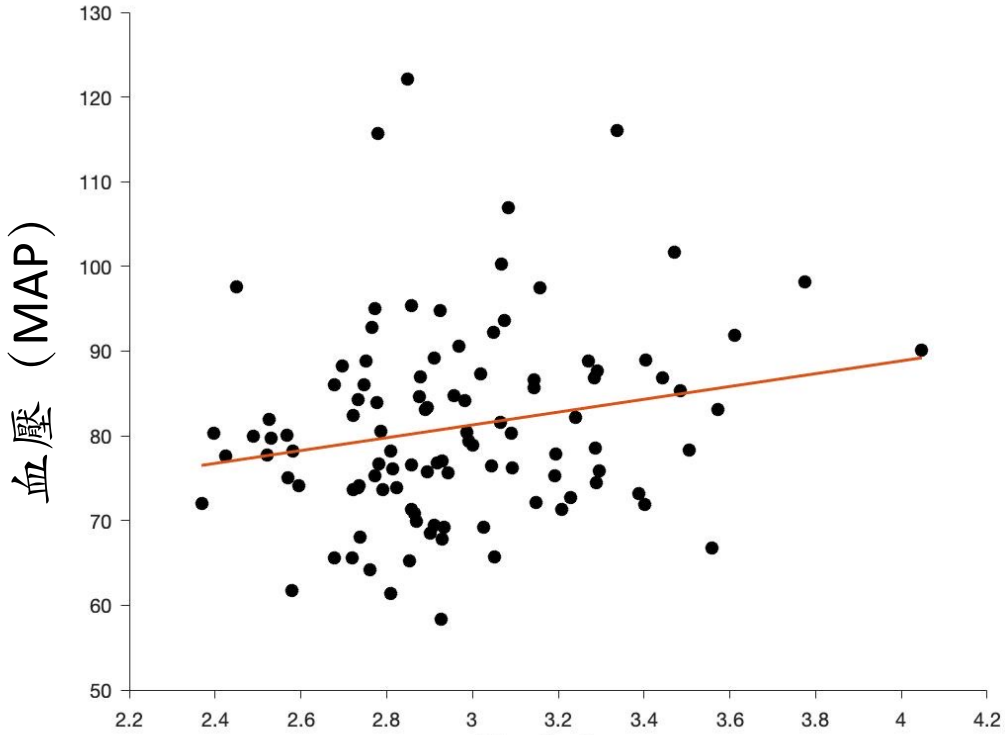
❶由穿戴裝置紀錄推估生理時鐘指數

(比對週間與週末生理時鐘差異)



無差異　　時鐘位移

❷大數據分析比對時鐘指數 vs.生理數值



❸利用使用者生理時鐘差異指數，推估可能引發疾病的危險因子

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Habitual sleep pattern in a community based population

- 304 eligible registered, 108 randomly selected, 105 recruited
- Demographic
  - Age 34 (30 - 39) , male 78%, 嗜睡(ESS≥10) 36.2%, 睡眠品質不佳(PSQI >5) 64.8%, 焦慮(HADS-A >7): 29.5%, 憂鬱(HADS-D >7): 21%
  - Sleep profile: total sleep time (TST) <6hr 68.5%

	Sleep log	Actiwatch				
	TST	bedtime	Get off bed	TST	Sleep latency	SE
7 day	405 (345 – 447)	01:06 (00:18 – 02:00)	07:30 (06:48 – 08:12)	339.5 (292.8 – 381.5)	8.5 (0 - 31.8)	81.9 (74.3 - 86.9)
Weekday	394 (340 – 430)	01:00 (00:18 – 01:48)	07:24 (06:42 – 08:00)	339 (290.8 – 379.1)	9.5 (0 - 31.5)	83.1 (75.9 - 87.6)
weekend	445(370 – 489)	01:12 (00:18 – 02:12)	07:54 (07:00 – 08:48)	345.9 (295.4 – 389)	7.5 (0 -34.5)	78 (69.3 - 83.7)

How can we do better?

好眠處方1：睡眠環境

I. 維持舒適的睡眠情境

A. 燈光：室內宜昏暗為主，避免明亮的燈光照射。

B. 溫度：房間溫度建議 25～26°C，可以適當使用冷氣、電風扇。

C. 避免噪音：保持房間環境是安靜，若是屋外有無法避免的噪音，如鐵道旁、公路旁、橋邊，可在房間加裝隔音窗戶或其他隔音設備。以確保睡眠環境是安靜的。舒緩的音樂或者開電風扇來產生背景聲音，以降低噪音的影響。提醒家中其他人勿來打擾。

D. 飲食：在睡前 4 到 6 小時內避免飲用含酒精性、咖啡因、茶類或其他提神飲料，睡前三小時避免大量飲食如：吃宵夜等。雖然酒精有暫時幫助入睡的效果，但在身體代謝之後反而有中斷睡眠的反彈效用。

好眠處方3：運動，安眠藥，日間小睡

IV.規律的運動

A. 每週運動 3 天，每天至少 30 分鐘。

B. 運動時期最大心跳：（220－年齡）*0.8

C. 日間運動有助於白天精神變好及夜晚睡眠品質但避免睡前三小時劇烈運動

V. 安眠藥使用

A. 持續使用安眠藥者，要規則服用藥物，避免自行調整或停止藥物，有用藥的問題應該與醫師討論。

VI.該不該睡午覺

A. 健康的午睡固定 20～30 分鐘最恰當，若是超過 30 分鐘，身體便會進入不易睡醒的深睡期，就容易打亂生理時鐘，影響正常晚覺。

好眠處方：以光照調節生理時鐘

睡眠衛生

睡眠衛生衛教影片

佳

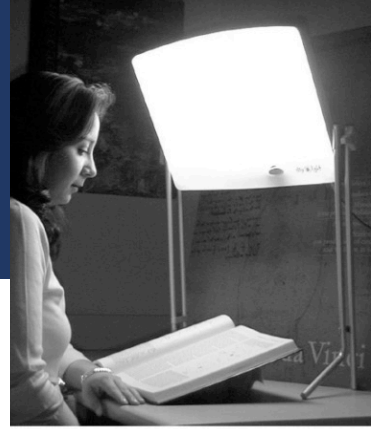
影

憧。

午

睡眠中心

Light therapy



❖ Apparatus

- Maximum illuminance of 10,000 lux with the patient seated in a position with the eyes about 30 cm from the screen

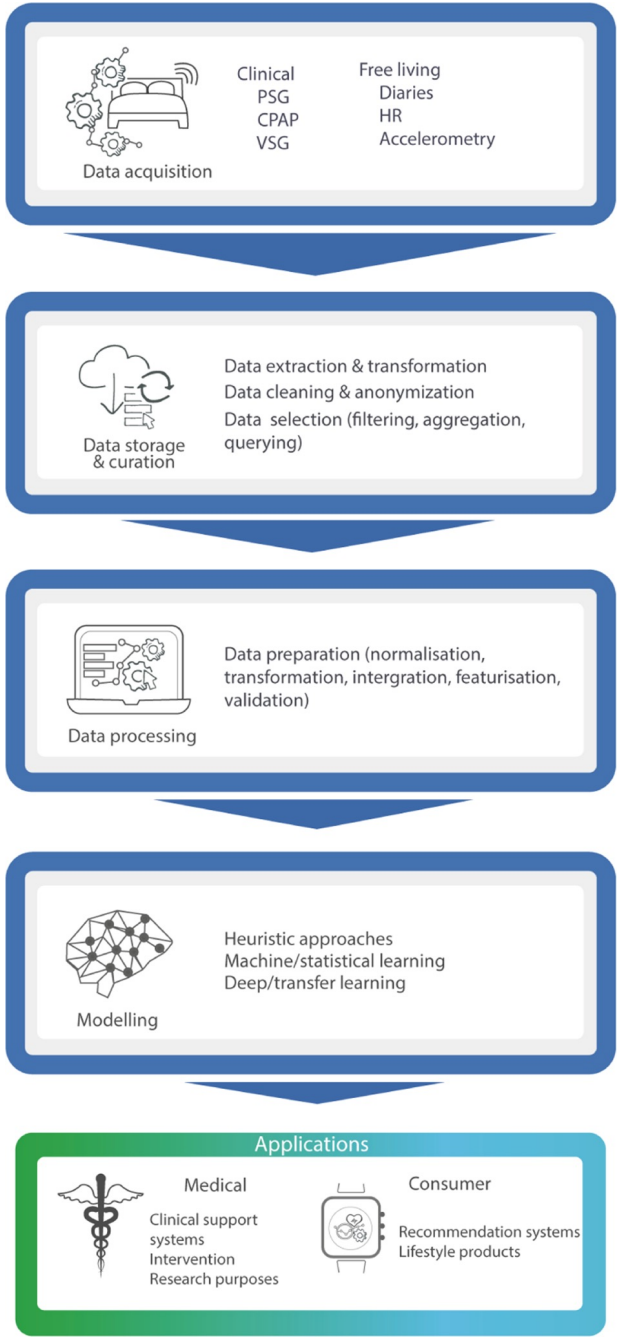
Philips Sleep & Wake-up Light

energy and mood light

❖ Adverse effect

- If evening light is timed too late, the patient can develop insomnia and hyperactivity
- If morning light is timed too early, the patient can awaken prematurely
- Mild visual complaints included blurred vision, eyestrain, and photophobia

Data-driven revolution in sleep science



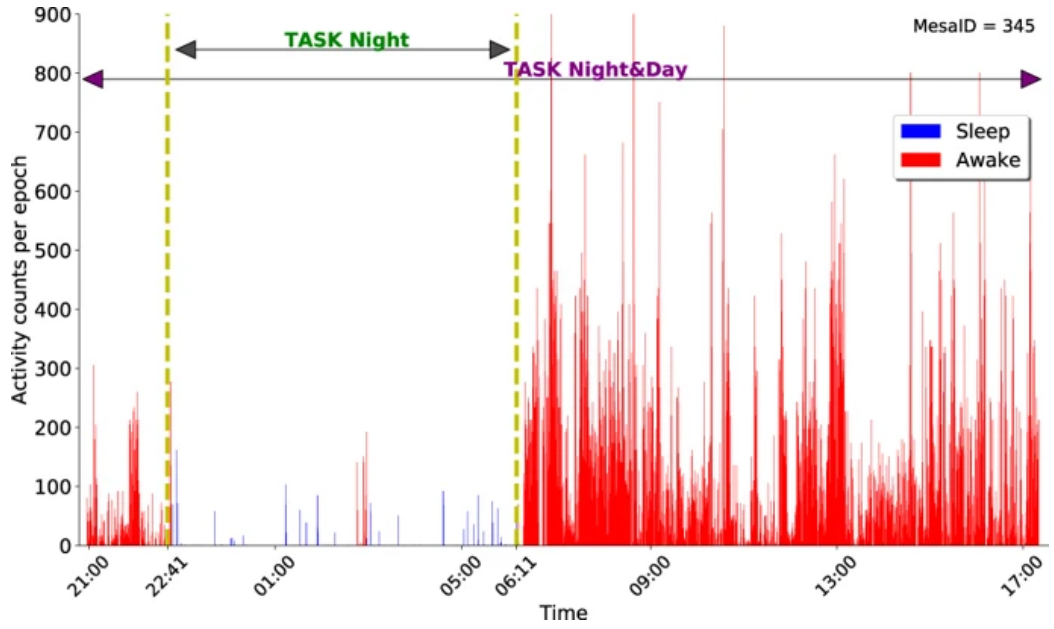
Very Strong ● Strong ◕ Moderate ◑ Weak ◔ None

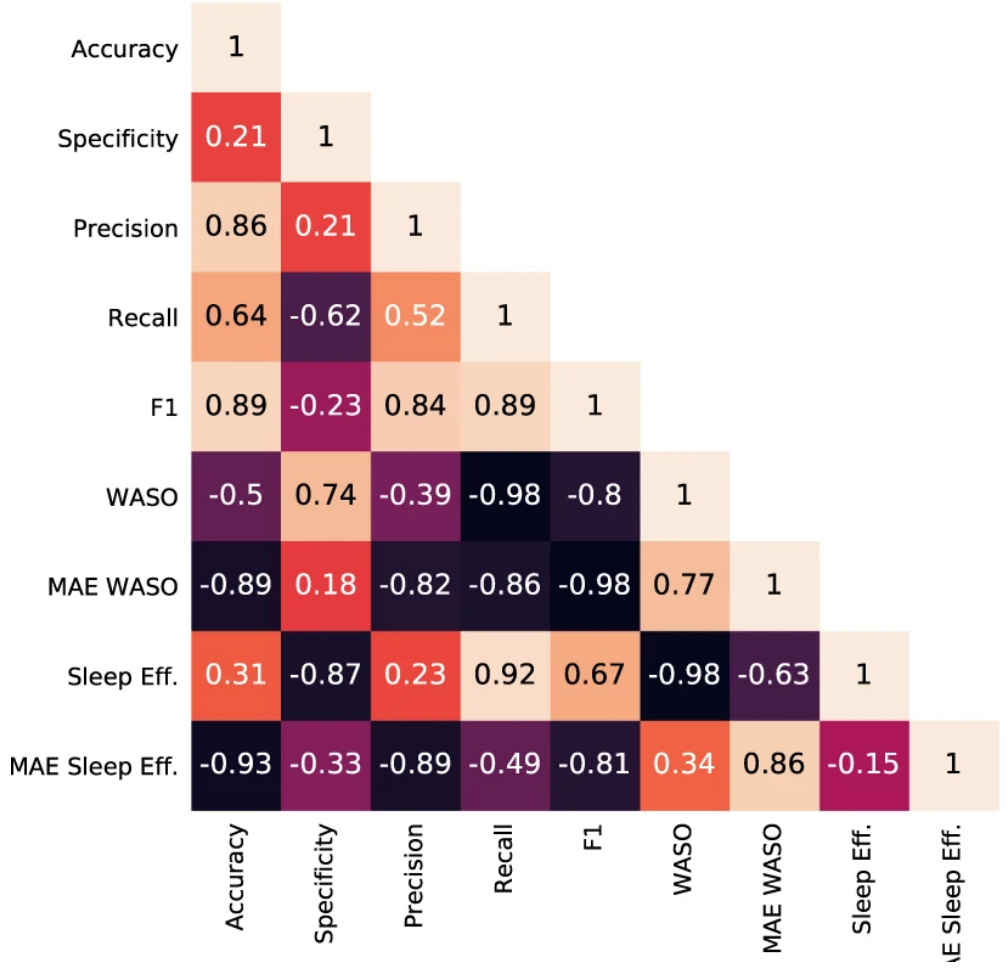
Device	Performance Metrics					
	Sleep Time	Sleep Quality	Sleep Stages	Sleep Disorders	Scalability	Usability
Polysomnography	●	◕	●	◕	◔	◔
Wearable Devices	◕	◑	◑	◑	●	●
Bed Sensors	◕	◕	◕	◕	◕	●
Videosomnography	◕	◕	◑	◕	◑	◔
Mobile Health	◔	◑	◔	◔	●	●
Sleep Diaries	◔	◑	○	◔	●	◑

Perez-Pozuelo I. npj digital medicine 2020

Predict sleep-wake with activity count with CNN and LSTM (MESA sleep study, n=6,814)

MESA: Multi-Ethnic Study of Atherosclerosis





Palotti J. npj Digital Medicine 2019

Expert scoring: AASM scoring manual

- Signal
  - F4,C4, O2-M1; F3, C3, O1-M2; E1-M2, E1-M1
  - Chin EMG, snore, nasal pressure, thermist, chest/abdomen movement, SpO2, ECG, leg EMG (PLM is not analyzed)
- Respiratory indices
  - Apnea: drop in thermist ≥90% for ≥ 10 sec with ≥90% duration meet the amplitude criteria
  - Hypopnea: drop in thermist ≥30% with ≥4% desaturation for ≥ 10 sec for ≥90% duration meet the amplitude criteria
  - ODI: desaturations ≥ 4% of sleep

Inter-scorer reliability using majority score as ground truth: in OSA patients

- EEG (kappa)

GT: ground truth

	Score 1 vs 2	Score 2 vs 3	Score 1 vs 3	Score 1 vs GT	Score 2 vs GT	Score 3 vs GT
Wake	0.95 (+-0.06)	0.97(+-0.08)	0.95(+-0.05)	0.96(+-0.03)	0.98(+-0.06)	0.98(+-0.05)
N1	0.83 (+-0.1)	0.94(+-0.1)	0.84(+-0.08)	0.86(+-0.09)	0.97(+-0.09)	0.98(+-0.04)
N2	0.82 (+-0.12)	0.94(+-0.12)	0.83(+-0.09)	0.85(+-0.10)	0.96(+-0.1)	0.97(+-0.04)
N3	0.93 (+-0.09)	0.97(+-0.09)	0.95(+-0.05)	0.95(+-0.05)	0.98(+-0.02)	0.99(+-0.02)
REM	0.95 (+-0.1)	0.97(+-0.1)	0.96(+-0.02)	0.97(+-0.03)	0.99(+-0.1)	0.99(+-0.02)

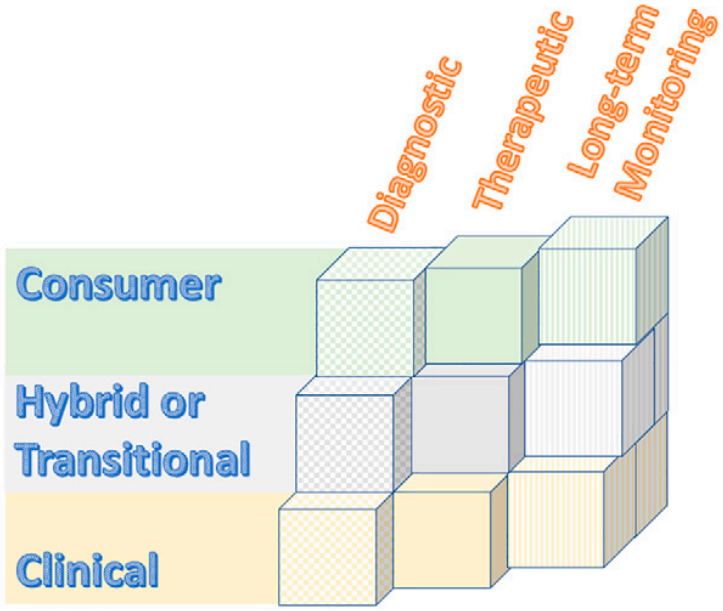
- Airflow (kappa)

	Score 1 vs 2	Score 2 vs 3	Score 1 vs 3	Score 1 vs GT	Score 2 vs GT	Score 3 vs GT
Obstructive	0.68(±0.12)	0.75(±0.17)	0.70(±0.16)	0.73(±0.11)	0.65(±0.16)	0.74(±0.12)
hypopnea	0.69(±0.11)	0.81(±0.10)	0.81(0.12)	0.80(±0.12)	0.70(±0.12)	0.79(±0.11)
Central	0.48(±0.21)	0.64(±0.26)	0.69(±0.24)	0.79(±0.20)	0.46(±0.22)	0.60(±0.21)
Mixed	0.49(±0.36)	0.68(±0.20)	0.67(±0.26)	0.69(±0.23)	0.44(±0.26)	0.71(±0.22)
No-event	0.80(±0.10)	0.85(±0.11)	0.83(±0.11)	0.81(±0.11)	0.80(±0.11)	0.84(±0.10)

Chiu HC and Liu PK In preparation

Evaluating consumer and clinical sleep technology

- sleep device/app type



- Guide to evaluating sleep technology

- Awareness of FDA terms
- Defining sleep term definitions across devices/apps
- Defining populations
- Data integrity
- Applications of new sensors, new sensor applications, or other novel technologies
- Awareness of proprietary AI/ML/DL algorithms
- Defining validation methods for claimed capabilities

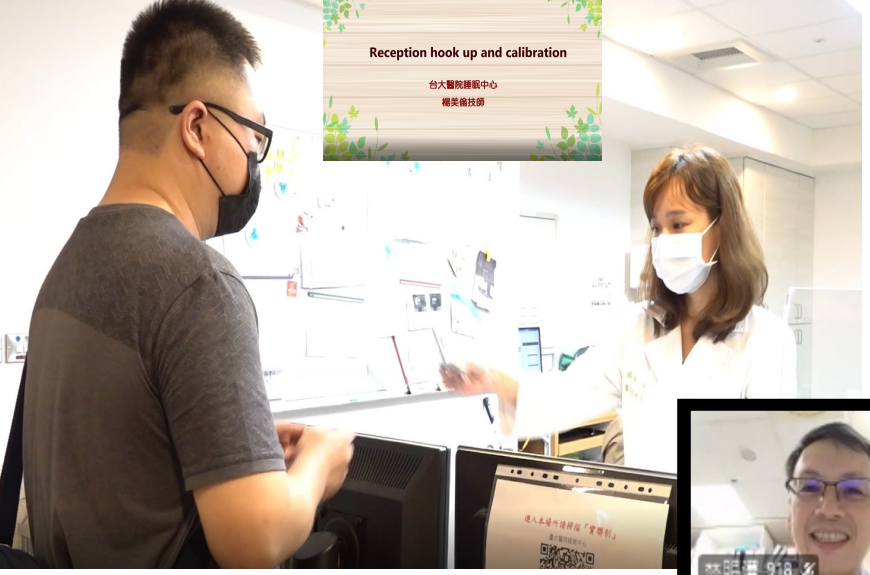
FDA terminology

- FDA classification: based on device/app safety risk, intended use, and indication for use
- FDA device/app: class I (low risk) , II (moderate-higher risk), III (high risk)
- Premarket notification or 510(K) FDA clearance
  - FDA determine if the product is equivalent to a predicate device/app already placed in Class I,II, III type category
  - Often required for Class I and II device/app and doesn't require clinical trial

Schutte-Rodin J Clin Sleep Med 2021

FDA terminology

- Premarket approval (PMA)
  - Class III device/app, require for safe and effective
  - Clinical trial supported with lab testing
- FDA approval
- FDA granted
  - DeNovo pathway before marketed for Class I, II device with low to moderate safety risk when no similar predicate device
- General wellness
  - Not require 510(K) clearance or PMA approval



Merry Christmas
Happy New Year

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