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Devices and Data: Filling the Gap in the Essential 8

Joe Jensen, MD

Grand Rounds

23 January 2023

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Thank You

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Disclosures

- Dose Health:
  - Co-founder, equity holder and current board member

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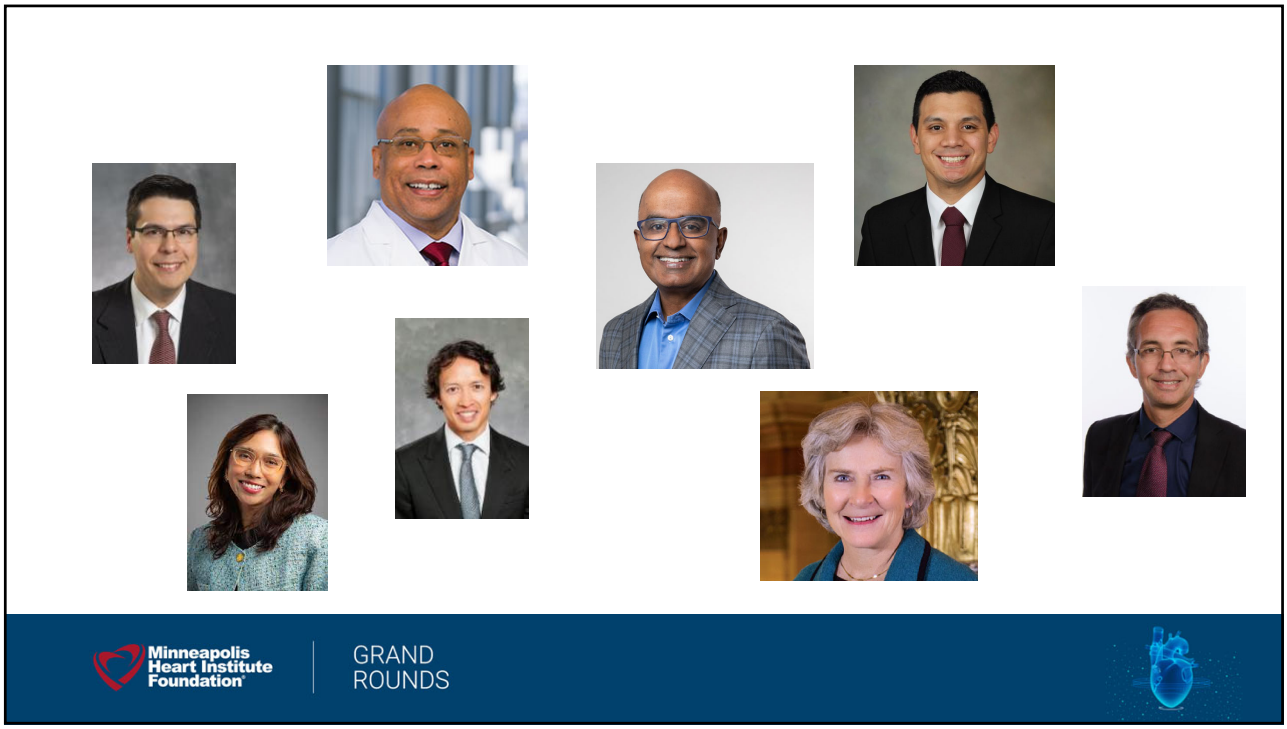

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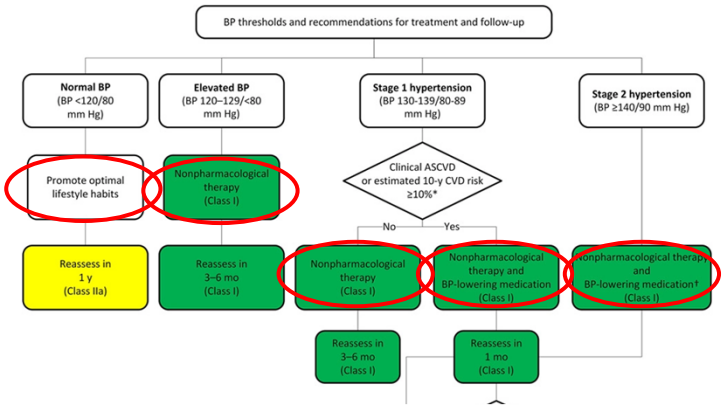
Back to basics



Prevention or Delay of Type 2 Diabetes and Associated Comorbidities

LIFESTYLE BEHAVIOR CHANGE FOR DIABETES PREVENTION

3.1 Monitor for the development of type 2 diabetes in those with prediabetes at least annually, modified based on individual risk/benefit assessment. E

3.2 Refer adults with overweight/obesity at high risk of type 2 diabetes, as identified by the Diabetes Prevention Program (DPP), to an intensive lifestyle behavior change program consistent with the DPP to achieve and maintain 7% loss of initial body weight, and increase moderate-intensity physical activity (such as brisk walking) to at least 150 min/week. A

3.3 A variety of eating patterns can be considered to prevent diabetes in individuals with prediabetes. B

3.4 Given the cost-effectiveness of lifestyle behavior modification programs for diabetes prevention, such diabetes prevention programs should be offered to patients. A Diabetes prevention programs should be covered by third-party payers and inconsistencies in access should be addressed.

3.5 Based on patient preference, certified technology-assisted diabetes prevention programs may be effective in preventing type 2 diabetes and should be considered. B

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12.1.2. Strategies to Promote Lifestyle Modification

Recommendation for Strategies to Promote Lifestyle Modification

COR	LOE	Recommendation
I	C-EO	1. Effective behavioral and motivational strategies to achieve a healthy lifestyle (ie, tobacco cessation, weight loss, moderation in alcohol intake, increased physical activity, reduced sodium intake, and consumption of a healthy diet) are recommended for adults with hypertension.[S12.1.2-1,S12.1.2-2]

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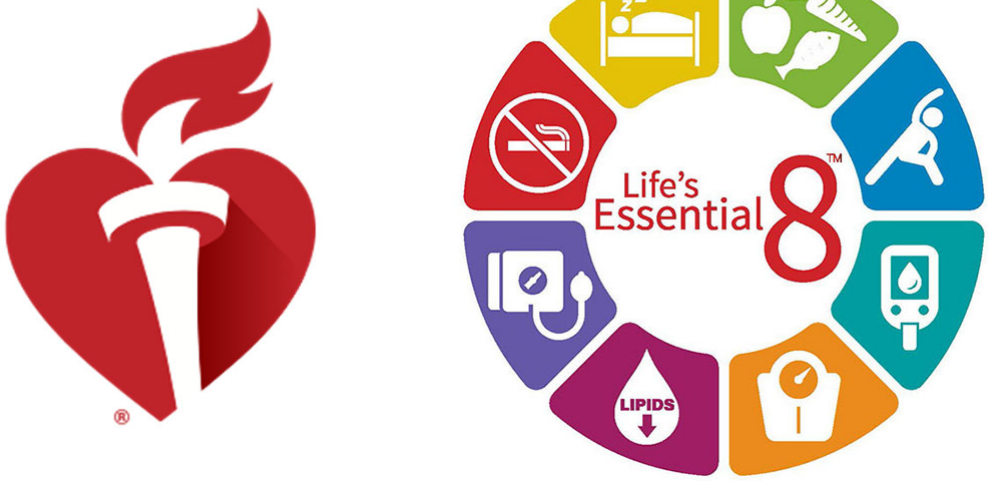

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WE ARE NOT GOOD AT THIS NOR DO WE HAVE THE TIME

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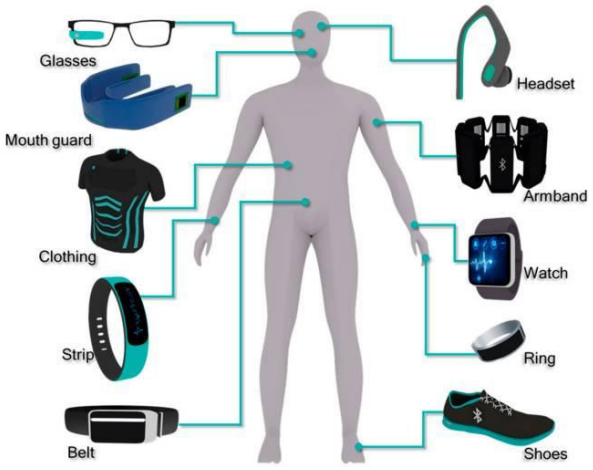
Industry has stepped in to fill the gap



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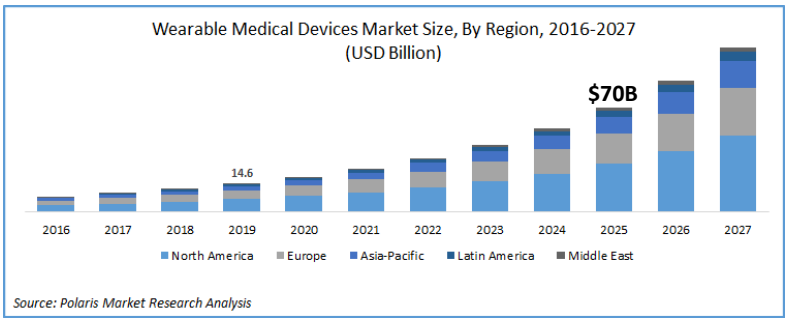

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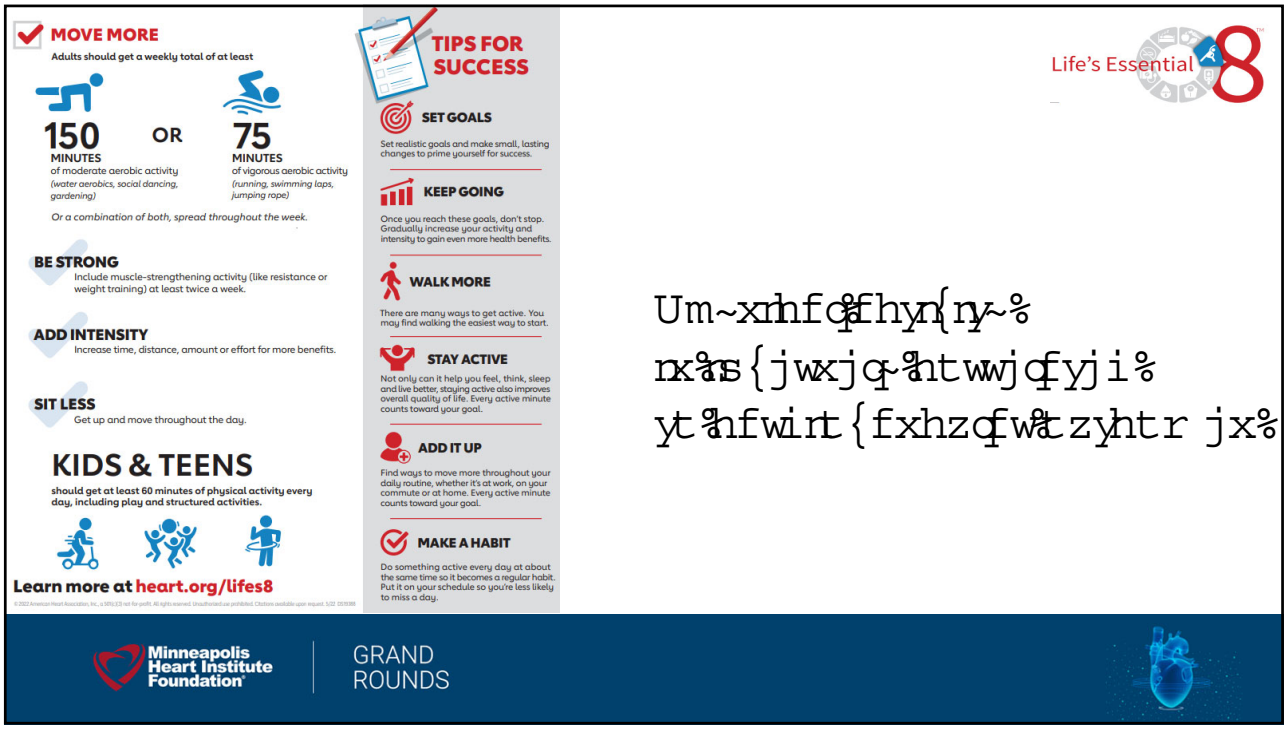

Life's Essential 8

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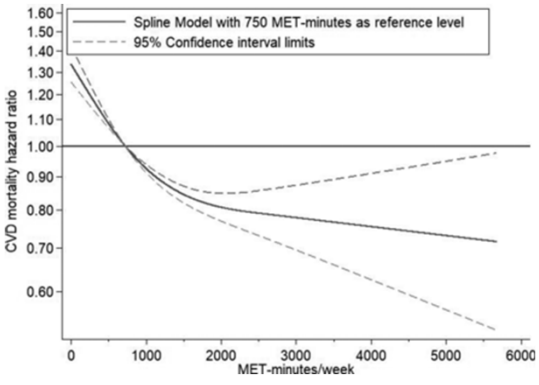
The Data

Life's Essential 8

- Meta-analysis of 48 studies with 2.6 million patients
- 750 MET-min was baseline activity level
  - Met-min of 1 = at rest
  - 6 mph = 10 METs -> 75 min/wk
  - 4 mph = 5 METs -> 150 min/wk
  - 2 mph = 2.5 METs -> 300 min/wk



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The Data

- 16,741 from Women's Health study
- Accelerometer for 7 days between 2011-2015
- Mean step count of 5,499/d
- 4,400 steps/d associated with significantly lower mortality
- Mortality decreased then leveled at 7,500 steps/d

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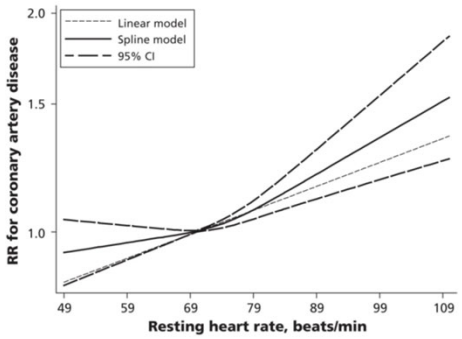
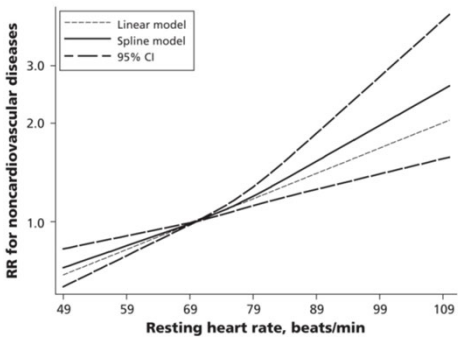
But Why? Heart Rate?





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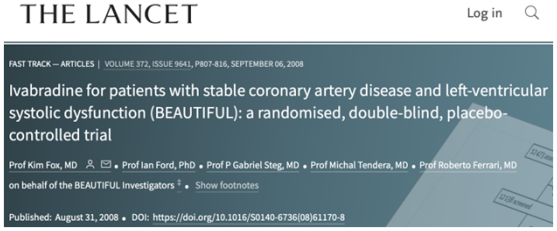
But Why? Heart Rate?


THE LANCET

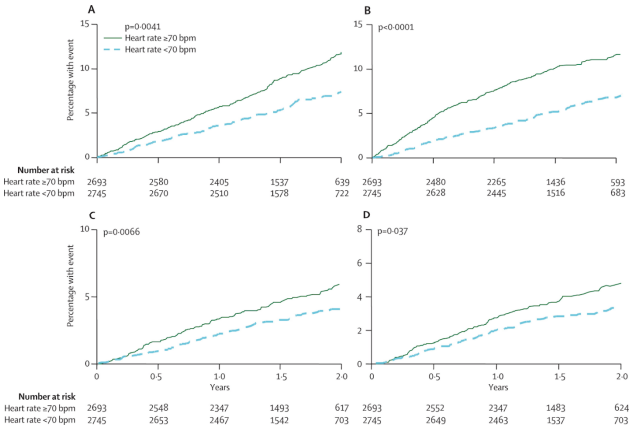
Log in

FAST TRACK — ARTICLES | VOLUME 372, ISSUE 9641, P807-816, SEPTEMBER 06, 2008

Ivabradine for patients with stable coronary artery disease and left-ventricular systolic dysfunction (BEAUTIFUL): a randomised, double-blind, placebo-controlled trial

Prof Kim Fox, MD • Prof Ian Ford, PhD • Prof P Gabriel Steg, MD • Prof Michal Tendera, MD • Prof Roberto Ferrari, MD on behalf of the BEAUTIFUL Investigators • Show footnotes

Published: August 31, 2008 • DOI: https://doi.org/10.1016/S0140-6736(08)61170-8



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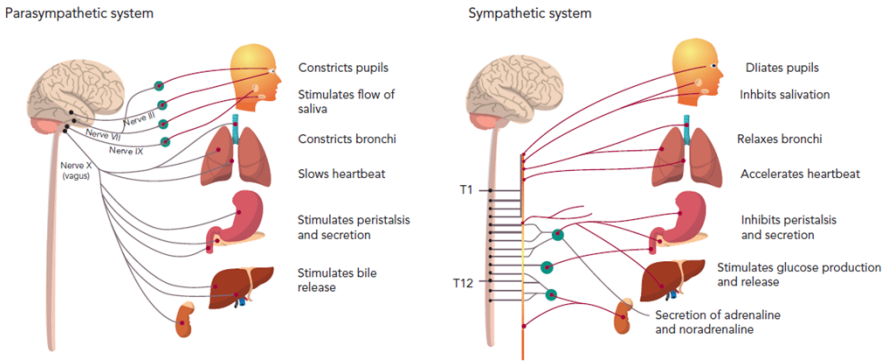
But Why? Heart Rate Variability (HRV)?

Figure 1: Anatomy of Parasympathetic and Sympathetic Nervous System with Connections and Effects on Various Organ Systems



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But Why? Heart Rate Variability (HRV)

Table 1: Sympathetic and Parasympathetic Effects on Target Organs Through Various Receptor Interactions

	Sympathetic		Parasympathetic	
Organ	Receptor Subtype	Effect	Receptor Subtype	Effect
Heart	Beta-1, beta-2 ? also alpha and DA_1 Alpha-1	↑ Heart rate ↑ Force of contraction ↑ Conduction velocity ↑ Automaticity (beta-2) ↑ Excitability ↑ Force of contraction	M_2	↓ Heart rate ↓ Force of contraction ↓ Conduction velocity
Arteries	Beta-1 DA_1, beta-2	Coronary vasodilatation Vasodilatation (skeletal muscle) Vasoconstriction (coronary, pulmonary, renal and splanchnic circulations, skin and skeletal muscle) Splanchnic and renal vasodilatation	M	Vasodilatation in skin, skeletal muscle, pulmonary and coronary circulations
Veins	Alpha-1, also alpha-2 Beta-2	Vasoconstriction Vasodilatation		
Lungs	Beta-2 Alpha-1	Bronchodilation Inhibition of secretions Bronchoconstriction	M_1, M_3	Bronchoconstriction Stimulation of secretions

DA_1 = dopaminergic receptors; $M/M_1/M_2/M_3$ = muscarinic receptors.

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But Why? Heart Rate Variability (HRV)

- HRV: physiologic variation in the duration of intervals between sinus beats
- What about respiratory sinus arrhythmia?

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Respiratory Sinus Arrhythmia

Nsmfcfyrts

- Diaphragm contracts
- Intrathoracic pressure lowers
- Atrial pressure lowers
- More blood returns to heart
- Atria expand
- Trigger baroreceptors
- Suppress vagal tone -> HR increase

J}mfcfyrts

- Diaphragm relaxes
- Chest cavity decreases
- Intrathoracic pressure increases
- Less venous return
- Inactivation of baroreceptors
- No longer suppress vagal tone
- HR decreases

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But Why? Heart Rate Variability (HRV)

- HRV: physiologic variation in the duration of intervals between sinus beats
- What about respiratory sinus arrhythmia?
  - HR increases with inspiration and decreases with expiration
- Root mean square of the differences in successive R-R intervals (RMSSD) is preferred
- Higher HRV = higher parasympathetic input

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But Why? Heart Rate Variability

Table 3: Mortality Risk Associated with Various Heart Rate Variability Measurements Using Ambulatory ECG

Study Name	Number of Patients	Monitoring Method	HRV parameters	Conclusions
Tsuji et al. 1994[41] (Framingham)	736	2-hour ambulatory ECG	VLFP, LFP, HFP, LFP/HFP, TP, SDNN, rMSSD, pNN50+	lnLF <1 SD from mean had increased all-cause mortality (HR 1.70, 95 % CI [1.37–2.09])
Tsuji et al. 1996[11] (Framingham Offspring)	2,501	2-hour ambulatory ECG	VLFP, LFP, HFP, LFP/HFP, TP, SDNN, rMSSD, pNN50+	All HRV parameters except LFP/HFP associated with increased risk of cardiac events (p=0.016–0.0496); adjusted HR for lnSDNN <1 SD from mean 1.45 (95 % CI [1.13–1.85], p=0.003)
Kikuya et al. 2000[12]	1,542	Ambulatory blood pressure monitor	SDNN	Patients in lowest tertile have increased risk of all-cause mortality (HR 3.70, p=0.003)
La Rovere et al. 1998[13] ATRAMI trial	1,284	24-hour Holter monitor	SDNN	SDNN <70 ms had increased risk of CV-related death (RR 5.3, 95 % CI [2.49–11.4], p<0.0001) compared to >105 ms
Klieger et al. 1987[14]	808	24-hour Holter monitor	SDNN	SDNN <50ms had increased risk of all-cause mortality compared with >100 ms (34 % versus 9 %, p <0.0001, RR 5.3)
Zuanetti et al. 1996[15] GISSI-2 trial	567	24-hour Holter monitor	SDNN, rMSSD, NN50+	Risk of all-cause mortality elevated for NN50+ <200, SDNN <70 ms, or rMSSD <17.5 ms (RR 2.8–3.5)
Adamson et al. 2004[16]	288	CRT-P	SDAAM	Elevated risk of all-cause mortality for SDAAM < 50 ms (HR 3.20, p=0.02)
Sherazi et al. 2015[18] MADIT-CRT trial	719	CRT-D	SDNN, SDANN, SDNNIX, rMSSD, VLF, LF, HF, LF/HF	SDNN <93ms associated with increased all-cause mortality (HR 2.10, 95 % CI [1.14–3.87], p=0.017)
Nolan et al. 1998[17] UK-Heart trial	433	24-hour Holter monitor	SDNN, rMSSD, sNN50	SDNN <93ms has all-cause mortality RR 1.62 (95 % CI [1.16–2.44])

CRT-D = cardiac resynchronisation therapy defibrillator; CRT-P = cardiac resynchronisation therapy pacemaker; HF = high frequency power; HRV = heart rate variability; LF = low frequency power; LF/HF = low frequency to high frequency power ratio; ln HF = natural log of the high-frequency measurement; pNN50 = percentage of RR intervals that differ by 50ms; rMSSD = root mean square of the differences in successive R-R intervals; SD = standard deviation; SDAAM = SD of 5 min median A-A intervals; SDANN = SD of 5 min R-R intervals; SDNN = standard deviation of NN intervals; SDNNIX = mean SD of all R-R intervals; TP = total power; VLF = very low frequency power.

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HRV: Not just for the sick

- Daily recordings of HRV are superior at increasing fitness and exercise performance than training based on conventional methods

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But Why? HR and HRV Hypotheses

- High HR increases hemodynamic stress and shortens diastolic phase
  - Increased mechanical load, tensile and shear stress
  - Increased BP and cardiac work
  - Increased oxygen consumption
- High HRV is a marker of sympathetic overactivity
  - Increased VF risk
  - Increased arrhythmia risk
  - Increased insulin resistance
- Increased activity levels can lead to lower resting HR and higher HRV!

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The Tools

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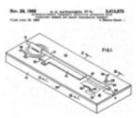
Tracks oxygen levels and easy way to track pulse

Adds more measurements to track fitness

First Pedometer (1760) → First Electrocardiogram (1895) → First Pulse Oximeter (1935) → First MEMS Device (1965) → FitBit Releases First Product (2009) → Apple Releases Apple Watch with ECG (2018) → Future

Tracks electrical activity of heart



Enables miniaturization of electrical systems

Tracks electrical activity of heart and potential diagnosis

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The Tools

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But How? Activity monitoring

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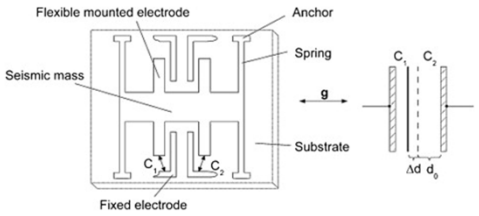

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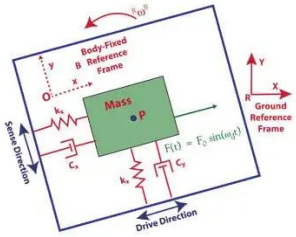

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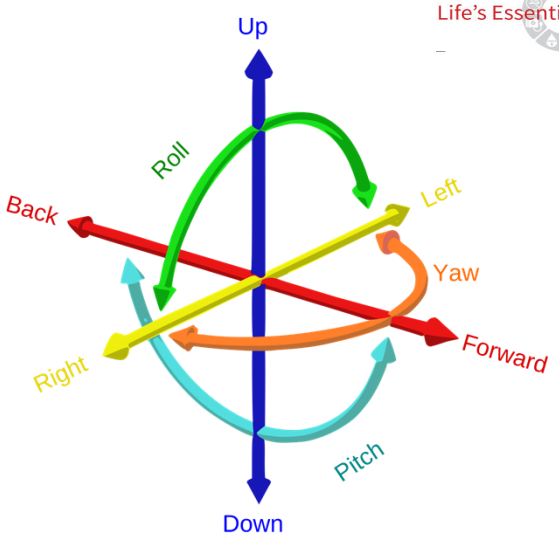
The Six Degrees of Freedom



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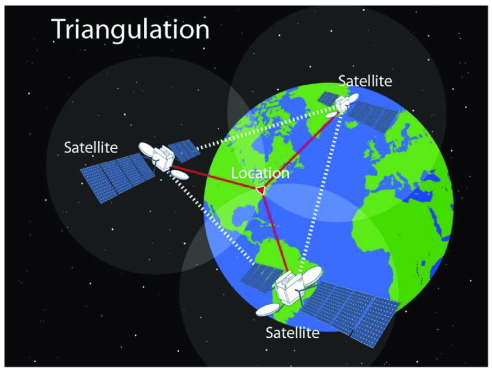
GPS



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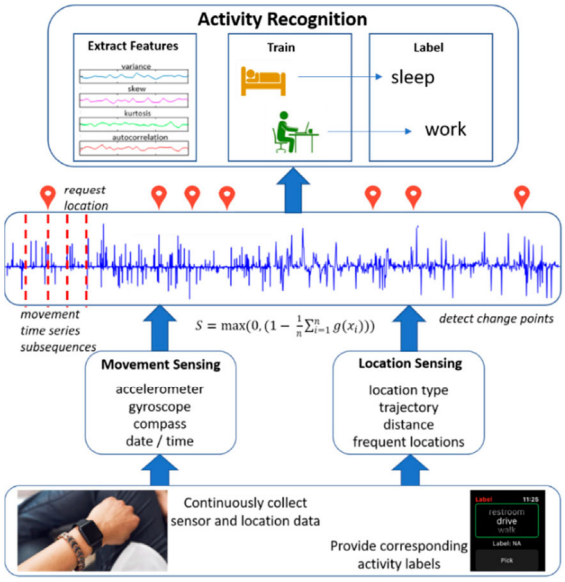
Putting it together



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But How? HR and HRV

1. Pulse oximetry
   1. Ratio of red to infrared light
2. Photoplethysmography (PPG)
   1. Optical technique that detects blood volume changes in microvascular bed
   2. Basically all devices use this technique
3. ECG
   1. Apple Watch and AliveCor

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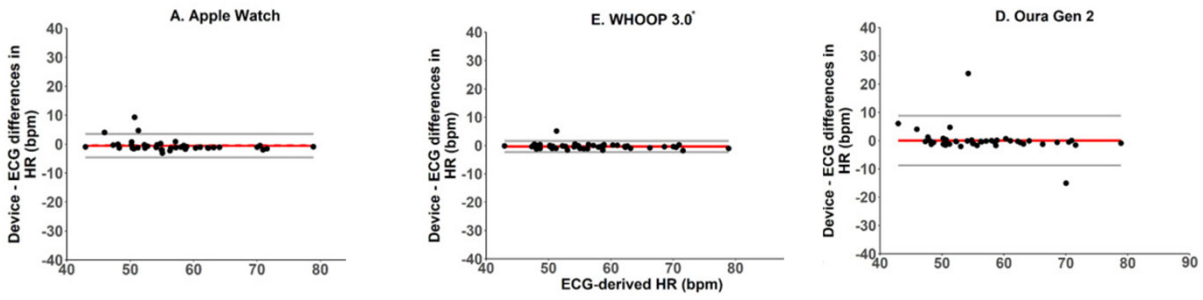
But How? HR and HRV



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The Devices

Company	Product name	Biological measurement	All studies on PubMed[a]	Number of clinical trials[b]	Number of cardiovascular clinical trials[c]	FDA status[d]
Watches						
Adidas	miCoach Fit Smart	HR, PA	0	1	1	Not cleared or approved
Apple	Apple Watch	HR, PA, falls, sleep and ECG	135	49	18	Cleared
Biobeat	BB-613WP	HR, PA and cuff-less BP	0	9	3	Cleared
Fitbit	Flex, One, Charge	HR, PA and sleep	612	530	40	Cleared
Garmin	Vivoactive, Vivofit, Forerunner	HR, PA and sleep	51	55	12	Not cleared or approved
Withings	Steel HR, Move, Move ECG, Pulse HR	HR, PA, sleep, ECG and SPO_2	20	3	2	Not cleared or approved
AliveCor	KardiaMobile	HR, single-lead and 6-lead ECG	28	13	11	Cleared
Oura	Oura Ring	HR, PA and sleep	7	7	0	Not cleared or approved

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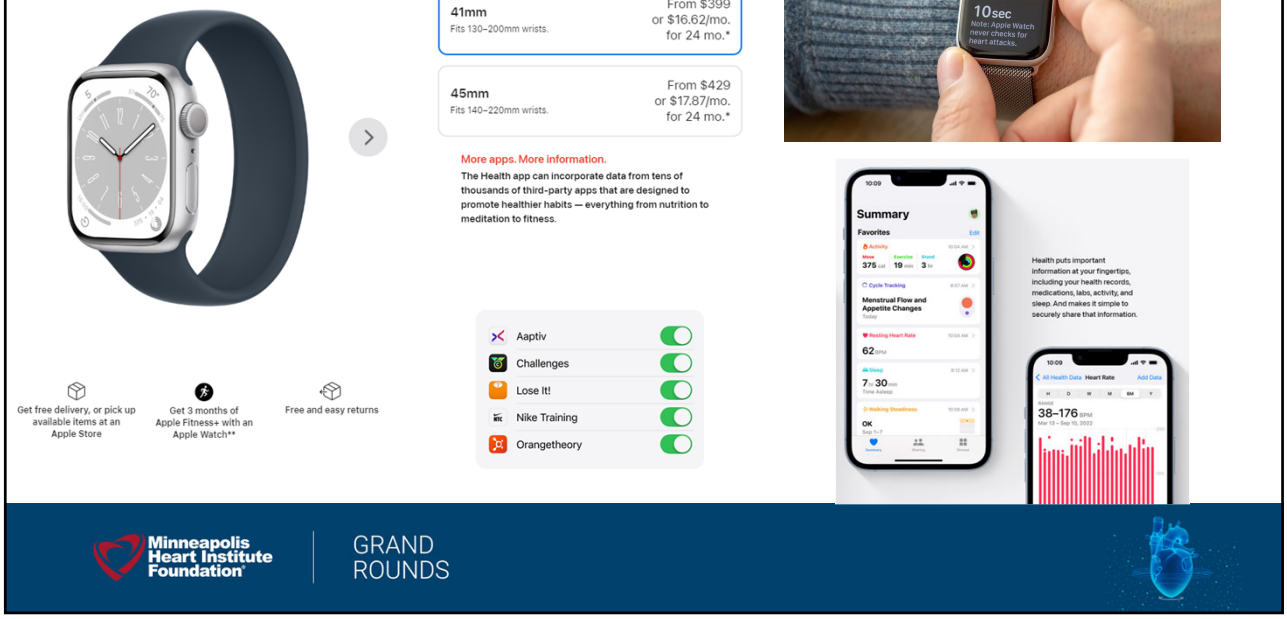

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The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Large-Scale Assessment of a Smartwatch to Identify Atrial Fibrillation

- ~420,000 patients over 8 months
- Whether a PPG device could detect AF in those without AF history
- Irregularity detected ->
  - 4 more readings taken at rest
  - If irregular -> notification sent
- Telemedicine visit initiated and EKG patch mailed to wear 7 days
- Surveys administered 90 days after initial notification
- 2,161 patients (0.52%) received irregular pulse notification
- 450 participants returned EKG patches
  - AF present in 34%
- PPV of 0.84 for AF on EKG patch with irregular pulse notification
- Subsequent Deep Neural Network training led to sensitivity of 98% and specificity of 90% in pre-cardioversion patients

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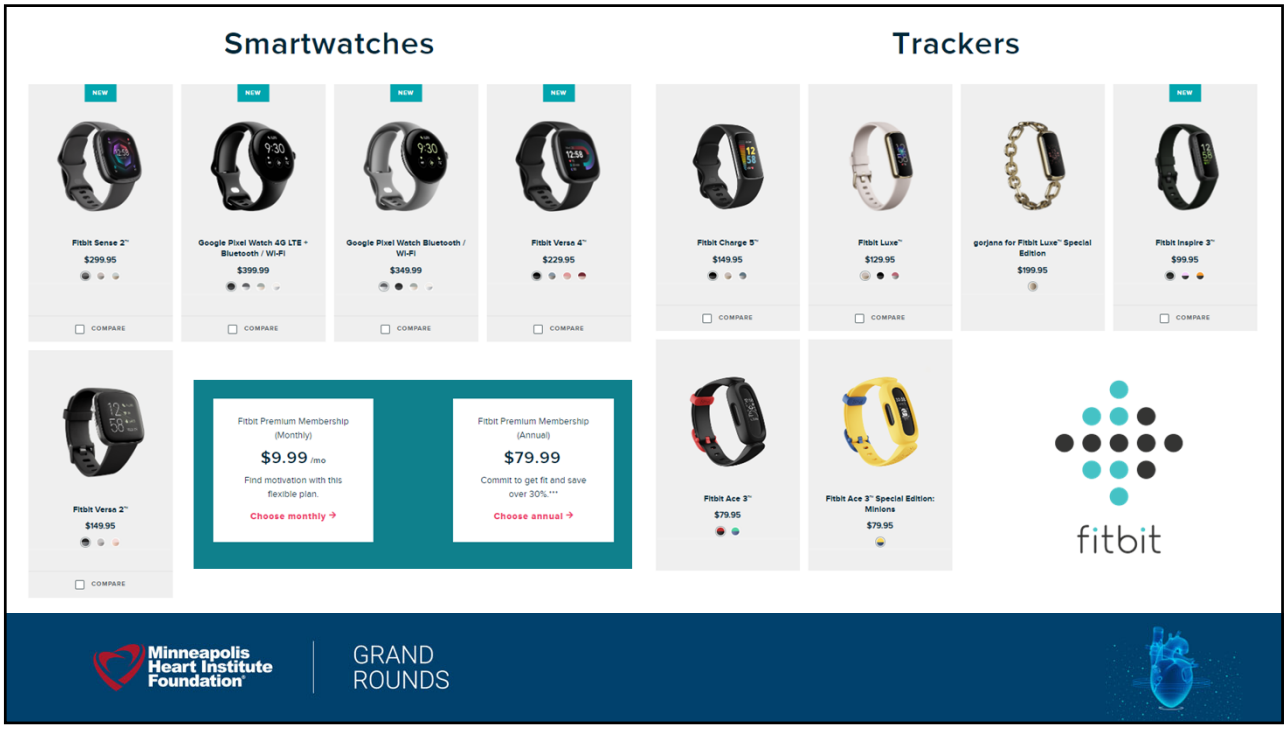

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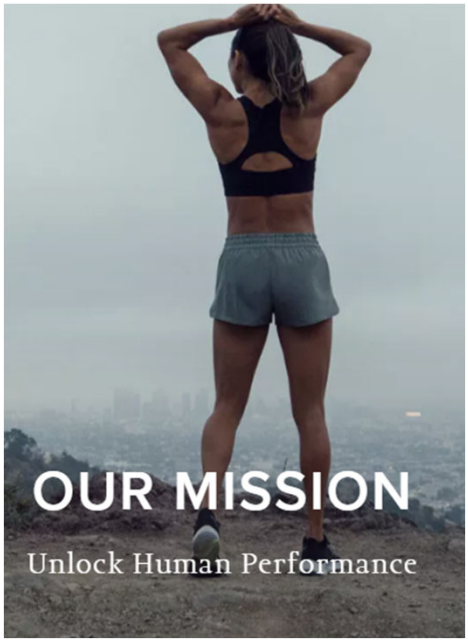

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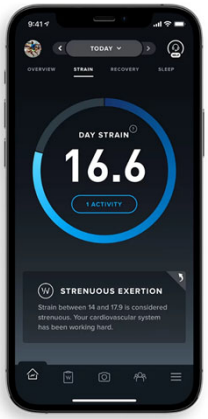

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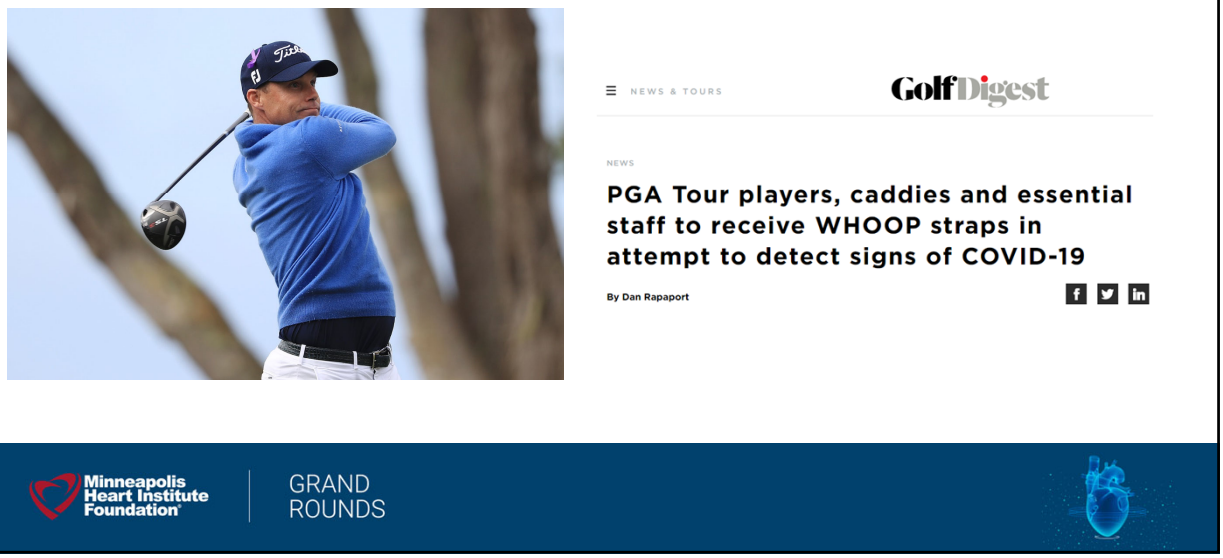
NEWS & TOURS
Golf Digest
NEWS
PGA Tour players, caddies and essential staff to receive WHOOP straps in attempt to detect signs of COVID-19
By Dan Rapaport
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PGA TOUR
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1 McILROY -11 17
2 ANCER -9 66
3 HOVLAND -8 67
MITCHELL -8 17
5 WOODLAND -7 17
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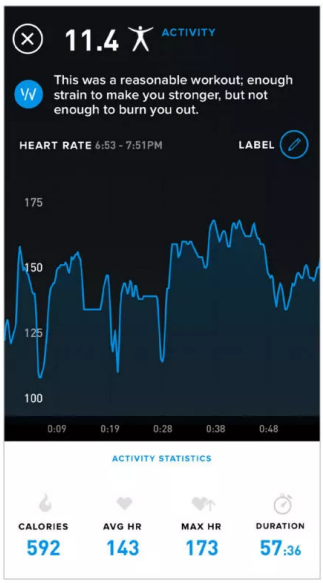
Bringing it back to medicine



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ANNUAL MEMBERSHIP PAY $300 UPFRONT SAVE 16%	MOST POPULAR	$25 per month
MONTHLY MEMBERSHIP 12 MONTH MINIMUM		$30 per month

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At Oura, we know that you are the source of your truth. Health starts from understanding you. And great health starts with good sleep.

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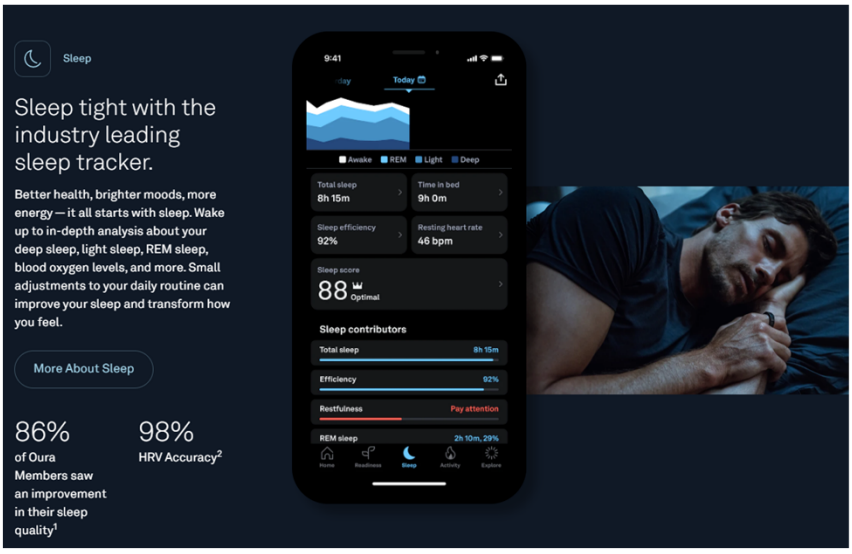

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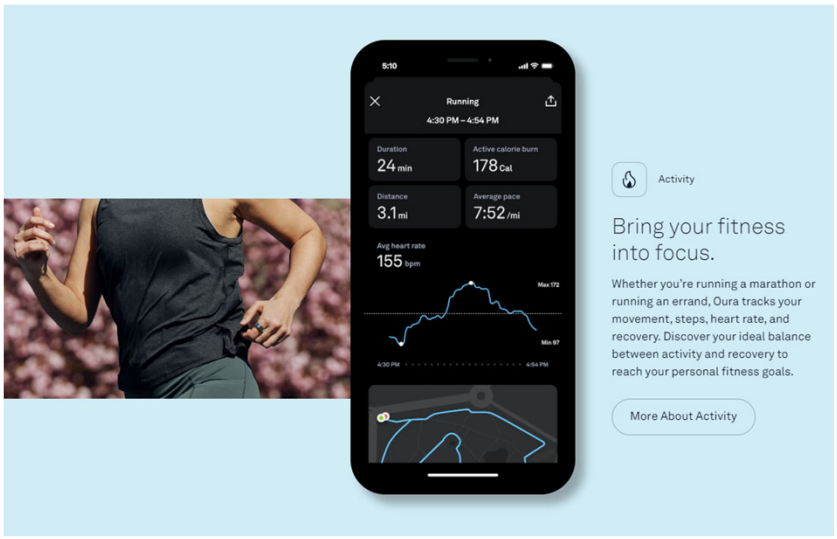

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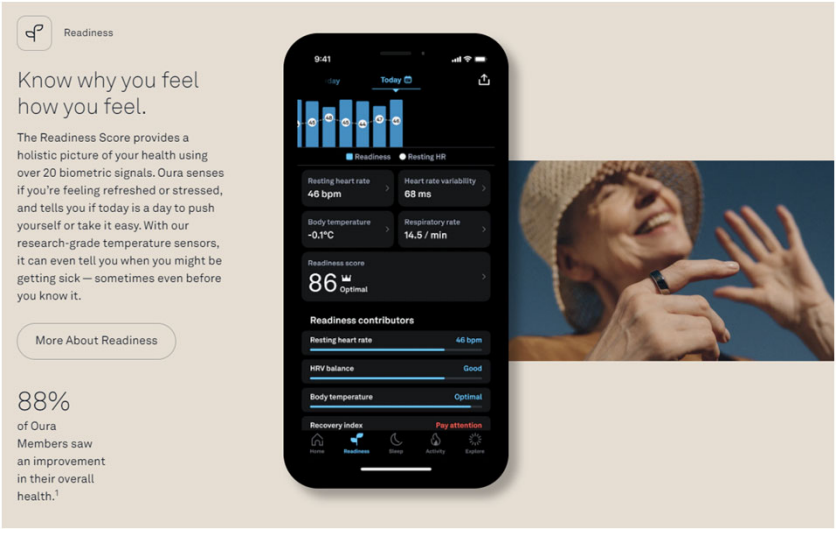

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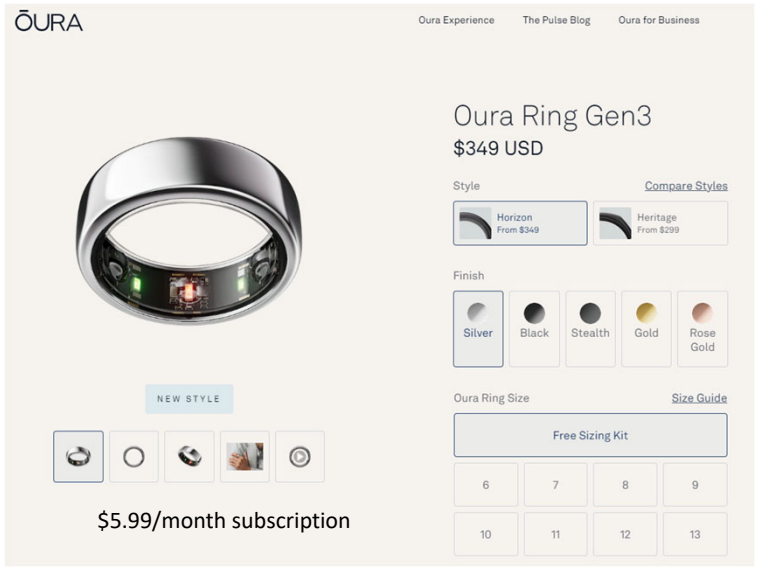

$5.99/month subscription

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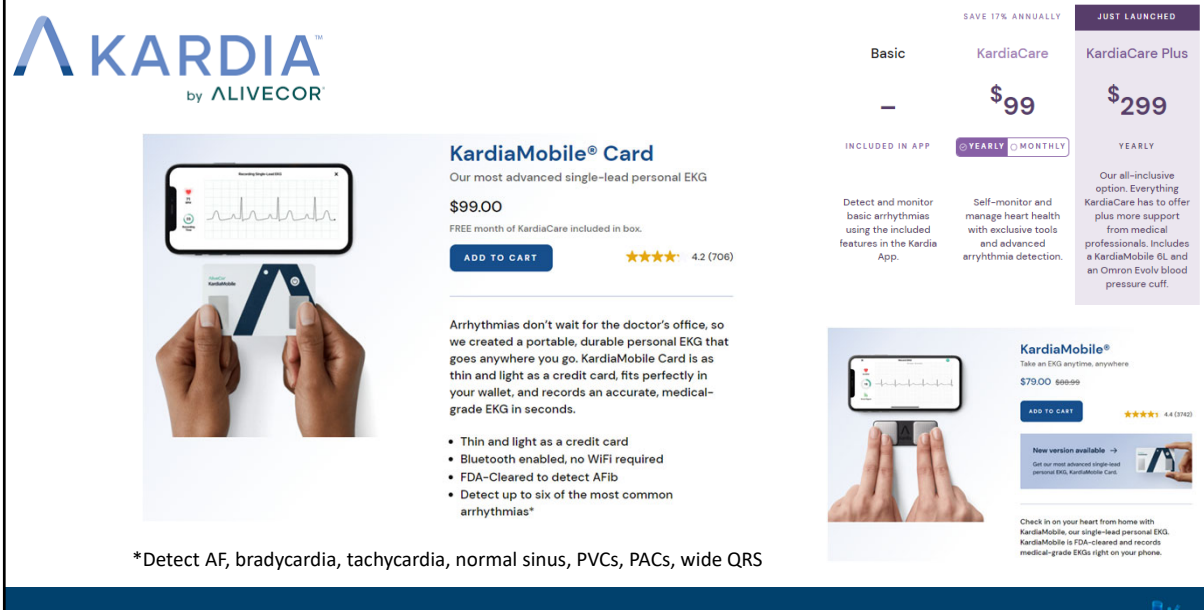

*Detect AF, bradycardia, tachycardia, normal sinus, PVCs, PACs, wide QRS

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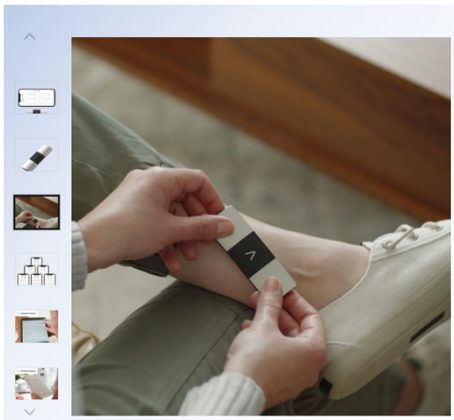

KardiaMobile® 6L

$129.00 ~~$139.99~~

ADD TO CART

4.5 (2224)

With KardiaMobile 6L, you can record unlimited six-lead EKGs, giving you and your doctor more detailed insight on your heart from home.

- Records EKG leads I, II, III, aVL, aVR, and aVF
- More data and deeper insights on your heart rhythm
- FDA-cleared, clinically approved, medical-grade EKG recordings
- Detects up to six of the most common arrhythmias*

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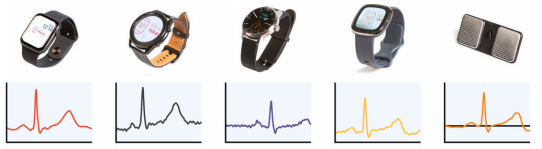
thePager

Clinical Validation of 5 Direct-to-Consumer Wearable Smart Devices to Detect Atrial Fibrillation: BASEL Wearable Study

GET ACCESS

Original Research Paper

Diego Mannhart, Mirko Lischer, Sven Knecht, Jeanne du Fay de Lavallaz, Ivo Strebel, Teodor Serban, David Vögeli, Beat Schaer, Stefan Osswald, Christian Mueller, Michael Kühne, Christian Sticherling, and Patrick Badertscher



- 201 consecutive patients presenting to cardiology service at a tertiary center
- AF present in 32%
- Manual review confirmed 99% of inconclusive tracings in single lead ECG

Manufacturer	Apple	Samsung	Withings	Fitbit	AliveCor
Version	Watch 6	Galaxy Watch3	ScanWatch	Sense	Kardia Mobile
Sensitivity (95% CI)	85% (72-94%)	85% (72-94%)	58% (42-72%)	66% (51-79%)	79% (64-89%)
Specificity (95% CI)	75% (67-83%)	75% (66-82%)	75% (67-83%)	79% (70-86%)	69% (60-77%)
Inconclusive tracings	18%	17%	24%	21%	26%
Preferred Choice*a	39%	12%	24%	15%	5%
Limit of HR interpretation*b	50-150 bpm	50-120 bpm	No information	50-120 bpm	50-100 bpm
Battery capacity*c	18 h*d	45 h*d	720 h*d	144 h*d	90 h / 2 y*e
Price*d	449	265	303	244	147

*a: Out of 165 analyzed patients, 10 patients were not able to decide between the available devices
*b: Information obtained from manufacturers website, 11/21
*c: Time with GPS disabled
*d: Information obtained on digitec.ch on 12.11.21, no discounts / special offers were included in the price, price includes tax / all prices in CHF
*e: 90 h net operating time, under regular use up to 2 years

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Beyond activity, HR, and HRV

AF and other arrhythmias	PPG tachograms or notification algorithms and single-lead and multi-lead ECG	Apple Watch (Apple, USA), AliveCor Kardia Band and KardiaMobile (AliveCor, USA), Zio Patch (iRhythm Technologies, USA)	Prospective cohort studies[19,51,52,53,55,56,57] randomized controlled trials[50,58]	AF screening via ECG patches in selected high-risk individuals is feasible and clinically valuable[50]
				AF screening through PPG has shown variable accuracy depending on the algorithms and devices used[19,51,52]
				AF screening through PPG coupled with ECG is feasible and practical; no clinical studies available; the HEARTLINE study aims[34] to examine this application and its effect on clinical outcomes
				The IPED trial[58] showed that a single-lead ECG monitor can improve outpatient arrhythmia detection in patients who present to the emergency room with palpitations or presyncope and no clear aetiology
				Wearables can be used to assess AF burden; rhythm-guided anticoagulation is a feasible approach in some patients with AF; no clinical studies exist but a trial examining smartwatch-guided anticoagulation therapy is under development
				Wearables were used in one study to confirm persistent AF before admission for cardioversion[33]
				Wearables can be used to guide rate control in patients with permanent AF; no clinical studies available

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Beyond activity, HR, and HRV

Coronary artery disease	Heart rate, step counting and single-lead ECG	Apple Watch	Prospective cohort study[76] case report[17]	In patients with type I myocardial infarction, the MICORE study[76] showed that a mobile app platform (including a smartwatch) improved secondary prevention management by reducing hospital readmissions and cost
				Wearables can be used to guide β-blocker titration in patients with chronic coronary syndrome; no available clinical studies
				Single-lead ECG wearables can be manipulated to acquire a 12-lead ECG for acute coronary syndrome diagnosis, as shown a in case report[17]

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Beyond activity, HR, and HRV

Cardiac rehabilitation	Step counting and heart rate	BioHarness 3 (Zephyr Technology, USA), Garmin Forerunner (Garmin, USA), Senswear mini armband (commercially discontinued), Yamax pedometers (Japan), Fitbit Charge, My Wellness Key accelerometer (commercially discontinued), Gex sensor (commercially discontinued)	Randomized controlled trials, a systematic review and a meta-analysis[85,86]	Home-based cardiac telerehabilitation using wearable sensors is equivalent or better than centre-based rehabilitation and can increase access to cardiac rehabilitation and reduce the cost

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Risk Assessment

PHYSICAL ACTIVITY ↓
HEART RATE ↑
HEART RATE VARIABILITY ↓
→ **MORTALITY** ↑

Current Age * | Sex * (Male / Female) | Race * (White / African American / Other)
Systolic Blood Pressure (mm Hg) * | Diastolic Blood Pressure (mm Hg) *
Total Cholesterol (mg/dL) * | HDL Cholesterol (mg/dL) * | LDL Cholesterol (mg/dL)
History of Diabetes? * (Yes / No) | Smoker? * (Current / Former / Never)
On Hypertension Treatment? * (Yes / No) | On a Statin? (Yes / No) | On Aspirin Therapy? (Yes / No)

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Move More References

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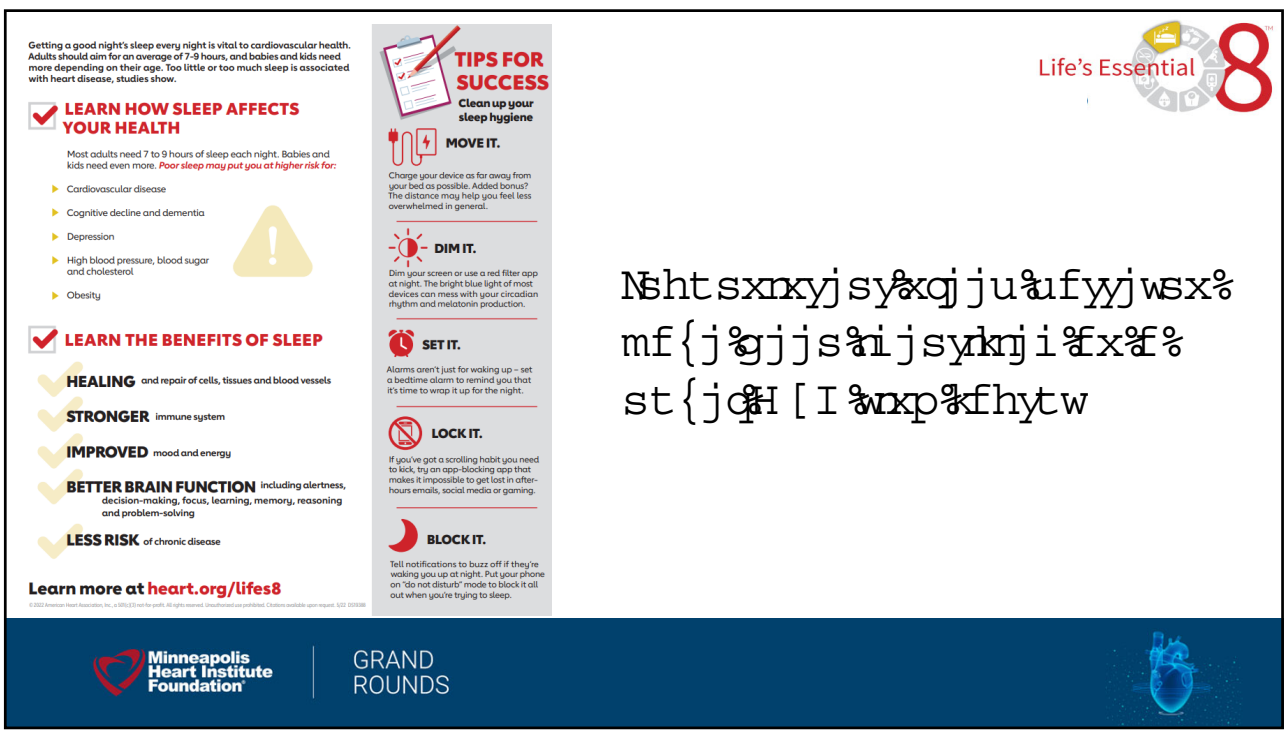

Life's Essential 8

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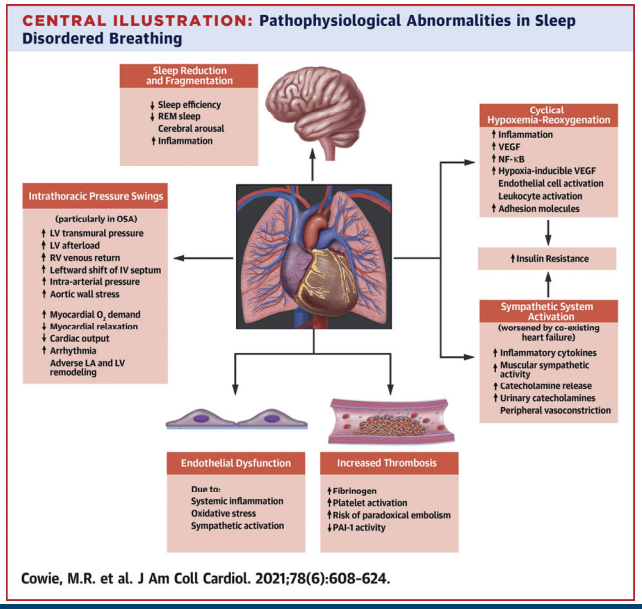
Sleep disordered breathing



Cowie, M.R. et al. J Am Coll Cardiol. 2021;78(6):608-624.

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Fast Facts

Life's Essential 8

- OSA predicted a 2.4 increase in mortality and a higher CVD incidence over 7.5 years in more than 5,000 participants in the MESA cohort who were free of known CVD at baseline
- Up to 50% of OSA patients may have hypertension, and 30% of hypertensive patients will likely have OSA
- Prevalence of sleep disordered breathing is higher in patients with AF than matched controls; AF harder to control with antiarrhythmics and more likely to recur after ablation

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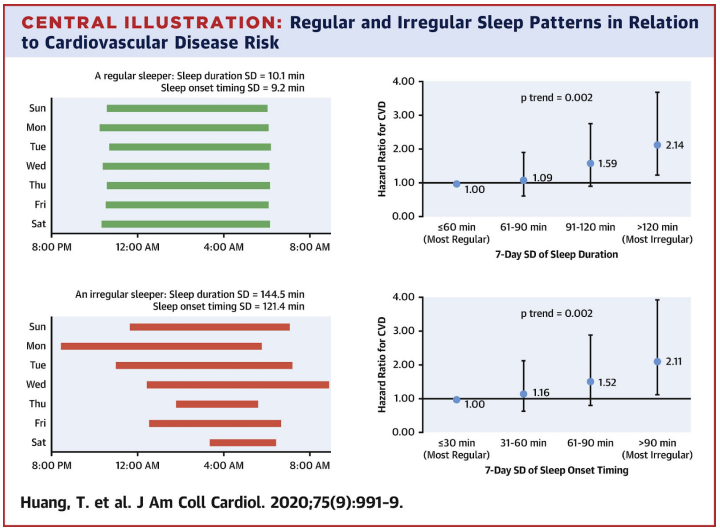
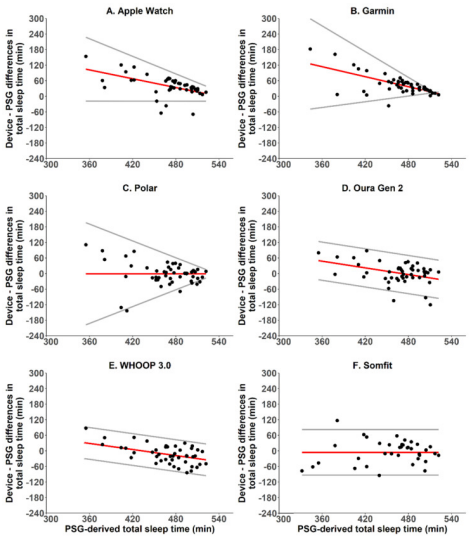
Non-obstructers



Huang, T. et al. J Am Coll Cardiol. 2020;75(9):991-9.

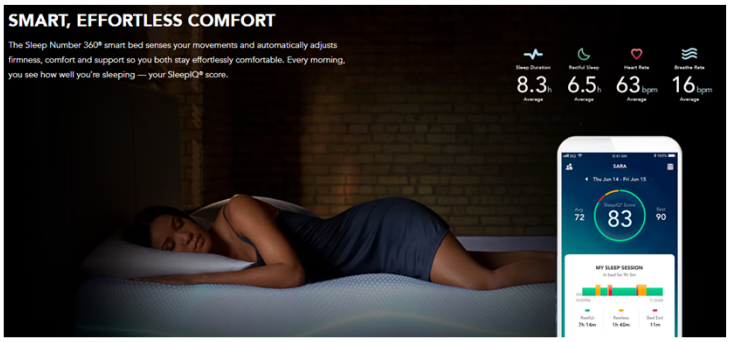
Device Data

- Time asleep
- Sleep stages
- Restlessness
- HR
- HRV
- Respirations



sleep number

Life's Essential 8



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sleep number

Life's Essential 8

- 10 billion hours of sleep data from 1.8 billion sleep sessions
- The 360® smart bed effortlessly adjusts throughout the night
- 28 more minutes of restful sleep per night—170 hours per year
- Collaboration with Mayo Clinic
  - Sleep Number funding several studies including daytime sleepiness and CV implications
  - Underserved community research: disordered sleep in Somali population
  - Disrupted sleep and markers of aging (telomeres, senescence)

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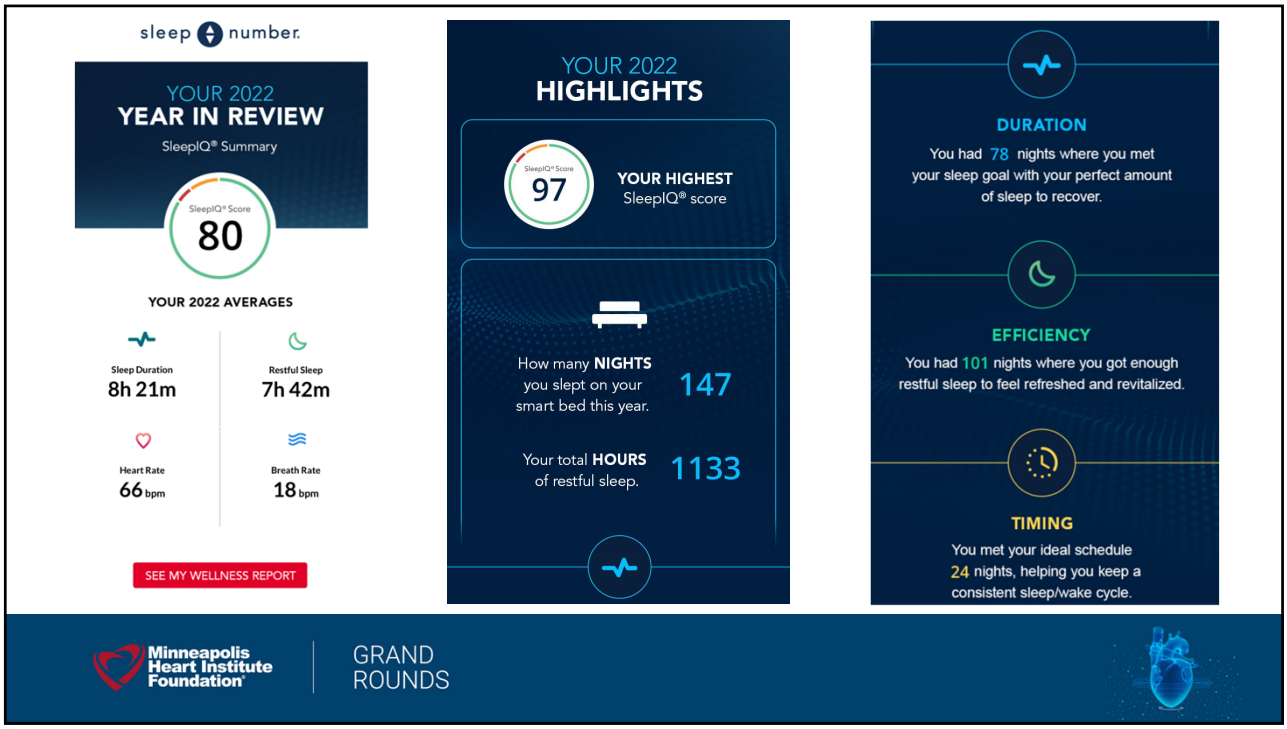
sleep number
YOUR 2022
YEAR IN REVIEW
SleepIQ® Summary
SleepIQ® Score
80
YOUR 2022 AVERAGES
Sleep Duration
8h 21m
Restful Sleep
7h 42m
Heart Rate
66 bpm
Breath Rate
18 bpm
SEE MY WELLNESS REPORT
YOUR 2022
HIGHLIGHTS
SleepIQ® Score
97
YOUR HIGHEST
SleepIQ® score
How many NIGHTS you slept on your smart bed this year.
147
Your total HOURS of restful sleep.
1133
DURATION
You had 78 nights where you met your sleep goal with your perfect amount of sleep to recover.
EFFICIENCY
You had 101 nights where you got enough restful sleep to feel refreshed and revitalized.
TIMING
You met your ideal schedule 24 nights, helping you keep a consistent sleep/wake cycle.
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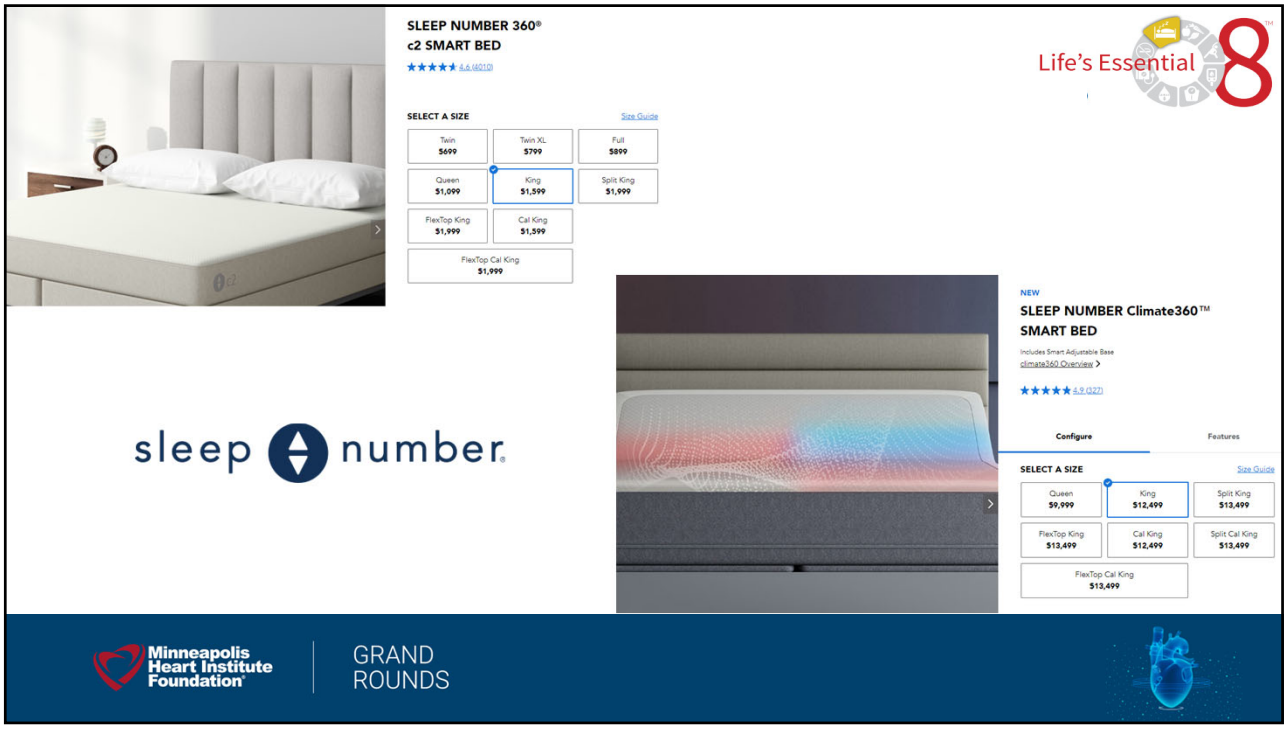
SLEEP NUMBER 360®
c2 SMART BED
SELECT A SIZE
Size Guide
Twin $699
Twin XL $799
Full $899
Queen $1,099
King $1,599
Split King $1,999
FlexTop King $1,999
Cal King $1,599
FlexTop Cal King $1,999
Life's Essential 8
sleep number
NEW
SLEEP NUMBER Climate360™
SMART BED
Configure
Features
SELECT A SIZE
Queen $9,999
King $12,499
Split King $13,499
FlexTop King $13,499
Cal King $12,499
Split Cal King $13,499
FlexTop Cal King $13,499
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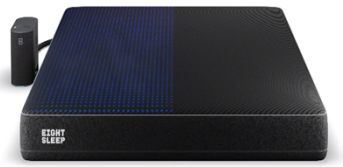
Life's Essential 8

The hot (better cold) area of sleep temperature

Sleep deeper while your Pod adjusts temperature to keep you asleep

With Temperature Autopilot, the Pod adjusts your sleeping temperature to your individual patterns, supporting the flow of each sleep cycle to maximize recovery. Temperature on each side of the bed can range from as low as 55°F to as high as 110°F.



- Keeping skin temperature within tight range enhances deep sleep
  - Improved HR and HRV
- Validation study with Oura
  - 300 patients before and after Eight Sleep
  - Deep sleep increased 10%
  - HRV decreased 6%
  - HR decreased 1%
    - 2% for HR >70
- Reduction of 1 bpm in sleeping HR is equivalent to a 1.6% reduction in risk of death from any cause
  - Marketing gone wrong?

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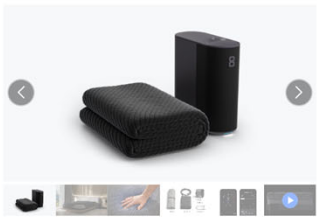
Life's Essential 8



Product description

The Pod 3 Cover improves your sleep, gives you more energy, and seamlessly fits onto any mattress. Each side cools and heats you and your partner, all while tracking your sleep without a wearable.

Included with the Pod

Pod 3 Cover

~~$2,495~~ $2,445 $50 off

Select size — Order now. Sale ends soon.

King ~~$2,495~~ $2,445

Select Cover type

Pod 2 Cover — Fits 10"-11" mattresses

Pod 3 Cover — Fits 10"-11" mattresses. Now with increased comfort and improved tracking

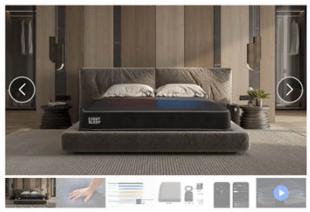
Most Popular — Pod 3 Cover with PerfectFit — Fits all mattresses. Now with increased comfort and improved tracking

Membership

Optimize your sleep with 8+ Pro — ~~$19/mo~~ $15/mo* — Remove

You and your partner will have access to:
- Temperature Autopilot
- Sleep content
- Digital coaching & data insights

8 EIGHT SLEEP



Product description

The Pod Mattress improves your sleep, gives you more energy, and upgrades your entire sleep experience. Each side cools and heats you and your partner, all while tracking your sleep without a wearable.

Included with the Pod

Pod 3 Mattress

~~$3,795~~ $3,695 $100 off

Select size — Order now. Sale ends soon.

King ~~$3,795~~ $3,695

Select Pod type

Pod 2 — 4 layer mattress

Pod 3 — 5 layer mattress with increased comfort and improved tracking

Most Popular — Pod 3 Max — 6 layer mattress with increased comfort and improved tracking + MaxChill™ layer

Membership

Optimize your sleep with 8+ Pro — ~~$19/mo~~ $15/mo* — Remove

You and your partner will have access to:
- Temperature Autopilot
- Sleep content
- Digital coaching & data insights

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How to get healthy sleep references

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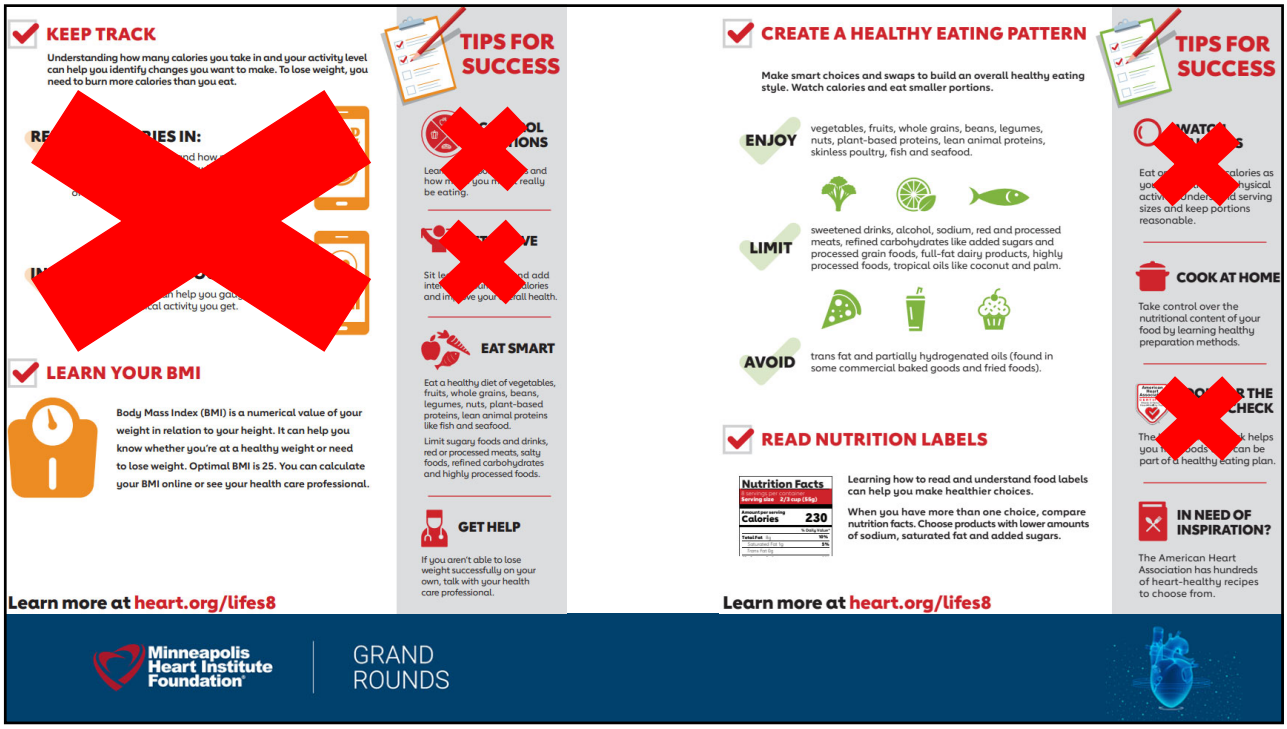

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Circulation
Volume 143, Issue 21, 25 May 2021; Pages e984-e1010
https://doi.org/10.1161/CIR.0000000000000973

American Heart Association.

Life's Essential 8

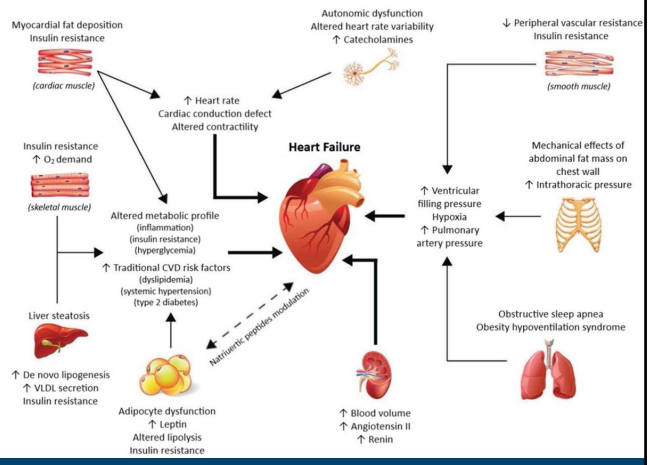
AHA SCIENTIFIC STATEMENT

Obesity and Cardiovascular Disease: A Scientific Statement From the American Heart Association

Excess adiposity promotes changes in cardiac function:

1) Directly through the effects on the myocardium and vasculature

2) Indirectly through obesity-related comorbidities



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Circulation
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American Heart Association.

Life's Essential 8

AHA SCIENTIFIC STATEMENT

Obesity and Cardiovascular Disease: A S
Statement From the American Heart A

Lifestyle mo

1) The diagnos

2) Associat tion and endothelial dysfunctior

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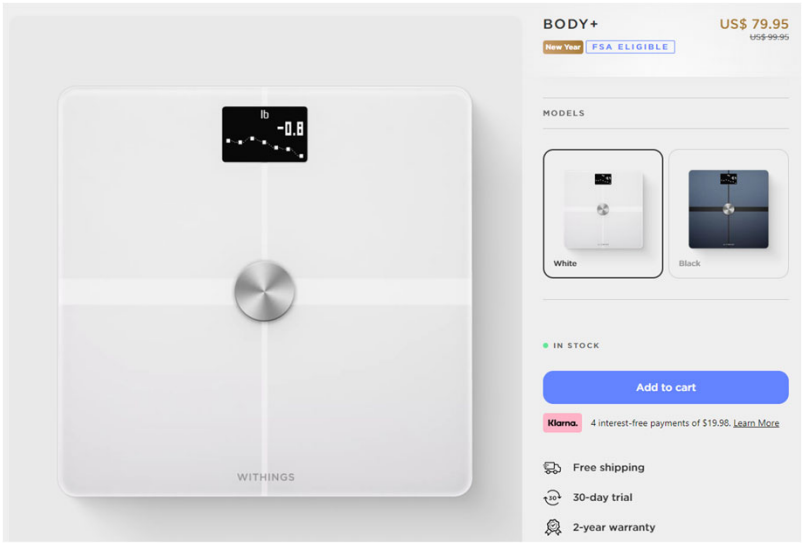

Life's Essential 8

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Life's Essential 8

Simple design, big impact

Cardiac Scale | Clinical Dashboard | Patient Experience

Easy-to-use cardiac scale

With one simple step, the Bodyport Cardiac Scale detects signals through a person's feet and sends data to the clinical care team in seconds. Advanced sensors and proprietary algorithms noninvasively measure a broad spectrum of hemodynamic biomarkers to assess heart function and fluid status.

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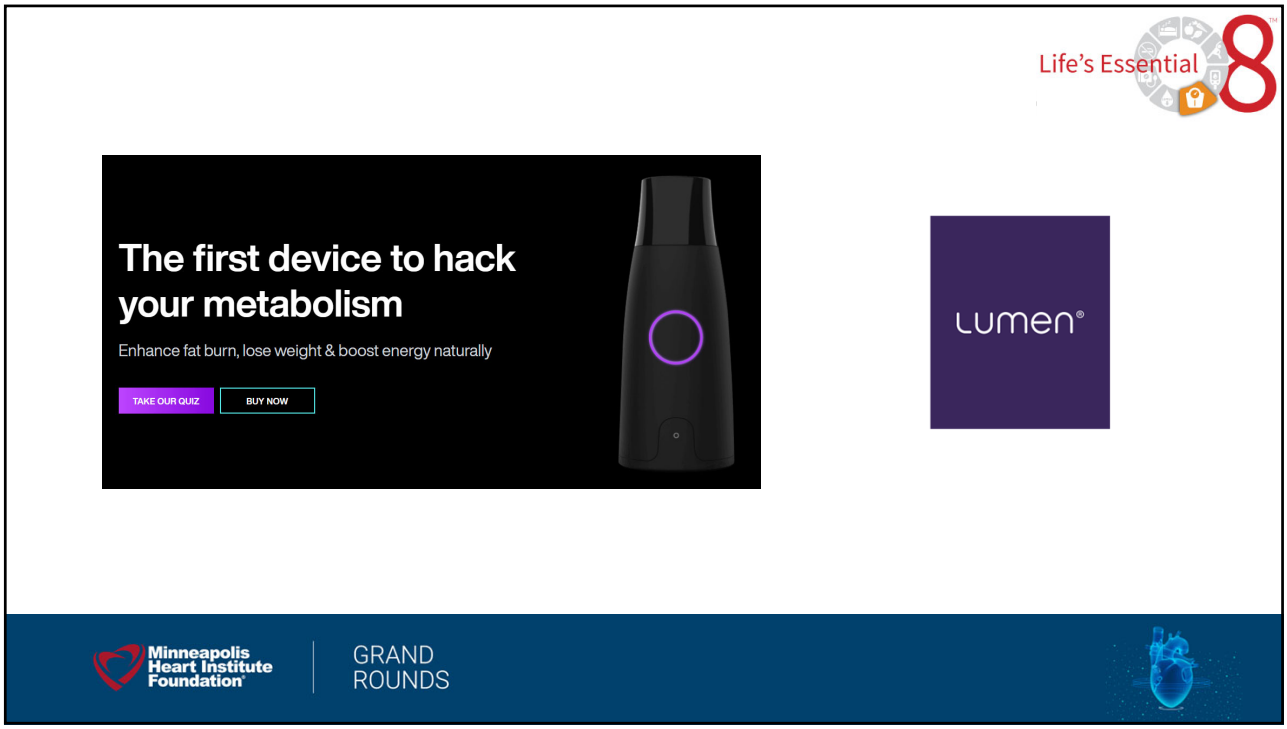
Life's Essential 8
The first device to hack your metabolism
Enhance fat burn, lose weight & boost energy naturally
TAKE OUR QUIZ
BUY NOW
lumen®
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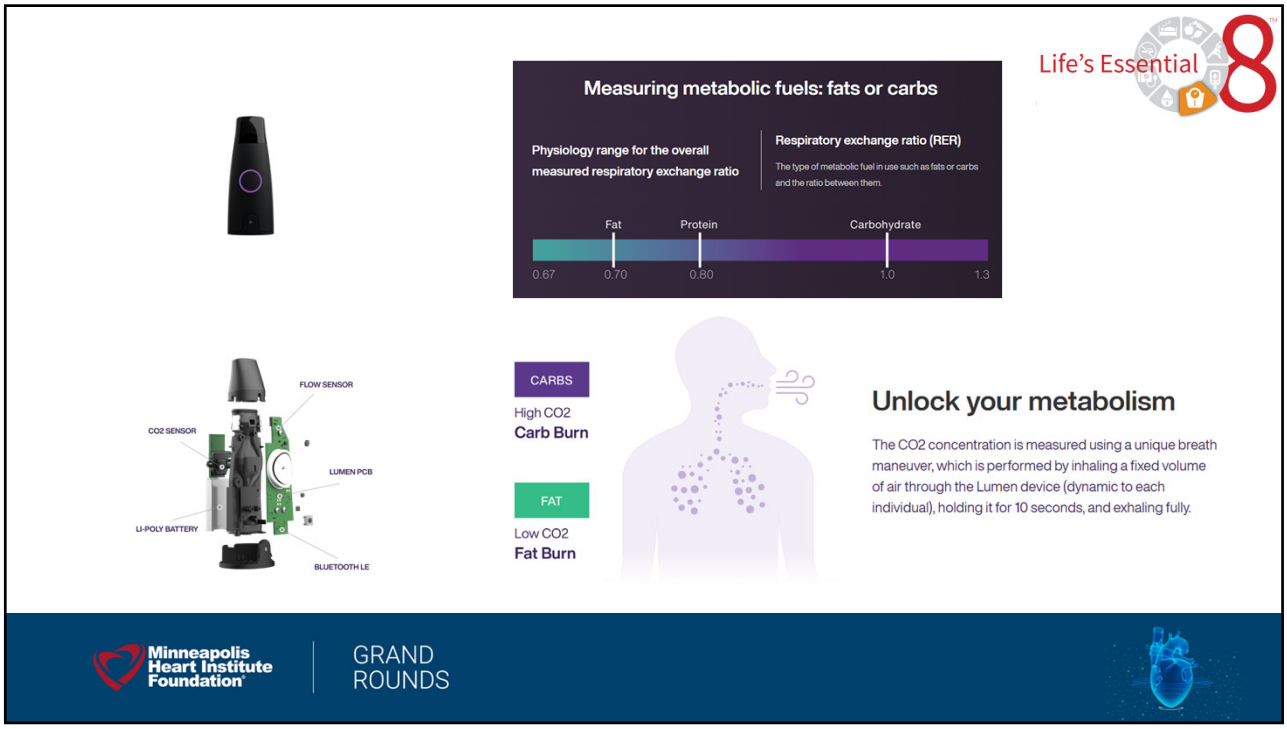
Life's Essential 8
Measuring metabolic fuels: fats or carbs
Physiology range for the overall measured respiratory exchange ratio
Respiratory exchange ratio (RER)
The type of metabolic fuel in use such as fats or carbs and the ratio between them.
Fat
Protein
Carbohydrate
0.67
0.70
0.80
1.0
1.3
FLOW SENSOR
CO2 SENSOR
LUMEN PCB
LI-POLY BATTERY
BLUETOOTH LE
CARBS
High CO2
Carb Burn
FAT
Low CO2
Fat Burn
Unlock your metabolism
The CO2 concentration is measured using a unique breath maneuver, which is performed by inhaling a fixed volume of air through the Lumen device (dynamic to each individual), holding it for 10 seconds, and exhaling fully.
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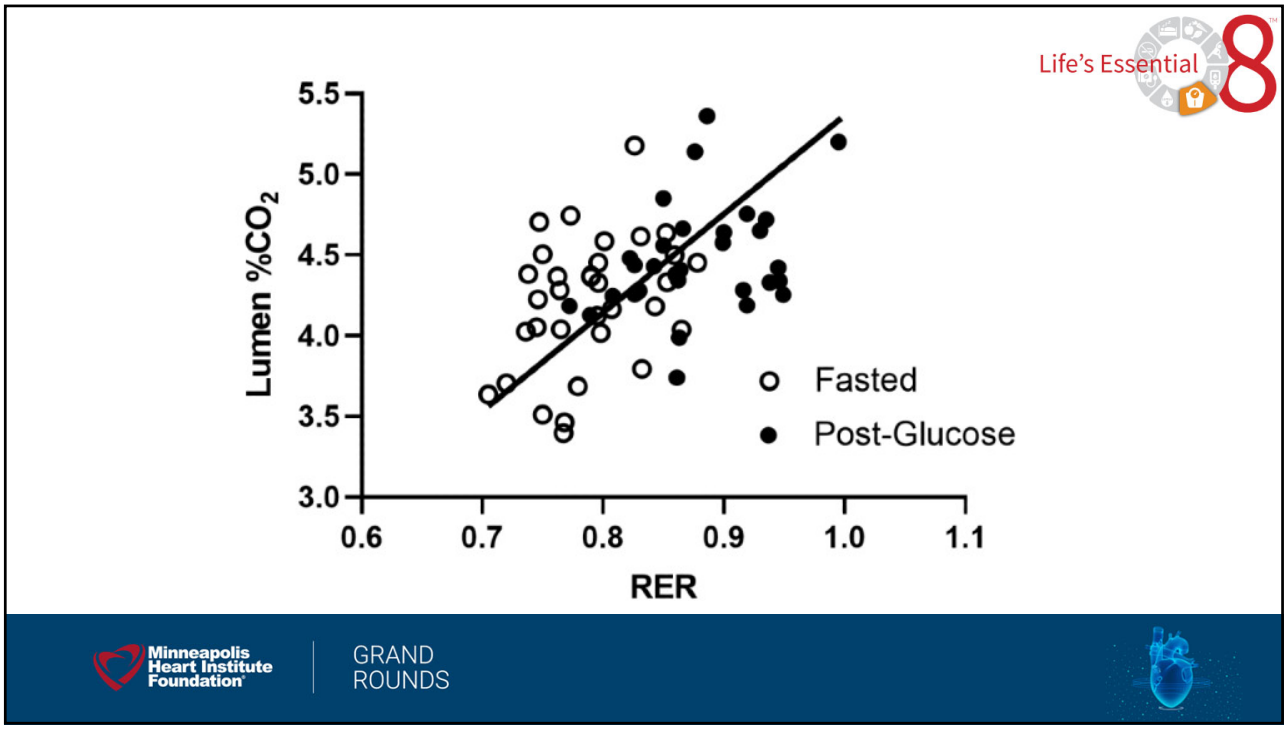
Life's Essential 8
Lumen %CO2
5.5
5.0
4.5
4.0
3.5
3.0
0.6
0.7
0.8
0.9
1.0
1.1
RER
Fasted
Post-Glucose
Minneapolis Heart Institute Foundation
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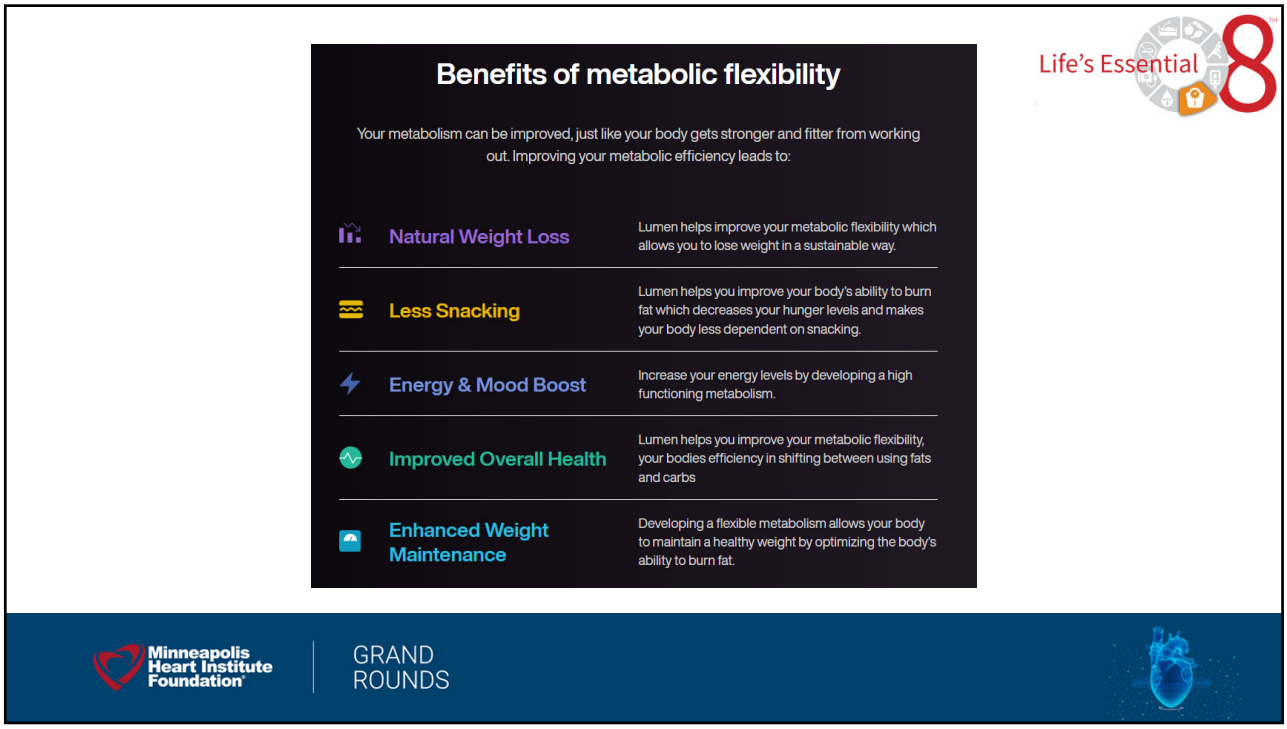
Life's Essential 8
Benefits of metabolic flexibility
Your metabolism can be improved, just like your body gets stronger and fitter from working out. Improving your metabolic efficiency leads to:
Natural Weight Loss
Lumen helps improve your metabolic flexibility which allows you to lose weight in a sustainable way.
Less Snacking
Lumen helps you improve your body's ability to burn fat which decreases your hunger levels and makes your body less dependent on snacking.
Energy & Mood Boost
Increase your energy levels by developing a high functioning metabolism.
Improved Overall Health
Lumen helps you improve your metabolic flexibility, your bodies efficiency in shifting between using fats and carbs
Enhanced Weight Maintenance
Developing a flexible metabolism allows your body to maintain a healthy weight by optimizing the body's ability to burn fat.
Minneapolis Heart Institute Foundation
GRAND ROUNDS

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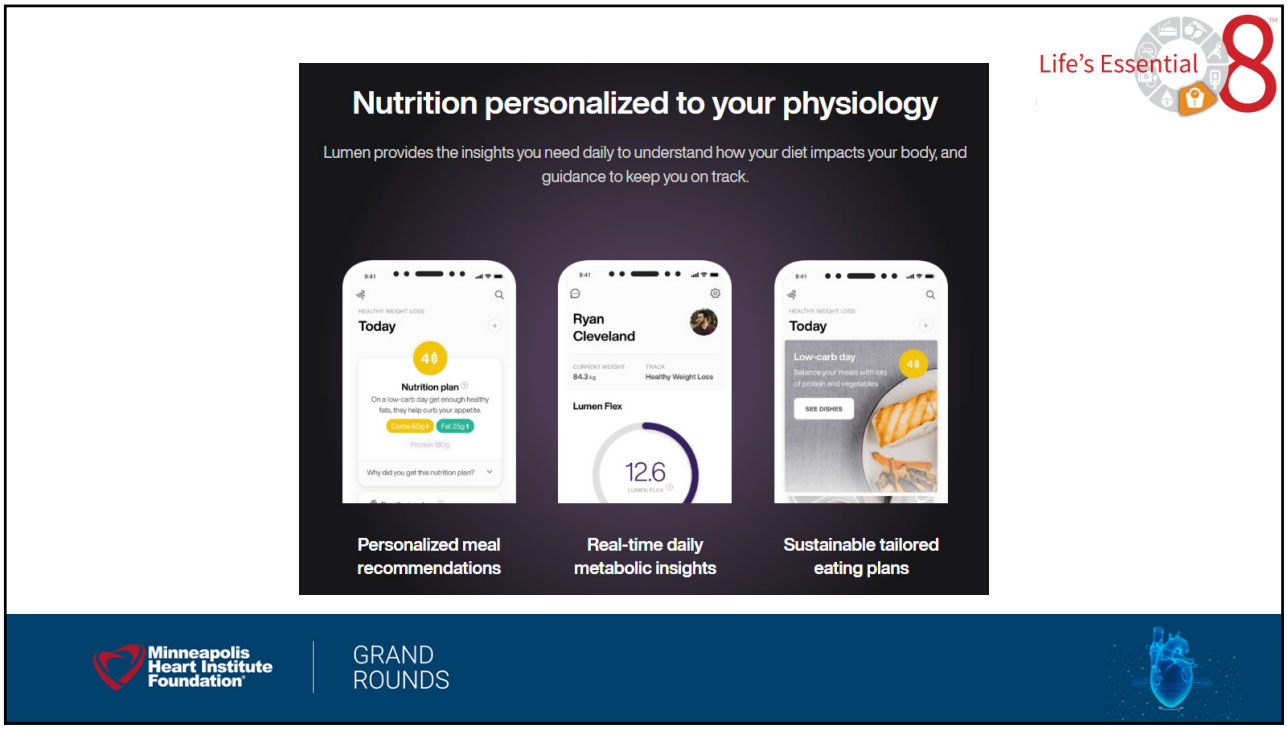
Life's Essential 8
Nutrition personalized to your physiology
Lumen provides the insights you need daily to understand how your diet impacts your body, and guidance to keep you on track.
Today
Nutrition plan
Ryan Cleveland
Lumen Flex
12.6
Today
Low-carb day
SEE DISHES
Personalized meal recommendations
Real-time daily metabolic insights
Sustainable tailored eating plans
Minneapolis Heart Institute Foundation
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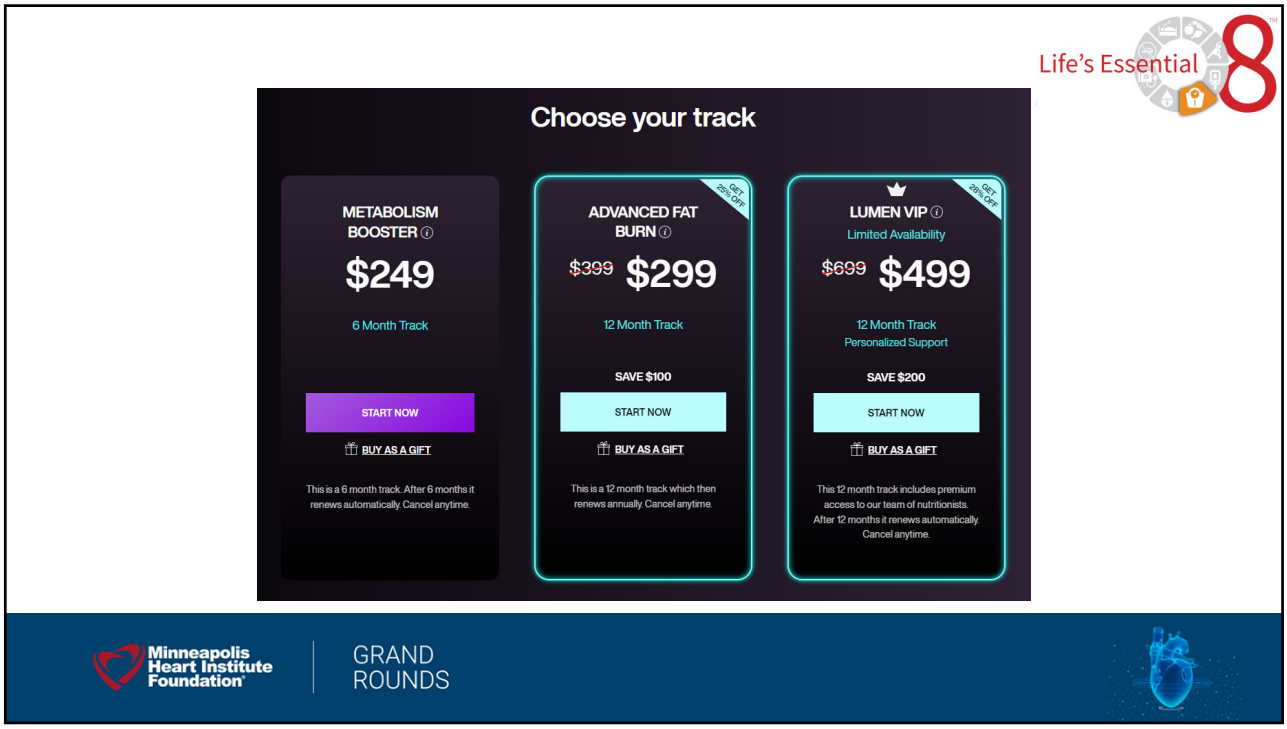
Life's Essential 8
Choose your track
METABOLISM BOOSTER
$249
6 Month Track
START NOW
BUY AS A GIFT
This is a 6 month track. After 6 months it renews automatically. Cancel anytime.
ADVANCED FAT BURN
$399 $299
12 Month Track
SAVE $100
START NOW
BUY AS A GIFT
This is a 12 month track which then renews annually. Cancel anytime.
LUMEN VIP
Limited Availability
$699 $499
12 Month Track
Personalized Support
SAVE $200
START NOW
BUY AS A GIFT
This 12 month track includes premium access to our team of nutritionists. After 12 months it renews automatically. Cancel anytime.
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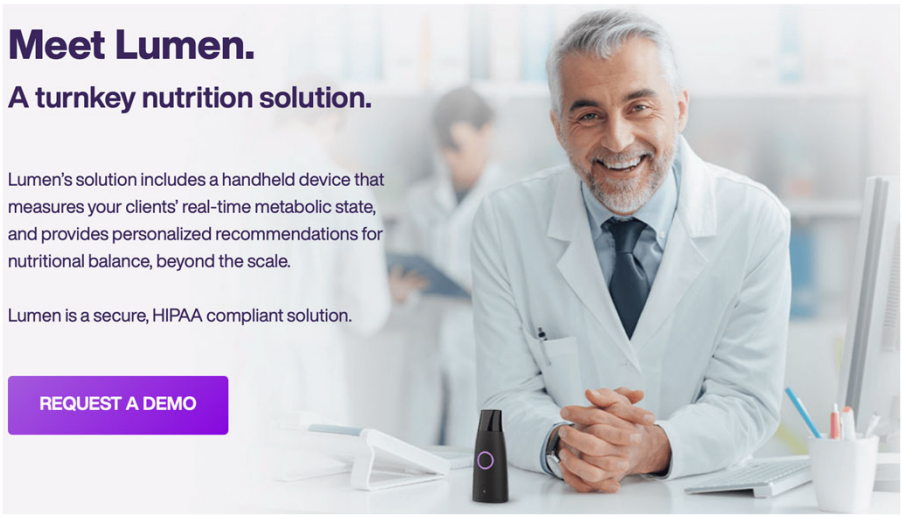

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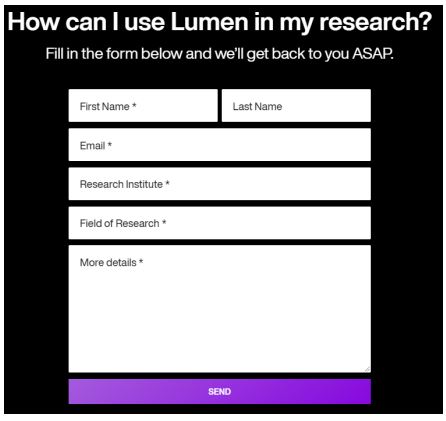
More to come

Life's Essential 8



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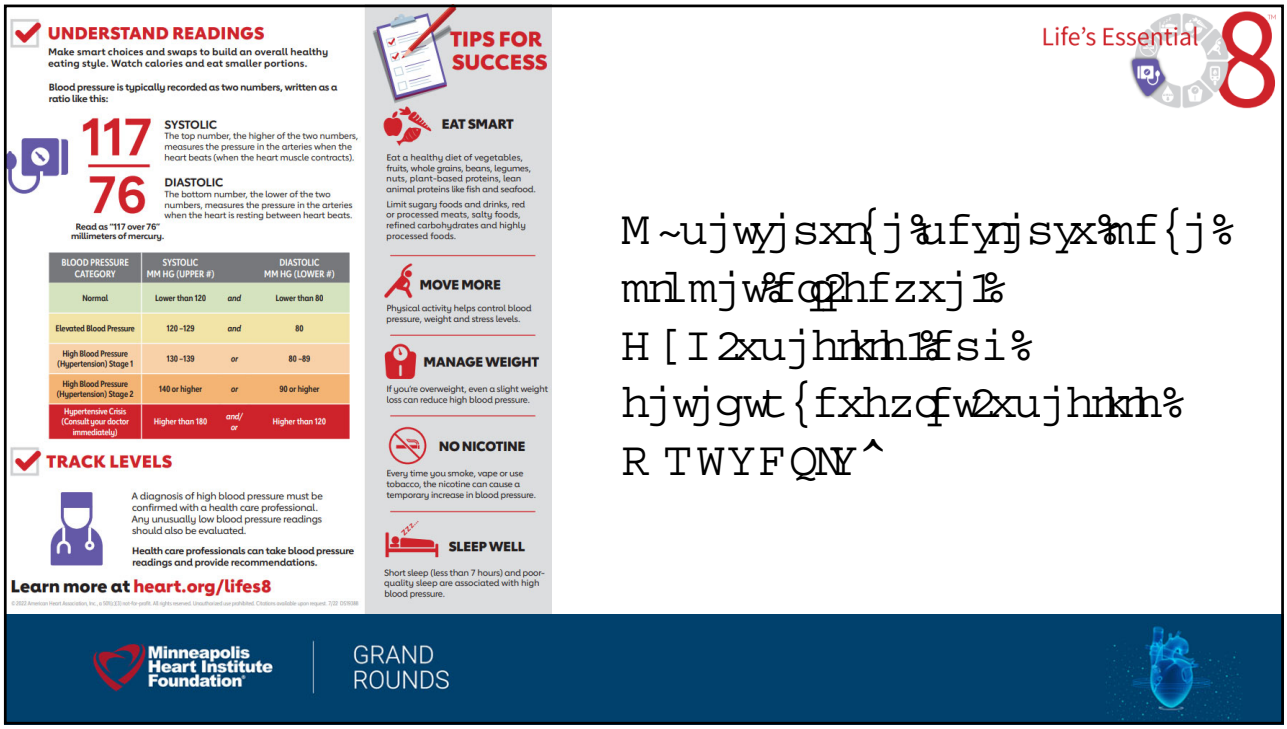
82


UNDERSTAND READINGS
Make smart choices and swaps to build an overall healthy eating style. Watch calories and eat smaller portions.
Blood pressure is typically recorded as two numbers, written as a ratio like this:
117
76
SYSTOLIC
The top number, the higher of the two numbers, measures the pressure in the arteries when the heart beats (when the heart muscle contracts).
DIASTOLIC
The bottom number, the lower of the two numbers, measures the pressure in the arteries when the heart is resting between heart beats.
Read as "117 over 76" millimeters of mercury.
BLOOD PRESSURE CATEGORY
SYSTOLIC MM HG (UPPER #)
DIASTOLIC MM HG (LOWER #)
Normal
Lower than 120
and
Lower than 80
Elevated Blood Pressure
120 -129
and
80
High Blood Pressure (Hypertension) Stage 1
130 -139
or
80 -89
High Blood Pressure (Hypertension) Stage 2
140 or higher
or
90 or higher
Hypertensive Crisis (Consult your doctor immediately)
Higher than 180
and/or
Higher than 120
TRACK LEVELS
A diagnosis of high blood pressure must be confirmed with a health care professional. Any unusually low blood pressure readings should also be evaluated.
Health care professionals can take blood pressure readings and provide recommendations.
Learn more at heart.org/lifes8
TIPS FOR SUCCESS
EAT SMART
Eat a healthy diet of vegetables, fruits, whole grains, beans, legumes, nuts, plant-based proteins, lean animal proteins like fish and seafood.
Limit sugary foods and drinks, red or processed meats, salty foods, refined carbohydrates and highly processed foods.
MOVE MORE
Physical activity helps control blood pressure, weight and stress levels.
MANAGE WEIGHT
If you're overweight, even a slight weight loss can reduce high blood pressure.
NO NICOTINE
Every time you smoke, vape or use tobacco, the nicotine can cause a temporary increase in blood pressure.
SLEEP WELL
Short sleep (less than 7 hours) and poor-quality sleep are associated with high blood pressure.
Life's Essential 8
M~ujwyjsxn{j%ufyrjsyx%nf{j%
mnlmjw%fqq2hfzxj1%
H[I2xujhnknh1%fsi%
hjwjgwt{fxhzqfw2xujhnknh%
RTWYFQNY^
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83

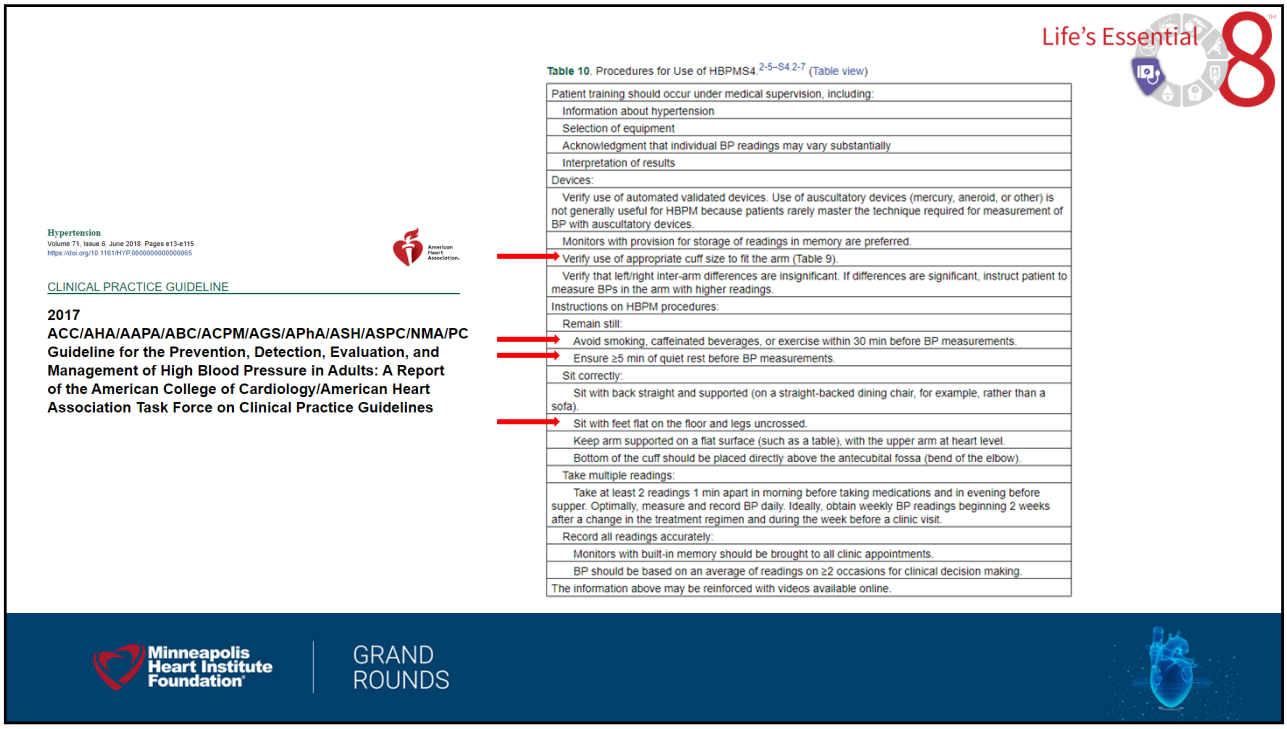
Life's Essential 8
Hypertension
Volume 71, Issue 6, June 2018; Pages e13-e115
https://doi.org/10.1161/HYP.0000000000000065
CLINICAL PRACTICE GUIDELINE
2017
ACC/AHA/AAPA/ABC/ACPM/AGS/APhA/ASH/ASPC/NMA/PC
Guideline for the Prevention, Detection, Evaluation, and Management of High Blood Pressure in Adults: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines
Table 10. Procedures for Use of HBPMS4.2-5–S4.2-7 (Table view)
Patient training should occur under medical supervision, including:
Information about hypertension
Selection of equipment
Acknowledgment that individual BP readings may vary substantially
Interpretation of results
Devices:
Verify use of automated validated devices. Use of auscultatory devices (mercury, aneroid, or other) is not generally useful for HBPM because patients rarely master the technique required for measurement of BP with auscultatory devices.
Monitors with provision for storage of readings in memory are preferred.
Verify use of appropriate cuff size to fit the arm (Table 9).
Verify that left/right inter-arm differences are insignificant. If differences are significant, instruct patient to measure BPs in the arm with higher readings.
Instructions on HBPM procedures:
Remain still:
Avoid smoking, caffeinated beverages, or exercise within 30 min before BP measurements.
Ensure ≥5 min of quiet rest before BP measurements.
Sit correctly:
Sit with back straight and supported (on a straight-backed dining chair, for example, rather than a sofa).
Sit with feet flat on the floor and legs uncrossed.
Keep arm supported on a flat surface (such as a table), with the upper arm at heart level.
Bottom of the cuff should be placed directly above the antecubital fossa (bend of the elbow).
Take multiple readings:
Take at least 2 readings 1 min apart in morning before taking medications and in evening before supper. Optimally, measure and record BP daily. Ideally, obtain weekly BP readings beginning 2 weeks after a change in the treatment regimen and during the week before a clinic visit.
Record all readings accurately:
Monitors with built-in memory should be brought to all clinic appointments.
BP should be based on an average of readings on ≥2 occasions for clinical decision making.
The information above may be reinforced with videos available online.
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Table 11. Corresponding Values of SBP/DBP for Clinic, HBPM, Daytime, Nighttime, and 24-Hour ABPM Measurements (Table view)

Clinic	HBPM	Daytime ABPM	Nighttime ABPM	24-Hour ABPM
120/80	120/80	120/80	100/65	115/75
130/80	130/80	130/80	110/65	125/75
140/90	135/85	135/85	120/70	130/80
160/100	145/90	145/90	140/85	145/90

Meta-analyses of RCTs have identified clinically useful reductions in SBP and DBP and achievement of BP goals at 6 months and 1 year when self-monitoring of BP has been used in conjunction with other interventions, compared with usual care.

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ABPM

- A systematic review by USPSTF: ABPM provided a better method to predict long-term CVD outcomes than did office BPs
  - Evidence suggests HBPM is similar
- Every 15-30 min during day and 15-60 min night
- Mean blood pressure, day/night and nocturnal dipping, early morning BP surge, symptomatic hypotension
- Medicare claims for ABPM between 2007 and 2010 were reimbursed at a median of $52 and were submitted for <1% of beneficiaries
  - ALWAYS covered!!!
  - Masked HTN, white coat HTN, response to treatment

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Life's Essential 8
3 Series® Upper Arm Blood Pressure Monitor
Model: BP7100 | Compare >
4.0 Write a review
The OMRON 3 Series Upper Arm home blood pressure monitor is designed for accuracy and stores 14 blood pressure readings for one user, and includes a wide-range D-ring cuff (fits arms 9" to 17" in circumference).
30-day MONEY BACK GUARANTEE
#1 DOCTOR AND PHARMACIST RECOMMENDED BRAND
QTY 1
$55.50 FSA
10 Series® Wireless Upper Arm Blood Pressure Monitor
Model: BP7450 | Compare >
3.8 Write a review
The OMRON 10 Series Wireless Bluetooth® Upper Arm home blood pressure monitor has a horizontally designed dual-display monitor and stores up to 200 readings for two users (100 per user), and includes a pre-formed Easy-Wrap Comfit Cuff (fits arms 9" to 17" in circumference).
30-day MONEY BACK GUARANTEE
#1 DOCTOR AND PHARMACIST RECOMMENDED BRAND
QTY 1
$110.00 FSA
Evolv® Wireless Upper Arm Blood Pressure Monitor
Model: BP7000 | Compare >
4.2 Write a review
The next step in eliminating heart attacks is here. Our new Evolv upper arm blood pressure monitor is compact, intuitive and clinically-accurate.
30-day MONEY BACK GUARANTEE
#1 DOCTOR AND PHARMACIST RECOMMENDED BRAND
QTY 1
$110.00 FSA
In Stock
BUY NOW
WHERE TO BUY >
Bundle with the KardiaMobile EKG Device for $169.99!
PURCHASE BUNDLE
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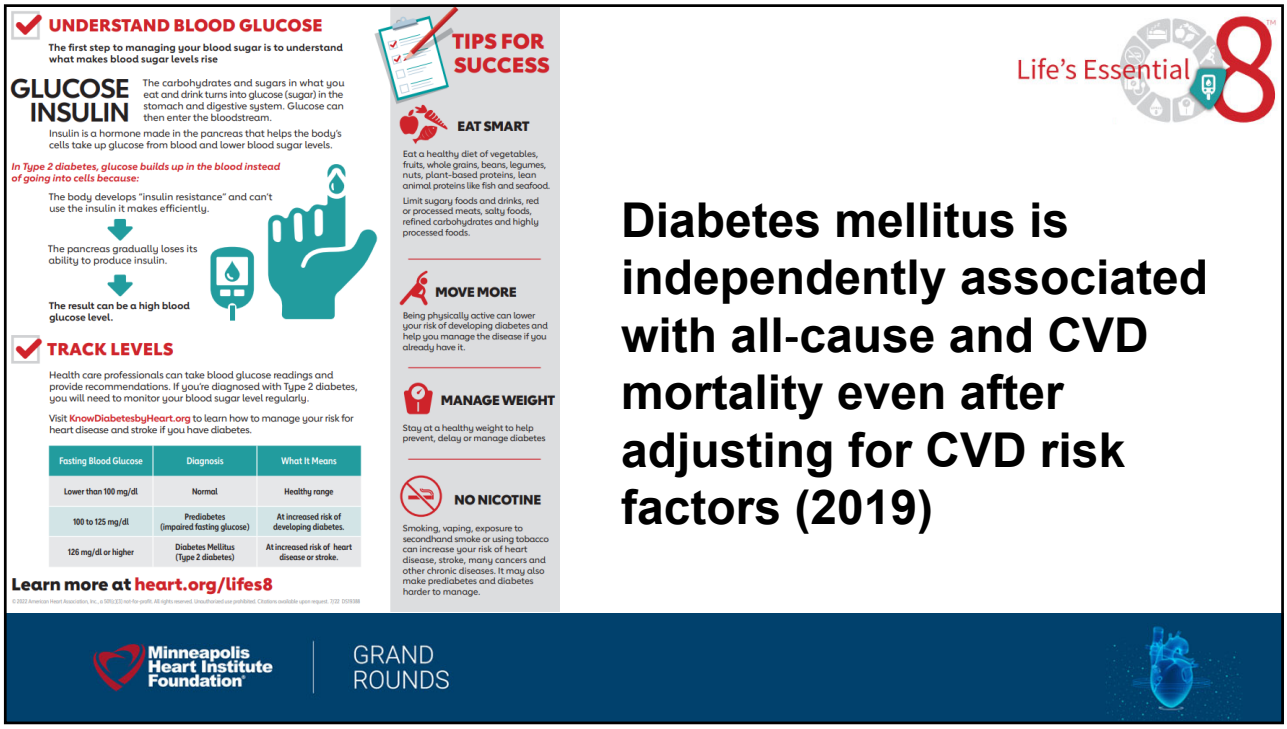
UNDERSTAND BLOOD GLUCOSE
The first step to managing your blood sugar is to understand what makes blood sugar levels rise
GLUCOSE
INSULIN
The carbohydrates and sugars in what you eat and drink turns into glucose (sugar) in the stomach and digestive system. Glucose can then enter the bloodstream.
Insulin is a hormone made in the pancreas that helps the body's cells take up glucose from blood and lower blood sugar levels.
In Type 2 diabetes, glucose builds up in the blood instead of going into cells because:
The body develops "insulin resistance" and can't use the insulin it makes efficiently.
The pancreas gradually loses its ability to produce insulin.
The result can be a high blood glucose level.
TRACK LEVELS
Health care professionals can take blood glucose readings and provide recommendations. If you're diagnosed with Type 2 diabetes, you will need to monitor your blood sugar level regularly.
Visit KnowDiabetesbyHeart.org to learn how to manage your risk for heart disease and stroke if you have diabetes.
Fasting Blood Glucose | Diagnosis | What It Means
Lower than 100 mg/dl | Normal | Healthy range
100 to 125 mg/dl | Prediabetes (impaired fasting glucose) | At increased risk of developing diabetes.
126 mg/dl or higher | Diabetes Mellitus (Type 2 diabetes) | At increased risk of heart disease or stroke.
Learn more at heart.org/lifes8
TIPS FOR SUCCESS
EAT SMART
Eat a healthy diet of vegetables, fruits, whole grains, beans, legumes, nuts, plant-based proteins, lean animal proteins like fish and seafood.
Limit sugary foods and drinks, red or processed meats, salty foods, refined carbohydrates and highly processed foods.
MOVE MORE
Being physically active can lower your risk of developing diabetes and help you manage the disease if you already have it.
MANAGE WEIGHT
Stay at a healthy weight to help prevent, delay or manage diabetes
NO NICOTINE
Smoking, vaping, exposure to secondhand smoke or using tobacco can increase your risk of heart disease, stroke, many cancers and other chronic diseases. It may also make prediabetes and diabetes harder to manage.
Life's Essential 8
Diabetes mellitus is independently associated with all-cause and CVD mortality even after adjusting for CVD risk factors (2019)
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Continuous Glucose Monitors

Life's Essential 8

- Real-time CGM or intermittently scanned CGM should be offered for diabetes management in adults on multiple daily injections or insulin pumps
- Clear data for Type 1, murky for Type 2

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Non-diabetics?

Life's Essential 8

- Higher glucose variability increases:
  - CVD and CVD Death
  - Alzheimer's
  - Frailty
  - Cancer Death
  - All-cause mortality
- Today's normal patient is tomorrow's diabetic
- Cost-prohibitive

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How to manage diabetes

- Raghavan, Sridharan, et al. "Diabetes mellitus–related all-cause and cardiovascular mortality in a national cohort of adults." *Journal of the American Heart Association* 8.4 (2019): e011295.
- American Diabetes Association; *Standards of Medical Care in Diabetes—2022* Abridged for Primary Care Providers. *Clin Diabetes* 1 January 2022; 40 (1): 10–38.
- Standl E, Schnell O, Ceriello A. Postprandial hyperglycemia and glycemic variability: should we care? Diabetes Care. 2011 May;34 Suppl 2(Suppl 2):S120-7.
- Zhang X, Li J, Zheng S, Luo Q, Zhou C, Wang C. Fasting insulin, insulin resistance, and risk of cardiovascular or all-cause mortality in non-diabetic adults: a meta-analysis. Biosci Rep. 2017 Sep 7;37(5):BSR20170947
- Luchsinger JA, Tang MX, Shea S, Mayeux R. Hyperinsulinemia and risk of Alzheimer disease. Neurology. 2004 Oct 12;63(7):1187-92.
- Pérez-Tasigchana RF, León-Muñoz LM, Lopez-Garcia E, Gutierrez-Fisac JL, Laclaustra M, Rodríguez-Artalejo F, Guallar-Castillón P. Metabolic syndrome and insulin resistance are associated with frailty in older adults: a prospective cohort study. Age Ageing. 2017 Sep 1;46(5):807-812.
- Tsujimoto T, Kajio H, Sugiyama T. Association between hyperinsulinemia and increased risk of cancer death in nonobese and obese people: A population-based observational study. Int J Cancer. 2017 Jul 1;141(1):102-111.
- Zhang X, Li J, Zheng S, Luo Q, Zhou C, Wang C. Fasting insulin, insulin resistance, and risk of cardiovascular or all-cause mortality in non-diabetic adults: a meta-analysis. Biosci Rep. 2017 Sep 7;37(5):BSR20170947.

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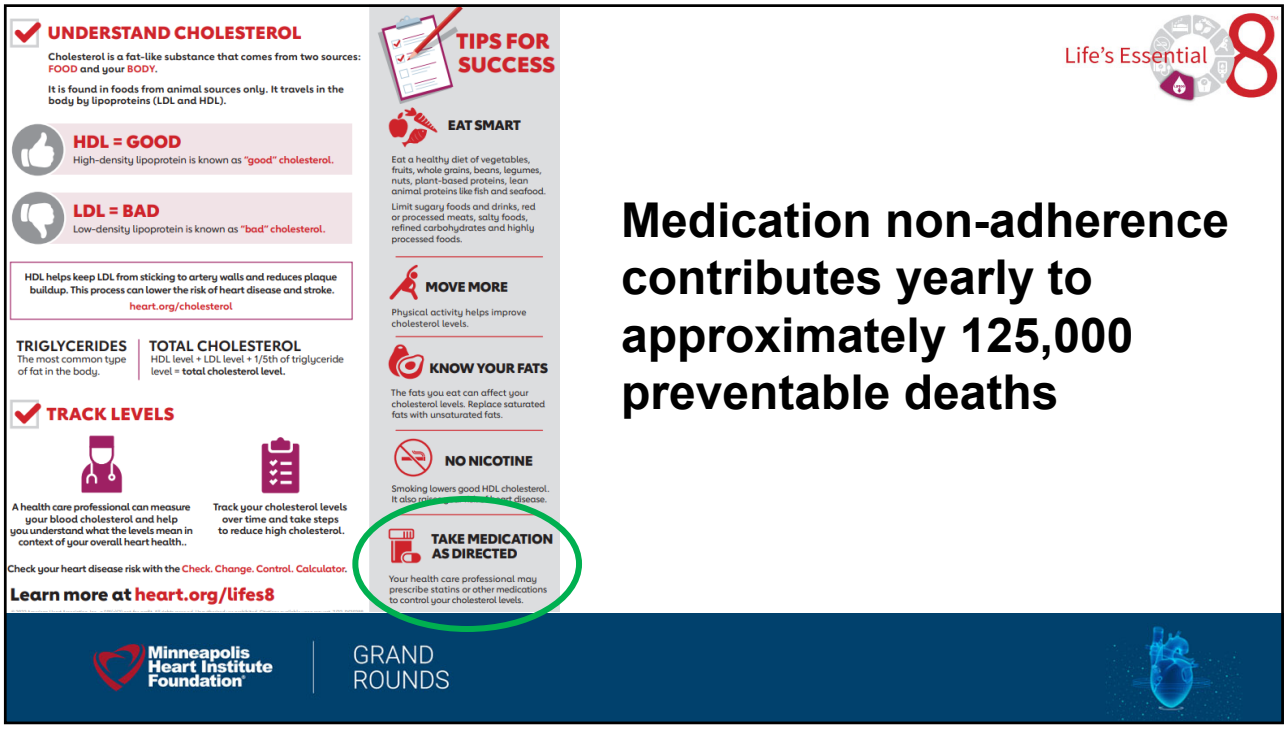

Life's Essential 8

Medication non-adherence contributes yearly to approximately 125,000 preventable deaths

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Life's Essential 8

The Problem

- 50% of CVD patients consistently take their medications
- Prevalence of the problem is difficult to assess
- This remains an undermanaged problem
- 25% of patients in the Ischemia trial self-reported non-adherence

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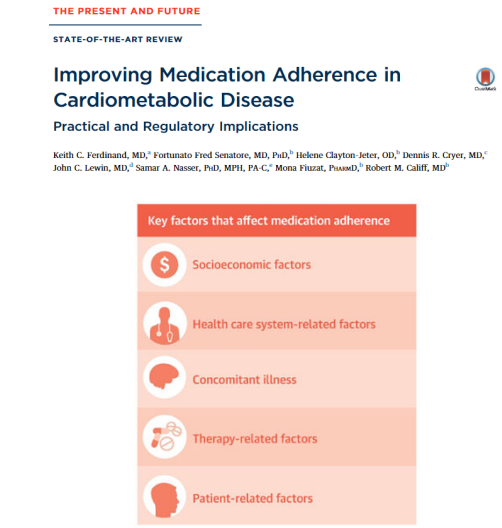
Life's Essential 8


THE PRESENT AND FUTURE

STATE-OF-THE-ART REVIEW

Improving Medication Adherence in Cardiometabolic Disease

Practical and Regulatory Implications

Keith C. Ferdinand, MD,[a] Fortunato Fred Senatore, MD, PhD,[b] Helene Clayton-Jeter, OD,[b] Dennis R. Cryer, MD,[c] John C. Lewin, MD,[d] Samar A. Nasser, PhD, MPH, PA-C,[e] Mona Fiuzat, PharmD,[b] Robert M. Califf, MD[b]

Key factors that affect medication adherence

- Socioeconomic factors
- Health care system-related factors
- Concomitant illness
- Therapy-related factors
- Patient-related factors

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1. Identify monitoring methods
2. Improve evidence base to better understand adherence
3. Develop patient/health provider team-based engagement strategies
4. Alleviate health disparities

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Life's Essential 8

DOSE HEALTH

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DOSE HEALTH

- 3,606,660 tracked dispenses
- 149,576 misses
- 96% adherence rate!
- Medicaid waiver service program
  - MN, WI, SD, NE, OR, UT, LA, ID
- 4,148 clients
- 6,547 devices

LIVING WELL DISABILITY SERVICES Transforming Lives

REM MINNESOTA

Lutheran Social Service of Minnesota

Dose Flip

$60/month

ORDER

Rental of up to 2 Dose Flips
Health Reminders
Adaptive Equipment
Notifications for caregivers

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Ways to substantially reduce non-adherence

1. Identify monitoring methods
2. Improve evidence base to better understand adherence
3. Develop patient/health provider team-based engagement strategies
4. Alleviate health disparities

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Medication Adherence

- Ferdinand K, Senatore F, Clayton-Jeter H, et al. Improving Medication Adherence in Cardiometabolic Disease. J Am Coll Cardiol. 2017 Jan, 69 (4) 437–451.
- Kolandaivelu K., Leiden B.B., O'Gara P.T.et al. : "Non-adherence to cardiovascular medications". Eur Heart J 2014; 35: 3267.
- Baroletti S. and Dell'Orfano H. : "Medication adherence in cardiovascular disease". Circulation 2010; 121: 1455.
- Kronish I. and Ye S. : "Adherence to cardiovascular medication: lessons learned and future direction". Prog Cardiovasc Dis 2013; 55: 590.
- Garcia R, Spertus J, Benton M, et al. Association of Medication Adherence With Health Outcomes in the ISCHEMIA Trial. J Am Coll Cardiol. 2022 Aug, 80 (8) 755–765. https://doi.org/10.1016/j.jacc.2022.05.045

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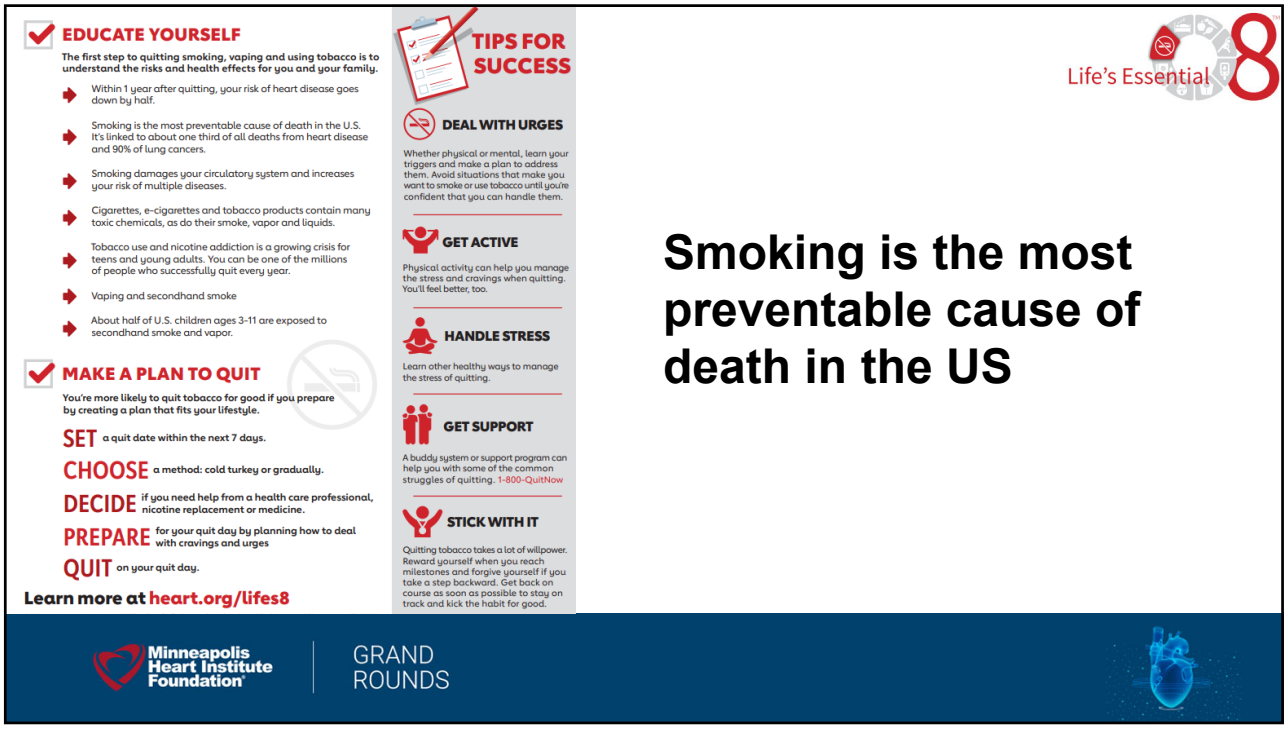

Smoking is the most preventable cause of death in the US

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Life's Essential 8

Nicotine cessation

Meta-Analysis: Effectiveness and Abstinence Rates for Smoking Cessation Therapies

Medication	Number of Arms	Estimated Odds Ratio (95% CI)	Estimated Abstinence Rate (95% CI)
Placebo	80	1.0	13.8
Monotherapies			
Varenicline (2 mg/d)	5	3.1 (2.5-3.8)	33.2 (28.9-37.8)
Nicotine nasal spray	4	2.3 (1.7-3.0)	26.7 (21.5-32.7)
High-dose nicotine patch (>25 mg) (these included both standard long-term duration)	4	2.3 (1.7-3.0)	26.5 (21.3-32.5)
Long-term nicotine gum (>14 weeks)	6	2.2 (1.5-3.2)	26.1 (19.7-33.6)
Varenicline (1 mg/d)	3	2.1 (1.5-3.0)	25.4 (19.6-32.2)
Nicotine inhaler	6	2.1 (1.5-2.9)	24.8 (19.1-31.6)
Clonidine	3	2.1 (1.2-3.7)	25.0 (15.7-37.3)
Bupropion SR	26	2.0 (1.8-2.2)	24.2 (22.2-26.4)
Nicotine patch (6-14 weeks)	32	1.9 (1.7-2.2)	23.4 (21.3-25.8)
Long-term nicotine patch (>14 weeks)	10	1.9 (1.7-2.3)	23.7 (21.0-26.6)
Nortriptyline	5	1.8 (1.3-2.6)	22.5 (16.8-29.4)
Nicotine gum (6-14 weeks)	15	1.5 (1.2-1.7)	19.0 (16.5-21.9)
Combination Therapies			
Patch (long-term; >14 weeks) + ad lib NRT (gum or spray)	3	3.6 (2.5-5.2)	36.5 (28.6-45.3)
Patch + bupropion SR	3	2.5 (1.9-3.4)	28.9 (23.5-35.1)
Patch + nortriptyline	2	2.3 (1.3-4.2)	27.3 (17.2-40.4)
Patch + inhaler	2	2.2 (1.3-3.6)	25.8 (17.4-36.5)
Patch + second generation antidepressants (paroxetine, venlafaxine)	3	2.0 (1.2-3.4)	24.3 (16.1-35.0)
Medications not shown to be effective			
Selective serotonin reuptake inhibitors	3	1.0 (0.7-1.4)	13.7 (10.2-18.0)
Naltrexone	2	0.5 (0.2-1.2)	7.3 (3.1-16.2)

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Habit?

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Aversion Therapy

- Pavlovian Condition
  - Humans are animals too!
- Associate habit with a negative stimulus
- Brain rewired to stop liking the habit

Journal of Substance Abuse Treatment
Volume 5, Issue 1, 1988, Pages 33-36

Original contribution

Long term outcome of clients treated in a commercial stop smoking program

James W. Smith MD

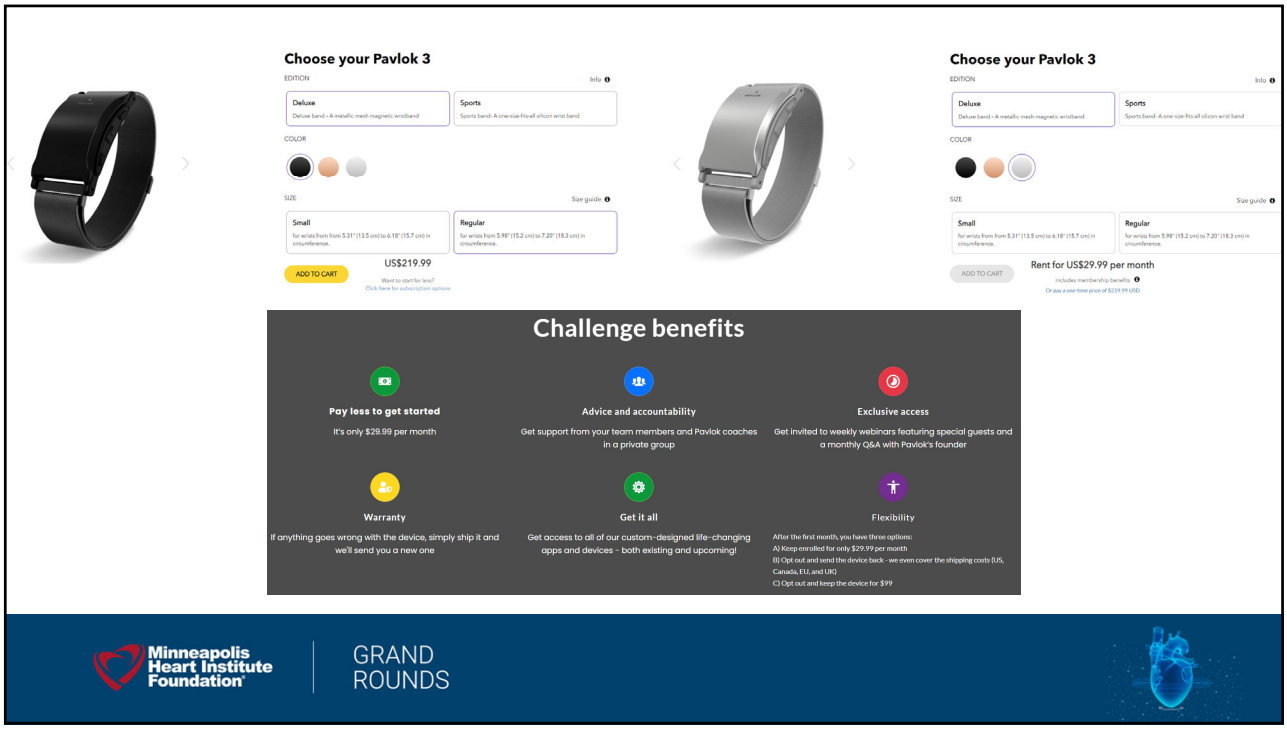
- 832 patients, 55% male, 3 phases
- 13 month f/u: 52% smoke free, 30% smoking less
- Greatest risk factor to not quit was living with another smoker (70%)

35 years later…

- 8 people who smoked 10-20 cigarettes per day
  - Shock with every puff for 2 weeks
  - Social support
- 6 stopped completely
- 2 cut down by 50%
- Further studies underway
- Hoping for FDA clearance and further clinical trials

PAVLOK

UMASS



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Concerns

- Device accuracy
  - Inaccurate data more harmful than no data; prevent digital overdiagnosis
  - Standards by medical societies to evaluate devices
  - Unified regulatory policies
- Separate actionable data from noise
  - Meaningful use criteria development; data integration
  - RCTs with long term f/u
  - Telehealth curriculum

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Concerns

- Patient Privacy
  - Data de-identification
  - HIPAA policy updates
  - Opt-in arrangements
- Cost
  - Pay close attention to a new health disparity
    - Threefold use difference between high/low SE status
  - $2,500 up front buy-in for all entry level devices outlined here

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The Future

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Devices and Data: Filling the Gap in the Essential 8

Joe Jensen, MD

Grand Rounds

23 January 2023

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