# Happy Health Becomes First Company to Receive FDA Clearance for Cuffless, Calibrationless Blood Pressure Measurement

*The clearance enables ongoing blood pressure measurements across day and night without any need for a blood pressure cuff or external calibration*

Happy Health Logo

AUSTIN, NY, UNITED STATES, October 5, 2026 /EINPresswire.com/ -- Happy Health, a digital health company building a comprehensive health platform for consumer-initiated, physician-led healthcare, today announced that the FDA cleared its wearable smart ring (Happy Ring) to measure ongoing, clinical grade blood pressure. The Happy Ring is the first wearable to achieve clearance for ongoing, passive blood pressure measurement without either an inflatable cuff or calibration.

For more than 100 years, blood pressure has been measured as a snapshot, typically in a doctor's office or at home with an inflatable cuff, even though some of the most important information emerges overnight. A large observational cohort analysis found nighttime systolic blood pressure was 5.91 times as informative as clinic blood pressure for predicting all-cause mortality and 6.04 times as informative for predicting cardiovascular death. Wearables have the potential to capture these changes ongoing, but every FDA-cleared wearable blood pressure technology to date has required calibration with a traditional cuff, meaning patients still have to take cuff measurements daily to calibrate.

"This is blood pressure's CGM moment," said Dustin Freckleton, MD, founder and CEO of Happy Health. "High blood pressure is the most prevalent and modifiable risk factor for heart disease, stroke, dementia and all-cause mortality, which makes seeing it in real life incredibly powerful. Just as CGMs freed glucose monitoring from the finger stick, we've freed blood pressure from the cuff, turning an occasional measurement into a passive signal that can reveal risk throughout everyday life, including overnight."

Happy Health validated its blood pressure technology against invasive arterial-line measurements, which measure blood pressure directly inside the artery and serve as a clinical reference standard. The FDA validation included 850 paired measurements across 85 patients, spanning normal blood pressure through Stage 2 hypertension. The study included patients across age, sex, BMI and skin tone, with no subjects excluded from the analysis.

The technology demonstrated:
-- 0.8 mmHg mean error for systolic blood pressure
-- 0.1 mmHg mean error for diastolic blood pressure

“Our design philosophy was simple: put hospital-quality sensors into a ring people would forget they were wearing,” said David Clift-Reaves, CTO of Happy Health. “Doctors love what they see in the clinical results and users appreciate knowing that they can trust the data, day after day.”

The Happy Ring captures over 2.8 million medical data points each night across sleep, respiratory, cardiovascular, neurological and metabolic systems. Its platform uses AI to build a personalized model of each person’s health, learning what is normal for them rather than relying solely on population averages. This allows meaningful changes to be detected earlier and with greater precision, with board-certified physicians in Happy Health’s 50-state network interpreting results, making clinical decisions and guiding diagnosis and care.

“The most interesting things in health happen between the averages,” said Paul Berns, Managing Director at ARCH Venture Partners. “Healthcare has historically compared each of us to everyone else. The opportunity now is to understand what is normal for you, and recognize when you begin to move away from it. That shift from population averages to personalized models is going to be fundamental to the future of healthcare.”

The clearance builds on the Happy Ring's existing FDA-cleared capabilities for at-home sleep apnea diagnosis. The device is the first and only FDA-cleared smart ring for at-home diagnosis of obstructive sleep apnea (OSA), enabling a physician-rendered diagnosis in as few as five nights with 98% accuracy compared against the gold standard in-lab polysomnography.

"Sleep apnea is one of the most common treatable causes of high blood pressure, and it goes undiagnosed in millions of people," said Jeffrey Durmer, MD, PhD, Chief Medical Officer of Happy Health. "For the first time, we can see sleep apnea and blood pressure together, night after night, and see how each responds to treatment. That gives physicians an opportunity to intervene earlier, before these conditions progress into cardiovascular disease"

Happy Health announced that it raised $75 million from ARCH Venture Partners and OpenLoop in August 2026.

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About Happy Health

Happy Health is a Texas-based digital health company building a physician-guided platform for healthcare in the home. It has advanced the first and only FDA-cleared smart ring for at-home diagnosis of obstructive sleep apnea and cuffless, no calibration blood pressure monitoring.

Combining clinical-grade wearable sensors, individualized physiological modeling, artificial intelligence, and board-certified sleep physicians, Happy Health helps identify disease earlier and bring diagnosis and treatment into the home.

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