

Enhancing patient comfort, flexibility, and compliance

System One sleep therapy system selection guide



We may call it System One, but we give you multiple options

Philips Respironics brings a family of System One solutions to the care team.

As Allies in Better Sleep and Breathing, we at Philips Respironics approach product development with your needs in mind. As a result, the enhanced System One sleep therapy system does even more to deliver **exceptional therapy**, increase **patient comfort**, and add essential **compliance** tools that you need in today's challenging sleep environment.

Patient comfort and appeal

- Flex Family technologies enhance patient comfort with proven pressure relief
- System One Humidity Control maintains constant and optimum humidity levels
- Heated Tube humidification option provides increased flexibility and patient comfort
- Opti-Start enhances auto-CPAP therapy, providing a customized starting pressure
- Adjustable PSmin provides clinicians additional options for patients who require auto bi-level therapy
- An attractive, sophisticated external design increases patient appeal

Compliance tools

- Exclusive CPAP-Check and Auto-Trial modes enhance patient compliance, while increasing operational efficiency
- Advanced Event Detection tracks patients' changing therapy needs
- Superb convenience in compliance monitoring with the choice of broadband, wireless/wired modems, or SD card data storage and transmission
- System One Resistance Control achieves complete system comfort by allowing the device and mask to work well together
- EncoreAnywhere patient compliance management provides real-time data access



Finding success in today's Sleep and Respiratory industries requires more than advanced technology; it takes the collaboration of experts. That's why Philips Respironics remains committed to working in harmony with the care team to produce solutions that can lead to healthier patients, healthier practices, and healthier businesses. At a time when caregivers and patients alike need a true ally, count on Philips Respironics.

System One, the number one prescribed sleep therapy system in the United States.

System One: a quality choice

With your input, in addition to the enhanced features and appearance of System One, we've included even more **quality and durability,** while providing you the same exceptional product and sales support.

System One quality comes through

- 25% quieter than its closest competitor
- Designed to eliminate water ingress
- Durable, easy-to-connect, top-mount tubing connections for an exceptional customer experience
- Commitment to quality excellence that earned
 Philips Respironics the prestigious 2011 Manufacturing
 Plant of the Year by Assembly Magazine
- Assembled in U.S.A.

Reliability

Through a combination of the intelligently designed water chamber, the risk of water ingress is virtually eliminated. A filled water chamber may be tilted and even turned upside down without leaking back into the device.





More of the features you want

We've packed in more meaningful features that contribute to healthy lives and healthy businesses.

Enhanced comfort

System One Humidity Control

- Philips Respironics' best humidification management is designed to prevent rainout and water damage
- Technology analyzes ambient temperature, relative humidity, and patient flow to maintain consistent and optimum humidity levels – even in changing conditions
- Dry Box technology isolates water from the inner workings of the device
- Heated Tube option provides additional comfort

Flex Family technologies

- · Improved patient comfort with proven pressure relief
- Digital Auto-Trak algorithm to help make it easier for patients to adapt to therapy by detecting the onset of inspiration and exhalation and allowing flow-based Flex technologies to deliver just the right pressure relief for every breath

Opti-Start feature on the REMstar Auto

- Optimal starting pressure that reduces events the patient can experience when falling asleep
- The algorithm is based on the patient's 90% pressure and is calculated every 30 hours

Quiet comfort

- Quiet when it matters most when in use by patient
- Noise reduction enhancements offer a restful night's sleep for happier patients

Proven efficacy

Advanced event detection

- Identifies complicated and changing conditions that may indicate alternative therapy
- Recognizes and reports when patients are experiencing symptoms beyond classic OSA, such as clear airway apneas and periodic breathing

Advanced event response

 Due to our advanced event detection, our algorithm does not react to clear airway apnea, reacting only to obstructive events providing the possibility for better treatment efficacy

EncoreAnywhere data management and reporting

- Intelligent patient management for improved compliance
- On-board data memory, SD card compatible, and along with available Broadband, wireless, and wired modem technology – allows patient data to be uploaded automatically on a daily basis
- Data management software enables patient data to be viewed virtually anywhere through a secure web site
- Integration of oximetry into EncoreAnywhere reporting allows the clinician to assess therapeutic benefit of the patient's PAP device by comparing oxygen tracings and advanced events in one convenient report



Your home sleep testing and long-term CPAP solution

With System One **REMstar Pro** and **REMstar Auto** you now have the ability to assess your home sleep testing patients' CPAP prescriptions. The Auto-Trial mode was designed to optimize pressure settings at home, while providing the long-term benefits of fixed CPAP therapy. This therapy uniquely adjusts to your patients' CPAP pressure needs over time through the system's CPAP-Check mode. EncoreAnywhere gives you the ability to remotely monitor AHI, leak, and many other advanced events recorded by your patients' REMstar Pro and Auto devices. It is flexible technology designed to simplify and enhance patient management.

Enhancing patient compliance

Auto-Trial mode delivers breath-by-breath auto-CPAP therapy for up to a total of 30 days per patient. At the end of the Auto-Trial period, the device automatically transitions into the CPAP-Check mode at the pressure the patient was at or below 90% of the trial period time.

Auto-Trial benefits include:

- The opportunity for clinicians to provide short-term auto-CPAP for patients who would benefit without having to prescribe a "full" auto-CPAP device
- Re-evaluation of therapeutic pressures for patients who:
- · Received a home sleep test
- May have had a poor in-lab titration study
- Experience a return of symptoms

Long-term CPAP solution

CPAP-Check mode checks on the user every 30 hours to determine if therapy pressure is optimal. If not, it automatically adjusts the nightly fixed CPAP pressure by 1 cm $\rm H_2O$ (with maximum upper and lower limits of 3 cm) to obtain an ideal pressure.

CPAP-Check benefits include:

- Therapeutic pressure is continuously monitored
- Long-term enhanced patient care patients are consistently on optimal CPAP pressure
- Therapy adapts to patient's pressure needs over time
- Remote management via EncoreAnywhere reduces the need for unnecessary interventions









REMstar Plus REMstar Auto A-Flex

REMstar Pro C-Flex

Your System One CPAP options

REMstar Auto[†]

- 4 modes (CPAP, Auto, CPAP-Check, Auto-Trial)
- A-Flex for comfort
- Opti-Start technology
- Advanced event detection
- Heated Tube option

REMstar Pro[†]

- 3 modes (CPAP, CPAP-Check, Auto-Trial)
- C-Flex+ for comfort
- Advanced event detection
- Heated Tube option

REMstar Plus[†]

- 1 mode (CPAP)
- C-Flex for comfort
- Patterns of use data reporting
- Heated Tube option

Ordering information	US part number	Canadian part number
REMstar Auto		
REMstar Auto A-Flex	DS560S	CA561S
REMstar Auto A-Flex with humidifier	DS560HS	CA561HS
REMstar Auto A-Flex with Heated Tube humidifier	DS560TS	CA561TS
REMstar Pro		
REMstar Pro C-Flex+	DS460S	CA461S
REMstar Pro C-Flex+ with humidifier	DS460HS	CA461HS
REMstar Pro C-Flex+ with Heated Tube humidifier	DS460TS	CA461TS
REMstar Plus		
REMstar Plus C-Flex	DS260S	CA261S
REMstar Plus C-Flex with humidifier	DS260HS	CA261HS
REMstar Plus C-Flex with		
Heated Tube humidifier	DS260TS	CA261TS

Product warranty

All System One devices and humidifiers come standard with a two-year warranty. US only.

 $^{^\}dagger Modem$ and SD card capable; optional integrated oximetry available.

Therapy for your noncompliant, nontolerant CPAP patients

Your System One bi-level options

Philips Respironics revolutionized sleep therapy by introducing bi-level positive airway pressure technology to treat obstructive sleep apnea. Emulating natural breathing with pressure relief at inhalation and exhalation, this proven technology does more than provide highly effective therapy – it delivers a level of comfort that can mean the difference between compliance and non-compliance for patients having difficulty adapting to traditional CPAP therapy.

BiPAP Auto

- 3 modes (CPAP, fixed bi-level, auto bi-level)
- · Adjustable PSmin
- Bi-Flex for comfort
- · Advanced event detection
- Heated Tube option
- Modem and SD card capable
- Optional integrated oximetry available

BiPAP Pro

- 2 modes (CPAP, fixed bi-level)
- Bi-Flex for comfort
- Advanced event detection
- Heated Tube option
- Modem and SD card capable
- · Optional integrated oximetry available

Bi-level Rescue Program

The Philips Respironics Bi-level Rescue Program is intended to help patients continue their PAP therapy when they are not able to tolerate standard treatment. A bi-level device provides comfort features that will increase the likelihood that these patients will be compliant with therapy. Order bi-level monograph (part number 1038429) for more details.

Ordering information	US part number	Canadian part number
BiPAP Auto		
BiPAP Auto Bi-Flex	DS760S	CA761S
BiPAP Auto Bi-Flex with humidifier	DS760HS	CA761HS
BiPAP Auto Bi-Flex with Heated Tube humidifier	DS760TS	CA761TS
BiPAP Pro		
BiPAP Pro Bi-Flex	DS660S	CA661S
BiPAP Pro Bi-Flex with humidifier	DS660HS	CA661HS
BiPAP Pro Bi-Flex with Heated Tube humidifier	DS660TS	CA661TS

Product warranty

All System One devices and humidifiers come standard with a two-year warranty. US only.



Therapy for your most complicated patients

Your System One advanced therapy options

BiPAP autoSV Advanced

Targets: complex, central, mixed sleep apneas, and Cheyne-Stokes respiration patients

- Clinically proven servo ventilation algorithm
- · Auto EPAP for a patient's changing needs
- Real time access to patient data via modems
- · Advanced event detection
- Bi-Flex for comfort
- · Encore data management and reporting
- New patient waveform reports
- Optional integrated oximetry available



Ordering information	US part number	Canadian part number
BiPAP autoSV Advanced	DS950S	CA951S
BiPAP autoSV Advanced with humidifier	DS950HS	CA951HS
BiPAP autoSV Advanced with Heated Tube humidifier	Coming soon	Coming soon

BiPAP AVAPS

Targets: COPD, obesity hypoventilation, restrictive disorders, and neuromuscular disorders

- AVAPS feature automatically adjusts pressure support to maintain a target tidal volume
- Automatically adapts to disease progression and changing patient needs
- Bi-Flex for comfort
- Improves ventilation efficacy¹
- Encore data management and reporting
- Auto-Trak provides advanced leak compensation and automatic triggering and cycling
- · Modem and SD card capable
- · Optional integrated oximetry available



Ordering information	US part number	Canadian part number
BiPAP S/T, C Series	1061420	CA1061421
BiPAP S/T, C Series, with humidifier	1061422	CA1061423
BiPAP AVAPS, C Series	1060485	CA1060486
BiPAP AVAPS, C Series, with humidifier	1061418	CA1061419

Product warranty

All System One devices and humidifiers come standard with a two-year warranty. US only.

¹ Storre, JH,et al. Average Volume-Assured Pressure Support in Obesity Hypoventilation: A Randomized Crossover Trial. Chest 2006:130;815-821



Sleep therapy accessories

Sleep therapy accessories	
Humidification	Part number
System One 60 Series humidifier	DS6H, IN6H (Canada)
System One 60 Series Heated Tube humidifier	DS6T, IN6T (Canada)
System One of series Figures rube namemer	(Includes 80 watt power supply and Heated Tube)
Water chamber (includes both 50 and 60 Series lids)	1063785
Heated Tube humidifier upgrade kit	6T-CONVKIT
Power supplies	Part number
60 watt power supply (for H and HS models)	1091398
80 watt power supply (for TS model only)	1091399
Power cord	1005894
Tubing	Part number
System One Heated Tube	SYS1HT15
System One Performance Tube (15mm)	1074400
Performance Tubing (22mm)	1032907
Filters	Part number
Pollen (foam) filter, reusable (1 per pack)	1035443
Pollen (foam) filter, reusable (2 per pack)	1029330
Ultra-fine filter, disposable (1 per pack)	1063096
Ultra-fine filter, disposable (2 per pack)	1035442
Ultra-fine filter, disposable (6 per pack)	1029331
Accessories	Part number
Device side panel	1099592
Carrying case	1063857
Data management accessories	
Data cards and accessories	Part number
SD card (10 pack)	1063859
SD card mailer (10 pack)	1065146
SD card cover (attached to device)	1063858
SD card reader	1047300
Modems	Part number
Wired flow modem	100200VV
Wired flow modem monthly service	100201W
Wireless flow modem	100200C, 100210C (Canada)
Wireless flow modem monthly service	100201C
Broadband modem	100200E
Modem oximetry accessories	Part number
Oximetry accessory	100205E
Masimo HPLP oximetry module	1075383
Masimo oximetry sensor	Various part numbers
Travel accessories	Part number
Shielded DC cord	1097568
DC battery adapter cable	532209
Shielded 12VDC power cord system	1099011
(includes shielded DC cord and battery adapter cable)	1077011
Universal portable battery pack	1028869
Offiversal politable battery pack	1020007



System One device selection guide

		Comfo	Comfort features		Encore data capture and reporting		
System One	Modes	Flex comfort	System One Resistance Control	Patterns of use	Advanced event detection	Flow waveform	Reimbursement
CPAP devices							
REMstar Auto	CPAP CPAP-Check Auto-Trial Auto CPAP	C-Flex C-Flex+ A-Flex	Standard	Standard	Standard	Standard	E0601
REMstar Pro	CPAP CPAP-Check Auto-Trial	C-Flex C-Flex+ A-Flex	Standard	Standard	Standard	Standard	E0601
REMstar Plus	CPAP	C-Flex	N/A	Standard	N/A	N/A	E0601
Bi-level device	es						
BiPAP Auto	CPAP Bi-level Auto bi-level	C-Flex Bi-Flex	Standard	Standard	Standard	Standard	RAD without back-up rate E0470
BiPAP Pro	CPAP Bi-level	C-Flex Bi-Flex	Standard	Standard	Standard	Standard	RAD without back-up rate E0470
Ventilatory devices							
BiPAP autoSV Advanced	Auto servo	Bi-Flex	Standard	Standard	Standard	Standard	RAD with back-up rate E0471
BiPAP AVAPS	CPAP, S, S/T, PC,T	AVAPS Bi-Flex	N/A	Standard	Standard	Standard	RAD with back-up rate E0471
BiPAP S/T	CPAP, S, S/T	Bi-Flex	N/A	Standard	Standard	Standard	RAD with back-up rate E0471

Advanced event detection:

Patient events are detected and logged for review by the care team for optimal patient care.

Philips Respironics devices with advanced event detection detect, respond to (some models), and log the following advanced events:

- Apnea Hypopnea Index (AHI)
- Respiratory-related arousal (RERA)

SnoreLeak

- Flow limitation (FL)
- Vibratory snore (VS)
- Obstructive airway apnea (OA)
- Large leak (LL)
- Clear airway apnea (CA)
- Periodic breathing (PB)

• Hypopnea (H)

Any Philips Respironics device with advanced event detection gives you the ability to review the patient flow waveform report.

Matching patients with the right therapy and products

Sleep therapy application guide for the System One platform

Therapy type	СРАР	Auto-CPAP	Bi-level without back-up rate	Auto Bi-level	Servo-ventilation	Bi-level with back-up rate
Therapy system	REMstar Plus with C-Flex DS260 (S, HS,TS) ¹ CA261 (S, HS,TS) ¹ (Canac REMstar Pro with C-Flex+ DS460 (S, HS,TS) ¹ CA461 (S, HS,TS) ¹ (Canac	(Canada)	BiPAP Pro with Bi-Flex DS660 (S, HS, TS) ¹ CA661 (S, HS, TS) ¹ (Canada)	BiPAP Auto with Bi-Flex DS760 (S, HS, TS) ¹ CA761 (S, HS, TS) ¹ (Canada)	BiPAP auto SV Advanced System One DS950 (S, HS) ¹ CA951 (S, HS) ¹ (Canada)	BiPAP AVAPS 1060485 device 1061418 core CA1060486 device (Canada) CA1061419 core (Canada) BiPAP S/T 1061420 device 1061422 core CA1061421 device (Canada) CA1061423 core (Canada)
Target	OSA patients Short-term Auto patients ² Home sleep testing patients ²	OSA patients Short-term Auto patients ² Home sleep testing patients ²	OSA patients OSA patients non-responsive or non-tolerant of CPAP	OSA patients OSA patients non-responsive or non-tolerant of CPAP	OSA and respiratory insufficiency patients with central apnea, periodic breathing such as Cheyne-Stokes respiration (CSR), or complex apnea	OSA and respiratory insufficiency patients with hypoventilation caused by restrictive thoracic disorders, obesity hypoventilation syndrome, central apnea, and COPD Pediatric and adult use AVAPS, C-Flex, and Bi-Flex features are not cleared for pediatric use
Algorithm	C-Flex and C-Flex+ provide pressure relief at beginning of exhalation Three patient-adjustable Flex settings Fixed CPAP pressure Trial period of breath-by-breath auto algorithm CPAP-Check algorithm ²	Flow-based proactive and reactive intelligence Delivers lowest mean average pressure levels Flow-based A-Flex pressure relief during inspiratory and expiratory phases Three patient-adjustable Flex settings	Fixed IPAP and EPAP pressures Flow-based Bi-Flex pressure relief during inspiratory and expiratory phases Three patient-adjustable Flex settings	Flow-based proactive and reactive intelligence Delivers lowest mean average pressure levels Flow-based Bi-Flex pressure relief during inspiratory and expiratory phases Three patient-adjustable Flex settings	Dynamic, breath-by-breath adjustment of pressure support Peak flow targeted Intra-breath support Auto-tirrating EPAP to alleviate the obstructive component of SDB Automatically calculated back-up rate in times of apnea	 Average volume assured pressure support (AVAPS) Maintains target Vt Slow adjustment over time (≤1 cm H₂O per min.) Modes: CPAP, S, S/T, T, PC Three patient-adjustable Bi-Flex settings
Settings	Ramp time 0-45 min Flex settings 1,2,3 System One Humidity Control 0-5 Classic Humidity Control C1-C5 Heated Tube Humidification Tube Temperature 1-5 Humidity level 1,2,3	Min CPAP 4-20 cm Max CPAP 4-20 cm Ramp time 0-45 min Flex settings 1,2,3 System One Humidity Control 0-5 Classic Humidity Control C1-C5 Heated Tube Humidification Tube Temperature 1-5 Humidity level 1,2,3	EPAP 4-25 cm IPAP 4-25 cm Ramp time 0-45 mi Flex settings 1,2,3 System One Humidity Control 0-5 Classic Humidity Control C1-C5 Heated Tube Humidification Tube Temperature 1-5 Humidity level 1,2,3	IPAP 4-25 cm maxIPAP=(minEPAP+3)-25	EPAP _{min} 4-25 cm ² EPAP _{max} 4-25 cm ² PS _{min} 0-21 cm PS _{max} 0-21 cm Max pressure 4-25 cm Breath rate (OffAuto, 4-30 BPM) Rise time 0-3 Ramp time 0-45 min Flex settings 1,2,3 System One Humidity Control 0-5 Classic Humidity Control C1-C5	IPAP

1 S = SD card capable

HS = System One humidifier and SD card capable

TS = System One Heated Tube humidifier and SD card capable

² REMstar Pro and Auto only

3 AVAPS

⁴ CA951 range is 4-20 cm.

Exceptional masks built with you in mind

Our latest mask innovations have been developed around input from patients and professionals like you who provide their care. As a result, our current portfolio of masks is designed to be as simple and unobtrusive as possible, while providing comfort, durability, and effective, hassle-free use. And with a wide range of choices, you're sure to find the mask you need.



Amara full-face mask

- Easy to fit, easy to use, easy to maintain
- Smallest and lightest full-face mask among leading traditional full-face masks
- Proven to fit 95% of patients' faces
- 60% fewer parts and 20% lighter than the leading traditional full-face mask
- All cushion sizes fit on the same size frame with a single click
- Developed with the patient and sleep professional in mind



TrueBlue gel nasal mask

- First blue gel nasal mask with Auto Seal technology
- Designed for quicker set-ups and fittings, fewer callbacks, and easier lab titrations
- Designed to deliver a higher degree of comfort, stability, and freedom of movement with minimal adjustments
- Delivers a more complete sleep solution



GoLife for Men and GoLife for Women

- Our first nasal pillows masks built around the unique features of men and women for a gender-specific fit that provides tremendous stability
- A simple concept with few parts
- Unique soft facial contour arms gently hug the face to maintain stability and a secure seal even as the patient moves
- Self-adjusting, optimally angled pillows for a one-step fit

30-Day Mask Satisfaction Promise Program*

Your patient will be satisfied with our mask or we'll replace it. If a patient discontinues use of a program-approved mask in favor of another mask during the first 30 days of use, we will replace the original mask at no charge.

*Certain terms and conditions apply. If you are interested in learning more about this program, please contact your Philips Respironics Account Manager or visit www.sleepapnea.com.



Just one more way we are working with you as Allies in Better Sleep and Breathing.



With you and your patients every step of the way

Device programs

Flex Promise Program

Our Flex Promise Program is Philips Respironics' commitment that if any patient is noncompliant on any of our Flex technologies, upon return of the unit with Flex technology, we will apply a 100% credit of the corresponding unit purchase price toward the purchase of a Philips Respironics bi-level device with Bi-Flex.

Bi-level Rescue Program

The Philips Respironics Bi-level Rescue Program is intended to help patients continue their PAP therapy when they are not able to tolerate standard treatment. Order bi-level monograph (part number 1038429) for more details.

System "One-Touch"

Non-warranty Service Program

The System "One-Touch" Non-warranty Service Program provides flexibility in managing patient repairs and is Philips Respironics' response to provide fast and cost-effective solutions for non-warranty repairs.

Mask programs

30-Day Mask Satisfaction Promise Program*

Your patient will be satisfied with our mask or we'll replace it. If a patient discontinues use of a program-approved mask in favor of another mask during the first 30 days of use, we will replace the original mask at no charge.

*Certain terms and conditions apply. If you are interested in learning more about this program, please contact your Philips Respironics Account Manager or visit www.sleepapnea.com.

Fit for Life mask resupply programs

Philips Respironics offers a comprehensive sleep apnea mask solution that helps keep you in touch with your patients through the lifetime of their therapy.

By offering a patient interface solution with a mask and resupply service included in the purchase price, Philips Respironics demonstrates a commitment to the long-term success of your patients' therapy and your business.

When you choose our masks, your patients will receive access to either our medSage or Encore Resupply services. The Fit for Life solution benefits both your patients and you by increasing patient compliance and satisfaction and helping you develop a standard, quality-driven approach to meeting the payer and industry requirements that are making in-house resupply programs more and more challenging.



Customer programs

Partners in Compliance Management

The Encore Anywhere compliance data management system makes patient data available easily and securely. Additional compliance management can be found at: www.sleepapnea.com/PCM. It's all part of our solution to help you meet your business goals, enhance staff efficiency, and coordinate patient care more quickly and easily.

Partners in Training

The Partners in Training web site is a sleep apnea awareness resource designed to help homecare providers, clinicians, and physicians better understand how to identify, treat, and manage sleep apnea, while helping to improve business/practice potential.

Patient awareness and education programs

Select from videos and literature that cover product set-up, reimbursement requirements, continuing education (CEUs), and patient awareness.

SleepMapper*

The SleepMapper self-management system supports patient care and helps your patients adhere to therapy by using clinically proven motivational and educational tools that patients can access directly from a smartphone, tablet, or computer.

SleepApnea.com

This web site offers patients and professionals 24-7 access to information on OSA. The site provides valuable information for undiagnosed patients, help for new patients navigating the world of products and treatment, and self-management tools for existing patients who want to be successful with their therapy.

*Coming soon.

Reference guide for US HCPCS codes

Product	US HCPCS code
CPAP (REMstar Auto, Pro, Plus, SE)	E0601
RAD, bi-level pressure capability without	E0470
back up rate (BiPAP Pro, BiPAP Auto)	
RAD, bi-level pressure capability with back up rate	E0471
(BiPAP autoSV Advanced, BiPAP S/T, BiPAP AVAPS)	
Heated humidifier (System One 60 Series humidifier)	E0562
Heated humidifier (System One 60 Series Heated Tube humidifier)	E0562
Heated tubing	A4604
Standard tubing	A7037
Filter, disposable (Ultra-fine filter)	A7038
Filter, non-disposable (Reusable filter)	A7039
Humidifier water chamber replacement	A7046

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Respironics, A-Flex, Amara, autoSV, Auto-Trak, Auto-Trial, AVAPS, Bi-Flex, BiPAP, C-Flex, CPAP-Check, Dry Box, Encore, EncoreAnywhere, Flex Family, GoLife, medSage, Opti-Start, REMstar, SleepMapper, System One, and TrueBlue are trademarks of Koninklijke Philips Electronics N.V. and its affiliates. All rights reserved.

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CAUTION: US federal law restricts these devices to sale by or on the order of a physician.

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