HEALTHTECH ASSESSMENT PROGRAMME

Home-testing devices for diagnosing obstructive sleep apnoea hypopnoea syndrome

Draft guidance – Themed Comments

Committee date: 19 June 2024

THEME: Performance of the Sunrise test

Comment number	Name and organisation	Section number	Comment	NICE Response
1	Consultee 1	3.3 The evidence for Sunrise is at high risk of bias so its accuracy is uncertain	Agree with this assessment	Thank you for your comments which the committee considered.
2	Consultee 12	1 People 16 years and over	I co - led the evaluation of the Sunrise device in NHS Scotland with [redacted] until April 2023 working with the Centre for Sustainable Delivery (CFSD). [redacted] was the Improvement Advisor for the this project also working within the CFSD. We found great value in using the device in the screening pathway for adults with suspected Sleep apnoea. The device can assist in modifying the patient pathway and reduce waiting times and can be used for screening and diagnosis based on MDT decision making. Many patients can go straight to CPAP/APAP following a Sunrise test and the first visit may be to discuss results and start CPAP therapy, which also is beneficial in the patient pathway. One service has found that up to 40% of referrals are suitable for a Sunrise test and where positive tests are found then they are started on CPAP therapy following MDT discussion.	Thank you for your comments which the committee considered. Based on further information received at consultation on the available studies assessing the Sunrise test, the committee amended the guidance at the second committee meeting to recommend use of Sunrise as an option to diagnose and assess the severity of obstructive sleep

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			The CFSD heath economics evaluation is due to be published soon and the NICE committee may be able to get site of this perhaps from the CFSD. It may be worth asking them. The formal Sunrise evaluation report has not been published yet however, the device has already been added to the National procurement framework and 5 NHS Scotland sleep services and now using the device in the screening pathway, with other services looking at adopting this technology. Responses have been very positive in terms of saving clinician time as analysis is automated. Freeing up time for clinicians as they don't have to manually score the Sunrise study. The administration of the Sunrise device and onboarding of the device can be done by less skilled staff making best use of resources. Up to 30% of patients can be screened out of the pathway remotely and this frees up clinic and further clinician time. There is reduced travel for patients living more remotely to sleep medicine centres and this is also environmentally friendly and has reduced travel costs for patients. My personal experience when I was Co-Lead for the Sleep Medicine Improvement workplan with the CFSD was very positive and I firmly believe as do many of my previous NHS colleagues that the Sunrise device should be recommended for use in adults as well as children. I was in my CFSD role until April 2023 and these comments are based on my experience working for the NHS as a Respiratory Nurse Consultant.	apnoea hypopnoea syndrome in people 16 years and over. See section 1.1 in the updated draft guidance.

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			Since 3rd of April 2023 I have been in my current role as the Clinical Affairs and Business Development Manager for Sefam UK who distribute the Sunrise device in the UK and this represents a conflict of interest since starting this role.	
3	Consultee 12	1.4 People 16 years and over	There is more evidence of the use of the Sunrise device in screening for OSA in adults than children so it would be good to understand why this recommendation was reached.	Thank you for your comments which the committee considered. Please see the response to comments 2 and 4.
4	Consultee 13	1.1 1.4 1.6 "Why the committee made these recommendations" 3.3 3.13	**Draft NICE Guidance - Sunrise Response** **1 Introduction** The draft guidance issued by the National Institute for Health and Care Excellence (NICE) regarding the use of home-testing devices for diagnosing obstructive sleep apnoea hypopnoea syndrome (OSAHS) in the National Health Service (NHS) in England has recently been published. The diagnostics advisory committee has decided not to recommend Sunrise as an option to diagnose and assess the severity of OSAHS in people 16 years and over. The draft guidance states that "more research is needed on *how accurately Sunrise diagnoses and assesses the severity of OSAHS in people 16 years and over.*"	Thank you for your comments which the committee considered. The external assessment group (EAG) highlighted that accuracy estimates from the Kelly (2022) data set produced using cut off values that had been established in the Pepin (2020) study were applied retrospectively, that is, after the study had been completed, but that it did consider

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			The committee wrote that "*the evidence for Sunrise is at high risk of bias so its accuracy is uncertain*" and that "*two test accuracy studies were included in the EAG's report for Sunrise (Pepin 2020 and Kelly 2022). But the EAG judged both studies to be at high risk of bias for the interpretation of the index test because they reported accuracy data using test cut-off points that were not predefined. The committee agreed that this was a significant issue because it meant that the studies would have overestimated diagnostic accuracy for Sunrise, although the size of this was hard to judge."* In addition, the committee explained that *"the company stated that the cut offs determined in the Kelly et al. (2022) study were either the same as, or close, to those the company recommends for use, as established by Pepin (2020). But when asked in the committee meeting why it had characterised the difference in cut off as small, and to what extent this may have affected test accuracy estimates, the company was unable to justify this comment."* The committee finally added that "*the committee agreed with the EAG that this was a substantial cause for concern, and that accuracy estimates should be generated from a different data set to that used to set test cut-off values. So, it considered that there was considerable uncertainty about the accuracy of the Sunrise device to identify and assess severity of OSAHS."* We would like to express our regrets that the Sunrise representative in charge of these aspects of our developments was unable to attend the first diagnostics advisory committee meeting to reassure the committee on these concerns. **In the present response, we clarify our developments and provide robust evidence of the Sunrise diagnostic accuracy, including diagnostic accuracy generated from data sets different from those used to set the test cut-off values.**	these data informative. The committee concluded that the accuracy estimates were acceptable for decision-making, and that it was appropriate to consider cost effectiveness estimates generated using these data. The committee noted that accuracy estimates from the Kelly (2022) data using the cut off set in Pepin (2020) (7.63 events per hour) rather than the optimised value set in Kelly (2022) (9.53 events per hour) had a sizeable impact on accuracy estimates, especially specificity. This justified the committee's previous concern. Based on the further information provided in this comment, the

			2 Part I: Sunrise Diagnostic Accuracy Evaluation **2.1 Rationale for Using the Obstructive Respiratory Disturbance Index and Device-Specific Cut-off Points as a Starting Point** *2.1.1 Obstructive Respiratory Disturbance Index* In the two test accuracy studies included in the EAG's report for Sunrise (Pépin *et al.* 2020[1] and Kelly *et al.* 2022[2]), OSAHS diagnosis was established according to **the recommendations of the third edition of the International Classification of Sleep Disorders (ICSD-3)**. **These recommendations promote the use of the obstructive respiratory disturbance index (ORDI)**, an index that also includes respiratory effort-related arousals (RERAs), in addition to obstructive apnoeas and hypopnoeas. Since Sunrise is capable of detecting RERAs[3], it was considered of interest to start with the ORDI and hence to align with the ICSD-3 recommendations. *2.1.2 Device-Specific Cut-off Points* While the American Academy of Sleep Medicine (AASM) rules for scoring respiratory events rely on airflow amplitude measured during polysomnography (PSG), the mandibular jaw movement (MJM) signal exploited by Sunrise captures the muscular trigeminal respiratory drive[4,5]. Since airflow amplitude is directly related to the respiratory drive, MJM can act as a reliable surrogate for airflow amplitude. **Due to the differences in signal nature between MJM used by Sunrise and airflow measured by PSG to score respiratory events, the conventional PSG cut-off points of 5 and 15 events/hour could not be directly applied to Sunrise measurements. It was therefore preferable to determine the most appropriate Sunrise cut-off points to accurately represent the correspondence between Sunrise and reference PSG signals, and the most appropriate translation grid between the two had to be determined.**	committee amended the guidance at the second committee meeting to recommend use of Sunrise as options to diagnose and assess the severity of obstructive sleep apnoea hypopnoea syndrome in people 16 years and over. See section 1.1 in the updated draft guidance. The EAG agreed with the company's assertion that Martinot (2022) was not a further report of the Pepin's data, as stated in the EAG's report. However, the only publication the EAG identified for the Martinot (2022) study was a letter to the editor of the Sleep journal which only gave limited details. So, the EAG was not able to do a critical appraisal. Discussion of this study was provided by the EAG in an addendum to its original report.

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			The method of determining device-specific cut-off points involves identifying threshold values that best differentiate between normal and abnormal health states based on a particular biomarker or measure. This is typically achieved by analysing the performance of these threshold values using receiver operating characteristic (ROC) curves where sensitivity (true positive rate) and specificity (true negative rate) can be balanced to find the most appropriate threshold values for best use in clinical practice[6]. **This method is a standard practice commonly used in the performance evaluation of devices and their comparison with the reference method.** **2.2 Initial Evaluation of Sunrise Diagnostic Accuracy with the Obstructive Respiratory Disturbance Index** The study conducted by Pépin *et al.*, published in 2020 in the Journal of the American Medical Association (JAMA) Network Open, represents the first comprehensive and prospective study to evaluate the diagnostic accuracy of Sunrise[1]. The study involved a very large sample of 376 consecutive adult patients with suspected OSAHS referred for in-laboratory PSG. **As the Pépin *et al.* 2020 study was the first to evaluate the diagnostic accuracy of Sunrise, no Sunrise-specific cut-off points had been established prior to this study.** **The diagnostic accuracy was evaluated by the authors for all possible threshold values of the Sunrise-ORDI scale at conventional PSG cut-off points of 5 and 15 events/hour, providing an unbiased and extensive evaluation of diagnostic accuracy across the entire Sunrise-ORDI measurement scale for the study.**	The EAG reviewed the Martinot (2017) study for Brizzy in light of the statement made in this comment that this study did not use predefined test cut offs. The EAG issued a correction changing its judgement on risk of bias and applicability concern for the Martinot (2017) study in the index test domain, assessed using the QUADAS-2 tool, was changed from low to high. The committee reconsidered its view on the evidence for Brizzy based on this. It concluded that there was a substantial cause for concern about the available data showing test accuracy for the Brizzy test. It reiterated its opinion that accuracy estimates should be generated from a different data set to that

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			The results of this evaluation were presented in the eFigure 6 of the Pépin *et al.* 2020 publication (supplemental content) for utmost transparency and are available for everyone to review (see the figure reproduced here below). The objective of this method was under no circumstances to increase or bias the diagnostic accuracy of Sunrise. Instead, these results have allowed reviewers and editors of this leading journal to recognize the diagnostic accuracy of Sunrise and to ensure the best use in clinical practice of the device by identifying the most appropriate Sunrise cut-off points for accurate OSAHS diagnosis.	used to set test cut-off values. So, the committee concluded that there was considerable uncertainty about the accuracy of the Brizzy device to identify and assess severity of obstructive sleep apnoea hypopnoea syndrome (OSAHS; see section 3.4 of the updated draft guidance). Because of this concern, the committee no longer considered the available accuracy evidence for Brizzy to be suitable for decision making (see section 3.14 of the updated draft guidance) and amended its recommendation on this device to state that more research is needed on using Brizzy to diagnose and assess the severity of OSAHS in people 16 years and over before it can be

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			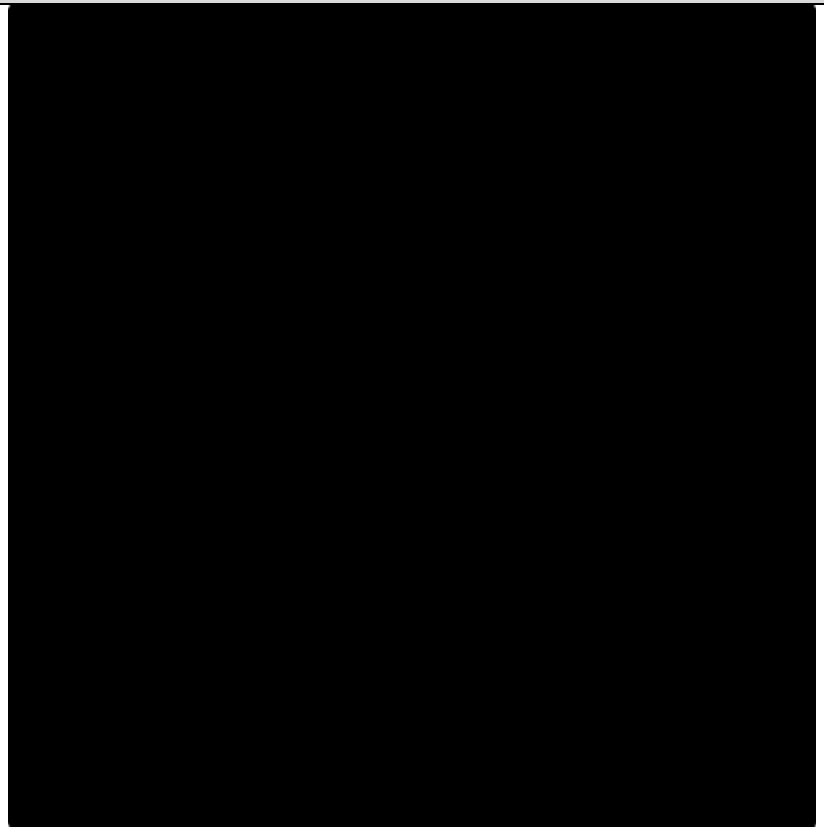 Image has been removed, see eFigure 6 from Pépin *et al*. 2020. The most appropriate threshold values for diagnosing OSAHS were identified to balance sensitivity and specificity and derived by using the maximum value of the Youden's index (i.e., the sum of sensitivity and specificity minus one). **Those cut-off points are the ones recommended for use.**	used in the NHS (see section 1.4 of the updated draft guidance).

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			The resulting Sunrise sensitivity and specificity are provided here below: • A sensitivity of 0.91 and specificity of 0.94 for the Sunrise cut-off point of 7.63 events/hour corresponding to the conventional PSG cut-off point of 5 events/hour. • A sensitivity of 0.92 and specificity of 0.84 for the Sunrise cut-off point of 12.65 events/hour corresponding to the conventional PSG cut-off point of 15 events/hour. **Importantly, this study presents the largest sample size among all cited references of the EAG's report used for evaluating the diagnostic accuracy of the home-testing devices. This is another important element confirming the robustness of the study results.** **2.3 Second Evaluation and Confirmation of Sunrise Diagnostic Accuracy with the Obstructive Respiratory Disturbance Index** A second study conducted by Kelly *et al.* was published in 2022 in Frontiers in Neuroscience evaluating Sunrise against in-home PSG[2]. **The diagnostic accuracy was also evaluated by the authors for all possible threshold values of the Sunrise-ORDI scale at conventional PSG cut-off points of 5 and 15 events/hour, providing here again an unbiased and extensive evaluation of diagnostic accuracy across the entire Sunrise-ORDI measurement scale for the study.** **The results of this evaluation were presented in the Figure 3 of the Kelly *et al.* 2022 publication for utmost transparency and are available for everyone to review (see the figure reproduced here below). Again, the objective of this method was under no circumstances to increase or bias the diagnostic**	

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			accuracy of Sunrise. Instead, these results have allowed reviewers and editors of this leading journal to recognize the diagnostic accuracy of Sunrise. **The Sunrise diagnostic accuracy for this second study, using the cut-off points identified in Pépin *et al.* 2020, is available for everyone to review in the Figure 3 of the Kelly *et al.* 2022 publication. This responds to the recommendation of the diagnostics advisory committee ("*accuracy estimates should be generated from a different data set to that used to set test cut-off values"*) and the results detailed here below confirm that there is no uncertainty about Sunrise diagnostic accuracy.** For the conventional PSG cut-off point of 5 events/hour presented here below, when applying the Sunrise cut-off point of 7.63 events/hour identified in Pépin *et al.* 2020 to the population of Kelly *et al.* 2022, the sensitivity is 0.96 and the specificity is 0.60.	

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			 Image has been removed, see Figure 3 from Kelly *et al.* 2022. **These sensitivity and specificity values are at least equal to or higher than those of the home-testing devices recommended for use in the NHS (e.g. WatchPAT[7] device with a sensitivity of 0.96 and a specificity of 0.25)**. For the conventional PSG cut-off point of 15 events/hour presented here below, when applying the Sunrise cut-off point of 12.65 events/hour identified in Pépin *et al.* 2020 to the population of Kelly *et al.* 2022, the sensitivity is 1.00 and the specificity is 0.75.	

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			 Image has been removed, see Figure 3 from Kelly *et al.* 2022. **These sensitivity and specificity values are at least equal to or higher than those of the home-testing devices recommended for use in the NHS (e.g. WatchPAT[7] device with a sensitivity of 0.88 and a specificity of 0.63).** **Therefore, by applying Sunrise cut-off points identified in Pépin *et al.* 2020 to a different data set, we unequivocally confirm here the high Sunrise diagnostic accuracy and the correct identification of the Sunrise cut-off points.** Regarding the following committee's comment "*the company stated that the cut offs determined in the Kelly et al. (2022) study were either the same as, or close, to those the company recommends for use, as established by Pepin (2020). But when asked in the committee meeting why it had characterised the difference in*	

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			cut off as small, and to what extent this may have affected test accuracy estimates, the company was unable to justify this comment", please see our feedback below: • The Sunrise cut-off points associated with the maximum value of Youden's index in the Kelly *et al.* 2022 study for the conventional PSG cut-off points of 5 and 15 events/hour are 9.53 and 12.65 events/hour, respectively. • The Sunrise cut-off point for the conventional PSG cut-off point of 15 events/hour is identical to the one identified in the Pépin *et al.* 2020 study. • The Sunrise cut-off point for the conventional PSG cut-off point of 5 events/hour presents a difference of 1.9 events/hour compared to the 7.63 events/hour cut-off point identified in the Pépin *et al.* 2020 study. This difference has been considered small, *i.e.* not clinically significant and is less than the interindividual variability observed between two manual PSG scorings. • In any case, as shown in the figures published and reproduced here above, we would like to highlight the fact that for the conventional PSG cut-off point of 5 events/hour, the Sunrise diagnostic accuracy associated with all threshold values between the two Sunrise cut-off points of 7.63 and 9.53 events/hour remains high and consistent. **These additional observations further confirm the robustness and high Sunrise diagnostic accuracy, with sensitivity and specificity values at least equal to or higher than those of the home-testing devices recommended for use in the NHS.** **2.4 Evaluation of Sunrise Diagnostic Accuracy with the Apnoea-Hypopnoea Index and Conventional PSG Cut-off Points** Despite the ICSD-3 recommendations favouring the ORDI, the AHI is commonly used by clinicians to diagnose OSAHS and assess its severity. In this context,	

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			Sunrise diagnostic accuracy has also been evaluated using the AHI and the conventional PSG cut-off points, like for other home-testing devices. The study conducted by Martinot *et al.* published in 2022 in the Sleep journal evaluated the diagnostic accuracy of Sunrise with the AHI at the conventional PSG cut-off points[8]. The results were presented both with and without the application the near-boundary double-labelling (NBL) method. The study involved a very large sample of 289 consecutive adult patients with suspected OSAHS referred for in-laboratory PSG. **This study was erroneously considered as a "secondary reference" of the Pépin *et al.* 2020 study by the EAG, and therefore, results were not considered to provide recommendations. We would like to insist on the fact that the population in the Martinot *et al.* 2022 study is entirely different from the one explored in the Pépin *et al.* 2020 study and must hence be considered as another independent proof of Sunrise diagnostic accuracy.** Sunrise sensitivity and specificity for both conventional PSG cut-off points of 5 and 15 events/hour is accessible for everyone to review from the confusion matrix presented in the Figure 1 of the publication (see a portion of the figure reproduced here below, showing the results without the application of the NBL method as presented on the left of the publication's figure) and the number of patients per severity of OSAHS reported in the publication.	

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			 Image has been removed, see Figure 1 from Martinot *et al*. 2022. The resulting Sunrise sensitivity and specificity are provided here below: • A sensitivity of 0.99 and specificity of 0.86 for the conventional PSG cut-off point of 5 events/hour. • A sensitivity of 0.92 and specificity of 0.94 for the conventional PSG cut-off point of 15 events/hour. **These results, obtained with conventional PSG cut-off points of 5 and 15 events/hour for evaluating Sunrise diagnostic accuracy, confirm without doubt that the diagnostic accuracy of Sunrise is at least equal to or higher than that of the home-testing devices recommended for use in the NHS.** **Importantly, this study presents the largest sample size after the Pépin *et al.* 2020 publication among all cited references of the EAG's report used for**	

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			evaluating the diagnostic accuracy of the home-testing devices. This is another important element confirming the robustness of the study results. **2.5 Evaluation of Clinical Decision-Making Using Sunrise Compared to Respiratory Polygraphy in the UK** The EAG's report also included a prospective, randomised, blinded study[9] conducted in the UK by a team led by Prof. Michael Polkey (Imperial College London, Guy's and St Thomas' NHS Foundation Trust, NHS Highland), and also including Professors Joerg Steier (King's College London, Guy's and St. Thomas' NHS Foundation Trust) and Mary Morrell (Imperial College London). The study, comparing Sunrise with respiratory polygraphy (RP) in terms of time to treatment decision and of clinical decisions made to treat patients, was presented in abstract form at the Winter Meeting of the British Thoracic Society in 2022 but has not yet appeared in full. For that reason, although the full data were available in confidence to the EAG we have not repeated them here as we believe this will enter the public domain and thus could jeopardise publication in a scientific journal. Nevertheless, the data presented to the committee at that stage show that, in a real-world UK study, Sunrise was if anything superior to RP for identifying people who would benefit from continuous positive airway pressure (CPAP) therapy and was additionally associated with savings of staff time and patient travel. **These findings further support the diagnostic accuracy of Sunrise, which enables clinicians to make informed clinical decisions.**	

3 Part II: Extensive Research on Sunrise

Moreover, we want to reiterate and underline the extensive research conducted on Sunrise to date. Sunrise is a CE-marked and FDA-approved device integrated into numerous clinical practices.

Its widespread adoption has led to multiple peer-reviewed publications in highly impactful journals authored by recognised key opinion leaders known for their work worldwide, all of which attest to the device's clinical performance.

3.1 Understanding the Sunrise MJM signal

Multiple peer-reviewed publications have focused on the rationale behind MJM analysis used by Sunrise to study sleep. A comprehensive analysis of the Sunrise MJM signal was published in 2023 in Frontiers in Sleep by Martinot *et al.*[4], and more recently, in 2024, by Malhotra *et al.* in the Journal of Clinical Sleep Medicine[5]. Sunrise has also proven to be a valid tool for detecting sleep bruxism[10,11] and identifying sleep stages[12], showing excellent agreement with rhythmic masticatory muscles activities and sleep stages manually scored from concomitant in-laboratory PSG recordings. The Sunrise MJM signal has also been shown to be a reliable surrogate for the oesophageal pressure signal in measuring respiratory effort during sleep[3].

These publications demonstrate the strength of the Sunrise MJM signal, how it can be easily read and reviewed (similar to the airflow signal) and how accurately it can identify sleep patterns and respiratory events. This is also the only home-testing device clinically validated against oesophageal pressure, making it unique in its ability to differentiate RERAs, central, and obstructive respiratory events.

3.2 OSAHS Characterisation

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			Although the AHI has been the most commonly used metric to diagnose and assess the severity of OSAHS for decades, this metric alone is insufficient to fully characterise OSAHS and its related risks[13]. In this context, alternative metrics are being investigated to further capture the diverse clinical manifestations and consequences of OSAHS[14]. With its powerful MJM signal and capability to accurately detect respiratory effort, Sunrise was able to compute a novel metric called REMOV. Expressed as the percentage of total sleep time spent with elevated respiratory effort, this objective measure derived from the Sunrise MJM signal has been shown to have strong associations with OSAHS-related comorbidities such as hypertension and type 2 diabetes[15,16]. Remarkably, REMOV was proven to be a stronger predictor of these conditions than traditional PSG-derived metrics like AHI. In addition, a study evaluating the use of Sunrise over three nights has highlighted the short-term AHI variability and risk of inaccurate OSAHS diagnosis and severity assessment based on a single night recording[17]. Results also revealed that factors like sleep time in deep non-rapid eye movement (NREM) sleep and with the head in a supine position contribute to AHI variability. **This makes Sunrise a valuable tool for capturing a more comprehensive picture of OSAHS, providing deeper insights into the condition's variability and its association with significant comorbidities.** ### 3.3 Clinical Applications Sunrise's applications in clinical practice highlight its ability to provide accurate assessments and help manage OSAHS patients. First, a study in children with severe OSAHS under CPAP or non-invasive ventilation recently demonstrated strong agreement between Sunrise MJM-AHI	

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			and PSG-AHI[18], validating Sunrise as a reliable alternative to PSG for assessing residual apnoea/hypopnoea respiratory events. Second, a recent study on 135 patients aimed to evaluate Sunrise's accuracy in assessing the impact of oral appliance treatment[19]. The study compared Sunrise metrics to those of in-laboratory PSG/RP at both the beginning and end of oral appliance titration. The results confirmed strong agreement between Sunrise-AHI and PSG/RP-AHI, with consistent AHI improvement observed across all settings. **These findings open up new perspectives for Sunrise's applications, particularly in its ability to titrate and monitor the efficacy of CPAP and oral appliances in a home setting.** ### 3.4 Service Evaluation in the UK Using Sunrise A service evaluation using Sunrise in real-life settings has been performed in the UK[20,21]. The service evaluation was performed in the context of an OSAHS clinic in Swansea Bay University Health Board (Wales) and the objectives were to describe and evaluate the use of Sunrise and whether a healthcare scientist (HCS) was able to make appropriate clinical decisions in the referral and management of patients. **The evaluation concluded that Sunrise is an effective option for patients** and that the HCS was able to provide safe and effective clinical decision-making in referral and management. ## 4 Conclusion **As a conclusion, we would like to reiterate and emphasize the following points :**	

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			• It was considered of interest to start with the ORDI and hence to align with the ICSD-3 recommendations. Due to the differences in signal nature between MJM used by Sunrise and airflow measured by PSG to score respiratory events, the conventional PSG cut-off points of 5 and 15 events/hour could not be directly applied to Sunrise measurements. It was therefore preferable to determine the most appropriate Sunrise cut-off points to accurately represent the correspondence between Sunrise and reference PSG signals, and the most appropriate translation grid between the two had to be determined. This method is a standard practice commonly used in the performance evaluation of devices and their comparison with the reference method. • As the Pépin *et al.* 2020 study was the first to evaluate the diagnostic accuracy of Sunrise, no Sunrise-specific cut-off points had been established prior to this study. The diagnostic accuracy was evaluated by the authors for all possible threshold values of the Sunrise-ORDI scale at conventional PSG cut-off points of 5 and 15 events/hour, providing an unbiased and extensive evaluation of diagnostic accuracy across the entire Sunrise-ORDI measurement scale for the study. The results of this evaluation were presented in the publication for utmost transparency and are available for everyone to review. The objective of this method was under no circumstances to increase or bias the diagnostic accuracy of Sunrise. Instead, these results have allowed reviewers and editors of this leading journal to recognize the diagnostic accuracy of Sunrise and to ensure the best use in clinical practice of the device by identifying the most appropriate Sunrise cut-off points for accurate OSAHS diagnosis. • In Kelly *et al.* 2022, the diagnostic accuracy was also evaluated by the authors for all possible threshold values of the Sunrise-ORDI scale at conventional PSG cut-off points of 5 and 15 events/hour, providing again	

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			an unbiased and extensive evaluation of diagnostic accuracy across the entire Sunrise-ORDI measurement scale for the study. The results of this evaluation were also presented in the publication for utmost transparency and are available for everyone to review. Again, the objective of this method was under no circumstances to increase or bias the diagnostic accuracy of Sunrise. Instead, these results have allowed reviewers and editors of this leading journal to recognize the diagnostic accuracy of Sunrise. • The Sunrise diagnostic accuracy for this second study, using the cut-off points identified in Pépin *et al.* 2020, is available for everyone to review in the publication. This responds to the recommendation of the diagnostics advisory committee and the results detailed above confirm that there is no uncertainty about Sunrise diagnostic accuracy. The sensitivity and specificity values are at least equal to or higher than those of the home-testing devices recommended for use in the NHS. Therefore, by applying cut-off points identified in the Pépin *et al.* 2020 study to a different data set, we unequivocally confirm here the high Sunrise diagnostic accuracy and the correct identification of the Sunrise cut-off points. • Moreover, in Martinot *et al.* 2022, Sunrise diagnostic accuracy has also been evaluated using the AHI and the conventional PSG cut-off points, like for other home-testing devices. This study was erroneously considered as a “secondary reference” and results were not considered to provide recommendations. These results (from a population entirely different from the one explored in the Pépin *et al.* 2020 study) confirm without doubt the diagnostic accuracy of Sunrise, at least equal to or higher than that of the home-testing devices recommended for use in the NHS.	

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			• Furthermore, the results of a study comparing clinical decision-making using Sunrise to respiratory polygraphy in the UK further support the diagnostic accuracy of Sunrise, which enables clinicians to make informed clinical decisions. • Finally, the widespread adoption of Sunrise has led to multiple peer-reviewed publications in highly impactful journals authored by recognised key opinion leaders known for their work worldwide, all of which attest to the device's clinical performance. **When we run the economic model using the Sunrise diagnostic accuracy data from Kelly *et al.* 2022 with the cut-off points identified in Pépin *et al.* 2020, as well as using the Sunrise diagnostic accuracy data from Martinot *et al.* 2022, Sunrise's cost-effectiveness is at least equal to or higher than that of the home-testing devices recommended for use in the NHS (see the table here below). With the committee' concerns about Sunrise diagnostic accuracy data being addressed, the results below confirm that Sunrise's cost-effectiveness estimates are no longer subject to uncertainties and are suitable for decision-making. Therefore, it can be concluded that Sunrise is also a cost-effective alternative to home oximetry and home respiratory polygraphy.**	

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	Sunrise			
	Base case of the EAG's report	Diagnostic accuracy data observed in Kelly *et al.* 2022 with the cut-off points identified in Pépin *et al.* 2020	Diagnostic accuracy data observed in Martinot *et al.* 2022	Other home-testing devices (base case of the EAG's report)
INMB vs respiratory polygraphy at £20,000 per QALY gained	£127	£435	£76	From -£36 to £141
INMB vs respiratory polygraphy at £30,000 per QALY gained	£100	£665	£7	From -£189 to £77
INMB vs oximetry at £20,000 per QALY gained	£1,152	£1,459	£1,100	From £989 to £1165
INMB vs oximetry at £30,000 per QALY gained	£2,039	£2,604	£1,945	From £1,749 to £2,016

Comment number	Name and organisation	Section number	Comment	NICE Response
			Surprisingly, the test accuracy study included in the EAG's report for Brizzy also used test cut-off points that were not predefined, and this was the only study evaluating Brizzy's diagnostic accuracy[22]. However, the EAG and the committee did not raise any concerns, and the device is recommended for use in the NHS. We are obviously concerned about the disparity in treatment between the evaluations and recommendations of the two devices. **In light of the clarifications presented above, which conclusively address the committee's concerns with objective data, we respectfully request that the guidance be changed to include Sunrise as a recommended option for diagnosing and assessing the severity of OSAHS in people 16 years and over. This change would reflect the evidence-based findings about Sunrise.** ## References 1. Pépin JL, Letesson C, Le-dong NN, et al. Assessment of mandibular movement monitoring with machine learning analysis for the diagnosis of obstructive sleep apnea. JAMA Netw Open. 2020;3(1):e1919657. 2. Kelly JL, Ben Messaoud R, Joyeux-Faure M, et al. Diagnosis of sleep apnoea using a mandibular monitor and machine learning analysis: one-night agreement compared to in-home polysomnography. Front Neurosci. 2022;16:726880. 3. Pépin JL, Le-Dong NN, Cuthbert V, Coumans N, Tamisier R, Malhotra A, Martinot JB. Mandibular movements are a reliable noninvasive alternative to esophageal pressure for measuring respiratory effort in patients with sleep apnea syndrome. Nat Sci Sleep. 2022;14:635–644. 4. Martinot JB, Pépin JL. Mandibular jaw movements as a non-invasive measure of respiratory effort during sleep: application in clinical practice. Front Sleep. 2023;2: 1145620.	

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Comment number	Name and organisation	Section number	Comment	NICE Response
			Apnea Using a Single Mandibular Movement Signal. Am J Respir Crit Care Med. 2021 Nov 15;204(10):1227-1231. 13. Kapur VK, Donovan LM. Why a Single Index to Measure Sleep Apnea Is Not Enough. J Clin Sleep Med. 2019 May 15;15(5):683-684. 14. Malhotra A, Ayappa I, Ayas N, Collop N, Kirsch D, Mcardle N, Mehra R, Pack AI, Punjabi N, White DP, Gottlieb DJ. Metrics of sleep apnea severity: beyond the apnea-hypopnea index. Sleep. 2021 Jul 9;44(7):zsab030. 15. Martinot JB, Le-Dong NN, Malhotra A, Pépin JL. Respiratory effort during sleep and prevalent hypertension in obstructive sleep apnoea. Eur Respir J. 2023 Mar 2;61(3):2201486. 16. Martinot JB, Le-Dong NN, Borel AL, Tamisier R, Malhotra A, Pépin JL. Respiratory effort during sleep and the rate of prevalent type 2 diabetes in obstructive sleep apnoea. Diabetes Obes Metab. 2023 Oct;25(10):2815-2823. 17. Martinot JB, Le-Dong NN, Tamisier R, Bailly S, Pépin JL. Determinants of apnea-hypopnea index variability during home sleep testing. Sleep Med. 2023 Nov;111:86-93. 18. Cassibba J, Aubertin G, Martinot JB, Le Dong N, Hullo E, Beydon N, Dupont-Athénor A, Mortamet G, Pépin JL. Analysis of mandibular jaw movements to assess ventilatory support management of children with obstructive sleep apnea syndrome treated with positive airway pressure therapies. Pediatr Pulmonol. 2024 Apr 9. 19. Pépin JL, Cistulli PA, Crespeigne E, Tamisier R, Bailly S, Bruwier A, Le-Dong NN, Lavigne G, Malhotra A, Martinot JB. Mandibular Jaw Movement Automated Analysis for Oral Appliance Monitoring in Obstructive Sleep Apnea: A Prospective Cohort Study. Ann Am Thorac Soc. 2024 May;21(5):814-822.	

Comment number	Name and organisation	Section number	Comment	NICE Response
			20. Curtis R, Hooper-Lee J, Perkins A. Use of a wearable sleep sensor in an OSA clinic: a service evaluation. European Respiratory Journal Sep 2023, 62 (suppl 67) PA4498. 21. Curtis R, Hooper-Lee J, Perkins A. Service evaluation of a pilot healthcare scientist led OSA clinic in primary care. European Respiratory Journal Sep 2023, 62 (suppl 67) PA3510. 22. Martinot JB, Borel JC, Cuthbert V, Guénard HJ, Denison S, Silkoff PE, Gozal D, Pépin JL. Mandibular position and movements: Suitability for diagnosis of sleep apnoea. Respirology. 2017 Apr;22(3):567-574.	
5	Consultee 17	Not specified	Dear Diagnostics Assessment Program Team I'm concerned by the position taken within this document in relation to not recommending the use of the Sunrise diagnostic solution within the NHS. Based on our team's critical appraisal of the literature, and the positive implementation and effectiveness experience within our initial service evaluation, we have adopted the Sunrise test within our routine OSA diagnostic pathways in NHS Scotland. The accuracy and clinical utility of the Sunrise device and the metrics it reports are backed up by extensive publications, predominantly from JL Pepin's group, in large cohort's of patients. Our appraisal of this data is that it is robust, confirming the accuracy, clinical effectiveness and cost effectiveness. I'm aware of further supporting information from unpublished RCT data from Brompton/GSST London, and unpublished service evaluation data from Wales and from our teams in NHS Highland and NHS Greater Glasgow and Clyde. Sunrise tests are in routine use in my service. They have enhanced our sleep diagnostic pathway with reliable clinical performance. Importantly they have improved patient access times to CPAP, offsetting service access inequalities	Thank you for your comments which the committee considered. Please see the responses to comments 2 and 4.

Comment number	Name and organisation	Section number	Comment	NICE Response
			for our remote-rural resident patients. Summarising this, the Sunrise solution has a reassuring published dataset using cutting-edge high-quality methodology which confirms its accuracy. The committee's recommendation not to adopt Sunrise within the NHS seems to be based solely on a misunderstanding of a single point of consideration in relation to differentiating the signal reported from mandibular movements vs reference data. I don't think the documents comments on this are correct. The committee's interpretation contradicts all previous peer-reviews of the Sunrise literature, including my team's. In addition to being a directly inappropriate decision, I'm concerned that this content puts NICE in an inconsistent position with the clinical expert community, and presents an inconsistent opinion within this guidance: the published data and clinical experience with some of the other wearable diagnostics recommended for NHS use is much less robust than the data for Sunrise. I don't think the document provides reassurance that these have been considered equitably. I don't think the recommendation not to use Sunrise in NHS is correct or supportable. We would not follow this document's recommendation in NHS Scotland, as it is currently written. I think that this document as written would significantly undermine the credibility of NICE as an organisation which can critically appraise current evaluation modalities and publications and provide supportable guidance on diagnostic tests and medical technologies. I think the Sunrise published evidence needs to be reconsidered and the content appraising that in this document revised. A revision of the recommendation on the Sunrise sensor in adult patients would logically follow from that re-appraisal. I'd be happy to link with the committee on interpretation of the literature on diagnostic testing and wearable sensors if that would be helpful - [redacted]	

Comment number	Name and organisation	Section number	Comment	NICE Response
			Thank you for the opportunity to comment on this document. [redacted] Consultant Physician: Sleep & Respiratory Medicine Clinical Lead: Respiratory Medicine, South Sector NHS GG&C + West of Scotland Innovation Hub	

Theme: Evidence for the performance and impact of interventions and comparators

Comment number	Name and organisation	Section number	Comment	NICE Response
6	Consultee 1	3.6 Home-testing devices may reduce healthcare resource use, but the extent is uncertain	There will be benefits in turn around time. Not all studies have to be interegated at length [some/many will be barn-door aka oximetry]. The raw data is interesting in less clear-cut cases and the information derived itself may shorten the patient journey eg early onset REM; PLMs [evident from the respiratory signals; position	Thank you for your comments which the committee considered.
7	Consultee 3	Not specified	I have a number of concerns about the completeness of the data set and the conclusions of the EAG. There are a number of WatchPAT studies missing as explained in other comments. Please advise why these studies were excluded (Iftikhar et al 2022 includes 17 studies alone) THe econominc modeling on oximetry comes from old studies with much worse oximetry devices with worse accuracy. Modeling the accuracy on newer	Thank you for your comments which the committee considered. The external assesment group (EAG) explained that it considered the most recent WatchPAT

			oximeters would yield vastly different results. The Brizzy device sensitivity of <75% for severe OSA is unacceptable clinically and should not be included as similarly accurate to the other devices referenced. If (as per your PICO criteria) you are looking for any non-contact device there are many more that have been missed.	device versions (300/ONE) to be most relevant to this assessment. The EAG also included studies that assessed the predecessor version (the WatchPAT 200U). The EAG stated that older versions cannot be expected to provide accuracy estimates comparable to updated versions. In the case of WatchPAT it noted that notable changes were introduced to its design from WatchPAT 200U onwards. This was why studies of earlier WatchPAT models are not included in the systematic review. Further detail on the inclusion criteria for the EAG's systematic review can be found in section 2 and Appendix 2 in the external assessment report. The EAG's model used accuracy estimates for

Comment number	Name and organisation	Section number	Comment	NICE Response
				oximetry from the NICE guideline (NG202). The EAG explained that it looked for more recent evidence, including consideration of a recent systematic review on different sleep studies, but could not identify any alternative values it considered suitable. Accuracy estimates for devices (including the Brizzy) were used in an economic model to assess the cost effectiveness of the tests. Please note that the recommendations have been amended in the updated draft guidance to recommend further research for the Brizzy device is needed (see responses to comment 4 above).

Comment number	Name and organisation	Section number	Comment	NICE Response
				The technologies to be assessed were set out in the scope for this assessment, based on discussions with healthcare professionals working in this area, and a scoping workshop held for the topic.
8	Consultee 3	Not specified	I would like to see more evidence discussion regarding the use of oximetry alone for patients. Old NICE guidance was against using oximetry but were generally from old stuides. Oximetry technology has significantly improved since then and more weight should be given to these new studies to assess the role of oximetry as a routine diagnostic tool	Thank you for your comments which the committee considered. The external assessment group's (EAG's) model used accuracy estimates for oximetry from the NICE guideline (NG202). The EAG looked for more recent evidence, including consideration of a recent systematic review on different sleep studies, but could not identify any alternative values it considered suitable. Further discussion of evidence for the

Comment number	Name and organisation	Section number	Comment	NICE Response
				accuracy of oximetry can be found in section 5.7.4 of the external assessment report.
9	Consultee 3	Not specified	No. There is a huge amount of unreferenced studies particularly on WatchPAT devices regarding their diagnostic accuracy. There is some debate around their accuracy or otherwise, but it needs to be accepted that some groups have questioned its accuracy, and the commitee should comment on this. (https://jcsm.aasm.org/doi/10.5664/jcsm.9808)	Thank you for your comments which the committee considered. The external assessment group (EAG) explained that it considered the most recent WatchPAT device versions (300/ONE) to be most relevant to this assessment. The EAG also included studies that assessed the predecessor version (the WatchPAT 200U). The EAG stated that older versions cannot be expected to provide accuracy estimates comparable to updated versions. In the case of WatchPAT it noted that notable changes were introduced to its design from WatchPAT 200U

Comment number	Name and organisation	Section number	Comment	NICE Response
				onwards. This was why studies of earlier WatchPAT models are not included in the systematic review. Further detail on the inclusion criteria for the EAG's systematic review can be found in section 2 in the external assessment report.
10	Consultee 3	Not specified	Probably not. Almost all of the studies (other than the AcuPebble study Devani et al) are comparing the novel devices in the ideal environment of the sleep laboratory. How these devices perform in the real world is a very different question which has not been assessed.	Thank you for your comments which the committee considered. The committee considered the available studies and noted that several were done in a hospital setting. Overall, the committee concluded that accuracy estimates from hospital-based studies are acceptable to estimate diagnostic accuracy for home testing (please see section 3.2 in the

Comment number	Name and organisation	Section number	Comment	NICE Response
				updated draft guidance).
11	Consultee 3	Not specified	There is arguably a paucity of evidence on these devices, many of the studies are the first validation studies of the new devices , further external validation of the devices in different clinical settings should be encouraged before widespread usage of the devices.	Thank you for your comments which the committee considered.
12	Consultee 3	3.2 Accuracy estimates from hospital-based studies are acceptable to estimate diagnostic accuracy for home testing	This is quite a serious jump. These novel devices work in different ways to PSG and polygraphy. The impact of different bed partners, different beds, noise, disruption, device setup by the patient in their own home without clinicains/technicians are incredibly important. From a health economic perspective, what is the failure rate of these devices when performed at home. How many repeat studies are required because patients are unable to do the first night study? This has not been accounted for in this evidence statement	Thank you for your comments which the committee considered. The committee considered the available studies and noted that several were done in a hospital setting. Overall, the committee concluded that accuracy estimates from hospital-based studies are acceptable to estimate diagnostic accuracy for home testing (please see section 3.2 in the updated draft guidance). The external assessment group (EAG) explained that

Comment number	Name and organisation	Section number	Comment	NICE Response
				failure rates for the tests had been considered in the economic model and analysis. For four of the devices (AcuPebble, Sunrise, WatchPAT 300 and WatchPAT ONE), data used in the model on failure rates are taken from sleep studies conducted in the home. Only the failure rates for Brizzy and NightOwl are taken from clinic-based sleep studies. The failure rate estimates used in the model indicate the number of repeat studies required. The estimates used are presented in Table 20 of the external assessment report. The need to repeat sleep studies, and the associated costs of this, are also included in the model (see section 5.7.5 and 5.7.12 of the

Comment number	Name and organisation	Section number	Comment	NICE Response
				external assessment report for more detail).
13	Consultee 5	Not specified	There were also accepted gaps around not simply the home utilisation of devices but the end-to-end processes and costs of analysing the data , support costs and ongoing management again given different pathways adopted It seems there needs to be more research and further data gathered to confirm fitness for purpose , gather feedback , identify and or implement changes required post any implementation .	Thank you for your comments which the committee considered.
14	Consultee 9	1.1 People 16 years and over	These devices are being recommended for home-testing. However, most were validated in hospital studies. The data collected in such a setting is not going to be representative of a true failure rate or signal quality for these devices. In a research setting there was likely support with usage, device application and troubleshooting provided by a trained healthcare professional.	Thank you for your comments which the committee considered. The committee considered the available studies and noted that several were done in a hospital setting. Overall, the committee concluded that accuracy estimates from hospital-based studies are acceptable to estimate diagnostic accuracy for home testing (please see section 3.2 in the updated guidance). The external assessment group (EAG) explained that

Comment number	Name and organisation	Section number	Comment	NICE Response
				failure rates for the tests had been considered in the economic model and analysis. For four of the devices (AcuPebble, Sunrise, WatchPAT 300 and WatchPAT ONE), data used in the model on failure rates are taken from sleep studies conducted in the home. Only the failure rates for Brizzy and NightOwl are taken from clinic-based sleep studies. The failure rate estimates used in the model indicate the number of repeat studies required. The estimates used are presented in Table 20 of the external assessment report. The need to repeat sleep studies, and the associated costs of this, are also included in the model (see section 5.7.5 and 5.7.12 of the

Comment number	Name and organisation	Section number	Comment	NICE Response
				external assessment report for more detail).
15	Consultee 9	1.2 People 16 years and over	In order to make a decision regarding which device would be appropriate for a patient, a trained staff member would have to carefully assess referral information and /or contact the patient. This can lead to increased workload and cost.	Thank you for your comments which the committee considered. Costs for staff time related to use of the devices were included in the external assessment group (EAG)'s model, and scenarios and sensitivity analyses in which the impact of increasing staff time requirements on cost effectiveness estimates were also provided by the EAG and considered by the committee in its decision making. Please see section 5.7.15 of the external assessment report for full detail.
16	Consultee 9	2.5 Care pathway and clinical need	In case patients are able to access their diagnostic data right after testing, this can induce significant anxiety around getting started on treatment quickly in the face of a positive test result. Although these devices allow for fast testing of a	Thank you for your comments which the committee considered.

Comment number	Name and organisation	Section number	Comment	NICE Response
			large patient number, centres may find the work burden being shifted from the diagnostic workload to increased waiting times for treatment initiation. A positive result also has consequences in the patient's legal ability to drive, as a patient with OSAHS, depending on the severity, must cease driving until satisfactory control of the condition and symptoms have been achieved as per current DVLA guidelines. If centres opt to review data to ensure acuity and presence of good signal without significant artefact, there is also a delay and associated cost in specialised staff time. The exact burden is unclear since there are no guidelines for scoring and interpretation of most of these devices' signals.	Costs for staff time related to use of the devices were included in the external assessment group (EAG)'s model, and scenarios and sensitivity analyses in which the impact of increasing staff time requirements on cost effectiveness estimates were also provided by the EAG and considered by committee in its decision making. Please see section 5.7.15 of the external assessment report for full detail.
17	Consultee 9	3.1 Impact of using home-testing devices for people with suspected OSAHS	Although these devices can be sent and returned by post, consideration should be made for staff time utilised for device management, troubleshooting patient issues with device utilisation and issuing repeat studies as appropriate, as well as trying to retrieve devices from the patients after the study is completed.	Thank you for your comments which the committee considered. The EAG explained that where companies have indicated that preparation of the devices and training in the use of devices by

Comment number	Name and organisation	Section number	Comment	NICE Response
				staff is required, these costs have been included in the model. The costs associated with organising collection or postal of the novel devices, and for any repeat studies are also included in the economic model. The model results are robust to changes in costs.
18	Consultee 9	3.6 Home-testing devices may reduce healthcare resource use, but the extent is uncertain	Both oximetry and respiratory polygraphy studies allow for the removal of artifact data and there are clear guidelines for scoring RP. There is no such guidance on best practice with these devices and even WatchPAT, which is mentioned in the AASM scoring guidelines, does not allow for full scoring as the channels are not like for like with traditional RP.	Thank you for your comments which the committee considered.
19	Consultee 10 OSA Alliance	3.1 Impact of using home-testing devices for people with suspected OSAHS	This section has missed the important human factor of sleeping in familiar surroundings records a more representative study than measurement in a sleep lab/hospital bed.	Thank you for your comments which the committee considered. The committee considered the available studies and noted that several were done in a hospital setting. Overall, the committee concluded

Comment number	Name and organisation	Section number	Comment	NICE Response
				that accuracy estimates from hospital-based studies are acceptable to estimate diagnostic accuracy for home testing (please see section 3.2 in the updated draft guidance).
20	Consultee 10 OSA Alliance	3.6 Home-testing devices may reduce healthcare resource use, but the extent is uncertain	We observe and agree with the anticipation that despite these 'novel' devices with new diagnostic algorithms, many clinicians will continue to prefer a secondary known measure such as pulse oximetry to confirm results and that this will reduce the perceived time benefits on healthcare resources.	Thank you for your comments which the committee considered. The committee acknowledged that using an oximeter alongside the newer home testing devices may be a preferred option (please see section 3.9 in the updated draft guidance).
21	Consultee 16 Nox Medical	1.7 1 Recommendations	We acknowledge the potential of emerging technologies such as photoplethysmography (PPG), peripheral arterial tone (PAT), and other analyses in respiratory assessment. While these novel technologies offer promising insights, we recognize the importance of addressing concerns regarding their fidelity and accuracy compared to traditional methods like polysomnography (PSG). Indirect measurements may be impacted by external factors such as comorbidities, medications, or environmental factors. Thus, we strongly recommend that breathing must be directly measured during the studies, as is	Thank you for your comments which the committee considered. The committee considered the available data on the devices identified by

			required in PSG studies, when assessing sleep-disordered breathing. In this chapter, there are a couple of points that we believe the committee should consider: - “In all cases, Type III device data led to either over- or underestimation of the total number of breathing disturbances but this was not always significant. Unattended/home Type III studies resulted in significantly lower sensitivity and specificity for detecting sleep-disordered breathing and higher technical failure rates (data loss ranging from 3.5% to 61%).“1 - PAT studies do not include any apnoea or hypopnoea scoring criteria. Respiratory events are derived from attenuation of the peripheral arterial tone (PAT) signal, accompanied by heart rate increase and oxygen desaturation at the end of a ‘respiratory event’. 1 - A meta-analysis published in 2022 stated - “In conclusion, this meta-analysis shows clinically significant discordance between PAT (specifically, WatchPAT) and PSG measurements of AHI, significant misclassification by WatchPAT studies especially for mild- and moderate-severity classes of sleep apnea, and poor diagnostic test performance.” 2 - Another meta-analysis from 2022 also stated - “PAT should not be used instead of PSG for the diagnosis of SAS in the clinical setting because the sensitivity and specificity of PAT are not sufficient.”3 1- Riha RL, Celmina M, Cooper B, Hamutcu-Ersu R, Kaditis A, Morley A, Pataka A, Penzel T, Roberti L, Ruehland W, Testelmans D, van Eyck A, Grundström G, Verbraecken J, Randerath W. ERS technical standards for using type III devices (limited channel studies) in the diagnosis of sleep disordered breathing in adults and children. Eur Respir J. 2023 Jan 6;61(1):2200422. doi: 10.1183/13993003.00422-2022. PMID: 36609518. 2- Iftikhar IH, Finch CE, Shah AS, Augunstein CA, Ioachimescu OC. A meta-analysis of diagnostic test performance of peripheral arterial tonometry studies. J	the external assessment group (EAG). The EAG explained that its review included primary evaluations and systematic reviews (and meta-analyses). Full detail on the EAG’s systematic review and quality assessment of the identified studies can be found in section 4 of external assessment report. Test failure rates are one of the outcome parameters included in the cost effectiveness analysis. The EAG model accounts for sleep studies failing to provide sufficient data to make a diagnosis, and therefore requiring a second sleep study. Only those failure that are likely to require a repeat sleep study in practice, at a cost to the NHS, are included in the model. Table 20 in the external

			Clin Sleep Med JCSM Off Publ Am Acad Sleep Med. 2022;18(4):1093-1102. doi:10.5664/jcsm.9808 3- Ichikawa M, Akiyama T, Tsujimoto Y, Anan K, Yamakawa T, Terauchi Y. Diagnostic accuracy of home sleep apnea testing using peripheral arterial tonometry for sleep apnea: A systematic review and meta-analysis. J Sleep Res. 2022;31(6):e13682. doi:10.1111/jsr.13682	assessment report shows estimates of failure rates used in the model (please see more detail in the section 5.7.5 of external assessment report). The committee considered the EAG's analyses and concluded that cost effectiveness estimates produced using some of the available studies were suitable for decision-making (see section 3.14 in the updated draft guidance for further detail). The novel testing devices were compared to the use of home oximetry or respiratory polygraphy in the assessment (the comparators), not as an alternative to the use of polysomnography (PSG). PSG was often used as a reference standard in studies, for the novel tests and also the comparator tests.

Comment number	Name and organisation	Section number	Comment	NICE Response
22	Consultee 16 Nox Medical	1.4 People 16 years and over	Why did the committee only include sunrise? We believe all devices using surrogate measures need more validation to diagnose OSA accurately. “RIP bands should be the standard technique used to discriminate between the types of respiratory events in a routine setting. Jaw movement, suprasternal pressure, accelerometers and use of indirect signals like peripheral arterial tonometry/photoplethysmography are alternatives that are less obtrusive but require further validation. “ Riha RL, Celmina M, Cooper B, Hamutcu-Ersu R, Kaditis A, Morley A, Pataka A, Penzel T, Roberti L, Ruehland W, Testelmans D, van Eyck A, Grundström G, Verbraecken J, Randerath W. ERS technical standards for using type III devices (limited channel studies) in the diagnosis of sleep disordered breathing in adults and children. Eur Respir J. 2023 Jan 6;61(1):2200422. doi: 10.1183/13993003.00422-2022. PMID: 36609518.	Thank you for your comments which the committee considered. The committee considered the available data and concluded that cost effectiveness estimates produced using some of the available studies were suitable for decision-making (see section 3.14 in the updated draft guidance for further detail).
23	Consultee 16 Nox Medical	3 Impact of using home-testing devices for people with suspected OSAHS	We do not believe that all relevant evidence has been taken into account. We urge the committee to consider the including these articles in the analysis or discussion. 1- Riha RL, Celmina M, Cooper B, Hamutcu-Ersu R, Kaditis A, Morley A, Pataka A, Penzel T, Roberti L, Ruehland W, Testelmans D, van Eyck A, Grundström G, Verbraecken J, Randerath W. ERS technical standards for using type III devices (limited channel studies) in the diagnosis of sleep disordered breathing in adults and children. Eur Respir J. 2023 Jan 6;61(1):2200422. doi: 10.1183/13993003.00422-2022. PMID: 36609518. 2- Iftikhar IH, Finch CE, Shah AS, Augunstein CA, Ioachimescu OC. A meta-analysis of diagnostic test performance of peripheral arterial tonometry studies. J Clin Sleep Med JCSM Off Publ Am Acad Sleep Med. 2022;18(4):1093-1102. doi:10.5664/jcsm.9808 3. Ichikawa M, Akiyama T, Tsujimoto Y, Anan K, Yamakawa T, Terauchi Y.	Thank you for your comments which the committee considered. Please refer to the response to comment 21.

Comment number	Name and organisation	Section number	Comment	NICE Response
			Diagnostic accuracy of home sleep apnea testing using peripheral arterial tonometry for sleep apnea: A systematic review and meta-analysis. J Sleep Res. 2022;31(6):e13682. doi:10.1111/jsr.13682 4. Bonsignore MR, Baiamonte P, Mazzuca E, Castrogiovanni A, Marrone O. Obstructive sleep apnea and comorbidities: a dangerous liaison. Multidiscip Respir Med. 2019;14(1):8. doi:10.1186/s40248-019-0172-9	
24	Consultee 18	1	Thank you for the opportunity to comment on the NICE draft recommendations regarding novel diagnostics for obstructive sleep apnoea (OSA). NICE and the committee should be congratulated on this important body of work in an area of medicine that is in need of significant focus and innovation. With approximately 8 million people in the UK with undiagnosed OSA, systems to identify and treat these patients to improve quality of life and prevent long term negative health outcomes are vital. This work is clearly the culmination of many hundreds of hours of hard work and provides a clear explanation of the issue at hand. Novel diagnostics that are able to provide diagnosis at scale are an exciting prospect to manage this ever growing burden of OSA. However, given the scale of the issue at hand, NICE-recommendation of any such device needs to be done with due caution given the potential scale of patient-safety concerns if the wrong decisions were made. I feel that it is crucial to address several critical issues that in my view were not fully considered in the recommendations.	Thank you for your comments which the committee considered.
25	Consultee 18	1.1 People 16 years and over	While novel diagnostics' accuracy is compared with PSG or PG measured AHI, it is important to evaluate their effectiveness in detecting OSA with clinically relevant endpoints which are likely to respond to treatment, such as sleepiness, CPAP responsiveness, cardiovascular risk, and driving risk. AHI varies significantly from night to night and is poorly correlated to these important patient related outcomes. The current recommendations do not discuss the limitations of the current standard OSA assessment measurements and instead assess performance of novel diagnostics against these limited standards. Without this caveat, it is my concern that by issuing a document that implies these devices	Thank you for your comments which the committee considered. Modelling done to assess the cost effectiveness of the tests used available accuracy data and linked this to test result

			may be able to some extent mimic standard PSG/PG, the reader may assume that the numbers they give are diagnostic in their own right.	impact on decisions about treatment, and in turn how these impacts on cardiovascular risk and road traffic accident risk. Full details of the modelling approach taken can be found in the external assesment report in section 5.5 (detail on the modelled impact of interventions can be found in section 5.7.11). The comparators for this assessment were tests currently used in the NHS: home oximetry and home respiratory polygraphy (please see the scope for further detail). The accuracy of these tests was also modelled, with any issues in their performance represented by accuracy figures used and factored into model cost effectiveness estimates (see section 5.7.4 in the assessment report for a discussion

Comment number	Name and organisation	Section number	Comment	NICE Response
				of how the accuracy of home oximetry and home respiratory polygraphy was modelled).
26	Consultee 18	2.4 Care pathway and clinical need	Contrary to the description in the recommendations, not all home PG kits are complex or require extensive hospital visits for setup. Many home PG kits are user-friendly and do not necessitate multiple wires, which significantly impacts the recommendations favouring new devices. Home oximetry is not invasive. The claim that novel diagnostics are less invasive or more comfortable lacks supporting evidence, particularly as compared to home oximetry and some of the standard conventional PG kits. This raises concerns about clinical equipoise when assessing novel diagnostic tests.	Thank you for your comments which the committee considered. The committee noted that any benefit in terms of comfort compared to currently used devices would be variable, but, in particular, not needing a nasal cannula, as for home respiratory polygraphy, was highlighted as a benefit. Patient experts at the committee meetings also highlighted potential benefits of less invasive devices as a benefit. Comment 49 in the consultation (see below) also highlighted the benefit of potential comfort

Comment number	Name and organisation	Section number	Comment	NICE Response
				when wearing the devices The EAG also identified some data on ease of use and acceptability of the newer tests, including comparison with respiratory polygraphy, as reported in section 4.7.2 of external assessment report.
27	Consultee 18	2.6 The interventions	A meta-analysis of the WatchPAT device has raised accuracy concerns that were not considered in the recommendations (https://doi.org/10.5664/jcsm.9808). There have been several other meta-analyses of the WatchPAT device which do not appear to have been considered. Furthermore, the reports that mandibular movement effectively tracks OSA has not been substantiated convincingly. Similarly, the WatchPAT One's claim of measuring sleep states has shown low correlation with EEG-based methodologies, particularly in patients with OSA. I think it would be important to discuss these claims in more detail within the recommendations so that users understand the potential limitations of some of the reported metrics generated by the outlined novel diagnostic tests. The argument that having some measure of sleep, by which to divide the overnight respiratory event count, somehow improves the diagnostic accuracy of the AHI seems rather spurious, particularly when compared to the much larger differences from night-to-night variation (https://doi.org/10.1016/j.chest.2020.01.039). The included data on the WatchPAT device shows very poor sensitivity in mild obstructive sleep apnoea, which in my opinion is likely to be no better than pulse oximetry, which is already widely in use and would not require centres to	Thank you for your comments which the committee considered. The external assessment group (EAG) explained that it considered the most recent WatchPAT device versions (300/ONE) to be most relevant to this assessment. The EAG also included studies that assessed the predecessor version (the WatchPAT 200U). The EAG stated that older versions cannot be expected to provide

			purchase new equipment. Studies considering the sensitivity and specificity of the oximetry channel alone from polygraphy showing good sensitivity and specificity to detecting OSA has not been considered (Chai-Coetzer et al. Thorax 2011;66(3):213-9 & Borsini et al. Sleep Sci. 2021; 14(1): 77–81). Whilst I accept that this is extrapolating data from a different device, I note that the committee considered evidence from the WatchPAT 200U as sufficient to make recommendations on the WatchPAT ONE and WatchPAT 300 despite no direct evidence for these devices. The disposable nature of the WatchPAT One raises environmental concerns and resource wastage, which could be mitigated if the device were designed to be reusable.	accuracy estimates comparable to updated versions. In the case of WatchPAT it noted that notable changes were introduced to its design from WatchPAT 200U onwards. This was why studies of earlier WatchPAT models are not included in the systematic review. Further detail on the inclusion criteria for the EAG's systematic review can be found in section 2 in the external assessment report. The committee considered the sustainability of these devices. It noted that some of the devices are reusable and others are single use only. Any reduction in the need to travel to healthcare centres to collect and return equipment may have benefits in terms of reducing carbon dioxide emissions. The

Comment number	Name and organisation	Section number	Comment	NICE Response
				committee discussed that disposable devices would have an environmental cost. But because reusable devices need to be returned, this may cause delays to the devices being available again if they are not returned promptly or are lost. Please see more detail in section 3.17 of the updated draft guidance.
28	Consultee 18	3.1 Impact of using home-testing devices for people with suspected OSAHS	Contrary to the description in the recommendations, not all home PG kits are complex or require extensive hospital visits for setup. Many home PG kits are user-friendly and do not necessitate multiple wires, which significantly impacts the recommendations favouring new devices. Home oximetry is not invasive. The claim that novel diagnostics are less invasive or more comfortable lacks supporting evidence, particularly as compared to home oximetry and some of the standard conventional PG kits. This raises concerns about clinical equipoise when assessing novel diagnostic tests.	Thank you for your comments which the committee considered. Please see the response to comment 26.
29	Consultee 18	3.1 Accuracy estimates from hospital-based studies are acceptable to estimate diagnostic	Experience with postal delivery systems for respiratory polygraphy has been suboptimal, with significant loss rates that must be considered in the economic evaluations. Additionally, many devices have only been evaluated in hospital settings, not in real-world scenarios where the failure rate could be much higher. This discrepancy questions the validity of the current economic models and raises concerns that devices will be used in the home having never been evaluated in this setting.	Thank you for your comments which the committee considered. Please see the response to comments 12 and 17.

Comment number	Name and organisation	Section number	Comment	NICE Response
		accuracy for home testing		
30	Consultee 18	3.3 Using test accuracy data from previous and similar versions was acceptable for NightOwl and the WatchPAT devices	The economic model assumptions regarding the time to report studies and set up devices seem unrealistic. For example, setting up an AcuPebble device in 0.5 minutes is questionable. Whilst a longer period of 20 minutes was included in the model, this was based on expert opinion. It is not clear what time was included in the modelling to analyse respiratory polygraphy, but the committee papers list 60-120 minutes for analysis of an Embletta home sleep study. In our centre, respiratory polygraphy takes an average of 12 minutes of a consultants time to report. Therefore, the time saved evaluating novel diagnostic studies will be hugely variable depending on the current method of reporting RP. The model also does not factor in the real-world delivery and return loss rates and operational challenges, which significantly impact the feasibility and cost-effectiveness of these novel diagnostics. There were no suitable studies to include into the health economic modelling and the EAG evaluation states that 'The cost-effectiveness analysis is limited by the availability and quality of data for many of the model components, including limited accuracy data in the home environment and the effects of post-hoc optimisation of thresholds for sensitivity and specificity.' I am surprised that given these limitations that a firm recommendation in favour of using most of the novel diagnostic tests has been reached.	Thank you for your comments which the committee considered. The committee noted variability in potential benefit from any time savings (please section 3.1 of the updated draft guidance). The external assessment group (EAG) has done several analyses related to timing and resource use associated with testing, varying parameters in the model, and the impact of this on cost effectiveness results was considered by the committee in making the recommendations (please see full detail in section 5.7 of external assessment report).
31	Consultee 18	3.12 Some home-testing devices are	The economic model assumptions regarding the time to report studies and set up devices seem unrealistic. For example, setting up an AcuPebble device in 0.5	Thank you for your comments which the

Comment number	Name and organisation	Section number	Comment	NICE Response
		cost effective for diagnosing OSAHS in people 16 years and over	minutes is questionable. Whilst a longer period of 20 minutes was included in the model, this was based on expert opinion. It is not clear what time was included in the modelling to analyse respiratory polygraphy, but the committee papers list 60-120 minutes for analysis of an Embletta home sleep study. In our centre, respiratory polygraphy takes an average of 12 minutes of a consultants time to report. Therefore, the time saved evaluating novel diagnostic studies will be hugely variable depending on the current method of reporting RP. The model also does not factor in the real-world delivery and return loss rates and operational challenges, which significantly impact the feasibility and cost-effectiveness of these novel diagnostics. There were no suitable studies to include into the health economic modelling and the EAG evaluation states that 'The cost-effectiveness analysis is limited by the availability and quality of data for many of the model components, including limited accuracy data in the home environment and the effects of post-hoc optimisation of thresholds for sensitivity and specificity.' I am surprised that given these limitations that a firm recommendation in favour of using most of the novel diagnostic tests has been reached.	committee considered. Please see the response to comment 30.
32	Consultee 18	4	In conclusion, while novel diagnostic devices hold promise, I feel that the current evidence is insufficient to make firm recommendations. Several studies seem to have been excluded from the systematic review without a clear explanation that I could identify. Furthermore, I feel that the current recommendation lack balance and that the economic modelling relies heavily on expert opinion. Many novel diagnostics tests have not been thoroughly evaluated at home where they will mostly be used and there is a lack of guidance on the settings and patient subgroups in which to consider novel diagnostics, for example whether individuals with a history of chronic cardiorespiratory disease should not be tested with these devices. I accept however that that the trade off from using cheaper devices with lower accuracy may allow more sleep studies to be done, but significantly lowering the diagnostic value of these studies must be understood and made very clear.	Thank you for your comments which the committee considered. Please refer to the response to comment 9 10 and 30. The committee considered the amount and quality of evidence available, and how the economic model had been produced, including how the

Comment number	Name and organisation	Section number	Comment	NICE Response
				impact of different test accuracy was captured in cost effectiveness estimates. Overall, the committee considered that there was sufficient evidence to recommend use of some these tests (as described in section 1.1 of the updated draft guidance).

Theme: Recommendations

Comment number	Name and organisation	Section number	Comment	NICE Response
33	Consultee 1	2.5 Care pathway and clinical need	All very much the case	Thank you for your comments which the committee considered.
34	Consultee 1	3.8 The home-testing devices may provide different outputs to oximetry and	Previously stated, oximetry and accompanying HR provide an internal control and should be obligatory	Thank you for your comments which the committee considered.

Comment number	Name and organisation	Section number	Comment	NICE Response
		respiratory polygraphy		
35	Consultee 1	3.13 Some home-testing devices are cost effective for diagnosing OSAHS in people 16 years and over	Although sleep can be staged from Oximetry the additional algorythms available in some devices give helpful information for the sleep physicain eg REM onset; effect of SWS on RDI	Thank you for your comments which the committee considered.
36	Consultee 1	3.16 Sustainability considerations	The delivery and recovery of devices is an issue. Anything that simplifies and does not compromise the patient journey has to be the way forward	Thank you for your comments which the committee considered.
37	Consultee 2	2.6 The interventions	It is likely that adding a pulse oximeter will be the main option for clinicians so that the results from the Acupebble and other such devices will be compared to the pulse oximetry. This gives validation to the results.	Thank you for your comments which the committee considered. The committee acknowledged that using an oximeter alongside the newer home testing devices may be a preferred option, so the functionality to be used with a third-party oximeter may be an important consideration for services considering which of the newer tests to purchase.

Comment number	Name and organisation	Section number	Comment	NICE Response
				Please see section 3.9 in the updated draft guidance.
38	Consultee 4	Not specified	Context for patients and the public You do state that this is guidance for the NHS However , SATA are particularly mindful that all guidance from NICE as a trusted source will be available and used by the public as people increasingly seek ways to self-help in diagnosing their conditions given constraints in NHS So, it seems important that you clarify the context with something like what follows “ Note any of the devices (when subject to regulatory approval) could and should only be used as part of a sleep pathway agreed with clinicians to ensure it is appropriate and best suited to what maybe differing individual patient needs ”	Thank you for your comments which the committee considered. The committee acknowledged that home-testing devices should be used as part of a sleep pathway agreed with clinicians to ensure the use of device suit people’s needs. Please see section 3.1 in the updated draft guidance.
39	Consultee 7	Not specified	ARNS do not have any further comments to submit regarding the draft guidance consultation for Novel home-testing devices for diagnosing obstructive sleep apnoea/hypopnoea syndrome at this stage.	Thank you for your comments which the committee considered.
40	Consultee 8	Not specified	I am a Professor of Biomedical Engineering at Imperial College with a decade-long interest in Obstructive Sleep Apnoea (OSA). I also lead a Centre that conducts research in physiological sensing, among other areas. I have read the documents related to this consultation with great interest. The recommendation is highly appreciated, as the current pathways in the NHS are quite suboptimal, and these devices have the potential to significantly improve patient experience, broaden diagnostic access, and reduce waiting lists. However, I was somewhat surprised to see that the evidence presented in the report concerning diagnosis solely using oximeters was downplayed, despite its	Thank you for your comments which the committee considered. As described in the scope for this work, the assessment was focussed on whether the newer devices should be used in place

Comment number	Name and organisation	Section number	Comment	NICE Response
			significant implications for patients. This is particularly concerning given the report's indication that the practice of using oximeters alone to diagnose OSA is widely followed in the NHS. Considering the report now acknowledges that there are alternative, easy-to-deploy technologies that can be used alone or in combination with oximeters, and given the evidence about the latter, the recommendation should discourage the use of oximeters in isolation for diagnosing OSA, based on both poor accuracy (as stated in the report) and potential health inequalities. It is also worth noting that the assumption that oxygen saturation variations are correct even if absolute values are not is a flawed conclusion. Current regulatory testing does not evaluate variations but only absolute values. If the absolute values are correct, it is reasonable to assume the variations will be too; however, the opposite is not mathematically valid and there is no scientific modeling to prove otherwise.	of home oximetry or home respiratory polygraphy. As noted in the comment, the draft recommendations do state some of the newer tests are recommended as options for use in place of home oximetry.
41	Consultee 10 OSA Alliance	3.8 The home-testing devices may provide different outputs to oximetry and respiratory polygraphy	We feel that it is important to be clear that these devices are for diagnosis of OSA/OHS and should not be extrapolated to management of other ventilatory problems such as DMD/MND etc where oximetry is currently used.	Thank you for your comments which the committee considered. The recommendations state that the use of the tests is to diagnose and assess the severity of obstructive sleep apnoea hypopnoea syndrome, and the title of the guidance also states that the device is in the context of use for obstructive sleep apnoea hypopnoea syndrome

Comment number	Name and organisation	Section number	Comment	NICE Response
42	Consultee 10 OSA Alliance	3 3 Committee discussion	As an overall comment, we observice that the devices are a helpful resource which will assist in streamling struggling diagnostic services.	Thank you for your comments which the committee considered.
43	Consultee 11 British Thoracic Society	3.8 The home-testing devices may provide different outputs to oximetry and respiratory polygraphy	Agree with discussion re different outputs and clinical importance of oximetry, particularly in patients with co-morbidities associated with potential for hypoxaemia (eg COPD). Reminder that hypoxic burden key prognosticator in OSA. Did/should cost analysis for non-oximetry devices include cost of adding in 3rd party oximeter, either in a proportion or all patients, in sensitivity analysis?	Thank you for your comments which the committee considered. The external assesment group (EAG) stated that the costs of adding oximetry devices to be used alongside the newer tests are very small and does not change the EAG's conclusion that these devices are cost effective compared to home respiratory polygraphy or oximetry.
44	Consultee 16 Nox Medical	2.6 The comparators	Many of these new technologies offer quick and simplified diagnosis of OSA. Differently from other common sleep disorders, 80% of patients with obstructive sleep apnea (OSA) show multiple comorbidities.4 That said, we believe these new technologies should only be utilized in comorbid-free patients or a list with well-defined exclusion criteria to specific comorbidities should be available. In a comorbid population, the accuracy of these devices can be seriously impacted. In this chapter, there is a point we believe the committee should consider:	Thank you for your comments which the committee considered. Please see the responses to comment 21 related to the Iftikhar et al. (2022) meta-

Comment number	Name and organisation	Section number	Comment	NICE Response
			-A meta-analysis published in 2022 stated - “In conclusion, this meta-analysis shows clinically significant discordance between PAT (specifically, WatchPAT) and PSG measurements of AHI, significant misclassification by WatchPAT studies especially for mild- and moderate-severity classes of sleep apnea, and poor diagnostic test performance.” 2 - This meta-analysis included studies of patients with hypertension, COPD, congestive heart failure, and other chronic conditions, and it addressed analytical errors in the original studies that sometimes suggested acceptable diagnostic test performance for WatchPAT. 2- Iftikhar IH, Finch CE, Shah AS, Augunstein CA, Ioachimescu OC. A meta-analysis of diagnostic test performance of peripheral arterial tonometry studies. J Clin Sleep Med JCSM Off Publ Am Acad Sleep Med. 2022;18(4):1093-1102. doi:10.5664/jcsm.9808 4- Bonsignore MR, Baiamonte P, Mazzuca E, Castrogiovanni A, Marrone O. Obstructive sleep apnea and comorbidities: a dangerous liaison. Multidiscip Respir Med. 2019;14(1):8. doi:10.1186/s40248-019-0172-9	analysis cited in this comment. The guidance recommendations (see section 1.2 in the updated guidance) state that when considering whether to use the specified home-testing devices (see section 1.1 in the updated guidance) in place of home respiratory polygraphy (RP) or home oximetry, to take into account the device outputs that are needed for decisions about care and whether the device can provide these, particularly for identifying OSAHS in people with comorbidities, including whether there is the option to use a third-party oximeter. The guidance also notes that there may be

Comment number	Name and organisation	Section number	Comment	NICE Response
				some cases in which it may be more appropriate to use home oximetry or home RP rather than the newer home-testing devices (see section 3.15 for further detail). This section notes that some home-testing devices may also have contraindications that could mean they cannot be used for everyone who currently has testing with home oximetry or home respiratory polygraphy. The devices are recommended for use only in accordance with their regulatory approval and specified intended use (in relation to diagnosing obstructive sleep apnoea hypopnoea syndrome).

Comment number	Name and organisation	Section number	Comment	NICE Response
45	Consultee 18	1.6 More research	The recommendations have listed several priorities for research including research comparing the accuracy of in hospital laboratory based PSG and at home respiratory polygraphy, and comparison of at home conventional and novel diagnostics. However, despite these important evidence gaps the draft recommendation will recommend the use of several novel diagnostic tests. Once approved, there will be little incentive for industry to generate these data to answer these important questions to enable us to provide high quality patient care. I feel this represents a missed opportunity for us to establish a firm evidence base as to whether the assessed novel diagnostics provide are cost-effective and provide good value for money for the NHS. The recommendation in section 2.7 against using oximetry alone for COPD-OSAHS overlap syndrome is noted, but the evidence supporting the use of novel diagnostics in this group is insufficient. More research in this area is warranted. Additionally, ongoing studies like the NIHR HTA study on the AcuPebble device should provide more robust at home data to inform these decisions (https://fundingawards.nihr.ac.uk/award/NIHR203393).	Thank you for your comments which the committee considered. The committee considered the amount and quality of evidence available and factored this into its decision making. Overall, the committee considered that there was sufficient evidence to recommend use of some these tests (as described in section 1.1 of the updated draft guidance). The areas the committee considered further research would be needed are described in section 1.6 of the updated draft guidance. These are distinct from the research priorities the external assesment group (EAG) suggested in its report which reflect the view of the EAG (an independent

Comment number	Name and organisation	Section number	Comment	NICE Response
				academic group), rather than the committee.
46	Consultee 18	2.6 The interventions	There is a lack of data on how well these novel diagnostics can identify central sleep apnoea. For instance, the study by Sanchez Gomez et al. only examined central events in 10 patients. I could not find evidence that the other included studies considered the performance of novel diagnostics in differentiating obstructive from central sleep apnoea. Furthermore, as outlined above, the recommendations provide limited guidance on the use of these devices in patients with conditions like heart failure or COPD, where more evidence is needed. This lack of guidance is likely to lead to significant variation in practice across the UK and I am concerned that this will lead to adverse patient outcomes.	Thank you for your comments which the committee considered. The recommendations for the use of the technologies are in the context of people with suspected obstructive sleep apnoea hypopnoea syndrome (OSAHS) rather than central sleep apnoea. The guidance recommendations (see section 1.2 in the updated guidance) state that when considering whether to use the specified home-testing devices (see section 1.1 in the updated guidance) in place of home respiratory polygraphy (RP) or home oximetry, to take into account the device outputs that are needed for decisions about care and whether

Comment number	Name and organisation	Section number	Comment	NICE Response
				the device can provide these, particularly for identifying OSAHS in people with comorbidities, including whether there is the option to use a third-party oximeter. The guidance also notes that there may be some cases in which it may be more appropriate to use home oximetry or home RP rather than the newer home-testing devices (see section 3.15 for further detail). This section notes that some home-testing devices may also have contraindications that could mean they cannot be used for everyone who currently has testing with home oximetry or home respiratory polygraphy. The devices are recommended for use

Comment number	Name and organisation	Section number	Comment	NICE Response
				only in accordance with their regulatory approval and specified intended use (in relation to diagnosing obstructive sleep apnoea hypopnoea syndrome).
47	Consultee 18	3.8 The home-testing devices may provide different outputs to oximetry and respiratory polygraphy	It is not clear the extent to which clinicians will be able to access detailed inspection of raw data with novel diagnostics, potentially leading to an over-reliance on the output metrics without the ability to assess artifacts or other diagnoses. This lack of transparency is a significant drawback. The devices do not seem to have been thoroughly evaluated in situations where these might arise such in patients with co-existent chronic cardio-respiratory disease or those with comorbid sleep disorders. Disorders such as central sleep apnoea and periodic limb movement disorder can be difficult to distinguish from obstructive sleep apnoea using traditional tests, requiring expert review of the raw data, and leading to markedly different management for patients. I feel that further guidance on where, and in what subgroups, to use novel diagnostics within the NICE guidelines and hence further research evaluating novel diagnostics in these areas is required.	Thank you for your comments which the committee considered. The extent to which the raw data outputs are available for the technologies is described in the scope.
48	Consultee 18	4	Many novel diagnostics tests have not been thoroughly evaluated at home where they will mostly be used and there is a lack of guidance on the settings and patient subgroups in which to consider novel diagnostics, for example whether individuals with a history of chronic cardiorespiratory disease should not be tested with these devices.	Thank you for your comments which the committee considered. Please see the response to comment 46.

Theme: Equality considerations

Comment number	Name and organisation	Section number	Comment	NICE Response
49	Consultee 6	Not specified	Having been part of one of these processes for another type of test a couple of years ago, I can see that the process has followed similar stages, evidence, expert opinions, research comparison and right to comment on the findings. I can see fierce criticism from some of the providers but also note the responses and adjustments made in the documents now available in the lengthy consultation documents. Whilst from a process perspective, it could appear in order I would like to draw attention to a very specific imbalance and equality impact issue that seems to have been completely ignored. I read this consultation with interest, having been part of previous consultations for lung cancer diagnostic tests and having recently experienced what I perceive to be a completely gender biased sleep study at home. Nowhere in the lengthy considerations has any mention been made of the major physiological differences between male and female anatomy especially for those with a large chest! The slightest thing different in a bed like a crumb or something sharp is sufficient to wake many people so having such a contraption strapped around your chest with the rigid plastic box between large breasts means that for a side sleeper like me, every turn meant a sharp dig into the falling breast (gravity means it falls) that momentarily woke me up not to mention the taped tube to the pulseoximeter on the finger and the nasal cannula. Even if men (the majority diagnosed) are overweight, their chest remains relatively flat compared to their abdomen compared to women whose weight can be spread across abdomen, chest and buttocks resulting in likely less discomfort/pain to experience than a person with large breasts. It would be helpful to capture not only gender/sex data but chest/bra size too. I imagine those with flatter chests of both sexes have less discomfort and more accurate readings than others.	Thank you for your comments which the committee considered. The committee further considered the potential impact and benefits of improved comfort of the newer devices, compared to current testing. Further detail of committee discussion of this has been added to section 3.1 in the updated draft guidance. The committee also considered that if the newer home-testing devices reduced reporting and staff time this could be a big benefit to help with waiting times. It noted that people currently can wait 6 weeks or more for a sleep study and that the waiting

Comment number	Name and organisation	Section number	Comment	NICE Response
			After emergency hospitalisation in October with breathing difficulties to a hospital with no respiratory department, the consultant I saw advised as my respiratory consultant had (days before when seen as an outpatient w/o symptoms that led to my hospitalisation) they would refer me for a sleep study. Discharged via virtual respiratory ward, readmitted after 2 days after stopping breathing and paramedics returned me to hospital. The choking/stopping breathing episodes occurred several times during my stay but no respiratory staff work there so only ENT involved. During my almost 3 week stay I decided to use the Apple Watch sleep function to check how disturbed sleep is in a hospital setting for anyone. It showed intermittent waking a few times a night. I accept it is not approved as a medical device but its pulse oximeter matched the hospital equipment readings so is a guide when oxygen levels drop. I had sleep study at home mid March 2024 recently given results of severe OSA waking 35 times an hour. When I explained the extreme discomfort of the device which meant (as in hospital) sleeping on my back was the only way to rest (not my usual sleeping position), the consultant wasn't interested saying I should tell the sleep team when I see them. There are currently several months' wait for that referral. Questions from respiratory physiotherapist, consultant do not bear out initial severe result - not sleepy in the day, no headaches, do not nod off as passenger in car journeys, watching tv, etc no history of COPD, never smoked but wake up tired. My personal medical history appears not to have been factored in yet in your considerations, many conditions are excluded without explanation. Are there others e.g. hiatus hernia, lung cancer, hypersensitive airways, asthma that may impact results? I found no answers in the documents. Being involved in health research for lung and other cancers, and commissioning for healthcare services for many years I always consider whether certain people may be disadvantaged by services/tests as respiratory conditions often impact those in areas of higher socio-economic deprivation. Gender strikes me as an obvious consideration. I have read comments about black/brown skin and pulsoximeter shortcomings but nothing about gender/sex and chest measurement which can be a real physical impediment to the current at home	lists are still growing. Both overdiagnosis and delays in getting a diagnosis were acknowledged as causing increased anxiety and impacting on people's earning capacity, ability to drive and other aspects of their life (see section 3.7 in the updated draft guidance document). The page numbers and comments at the bottom of the comment appear to refer to the external assesment group's report, rather than the draft guidance. Data and statistics cited in this report will be limited by what data are available. Patient reported outcomes were considered in the

Comment number	Name and organisation	Section number	Comment	NICE Response
			tests. It could lead to over or inaccurate diagnoses. The adverse impact could be increased anxiety from over diagnosis, impact on earning capacity, ability to drive and other aspects. Not only does it take months to do the tests but months to get results and follow up. What are people supposed to do in the meantime - especially if they work freelance, i.e. not on benefits, regular income or pension? There is meant to be parity of esteem on mental and physical health yet such waits can significantly impact some patients. p42 I note some attempt has been made in the clumsy adjustment for gender in the pregnancy description stating 'pregnant women and pregnant people' rather than 'those who are pregnant' yet no other reference to gender/sex is mentioned. p29 1.1.1 I'm curious about the age parameters as the tests show for children to age 16 yet stats for adults show 30-69. Why is that? are those between 16-30 ineligible? or those over 69? Another group of people impacted are those who may get seen initially at a DGH without respiratory consultants/sleep team then passed elsewhere with disconnect between primary, secondary, tertiary care with scope to mismanage, misdiagnose and cause additional time/travel/costs delay to patients in this situation. p211 doesn't mention the impacts of false positives - anxiety, driving, travel, employment type restrictions that may follow as a result or concerns that they may impact. p212 no consideration for male/female. there appears little mention of under compliance of CPAP machines once patients are prescribed them and why mandibular devices may be more popular for some. p28 extremely disappointing that no HR QOL tests done nor any factors reported on these for those who had tests or CPAP as a comparator. In an era when PROMs are encouraged in studies, how can these not be captured for comparison? I think if the data is available to explore gender and whether any consideration is	external assessment report and the cost effectiveness estimates generated. Please see more detail in section 4.7 and 4.10 of external assessment report.

Comment number	Name and organisation	Section number	Comment	NICE Response
			given around chest size and suitability of the current or future suggested at home kits this could seriously improve current knowledge and may lead to improved outcomes in future.	
50	Consultee 9	2.6 The interventions	The requirement for use of a smartphone as part of the test may introduce difficulties for elderly patients, some patients with disabilities and those that live in areas with poor network signal.	Thank you for your comments which the committee considered. The committee noted that some people have limited access to a smartphone or internet connection, including having limited internet data or living in areas with poor network signal, and some people will be less comfortable using smartphones. This is discussed in the updated guidance, section 3.13. The recommendations also note that when deciding whether to use the recommended newer tests over home oximetry or home respiratory polygraphy, to consider the internet

Comment number	Name and organisation	Section number	Comment	NICE Response
				and smartphone access that would be needed to use the device (see section 1.2 of the updated draft guidance).
51	Consultee 10 OSA Alliance	3.7 Evidence in children and young people under 16 years is limited	Further to the observations about the ongoing research into the use of these devices for diagnosis in children, we observe that this might equally apply to underweight patients. We question whether the studies are validated in this group of patients? All the studies have been in overweight or normal weight patients.	Thank you for your comments which the committee considered. The external assessment group (EAG) explained that there was little or no data specifically for the use of the devices for people who are underweight. Section 3.15 in the draft guidance notes that some home-testing devices may have contraindications that could mean they cannot be used for everyone who currently has testing with home oximetry or home

Comment number	Name and organisation	Section number	Comment	NICE Response
				respiratory polygraphy. The devices are recommended for use only in accordance with their regulatory approval and specified intended use (in relation to diagnosing obstructive sleep apnoea hypopnoea syndrome).
52	Consultee 10 OSA Alliance	3.12 Place of attachment and access to the internet or a smartphone	Separate research has indicated that there are areas of digital poverty in the UK and among people living on an annual household income of £25K or less, one in five doesn't use the internet. There is also less digital activity in older patients and those with disabilities, it is therefore essential that existing testing equipment continues to be available, particularly for those Trusts operating in more deprived areas.	Thank you for your comments which the committee considered. The committee noted that some people have limited access to a smartphone or internet connection, including having limited internet data or living in areas with poor network signal, and some people will be less comfortable using smartphones. Please see the updated guidance section 3.13. The recommendations also note that when

Comment number	Name and organisation	Section number	Comment	NICE Response
				deciding whether to use the recommended newer tests over home oximetry or home respiratory polygraphy, to consider the internet and smartphone access that would be needed to use the device (see section 1.2 of the updated draft guidance).
53	Consultee 11 British Thoracic Society	3.9 Diagnostic accuracy in people with brown or black skin	Mostly agree with discussion. Plausible argument that oxygen desaturation from baseline being the OSAHS diagnostic metric protects from potential inaccuracies due to skin colour. However if skin colour could affect baseline oximetry accuracy then is there evidence to say it wouldn't affect detection of change? Agree more research needed.	Thank you for your comments which the committee considered.
54	Consultee 14	1.6 – More research	The committee recommends that more research is needed to assess the accuracy of home-testing in diagnosing people with dark skin. We wish to comment that this issue, which is related to recent findings over the lower accuracy of oximetry devices in dark skin, is not limited to home-tests, but relevant to any sleep study that relies on oximetry measurement, including In-lab polysomnography. In fact, the AASM scoring guidelines rely on measurement of oxygen desaturations as one of the conditional parameters for scoring Hypopnoea. Furthermore, devices that are not using oximetry, are still validated against the gold standard (in-lab Polysomnography), that relies on oximetry, and thus not exempt from this risk. Through our activity in the US, we have learnt that the FDA is already considering upgrading their requirements for validation of non-invasive oxygen	Thank you for your comments which the committee considered.

Comment number	Name and organisation	Section number	Comment	NICE Response
			saturation measurement, in order to address the concerns over performances in subjects with dark skin, ensuring that new devices will not be at risk of underperforming with certain populations. We also estimate that a change in the relevant ISO standard is inevitable, and thus we estimate that all CE marked devices would become aligned with the new standard in the future. The committee should also take into consideration the growing interest amongst sleep medicine researchers in another method of calculating oxygen desaturations, which is known as Hypoxic Burden. Recent studies showed that Hypoxic burden may be a better predictor of cardiac risk than Apnoea Hypopnea Index. Therefore, we believe that it is reasonable to estimate that the role of oxygen saturation measurement in sleep apnoea diagnosis will increase in the future.	
55	Consultee 15	3.1	The section states: “It was also noted that for people with mobility issues, returning devices by post may also be an issue.” While this is an important consideration, in many cases returning a device by post would be easier for patients with mobility issues than having to return the device to a hospital. Some of the reusable devices allow booking of a collection from home (eg with Royal Mail) for no additional charge to the patients, as a prepaid return envelope is provided.	Thank you for your comments which the committee considered.

Theme: NICE process

Comment number	Name and organisation	Section number	Comment	NICE Response
56	Consultee 4	Not specified	At 1.2 Page 3 you state with some caveats that when approved devices will be used " in place of " (presumably oximetry and current home RP systems) It is not understood what conditions maybe sought or needed when applying for regulatory approval and if or how the NICE GL when published may inform that approval process or not. However as currently described it is assumed that any regulatory approval process must go well beyond safety of devices meeting UK standards. It seems as though the regulatory approval process will be such as to test and assure the quality of the design specification and standards being embedded and operated within a device where this may be used in place of existing oximetry and RP .	Thank you for your comments which the committee considered. NICE guidance does not replace or act in place of regulatory approval. A technology is only evaluated by NICE if it has or is expected to have regulatory approval (or appropriate regulatory signal) by the planned draft or final guidance publication date (for full detail please see the CHTE programme manual section 2.2).
57	Consultee 4	Not specified	Its assumed that all devices once "approved "will be regularly changed and models upgraded with new versions and specifications. Given assumptions and assurances which have informed the content of the draft GL so far are there inbuilt conditions or criteria set that identifies when such changes to devices will be notified and or need further assurance or even NICE approval ?	Thank you for your comments which the committee considered. Guidance can be reviewed at any time if there is reason to do

Comment number	Name and organisation	Section number	Comment	NICE Response
			The description and availability of " home testing devices for diagnosing " will be of significant ongoing interest to the public who may seek to buy/ obtain & use hence the need to recommend utilisation as part of a clinically agreed pathway Regulatory approval may see home testing devices being made available for retail sale to the public it is assumed that this will have featured in discussion by committee to consider how any such access can and will need to be managed by NHS .	so, including changes in changes in the regulatory status of the technology or regulatory extensions to its approved indication. (for full detail please see the CHTE programme manual section 8). The committee makes recommendations to NICE about the clinical effectiveness and value for money of technologies for use within the NHS (for full detail please see the CHTE programme manual section 6). Section 3.1 of the updated guidance has been amended to state that the tests should be used as part of a sleep pathway agreed with clinicians.

Comment number	Name and organisation	Section number	Comment	NICE Response
58	Consultee 4	Not specified	It was understood and hoped that the output of GL analysis of devices or in its recommendations would help support a reduction in the variation in practice and help the drive towards a more clearly defined quality sleep pathway. The output seems to have simply extended the range of options and choices with a risk of further fragmentation. Does and will NICE carry out a PIR? The committee have accepted that translation of evidence from devices tested in hospital is acceptable as being representative for use of devices in the home but this will only be tested in the real world when implemented and feedback will be vital to validate assumptions and drive change	Thank you for your comments which the committee considered. Guidance can be reviewed at any time if there is reason to do so, including changes in the evidence base (for full detail please see the CHTE programme manual section 8). When notified by stakeholders or through NICE's own surveillance activities that there is relevant new information that could affect guidance, NICE will do a short surveillance review to establish whether the guidance should be amended, updated, withdrawn or not updated. If the new data is likely to have a material effect on the recommendations then NICE will do an update of the guidance.

Comment number	Name and organisation	Section number	Comment	NICE Response
				The guidance specifies any further data collection that the committee has requested (see section 1.6 of the updated draft guidance).
59	Consultee 5	Not specified	There is reference to an implementation team to support the GI but it is not clear on its scope TOR ,etc More detail in final version would be helpful to provide assurance about how this GL when approved will be taken forward and work to drive improvements in what will be extended access to quality and service in diagnosing monitoring and managing care with and for people with OSAHS	Thank you for your comments which the committee considered.
60	Consultee 16 Nox Medical	2.5 The interventions	To the best of our knowledge, this is the first time that device names/brands are being specified in a NICE document. If considering including names of specific devices: - Not “all” available devices are mentioned . Mentioning only some devices we believe might influence the decision of clinical teams, please consider including "all" available. - The fact that different technologies are being considered, but no reference is given to accuracy, side by side, and if accuracy is impaired in different comorbid populations. . Are all technologies the same? Do they provide the same accuracy? How to choose the technology to use in a specific group of patients? - Different prices and price ranges are mentioned . Are prices for all hospitals the same? How was that confirmed? - Why does the committee want to present volume discounts? To the best of our knowledge, some of the equipment mentioned is not widely available in the UK, if available at all, please consider including "all" the available devices/technologies.	Thank you for your comments which the committee considered. Guidance produced by the NICE Diagnostics Assesment Programme routinely specifies specific devices in recommendations (previous examples of guidance can be found here). Guidance in this programme is produced according to the NICE health technology evaluations: the manual. This notes that

				devices are only assessed as a class in exceptional circumstances if evidence is available to support their clinical equivalence (section 4.2.17). The technologies to be included in the assessment are specified in the scope published on the NICE website. This was generated based on discussions with healthcare professionals working in this area, and a scoping workshop held for the topic. CHTE programme manual section 2 describes the scoping process in more detail. The costs used for the devices for this assessment are described in section 5.7.12 of external assessment report.

Comment number	Name and organisation	Section number	Comment	NICE Response
61	Consultee 16 Nox Medical	6 Committee members	We appreciate the valuable contributions of all committee members. However, we believe that having an Industry Partner who directly benefits from the guidelines under discussion as an active member of the Committee may present a potential conflict of interest. We kindly suggest reconsidering this arrangement or considering the inclusion of more industry partners to ensure the integrity and impartiality of the decision-making process.	Thank you for your comments which the committee considered. The published declarations of interest registers for both standing committee members and specialist committee members can be found here: Standing Committee Specialist Committee Members NICE's declaration of interest policy can be accessed from a link within these documents.

Theme: Comments on wording in the guidance

Comment number	Name and organisation	Section number	Comment	NICE Response
62	Consultee 1	2.1 Obstructive sleep apnoea hypopnea syndrome	Clarity please with the use of the phrase OSAHS	Thank you for your comments which the committee considered.
63	Consultee 1	2.2 Obstructive sleep apnoea hypopnea syndrome	OSAHS is NOT caused by hypertension, T2DM or CVD	Thank you for your comments which the committee considered. The text has been amended to: “In adults OSAHS is associated with various adulthood conditions such as overweight or obesity, hypertension, type 2 diabetes and cardiovascular disease.”
64	Consultee 1	2.3 Care pathway and clinical need	Oximetry properly interpreted does not cause confusion in patients with other causes of hypoxemia	Thank you for your comments which the committee considered.
65	Consultee 1	2.4 Care pathway and clinical need	Disagree; depends what you mean by sensitive	Thank you for your comments which the committee considered. Section 2.4 has been amended to remove the

Comment number	Name and organisation	Section number	Comment	NICE Response
				statement about sensitivity.
66	Consultee 10 OSA Alliance	2.2 Obstructive sleep apnoea hypopnea syndrome	OSAHS is ASSOCIATED with various adult conditions and is not “caused” by them.	Thank you for your comments which the committee considered. The text has been amended to: “In adults OSAHS is associated with various adulthood conditions such as overweight or obesity, hypertension, type 2 diabetes and cardiovascular disease.”
67	Consultee 15	Table 1	The Table is potentially subject to interpretation. It states for AcuPebble SA100 “(£40 to £60 per reusable device depending on volume of sleep studies)”. It should say “£40 to £60 per test depending on volume of sleep studies” because the device is not charged for.	Thank you for your comments which the committee considered. The text has been amended to: “£40 to £60 per test depending on volume of sleep studies”.
68	Consultee 15	Table 1	The table states, for AcuPebble SA100: Internet: during set up and to finish the study (can be done by a healthcare professional).	Thank you for your comments which the committee considered.

Comment number	Name and organisation	Section number	Comment	NICE Response
			It should say: Internet: “To create study in the system (healthcare professional) and to upload the data (this can be done when the device is received by a healthcare professional).	The text has been amended to:” Internet: to create study in the system (healthcare professional) and to upload the data (this can be done when the device is received by a healthcare professional).”
69	Consultee 15	Table 1	Currently the table states, for AcuPebble SA100: “Smartphone: yes, can be provided when purchased” It should state: “Smart device (phone or tablet): yes, manufacturer provides it to carry out the test at no additional cost.”	Thank you for your comments which the committee considered. The text has been amended to:” Smart device (phone or tablet): yes, manufacturer provides it to carry out the test at no additional cost.”
70	Consultee 19 Stowood	1.1 People 16 years and over	When reviewing this Recommendation as a standalone document, it is not clear what these are alternative options to, i.e. respiratory polygraphy. Suggest re-working this sentence to: "Use the following home-testing devices as alternative options to respiratory polygraphy (RP) or home oximetry to diagnose..."	Thank you for your comments which the committee considered. Section 1.2 in the updated guidance states that use of these devices is in place of

Comment number	Name and organisation	Section number	Comment	NICE Response
				home respiratory polygraphy (RP) or home oximetry.
71	Consultee 19 Stowood	1.7 More research	This comment could lead to confusion and potential incorrect choice of devices due to misunderstandings about accuracy. Suggest this sentence is either fully evidenced or removed.	Thank you for your comments which the committee considered. The statement in section 1.7 in the draft guidance is standard wording used to denote how access to technology for uses the committee has recommended use only in the context of research should be provided.
72	Consultee 19 Stowood	3.5 Using test accuracy data from previous and similar versions was acceptable for NightOwl and the WatchPAT devices	Is this a typo? WatchPAT 200U is not the most recent version.	Thank you for your comments which the committee considered. The text has been amended to: “The EAG included data in its report from studies that used the WatchPAT 200U, which is the earlier version of this device.”