NICE National Institute for Health and Care Excellence

Health Tech programme

GID-HTE10065: Digital technologies for applying algorithms to spirometry to support asthma and COPD diagnosis in primary care and community diagnostic centres

Draft Guidance Collated Comments

Table 1: Importance of clinical context

Comment Number	Consultee number/ organisation name	Page number	Section number	Comment	NICE Response/EAG considerations
1.	LungHealth			As a group of Respiratory Consultant Physicians and founders of LungHealth ([redacted]), we have read the draft guidance for HTE10065 with surprise. We are perplexed at some of the comments made in the guidance. We do not feel that these are reasonable interpretations of the evidence clinically. It is important to realise that the diagnosis of lung disease whether this is COPD, Asthma, lung fibrosis is always going to be a clinical one combined with the results of lung function testing. One can and should never make a diagnosis based on lung function testing alone. The implications of labelling a patient with a condition such as "COPD" or "interstitial lung disease" based on the results of lung function testing alone should be considered particularly given the current nature of primary care. There is a shortage of skilled staff in primary care at present and furthermore, staff who are skilled in the interpretation of spirometry. There is a real risk that staff with suboptimal training will extrapolate a	Thank you for your comment, the committee has considered this. It agreed that the guidance should emphasise the importance of a clinical assessment being done and considered alongside spirometry to inform diagnosis. Section 1 of the guidance notes that "[ArtiQ.Spiro] can only be used: • following clinical assessment and with clinical oversight from a healthcare professional to make the final diagnosis". The necessity of a structured clinical assessment is acknowledged in section 3.4 of the guidance, noting that "Objective tests should be done to confirm a diagnosis *after clinical assessment*, to help healthcare professionals differentiate between obstructive and restrictive lung conditions."

Comment Number	Consultee number/ organisation name	Page number	Section number	Comment	NICE Response/EAG considerations
				diagnosis of lung disease simply based on spirometry alone possibly leading to an erroneous diagnosis of a lung condition and/or the real cause of the patient's symptoms being missed. LungHealth software provides the due clinical context for every patient undergoing spirometry. The purpose of the LungHealth software was not to replace the other technologies but to serve as an adjunct to these technologies ensuring that behind each lung function measurement, there was appropriate clinical context. It is only by combining the appropriate clinical context with the lung function measurements that one arrives at a correct diagnosis. This is reflected in all major national and international clinical guidelines We are surprised that these points above have not been considered by the committee in their decision making. There is a real risk that in the "real world" of primary care as it stands, non-specialist staff will over and underdiagnose cardio-respiratory disease potentially leading to a delayed diagnosis of the actual reason why a patient is breathless along with an increase in morbidity, mortality and emergency healthcare utilisation. We therefore feel that the "standard" national pathway for "Diagnostic Spirometry" should incorporate the integration of clinical decision support system software with spirometry in order to reach an accurate diagnosis.	
2.	LungHealth			It is fundamentally important to consider that the diagnosis of lung disease CANNOT and SHOULD NOT be made on lung function alone. It is important	Thank you for your comment, the committee has considered this. It agreed that the guidance should emphasise the importance

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				to understand that the diagnosis of any lung disease (and hence the term "Diagnostic spirometry") is made on the basis of a targeted clinical history coupled with lung function measurements. The absence of any of these two components leads to a lack of diagnostic accuracy and thus the delivery of suboptimal care. One cannot make a diagnosis of a potentially serious lung condition based on numbers. Correlating it with a targeted clinical history is essential if we are to accurately diagnose patients. This concern is further amplified given the current condition in primary care where there is a shortage of There is a concern that should such a recommendation be released to Primary care, healthcare professionals people will make a "diagnosis" of a lung condition in their patients based only on the spirometry and "AI" which amounts to a sub-optimal standard of care due to a lack of diagnostic accuracy. There is a danger of labelling a patient with a diagnosis they may not necessarily have e.g Lung fibrosis which requires a detailed clinical history and relevant imaging. Similarly a diagnosis of COPD requires a compatible clinical presentation that cannot be delivered on the basis of lung function alone. The above was one of the motivations behind the creation of LungHealth as we were keen to address inconsistencies and inequality in the delivery of care. It is this gap that LungHealth fills and has done for thousands of patients leading to us publishing hard outcomes in thousands of patients. We feel that the	of a clinical assessment being done and considered alongside spirometry to inform diagnosis. Section 1 of the guidance notes that “[ArtiQ.Spiro] can only be used: • following clinical assessment and with clinical oversight from a healthcare professional to make the final diagnosis”. The necessity of a structured clinical assessment in the diagnosis of lung conditions is acknowledged in section 3.4 of the guidance, noting that “Objective tests should be done to confirm a diagnosis *after clinical assessment*, to help healthcare professionals differentiate between obstructive and restrictive lung conditions”. This aim of this NICE assessment is to make recommendations on digital technologies applying algorithms to *spirometry* to support asthma and COPD *diagnosis*. It is acknowledged that spirometry is just once part of the diagnostic pathway for lung conditions. A clinical risk noted in the “what this means in practice” section is that “[Algorithm outputs] may support healthcare professionals to make diagnoses, but *do not replace clinical judgement or the need for a clinical assessment to be done*”. It is also acknowledged that prognosis/staging of COPD may be done alongside a diagnosis being made. However, prognostic ability of

NICE National Institute for Health and Care Excellence

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				capability and functionality of LungHealth has not been represented accurately in the draft. The purpose of LungHealth was to be an adjunct to spirometry to create a system and clinical pathway where patients undergoing spirometry with any recognised and validated system underwent a LungHealth review to provide the appropriate clinical context. LungHealth has algorithms that are based on established national and international criteria which allow the validation of any spirometry performed as well as containing the key questions in it's decision support software that enable the appropriate clinical context e.g. smoking history, staging of COPD that actually leads to an accurate diagnosis of a lung condition and the correct therapy being initiated. For example. in the absence of the clinical context provided by LungHealth, one cannot label a patient as "COPD" but rather "airflow obstruction".	technologies is out of scope for this assessment which focuses on diagnosis in people with suspected lung conditions. Technologies included in this NICE assessment will be considered in terms of their algorithmic support for spirometry, including: • quality assessing spirometry performance • interpreting spirometry results (for example, recognising whether the spirometry trace is obstructive, restrictive, or otherwise) • suggesting a diagnosis based on spirometry results and other clinical factors. The technologies in this guidance may have additional functions or use cases are out of scope for this assessment. The recommendations in this guidance apply to digital technologies when they are used for providing algorithmic support for spirometry, to support diagnosis of asthma and COPD.
3.	Association of Respiratory Nurses (ARNS)		2.1	The technologies provide support by: - Suggesting a diagnosis based on spirometry results and other clinical factors. Important to add note that spirometry should not be used alone to diagnose	Thank you for your comment, the committee has considered this. It agreed that the guidance should emphasise the importance of a clinical assessment being done and considered alongside spirometry to inform diagnosis. Section 1 of the guidance notes that “[ArtiQ.Spiro] can only be used:

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					• following clinical assessment and with clinical oversight from a healthcare professional to make the final diagnosis”. An acknowledged clinical risk in the guidance is that “Algorithm outputs from ArtiQ.Spiro may support healthcare professionals to make diagnoses, but do not replace clinical judgement or the need for a clinical assessment to be done.” This is stated explicitly in section 2 of the original EAG report: “From information provided by companies and from company websites, the EAG note that technologies included in this assessment: […] Are to support and aid the clinician in reporting, that is, they will not be used autonomously without human interpretation. The EAG note that a comment was made during stakeholder consultation around the particular importance of this, and the expertise of the clinician, when the technology does not include clinical history taking in its algorithm.”
4.	Association of Respiratory Nurses (ARNS)		3.23	If considering spirometry at home, patient safety to perform tests in this environment should be considered; a review of contraindications should be completed prior.	Thank you for your comment. No evidence was identified in which technologies in-scope were used in a home-based setting (other than NuvoAir which is no longer available in the NHS). Section 3.16 of the guidance notes the potential benefits of bringing diagnostic spirometry closer to a

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					person's home (e.g. increasing the number of asthma diagnoses that can be based on a series of spirometry measurements). Recommendations for technologies were made based on their intended use at the time of assessment. If the technologies are used in a home setting and evidence becomes available on this, then this may be considered following the evidence generation period. The EAG note that not all technologies are indicated for use in a home setting and that technologies which are indicated and initially included in the EAG report are now no longer being considered in this assessment (NuvoAir, MIR Spiro). Safety and oversight of home spirometry was considered within section 7 of the EAG report.

NICE National Institute for Health and Care Excellence

Table 2: Importance of clinical oversight

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5.	ARTP			General comments "1 - The guidance would benefit from clearer articulation of professional accountability when AI-supported interpretation is used, including documentation of responsibility where algorithm outputs influence diagnostic decisions. This is particularly important where spirometry is performed or interpreted by staff without specialist respiratory physiology registration…" 2 - Community diagnostic centres operate under varying models. The guidance would benefit from distinguishing between CDCs delivering secondary care-led respiratory physiology services and those operating primary-care-led models, as governance, supervision, and diagnostic risk differ substantially. Recommendations (1.1–1.3) The guidance should more explicitly state that algorithm outputs are decision-support only and must	Thank you for your comment, the committee has considered this. It agreed that the guidance should emphasise the importance of clinical oversight from a healthcare professional to confirm a diagnosis. Section 1 of the guidance notes that "[ArtiQ.Spiro] can only be used: • following clinical assessment and with clinical oversight from a healthcare professional to make the final diagnosis". **Recommendations:** The committee agreed that the guidance should emphasise the importance of clinical oversight when using the technologies to support diagnosis. Section 1 of the guidance notes that "[ArtiQ.Spiro] can only be used: • following clinical assessment and with clinical oversight from a healthcare professional to make the final diagnosis". This is stated explicitly in section 2 of the original EAG report: "From information provided by companies and from company websites, the EAG note that technologies included in this assessment: […] Are to support and aid the clinician in reporting, that

				not be used as a substitute for expert clinical interpretation. Diagnostic spirometry remains a technically complex investigation requiring accredited training, competency assessment, and governance oversight. Without this clarification, there is a risk of inappropriate reliance on algorithm-generated diagnostic suggestions, particularly in borderline or normal spirometry. Potential benefits and Managing risk (pages 4–6) The repeated reference to "less experienced staff" performing and interpreting diagnostic spirometry risks underplaying the importance of formal training, accreditation, and quality assurance. ARTP recommends explicit reference to delivery within IQIPS-aligned governance frameworks, with defined supervision and escalation pathways, particularly within community diagnostic centres. Spirometry and asthma diagnosis in children and young people (3.5-3.6) Although the guidance notes that asthma diagnosis is more challenging in children and young people, this risk is not sufficiently reflected in the recommendations. Paediatric spirometry has higher technical failure rates and greater interpretative uncertainty. ARTP recommends that the guidance include stronger cautionary language for use in children, including the expectation of specialist	is, they will not be used autonomously without human interpretation. The EAG note that a comment was made during stakeholder consultation around the particular importance of this, and the expertise of the clinician, when the technology does not include clinical history taking in its algorithm." **Potential benefits and Managing risk:** Data directly comparing diagnostic accuracy when used by ARTP or non-ARTP accredited staff was not available for any of the included technologies. The EAG would highlight section 3.2 of the original report which states: "As noted in the Final Scope, it is recommended that all staff performing or interpreting spirometry in the UK should be certified and registered on the Association for Respiratory Technology and Physiology (ARTP) Spirometry Register, which helps staff to ensure good clinical practice (Warren 2023)." Section 3.4 of the evidence generation plan notes that information has been identified for collection on: "resource use, including staff time, band, level of experience and accreditation of healthcare professionals using the technology (for example ARTP accreditation), and time taken to do and interpret spirometry". **Spirometry and asthma diagnosis in children and young people** Section 3.17 of the guidance has been amended to note that more caution is

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				oversight and clear escalation pathways where AI-supported interpretation is used. Unmet need and innovative aspects (3.7-3.8) 1 - While increased access to spirometry is a valid system objective, access should not be conflated with diagnostic quality. There is a risk that algorithm-supported spirometry could be interpreted as compensating for reduced expertise. The guidance should clarify that algorithm use does not mitigate the need for high-quality test performance or expert review. 2 - References to AI enabling diagnostic spirometry to be delivered by "less experienced staff" risk being interpreted as justification for substitution of specialist respiratory physiology expertise. The guidance should explicitly state that AI-supported interpretation is not intended to replace trained respiratory physiologists or clinical scientist-led services, but to support delivery within appropriately governed diagnostic pathways.	necessary when using technologies in populations of children and young adults (where indicated for use in these populations). The committee agreed that more research on diagnostic accuracy of the technologies in populations of children and young people is needed. We have added in the evidence generation plan that the real-world prospective comparative cohort study should include young people and adults. The EAG note that the use of technologies in people under the age of 18 years differ between technologies (see Table 2 of the EAG report); evidence generation should align with the respective indications for use. **Unmet need and innovative aspects (3.7-3.8)** The committee identified diagnostic accuracy as an evidence gap requiring further research.
6.	Association of Respiratory Nurses (ARNS)		3.32	If restriction is found on spirometry - though this is not diagnostic for ILD, should the technologies trigger this as a potential red flag to the clinician, to consider referral to a specialist (if symptoms and history suggestive of possible ILD). Similarly if a patient is found to have very severe airflow obstruction, indicative of very severe disease -	Thank you for your comment. Section 1 of the guidance notes that "[ArtiQ.Spiro] can only be used: • following clinical assessment and with clinical oversight from a healthcare professional to make the final diagnosis".

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				should this be a red flag trigger for technologies to suggest referral to a specialist for further review	

Table 3: diagnostic accuracy

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5.	ARTP			"Diagnostic accuracy (3.11-3.14) ARTP agrees with the committee's concern regarding false-positive diagnoses, particularly where the sensitivity for identifying normal spirometry is low. This is clinically significant in asthma, where mislabelling may result in unnecessary long-term treatment. The guidance should emphasise caution when using algorithm-supported spirometry in undiagnosed populations and reinforce alignment with NICE asthma diagnostic pathways. Diagnostic accuracy (3.11-3.16) The guidance discusses diagnostic accuracy but does not sufficiently consider how AI-supported spirometry interpretation may influence prescribing decisions in primary care. In practice, diagnostic	Thank you for your comment, the committee has considered this. A clinical risk has been added to the section "Managing the risk of use in the NHS during the evidence generation period", acknowledging that "Algorithm-supported diagnosis could influence prescribing decisions, with potential risks and harms in both overtreating and undertreating asthma and COPD". The committee agreed that the guidance should emphasise the importance of a clinical assessment being done and considered alongside spirometry to inform diagnosis. Section 1 of the guidance notes that "[ArtiQ.Spiro] can only be used: • following clinical assessment and with clinical oversight from a healthcare professional to make the final diagnosis".

Comment Number	Consultee number/ organisation name	Page number	Section number	Comment	NICE Response/EAG considerations
				interpretation and treatment initiation are closely linked, particularly for asthma and COPD. The guidance would be strengthened by explicitly acknowledging the risk of inappropriate treatment initiation following false-positive diagnoses and reinforcing the need for alignment with NICE diagnostic and prescribing pathways. Asthma diagnosis (3.16-3.17) Spirometry alone is insufficient for asthma diagnosis and is subject to temporal variability. The guidance should explicitly reinforce that algorithm-supported spirometry must be integrated into multi-test diagnostic pathways and should not be interpreted as confirmatory in isolation, particularly in children and young people.”	
7.	NIHR			The summaries of clinical and cost effectiveness are cautious, balanced and broadly reflect the uncertainty and early nature of the available evidence. It appropriately highlights the need for further assessment in a more typical population for primary care with lower disease prevalence. However, there are two potential gaps/additional uncertainties to highlight: 1) The ArtiQ study comparing the software interpretation with primary care clinician interpretation to establish superior diagnostic accuracy is actually likely to have underestimated	Thank you for your comment, the committee has considered this. 1) The EAG consider that this comment relates to the Doe et al. 2025a study reporting outcomes from the SPIRO-AID study (NCT05933694). The EAG note that the level of experience was not reported (job roles and spirometry responsibilities captured within Supplementary Table 4), authors excluded “specialist respiratory clinicians with the right to practice as a consultant in the National Health Service, as they

				accuracy. Primary care clinicians volunteering to take part in such a study will not reflect the overall skill level (they will be vastly more experienced), and even though they may not have the formal ARTP registration/certification, will be respiratory interested professionals probably performing/interpreting their own spirometry in primary care (which is also now atypical). The difference between the groups is therefore likely to be much greater in a real-life situation, and ArtiQ likely to increase the diagnostic accuracy of interpretation to a much greater extent, with resulting impact on clinical (and potentially cost, although see following point below on this) effectiveness. 2) In several places the guidance highlights that improving the diagnostic accuracy of spirometry will result in an increase in spirometry services closer to home, and increased capacity and reduced backlog. Sadly, that ship has sailed with the (mostly appropriate) introduction of guidance around ARTP interpretation and spirometry quality standards for primary care - most GP practices who were offering spirometry stopped at the start of Covid and didn't restart, and have absolutely no desire to. Nurses who previously performed spirometry have often retired and there is limited appetite for training staff when there is very little funding available, it is no longer seen as a primary care test for many, and it is no longer a critical test in the asthma diagnostic pathway as it was previously, when it was required for the QOF. Our research group will be publishing survey and qualitative work on this in the next six months, conducted as part of the NIHR i4i-funded CORMORANT programme, which is evaluating N-Tidal as an alternative to spirometry in primary care.	are expected to have expertise in respiratory diagnostics". The EAG acknowledge that this technology ArtiQ.Spiro may benefit from further evidence collection to ensure generalisability of the RCT results in a larger population in a real-world NHS context in Section 8.3 and Table 39 of the EAG report. 2) Section 3.21 of the guidance notes that implementation of the technologies included in this guidance is unlikely to improve access to diagnostic spirometry in areas where spirometry is not commissioned. The EAG note that the aim of this NICE assessment is to make recommendations on digital technologies applying algorithms to *spirometry* to support asthma and COPD diagnosis, therefore N-Tidal was out of scope of this assessment. The EAG note that not all technologies are indicated for use in a home setting and that technologies which are indicated and initially included in the EAG report are now no longer being considered in this assessment (NuvoAir, MIR Spiro). Evidence of the use of the included technologies to support initial diagnosis of lung conditions in a home setting was not available. The EAG considered a range of scenarios relating to differences in diagnostic accuracy in Appendix B4 of the EAG report and have acknowledged the lack of available robust

Comment Number	Consultee number/ organisation name	Page number	Section number	Comment	NICE Response/EAG considerations
				Unless there was significant funding/incentive provided to restart spirometry in an HCA+ArtiQ model, primary care is unlikely to go for this - it's just a decade too late. So cost effectiveness analyses probably need to focus more around the benefits of more accurate diagnosis for clinic spirometry as well as the potential for use in home-based serial monitoring for asthma diagnosis (as a hardware+software package with coaching). Poor accuracy of interpretation is a big concern, and this was highlighted in our survey/qual work (happy to share preliminary results if helpfuL) - from both secondary and primary care. In some areas e.g. Wales the delivery model has been for spirometry to be performed at a hub/CDC but the interpretation has not been funded, and the results then go back to GPs who don't understand what they mean and are unable to interpret them, just using the automated response to make a guess, which can result in over and under-diagnosis. This is where ArtiQ (and potentially others) have potential to make a big impact on clinical care - but the cost benefits are likely to be much more modest (and very hard to estimate).	data and reiterate that the conceptual modelling conducted for this assessment was to identify key evidence gaps and model drivers to support future economic modelling, see section 6.4 in the EAG report. The committee recommended further evidence generation for ArtiQ.Spiro on diagnostic accuracy. Future studies may therefore capture evidence on diagnostic accuracy that can be considered by the committee.
8.	Association of Respiratory Nurses (ARNS)		3.7	Technologies that apply algorithms to spirometry may give faster access to diagnostic spirometry with improved accuracy of interpretation	Thank you for your comment. The committee concluded that more evidence is needed on the diagnostic accuracy of the technologies when used in primary care and community diagnostic centres.

Table 4: LungHealth functionality and evidence

Comment Number	Consultee number/ organisation name	Page number	Section number	Comment	NICE Response/EAG considerations
9.	LungHealth			The recommendation in 3.11 states "Comparative diagnostic accuracy evidence (for example, compared with a reference standard) was lacking for LungHealth" We feel that this has not considered the myriad of evidence in thousands of patients who have undergone the LungHealth review. For instance, if one considers the paper by Chakrabarti et al (NPJ Prim Care Respir Med. 2025;35(1):12.), this was a study performed in 5221 patients undergoing review using the LungHealth software. They were patients who had already been on the primary COPD register undergoing "Usual Care". They should have all been correctly diagnosed with COPD yet we find that following the review, 21.1% of patients were found not to have the diagnosis of COPD based on when the spirometry was entered into the LungHealth software. These were patients who had undergone spirometry and needed a revision of the diagnosis because the spirometry was not interpreted correctly yet these patients were already being treated for a diagnosis of COPD. The methodology behind this study is the most optimal because it takes existing patients in the COPD register. Furthermore, other studies in other regions using the LungHealth software have mirrored precisely the same findings and reflect the "real world". Furthermore, the study in the link https://www.pcrs-uk.org/conference-abstract-gallery/abstract/605 reflects a real world review using the LungHealth software in 103 patients on the spirometry waiting list for suspected COPD. The software resulted in a COPD	Thank you for your comment. This assessment looks at the technologies when used to give an initial diagnosis, but section 3.18 notes that “The committee discussed that, in practice, technologies that apply algorithms to spirometry could also be used to support a corrective diagnosis of asthma or COPD, if it is suspected that the initial diagnosis was incorrect”. Comparative diagnostic accuracy evidence (for example, compared with a reference standard) in an undiagnosed population was lacking for LungHealth, with the paper by Chakrabarti et al (NPJ Prim Care Respir Med. 2025;35(1):12.) not including a comparator, and in a population of patients with an existing diagnosis of COPD. The external assessment group considered evidence from a poster submitted by LungHealth, in which LungHealth was used alongside ArtiQ Spiro software (mixed intervention) in 103 patients, as part of the Best Respiratory Evaluations And Treatments in Healthcare Efficiency (BREATHE) study (Chakrabarti et al. 2025d). The EAG note that the study included a mixed population of people with and without a diagnosed lung condition, and lacked a reference standard to confirm

Comment Number	Consultee number/ organisation name	Page number	Section number	Comment	NICE Response/EAG considerations
				diagnostic rate of 39.8%. The same findings were mirrored in a "Breathlessness Clinic" hosted by Everton FC taking unselected 261 adults with breathlessness using the LungHealth software leading to a similar COPD diagnosis rate of 38% (see https://publications.ersnet.org/content/erjor/11/6/00669-2025). We as Respiratory Clinicians do not feel that the clinical significance of these studies have been appreciated and have been taken into account during the recommendations made in the draft. This is more so given the fact that these are studies involving hundreds or even thousands of patients who have undergone review using the software which has been designed by Respiratory Clinicians to address the very challenges faced by healthcare professionals in accurately diagnosing lung disease. These are not studies conducted in closed environments but rather in the real world of primary care. The fact that the studies show a consistent misdiagnosis rate across all the papers prior to the introduction of the software. Furthermore, we are disappointed that the significance of the LungHealth software in terms of functionality has not been considered in the analysis and draft recommendation. Functionality and usability is critical in the real world that we as clinicians practice in The LungHealth software has read and write back to EMIS and Systm 1 (the GP clinical server). This is precisely why the LungHealth software has been able to be used in clinical pathways in thousands of patients in primary	the accuracy of diagnosis (see section 5.2.4 of the EAR). This paper includes a mixed intervention, with both LungHealth and ArtiQ.Spiro providing elements of algorithmic support for spirometry. The EAG note that it is not possible to attribute the study results to individual technologies. The research recommendations made by committee encourage evidence to be collected that demonstrates the benefits of individual intervention technologies in section 1 of the guidance. The EAG concluded that the validity and generalisability of results from this study are therefore unknown. The committee concluded that more research is needed on the diagnostic accuracy of LungHealth before it can be used in the NHS. The evidence generation plan outlines that more evidence is needed on the sensitivity and specificity, ideally compared with current NHS care. This is particularly important in an undiagnosed population. Technical abilities of LungHealth were summarised in Table 2 of the original EAG report. The technologies in scope include a mixture of hardware and software. Integration within an NHS environment is considered in the EAG report see section 7.

Comment Number	Consultee number/ organisation name	Page number	Section number	Comment	NICE Response/EAG considerations
				care because it integrates into clinical pathways. In the current state of healthcare globally, functionality and integration within existing systems must always be considered if we are to truly deliver excellence in patient care. There is another component to the evidence for LungHealth that has been not been considered to our satisfaction. As a clinician, simply diagnosing a patient as having "airflow obstruction" does not constitute a satisfactory standard of care. A patient should leave with some form of disease staging that thus guides therapy decisions enabling early and accurate treatment in order to improve outcomes. Staging of COPD can only occur with the clinical context available e.g. MMRC score for breathlessness, exacerbation and admission history. Unlike any other technology currently available, the LungHealth software stages every patient with COPD by combining the algorithmic interpretation of the spiromety with the clinical staging thus ensuring that every patient will leave the spirometry hub with a disease staging and thus a treatment recommendation. We would thus argue that such functionality would be suited for non-specialist staff to deliver guideline level care. It is important to note that the LungHealth software has already been used in combination with ArtiQ.Spiro successfully in the clinical paper below and would thus complement this technology:	With regards to training of staff, the EAG would highlight section 3.2 of the original report which states: “As noted in the Final Scope, it is recommended that all staff performing or interpreting spirometry in the UK should be certified and registered on the Association for Respiratory Technology and Physiology (ARTP) Spirometry Register, which helps staff to ensure good clinical practice (Warren 2023).”

Comment Number	Consultee number/ organisation name	Page number	Section number	Comment	NICE Response/EAG considerations
				https://publications.ersnet.org/content/erjor/11/6/00669-2025	
10.	LungHealth			The key point here regarding the ethos and the functionality of the LungHealth software and one of the primary motivations was to address healthcare inequality through the following areas: 1. It's functionality including the ability to deliver patient reports remotely and securely to any primary care practice from any location means that it can integrate into any pathway. This means that it can be used in locations and in populations who would otherwise struggle to engage with traditional healthcare services and models. A prime example is it's use in the Everton In the Community project diagnosing the cause of breathlessness in a population suffering significant deprivation and who otherwise struggle to engage with healthcare services. Please see the excerpt from the paper https://publications.ersnet.org/content/erjor/11/6/00669-2025 below: "In traditional medical practice, the extent to which a given patient receives guideline-standard care is dependent on the level of knowledge held by the healthcare professional conducting the review. The advantage in using a CGC is that it ensures that every aspect of what constitutes "guideline standard" practice in evaluating breathlessness becomes compulsory during every review. This is further enhanced by the intelligent interpretation of investigations entered into the CGC, the automated staging of COPD, the	Thank you for your comment. This aim of this NICE assessment is to make recommendations on digital technologies applying algorithms to *spirometry* to support asthma and COPD diagnosis. The unmet system need in terms of diagnostic spirometry is acknowledged in sections 3.7 and 3.8 of the guidance. Technologies included in this NICE assessment will be considered in terms of their algorithmic support for spirometry, including: • quality assessing spirometry performance • interpreting spirometry results (for example, recognising whether the spirometry trace is obstructive, restrictive, or otherwise) • suggesting a diagnosis based on spirometry results and other clinical factors. LungHealth's functions of "intelligent interpretation of investigations entered into the CGC, the incorporation of key safety alerts and embedding the "learning" of multiple specialists into its programming" are therefore relevant technology functions for the scope of this assessment, with evidence on this considered by committee. The committee recommended more evidence generation on the impact of the technologies (including LungHealth) on the

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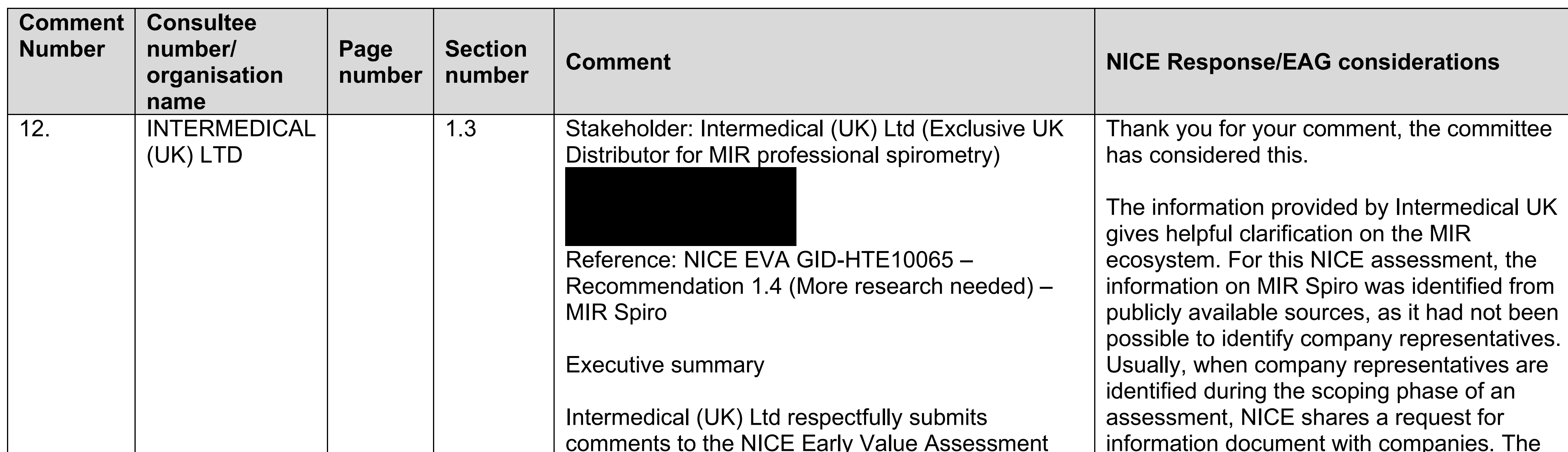
				incorporation of key safety alerts and embedding the “learning” of multiple specialists into its programming" 2. The LungHealth platform can be programmed into any language 3. The LungHealth platform can and has been used in a remote manner and this enabled COPD reviews to continue for patients during the Covid pandemic 4. The LungHealth technology platform ensures that all relevant questions must be completed thus ensuring that every patient receives a guideline level review during every consultation	NHS care pathways for asthma and COPD when using the technologies to support diagnosis in primary care and community diagnostic centres. It is acknowledged that spirometry is just one part of the diagnostic pathway for lung conditions. Technologies may also able to apply algorithms to support other parts of the diagnostic pathway (for example, the additional functions described by LungHealth). Technologies in-scope have been assessed in terms of the functions outlined in section 2.1 of the guidance. Thank you for the highlighting the publication by Chakrabarti et al. 2025; which was published on 01 December 2025 which was after the EAG report was submitted and after the first committee meeting. This research letter presents additional data from the “Beat Breathlessness” study, which was considered in the EAG report (see Appendix A5, number 93, ERJ Open Res, 2025c, in press). This study included general population screening and a mixed intervention, including the use of ArtiQ.Spiro and LungHealth.
11.	LungHealth			We have submitted to NICE this month a publication detailing the staff and the patient experience of using the LungHealth software again in the "real world" of the	Thank you for your comment. Subsequent evidence supplied by LungHealth has been reviewed and summarised by the EAG:

Comment Number	Consultee number/ organisation name	Page number	Section number	Comment	NICE Response/EAG considerations
				NHS. This was conducted independently of the LungHealth team with the software in use in the NHS and has been presented at the Primary Care Respiratory Society conference in 2025. This complements the functionality of LungHealth cited above. Our study performed in Everton in the Community has been published in the European Respiratory Journal https://publications.ersnet.org/content/erjor/11/6/00669-2025	The EAG have reviewed two supplied documents, which included a poster and data summary for the MISSION project, which is a real-world evaluation of LungHealth implemented across up to 150 GP practices across Greater Manchester. Similar to evidence previously considered within the EAG report, the EAG note that this study includes patients who have an existing diagnosis of asthma or COPD and did not report the number of people who underwent LungHealth to support initial diagnosis. As such, as noted in Table 37 of the EAG report, this study presents only partial alignment to the scope of the decision problem. Furthermore, the information provided does not report the proportion of patients who have undergone spirometry alongside the use of the technology, therefore its use as a decision aid to support the initial diagnosis of asthma, COPD or restrictive lung conditions alongside spirometry remains unknown. Some key findings have been presented below: MISSION feedback PDF (data summary) • A 6-point Likert scale (1=strongly disagree, 6=strongly agree) was used across all groups (clinicians, patients, lead GP or practice manager part of the study set up meeting) across different numbers of questions.

Comment Number	Consultee number/ organisation name	Page number	Section number	Comment	NICE Response/EAG considerations
					• Reporting timepoints were not defined and an average score across all or a subset of questions was also not reported. • Clinician feedback from 29 respondents (role not specified, only one with ARTP accreditation, 5 with respiratory, asthma, COPD or both qualifications, 23 with no formal respiratory qualifications) for 20 questions relating to technology use and confidence in decision making with an average score of 4.91 out of 6. • Patient feedback from 52 patients across 8 questions with an average score of 5.83 out of 6. The EAG note that LungHealth was used as part of a broader consultation and review process, therefore the generalisability of results specifically relating to the technology remains unclear. • Feedback from 3 GP practices with only 1 of 8 questions explicitly relating to feedback on LungHealth, with an average score of 3.58 out of 6. MISSION PCRS poster.pptx (Poster results, Gumbridge et al. 2026): • 79% respondents hadn't received formal respiratory training prior to participation in the MISSION project. • 59% agreed that the LungHealth software allowed them to provide improved respiratory reviews.

Comment Number	Consultee number/ organisation name	Page number	Section number	Comment	NICE Response/EAG considerations
					• 66% agreed that regular use of the software would improve knowledge and management of patients with respiratory conditions. • 90% agreed they were more confident with recognising exacerbations and acute presentations. • 76% felt more confident about decision making on non-pharmacological interventions recommended.

Table 5: inclusion of MIR Spiro



Comment Number	Consultee number/ organisation name	Page number	Section number	Comment	NICE Response/EAG considerations
12.	INTERMEDICAL (UK) LTD		1.3	Stakeholder: Intermedical (UK) Ltd (Exclusive UK Distributor for MIR professional spirometry) Reference: NICE EVA GID-HTE10065 – Recommendation 1.4 (More research needed) – MIR Spiro Executive summary Intermedical (UK) Ltd respectfully submits comments to the NICE Early Value Assessment	Thank you for your comment, the committee has considered this. The information provided by Intermedical UK gives helpful clarification on the MIR ecosystem. For this NICE assessment, the information on MIR Spiro was identified from publicly available sources, as it had not been possible to identify company representatives. Usually, when company representatives are identified during the scoping phase of an assessment, NICE shares a request for information document with companies. The

Comment Number	Consultee number/ organisation name	Page number	Section number	Comment	NICE Response/EAG considerations
				consultation on digital technologies that apply algorithms to spirometry (GID-HTE10065). Our submission focuses on a key point of scope and classification relating to MIR Spiro, and provides clarifying information to support reconsideration of Recommendation 1.4. From our perspective as the exclusive UK distributor of MIR professional spirometry systems, MIR Spiro appears to have been considered within the assessment in a way that could unintentionally imply it is a diagnostic algorithm or diagnostic-support software. In practice, MIR Spiro functions as a workflow, test execution, visualisation and data-management environment for measurements produced by regulated spirometers. It does not, in and of itself, deliver autonomous diagnostic conclusions. To avoid any ambiguity, it is important to separate the MIR ecosystem into: MIR spirometers (regulated measuring devices) – used widely in clinical settings to acquire spirometry measurements to recognised international standards; and MIR Spiro (software interface) – used to run tests, display curves/values, manage patient records and export results for clinical interpretation, audit and record keeping.	purpose of the request for information document is for NICE to gather information on the technology, and make a decision on whether the technology is in-scope of the assessment. MIR Spiro was a technology identified by NICE in the early stages of topic scoping as being potentially relevant, and subsequently remained in the final scope of the assessment. The committee have reviewed the information provided by Intermedical UK and MIR during consultation on the draft guidance. A decision was made by the Committee Chair (following advice from a specialist committee member) that MIR Spiro is not within the scope of this assessment and should be removed from this guidance (see section 2.4 of the final guidance).

Comment Number	Consultee number/ organisation name	Page number	Section number	Comment	NICE Response/EAG considerations
				In routine use, clinical interpretation remains the responsibility of the trained healthcare professional. Where AI-supported interpretation is required, MIR workflows can support integration with approved analytic tools (for example, technologies referenced within NICE recommendations), allowing quality spirometry data to contribute to AI-enabled pathways without misclassifying MIR Spiro as a standalone diagnostic algorithm. We therefore request that NICE: Classifies MIR Spiro appropriately as a workflow and data-management interface within a regulated spirometry solution, rather than as a diagnostic algorithmic technology; Distinguishes the clinical performance of MIR spirometers (as measuring devices) from the software interface used to operate and manage those measurements; and Acknowledges the practical interoperability of MIR workflows with analytic/algorithmic solutions where these are deployed under NICE evidence generation arrangements. This framing better reflects the way MIR systems are procured, deployed and used across NHS respiratory pathways, and reduces the risk of conclusions being drawn from assumptions about	

Comment Number	Consultee number/ organisation name	Page number	Section number	Comment	NICE Response/EAG considerations
				intended purpose. Key positioning statement MIR Spiro is not positioned as an autonomous diagnostic algorithm. It is a spirometry workflow and data-management interface that supports clinicians by enabling standards-aligned test execution, results visualisation and secure export/archiving of spirometry outputs. Where AI interpretation is required, MIR outputs may be made available to external analytic solutions (where technically and contractually appropriate), enabling AI-enhanced workflows without changing the fundamental role of MIR Spiro as an interface around device-acquired measurements. 1. Clarification on classification and intended use 1.1 What MIR Spiro does (and does not do) Based on how the software is deployed in UK services, MIR Spiro is used to: Guide and record spirometry manoeuvres performed using the spirometer Display curves and numeric outputs produced by the measuring device	

Comment Number	Consultee number/ organisation name	Page number	Section number	Comment	NICE Response/EAG considerations
				Support operator workflow (patient selection, test sessions, record management) Enable export, reporting and archiving for clinical records and audit MIR Spiro is not deployed as an “algorithmic diagnostic technology” that replaces clinical judgement. Any diagnostic conclusion remains with the clinician, informed by spirometry results, clinical history and other investigations as required. 1.2 Avoiding scope misalignment Placing MIR Spiro into an assessment category designed for algorithmic interpretation tools risks conflating: the measurement and quality capture function (device + workflow software), with the interpretation/diagnostic algorithm function (software that applies diagnostic logic). Intermedical (UK) Ltd encourages NICE to ensure the evaluation framework reflects this distinction, as it has practical implications for evidence expectations, modelling assumptions and procurement comparisons. 2. Interoperability with analytic tools where appropriate	

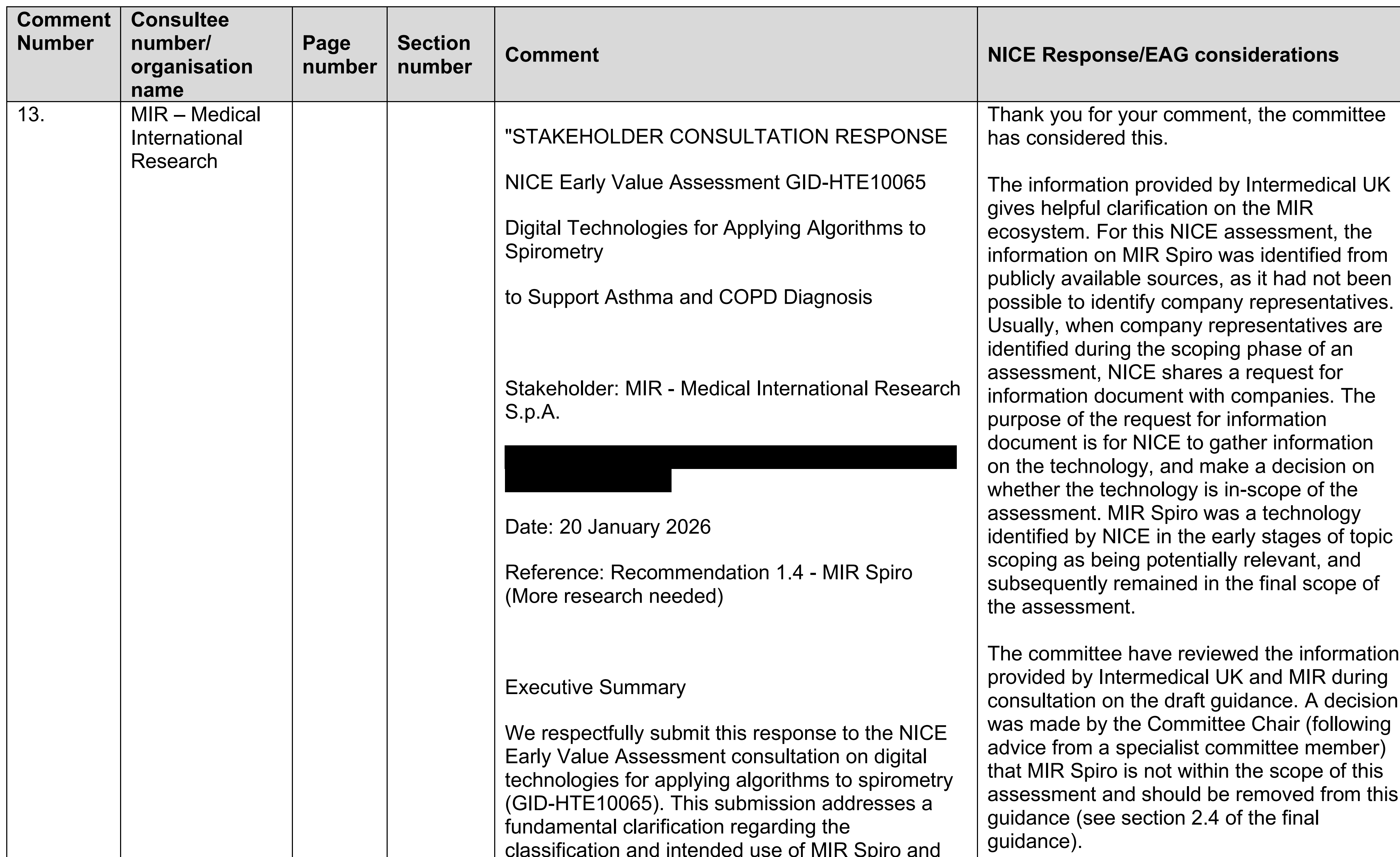
Comment Number	Consultee number/ organisation name	Page number	Section number	Comment	NICE Response/EAG considerations
				NICE's evaluation recognises the potential role of algorithmic interpretation tools under evidence generation arrangements. In operational terms, NHS services often require both: high-quality, standards-aligned spirometry acquisition, and optional algorithmic support to assist interpretation or quality improvement. MIR spirometry outputs can be made available to external analytic tools via established data pathways (subject to local governance and technical configuration). This enables services to combine reliable acquisition with algorithmic support where adopted, without reclassifying MIR Spiro itself as a diagnostic algorithm. 3. Cost structure and economic inputs We note the External Assessment Group commentary regarding the absence of per-patient cost inputs for MIR Spiro. As the UK distributor supporting implementation, Intermedical (UK) Ltd can provide an indicative cost framework to support future modelling: Cost component Indicative position MIR professional spirometry hardware Defined by model configuration	

Comment Number	Consultee number/ organisation name	Page number	Section number	Comment	NICE Response/EAG considerations
				MIR Spiro software Gold version available at no additional cost; Platinum version via annual subscription (where selected) Consumables Typically <£3 per test when using disposable turbine; approximately £1–£2 when using BVF filter and reusable turbine under appropriate decontamination process Training Provided at no charge by Intermedical (UK) Ltd as part of deployment support (subject to scope) Integration / SDK (where required) Annual subscription where SDK functionality is commissioned Detailed, model-specific pricing and deployment assumptions can be provided directly to NICE to support a consistent economic approach. 4. Standards alignment and technical quality (device ecosystem) From a service delivery standpoint, the key clinical value of the MIR pathway is the ability to support quality-assured spirometry acquisition aligned to internationally recognised standards. MIR professional spirometry systems are deployed to support consistent measurement quality, appropriate reporting, and auditable record keeping across clinical settings. Indicative technical characteristics supported within the MIR professional range include:	

Comment Number	Consultee number/ organisation name	Page number	Section number	Comment	NICE Response/EAG considerations
				Technical area Position ATS/ERS standards alignment Supported across professional range (per manufacturer technical files and device configuration) Sampling performance High-resolution digital acquisition (model dependent) Reference values GLI reference sets available (configuration dependent) Reproducibility/quality prompts Automated quality prompts aligned to spirometry criteria (device/software workflow dependent) Certifications / registrations Relevant certifications held by devices, with UK regulatory registration pathways maintained (Intermedical (UK) Ltd can provide model-specific technical sheets and regulatory references alongside deployment configuration details to ensure NICE has consistent inputs.) 5. Evidence generation proposal (UK deployment context) Intermedical (UK) Ltd is supportive of pragmatic evidence generation that reflects real NHS workflows, particularly in primary care and community diagnostic environments. As the exclusive UK distributor, we have supported the placement of a substantial installed base of professional spirometers in the UK over time, and we believe a meaningful proportion remains in	

Comment Number	Consultee number/ organisation name	Page number	Section number	Comment	NICE Response/EAG considerations
				active clinical use. A proportionate, service-friendly evidence approach could include: Phase Timeline Focus Phase 1 0–3 months Pilot deployments in 3–5 NHS sites using MIR workflow for acquisition and reporting; confirm interoperability pathway with selected analytic tools where used; capture operational and cost inputs Phase 2 3–6 months Prospective evaluation in primary care / community diagnostic settings assessing test quality, repeat rates, staff experience, and impact on onward pathway decisions Phase 3 6–12 months Real-world evidence on utilisation, pathway impact, and service outcomes; consolidate economic parameters for NICE submission Intermedical (UK) Ltd can support site onboarding, training, and the practical capture of cost and workflow metrics needed for robust modelling. 6. Requests to NICE Intermedical (UK) Ltd respectfully asks NICE to: Reconfirm the correct classification of MIR Spiro as a workflow and data-management interface for spirometry acquisition, rather than a standalone	

Comment Number	Consultee number/ organisation name	Page number	Section number	Comment	NICE Response/EAG considerations
				diagnostic algorithmic technology; Separate assessment of device acquisition performance (spirometers as regulated measuring devices) from any evaluation intended for algorithmic interpretation tools; Recognise interoperability in practice, where MIR spirometry outputs may be used alongside analytic tools adopted under NICE evidence-generation recommendations; Accept the cost framework provided (with an offer of detailed pricing assumptions) to enable future modelling; and Support proportionate UK evidence generation focused on real-world workflow value, including optional integration pathways where sites adopt algorithmic support. Intermedical (UK) Ltd remains committed to supporting NHS services with quality-assured spirometry acquisition and practical deployment support, and we welcome the opportunity to provide additional technical documents, cost assumptions and implementation evidence to assist NICE in finalising its recommendations.	



Comment Number	Consultee number/ organisation name	Page number	Section number	Comment	NICE Response/EAG considerations
13.	MIR – Medical International Research			"STAKEHOLDER CONSULTATION RESPONSE NICE Early Value Assessment GID-HTE10065 Digital Technologies for Applying Algorithms to Spirometry to Support Asthma and COPD Diagnosis Stakeholder: MIR - Medical International Research S.p.A. Date: 20 January 2026 Reference: Recommendation 1.4 - MIR Spiro (More research needed) Executive Summary We respectfully submit this response to the NICE Early Value Assessment consultation on digital technologies for applying algorithms to spirometry (GID-HTE10065). This submission addresses a fundamental clarification regarding the classification and intended use of MIR Spiro and	Thank you for your comment, the committee has considered this. The information provided by Intermedical UK gives helpful clarification on the MIR ecosystem. For this NICE assessment, the information on MIR Spiro was identified from publicly available sources, as it had not been possible to identify company representatives. Usually, when company representatives are identified during the scoping phase of an assessment, NICE shares a request for information document with companies. The purpose of the request for information document is for NICE to gather information on the technology, and make a decision on whether the technology is in-scope of the assessment. MIR Spiro was a technology identified by NICE in the early stages of topic scoping as being potentially relevant, and subsequently remained in the final scope of the assessment. The committee have reviewed the information provided by Intermedical UK and MIR during consultation on the draft guidance. A decision was made by the Committee Chair (following advice from a specialist committee member) that MIR Spiro is not within the scope of this assessment and should be removed from this guidance (see section 2.4 of the final guidance).

				provides additional evidence to support reconsideration of Recommendation 1.4. We believe that MIR Spiro has been incorrectly included within the current assessment scope, as it does not claim to be—nor is it positioned or marketed as—a diagnostic software solution. Evaluating it within a framework intended for diagnostic or diagnostic-support algorithms risks misrepresenting its intended purpose and may inadvertently undermine the established diagnostic contribution of the MIR system, particularly its certified devices. It is essential to distinguish between the two components of the MIR ecosystem: - MIR spirometers (hardware), widely recognised and validated in clinical and research environments; and - MIR Spiro, which serves strictly as a viewer, data capture and management interface for measurements performed by the device. In this configuration, MIR Spiro does not interpret spirometry results, does not apply analytical or diagnostic algorithms, and does not autonomously generate diagnostic conclusions. Its role is solely to enable clinicians and trained operators to execute tests, visualise results and archive spirometry data. We also wish to emphasise that both MIR spirometers and the MIR Spiro software operate fully in accordance with ATS/ERS technical standards and guidelines, providing no more and	

				no less functionality than is required for compliance with internationally accepted spirometry practice. This reinforces their role as tools for accurate test execution and data capture, not diagnostic decision-making. For this reason, focusing evaluative scrutiny on MIR Spiro as if it were a standalone diagnostic system—rather than as part of a regulated device ecosystem that relies on professional clinical interpretation—results in an inaccurate classification and an incomplete appreciation of its use and value. Furthermore, in light of NICE's recognition of ArtiQ.Spiro, particularly as stated under Recommendation 1.1, where the technology is conditionally recommended for use during the evidence-generation period in primary care and Community Diagnostic Centres, we highlight that: - MIR Spiro integrates seamlessly with ArtiQ, and - can therefore already be deployed in combination with MIR spirometers to support test quality and contribute to diagnostic pathways where clinically appropriate. Given the above, we respectfully request that NICE: 1. Correctly classify MIR Spiro as a workflow, data-management and standards-compliance tool, rather than a diagnostic technology; 2. Evaluate separately the independently validated clinical performance of MIR spirometers, which	

				comply with ATS/ERS requirements and are widely adopted in practice; 3. Acknowledge the complementary role of MIR systems when used together with approved analytic tools —such as ArtiQ— as referenced in Recommendation 1.1. We believe that this more accurate framing better reflects the regulatory positioning, clinical function and evidence-based operating scope of MIR technologies in respiratory assessment, and avoids conclusions based on assumptions that do not correspond to their intended role within NHS diagnostic pathways. KEY CLARIFICATION MIR Spiro is NOT a diagnostic software. MIR Spiro is a spirometry software that serves as a DECISION SUPPORT TOOL FOR CLINICIANS providing accurate spirometric data to support clinical diagnosis. When integrated with ArtiQ.Spiro (NICE Recommendation 1.1), it contributes to AI-enhanced diagnostic workflows.	

				1. Clarification: MIR Spiro as Decision Support Tool We believe there is a fundamental misunderstanding in the current assessment that requires clarification. MIR Spiro (including Spirobank Smart) is a spirometry measurement device - it is not, and does not claim to be, a standalone diagnostic software. The intended use of MIR Spiro is to provide high-quality, ATS-compliant spirometric data that supports clinical decision-making. The device serves as a decision support tool, delivering accurate measurements that clinicians use as part of their diagnostic process. The final diagnosis always remains with the healthcare professional. The assessment appears to evaluate MIR Spiro as if it were a competing diagnostic software algorithm. However, MIR Spiro should not be evaluated in the same category as AI-based diagnostic software solutions, as it serves a fundamentally different purpose: data acquisition and decision support, not autonomous diagnosis. 1.1 Integration with ArtiQ.Spiro For users who require AI-enhanced diagnostic support, MIR Spiro has an existing integration with ArtiQ.Spiro - the very technology that NICE has recommended for use with evidence generation under Recommendation 1.1. Through this integration, MIR spirometers can contribute	

				spirometric data to AI-based diagnostic workflows, while maintaining their core function as decision support tools. - MIR SPIRO (Measurement Device) Decision support tool ATS 2019 compliant - INTEGRATION Data transfer via SDK / API - ArtiQ.Spiro (AI Software) Diagnostic algorithms NICE Rec. 1.1 Therefore, MIR Spiro can be used either: (1) as a standalone decision support tool providing quality-assured spirometric data to clinicians, or (2) integrated with ArtiQ.Spiro for AI-enhanced diagnostic workflows. In either case, the device supports rather than replaces clinical diagnosis. 2. Addressing Missing Cost Data The External Assessment Group (EAG) noted that per-patient technology costs for MIR Spiro were not available, preventing economic modelling. We provide the following cost structure to enable inclusion in future economic analyses:	

				Cost Component: MIR Professional Spirometry Range Value: defined depending on the specific models. Cost Component: Software/App License Value: the Professional version of the software is available free of charge; the Platinum version, which includes additional features, is provided under an annual subscription. Cost Component: Consumables (FlowMIR disposable turbine or BVF filter) Value: less than £3 per test when using the disposable turbine; approximately £1–2 per test when using the BVF filter with a reusable, sterilised turbine. Cost Component: Training Value: provided free of charge via Intermedical (UK) LTD. Cost Component: IT Integration (SDK) Value: annual subscription required for the SDK.	

				Detailed pricing information is available upon request and can be provided directly to NICE for economic modelling purposes. 3. Technical Standards and Quality As a spirometry measurement device designed to support clinical decision-making, the MIR Professional Spirometry Range meets and exceeds all relevant technical standards for spirometry acquisition: Technical Specification: ATS/ERS 2019 Standards MIR Professional Spirometry Range: fully compliant. Technical Specification: ATS 2021 Standards MIR Professional Spirometry Range: fully compliant. Technical Specification: Sampling Rate MIR Professional Spirometry Range: 10 milliseconds (high precision).	

				Technical Specification: GLI Reference Values MIR Professional Spirometry Range: GLI 2012/2022 multi-ethnic. Technical Specification: Quality Check (Reproducibility) MIR Professional Spirometry Range: automatic, according to ATS criteria. Technical Specification: Age Range MIR Professional Spirometry Range: 5–93 years (including paediatric). Technical Specification: Certifications MIR Professional Spirometry Range: CE, FDA, ISO 26782, registered on MHRA. The 10-millisecond sampling rate provides high-precision data acquisition essential for accurate spirometry interpretation. According to ATS/ERS guidelines, only digital spirometers and peak flow meters can fully comply with ATS 2019 standards - mechanical devices cannot meet these requirements. This technical capability ensures	

				that clinicians receive the highest quality data to support their diagnostic decisions. 4. Evidence Generation Proposal While we maintain that MIR Spiro should be recognised as a decision support tool rather than a diagnostic software, we are committed to supporting evidence generation demonstrating its value in clinical workflows. We have placed in the UK Market over 8,000 professional spirometers and we believe than more than half is in current clinical use in the UK via our exclusive distribution Intermedical (UK) Ltd Phase: Phase 1 Timeline: 0–3 months Activities: deployment of MIR Spiro as a decision support tool in 3–5 NHS pilot sites; evaluation of integration with ArtiQ Spiro; cost data collection. Phase: Phase 2 Timeline: 3–6 months Activities: prospective study evaluating clinical utility as a decision support tool in primary care/community diagnostic centres, measuring	

				impact on clinician confidence and diagnostic pathways. Phase: Phase 3 Timeline: 6–12 months Activities: real-world evidence on care pathway impact, resource utilisation, and patient outcomes; data submission to NICE. 5. Conclusion and Requests We respectfully request that the committee: 1. Recognise that MIR Spiro is not, and does not claim to be, a diagnostic software - it is a spirometry software designed as a decision support tool for clinicians. 2. Reconsider the classification of MIR Spiro, as it should not be evaluated in the same category as AI-based diagnostic software solutions. 3. Acknowledge the existing integration between MIR Spiro and ArtiQ.Spiro (Recommendation 1.1), which enables MIR devices to contribute to AI-enhanced diagnostic workflows when required. 4. Consider the cost data provided to enable inclusion in future economic modelling.	

Comment Number	Consultee number/ organisation name	Page number	Section number	Comment	NICE Response/EAG considerations
				5. Support evidence generation for MIR Spiro as a decision support tool, including its integration with ArtiQ.Spiro in NHS settings. MIR is committed to supporting the NHS in improving access to quality-assured spirometry and welcomes further discussion with the committee regarding the appropriate role and classification of our technology. For further information, please contact: [redacted] [redacted] [redacted] [redacted] [redacted] [redacted]	

Table 6: evidence generation plan

Comment Number	Consultee number/ organisation name	Page number	Section number	Comment	NICE Response/EAG considerations
14.	Association of Respiratory Nurses (ARNS)		2.1	Include: Reduced waiting time to receive an accurate diagnosis	Thank you for your comment. This has been included in the evidence generation plan as “time to accurate diagnosis”
15.	Association of Respiratory Nurses (ARNS)		2.1	Re: Accreditation - use example of ARTP accreditation	Thank you for your comment. This has been added.
16.	Association of Respiratory Nurses (ARNS)		2.1	What is the environmental impact of using AI? (if any)	Thank you for your comment. Unfortunately factoring in the environmental impact of using AI is beyond the scope of this current early value assessment. Sustainability considerations have been reported in section 7 of the EAG report. The EAG note that each technology may offer different implementation strategies, which may require different considerations relating to the environmental impact (such as technologies delivering a home-based compared with a clinic-based assessment).
17.	Association of Respiratory Nurses (ARNS)		3.1	Table 1 - can screening for possible misdiagnosed patients be included? ie. underdiagnosis and over diagnosis. Does the previous spirometry trace support a diagnosis of asthma / COPD?	Thank you for your comment. This aim of this NICE assessment is to make recommendations on digital technologies applying algorithms to *spirometry* to support asthma and COPD diagnosis. Where evidence was available, the EAG also reported outcomes pertaining to the use of the technologies when used after an initial diagnosis was made. Screening is outside of

Comment Number	Consultee number/ organisation name	Page number	Section number	Comment	NICE Response/EAG considerations
					the remit of this NICE assessment. In section 3.18 of the guidance "The committee discussed that, in practice, technologies that apply algorithms to spirometry could also be used to support a corrective diagnosis of asthma or COPD, if it is suspected that the initial diagnosis was incorrect."
18.	Association of Respiratory Nurses (ARNS)		3.4	Re: Accuracy when used by different healthcare professionals - e.g. ARTP vs non-ARTP accredited individuals	Thank you for your comment. We have added ARTP accreditation in the data to be collected section of the evidence generation plan. Data directly comparing diagnostic accuracy when used by ARTP or non-ARTP accredited staff was not available for any of the included technologies. The EAG would highlight section 3.2 of the original report which states: "As noted in the Final Scope, it is recommended that all staff performing or interpreting spirometry in the UK should be certified and registered on the Association for Respiratory Technology and Physiology (ARTP) Spirometry Register, which helps staff to ensure good clinical practice (Warren 2023)."
19.	Association of Respiratory Nurses (ARNS)		3.4	Add: Patient feedback and experience (qualitative data)	Thank you for your comment. The evidence gaps that need to be addressed are decided by committee. The study design recommended in the evidence generation plan is intended address the evidence gaps identified by the committee.

Comment Number	Consultee number/ organisation name	Page number	Section number	Comment	NICE Response/EAG considerations
					Patient experience was not identified as an essential or supportive evidence therefore qualitative survey has not been recommended in the evidence generation plan.
20.	Association of Respiratory Nurses (ARNS)		5	Emphasise importance of including children in studies	Thank you for your comment. We have added in the evidence generation plan that the real-world prospective comparative cohort study should include young people and adults. The EAG note that the use of technologies in people under the age of 18 years differ between technologies (see Table 2 of the EAG report); evidence generation should align with the respective indications for use.
21.	Association of Respiratory Nurses (ARNS)		5	Re: Some evidence on spirometry performance quality assessment and spirometry pattern interpretation. Recommend use of ATS/ERS standards	Thank you for your comment. ATS/ERS standards have been added in section 5 “Minimum evidence standards” in line with the published COPD guidance.
22.	Association of Respiratory Nurses (ARNS)		5	Re: Diagnostic accuracy of the technology, ideally compared with standard care. As previously stated, FeNO and blood eosinophil count are first line tests for adult asthma, and FeNO for children (BTS/NICE/SIGN 2024). This will reduce the need for spirometry to diagnose asthma.	Thank you for your comment. The comparator used for this assessment was spirometry without the support of the algorithm technologies to reflect where these technologies would be used within the care pathway if adopted into the NHS, such as rather than replacing existing first line diagnostic tests.

Comment Number	Consultee number/ organisation name	Page number	Section number	Comment	NICE Response/EAG considerations
23.	NIHR			The recommendations are proportionate and broadly sound as a basis for early-use guidance to the NHS, appropriately limiting routine use to ArtiQ during a defined evidence generation period while acknowledging some residual uncertainty. The associated evidence generation plan is well aligned with the key gaps, particularly around diagnostic accuracy, pathway impact, resource use and subgroup effects, and its emphasis on real-world prospective data and inclusion of different staff using the technology is important for both implementation and health economic evaluations. However, the recommendation and evidence generation plan implies that the required evidence could be generated as a service evaluation alongside use paid for through core NHS funds. As there is so much variation in spirometry services and expertise between regions and individual GP practices, finding any control/comparator group will be very difficult without ongoing uncertainty in findings, and for firm conclusions to be drawn it probably needs a well-conducted individually randomised controlled trial, with independent diagnostic outcome evaluation, potentially including sites already performing spirometry and those not. Explicit guidance on this, and suggestions for research funding sources, might be helpful here (DOI: Our HRC has been asked to support a service evaluation of ArtiQ and we didn't	Thank you for your comment. NICE notes that the evidence generation plan is not a not a study protocol but suggests an approach to generating the information needed to address the evidence gaps. We have recommended that a real-world prospective comparative cohort study alongside using national clinical audit datasets are used as sources of evidence. As the spirometry services are heterogenous, the comparative cohort study could generate some evidence at the service on the effects of the technology. In addition, for assessing comparative treatment effects, well-conducted randomised controlled trials are the preferred source of evidence. The EAG note that not all technologies are indicated for use in a home setting and that technologies which are indicated and initially included in the EAG report are now no longer being considered in this assessment (NuvoAir, MIR Spiro). Evidence of the use of the included technologies to support initial diagnosis of lung conditions in a home setting was not available. Section 3.16 of the guidance notes the potential benefits of bringing diagnostic spirometry closer to a person's home (e.g. increasing the number of asthma diagnoses that can be based on a series of spirometry

Comment Number	Consultee number/ organisation name	Page number	Section number	Comment	NICE Response/EAG considerations
				think it could be done with the resources available to be able to produce sufficiently certain results. While the guidance appropriately recommends ArtiQ for clinic spirometry (and its role as a tool for supporting spirometry interpretation by non-experts rather than restoring spirometry services in primary could be better highlighted), it would be helpful to emphasise the potential role for such technologies (the others) for home-based monitoring for asthma, which remains a significant unmet need in diagnosis and the problems associted with a one-off clinic measurement 'snapshot' in asthma. Highlighting this here would be helpful for these technologies and funders to promote developing evidence specifically in this area.	measurements). Evidence of diagnostic accuracy based on a series of diagnostic spirometry tests was not available. Recommendations for technologies were made based on their intended use at the time of assessment. If the technologies are used in a home setting and evidence becomes available on this, then this may be considered following the evidence generation period.
24.	ARTP			2.1: Essential evidence – Diagnostic accuracy 1 - ARTP supports the prioritisation of diagnostic accuracy but recommends that false-positive and false-negative rates are stratified by operator role, training, and accreditation status. This is essential to understand whether algorithm performance varies according to the workforce model. 2 - The evidence generation requirements would benefit from a clearer definition of reference standards for diagnostic accuracy. ARTP recommends that comparative accuracy assessments include comparison against interpretation by appropriately trained and accredited respiratory physiology professionals, rather than	Thank you for your comments. 1. The evidence generation plan notes that resource use, including staff time, band, level of experience and accreditation of healthcare professionals using the technology (for example ARTP accreditation), and time taken to do and interpret spirometry should be collected. These should allow for analysis of the outcome data while considering these variables. 2. The evidence generation plan recommends that more evidence is needed on the sensitivity and specificity of the technology, ideally compared with

				relying solely on local “standard care”, which may vary substantially in quality. 2.1: Impact on NHS care pathway Evidence generation should explicitly assess downstream consequences of algorithm-supported diagnosis, including reversals of diagnosis, unnecessary treatment initiation, and additional referrals generated by indeterminate or discordant results. 3.3–3.4: Evidence collection plan and data items ARTP welcomes the inclusion of staff band and accreditation in resource-use data. It is recommended that evidence generation also captures whether spirometry was delivered within an accredited (e.g. IQIPS-aligned) service, as this is a key determinant of diagnostic quality. 3.3: Silent evaluation The proposed silent evaluation approach is supported. ARTP recommends this be strongly encouraged before full deployment to mitigate patient safety risks, particularly in services with limited spirometry expertise.	current NHS care. The scope for this topic notes that the recommended usual care is that quality assurance, interpretation and diagnosis is done with an accredited clinician. Thank you for your comment to section 3.3 & 3.4 of the evidence generation plan. 4. At the end of the evidence generation period during EVA exit, NICE will consider the practical implications for services that have already implemented the technology. 6. Recommendation 1.1 in the guidance has been amended to state that ArtiQ.Spiro can only be used “after a clinical assessment has been done, *with clinical oversight from a healthcare professional to make the final diagnosis*”

				3.4: Data to be collected The guidance does not address transparency or explainability of AI-supported diagnostic outputs. For safe clinical use, it is important that users can understand, interrogate, and audit how algorithm-derived classifications are generated. ARTP recommends that consideration be given to explainability and auditability of AI outputs as part of implementation and evidence generation. 4 Monitoring While the plan notes that NICE may withdraw guidance if evidence generation requirements are not met, it does not consider the practical implications for services that have already implemented the technology. The guidance would be strengthened by acknowledging the need for transition or mitigation planning to manage patient safety and service continuity should recommendations be withdrawn at the end of the evidence generation period. 6: Implementation considerations ARTP considers that the safe and consistent deployment of AI and machine-learning-supported interpretation of respiratory diagnostics would benefit from the parallel development of profession-led guidance. This could address issues such as governance, accountability, minimum training and	

Comment Number	Consultee number/ organisation name	Page number	Section number	Comment	NICE Response/EAG considerations
				competency requirements, audit expectations, and integration with existing quality assurance frameworks. NICE guidance would be strengthened by explicitly acknowledging the role of professional organisations in supporting the safe implementation of evidence during the evidence generation period. 6: Implementation considerations – Equalities ***While improved geographic access may reduce inequality, there is a risk of introducing differential diagnostic quality across populations. Equality considerations should explicitly include diagnostic accuracy and governance, not solely proximity or availability.***	

Table 7: general comments, questions and editorial suggestions

Comment Number	Consultee number/ organisation name	Page number	Section number	Comment	NICE Response/EAG considerations
25.	Association of Respiratory Nurses (ARNS)		1.1	Comparison of ArtiQ vs Usual Care. Can Arti.Q be used to screen previous results to review diagnostic accuracy (reduce misdiagnosis). Important to ensure children are included in studies.	Thank you for your comment. Section 3.18 of the guidance notes that “The committee discussed that, in practice, technologies that apply algorithms to spirometry could also be used to support a corrective diagnosis of

Comment Number	Consultee number/ organisation name	Page number	Section number	Comment	NICE Response/EAG considerations
					asthma or COPD, if it is suspected that the initial diagnosis was incorrect. "
26.	Association of Respiratory Nurses (ARNS)		2.1	As part of quality assessment for spirometry performance - does the technology include error specifics and suggestions of how to correct the error whilst with the patient?	Thank you for your comment. Section 5 of the published scope for this assessment gives information on the technologies included. ArtiQ.Spiro can support staff in performing quality assessed spirometry with abnormality detection, based on international ATS/ERS guidelines. This real-time support provides detailed and actionable user feedback if the quality of the trial is suboptimal, so the user can coach the patient better for a next trial and interpreting results.
27.	Association of Respiratory Nurses (ARNS)		2.3	Should NuvoAir be removed from table 1 - previous page states that this is not available to the NHS	Thank you for your comment. This has now been removed from Table 1.
28.	Association of Respiratory Nurses (ARNS)		2.3	ArtiQ Spiro - Component parts. Which spirometers is this software compatible with? Do they use updated GLI race neutral reference values, recently recommended by ARTP?	Thank you for your comment. Section 5 of the published scope for this assessment gives information on the technologies included. ArtiQ.Spiro is currently integrated with 2 spirometer providers, i.e. Vitalograph (Spirotrac6 software) and MedChip (SpiroConnect software). ArtiQ.Spiro's instructions for use notes that "ArtiQ.Spiro calculates reference (predicted) values per the Quanjer GLI-2012 equations (Quanjer 2012). Alternatively, the GLI Global (2022) reference equations can be used for the spirometric indices calculation (Bowerman 2022). Where no GLI Global

Comment Number	Consultee number/ organisation name	Page number	Section number	Comment	NICE Response/EAG considerations
					(2022) spirometry reference equations are available, “Other/Mixed” is used as ethnicity.”
29.	Association of Respiratory Nurses (ARNS)		2.3	Recommend inclusion for companies to disclose their Carbon Reduction Plans for UK carbon emissions	Thank you for your comment. NICE requests companies to disclose their carbon reduction plan. Section 2.5 of the guidance notes that manufacturers of ArtiQ.Spiro and LungHealth have provided publicly available Sustainability and Carbon Reduction Action Plans. The EAG have noted in section 7 of the EAG report that “manufacturers of ArtiQ.Spiro, LungHealth and NuvoAir have provided publicly available Sustainability and Carbon Reduction Action Plans. The manufacturer of GoSpiro stated that they have a Carbon Reduction Plan, but this was not shared with the EAG at the time of writing.”
30.	Association of Respiratory Nurses (ARNS)		3.1	Include mixed pattern (obstructive and restrictive) airways conditions in this section	Thank you for your comment. An example has been added.
31.	Association of Respiratory Nurses (ARNS)		3.4	Include mixed pattern (obstructive and restrictive) airways conditions in this section	Thank you for your comment. Patterns that are both restrictive and obstructive have been added as an example to section 3.6 of the guidance.
32.	Association of Respiratory Nurses (ARNS)		3.5	NICE guideline on COPD recommends post-bronchodilator spirometry as first line objective test for diagnosing COPD	Thank you for your comment. This section has been amended for clarity.
33.	Association of Respiratory		3.6	Include vital capacity (VC) as a standard measurement. There are more than 2 measurements taken during spirometry; VC, peak expiratory flow	Thank you for your comment. This section has been amended for clarity.

Comment Number	Consultee number/ organisation name	Page number	Section number	Comment	NICE Response/EAG considerations
	Nurses (ARNS)			FEF2575 as examples. Include mixed pattern (obstructive and restrictive) airways conditions in this section, not just "obstructive, restrictive or normal"	
34.	Association of Respiratory Nurses (ARNS)		3.7	How has the estimated backlog been decided? Is there a reputable reference?	Thank you for your comment. The estimated backlog comes from the Spirometry Task and Finish Group (2021). This reference has been added for clarity. It is noted that “The exact number of patients caught in the backlog for diagnostic spirometry is unknown but is estimated to be around 200–250 patients per 500,000 population (based on estimates from a CCG database of patients newly prescribed inhaled bronchodilators in the absence of systematic evidence)”
35.	Association of Respiratory Nurses (ARNS)		3.7	Will these technologies reduce the number of misdiagnosed patients?	Thank you for your comment. This value proposition was considered in the EAG economic modelling sensitivity analysis (reduction in false positives). The committee concluded that more evidence is needed on the diagnostic accuracy of the technologies, including the number of false-positive and false-negative results.
36.	Association of Respiratory Nurses (ARNS)		3.16	It is important to note that spirometry is now a second line objective test for asthma. FeNO & blood eosinophil count is the first line test for asthma diagnosis in adults, and FeNO for children.	Thank you for your comment. Section 3.5 of the guidance notes that “NICE’s guideline on asthma recommends spirometry as the second-line objective test (with bronchodilator reversibility) for diagnosing asthma in people aged 5 years and over. NICE’s guideline on asthma notes that diagnostic testing is harder in children and young people (aged 5 to 16 years) because

Comment Number	Consultee number/ organisation name	Page number	Section number	Comment	NICE Response/EAG considerations
					they may find some tests difficult to do and be unwilling to have blood tests.” This assessment focused on where spirometry was used (the order at which the objective tests was not the subject of this assessment – however could be altered in the economic model if the impact was of interest).
37.	NIHR			The committee appropriately acknowledges the limitations of the current evidence base, particularly the lack of robust real-world diagnostic accuracy data, longitudinal outcomes and subgroup analyses, and these gaps are clearly reflected in the evidence generation plan. However, there are 3 additional areas which could be considered: 1) In relation to spirometry interpretation by ArtiQ et al, it would be helpful to know whether the report is able to confirm whether the spirometry is post-bronchodilator, in the case of COPD - as this is required for diagnosis and is a common error made by non-specialist interpreters that they don't realise that spirometry needs to be post-bronchodilator for a formal diagnosis to be made. 2) There is limited consideration of evidence relating to serial or home-based monitoring for asthma, despite recognition that asthma diagnosis may be more accurate when spirometry is repeated over time and closer to symptom variability. This	Thank you for your comments. No evidence was identified in which technologies in-scope were used in a home-based setting (other than NuvoAir which is no longer available in the NHS). Section 3.16 of the guidance notes the potential benefits of bringing diagnostic spirometry closer to a person’s home (e.g. increasing the number of asthma diagnoses that can be based on a series of spirometry measurements). 1) The EAG took a pragmatic approach to the inclusion of evidence relating to diagnostic accuracy following discussion with Clinical Experts at the scoping workshop, who noted that spirometry before and after the use of bronchodilators is not always available or performed routinely within primary or community care settings. The EAG note that the proportion of patients undergoing spirometry with bronchodilators was poorly reported across the included

				represents an important unmet need in current pathways and may be an area where future technologies (or extensions of existing ones) could add value beyond single time-point diagnostic support. Further assessment of the evidence (and lack thereof) around home monitoring for asthma diagnosis would be helpful, as the current technologies generate vast quantities of data unsuitable for rapid primary care assimilation and interpretation, where AI-based tools could make a huge difference. 3) Some technologies (especially NuvoAir, RIP) offered coaching around spirometry technique and support with the diagnostic process and this was really valuable for the non-expert in primary care to be able to hand this part over, and be able to increase the quality. This was mentioned in relation to children but not in adults where coaching can really increase the quality of spirometry (and this is well established in evidence/guidance).	literature and with outcomes not reported exclusively for this subgroup in any study. Evidence of diagnostic accuracy based on a series of diagnostic spirometry tests was not available. Recommendations for technologies were made based on their intended use at the time of assessment. If the technologies are used in a home setting and evidence becomes available on this, then this may be considered following the evidence generation period. 2) This assessment looks at the technologies when used to give an initial diagnosis therefore the use of technologies for home monitoring falls outside the scope. The EAG note that not all technologies are indicated for use in a home setting and that technologies which are indicated and initially included in the EAG report are now no longer being considered in this assessment (NuvoAir, MIR Spiro). Evidence of the use of the included technologies to support initial diagnosis of lung conditions in a home setting was not available. NICE are conducting a separate early use assessment focusing on the use of digital technologies to support self-management of asthma (HTE10063). 3) Outcomes relating to the use of digital coaching tools were not considered within the scope of this assessment, nor was any evidence reporting such outcomes identified by the EAG.

Comment Number	Consultee number/ organisation name	Page number	Section number	Comment	NICE Response/EAG considerations
38.	NIHR			While the guidance appropriately recommends ArtiQ for clinic spirometry (and its role as a tool for supporting spirometry interpretation by non-experts rather than restoring spirometry services in primary could be better highlighted), it would be helpful to emphasise the potential role for such technologies (the others) for home-based monitoring for asthma, which remains a significant unmet need in diagnosis and the problems associted with a one-off clinic measurement 'snapshot' in asthma. Highlighting this here would be helpful for these technologies and funders to promote developing evidence specifically in this area.	Thank you for your comment. Section 3.16 of the guidance notes the potential benefits of bringing diagnostic spirometry closer to a person's home (e.g. increasing the number of asthma diagnoses that can be based on a series of spirometry measurements). Evidence of diagnostic accuracy based on a series of diagnostic spirometry tests was not available. Recommendations for technologies were made based on their intended use at the time of assessment. If the technologies are used in a home setting and evidence becomes available on this, then this may be considered following the evidence generation period. This assessment looks at the technologies when used to give an initial diagnosis therefore the use of technologies for home monitoring falls outside the scope. NICE are conducting a separate early use assessment focusing on the use of digital technologies to support self-management of asthma (HTE10063).
39.	NIHR			The equality impact assessment appropriately identifies potential risks related to age, disability, deprivation, ethnicity and digital exclusion, and the committee demonstrates awareness of these issues. ArtiQ is used by the HCP rather than the patient, however there will still be issues around digital literacy of health care staff, and careful implementation will be required to avoid widening existing inequalities. Young children are excluded but this is appropriate given the very limited evidence	Thank you for your comment. No evidence was identified in which technologies in-scope were used in a home-based setting (other than NuvoAir which is no longer available in the NHS). Section 3.16 of the guidance notes the potential benefits of bringing diagnostic spirometry closer to a person's home (e.g. increasing the number of asthma diagnoses that can be based on a series of spirometry measurements). Recommendations for

Comment Number	Consultee number/ organisation name	Page number	Section number	Comment	NICE Response/EAG considerations
				in this age group. Expansion of home or community-based monitoring, if designed inclusively, could help mitigate some access barriers, particularly for people who struggle to attend clinic-based testing, but this remains an unmet need not fully addressed by the current technology (it is the others rather than ArtiQ which are trying to do this). As discussed above, the assertion that this will be helping those with mobility or neurodivergence problems by bringing diagnostic testing closer to home I think is false because the technology on its own is unlikely to re-establish diagnostic spirometry services in primary care.	technologies were made based on their intended use at the time of assessmentThis assessment looks at the technologies when used to give an initial diagnosis therefore the use of technologies for home monitoring falls outside the scope. NICE are conducting a separate early use assessment focusing on the use of digital technologies to support self-management of asthma (HTE10063). The EAG note that not all technologies are indicated for use in a home setting and that technologies which are indicated and initially included in the EAG report, are now no longer being considered in this assessment (NuvoAir, MIR Spiro). Evidence of the use of the included technologies to support initial diagnosis of lung conditions in a home setting was not available. If the technologies are used in a home setting in the future and evidence becomes available on this, then this may be considered following the evidence generation period. The committee concluded that further evidence of the impact of all technologies on access to diagnostic spirometry in care pathways is needed. The equality consideration related to bringing diagnostic testing closer to home is therefore intended to demonstrate groups of people who may

Comment Number	Consultee number/ organisation name	Page number	Section number	Comment	NICE Response/EAG considerations
					benefit from testing closer to home should this happen in practice.