Appendix B Requirements list developed based on exploring, validating, and translating values into requirements

Value	Requirements
Patient-centred care and improved patient outcomes	
Accessible, effective, and rapid communication with HCPs	The system supports easy patient communication with a nurse or lifecoach through a dedicated phone number or WhatsApp, ensuring coordination with the pulmonologist or a PA.
	A help button in the app enables patients to request personal contact with a HCP when experiencing exacerbation-related symptoms, ensuring low-threshold access to support.
Personalized and continuous patient-HCP contact	A yearly in-person check-up is advised to maintain personal contact, with the option to schedule digital sessions in the intervening period if needed.
	In acute scenarios, such as a suspected exacerbation, it is advisable to schedule an in-person visit within two days at most.
	If the patient feels well, appointments with HCPs can take place by phone or video call, facilitated through the app.
	To facilitate trust, it is important that the HCPs involved in remote monitoring know the patient.
	Patients are listened to and receive timely responses when they call, with regular HCP-patient contact to address any difficulties with RPM use.
The patient is being looked after	The system indicates when a patient's monitored values are abnormal and the patient needs to be contacted by HCPs.
Besides numerical data, the patients' subjective outcomes are also assessed.	The system supports a personalized approach, including disease burden, to assess a patient's condition, moving beyond standard exacerbation protocols and over-reliance on clinical classifications such as GOLD.
	Reaching out to the patient or patient-initiated contact with the HCPs is based on an objectively measured data form.
User-friendly and inclusive device	
Easy-to-use	The application (App) and device should have a clear and comprehensive display and an intuitive interface for use on phone, tablet, and PC.
	The device has few buttons (one or two) and settings. If you wish to use the device, you just need to turn it on and blow.*
	The device is compact, handy, easy to handle, not too heavy and fits into a (hand)bag. The design is familiar to patients (i.e., looks like an inhaler for instance).
	Objectively-measured results are visualized with limited text and are easy to interpret due to use of familiar traffic light colours. In case of deteriorating results, the patient will receive a signal or alarm.
	The device provides audible or visual feedback (e.g., a light bar that gradually illuminates) confirming correct use.
	Patients can change incorrectly-entered answers.
	The app has a dedicated 'contact details' section where patients can update their information.
	The app can be connected to existing health apps to ensure only one app is needed.
	The device is Bluetooth-enabled and can be connected to a phone or other device.
Demands minimal time and effort from patients	Correctly blowing into the device is easy, and requires minimal effort, and daily use takes no more than 5 minutes.*
	Data is automatically transferred to the app and shared with HCPs without patient action, with text or sound confirmation when successfully sent.
	The system enables flexible, low-burden monitoring, balancing regularity with feasibility (e.g., increased frequency when symptoms worsen) to establish individual baselines and detect changes without requiring daily input.
	The system uses minimal, low-burden input (e.g., a single question or 1–10 rating scale) to monitor patient well-being.
Monitoring can be continued during travelling	The system allows patients to continue monitoring while on holiday, enabling remote connection with HCPs through the app, but can also be switched to "holiday mode" by the patient to indicate non-use.
	The device fits into a small box or can be worn as a small purse, and can be taken on a plane.
	Information will be provided concerning use while travelling.
The device does not control patient's lives and does not worry or frighten patients	The device can be used multiple times per day but will block after frequent use (e.g., 3 times) to avoid overly intrusive routines.
Product encourages adherence to RPM	The app has gamification elements such as a streak tracker, point system, or an occasional quiz to enhance engagement and motivation.
	The app provides gentle reminders to support monitoring without being too intrusive.
	People who are not motivated can easily opt out.
	The app should present short questions in a consistent order but with varying content to reduce habitual or mechanical answering, and should trigger follow-up assessments (e.g., CCQ) when symptom changes are reported.
	Patients have sufficient mouthpiece filters and ordering new ones is easy.*
Inclusive	The app has visual and auditory features such as various sound signals, vibration cues, and the option to have text read aloud, all of which can be easily switched on/off.
	Patients have basic digital and language skills, access to Wi-Fi, and the ability to use WhatsApp. Patients with very low literacy or digital ability may need alternative support outside RPM.
	The app allows patients to send voice messages to their HCP instead of typing.
	The app notifies users when measurements are missed, supporting users in remembering to complete measurements, particularly users with lower literacy.
	The app supports multilingual use (i.e., Dutch, English, Turkish, Arabic, Polish, Spanish) and real-time translation of communication. Inclusivity assessment can be performed by a language ambassador.
	The app and device communicate using simple, clear language with minimal text and supportive visual aids (e.g., icons, colour coding, short videos), adaptable to different literacy levels.
	Via a dashboard, HCPs can easily access and interpret the data during a patient consultation.

Data accessible to HCPs	A shared digital platform, with integrated patient records accessible to both the involved HCPs and the patient as data owner, enables transparent data sharing and transdisciplinary collaboration.
	The system automatically transfers monitoring data to the patient's medical record (e.g., HiX or GP systems), notifies HCPs in case of abnormal results, and provides patients with appropriate follow-up advice.
Reusable and durable device	The device is reusable by other patients.
	The device is durable (i.e., robust and withstand drops), easy to maintain, has a detachable mouthpiece, and washable parts.

Clear agreements on responsibility of care

Well-defined care process for both patients and HCPs	Comprehensive guidelines must be in place to ensure timely and regular contact between HCPs and patients when needed.
	The system ensures that access to care is well-organized, is clearly communicated to patients (including urgent and out-of-hours instructions), and is supported by timely responses and thorough documentation of all agreements and clinical actions.
	Contact with HCPs is personalized per patient, patients agree which HCPs (nurse, GP, pulmonologist) to contact, when to contact them, and who acts as a back-up.
	The app allows patients to report any changes to their medication and whether they have (had) GP visits.
	The monitoring system and process can assist in timely communication about hospitalization, to support a smoother admission process.
	A designated GP facilitates effective RPM; patients treated by multiple specialties are assigned a coordinating nurse as primary contact.
Clear interdisciplinary care agreements between HCPs	Monitoring data is accessible to both the GP and pulmonologist, but clear agreements need to be made concerning respective responsibilities of primary and secondary care. The hospital remains primary caregiver, with the GP as supporting physician. Once a patient stabilizes, these roles can be reversed.
	The nurse specialist in secondary care is the designated HCP who monitors the patient and ensures that relevant information is shared with the pulmonologist.
	RPM is embedded at the GP's office, where the role of the primary care nurse is to guide and monitor patients. Patients remain in close contact with the GP or primary care nurse, who communicates any significant changes in a patient's well-being to the pulmonologist. A secondary care team also has RPM data access, but the pulmonologist remains the final responsible caregiver.
	Clear regional care agreements define when patients are seen by the GP or pulmonologist, in alignment with RPM, and supported by integrated care networks and multidisciplinary collaboration tools.
	A centralized RPM centre—organized regionally or nationally—monitors patients, filters alerts, and escalates complex cases to either a GP, in case of patients who live more remotely, or nurse specialists. Monitoring responsibilities may be shared across hospitals and eNurses.
	Allied health professionals—such as physiotherapists, dieticians, and psychologists— have a supportive role in home monitoring.
	HCPs decide which patients are suitable for RPM.
HCPs are responsible for the practical aspects of monitoring	HCPs actively monitor incoming RPM data; protocols clearly define who and when action is taken. Monitoring may be supported by home care nurses, with pulmonologists and nurse specialists responsible for clinical decisions.
Patients are responsible for raising alarm	Patients actively review their monitoring results and contact HCPs when values are abnormal or when feeling unwell.

Improving patient empowerment

Raising understanding of the patient's own disease	Patients have access to a user-friendly dashboard in the app, allowing them to review their results over time using graphs, colours, or numbers, depending on individual preference and understanding.
	Patients can communicate with peers via a group chat or the app.
	The app has a questionnaire to monitor whether patients can perform daily activities and to help increase patient awareness of their own well-being.
Patients gain control	The device and app can be used when changes in symptoms are experienced.
	The app makes patients aware of actions they have to take when symptoms increase (e.g., contact HCPs or start medication).
Involvement of other individuals in the patient's social environment	Involvement of the patient´s partner requires caution since they might have a skewed perspective on the patient's well-being.
	Informal caregivers (e.g., family or chosen buddies) are involved in monitoring, receive information and alerts (with patients' consent), and can support recognition and response to symptoms. Their involvement can help motivate patients, enhance safety, and improve inclusivity.
Reassuring patients	Patients can see that their well-being has improved in the last months while using the RPM app.
	The device does not explicitly alert patients to a predicted exacerbation within X days and does not display prediction results to patients, in order to avoid unnecessary stress and burden.
	The device allows use on holidays and can help avoid visits to unfamiliar doctors.
	The device reassures patients when results are normal (e.g., by showing a green screen), but triggers follow-up contact with HCPs when symptoms increase.

Providing high-quality information and guidance

Patient guidance and feedback tailored to the RPM data	The app includes a clear, colour-coded exacerbation action plan that outlines which steps to take, who is responsible, and when to act in case of worsening symptoms.
	Advice from HCPs, such as tips, medication changes, and oxygen use, is provided through the app.
	Patients receive personalized feedback based on their measured values, providing guidance on when to adjust medication, repeat measurements, follow the exacerbation action plan, or contact HCPs.
Customizable settings and goals in the RPM app	The threshold determining whether a result is normal/abnormal is personalized per patient.
	Monitoring helps establish the patient's personal baseline by regularly collecting data, even when the patient feels well, allowing accurate tracking of changes over time.
	Patients can personalize monitoring frequency.
	Possibility to customize whether reports can be seen by the patient.
	The app allows patients to track tailored goals (e.g., physical activity, weight, daily functioning) and medication use, with goals set jointly with HCPs.
	Patients can only adjust their settings and goals in the app together with their HCPs.

Encourage adherence to the RPM process	Patients understand and appreciate the value of RPM when they experience fewer exacerbations, fewer hospitalizations, and improved well-being.
	Monitor at fixed times, ideally daily, to help patients build a consistent routine, enabling early detection of deterioration and supporting those with limited health literacy or language barriers through predictable and structured use.
	The system helps patients monitor their well-being using informative graphs, which help them understand their disease and anticipate exacerbations.
	The results are reliable.
	The app provides a step-by-step plan with personalized goals and clear guidance, helping patients manage daily tasks and routines.
	Patients know how to contact HCPs.
	Patients receive personal feedback from HCPs based on the data, ensuring they feel monitored, supported, and heard through active coaching.
Educate patients about COPD	Information provision is tailored to a patient's situation, taking into consideration differences in experiences throughout diagnosis and treatment.
	Questions are adapted to someone's understanding to ensure content is personalized and suits their cognitive understanding (e.g., adaptive questioning is used in which questions become more challenging as patients demonstrate competence).
	Information is delivered in modules with short and informative videos.
	RPM includes education about exacerbations and medication usage.
Action plan for patients feeling unwell without signs of exacerbation.	An additional questionnaire (e.g., CCQ) pops up when the patient indicates feeling unwell without objective measurements indicating an exacerbation.
	Any agreements made with the GP must be documented in the patient's health record, so that an emergency department or out-of-hours GP staff are informed if the patient's condition worsens over the weekend.
Optimizing care delivery	
The benefits outweigh the burden	Earlier detection leads to fewer visits and exacerbations, which reduces healthcare costs.
	A balance is needed between increased patient oversight through RPM and the added workload for HCPs, while managing patient expectations concerning monitoring that is not 24/7.
	Monitoring centres only notify HCPs in case of serious medical consequences.
	The primary motive should not be cost reduction; instead, the focus must be on improving health outcomes, even if initial financial and workload investments increase. Increased workload will ultimately be outweighed by long-term benefits.
	A large number of patients must participate in RPM to justify the need for a RPM nurse.
	Minimize extra workload for HCPs by only using multiple-choice questions and providing simple app-based information, where HCPs only review abnormal results. Use non-sensitive thresholds to avoid unnecessary alerts and contacts.
Reducing hospital admissions and visits to HCPs	Consultation time should increase e.g., from 15 to 20 minutes.
	Prevent acute events and emergency visits via eHealth-enabled monitoring of gradual symptom changes, enabling timely medication adjustments.
	Patients living far from the hospital will visit their GP more often instead of the hospital. When their condition is stable, RPM supports video or telephone consultations with pulmonologists.
	Consultations become shorter or less frequent (e.g., every 18 months) thanks to RPM insights. Online consultations can replace in-person visits, and consultations can be skipped when patients are stable.
Comprehensive implementation process	
Addition to existing care	Communication goes beyond regular appointments and visits between patient and HCPs.
	RPM supports daily care by providing insight into the past months, which can be used in consultations.
	RPM and existing measurements, such as spirometry and oxygen saturation, complement rather than replace each other. eHealth tools support existing care pathways by making exacerbations more measurable and empowering patients and HCPs to make more informed decisions.
Broad support among HCPs	Implementation builds on existing collaborations between GP practices within the same region, aligning with ongoing initiatives.
	HCPs consistently introduce RPM, supported by supervisors and agreements, reinforced through recurring evaluation moments, daily meetings, and notifications in their electronic health record.
	RPM should be part of standardized care within a healthcare facility.
HCPs encourage and motivate patients to start using RPM	Patients feel they are taken seriously and treated with respect by their HCPs. HCPs actively explore what each patient requires to manage their health, tailoring support to the patient's knowledge, skills, and circumstances.
	Simplify the process for doctors by creating a reminder (e.g., QR code on their desk) or checklist for each consultation, prompting them to ask patients about participating in the RPM and allowing them to request RPM installation by a nurse.
	HCPs consistently recommend RPM to patients, clearly explaining its added value, such as increased insight, support, and long-term efficiency, while jointly setting expectations, motivating use, and encouraging patient self-management.
Clear instruction and guidance for patients	Videos explain how to use RPM, nurses can help onboarding the RPM, and excessive text-based installation manuals are avoided.
	In the first weeks, patients receive structured follow-up and can call with questions, and schedule digital or optional physical check-ins with a nurse to follow-up on correct use.
	Patients are taught how to contact their HCP (with emphasis on not using the app in case of emergency), and when to contact their primary or secondary care HCPs.
	Implementation and evaluation of RPM use includes clear instruction for patients, either individually or in group sessions supported by both written and verbal explanations (to ensure inclusivity for illiterate patients).
	Integrate RPM during hospitalization and rehabilitation by using the app daily to raise awareness and track symptoms for a smoother transition to the home setting.
	Teach patients when to monitor during the day/week (e.g. before taking medication alongside inhaler use).
	Clear instructions are provided, both written and visual, on device use (e.g. sitting vs. standing, timing relative to medication, blowing force and on proper cleaning and maintenance).

	Information is provided by someone not affiliated with the device developer.
	Inform patients that their treating doctor is involved in treatment decisions, as the RPM team consults their doctors.
Clear instructions and training for HCPs	Involve the entire HCP team from the beginning and introduce regular training sessions for new HCPs.
	RPM is most suitable for patients with GOLD stage 2 or higher who experience frequent or unpredictable exacerbations and are digitally capable, rather than for patients with strong self-management skills or patients with digital or cognitive barriers.
	HCPs receive clear, accessible handouts with instructions and support, including training, easy-to-reach contact points for questions, and guidance from the company.
Better (or more adequate) care provided to patients by HCPs	
Accelerated start of treatment	Ensure short lines of communication between key care providers involved in patient's care.
	Earlier intervention based on threshold values allows timely adjustment of inhalation medication, avoiding the need for more aggressive treatment.
	In case of specific alarming symptoms, the system immediately signals the need for in-person assessment, bypassing standard protocols.
	Following an exacerbation, the app automatically notifies the physiotherapist when the patient returns home, enabling rapid re-engagement of care.
Improving care after exacerbations	After hospitalization, patients are closely monitored at home, ideally daily or every other day, to assess recovery, guide (and taper) medication adjustments, and provide reassurance. This allows for earlier discharge, structured follow-up, and better evaluation of treatment effectiveness.
HCPs obtain more insights into disease and patients' treatment	Patients regularly (at least once a month) complete a short questionnaire using validated tools (e.g., MRC or CCQ) to assess symptoms and overall well-being.
	Include early-stage COPD in RPM to begin optimizing care at an early stage, as well as to identify treatable traits.
	HCPs across primary and secondary care have shared access to a comprehensive overview of the patient's health status (medication, exacerbations, admissions, treatment changes) to enable proactive, personalized care.
Differentiate diagnoses	Monitor (myocardial) fluid balance and key symptoms to distinguish between COPD and comorbidities such as heart failure, pulmonary embolism, pneumonia, or rhinitis.
	Ensure collaboration with cardiologists for patients with overlapping symptoms (e.g. chest pain, leg oedema, orthopnoea).
Safe and Reliable	
Minimal technical errors and malfunctions	The technology must be reliable and robust: the system functions smoothly without crashes or delays, results must always be transmitted correctly, and the device is not affected by external factors such as air pollution, diet, co-medication, or lung fibrosis.
	A designated person or helpdesk should be available to answer technical questions or to reach out in case of malfunction.
	The device has been validated in a symptomatic population.
Good privacy & security	Integrate with existing PGO's (personal health environments).
Reliable results, based on objective and patient-reported data	Measurements are taken in real-time.
	The device's threshold should not be overly sensitive; the device should use pattern recognition and be accurately calibrated to avoid false alerts, achieving at least 98% accuracy in most cases.
	The device can automatically detect changes in the patient's normal values.
	The device minimizes incorrect results caused by improper use or external factors that might influence breath analysis (e.g. food, smoking, medication, stress, or recent weight changes). When a patient receives an abnormal result a questionnaire pops-up to check for these factors.
	Short questions pop-up about a patient's well-being using visuals such as scales and icons. Patients must understand the importance of responding to these questions to ensure thoughtful and accurate responses.
	Remote monitoring combines spirometry, oxygen saturation, heart rate, weight tracking, and context-specific questionnaires about symptoms (e.g., shortness of breath, fatigue), functioning (e.g., ability to perform daily activities), medication use (e.g., extra inhalers taken), and environmental factors (e.g., exposure to smoke), with additional questions triggered after abnormal results.

Definitions: COPD; Chronic Obstructive Pulmonary Disease, HCPs; Healthcare professionals, RPM; Remote Patient Monitoring, CCQ; Clinical COPD Questionnaire, MRC; Medical Research Council Dyspnea Score, GOLD; Global Initiative for Obstructive Lung Disease.

*; fully or parly applicable to the breath analysis device.

Micro; Individual actors (e.g. cardiologists, clinicians, ICT managers, eHealth sales representatives, professional nurses, caregivers, patients, family doctors) - **Level of patient care**, Meso; Intra-organisational actors (e.g. private and public hospitals, clinics, local health-care organisations, technology providers, patient communities, health tech start-ups, information providers, technology consultants) - **Healthcare institute**, Macro; Government actors (e.g. government agencies, WHO, EC, the European Society of Cardiology, the Ministry of Health, the Italian Federation of Cardiology, the Italian National Institute of Health) - **Healthcare policy.**