Digital AIRQ® Construction Set

A guide for Implementing the
Asthma Impairment and Risk Questionnaire (AIRQ®)
into Electronic Medical Records (EMR) Platforms

PRECISION

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AIRQ®: AN INTRODUCTION

We're excited you're implementing AIRQ®! Whether you're using it in a study or have made the decision to implement it in your practice, here's everything you need to know to implement a valid, digital version of AIRQ® in your EMR system.

If your clinical workflow only has PRO results provided to patients in the context of a clinic visit, you will see we have provided for carve-outs around the calculation and presentation of the score (and the accompanying "stick" graphic). Please follow the instructions consistent with your workflow.

There are 2 versions of the AIRQ® available for you to implement:

- AIRQ®—The version referred to solely as "AIRQ®" is taken by the patient once every 12 months and is the version used as the visual reference in this guide
- Follow-up AIRQ®—This version is taken by the patient whenever they see their health care professional (HCP) between annual visits to assess the impact of interventions or change in clinical status

As a reminder, the sole difference between the AIRQ® and the Follow-up AIRQ® is the look-back period specified for the final 3 questions. The AIRQ® has a 12-month look-back period, the Follow-up AIRQ® has a 3-month look-back period. A section further detailing the differences between the two instruments is found later in this document.

If you have any questions about these instructions or remaining true to the AIRQ® validation principles, please reach out to your licensing representative at RWS by contacting astrazeneca@rws.com!

Here are links to the current versions of AIRQ®, in US English, both in digital and printable form:

1. Digital AIRQ®: www.digitalairq.com
2. Printable AIRQ®: www.printairq.com

Throughout this document, we will refer to the AIRQ® as seen in either of these locations as *your reference AIRQ®*, so please keep it handy either on the screen or printed out as you go through your implementation.

This guide will provide instructions for implementing AIRQ® in US English and US Spanish.

AIRQ® is available in many other languages. You can find official translations of AIRQ® at http://us.translations.airqassets.com. You can use those translations in concert with these instructions to implement AIRQ® in your EMR in your desired language(s).

We ask that you do not translate AIRQ® yourself. If you need AIRQ® translated into a language not currently offered by AstraZeneca, please contact astrazeneca@rws.com with your request. A translation fee payable to RWS will apply. AstraZeneca does not benefit from such translation fees.

AIRQ® INFORMATION FOR HEALTH CARE PROFESSIONALS

AIRQ® Indications

The AIRQ® is a patient assessment tool intended to help identify patients 12 years of age and older whose health may be at risk because of uncontrolled asthma. This assessment is based on a series of patient-facing questions about asthma medications, respiratory symptoms, and utilization of health care resources. Depending on the patient's responses to these questions, the patient will receive a score reflecting their level of asthma control. After completion of the AIRQ®, the patient and health care professional should discuss the responses to each of the individual questions, the total AIRQ® score, and the patient's level of asthma control, and form a treatment plan.

The AIRQ® Is Not Intended To:

- Diagnose asthma
- Replace the advice or treatment of a health care professional
- Direct specific actions to treat, mitigate, or improve asthma
- Collect or store any laboratory values or lung function test values

Health Care Professional Instructions for Use

1. Provide your patient with the AIRQ® during or immediately prior to their appointment.
2. Examine the responses to each of the individual questions, the total AIRQ® score, and the patient's level of asthma control.
3. Discuss responses to each of the individual questions, the total AIRQ® score, and the patient's level of asthma control with your patient.
4. Determine a treatment plan with your patient based on the information you've learned during your discussion and clinical assessment of the patient, and through responses to the AIRQ® questions.

Information on the Validation and Interpretation of AIRQ®

1. AIRQ® is a 10-item, equally weighted, yes/no composite asthma control questionnaire that includes 7 impairment and 3 risk items.
2. The AIRQ® was validated against a standard of ACT™ score (impairment) + prior-year, chart-documented exacerbations (risk) in 442 patients 12 years of age and older who were previously diagnosed with asthma.
3. Multivariable logistic regression analyses were used to determine questions with the greatest validity in discriminating between patients of varying levels of control.
4. A total of 10 questions were identified for inclusion in the AIRQ®.
5. The AIRQ® performed well with respect to the ACT™ + exacerbations standard in identifying well-controlled vs not well-/very poorly controlled and well-/not well-controlled vs very poorly controlled asthma, with area under the ROC (receiver operating characteristic) curves of 0.94 and 0.93, respectively.
6. The combination of selected AIRQ® items and cut points of control demonstrated a sensitivity of 0.90 to identify patients whose asthma was well-controlled (cut point of ≥2), and a specificity of 0.96 to determine patients whose asthma was very poorly controlled (cut point of ≥5).
7. For further information on the development and cross-sectional validation of the AIRQ®, please refer to Murphy KR, et al. *J Allergy Clin Immunol Pract*. 2020;8(7):2263-2274.e5. and Murphy KR, et al. *J Allergy Clin Immunol Pract*. 2021;9(1):603.

OBTAINING YOUR AIRQ® LICENSE

We request that everyone who uses AIRQ® obtain a license from our licensing partner, RWS.

Use of AIRQ® as part of the treatment of patients in clinical practice or in an investigator- initiated clinical trial is **free in perpetuity**. Any use of AIRQ® in an industry-funded clinical trial may have an associated cost as outlined in the licensing agreement.

We ask that you obtain a license so that we can track where AIRQ® is in use, in the event we need to communicate with all practices using AIRQ® about any future changes to the tool.

To obtain your license to use AIRQ®, please send an email to astrazeneca@rws.com requesting the AIRQ® licensing form. RWS will send you a form to complete, and upon return of the completed form, you'll be sent an email indicating that you are licensed.

PATIENT-FACING AIRQ® VS CLINICIAN-FACING AIRQ®

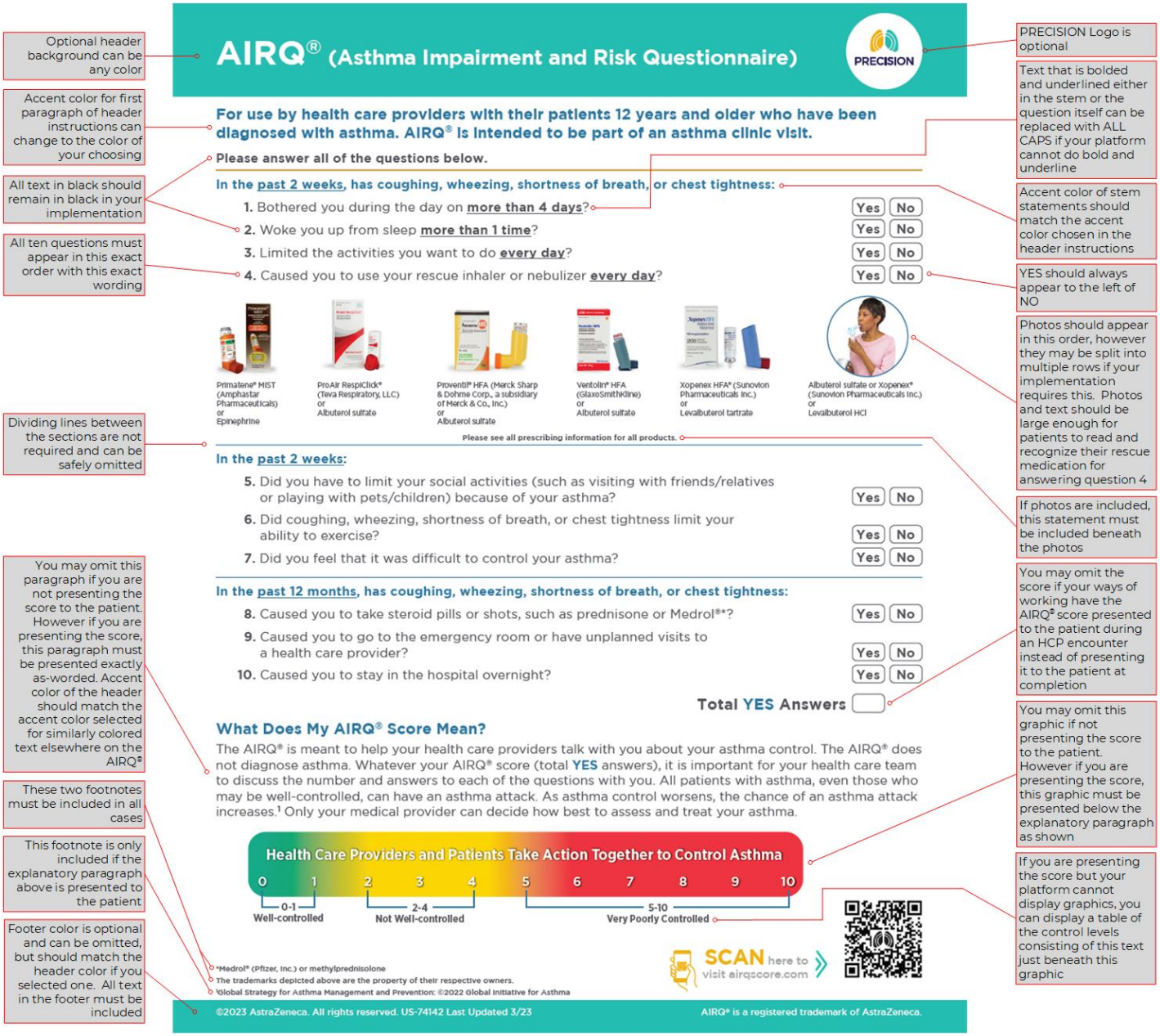
All the formatting requirements summarized on the following page and referenced elsewhere in this guide are intended for an AIRQ® which will be patient-facing in any manner.

If your digital form will **only** be used for data entry by a clinician transcribing patient AIRQ® responses and scores into your EMR, you only need be concerned with ensuring the questions are displayed in the exact same order and are written with the exact same verbiage seen on your reference AIRQ®.

If you are creating a digital form which will be completed by a patient, please faithfully follow all the requirements referenced on the following page and in each section of this guide.

AIRQ® IMPLEMENTATION SUMMARY

Here is a summary of the implementation instructions as a visual reference, with a linked copy below if you want to zoom in more clearly.



Download AIRQ® Implementation Summary

IMPLEMENTATION BY SECTION

The Header and Instructions

All of the initial instructions that appear above question 1, inclusive of the header at the top of the AIRQ®, must be reproduced exactly as written.

We understand that your digital platform may limit the available formatting, so it is acceptable if there is no difference in decoration between the header and the instructions. However, aside from the exception around not presenting the stick or score (see below), all words in the header and the instructions must appear verbatim, and the paragraphs must be structured as shown.

If you do not specify that the AIRQ® should present the score to the patient, you may omit the line that reads "Click Calculate Score" and replace it with brief instructions directing the patient to click whichever Submit button your digital tool will provide to submit the form for processing. In this scenario, the explanatory text, the "stick" graphic, and the accompanying footnote that appears below the score calculation on your reference AIRQ® will be omitted.

The Questions

Each of the 10 questions on the AIRQ® must be presented in the exact order and exactly as worded as shown on your reference AIRQ®. Each question has only two allowable answers: "Yes" or "No." "Yes" must appear to the left of "No," as seen on your reference AIRQ®.

All questions are required. Your system should not allow incomplete AIRQ® to be submitted.

For implementation as a 1-page, whole-form format, ensure that each section of questions is preceded by its corresponding stem language (eg, *In the past 2 weeks*...).

The font you choose should be a clean-looking, sans-serif font, if one is available. Be sure to respect all bolding and underlining seen in your reference AIRQ®. If your platform cannot bold and underline the text, it is acceptable to use ALL CAPS instead.

All text shown in black on your reference AIRQ® should continue to appear in black. The color used for nonblack text can vary based on your implementation; however, coloring should remain consistent throughout your implementation. For example, any text appearing in blue on your reference AIRQ® can use an accent color besides blue; however, all such blue text should be converted to whichever accent color you choose.

Usage of an accent color for the nonblack text within AIRQ® is preferential but not required. All text can be black if that's all that your system supports.

Question 4 has an array of accompanying photos that we strongly recommend be presented beneath the text of the question and in the order shown. AIRQ® has been validated without the photos, however, we believe the photos increase the accuracy of answers to Question 4.

If you have the ability to include the photos, they should ideally be sized so that they all fit on one line, as shown on your reference AIRQ®. However, depending on the limitations of your digital platform, you may balance the size of the photos with their readability, wrapping them across multiple lines. Ultimately, you should ensure that the photos are effective so that patients can glean the information from the photos designed to help them answer Question 4 accurately.

If your platform won't allow you to display photos directly within a question, you can present these photos at the top of the AIRQ® (underneath the header instructions) and reference the photos in the wording of Question 4 by adding this text at the end of the question: "(Please scroll up for pictures of medicines referenced in this question.)"

Here is a ZIP file containing these photos; your IT department may need to resize them to be suitable for your implementation. Note that photo arrays are not available in Italian (Italy), Spanish (Spain) or German (Germany) because of how AIRQ® was validated without the photos in these markets and languages.

Download Desktop-Friendly AIRQ® Inhalers Photo Files

Download Mobile-Friendly AIRQ® Inhalers Photo Files

Completing the Form and Changing Answers After Completion

Our digital implementation of AIRQ® enforces that the questions be initially answered in order from Question 1 to Question 10. Patients are not prevented from going back to change their answers after initially responding to a question, but they cannot skip a question to answer an ensuing question.
This is the ideal behavior, but it is not required. What is required is that all 10 questions be answered before the form is submitted by the patient. Incomplete AIRQ® cannot be submitted.

Another important situation to consider is whether your system will allow patients to change answers on the form after they have submitted it for scoring. While our digital implementation of AIRQ® allows this, **the best practice here is to disable changes to the form after it has been submitted to avoid any confusion between the patient and your clinical staff.**

Validating the Form and Calculating the Score (Score Presented to Patient)

If you specify that the score is <u>not</u> immediately calculated and presented to the patient, you may skip all the instructions in this section and instead follow the instructions in the "Submitting the Form" section (page 10).

Present a button labeled "Calculate Score" that is aligned with the right margin and directly beneath Question 10. As mentioned before, this button should validate the form to ensure that all questions are answered before submission of the form is allowed.

Ideally, the "Calculate Score" button is not activated by your platform until all 10 questions have been answered. But if your platform will not support this behavior, it is acceptable to allow patients to click the button anytime so long as the button will validate that all 10 questions have been answered before accepting the form for submission.

If the validation script finds that 1 or more questions have not been answered, an error message (a pop-up dialog box is preferable but not required) will be displayed that reads "Please answer all 10 questions before submitting the AIRQ®."

If all 10 questions are answered when the user clicks "Calculate Score," the form should be accepted, and the score should be calculated and presented to the user. You should not present any warning or informational messages asking for confirmation before accepting the form and calculating the score. Once the user clicks the button, the form should be processed and accepted.

To calculate the score, tally all of the patient's YES answers. Each YES answer = 1 point; each NO answer = 0 points. The score will be an integer from 0 to 10.

Presenting the Score to the Patient

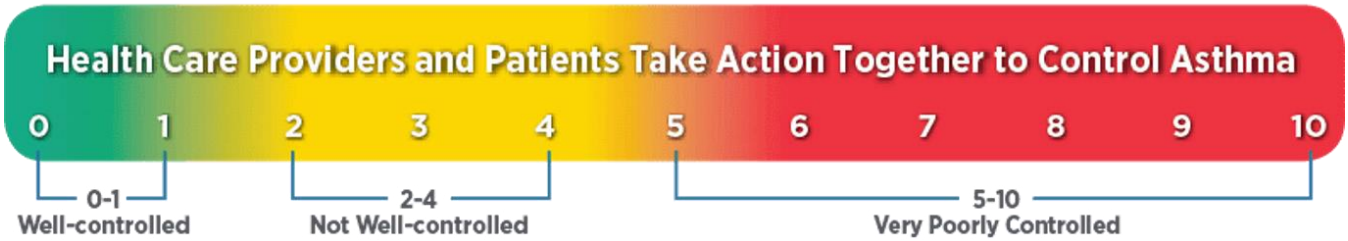
If you specify that the score is <u>not</u> immediately calculated and presented to the patient, you may skip all the instructions in this section and proceed to the "Submitting the Form" section (page 10).

Beneath the button labeled "Calculate Score" should be some static text that reads "The score is calculated from the total number of YES responses from the questions above." The expected behavior is, upon submission, this text will be replaced with the text presenting the user's score as indicated in the next paragraph, however, this is not required. If your platform cannot replace text upon submission of a form, you can omit the text describing how the score is calculated and simply present the score to the user upon submission, as indicated below.

Upon submission of the AIRQ®, underneath the "Calculate Score" button, you should present the patient's score. The verbiage must read exactly: "Your AIRQ® Score (total YES responses) is <score value>."

Underneath the patient's score should be, verbatim, the explanatory "What Does My AIRQ® Score Mean?" paragraph, the "stick" graphic, and the accompanying Global Strategy for Asthma Management and Prevention footnote that appears on your reference AIRQ®:

> **What Does My AIRQ® Score Mean?**
>
> The AIRQ® is meant to help your health care providers talk with you about your asthma control. The AIRQ® does not diagnose asthma. Whatever your AIRQ® score (total YES answers), it is important for your health care team to discuss the number and answers to each of the questions with you. All patients with asthma, even those who may be well-controlled, can have an asthma attack. As asthma control worsens, the chance of an asthma attack increases.[1] Only your medical provider can decide how to best assess and treat your asthma.



[1]Global Strategy for Asthma Management and Prevention: ©2021 Global Initiative for Asthma.

You do not need to replicate the exact line wrapping in the explanatory paragraph seen here, so long as the text appears verbatim and all in 1 paragraph. A high-resolution copy of the "stick" image shown above is embedded below; your IT department may need to resize it appropriate to your implementation.

Download AIRQ® Stick Graphics

Submitting the Form (Score Not Presented to Patient)

Follow the instructions in this section only if you specify that the score is <u>not</u> immediately calculated and presented to the patient.

Present a button labeled "Submit AIRQ®" that is aligned with the right margin and directly beneath Question 10. As mentioned before, this button should validate the form to ensure that all questions are answered before submission of the form is allowed.

Ideally, the "Submit AIRQ®" button is not activated by your platform until all 10 questions have been answered. But if your platform will not support this behavior, it is acceptable to allow patients to click the button anytime so long as the button will validate that all 10 questions have been answered before accepting the form for submission.

If the validation script finds that 1 or more questions have not been answered, display an error message (a pop-up dialog box is preferable but not required) that reads "Please answer all 10 questions before submitting the AIRQ®."

If all 10 questions are answered when the user clicks "Submit AIRQ®," the form should be immediately accepted. You should not present any warning or informational messages asking for confirmation before accepting the form.

Presenting the Footer

The footer must contain all the elements, verbatim, as seen in your reference AIRQ®:

- Credit for Pfizer's ownership of the Medrol® registered trademark
- Specific verbiage indicating that all trademarks are the property of their respective owners
- Global Strategy for Asthma Management and Prevention footnote referenced in the "What does my AIRQ® score mean?" paragraph
- Our copyright statement
- Our AIRQ® registered trademark statement

Ensuring Responsive Design and Mobile Device Considerations

Depending on how you plan on implementing AIRQ® and the capabilities of your particular platform, patients may be taking AIRQ® on a broad variety of devices with many different screen sizes and resolutions.

Be sure to test your implementation of AIRQ® on a representative set of target devices, both in portrait and landscape modes, to ensure that the AIRQ® is behaving in a manner that facilitates a good patient experience on those devices.

When taking AIRQ® on a small-form-factor mobile device, it is acceptable to present the questions on the screen one at a time. However, please ensure that each question is preceded by the stem text from the top of each respective section to retain context (eg, *In the past 2 weeks…*).

It is good practice to enable end users to navigate backward to change answers to questions they've previously answered, but it is not required to remain consistent with AIRQ®'s validation.

Furthermore, it is also good practice to present all 10 questions and their answers to the patient after Question 10 has been answered to allow them to easily review their answers before submitting the AIRQ® to be scored, as well as to enable them to jump back to a specific question to easily change their answer. However, neither of these capabilities are required either.

Please review how AIRQ® behaves on a small-form-factor mobile device by using your small-form-factor mobile device to navigate to www.digitalairq.com and complete a test AIRQ®.

IMPLEMENTING THE FOLLOW-UP AIRQ®

It is recommended that patients complete the AIRQ® once, about every 12 months, at their annual visit. If you wish for patients to complete the AIRQ® for HCP encounters between annual visits, patients should complete the Follow-up AIRQ®.

The Follow-up AIRQ® is almost entirely identical to the AIRQ®; the sole exception is the stem language appearing immediately before Question 8:

AIRQ®	**Follow-up AIRQ®**
In the past 12 months, has coughing, wheezing…	In the past 3 months, has coughing, wheezing…

If you wish to administer the Follow-up AIRQ® in your practice, you will need to implement a second version of the AIRQ® in your system, observing the sole difference in language as noted above. It would be up to your staff to ensure that the patient is directed to the appropriate version of the AIRQ®, whether they need to complete the AIRQ® for their annual visit or the Follow-up AIRQ® between annual visits.

IMPLEMENTING AIRQ® IN ANOTHER LANGUAGE

Both the AIRQ® and Follow-up AIRQ® are now available in 16 languages and dialects:

- Spanish (Spain, US)
- French (France, Canada)
- German (Germany)
- Italian (Italy)
- Japanese (Japan)
- Arabic (Lebanon)
- Hindi (India)
- Hebrew (Israel)
- Thai (Thailand)
- Romanian (Romania)
- Indonesian (Indonesia)
- English (US, UK, Canada)

You can obtain these official translations at http://us.translations.airqassets.com.

If you need AIRQ® translated into another language, we ask that you work with RWS to obtain an officially translated version and not to translate AIRQ® yourself. Please email astrazeneca@rws.com with your request.

ANY QUESTIONS?

If you have any questions about your implementation of AIRQ® and/or remaining consistent with the AIRQ® validation principles, please contact your licensing representative at astrazeneca@rws.com.

NOTES

- The Customer (eg, physician, medical group, IDN) shall be solely responsible for implementation, testing, and monitoring of the instructions to ensure proper orientation in each Customer's system
- Capabilities, functionality, and setup (customization) for each individual system vary. AstraZeneca shall not be responsible for revising the implementation instructions it provides to a Customer in the event that Customer modifies or changes its software, or the configuration of its system, after such time as the implementation instructions have been initially provided by AstraZeneca
- While platforms may assist health care professionals in identifying appropriate patients for consideration of assessment and treatment, the decision and action should ultimately be decided by a health care professional in consultation with the patient, after review of the patient's records to determine eligibility, and AstraZeneca shall have no liability thereto
- The instructions have not been designed for and are not tools and/or solutions for meeting Advancing Care Information and/or any other quality/accreditation requirement
- All products are trademarks of their respective holders, all rights reserved. Reference to these products is not intended to imply affiliation with or sponsorship of AstraZeneca and/or its affiliates
- Please provide any feedback on the instructions or use of the AIRQ® to precisionfeedback@astrazeneca.com