

IQoro® feasibility kit for Healthcare Professionals

The IQoro® Feasibility Kit has been designed to help you as an HCP to provide you with the practical support you need to introduce it to your patients and clients. It includes demo devices to help you to make your clinical “decision to supply” and to support your purchasing decision.

The kit contains a “Large” (adult) demo device, and a “Small” (child) demo device so that you can choose the right size for your patient; and to investigate the overall acceptability and feasibility of the IQoro® treatment method. We usually say that children of 12 years old or more should use the larger device (the greater the area of IQoro® that the mouth can accommodate, the better the result), but all individuals are different. Also, some petite adults may only manage the smaller device. Secondly, you may wish to ensure that your patient is generally receptive to the IQoro® regime: all patients cases are unique, and some may refuse any such oral intervention.

Our point is that you would not want to open a new IQoro® pack only to find in the first minute that it is the wrong size, or not feasible for your patient. IQoro® is a CE-marked Class 1 Medical Device approved for multiple use with a single patient. An expensive experiment if it is not suitable!

Now that the kit has been accepted and signed for, its use and maintenance becomes your clinical responsibility, or that of your department - you will need to agree which. As such, due care and attention needs to be given to maintaining the health and safety of the device, including a visual inspection before use and an appropriate cleaning regime in place. If, on visual inspection, you have any concerns about a device, do not use. Please instead contact us at info@iqoro.com and we will handle your request promptly.

Contents:

- Receipt for this kit. This document, two copies, one for you and one for us. Please keep your copy.
- 1 x ‘Large’ IQoro® demo device
- 1 x ‘Small’ IQoro® demo device
- A4 version of the diary sheet found in the manual
- Step-by-step tips sheet on how to use for the first time
- ‘Train the trainer’ tips sheet on how to introduce to the weak or elderly
- One of each of our 3 product brochures – all slightly different content and aims. Order more of whichever are most helpful to you via info@iqoro.com

What’s an IQoro® “demo” device?

IQoro® is a CE-marked, Class 1 Medical Device, it is approved for multiple use, for a single patient. The demo version is provided to you in this pack on a not-for-resale and not-for-treatment basis. This is important to note, as all products issued to patients should be part of a MHRA process so that they can be tracked by both your institution and the IQoro® company, in the unlikely event of a product recall.

It is also likely that your device in the pack is not the latest, current model – for example earlier models had a cut-out in the handle which was found to encourage an asymmetrical grip by the patient, with sub-optimal results.

Agreement

Here's our simple agreement:

Your details

Name of person taking the Feasibility kit & signing this form:

Role: _____

Department/ Organisation/ Institution Name and address:

Tel no.: _____

E-mail address: _____

Your devices

Size: S / L

Colour: Turquoise/Clear

Size: S / L

Colour: Turquoise/Clear

Our agreement

I acknowledge receipt of the demo device(s) listed above. I understand that they are not for resale, and not for treatment.

The devices have been given to me in order to allow me to:

- a) to determine the best size fit for my patients, and
- b) to establish the likelihood of acceptability by my patient of this treatment method

On signing for, and accepting this Feasibility pack I take responsibility for ensuring that I / my department will implement a process to record and ensure the regular checking and cleaning as recommended by the manufacturer before each patient use.

Signed:

Date: