

## POST-MARKET EVALUATION, IN THE UNITED KINGDOM AND SWEDEN, OF THE IQoro® PROGRAMME FOR REMEDIATION OF DYSPHAGIA, HIATUS HERNIA AND REFLUX, SLEEP APNOEA AND SNORING.

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*Observation of internet search activity, and the success of IQoro® in delivering nearly 5,000 devices to patients in Europe, indicates that people with dysphagia following stroke, Hiatus hernia and GERD (Gastro Esophageal Reflux Disease), or snoring and sleep apnoea are seeking an easy-to-use, home-based solution for the remediation of their conditions and relief of their symptoms. This study set out to determine whether the IQoro® training regime has delivered a treatment alternative that could be recommended by health care providers for people with these three groups of conditions.*

*The research method employed was an email-based survey sent to all users of the IQoro® device registered with the manufacturer (MYoroface AB) with a current email address. In total, 658 adults responded to the questionnaire, with a response rate of 51.8%. The study aims were to collect and analyse information regarding the utility, usability and benefit provided by IQoro®. The three indication groups (dysphagia, Hiatus hernia, and/or snoring and sleep apnoea) showed co-morbidity and hence the sum of the three groups shows a total of more than 100%. Users reported their main reason for IQoro® treatment was: dysphagia following stroke (15.0%), hiatus hernia and reflux (56.3%) and snoring and/or sleep apnoea (47.1%). For place of training, 99.4% of participants reported that training took place in the home, and was conducted without assistance for 97.9% of participants, implying that health care professional involvement was minimal. The results supported that IQoro® was easy to use, had high compliance in terms of training regime and the majority of participants indicated that IQoro® had delivered significant observable benefits in their daily quality of life.*

*The data suggests that that IQoro® should be part of the recommended battery for clinicians and healthcare systems in need of a safe and effective home-based treatment regime in preference to pharmaceutical and/or surgical solutions for dysphagia, hiatus hernia and reflux, sleep apnoea.*

### 1. INTRODUCTION

The IQoro® treatment regime is based on a pathway of invention<sup>1</sup>, continuous innovation<sup>2</sup> and research<sup>3-14</sup>, that has been reported over approximately 20 years. The research evidence has been built in a methodical manner to address questions relating to measurement technique, comparison treatments (e.g. palatal plate), time since stroke onset, natural remission and sustained effectiveness at long-term follow-up.

From its initial inception as a treatment for dysphagia sufferers, a coherent programme of studies has researched and proven its effectiveness in addressing central facial paralysis, Hiatus hernia and GERD, snoring and sleep apnoea, impaired postural control and other conditions in the same muscular chain and controlled from common neurological regions.

IQoro® has been rigorously studied in the area of dysphagia following stroke. In a 2008 study, 30

patients with dysphagia following stroke participated through continuous inclusion. Training was carried out three times a day (totally 1 ½ minutes) for five weeks. Measures were conducted at baseline and after treatment. The prototype IQoro® system demonstrated improvements in lip force ( $p < 0.001$ ) and swallowing capacity ( $p < 0.001$ ). Importantly, the interval between stroke onset and start of treatment, ranging from a few days up to 10 years, had no significant influence on the treatment results, nor did age or gender. This finding is important as it suggests that improvements were not due to natural remission immediately post stroke and that it is possible to remediate swallowing dysfunction irrespective of the amount of time from stroke to IQoro® intervention<sup>8</sup>.

Once the efficacy of the IQoro® treatment was established, it was important to compare with the current gold standard for treatment in its country of origin - Sweden. An investigation<sup>7</sup> compared the

IQoro® treatment with a palatal plate (gold standard). The study was a retrospective evaluation comparing 12 patients with a palatal plate with 14 patients using the IQoro®. Results showed that there was a significant outcome effect ( $P < 0.002$ ) of intervention and no significant difference between the two interventions. A follow-up study<sup>9</sup> demonstrated ( $n=31$ ) that the improvement was not related to time since onset of stroke. Importantly, while the training effects may have been similar, the IQoro® delivers a significant advantage in terms of cost, training time and practicality.

The IQoro system has been demonstrated by several studies to be effective in the remediation of swallowing post stroke<sup>3,5,7-10,13</sup>, equal in effectiveness to other methods that are costlier and more time intensive<sup>7,9</sup>, and the improvement is not related to natural remission or time since stroke<sup>3,7-9</sup>. IQoro training is shown to be successful when implemented for patients who are up to ten years' post stroke<sup>13</sup>.

Other studies<sup>11,12</sup> have shown the effectiveness of IQoro® in treating GERD and other reflux conditions as caused by Hiatus hernia.

The current study aims to fill in the missing areas of research through being a post-market investigation of the effectiveness of the training regime. Importantly, the aim was to determine the self-reported ease-of-use and outcome benefit from a large cohort of participants using the training programme in the community rather than under the clinical conditions of a healthcare-system based investigation. At the same time, the indications for use were expanded from dysphagia following stroke, to also include people with Hiatus hernia and GERD, and those with snoring and/or sleep apnoea. Therefore, it was important to determine the utility of the IQoro® training regime for these latter two indications also.

The current study is a post-market utility and efficacy investigation of the IQoro® training regime for participants who use the device in their home or wherever they happen to be when a session is due: work, school, restaurant, etc.

The implications for the cost and value benefit from a home-based treatment solution for these three indications is potentially enormous for health care clinicians and providers.

## 2. METHODS

**Participants:** All registered users of the IQoro® training programme located in Sweden ( $n=1270$ ) or the United Kingdom ( $n=49$ ) for whom an active email address was available were asked to participate in this post-market evaluation. These were patients who had registered with the manufacturer between June 2014 and September 2017. Of the 1319 potential participants, 658 responded to the questionnaire (participation rate = 51.8%). Of the 658 participants, 594 were able to answer on their own (90.3%) and 64 answered on behalf of the IQoro® user (9.7%). Of the participants 59.9% were female and 39.6% male with 0.5% preferring not to answer. The average age of participants was 64 years (Range: 21 – 97 years).

**Materials:** A ten-question questionnaire was administered (Appendix A). The questions focused on demographics (1-4), utility (5-7), ease-of-use (8), satisfaction (9) and a qualitative open response question (10). For questions on ease-of-use, (5 questions) and satisfaction (3 questions) results were recorded on a five-point Likert scale, with 1 being fully disagree, to 5 being fully agree, and 3 being the mid-point. The questionnaire was written in English by the author, translated into Swedish by another person, and reverse-translated back into English by a third party proficient in both languages. The reverse translation was accurate and did not show any ambiguities. Participants were able to answer the questionnaire in English or Swedish, and the results could thus be validly consolidated at the completion of the data collection.

**Procedures:** In total, 1319 emails with a link to the questionnaire -administered by SurveyMonkey™ - were sent to users who had registered their email address with the manufacturer. A follow-up email was sent after four weeks to those participants who had not responded. Of the 658 participants, 621 (95.5%) had begun training with IQoro, the other 37 (4.5%) had not begun training and were therefore excluded from any further data analysis. As IQoro® can be used for patients who have either (a) dysphagia following stroke, (b) Hiatus hernia and GERD, or (c) snoring and sleep apnoea, the results will be presented for the combined data, and for each indication. As there is comorbidity across the indications, there may be overlap across the groups.

### 3. RESULTS

The typical users of the IQoro® system are older adults with an average age of 64 years (Figure 1) and a median of 70 years, with slightly more females (60.2%) than males (39.2%) seeking treatment from the IQoro® program. Therefore, the data represents a broad age and gender spectrum of users and indicates that IQoro® could be of use by adults throughout lifespan. 95.5% of the 658 users (n=621) have begun to use IQoro and are the focus of this investigation.

Examining indications (Table 1), the participants self-identified as 15.0% as swallowing difficulties following stroke, which was the original indication for use of IQoro. The largest category though was patients who responded that they had the broader dysphagia symptoms of reflux, heartburn, and Hiatus hernia with 56.2% participants. Interestingly, the remaining 47.0% of patients reported that they used the IQoro® training

programme to improve the symptoms of snoring or sleep apnoea which is a newer indication for use with only fairly recent research evidence compared with the two more traditional indications. Therefore, this study presents new data on the wider-than-expected uptake of IQoro® to address the conditions and symptoms of snoring and sleep apnoea.

The above figures should be considered to probably under-represent people with dysphagia following stroke, as it is likely that such people may have speech, communication or other difficulties, which limit their ability to link to the internet compared to other indication groups.

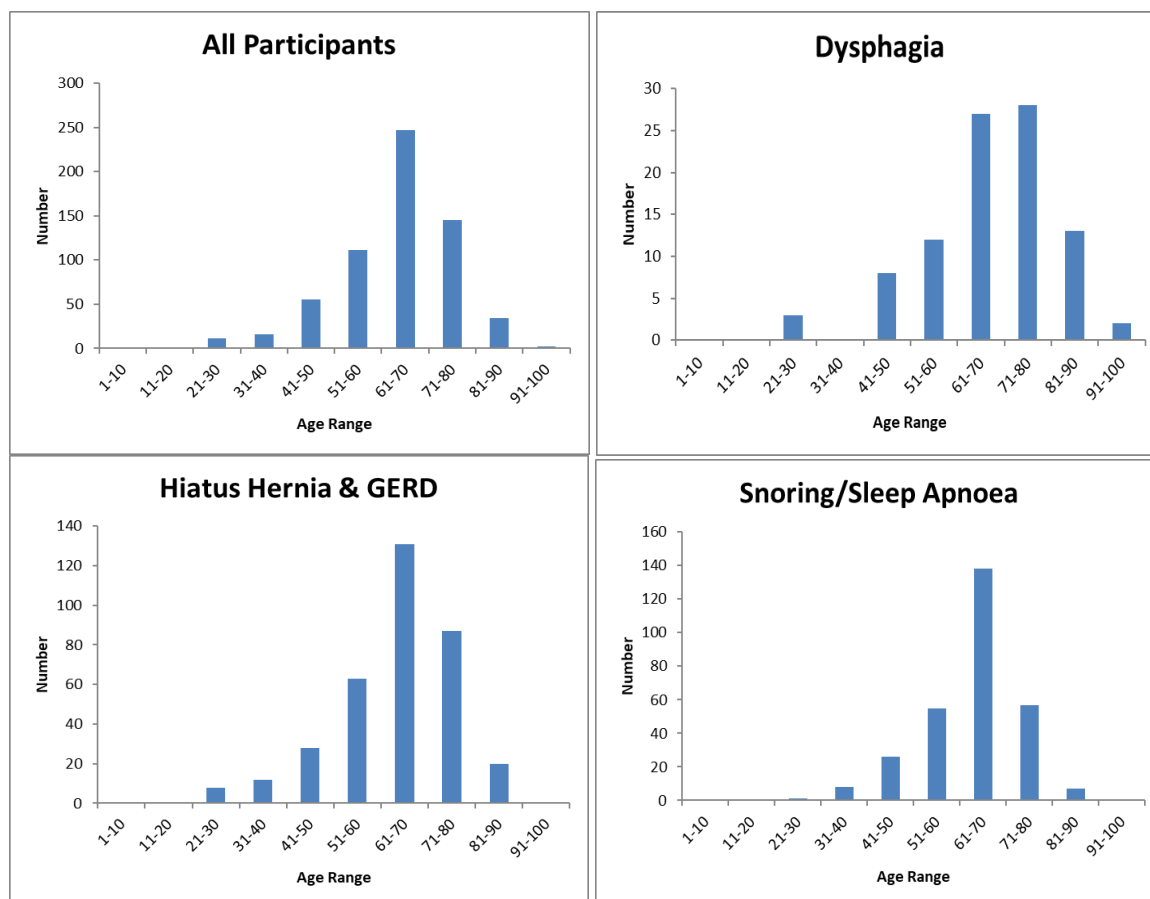
Interestingly, examination of the participant information, shows that the participants with dysphagia following stroke were older, and that a significantly larger proportion required help from a carer to fill in the questionnaire.

**Table 1. Information about the participants and indications**

Indication	Number	Percentage (%)	Mean age (years)	Female (%)	Male (%)	Assistance Required (%)
All indications	621	100	64.0	59.3	40.4	8.9
Dysphagia	93	15.0	67.6	52.7	46.2	29.0
Reflux, GERD	349	56.3	63.8	63.3	36.4	5.4
Snoring, Apnoea	292	47.1	63.2	58.6	41.1	6.2

**Table 2. Comorbidity of indications.**

Indication	Dysphagia (%)	Reflux (%)	Snoring/Sleep Apnoea (%)
All indications	15.0	56.3	47.1
Dysphagia	100.0	16.1	10.8
Hiatus hernia and GERD	4.0	100.0	25.8
Snoring/Sleep Apnoea	3.4	30.8	100



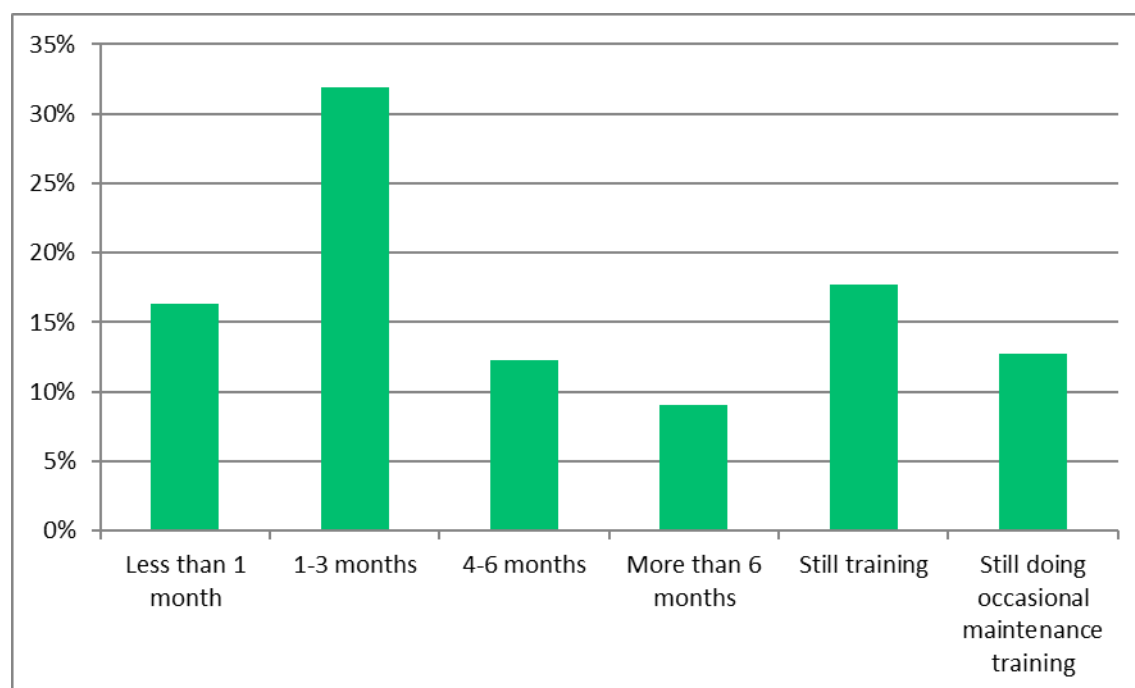
**Figure 1.** Histogram of the age of IQoro users at the time of the post-market evaluation both as a group, and separated by indications.

**Table 3.** Training location

Indication	Hospital (%)	Own home (%)	Care home (%)
All indications	0.2	99.4	0.5
Dysphagia	0.0	96.8	3.2
Hiatus hernia and GERD	0.3	99.7	0.0
Snoring/Sleep Apnoea	0.0	100.0	0.0

When asked about place of training, 99.4% reported using the IQoro® system in their own homes, with one user reporting use in the hospital and three in a residential care unit: the care home patients were mostly for the indication of dysphagia following stroke. Some care should be taken with interpretation of this number, as the data was collected through an internet-based questionnaire of users who had registered for use of IQoro® and, as such, would be biased towards users who used a home-based training programme, or who were now discharged to their home following a period of time in hospital.

The ease of use data indicates that IQoro® can be used at home by the participants with minimal, if any, training provided by a health care professional. Given that previous studies described successful use in, or under the direction of, a hospital or clinic it is pleasing to contend further that the IQoro® system can be used successfully by patients outside of institutions and can be used in a home-based situation too.



**Figure 2.** *Data on how long participants had trained with IQoro®.*

Analysis of the total length of time trained at the time of the survey (Figure 2) demonstrates three results. Firstly, there were a number of people in the cohort (16.3%) who had only recently received their IQoro® and had barely begun to train - as indicated by the “Less than one month of training” response. The largest respondent group had trained for approximately three months (44.2%), and others up to six months. Some patients, across all indications, required longer training (26.7%) than six months. This would tally with the manufacturer’s labelling that suggests that some conditions – particularly Hiatus hernia – require ongoing “maintenance” training to retain the successful outcome of the treatment provided with the IQoro® device. Another explanation could be muscular based rather than neurological base, for users to report in this group with degenerative diseases that have noticeable benefit from IQoro®, but whose underlying condition will worsen without treatment, requiring ongoing IQoro® treatment.

In terms of ease-of-use, the participants were asked five questions specifically related to their ability to use IQoro®, with or without assistance, as per the instructions (Figures 3-6). The

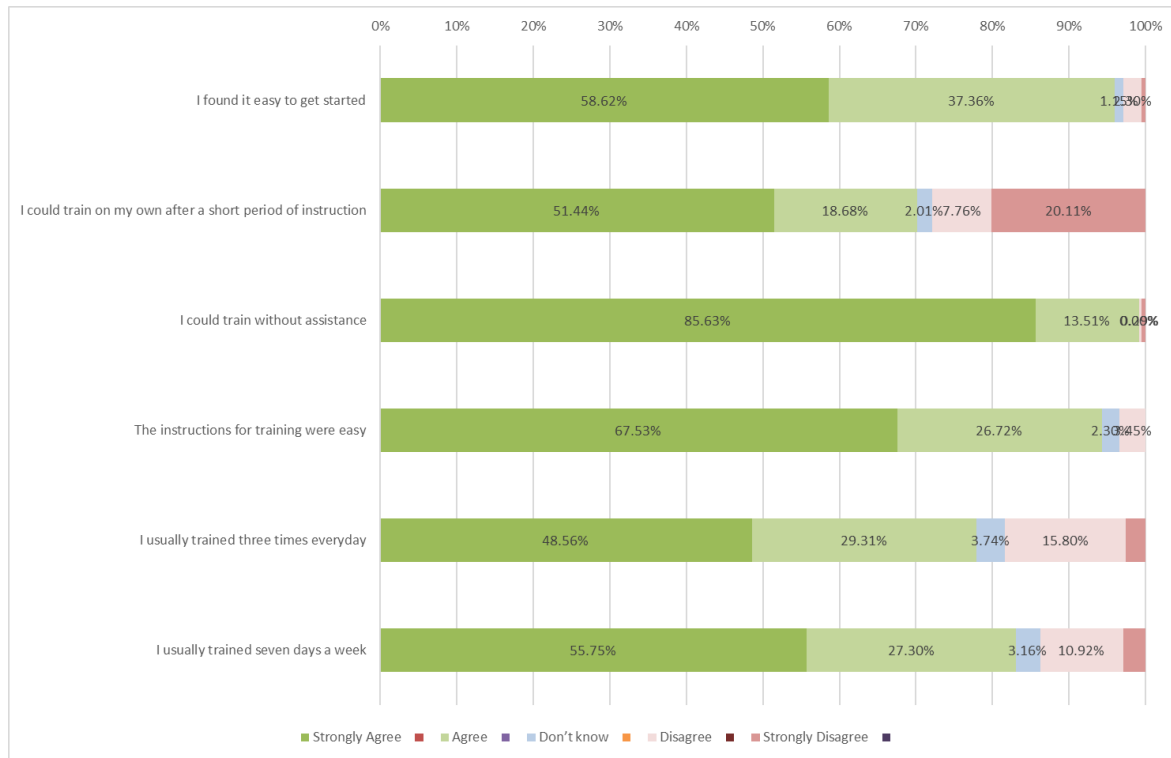
instructions for IQoro are that users should train with the device three times per day (for 1½ minutes) seven days per week. Examination of the data showed that 80.1% of patients trained each day and 73.8% reported that they trained three times a day indicating good compliance with the procedures. In terms of instructions and ease-of-use, 94.9% reported that they agreed that it was easy to start using IQoro®, and 94.9% reported that the instructions were easy to follow. Importantly, 98.0% reported that they were now able to use IQoro® without assistance. In terms of training to this level of independence, 68.1% reported that they were able to learn over a short time period. However, 29.9% disagreed and responded that assistance was required over a longer period of time. Therefore, for the majority of patients, the conclusion can be safely drawn that IQoro® can be used according to the prescribed training programme at home, and with minimal outside assistance. Presumably, for some patients following stroke, assistance could be provided as required in the hospital setting, and with ongoing training carried out in the home. Therefore, IQoro® could be considered as an appropriate home-based therapy program.



**Figure 3.** Data on the ease of use of the IQoro training programme for all participants.



**Figure 4.** Data on ease-of-use of the IQoro® for participants with the condition dysphagia following stroke.



**Figure 5. Data on ease-of-use of the IQoro® for participants with the condition Hiatus hernia and GERD.**

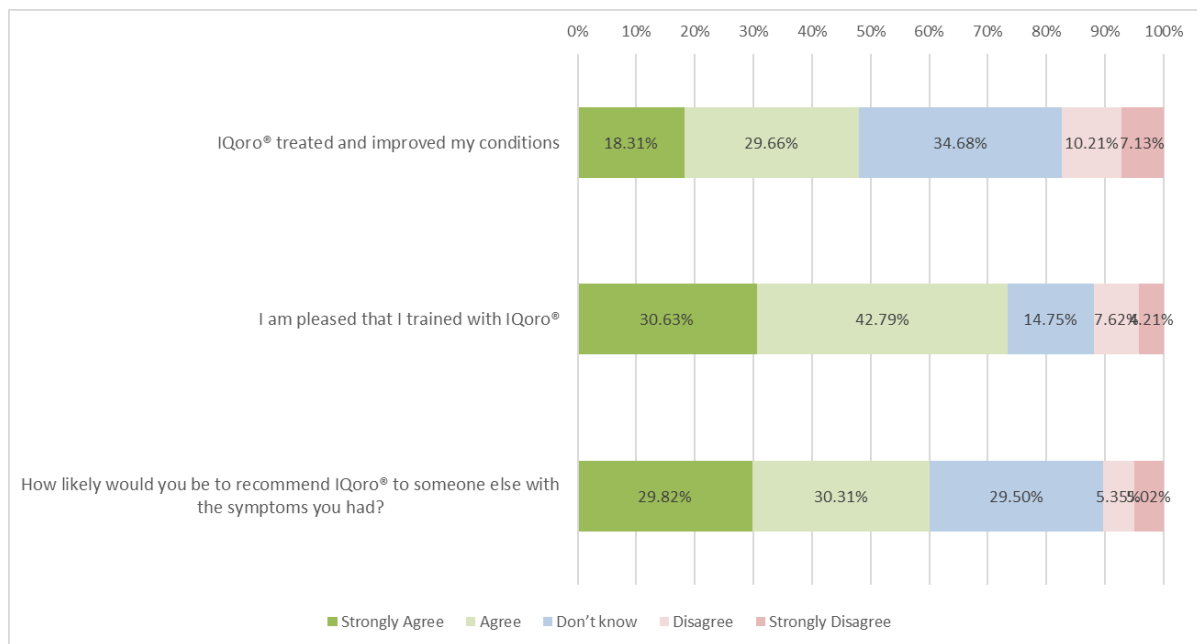


**Figure 6. Data on ease-of-use of IQoro® for participants with the condition snoring and/or sleep apnoea.**

Patient satisfaction was addressed by three questions (Figures 6-9). Given that most patients were elderly, with a number with swallowing, reflux or snoring/sleep apnoea all sometimes presenting as concomitant indications, the task of gauging satisfaction for one target condition or that the symptom addressed by IQoro may be part of a much larger disease state was challenging. It was pleasing to see that 48.0% agreed that IQoro® treated and helped their problems, with only 17.3% disagreeing. Depressing the agreement score is the risk that patients with a multiplicity of conditions may report negatively when some

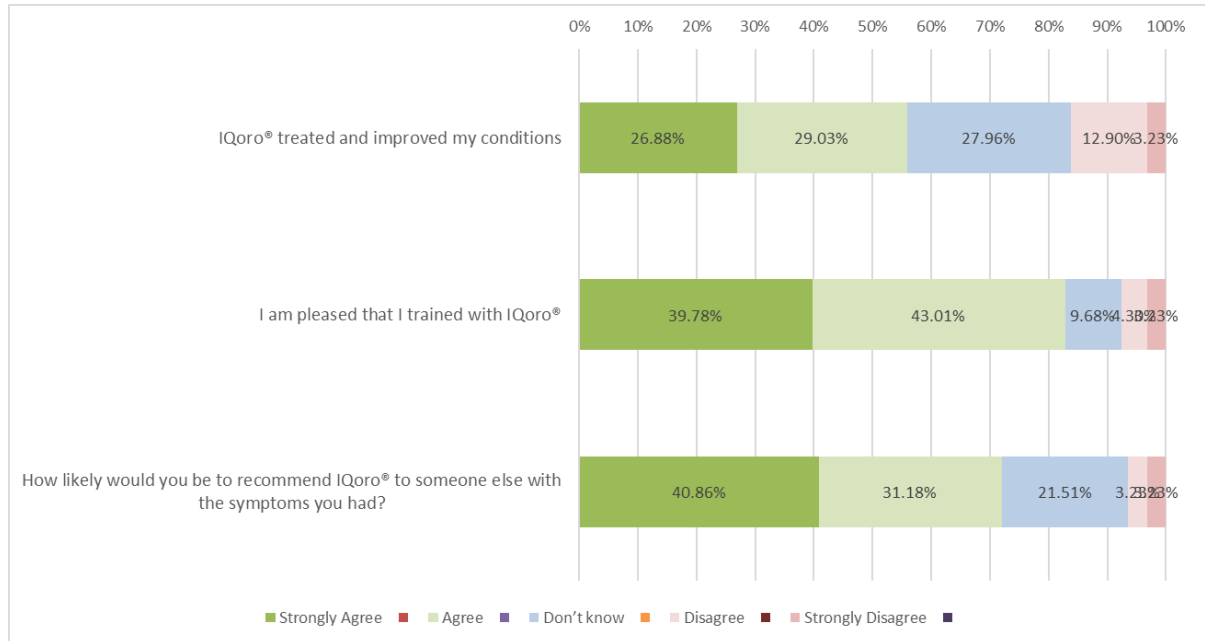
symptoms still remain - even when one condition has been successfully treated.

Similarly, 74.3% were pleased that they had started IQoro® treatment, with only 11.8% being dissatisfied. To the crucial question of whether they would recommend IQoro® to someone with the same symptoms as themselves, only 10.3% of patients stated that they would not. Analysis of data between the three indications demonstrates a similar spread of results with slightly more favourable results for those addressing dysphagia following stroke.

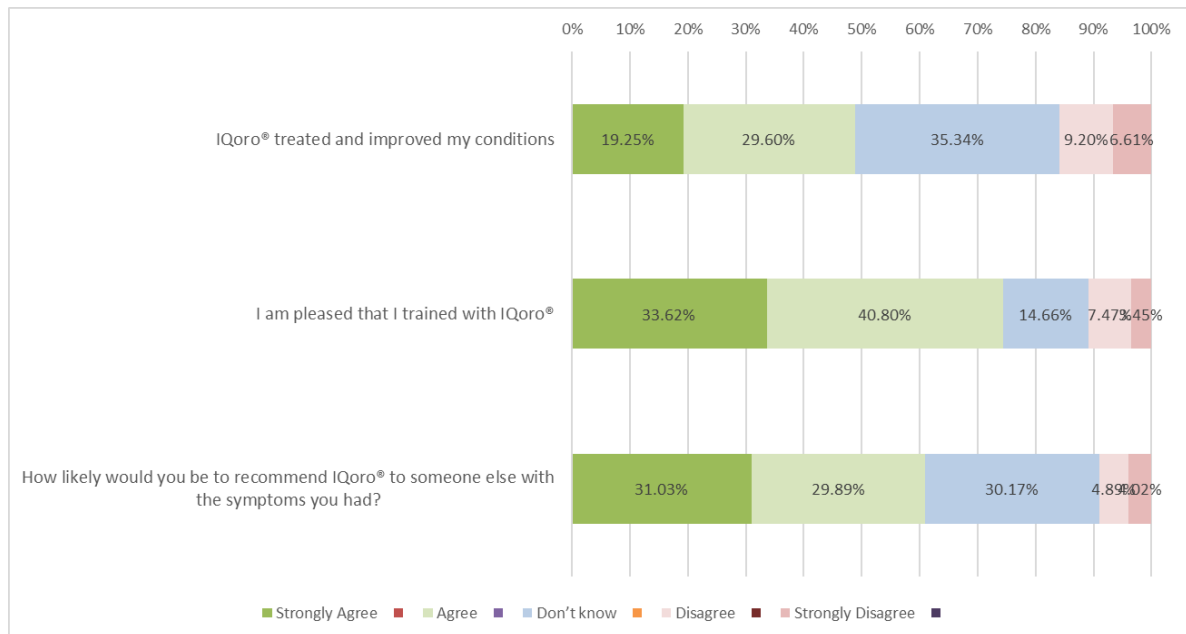


**Figure 6.** *Self-report of satisfaction of the IQoro training programme for all participants.*

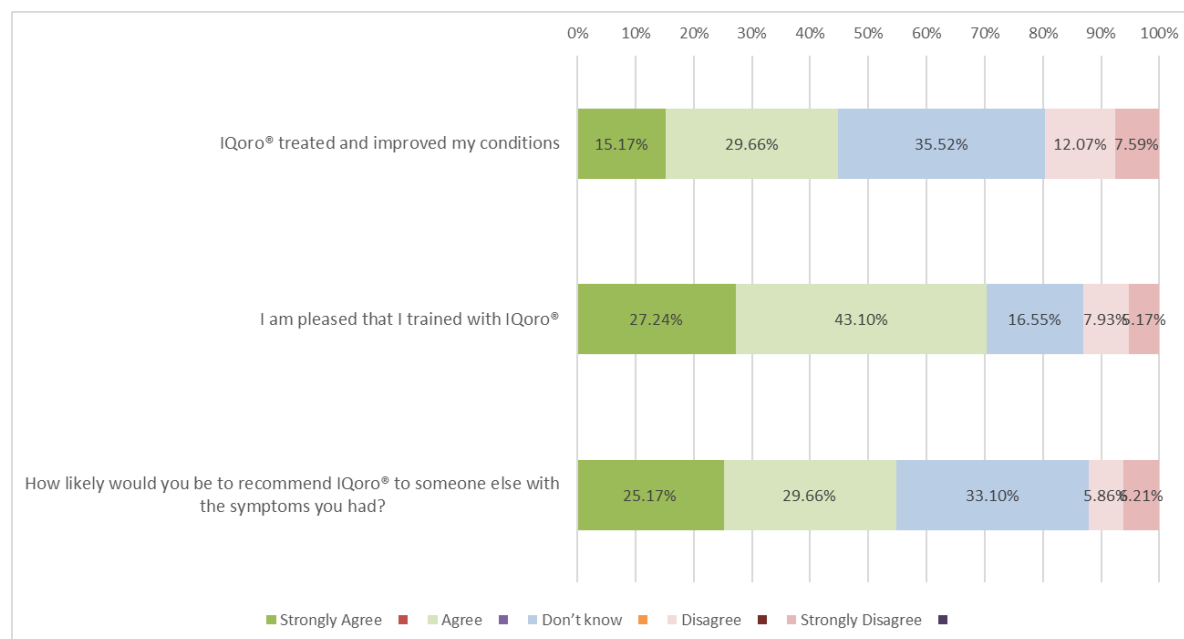




**Figure 7.** *Self-report of satisfaction of the IQoro training programme for participants addressing dysphagia following stroke.*



**Figure 8.** *Self-report of satisfaction of the IQoro training programme for participants addressing Hiatus hernia and GERD.*



**Figure 9. Self-report of satisfaction of the IQoro training programme for participants addressing snoring and sleep apnoea.**

#### 4. DISCUSSION

The study aimed to provide a post-market evaluation of the experience of users of the IQoro® training program. Previous studies have documented the significant benefits that IQoro® provides for dysphagia following stroke and in resolving the symptoms of Hiatus hernia and GERD. However, questions have remained unanswered as to whether usability and effectiveness would be equally successful outside of a clinically-led investigation. Additionally, the new indication of snoring and sleep apnoea has not received the same methodical treatment as the other classical indications of dysphagia and Hiatus hernia.

In terms of population, it was interesting that of the 658 participants, the majority were primarily addressing Hiatus hernia (56.3%); the second-largest group snoring and sleep apnoea (47.1%); and just 15.0% with dysphagia following stroke. The manufacturer reported being cautious of this as being truly representative for two reasons. First, the study required identification of the individual, and where devices were procured by healthcare institutions for prescription to a patient, the patient’s response would be expected to be much harder to elicit. Stroke survivors are suspected to be over represented in this category. Second, the response rate was a robust 51.8% which is very significant but, not high enough to ensure a full representation of the whole

population. Despite, those limitations it is clear that the 658 participants represent a significant proportion of the IQoro® population and provide an accurate indication of utility, usability and benefit of treatment as perceived by users.

Where treatment takes place is an important issue when evaluating IQoro®’s applicability. The IQoro® treatment programme is unique in that it can be applied in the hospital, or in the community-care home or domiciliary setting - as a self-administered home-based treatment. For the current study, 99.4% of participants reported that they were using the IQoro® treatment programme from their homes. The current investigation provides solid evidence that IQoro® is an effective self-administered tool for the treatment of dysphagia, Hiatus hernia and snoring or sleep apnoea in the patient’s home. Widespread use of IQoro® in addressing these three condition groups would have enormous implications in terms of reducing costs and burdens on national healthcare systems.

The data was collected in December 2017, with the manufacturer reporting significant growth in patients, month-by-month, and thus the population pool was skewed towards the newer starters, and with those whose treatment started more recently being overrepresented. IQoro® is promoted as a training programme that is used for up to three months to address dysphagia after stroke, and perhaps twice as long when treating Hiatus hernia or snoring or sleep apnoea. This may

decrease the effectiveness ratings as this cohort may have not reached the end of their programme. This effect is likely also seen in the satisfaction data where an unnaturally large percentage answered 'Don't know' when asked whether IQoro® had treated their condition (34.5%), or whether they would recommend IQoro® to others (29.5%). A probable explanation was that many respondents were not far enough into their programme to render a solid opinion.

The data showed that 60.5% of participants have used IQoro® for the recommended time of six months or less. Importantly, 30.5% of participants reported that they continued to perform periodic training over a longer time. A home-based treatment that continues to meet the needs of the patient for occasional treatment or for consolidation of gains is an important and potentially unmet medical need.

For a potential home-based training regime, it is critical to evaluate both ease-of-use and utility. Figures 3-6 highlight the ease-of-use across a number of critical dimensions. These include how easy it was to learn to use the device, how easy it was to use without assistance and finally how easy to comply with the recommended training programme: three times a day, seven days a week.

For questions on the dimension of the ability to start using the device, 96.0% agreed that it was easy to use the training regime, with 95.0% agreeing that the instructions for use were easy to follow. Importantly, 97.8% agreed that it was possible to train without assistance. For training, however, 28.6% indicated that they required support at the start of the rehabilitation programme. This support, could be provided by a friend or relative, and did not need to be a trained healthcare professional. Support with initial training, could be expected in any training regime, and highlights the need for possible other methods of instruction and evaluation such as, easy to access to YouTube videos provided by the manufacturer to reinforce the key aspects of training.

For IQoro® training it is important that patients can keep to a regime of three sessions per a day (30 seconds per session) over seven days a week. Compliance is always a challenge for any treatment but, based on the data presented here, 81.2% of patients reported that they were able to follow this training regime. While it is unclear, as to whether some training is better than no training and the degree of compliance required, it was

pleasing to note that the clear majority of participants were able to find the training regime easy to use, and were able to remain in compliance with the intensity of training required.

The measurement of effectiveness of treatment was complicated somewhat by the fact that IQoro is designed to target one area of a person's disability or daily challenge, for example, dysphagia post-stroke, but is unlikely to improve gross motoric dysfunction. Therefore, interpreting perceptions of benefit are challenging when multidimensional factors are rated on a single scale. Despite this, across the three questions of benefit for the three indications the results were overwhelmingly positive with the majority of participants agreeing that the IQoro® treatment improved their symptoms. Importantly, only 10.3% of patients reported that they would not recommend IQoro® for people with similar symptoms. While previous studies have highlighted the benefit of IQoro in a clinical and research population, this is the first investigation to demonstrate clear improvement of IQoro following a home-based training regime.

## 5. CONCLUSION

The present investigation evaluated whether the IQoro® training regime could provide benefits for patients as a home-based training regime. With 658 included participants this is the largest post-market investigation of the IQoro® training regime. Three indications were investigated, those with dysphagia following stroke, those with Hiatus hernia and GERD, and those people who reported challenges with snoring and/or sleep apnoea. The results clearly showed that IQoro® was easy to use, had high compliance in terms of training regime and the majority of participants indicated that IQoro® provided them with significant observable benefits in their daily quality of life.

Therefore, IQoro® can be recommended by health care providers as a suitable home-based training regime for the remediation of symptoms for dysphagia, central facial paralysis and other symptoms following stroke, Hiatus hernia and GERD, and snoring and sleep apnoea. The use of a home-based therapy solution promises potential benefits in terms of reduced cost to the healthcare system and ability for patients to use the treatment at home rather than thickened fluids or to seek more complex medical and surgical solutions.

## 6. REFERENCES

1. Hagg M, inventor Device for training of the face, lip and throat muscles. Sweden patent 2014/142735. 2014.
2. Myroface AB. Technical File. MYO102-10 2014.
3. Hagg M, Anniko M. Lip muscle training in stroke patients with dysphagia. *Acta Otolaryngol* 2008;128:1027-33.
4. Hagg M, Anniko M. Influence of lip force on swallowing capacity in stroke patients and in healthy subjects. *Acta Otolaryngol* 2010;130:1204-8.
5. Hagg M, Larsson B. Effects of motor and sensory stimulation in stroke patients with long-lasting dysphagia. *Dysphagia* 2004;19:219-30.
6. Hagg M, Olgarsson M, Anniko M. Reliable lip force measurement in healthy controls and in patients with stroke: a methodologic study. *Dysphagia* 2008;23:291-6.
7. Hagg M, Tibbling L. Longstanding effect and outcome differences of palatal plate and oral screen training on stroke-related dysphagia. *The Open Rehabilitation Journal* 2013;6:35-42.
8. Hagg M, Tibbling L. Four-quadrant facial function in dysphagic patients after stroke and in healthy controls. *Neurol Res Int* 2014;2014:672685.
9. Hagg M, Tibbling L. Effect of oral IQoro and palatal plate training in post-stroke, four-quadrant facial dysfunction and dysphagia: A comparison study. *Acta Otolaryngol* 2015;135:962-8.
10. Hagg M, Tibbling L. Effect of IQoro(R) training on impaired postural control and oropharyngeal motor function in patients with dysphagia after stroke. *Acta Otolaryngol* 2016:1-7.
11. Hagg M, Tibbling L, Franzen T. Esophageal dysphagia and reflux symptoms before and after oral IQoro(R) training. *World J Gastroenterol* 2015;21:7558-62.
12. Hagg M, Tibbling L, Franzen T. Effect of IQoro<sup>(R)</sup> training in hiatal hernia patients with misdirected swallowing and esophageal retention symptoms. *Acta Otolaryngol* 2015;135:635-9.
13. Hagg MK, Tibbling LI. Effects on facial dysfunction and swallowing capacity of intraoral stimulation early and late after stroke. *NeuroRehabilitation* 2015;36:101-6.
14. Hägglund P, Olai L, Ståhlhake K, et al. Study protocol for the SOFIA project: Swallowing function, Oral health, and Food Intake in old Age: a descriptive study with a cluster randomized trial. *BMC Geriatrics* 2017;17.