

Iowa Oral Performance Instrument

VERSION 1.0.2.0

ENGLISH IOPI[®] REPORT GENERATOR User Manual



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IOPI[®] Icons

SYMBOL	TITLE	DESCRIPTION	REFERENCE ¹
REF	Catalogue Number	Indicates the manufacturer's reference number so that the medical device can be identified	ISO 15223-1, Clause 5.1.6
LOT	Lot Number	Indicates the manufacturer's lot number so that the lot can be identified	ISO 15223-1, Clause 5.1.5
	Date of Manufacture	Indicates the date when the medical device was manufactured	ISO 15223-1, Clause 5.1.3
UDI	UDI	Indicates a carrier that contains unique device identifier information	ISO 15223-1, Clause 5.7.10
	Manufacturer	Indicates the medical device manufacturer	ISO 15223-1, Clause 5.1.1
ĺ	Consult Instructions For Use	Indicates the need for the user to consult the printed or electronic instructions for use	ISO 15223-1, Clause 5.4.3
()	CE Marking of Conformity	Signifies European technical conformity	Regulation (EU) 2017/745 Article 20
UK CA	UK Conformity Assessed	Signifies United Kingdom technical conformity	UK MDR 2002 (SI 2002 No 618) Section 10
EC REP Authorized Representative in the European Community/ European Union		Indicates the authorized representative in the European Community/European Union	ISO 15223-1, Clause 5.1.2

1. Standards used: BS EN ISO 15223-1:2021, Medical devices – Symbols to be used with information to be supplied by the manufacturer.

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General Definitions

TERM	UNITS	DEFINITION
IOPI [®] Pro		Iowa Oral Performance Instrument (IOPI®) Model 3.1
IOPI [®] Trainer		Iowa Oral Performance Instrument (IOPI®) Model 3.2
Event		A record of pressure data when the pressure meets or exceeds 5 kPa.
Index Number		[IOPI® PRO] A unique number ranging from 100-999 that identifies a data file stored on the IOPI® Pro.
Peak	kPa	[IOPI® PRO] The maximum pressure from an event collected in Peak Mode. If the pressure exceeds 100 kPa, the pressure is reported as '>100.'
Target	kPa	The minimum pressure necessary to illuminate the top green light of the LED array. [IOPI® PRO] This value is set in Target Mode. [IOPI® TRAINER] This value is set in Program Mode.
Repetition (Rep)		[IOPI® PRO] An exercise event collected in Target Mode. [IOPI® TRAINER] An exercise event collected in Run Mode.
Rep Max	kPa	The maximum pressure during a repetition of the exercise. If the pressure exceeds 100 kPa, the pressure is reported as '>100.'
Attempted Reps		 [IOPI® PRO] The number of exercise repetitions in Target Mode (successful reps + failed reps). [IOPI® TRAINER] The number of exercise repetitions in Run Mode (successful reps + failed reps).
Successful Reps		The number of attempted reps where the rep max met or exceeded the programmed target value.
Failed Reps		The number of attempted reps where the rep max did not meet or exceed the programmed target value.
Set		A group of exercise repetitions.
Set Number		A number assigned to a set.

Indications For Use

IOPI® Report Generator software is an accessory approved for use with the IOPI® Model 3.1 (Pro) and/or the Model 3.2 (Trainer), which are medical devices that measure, evaluate, and increase the strength and endurance of the tongue and lip in patients with oral motor disorders, including dysphagia, dysarthria, and obstructive sleep apnea. This software provides healthcare professionals with a report of device usage to allow them to document and analyze patient progress and usage. This software is intended for clinical use only.

Introduction

IOPI[®] Report Generator software is designed to allow users of the IOPI[®] Model 3.1 (Pro) and/or the Model 3.2 (Trainer) to easily download and evaluate events recorded during device usage. It is a tool to help organize the documentation of patient IOPI[®] device usage data and facilitate its analysis.

The generated reports can be saved and printed as a PDF or Word document. The data can also be exported as an Excel, comma-separated values (CSV), or tab-separated values (TSV) file.

Operating System Requirements

This application is intended to run on:

- Windows 11 operating system or Windows 10 operating system that is still under support by Microsoft
- Requires .NET Framework 4.8 (if this is not installed by default, go to https://dotnet.microsoft.com/en-us/download/dotnet-framework/net48 and install the runtime)

Quick Start

Insert the provided USB drive into your computer and click on: **IOPI® Report Generator Quick Start.**

IOPI® Report Generator INSTALLATION

Select the **Install IOPI® Report Generator** button on the Quick Start window and follow the setup instructions.

RUN FROM USB DRIVE

This procedure may be necessary if the user is not authorized to install an application directly on a computer. All the program files remain on the provided USB drive.

Select the **Run IOPI® Report Generator From USB** button on the Quick Start window.

FTDI DRIVER

The IOPI Series 3 devices require a driver made by FTDI. This driver may already exist or may automatically download on a Windows 10 or Windows 11 computer. If you are experiencing connection issues, the computer most likely does not have the correct driver. Follow the instructions below to manually install the FTDI driver.

Select the **Update FTDI Driver** button on the Quick Start window and follow the instructions. Updated drivers may be available from the FTDI website *https://ftdichip.com/drivers/vcp-drivers/*. Note that the "setup executable" version is required.

Preferences

When the IOPI® Report Generator software is opened for the first time, an IOPI® Report Generator Preferences window will appear (see Figure 1). This window allows you to set preferences for language, standard bulb locations, and the default patient file directory.

🚟 IOPI® Report Generator F	Preferences	
IDPI MEDICAL	Set preferences for language, defa patient file directory path.	ult bulb locations, and the default
<u>L</u> anguage		
English (English)	•	
Bulb Loca <u>t</u> ions		
Anterior Tongue	*	Remove
Posterior Tongue		
Left Lip		New Bulb Location
Right Lip		
	~	Add
Patient <u>File</u> Directory		
C:\IOPI		ОК
	<u>B</u> rowse	Cancel

Figure 1. IOPI® Report Generator Preferences window.

To set a language preference, select the arrow for the language dropdown menu and click on the desired language. The language change will take effect when the program is restarted.

For standard bulb location preferences, you can add, remove, or edit locations. To add, type the new location into the New Bulb Location field and select 'Add.' To remove, select a bulb location in the Bulb Locations list and select 'Remove.' To edit a location name, highlight a bulb location in the Bulb Locations list and edit the text as desired. To change a location list placement, select a bulb location and move it either up or down in the list by using the up and down arrow buttons above the list.

For patient file directory preferences, you can edit the default directory by either browsing for a directory or directly inputting a directory. To browse, select the 'Browse' button. To directly input, type the directory path into the Patient File Directory field.

Select the 'OK' button to save your preferences and proceed to the home window of IOPI® Report Generator. If you would like to customize preferences later, select the 'Cancel' button to dismiss the window. To access the window after initial setup, use the keyboard command Ctrl+Shift+P. Attempting to connect to an IOPI® device will display the Preferences window if no preferences have been saved.

KEYBOARD SHORTCUTS

Keyboard shortcuts are available for all operations. Press the ALT key to display the underscore under the letter that serves as the shortcut key.

USER INTERFACE

User interface images with sample data are displayed in Appendix A.

DOWNLOADING DATA

- 1. Using the supplied mini-USB to USB cable, connect the mini-USB end of the cable to the IOPI[®] Data Out Port [←] and the USB end of the cable to the computer.
- 2. Turn the IOPI[®] device on by pressing and holding the Power $[\bigcirc]$ button.
- 3. Open the IOPI[®] Report Generator application.
- 4. Press the Connect $[\mathscr{P}]$ button on the button bar.
- 5. When successfully connected, the IOPI[®] device will display the stored data
 [>] symbol on the bottom of the display. In addition, the serial number and IOPI[®] device type will be displayed in the IOPI[®] Report Generator title bar and the Download [(1)] button on the button bar will become active.
- 6. Press the Download [①] button on the button bar.

6.1 IOPI® Pro

An index selection window will open (see Figure 2) that displays the index numbers for all the stored data files on the connected device as well as the date and time that data was first recorded and the number of Peak and Target events. For more information regarding index numbers, see Appendix B. The window also displays a column to assign Bulb Location and fields for Patient ID, Default Bulb Location, New Bulb Location, and Location Mapping File.

First, assign a patient ID and enter it into the Patient ID field. This field is required to download the data.

	PL	Select the indices to be don tongue bulb locations.	wnloaded and displayed, a	and specify their			
Select	Index	Bulb Location	Start Time	Peak Events	Target Events		Patient ID
	100	•	2/12/2018 1:23 PM	3	41		
	101	•	2/12/2018 1:27 PM	3	37		Default Bulb Location
	102	•	2/13/2018 1:30 PM	3	27		Anterior Tongue 🔹
	103	•	2/13/2018 1:31 PM	0	29		
	104	•	2/15/2018 1:33 PM	0	36		New Bulb Location
	105	•	2/15/2018 1:34 PM	0	38		
	106	-	2/15/2018 1:35 PM	3	35		Add
	107	•	2/16/2018 10:21 AM	5	37		
	108	•	2/16/2018 10:21 AM	3	0		Location Mapping File
	109	•	2/19/2018 1:41 PM	3	36		
	110	•	2/19/2018 1:43 PM	3	0		Lord
						*	Save OK Cancel

Figure 2. Index selection window for an IOPI® Pro with sample data.

Next, pick and categorize the indexed data files you want to download by selecting the checkbox(es) associated with the index numbers and assigning the Tongue Bulb location that was used during data collection. This step is also required to download data.

When you select an index number, the Bulb Location column will automatically populate with the location displayed in the Default Bulb Location field. You can change the Default Bulb Location by using the Default Bulb Location dropdown menu. If you would like to assign the same bulb location to all the data files, you can select the Select All checkbox. This will select all the index checkboxes and assign the Default Bulb Location to every row in the Bulb Location column.

The Bulb Location column dropdown menus can be used to assign or change bulb locations for individual index numbers.

If you do not see the Bulb Location you used to collect the data in the Default Bulb Location dropdown menu, you can add the location by typing it into the New Bulb Location field and then selecting 'Add' directly underneath the field. This will add the new location to both the Default Bulb Location dropdown menu and the Bulb Location column dropdown menus for the current session, which allows you to assign the new location accordingly. To add a Bulb Location that persists through more than one session, see the Preferences section on page 6.

You can optionally save the index number and Bulb Location associations you have set up using the Location Mapping File feature. Once a Patient ID is entered and the index numbers and Bulb Locations have been selected and assigned, the 'Save...' button under the Location Mapping File field will become active. Select 'Save...' to create a tab-separated file located in the patient data file with the index number and Bulb Location associations. The File name field contains an automatically generated file name in the format XX_YYMMDD_HHMMSS_LOCATION_MAPPING where XX is the Patient ID, YYMMDD is the date, HHMMSS is the time that the location mapping file was created. If you would prefer a different directory and/or file name, enter it into the File name field or select Browse.

A location mapping file can be loaded in future downloads by reentering the Patient ID and selecting the 'Load...' button so you do not have to reenter information. NOTE: Location Mapping Files are only valid if the device memory has not been cleared since the Location Mapping File was created. Once the memory has been cleared, the index numbers will be reused for new data and thus the Location Mapping File tags, which require a match of both index number and timestamp, will not correspond correctly.

Once you have selected index numbers and assigned Bulb Locations, select 'OK' to download your data. If at any point you decide that you do not want to download the data, select either 'Cancel' or the red 'X' in the top right corner to close the window.

After the data file(s) are downloaded, the IOPI[®] Pro does not need to remain connected to the computer to view the downloaded data.

6.2 IOPI® Trainer A window will open (see Figure 3) that displays fields for Patient ID and Bulb Location. First, assign a patient ID and enter it into the Patient ID field. This field is required to download the data.

Event Download		x
IOPI MEDICAL	Specify the tongue bulb location for all downloaded events.	
Patient ID		
Rulh Location		
Anterior Tongue	•	
New Bulb Location	OK	
	Cancel	

Figure 3. Download window for an IOPI® Trainer.

Next, use the dropdown menu to select the Bulb Location that was used to collect the data you are downloading. If you do not see the Bulb Location you used, you can specify the location by entering it into the New Bulb Location field and then selecting 'OK'. To add a Bulb Location to the Bulb Location list, see the Preferences section on page 6.

Once you have assigned a Patient ID and a Bulb Location, select 'OK' to download your data. If at any point you decide that you do not want to download the data, select either 'Cancel' or the red 'X' in the top right corner to close the window.

All stored data on the device will be downloaded. After the data is downloaded, the IOPI[®] Trainer does not need to remain connected to the computer to view the downloaded data.

REPORT INFORMATION

IOPI[®] Report Generator displays the downloaded data for the current Bulb Location on four tabs:

- Summary (1) is a quick reference for a general overview of the downloaded data.
- Peak Data ([^]) displays the data that was collected in Peak Mode using an IOPI[®] Pro; the IOPI[®] Trainer does not have a Peak Mode, so when data is downloaded from a Trainer the Peak Data tab is inactive.
- Target Data (
) displays the data that was collected in Target Mode on an IOPI[®] Pro or in Run Mode on an IOPI[®] Trainer.
- Target Chart (.....) displays a bar chart that corresponds to the data on the Target Data tab.

A fifth tab, Notes (), is available to input any necessary and/or helpful notes about the data for the current Bulb Location.

The information displayed on each tab is described in the following sections.

SUMMARY TAB

This tab, when selected, displays summary data as shown in Appendix A, Figure A1. Summary values are based solely on downloaded event data, the details of which are shown on the Peak Data and Target Data tabs.

NOTE: The summary values are only as valid as the integrity of the included data.

The following table defines each value.

Table 1. Summary Tab Definitions

TERM	DEFINITION
Patient ID	The Patient ID that was entered during download.
Current Bulb Location	The Bulb Location that was assigned to the data being displayed. [IOPI® PRO] The dropdown menu can be used to switch between data that was identified as a different Bulb Location. The displayed report values will adjust to reflect the data corresponding to the Bulb Location that is selected.
PEAK MODE DATA	
Maximum Pressure (kPa)	[IOPI® PRO] The maximum pressure from all events collected in Peak Mode for the current Bulb Location. If the pressure exceeds 100 kPa, the pressure is reported as '>100.'
TARGET MODE DATA	A Contraction of the second se
Average # Sets/Day	The average number of sets of exercise performed per day. Example: Patient C performed 6 sets of exercise on Monday, 4 sets of exercise on Wednesday, and 2 sets of exercise on Friday. The Average # Sets/Day would be 4 (12 Sets/3 Days).
Total # Days	The total number of days when exercises were performed. Example: Patient A performed exercises on Monday, Wednesday, and Friday for 2 weeks. The Total # Days would be 6.
Total # Sets	The total number of sets of exercise performed. Example: Patient B performed 3 sets of exercise on Monday, Wednesday, and Friday for 2 weeks. The Total # Sets would be 18 (3 Sets/Day x 6 Days)
Total Attempted Reps	The total number of attempted repetitions across all sets of exercise.
Total Successful	The total number of successful repetitions, which means that the pressure exerted on the bulb during the rep was greater than or equal to the target pressure, across all sets of exercise.
керѕ	[IOPI® TRAINER] This is the same value displayed when pressing the Total $[\sum]$ button.
Total Failed Reps	The total number of failed repetitions, which means that the pressure exerted on the bulb during the rep was less than the target pressure, across all sets of exercise.
Average Success Percentage per Set	Average success percentage for all sets of exercise. This calculation averages the Success (%) data in Target Mode Set Data. Example: If set 1 had 50% success and set 2 had 70% success, the average success % per set would be 60% ((50%+ 70%)/2).
Average Success Duration (sec)	The average amount of time the green light was illuminated for all successful reps. This calculation averages the Target Duration data in Target Mode Event Data for successful rep events.

PEAK DATA TAB

This tab, when selected, displays maximum pressure data collected in Peak Mode on the IOPI[®] Pro only as shown in Appendix A, Figure A2.

When an IOPI[®] Trainer is connected, this tab is inactive.

The following table defines each term on the Peak Data tab.

Table 2. Peak Data Tab Definitions

TERM	DEFINITION					
PEAK INDEX DATA						
Index	The unique number ranging from 100-999 that identifies a data file.					
Date	The year (Y), month (M), and day (D) that the associated data file was recorded, displayed according to the current language preference. For example, in US English, the format is MM/DD/YYYY.					
Time	The hour (H) and minute (M) that the first Peak Mode event in the associated data file was recorded, displayed according to the current language preference. For example, in US English, the format is HH:MM AM/PM.					
Events	The number of Peak Mode events recorded in the associated data file.					
Maximum Pressure (kPa)	The greatest bulb pressure recorded in Peak Mode in the associated data file. If the pressure exceeds 100 kPa, the pressure is reported as '>100.'					
PEAK EVENT DAT	Ā					
Event	The number assigned to each peak measurement in a data file. The first event in each data file is assigned the number 1. Each additional event within the same data file increments the event number by +1.					
Event Time	The hour (H), minute (M), and second (S) that the event started, displayed according to the current language preference. <i>For example, in US English, the format is HH:MM:SS AM/PM</i> .					
Maximum Pressure (kPa)	The greatest bulb pressure recorded during the event.					

TARGET DATA TAB

This tab, when selected, displays exercise set and repetition data collected in Target Mode on either the IOPI[®] Pro or the IOPI[®] Trainer as shown in Appendix A, Figure A3.

The following table defines each term on the Target Data tab.

Table 3. Target Data Tab Definitions

TERM	DEFINITION
TARGET SET D	ATA
Index	[IOPI® PRO] The index number associated with each set of data.
Set	The unique number assigned to each set. Every time the device is turned on, the initial set number is 1. This number increases by +1 every time the Reset $[\rightarrow 0 \leftarrow]$ button is pressed when exercise repetitions are being performed.
Date	The year (Y), month (M), and day (D) that the data for a set was recorded, displayed according to the current language preference. <i>For example, in US English, the format is MM/DD/YYYY.</i>
Time	The hour (H) and minute (M) when the set started, displayed according to the current language preference. <i>For example, in US English, the format is HH:MM AM/PM</i> .
Target (kPa)	The minimum pressure that is necessary to illuminate the top green light of the LED array. If several different targets were set within a set, the range of targets is displayed.
Avg Dur (sec)	The average duration, as defined below in Target Event Data, for all successful reps for a given set.
Success/ Total Reps	Successful repetitions as a percentage of the number of attempted repetitions for a given set of exercises.
TARGET EVEN	T DATA
Set:Rep	The set and rep number associated with each exercise rep. The first rep number in each set is 1. This number increments by +1 every time an exercise repetition is performed. The rep details of each set can be collapsed or expanded by selecting the associated arrow in the title row of each event data table.
Time	The hour (H), minute (M), and second (S) that the rep started, displayed according to the current language preference. <i>For example, in US English, the format is HH:MM:SS AM/PM</i> .
Target (kPa)	The minimum pressure that is necessary to illuminate the top green light of the LED array for each rep.
Rep Max (kPa)	The greatest bulb pressure recorded during the rep. If the pressure exceeds 100 kPa, the pressure is reported as '>100.'
Success	An indication of whether the bulb pressure reached the target or not. A checkmark indicates successfully meeting or exceeding the target while an 'X' indicates failing to meet the target.
Target	The amount of time the green light was illuminated, which means that the pressure exerted on the bulb during the rep was greater than or equal to the target, for each rep.
Duration (sec)	Note: The timing for this measurement continues if the pressure briefly drops below the green light, allowing for patients to recover and return to the green light. The timer stops if the pressure drops to the top amber light for more than 2 seconds.

TARGET CHART TAB

This tab, when selected, displays a bar chart of the set data from the Target Data tab as shown in Appendix A, Figure A4. The title of the chart identifies both the dates over which the displayed data was recorded and the bulb location that was assigned. The chart can show up to eight sets. Additional sets can be viewed by using the scroll bar on the x-axis of the chart or by using the mouse to grab and drag the chart to the left or to the right.

For each exercise set, the height of the bar represents the total attempted reps. Within each bar, the lower green area represents the number of successful reps and the upper gray area represents the number of failed reps. The successful and failed rep numeric counts for each bar can be viewed by hovering over the bar of interest.

Under each bar, the following set information is provided:

Set number Success ratio Success percentage (%) Average Duration (sec) Target (kPa) Date Time

NOTES TAB

This tab, when selected, provides a place for you to enter any notes you may have on the patient and/or the session(s) specific to the current bulb location as shown in Appendix A, Figure A5.

Filtering Data

When using an IOPI[®] Pro, displayed data in the Peak and Target tabs can be restricted to specific data files to allow focused viewing. This feature is not available for IOPI[®] Trainer data.

Select the Filter [\clubsuit] button on the button bar. Use the checkboxes on the resulting window (see Figure 4) to select the specific index number(s) you would like to view. See the Downloading Data section of this manual to assign Default Bulb Location(s) and/or New Bulb Location(s), or to use a Location Mapping File.

Event Index	Filtering	Filter the indices to b	e disp	layed and/or edit their to	ngue bulb locatio	ns.		
Select	Index	Bulb Location		Start Time	Peak Events	Target Events		Patient ID 5000000B
1	100	Anterior Tongue	•	2/12/2018 1:23 PM	3	41	*	
✓	101	Posterior Tongue	•	2/12/2018 1:27 PM	3	37		Default Bulb Location
	102	-	•	2/13/2018 1:30 PM	3	27		Anterior Tongue 🔹
	103		•	2/13/2018 1:31 PM	0	29		
1	104	Anterior Tongue	•	2/15/2018 1:33 PM	0	36		New Bulb Location
V	105	Posterior Tongue	-	2/15/2018 1:34 PM	0	38		
	106		•	2/15/2018 1:35 PM	3	35		Add
	107		•	2/16/2018 10:21 AM	5	37		
	108		•	2/16/2018 10:21 AM	3	0		Location Mapping File
<	109	Anterior Tongue	•	2/19/2018 1:41 PM	3	36		
	110		•	2/19/2018 1:43 PM	3	0		
							*	Save OK Cancel

Figure 4. Filter window for an IOPI® Pro with sample data.

Once you have selected the desired index numbers, select 'OK' to filter your data. If you decide that you do not want to filter the data, select either 'Cancel' or the red 'X' in the top right corner to close the window. To restore filtered data, select the Filter []] button again, select the Select All checkbox at the top of the checkbox column, and then select 'OK.'

Saving Reports

To save a report, press the Report []] button on the button bar and select either PDF document or Word document from the File Type dropdown menu in the resulting window (see Figure 5). The File name field contains an automatically generated file name starting with the directory (specified in Preferences) and followed by XX_YYMMDD_HHMMSS_IOPI_DEVICE_REPORT, where XX is the Patient ID, YYMMDD is the date, HHMMSS is the time that the Report button was selected, and DEVICE is either PRO or TRAINER. If you would prefer a different directory and/or file name, enter it into the File name field or select Browse. If you would like to copy the file name to the clipboard, open the file after it is created, include event data in your report, or include empty

IOPI® Pro Re	eport					×
IOP	Į	Specify the nar	me of the repo	ort and the typ	e of file to create.	
File Type:	PDF PD	document 🔹				
File name:					Browse	
D:\IOPI\500	0000B\500	0000B_180222_083	3504_IOPI_PR	D_REPORT.pdf		
Copy file	name to cli	pboard				
Open file	after it is ci	eated				
V Include ev	/ent data (l	lote: ALL events w	ill be included	d)		
Include er	mpty summ	ary pages				
				ОК	Cancel	

summary pages in your report, select the appropriate checkbox. Select 'OK' to save and view the report. If at any point you decide that you do not want to save the report, select either 'Cancel' or the red 'X' in the top right corner to close the window.

Figure 5. Report window for an IOPI® Pro.

Exporting Report Data

To export report data, press the Report []] button on the button bar and select either Excel workbook, comma-separated, or tab-separated file from the File Type dropdown menu in the resulting window (see Figure 5). The File name field contains an automatically generated file name starting with the directory (specified in Preferences) and followed by XX_YYMMDD_HHMMSS_IOPI_ DEVICE_REPORT, where XX is the Patient ID, YYMMDD is the date, HHMMSS is the time that the Report button was selected, and DEVICE is either PRO or TRAINER. If you would prefer a different directory and/or file name, enter it into the File name field or select Browse. If you would like to copy the file name to the clipboard, open the file after it is created, include event data in your export, or include empty summary pages in your report, select the appropriate checkbox. Select 'OK' to export the report data. If at any point you decide that you do not want to export the report data, select either 'Cancel' or the red 'X' in the top right corner to close the window.

NOTE: Date data in comma-separated or tab-separated files are exported as MM/DD/YYYY. If the computer opening the file has different regional settings, the computer may interpret and reformat the date data per the regional settings. For example, an event recorded on July 1, 2022 (exported as 07/01/2022), will be interpreted as January 7, 2022, when the computer's regional settings are DD/MM/YYYY.

Viewing Patient Files

Saved patient files (which include reports, exported report data, and location mapping files) can be viewed by manually accessing the patient file directory or by selecting the Patient Files [], button on the button bar.

Viewing User Manual

The user manual can be viewed by selecting the User Manual [[1]] button on the button bar.

Closing The Program

To exit the program, select the red 'X' in the top right corner of the main IOPI[®] Report Generator window. Any data that has not been saved as a report or exported will need to be downloaded again in order to be viewed.

NOTE: Once the data is cleared from the device, it cannot be downloaded into IOPI® Report Generator. Only the generated reports/exported data can be viewed.

Technical Specifications

APPLICATION	
Indications for use	IOPI® Report Generator software is an accessory approved for use with the IOPI® Model 3.1 (Pro) and/or the Model 3.2 (Trainer), which are medical devices that measure, evaluate, and increase the strength and endurance of the tongue and lip in patients with oral motor disorders, including dysphagia, dysarthria, and obstructive sleep apnea. This software provides healthcare professionals with a report of device usage to allow them to document and analyze patient progress and usage. This software is intended for clinical use only.
MANUFACTURER	
	IOPI[®] Medical LLC 18500 156th Ave NE, STE 104, Woodinville, WA 98072 U.S.A. Tel: +1 (425) 549-0139
AUSTRALIAN SPONSOR	
	EMERGO AUSTRALIA Level 20 Tower II, Darling Park, 201 Sussex Street Sydney, NSW 2000 Australia
EU AUTHORIZED REPRESEN	TATIVE
EC REP	EMERGO EUROPE Westervoortsedijk 60 6827 AT Arnhem The Netherlands
UK RESPONSIBLE PERSON	
	SEVERN HEALTHCARE TECHNOLOGIES LTD. 42 Kingfisher Court, Hambridge Rd. Newbury, Berkshire RG14 5SJ United Kingdom

Please report any serious incident that has occurred in relation to IOPI[®] Report Generator to the manufacturer (IOPI Medical) and the authority having jurisdiction in the locale in which the user is established.

APPENDIX A: User Interface Images

IOPI [®] Report Generator (v1.0.1.0) C	Connected to Devi	e: IOPI31000239 (fw	v 804-3002-04 (v6.4))) Pro			
TODI	e ^o	€	Ŷ			() mm	
MEDICAL	Connect	Download	Filter	Report	Patient Files	User Manual	
😰 Summary 🚵 Peak Data	Target I	Data 📶 Targe	t Chart No	otes			
Summary D	Data						
Patient ID				50000	000B		
Current Bulb Location	n	Ar	nterior Tongue		•		
Peak Mode Data							
Maximum Pressure (kP	'a)				24.3		
Target Mode Data							
Average # Sets/Day					3.0		
Total # Days					3		
Total # Sets					9		
Total Attempted Reps					113		
Total Successful Rep	os				90		
Total Failed Reps					23		
Average Success Percer	ntage per Set				80%		
Average Success Duration	ion (sec)				0.4		

Figure A1. Summary Tab with sample IOPI® Pro data.



Figure A2. Peak Data Tab with sample IOPI® Pro data.

APPENDIX A: User Interface Images

IOI	T		P	€		Ŷ				(ii)					
MEDICA			Connect	Download	F	filter	Report		Patient Files	User Manual					
Summary	🏊 Pea	k Data	Target D	ata 🔟 T	arget Char	t 📃 N	otes								
		Targ	et Set Dat	a (Anteri	or Ton	gue)				Tar	get Eve	nt Data			
Select	Index	Set	Date	Time	Target (kPa)	Avg Dur (sec)	Success/Total Reps (%)		Set:Rep	Time	Target (kPa)	Rep Max (kPa)	Success	Target Duration (sec)	
√	100	1	2/12/2018	1:24 PM	13	1.0	10/14 (71%)	~	⊿ Set: 1					Reps: 14	Â
1	100	-	2/12/2018	1:25 PM	13	0.3	10/14 (71%)		1:1	1:24:41 PM	13	13.9	~	1.02	1
	104	4	2/15/2018	1-33 PM	17	0.2	10/11 (90%)		1:2	1:24:44 PM	13	13.9	~	0.96	U
	104	5	2/15/2018	1:33 PM	17	0.3	10/12 (83%)		1:3	1:24:47 PM	13	8.7	×	0	
	104	6	2/15/2018	1:33 PM	17	0.4	10/13 (76%)		1:4	1:24:50 PM	13	13.8	~	0.6	
V	109	7	2/19/2018	1:42 PM	19	0.2	10/11 (90%)		1:5	1:24:55 PM	13	13.7	~	1.92	
	109	8	2/19/2018	1:42 PM	19	0.3	10/12 (83%)		1:6	1:24:58 PM	13	14.2	~	1.06	
V	109	9	2/19/2018	1:42 PM	19	0.2	10/13 (76%)		1:7	1:25:02 PM	13	13.9	~	1.64	
-									1:8	1:25:04 PM	13	13.6	\checkmark	0.76	
									1:9	1:25:07 PM	13	11.1	×	0	
									1:10	1:25:09 PM	13	9.1	×	0	
									1:11	1:25:13 PM	13	13.0	~	0.31	
									1:12	1:25:18 PM	13	13.8	~	1.3/	
									1:13	1:25:20 PM	13	9.4	×	0	
									1:14	1.25:22 PM	13	13.5	~	0.41 Repr: 12	
									= 366.2					webs: 13	11

Figure A3. Target Data Tab with sample IOPI® Pro data.



Figure A4. Target Chart Tab with sample IOPI® Pro data.

IOPI® Report Generator (v1.0.1.0)	Connected to Devi	e: IOPI31000239 (fw	804-3002-04 (v6.4))) Pro			-
TODI	P	ŧ	\$		3		
MEDICAL	Connect	Download	Filter	Report	Patient Files	User Manual	
😰 Summary 🚵 Peak Da	ata 🎯 Target	Data 📶 Target	Chart No	tes			
		Notes (Ante	rior Tongue)			

Figure A5. Notes tab.

APPENDIX B: Index Numbers On The IOPI[®] Pro

When using an IOPI® Pro, a three-digit index number ranging from 100-999 is displayed for three seconds when powered on. Index numbers are used to identify stored data files, and they increment when the device is powered on if data was stored in the previous session. The user must know which index number(s) correspond(s) to the data they wish to download. The user can select more than one index number to download at a time, and they do not need to be in sequence. For example, if the index numbers relating to data from Patient A are 103, 107, and 111, these three index numbers may be selected for download. Note that the data included in the report reflects the integrity of the data downloaded. If, for example, the first few events recorded in Index 103 were not actual exercise repetitions but rather the healthcare professional demonstrating how the device works, then this non-patient data will be included not only in the raw data but it will affect the summary values displayed on the Summary Tab.

The index numbers can be used creatively so that they are useful to you. For example, if you would like to have the patient practice with the positioning of the Tongue Bulb but do not want this data to be part of his or her report, when you are ready to start data collection simply turn the IOPI[®] Pro off and then on again and a new index number will be assigned; you would only select the new index number when downloading data for the patient report.

You could also use different index numbers to group different tasks. Perhaps you want to have the patient perform exercises of both the anterior and posterior tongue. If you turn the device off and on between bulb locations, then the data for each location will have its own index number associated with it. For example, the following table (Table B1) shows a possible log of the index numbers related to a particular patient, along with the location of the bulb and the associated task. To generate a report about the anterior tongue, you would select index numbers 103, 107, and 111. To generate a report about the posterior tongue, you would select index numbers 105, 108, and 112.

Table B1. Sample IOPI[®] Pro index number log.

INDEX #	LOCATION	TASKS
103	Anterior Tongue	Peak Mode: 3 Pmax, Target Mode: Target @ 60%, 3 sets of 10 reps
105	Posterior Tongue	Peak Mode: 3 Pmax, Target Mode: Target @ 60%, 3 sets of 10 reps
107	Anterior Tongue	Peak Mode: 3 Pmax, Target Mode: Target @ 60%, 3 sets of 10 reps
108	Posterior Tongue	Peak Mode: 3 Pmax, Target Mode: Target @ 60%, 3 sets of 10 reps
111	Anterior Tongue	Peak Mode: 3 Pmax, Target Mode: Target @ 80%, 3 sets of 10 reps
112	Posterior Tongue	Peak Mode: 3 Pmax, Target Mode: Target @ 80%, 3 sets of 10 reps

As long as you do not erase the data from the IOPI® Pro unit, you can continue to log the index numbers associated with the locations/tasks and use saved bulb location assignments from a location mapping file so that you can easily create reports over longer periods of time. Once you erase a data file from the device, however, you will only be able to view the data via a previously saved or exported report.

Please note that the IOPI® Trainer is intended to be used with one patient at a time performing one exercise protocol. It stores all events in a single data file, and thus there are no index numbers displayed on the device. All the stored data will download as one file. It is advised to clear the memory before using the IOPI® Trainer for a different exercise or with a new patient. If a patient is assigned to perform multiple tasks on the IOPI® Trainer for one continuous session, then the values displayed on the Summary Tab will not reflect accurate information about any of the tasks. The downloaded event data may still be valuable to the clinician if it is viewed on the Target Data Tab and filtered and/ or exported and segregated manually.



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