MACRODUCT®
ADVANCED

MODEL 3710 SYS

USER'S MANUAL

Sweat Collection System

ELITechGroup

MACRODUCT® ADVANCED SWEAT COLLECTION SYSTEM

Model 3710 SYS

User's Manual

57-0192-01F (Last update 2024-May-30)

REF

Manufactured in the United States of America by:
ELITechGroup Inc.
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Logan, Utah 84321 USA

CE
2797

The Notified Body number 2797 above signifies that British Standards Institute BSI has certified the Quality System of ELITechGroup Inc., according to Annex IX, Chapter I, II, and III of the Medical Device Regulation 2017/745 (MDR). The scope of the certificates is:

MDR 755196
Devices for non-invasive, non-sterile, iontophoretic transdermal administration of substances and collection of sweat.

MDR 755197
Macroduct Advanced Supply Kit (SS-268, SS-268-ND), Macroduct Supply Kit (SS-032, SS-032-ND)

Certificate MDR 755196 covers the Class IIa devices Macroduct Advanced Model 3710, Macroduct Advanced Electrode Cable Assembly AC-203. Certificate MDR 755197 covers the Class III products Macroduct Advanced Supply Kit (SS-268, SS-268-ND), Macroduct Supply Kit (SS-032, SS-032-ND). Together with the Declaration of Conformity issued by the manufacturer according to Annex IV, this allows the CE marking of these devices. There are no other devices or accessories to which the CE certificates or the BSI Notified Body Number 2797 apply.

Macroduct Advanced Sweat Collector patent number:

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Using This Manual

This manual provides instructions to install, operate, and maintain the Macroduct® Advanced Sweat Collection System. The manual is an important part of the product. Read it carefully and completely before setup and first use of the device. Anyone operating the Macroduct Advanced Sweat Collection System must be thoroughly familiar with the procedures and cautionary information detailed in this manual before attempting to use this equipment.

If additional accident prevention and environmental protection requirements exist in the country of operation, this manual must be supplemented by appropriate instructions to ensure compliance.

Safety Regulations (Macroduct Advanced Model 3710)

Classification

The Macroduct Advanced Model 3710 is classified as Type BF Medical Equipment, Internally Powered.

This device has been built and tested in accordance with safety regulations under EN 60601-1 3.1 edition. In order to maintain this condition and ensure safe operation, the operator must observe all the instructions and warnings contained in this manual. For current information about applicable standards, please refer to the CE Declaration of Conformity included with the documents shipped with this device.

NOTE: *This equipment complies with the following emission and immunity requirements: EN 60601-1-2 and EN 55022/FCC 47 CFR Part 15.*

Specification of Safe Use

Using this device in a manner not specified by ELITechGroup Inc. may impair the safety protection designed into the device and lead to injury. Do not use where flammable anesthetic is present or in any oxygen-enriched environment.

WARNING!
Do not use this equipment if it is not functioning properly.

Statement of Environmental Limits

This device is tested for safe operation at 15 °C to 30 °C, relative humidity ≤ 85%, non-condensing, and atmospheric pressure ≥ 79.5 kPa.

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Understanding Warnings

This manual uses three warning levels to alert the operator to important information as shown in the following examples.

WARNING!
A Warning alerts to the possibility of personal injury, death, or other serious adverse reactions stemming from the use or misuse of this device or its components.

CAUTION:
A Caution alerts to possible problems with the device associated with its use or misuse. Such problems include device malfunction, failure, damage, damage to the sample, or damage to other property. Where applicable, a Caution may include precautions to be taken to avoid the hazard.

NOTE: *A Note reinforces or supplies additional information about a topic.*

Specific Warnings

Pay particular attention to the following safety precautions. If these safety precautions are ignored, personal injury or damage to the device may occur. Each individual precaution is important.

WARNING!
Due to the possibility of an explosion, never attempt iontophoresis on a patient receiving oxygen-enriched respiratory therapy in an enclosed space, such as an oxygen tent (nasal cannula is acceptable). With medical approval, remove the patient from that environment during iontophoresis.

WARNING!
Do not stimulate or collect sweat from the following sites:

- **Head, including forehead (possible burns).**
- **Trunk (current crossing heart).**
- **Any area of inflammation (e.g. eczema or rash); serous or bloody discharge (contamination).**

WARNING!
Do not use over areas with metal plates/pins.

WARNING!
Never attempt to reuse single use components/accessories.

WARNING!
Do not use electrodes or pilogel discs that have been altered or appear damaged.

WARNING!
Consult a physician before performing a test on patients with clinically diagnosed cancer.

WARNING!
Consult a physician before performing a test on patients who have had previous adverse reactions to electrotherapy.

CAUTION:
Collection of sweat should be carried out at a time when the patient is clinically stable, well-hydrated, free of acute illness, and not receiving mineralocorticoids.

CAUTION:
Pilogel discs should be refrigerated at 2 °C to 10 °C. DO NOT FREEZE. Never use discs that have been frozen or that are cracked.

CAUTION:
This equipment has been designed and tested to CISPR 11 Class A and FCC Part 15 Class A. In a domestic environment it may cause radio interference, in which case, the operator may need to take measures to mitigate the interference.

CAUTION:
Only spare parts and accessories supplied or specified by ELITechGroup should be used with this device, including the battery charging power supply and power cord used for charging the device. Using non-approved parts may affect the performance and safety features of the device. If the device is used in a manner not specified by ELITechGroup, the protection provided by the device may be impaired. If in doubt, contact an ELITechGroup representative.

CAUTION:
The USB connection on the device is intended to be used by authorized personnel. For security purposes, it is recommended to execute a virus/malware scan on any USB flash drives or computers prior to making connection. As good practice it is recommended to remove any USB connection prior to performing iontophoresis on a patient.

Contraindications

- Patients with an implanted device, such as a defibrillator, neurostimulator, pacemaker, or ECG monitor.
- Patients with a history of epilepsy or seizures.
- Patients who are pregnant.
- Patients that have a known sensitivity or allergy to any ingredient.
- Over damaged, denuded skin or other recent scar tissue.
- Patients with Cardiac Conditions or with suspected heart problems.

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Functional Description

Macroduct Advanced Sweat Collection System is intended for laboratory use by qualified personnel for stimulation and collection of sweat from humans to assist in the laboratory diagnosis of cystic fibrosis.

The system safely and efficiently accomplishes the stimulation of human sweat through pilocarpine iontophoresis using the Macroduct Advanced Model 3710. The Macroduct Advanced Sweat Collector collects a sample of the stimulated sweat. Markings on the tube indicate if a sufficient sweat rate was achieved during the collection of sweat. The sample can then be analyzed for indications of cystic fibrosis with the Sweat-Chek™ Sweat Conductivity Analyzer using the principle of total electrolyte concentration in the sweat sample, or with the ChloroChek® Chloridometer® using the principle of coulometric titration.

The Macroduct Advanced Sweat Collection System consists of the Macroduct Advanced Model 3710, which is a microprocessor-controlled device powered from a rechargeable lithium-ion battery, battery charging power supply and cord for charging the battery, electrode cable assembly, and a kit of single-use supplies (Pilogel discs and collectors). The Macroduct Advanced Model 3710 automates and controls the sweat collection process used to detect cystic fibrosis. In that sweat collection process, pilocarpine ions are 'pushed' into the sweat glands of the skin by a small electric current (1.5 mA DC) where they stimulate sweat in the same way as the chemicals released by the brain to control body heat through sweating on a hot day. After sweating has been stimulated in a particular area, the electrodes are removed and the skin is cleaned. A plastic Macroduct Advanced Sweat Collector is strapped to the stimulated area so that the emerging sweat is directed into plastic tubing coiled on the surface of the collector. The pure sweat collected in this tubing may be analyzed by methods that are compatible with the sample volume.

Clinical Benefits

- The Macroduct Advanced Sweat Collection System is able to consistently collect adequate volumes of native sweat samples for analysis.

Indications for Use

- Health care providers who wish to collect sweat for the diagnosis of cystic fibrosis (CF).
- Patients who may exhibit clinical symptoms of CF.
- Known CF gene carriers.

Target Population

The Macroduct Advanced Sweat Collection System is meant to be used for providing the sweat test sample, which thereafter is tested in support of the diagnosis of Cystic Fibrosis, in people.

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Key Features

- Step-by-step instructions for the sweat stimulation and sweat collection processes.
- Easily attached electrodes and collector.
- Profiled electrical current to reduce patient discomfort during sweat stimulation.
- Automatic logging of important data during the iontophoresis and sweat collection process.
- Continuously monitors iontophoresis current to maximize patient safety.
- Elliptical-shaped collector, Pilogel discs, and electrodes to better fit small arms (neonate and toddler-sized arms).
- Complete patient mobility during sweat collection.
- Easily confirmed sweat rate and total sweat yield gauged by the operator.
- Uncompromised sweat specimen.
- Air-free collector prevents condensate error.
- Negligible (≤ 0.1 microliters per hour) sweat evaporation rate.
- Exportable log files using a micro USB connector.

Intended Use

The Macroduct Advanced Model 3710 Sweat Collection System is intended only for clinical laboratory use by qualified medical personnel for stimulation and collection of sweat from humans for analysis for the diagnosis of cystic fibrosis.

WARNING!
The small nut used as part of the electrode cable connector is a choking hazard if swallowed. Keep out of reach of children.

WARNING!
The electrode cable assembly wires are choking hazard if wrapped around the neck. Keep out of reach of children.

WARNING!
The small non-skid feet used as part of the Macroduct Advanced inducer is a choking hazard if swallowed. Keep out of reach of children.

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Table 1: Explanation of Symbols

SYMBOL	STANDARD REFERENCE	STANDARD TITLE	SYMBOL TITLE	SYMBOL MEANING
	IEC 60601- 1 Reference no. Table D1, Symbol 8 (IEC 60417-5032)	Medical electrical equipment — Part 1: General requirements. for basic safety and essential performance	Alternating current	To indicate on the rating plate that the equipment is suitable for alternating current only; to identify relevant terminals
	ISO 15223-1: 2021 Reference no. 5.1.2	Medical devices — Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements.	Authorized Representative in the European Community/ European Union	Indicates the authorized representative in the European Community / European Union
	MU600_00_016e V3.0	Information Sheet Obligations Economic Operators CH	Swiss Authorized Representative	Indicates the authorized representative in Switzerland
	ISO 15223-1: 2021 Reference no. 5.1.5. (ISO 7000-2492)	Medical devices — Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements.	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified. Synonyms for “batch code” are “lot number”, “lot code” and “batch number”.
	ISO 15223-1:2021 reference no. 5.4.1 (ISO 7010 – W009)	Medical devices — Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements.	Warning; Biological hazard	Bio-contamination warning: Use care when operating upper cooling system and initiation needle.
	ISO 15223-1: 2021 Reference no. 5.1.6. (ISO 7000-2493)	Medical devices — Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements.	Catalogue number	Indicates the manufacturer's catalog number so that the medical device can be identified ISO 15223 Catalogue number ISO 7000 Catalog number
	ISO 15223-1: 2021 Reference no. 5.7.7	Medical devices — Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements.	Medical device	Indicates the item is a medical device
	ISO 15223-1: 2021 Reference no. 5.4.4. (ISO 7000-0434A)	Medical devices — Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements.	Caution	To indicate that caution is necessary when operating the device or control close to where the symbol is placed, or to indicate that the current situation needs operator awareness or operator action in order to avoid undesirable consequences
	EU 2017/745 EU Reference no. ANNEX V	REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/ EEC and 2010/227/EU	CE marking	(43) ‘CE marking of conformity’ or ‘CE marking’ means a marking by which a manufacturer indicates that a device is in conformity with the applicable requirements set out in this Regulation and other applicable Union harmonization legislation providing for its affixing
	ISO 15223-1: 2021 Reference no. 5.5.5. (ISO 7000-0518)	Medical devices — Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements.	Contains sufficient for <n> tests	Indicates the total number of tests that can be performed with the medical device
	ISO 15223-1:2021 Reference no. 5.4.3. (ISO 7000-1641)	Medical devices — Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements.	Consult instructions for use or consult electronic instructions for use	Indicates the need for the user to consult the instructions for use

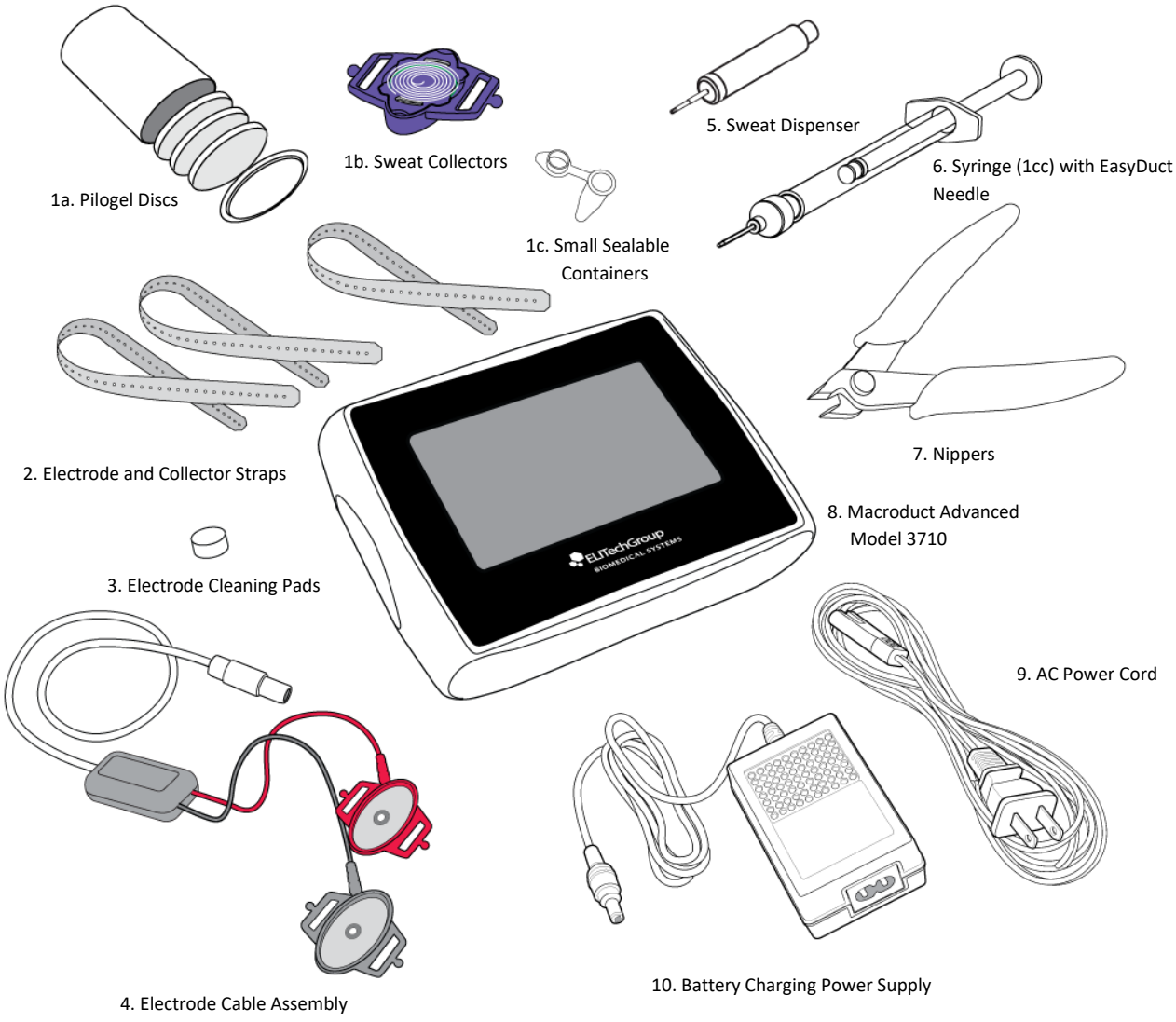
SYMBOL	STANDARD REFERENCE	STANDARD TITLE	SYMBOL TITLE	SYMBOL MEANING
	ISO 15223-1:2021 Reference no. 5.4.2. (ISO 7000- 1051)	Medical devices — Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements.	Do not re-use	Indicates a medical device that is intended for one single use only NOTE: Synonyms for “Do not reuse” are “single use” and “use only once”.
	ISO 15223-1: 2021 Reference no. 5.2.8. (ISO 7000-2606)	Medical devices — Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements.	Do not use if package is damaged and consult instructions for use	Indicates a medical device that should not be used if the package has been damaged or opened and that the user should consult the instructions for use for additional information
	IEC-TR-60878 Reference no. ISO 7000-1135	Graphic symbols for use on electrical equipment in a medical practice	General symbol for recover/recyclable	To indicate that the marked item or its material is part of a recovery or recycling process
	ISO 15223-1: 2021 Reference no. 5.1.1. (ISO 7000-3082)	Medical devices — Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements.	Manufacturer	Indicates the medical device manufacturer
	ISO 15223-1: 2021 Reference no. 5.1.3. (ISO 7000-2497)	Medical devices — Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements.	Date of manufacture	Indicates the date when the medical device was manufactured
	DIRECTIVE 2012/19/ EU (WEEE)	N/A	Collect separately	Separate collection for waste of electrical and electronic equipment. Do not dispose of battery in municipal waste. The symbol indicates separate collection for battery is required
	ISO 15223-1: 2021 Reference no. 5.1.7. (ISO 7000-2498)	Medical devices — Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements.	Serial number	Indicates the manufacturer's serial number so that a specific medical device can be identified
	ISO 15223-1: 2021 Reference no. 5.4.7. (ISO 7000-3702)	Medical devices — Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements.	Contains a medicinal substance	Indicates a medical device that contains or incorporates a medicinal substance
	ISO 15223-1: 2021 Reference no. 5.3.7. (ISO 7000-0632)	Medical devices — Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements.	Temperature limit	Indicates the temperature limits to which the medical device can be safely exposed
	ISO 15223-1: 2021 Reference no. 5.1.4. (ISO 7000-2607)	Medical devices — Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements.	Use by date	Indicates the date after which the medical device is not to be used
	iso_grs_7010_WOO1	Medical devices — Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements.	General warning sign	To signify a general warning
	GHS02	Globally Harmonized System of Classification and Labeling of Chemicals (GHS), Eighth Revised Edition	flammable	Medical device contains materials that are flammable. Appropriate caution should be taken
	GHS03	Globally Harmonized System of Classification and Labeling of Chemicals (GHS), Eighth Revised Edition	Oxidizing	Medical device contains materials that are oxidizing. Appropriate caution should be taken
	GHS05	Globally Harmonized System of Classification and Labeling of Chemicals (GHS), Eighth Revised Edition	Corrosive	Medical device contains materials that are corrosive. Appropriate caution should be taken
	GHS06	Globally Harmonized System of Classification and Labeling of Chemicals (GHS), Eighth Revised Edition	Toxic	Medical device contains materials that are toxic. Appropriate caution should be taken

SYMBOL	STANDARD REFERENCE	STANDARD TITLE	SYMBOL TITLE	SYMBOL MEANING
	GHS07	Globally Harmonized System of Classification and Labeling of Chemicals (GHS), Eighth Revised Edition	Harmful	Medical device contains materials that are harmful. Appropriate caution should be taken
	GHS08	Globally Harmonized System of Classification and Labeling of Chemicals (GHS), Eighth Revised Edition	Health Hazard	Medical device contains materials that are a health hazard. Appropriate caution should be taken
	GHS09	Globally Harmonized System of Classification and Labeling of Chemicals (GHS), Eighth Revised Edition	Environmental Hazard	Medical device contains materials that are an environmental hazard. Appropriate caution should be taken
	N/A	Administrative Measure on the Control of Pollution Caused by Electronic Information Products (China)	Environment Friendly Use Period	Indicates the period of time before any RoHS substances are likely to leak out causing harm to the environment.
	ISO 15223-1: 2021 Reference no. 5.3.8. (ISO 7000-2620)	Medical devices — Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements.	Humidity limitation	Indicates the range of humidity t which the medical device can be safely exposed
	IEC 60601-1, Table D.1, Symbol 20	Medical electrical equipment, Part 1: General requirements for basic safety and essential performance	Type BF applied part	To identify a type BF applied part complying with IEC 60601-1.
	ISO 15223-1: 2021 Reference no. 5.4.1 (ISO 7000-0659)	Medical devices — Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements.	Biological risks	Indicates that there are potential biological risks associated with the medical device
	IEC 60601-1, Table D.2, Symbol 10	Medical electrical equipment, Part 1: General requirements for basic safety and essential performance	Follow instructions for use	Refer to instruction manual/booklet.
	IEC 60417:2002 (60417-5010)	Graphical Symbols For Use On Equipment	"ON"/"OFF" (push-push)	To indicate connection to or disconnection from the mains, at least for mains switches or their positions, and all those cases where safety is involved. Each position, "ON" or "OFF", is a stable position.
	IEC 60417:2002 (60417-5926)	Graphical Symbols For Use On Equipment	Polarity of d.c. power connector	To identify the positive and negative connections (the polarity) of a d.c. power supply, or the positive and negative connections on a piece of equipment to which a d.c. power supply may be connected.
	ISO 7000:2019 (7000-3650)	Graphical symbols for use on equipment — Registered symbols	Universal Serial Bus (USB), port/plug	To identify a port or plug as meeting the generic requirements of the Universal Serial Bus (USB). To indicate that the device is plugged into a USB port or is compatible with a USB port.

SECTION 1: INTRODUCTION

1.2 Device Description

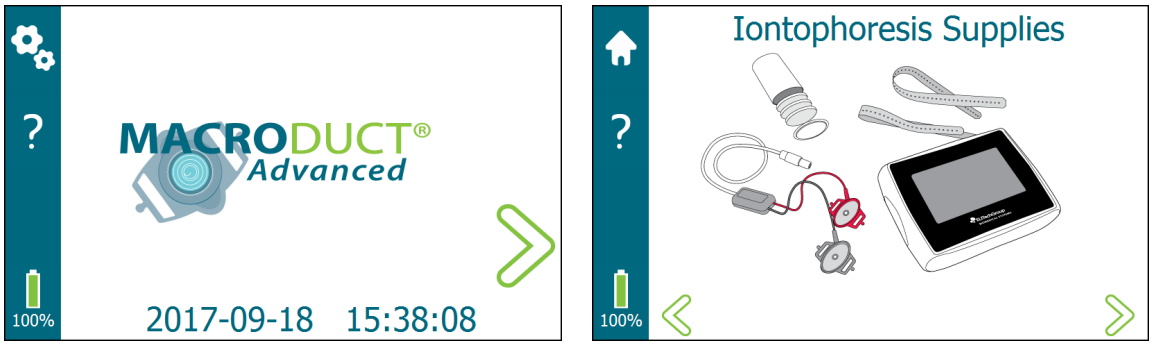
Figure 1: System Components



The following are included in the carrying case:

1. Macroduct Advanced Supply Kit for 6 Sweat Tests (SS-268)
   - 1a. Pilogel Discs (12)
   - 1b. Macroduct Advanced Sweat Collectors (6)
   - 1c. Small Sealable Containers (6)
2. Straps for electrode and collector, set of 18 (SS-269)
3. Electrode Cleaning Pads, package of 10 (SS-271)
4. Electrode Cable Assembly (AC-203)
5. Sweat Dispenser (RP-065)
6. Syringe (1 cc) with EasyDuct Needle (AC-193)
7 Nippers (RP-066)
8. Macroduct Advanced Model 3710
9. AC Power Cord
10. Battery Charging Power Supply
11. USB Cable (RP-538) (not shown)

Figure 2: Display



Touchscreen

Operator interaction with the graphical user interface occurs though the touchscreen. Tap the active area on the display with a finger to select an icon, menu item, or button. The touchscreen sensitivity allows gloves to be worn during use. To avoid damaging the touchscreen, do not tap it with anything sharp or apply excessive pressure to it with fingertips. Dragging, swiping, and pinching gestures are not used.

Display

The display is divided into functional regions for ease of use.

- A **task bar** is located on the left side of the display. Depending upon the screen, the task bar allows access to Settings, Home, and context-sensitive Help. The battery charge level is displayed in the lower left corner.
- A **screen title region** is located along the top of the display that is used to display the title of the screen or display information relating to the screen.
- **Navigation arrows** are located on the bottom left and right side of the display. Depending upon the screen, these arrows navigate to the next or previous screen or are used to navigate menus and selection lists.
- The remainder of the display is a **graphics/operator input** region where process information is provided along with interaction from the operator when setting device parameters, entering information, and managing processes.

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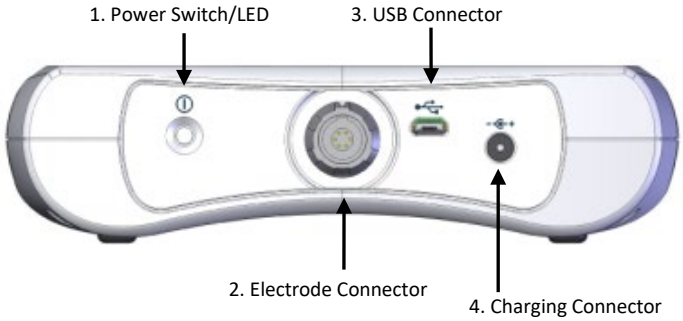
Figure 3: Top Panel



Item	Description
1a. Power Switch	Powers the device ON when held down for 1-2 seconds. Prompts to power off the device when held down for 2-3 seconds. Resets the device when held down for 4-5 seconds.
1b. LED – Green/Amber	The power switch contains a two-color LED used to indicate status. A green LED indicates that the device is powered ON. When the charging power supply is plugged in: A flashing amber LED indicates that the battery is being charged. A solid amber LED indicates that the battery is fully charged.
2. Electrode Connector	The electrode connector is a 6-pin push-pull locking medical connector that mates with the electrode cable assembly.
3. USB Connector	The micro USB connector is used when connecting the device to a computer or USB flash drive.
4. Charging Connector	The battery charging power supply connects to the circular DC power charging connector to charge the battery. When connected, the iontophoresis-related circuits are disabled and access to the user interface is not allowed except for the battery charging screen.

Figure 4: Model/Serial Number Identification label

The following label is located on the back of the device:

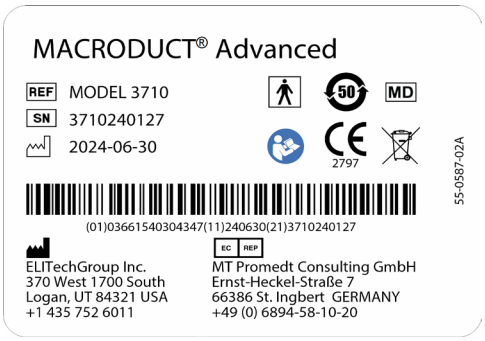
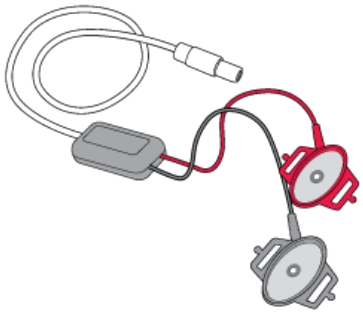


Figure 5: Electrode Cable Assembly



The electrode cable assembly connects to the device at the electrode connector on the top panel.

Both electrodes, one red for the anode (positive) and one black for the cathode (negative), have a stainless-steel disc as the electrode plate. In the center of each electrode is a pin for detecting the Pilogel disc. The electrodes provide current from the device through the Pilogel discs to the patient skin during iontophoresis.

Figure 6: Pilogel Discs

Elliptical Pilogel discs are included in the SS-268 Macroduct Advanced Supply Kit. The discs are approximately 6 mm (0.25 inch) thick and sized to fit snugly into the standard recessed electrodes. They are supplied in a resealable vial containing 12 discs each and are intended for single use (sufficient for six iontophoretic sweat stimulations). Discs are to be used in both positive (red) and negative (black) electrodes (applied parts). Sweat stimulation occurs under the positive (red) electrode, while the negative electrode completes the electrical circuit.

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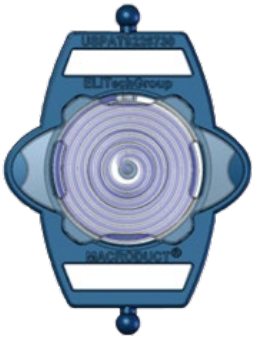
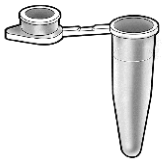
Figure 7: Macroduct Advanced Sweat Collector



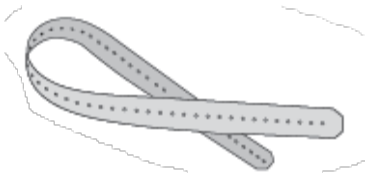
The Macroduct Advanced Sweat collectors are used to collect the sweat after iontophoresis. Six individually packaged collectors are included in the SS-268 Macroduct Advanced Supply Kit and are intended for single use.

Figure 8: Small Sealable Containers



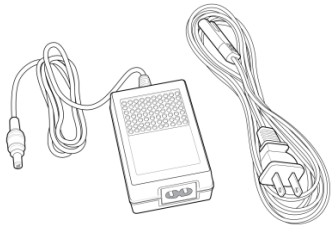
The small sealable containers (200 µL micro-centrifuge tubes) are included in the SS-268 Macroduct Advanced Supply Kit and are used to store sweat samples for up to 72 hours at 2 – 30 °C when properly used. The small sealable containers come packaged in a set of six (enough for six tests) and are intended for single use.

Figure 9: Collector and Electrode Straps



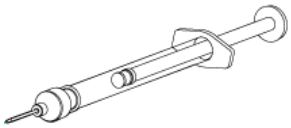
The Macroduct Advanced straps are used to attach the electrodes and collector to a patient (applied part). The straps are disposable or can be re-used (see Section 5.4 for cleaning/disinfecting information) and come packaged in a set of 18 (enough for six tests, one strap for each electrode and one strap for the collector). The straps were designed for ease of use and can accommodate a wide range of limb sizes. The non-allergenic straps are a non-latex thermoplastic elastomer material.

Figure 10: Battery Charging Power Supply and AC Power Cord for Battery Charging



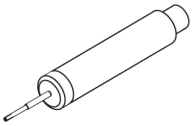
The Macroduct Advanced Sweat Collection System includes a universal input battery charging power supply and AC power cord (120 V cord shown).

Figure 11: EasyDuct Needle with 1 cc Syringe



The syringe and EasyDuct needle are used to harvest a sweat sample. The EasyDuct needle is specially designed for easy insertion into the collector tubing.

Figure 12: Sweat Dispenser

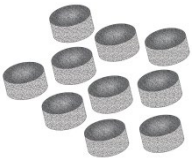


The sweat dispenser is an optional tool used to harvest and store a sweat sample in the small sealable containers. The sweat dispenser uses a reduced-end blunt needle for easy insertion into the collector tubing.

Figure 13: USB Cable

The USB cable is a 6-foot long USB A Male to USB Micro B Male cable used to interface the Macroduct Advanced Model 3710 to a computer USB port.

Figure 14: Electrode Cleaning Pads



The electrode cleaning pads are packaged in a pack of 10 and are used to clean and buff the electrodes. They are a mild abrasive pad, which provide gentle, yet thorough, cleaning of the electrodes. The pads are sized to easily fit within the electrodes and can be used with a fingertip.

1.3 Touchscreen and Operator Interface

The operator controls all device functions from the interactive touchscreen display.

Table 2: Main Function Icons

Icon	Name	Description
	Home	Returns the operator to the Home screen.
	Help	Accesses context-sensitive help menu.
	Settings	Accesses the Settings screen.
	Battery Indicator	Displays the amount of charge remaining in the battery.
	Battery Low Indicator	Indicates that the battery is low and should be recharged.
	Cancel	Cancels a process or function.
	Forward Arrow	Advances to the next screen.
	Back Arrow	Returns to the previous screen.
	Selected	Shows that the associated option is selected.
	Unselected	Shows that the associated option is not selected.
	Begin	Begins the step-by-step iontophoresis setup procedure from the Home screen.
	Start Iontophoresis	Starts the iontophoresis sweat stimulation process.

Table 2: Main Function Icons (continued)

Icon	Name	Description
	Start Timer	Starts the sweat collection timer.
	Emergency Cancel	Cancels the iontophoresis process.
	Stop	Stops the sweat collection timer.
	Stop Inactive	Indicates the Stop icon is inactive or has already been pressed to stop the timer.
	Exit	Exits from a process.
	Sufficient Sweat Rate	Indicates that the sweat rate was sufficient (operator selected).
	Indeterminate Sweat Rate	Indicates that the sweat rate was indeterminate (operator selected). The sweat sample must be measured by another means, such as a balance or scale.
	Insufficient Sweat Rate	Indicates that the sweat rate was not sufficient (operator selected).

1.3 Touchscreen and Operator Interface

Table 3: Settings Icons

Icon	Name	Description
	System	Accesses the System screen. Provides access to functional tests and summary logs.
	Date/Time	Accesses the Date/Time screen.
	Power Management	Accesses the Power Management screen and Battery Calibration selection.
	Language	Accesses the Language screen. Available languages include English, French, German, Italian, Portuguese, and Spanish.
	Options	Accesses the Options screen.
	System Information	Accesses the System Information screen. Provides device specific information including the model, serial number, and software version(s).
	Calendar	Indicates the set date function when setting the date from the Set Date/Time screen.
	Clock	Indicates the set time function when setting the time from the Set Date/Time screen.
	24 Hour	Indicates the 24-hour time format when viewing the time.
	12 Hour	Indicates the 12-hour time format when viewing the time.

Table 3: Settings Icons (continued)

Icon	Name	Description
	Up or Increase	Moves up though a pick list or selection, or increases a value.
	Down or Decrease	Moves down though a pick list or selection, or decreases a value.
	Slider Bar	Sets the brightness of the display.
	Progress Indicator	Indicates that a process is in progress (i.e. battery calibration discharge). The icon rotates giving an indication that the process is active.

Table 4: Keyboard/Keypad Keys

Key	Name	Description
	Backspace/Delete	Deletes or backspaces over last-typed data.
	Enter	Enters typed data.
	Exit	Exits without saving the entry.
	Upper/Lower case toggle	Switches back and forth between the upper and lower-case keyboard.

1.4 Macroduct Advanced Model 3710

The Macroduct Advanced Model 3710 is an integral part of the Macroduct Advanced Sweat Collection System. Its design is based on years of clinical experience, research, and product development, with patient safety and comfort given paramount importance. It is a fully automatic device featuring advanced electronic circuitry and many fail-safe and operator convenience features.

How It Works

After tapping from the Home screen, the operator is prompted though a step-by-step iontophoresis procedure. During the procedure, the operator may enter operator, test, and kit LOT information and the location where the electrodes attach to the patient. Before iontophoresis can begin, a number of checks are automatically conducted by the Macroduct Advanced. These checks include ensuring the iontophoresis circuitry is working correctly, the proper electrode is connected to the device, and each electrode contains a Pilogel disc.

When all of the safety conditions have been met, iontophoretic current increases to 1.5 mA during an approximate 20-second interval, remains at 1.5 mA for approximately 5 minutes, then decreases in the final 5 seconds to zero. This ramping of iontophoretic current prevents the sensation of electrical shock that results when current changes abruptly.

Normal iontophoresis takes approximately 5½ minutes. The operator should remain with the patient during iontophoresis.

When iontophoresis has been completed, the operator is prompted though a step-by-step procedure to prepare for sweat collection. After the collector has been attached and sweat can be seen in the center of the collector tubing, or within four minutes, the operator starts the collection timer. Sweat collection should continue for 30 minutes or until the collector tubing is full (whichever comes first), at which time the operator stops the timer. The operator is prompted though a step-by-step procedure which includes determining if the sweat rate is sufficient, removing the collector, and completing the sweat collection process.

Error Conditions

When an error condition occurs, a pop-up message displays the error code and a brief description of the error. Refer to Section 5.1 Troubleshooting, for further details.

Following are examples of error messages:

Battery Charge Level Indicator

The Macroduct Advanced displays a battery indicator that shows the charge level of the battery (green bar inside the battery icon). The higher the green bar, the greater the battery charge level. When the battery charge level is low, the green bar turns to red, indicating the battery should be recharged.

Electrodes

The high-grade stainless steel electrodes require only minimal maintenance. This consists of cleaning the electrodes with isopropyl alcohol after each use so they will be ready for the next procedure. It is recommended to buff them with the electrode cleaning pads (REF: SS-271) with the use of each new Macroduct Advanced Supply Kit (REF: SS-268), or approximately every six tests (See Section 5.2). Electrode cable assembly lead wires should be periodically inspected for breaks or cracks in the insulation. If electrode wires, insulation, or the plastic electrode housing exhibit cracks or breaks, the entire electrode cable assembly should be replaced.

1.5 Pilogel Iontophoretic Discs

Pilogel iontophoretic discs were developed specifically to efficiently transport pilocarpine ions while maintaining a moist skin interface. See Appendix A: Pilogel Information.

WARNING!
Pilogel is considered harmful. Do not ingest. Consult the SDS sheet for more information.

Efficient Sweat Production

Reliable, uniform, gel-to-skin contact ensures delivery of pilocarpine over the whole skin area, thus providing total gland stimulation and maximal sweat yield.

Despite being mostly water and presenting a "wet" surface to the skin, Pilogel discs do not exude fluid even under the pressure applied during limb attachment. This generally avoids the problem of "bridging" between electrodes. Gel-fitted electrodes may be placed in close proximity without risking a short circuit, a great advantage when dealing with neonates.

Pilogel eliminates the need to apply gauze or paper pads. The discs are immediately ready for use.

Ensuring Patient Safety

The Macroduct Advanced 3710 system performs the sweat test using an established, safe, and effective process.

Pilogel discs provide an air-free continuous conduction medium and even distribution of current over the stimulated skin area, reducing the possibility of minor electrical burns to the skin.

The Pilogel disc fits snugly into the recess of the electrode, preventing disc separation from the electrode. This virtually eliminates any possibility of a minor skin burn from direct metal-to-skin contact.

Burns During Iontophoresis

The Macroduct Advanced Sweat Collection System has become the most frequently used system in hospitals and clinics worldwide.

While the Macroduct Advanced system is clearly superior to previous methods, minor burns during iontophoresis have not been totally eliminated. Based on reports from practitioners using the Macroduct 3700 and the Macroduct Advanced 3710, less than one burn in 50,000 iontophoretic procedures is estimated.

Burn descriptions vary from “tiny black pinholes in the skin” to “crater-like, third degree burns two to three millimeters in diameter.” In most of the reported cases the patients exhibited no sign of pain or discomfort during iontophoresis, and the burn was not discovered until the electrodes were removed.

If the procedures outlined in the manual are followed correctly, burns should be extremely rare.

We strongly recommend the following burn prevention procedures:

- Discard Pilogel discs that have an unusual appearance or appear damaged (fractures, discs that do not fit properly in the electrode, etc.).
- Electrode strap pressure should promote firm contact between the skin and the Pilogel disc. Straps should not be tight enough to crush the disc between skin and electrode, or cut off the patient's blood circulation.
- Leave skin slightly wet after washing the area where the electrode will be attached.

  (Or)

- Add a drop of deionized water to either the skin or the Pilogel surface (after installation in the electrode).

If a minor burn does occur, it should be evaluated by a qualified medical professional and treated appropriately. The operator of the system should report all burns to ELITechGroup immediately and should be prepared to have a qualified professional provide specific information to determine whether the event is reportable to the FDA and other regulatory authorities.

WARNING!
Although these recommendations are designed to prevent burns during iontophoresis, there is no guarantee they will not occur.

1.6 Macroduct Advanced Sweat Collector

The Macroduct Advanced Sweat Collector is a disposable plastic device with a shallow, elliptical concave undersurface that covers the skin area that has been stimulated by pilocarpine iontophoresis. The collection surface is contoured such that when firmly applied to the stimulated area, the skin bulges into the concavity, leaving no air space. At the apex of the conical surface, a tiny orifice leads to a small-bore plastic tube or duct, which is coiled into a spiral.

Sweat becomes visible in the spiral tube of the collector typically within one to four minutes, depending upon the relative elasticity of the skin and the subject's sweating rate.

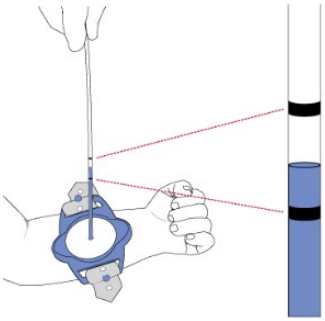
NOTE**:** *Due to possible biological contamination and cross contamination of the sweat sample, the Macroduct Advanced Sweat Collector is a single-use device.*

NOTE**:** *For best results, the stimulated skin area should cover reasonably deep flesh/musculature. Thin skin sections overlaying palpable tendons or bony structures are not suitable as collection sites.*

The emergent sweat is turned blue by contact with a small amount (≤ 10 10^{-9}mol) of blue water-soluble dye (FD&C certified food color) applied to the Macroduct Advanced collector contoured surface during the manufacturing process. This allows easy assessment of the volume produced at any time during collection.

This dye does not interfere with sweat chloride assay by colorimetry, coulometric titration, or sweat conductivity analysis. The dye contributes slightly to the osmolality and sodium content of the sweat sample. Even with a low sweat yield of only 20 µL, this contribution will not exceed 1.5 mmol/kg and is negligible.

The spiral collection tube capacity is approximately 85 µL. This is adequate for average sweat production levels (40 to 60 µL) in 30 minutes of collection. This volume is sufficient for all current methods of sweat analysis (see Notes Regarding Sweat Rate on the following page).



The collector tubing has two black marks printed on the outside surface of the tubing to gauge whether sweat rate is sufficient, based on the 30 minute collection time. Sufficient sweat rate is defined as 1g/m^2/min.

With the tubing extended from the collector (while the collector is still attached to the limb), sweat below the first mark indicates an insufficient sweat rate. Because of the tolerances of the tubing, this mark can represent a maximum of 15 µL and a minimum of 10.4 µL of sweat collected.

Sweat above the second mark indicates a sufficient sweat rate. Because of the tolerances of the tubing, this second mark can represent a maximum of 22.7 µL and a minimum of 15 µL of sweat collected. If the sweat is between the two marks, then it is indeterminate if a sufficient sweat rate has been achieved and another means (e.g. weighing the sweat sample) must be used to confirm sufficient sweat rate. Guidance on how to determine sufficient sweat rate of indeterminate samples can be found in the CLSI Sweat Test protocol[1].

At the end of the collection period, the collector should remain on the limb until the sweat specimen is removed by severing the plastic tube at its attachment point. See complete instructions in Section 3 before attempting this procedure.

1.6 Macroduct Advanced Sweat Collector

Advantages of the Macroduct Advanced Sweat Collector

- By preventing any exposure to air, the collected sweat is not subject to condensate error.
- Sweat evaporation can only occur at the advancing meniscus in the plastic collecting duct. This has been found by measurement to produce a negligible loss of 0.1 µL/h.
- The operator can gauge the amount of sweat produced at any time, a unique and unprecedented feature that eliminates guesswork in deciding the duration of the collection period.
- The patient has complete mobility during the collection period. (The collector can be over-wrapped with an elastic bandage if needed.)
- Collects sweat passively and automatically, driven by the natural hydraulic pressure of the sweat gland to the skin surface.

Notes Regarding Sweat Rate

Official guidelines[1] specify a minimum sweating rate of 1g/m^2/min for a sweat test to be considered valid in the diagnosis of cystic fibrosis. This avoids the possibility of a false negative when a partially functional CFTR ion channel returns chloride and other ions to the body during sweating, but at an abnormally slow rate. The established volume to meet this rate with the Macroduct Advanced is 15 µL within 30 minutes.

1. CLSI Sweat Testing: Specimen Collection and Quantitative Chloride Analysis. 4th ed. CLSI guideline C34. Wayne, PA: Clinical and Laboratory Standards Institute; 2019.

SECTION 2: MACRODUCT ADVANCED SYSTEM SETUP

2.1 Unpacking

1. Before opening the package, inspect it for damage. Contact the shipping or carrier company if any damaged is observed.
2. The Macroduct Advanced Model 3710 and the accessories come neatly packaged in a carrying case. The accessories are stored in a compartment under the device. Carefully unpack and inspect the device and accessories. Check for damage that may have occurred during shipment. Make sure everything is removed from the shipping package. Contact ELITechGroup if any damage to the device or accessories is observed.
3. Check that the contents of the package(s) match the packing list for the device and accessories.

NOTE: *Keep the box and packaging material to repack the device when transporting it to another location or back to the manufacturer for service.*

2.2 Charging the Battery

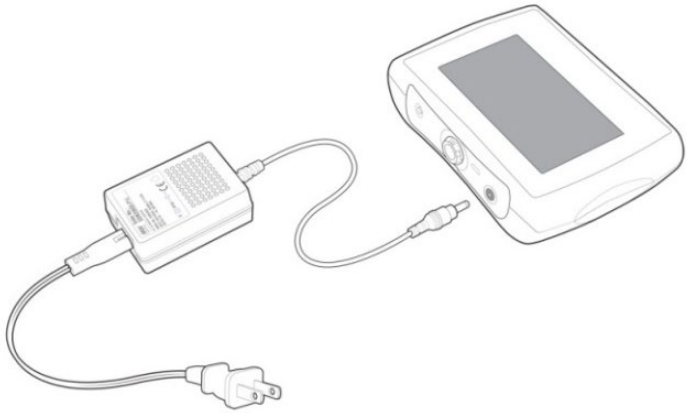
For safety, the device is shipped from the factory with the battery partially charged and in shipping mode. **At first use, the device must be plugged into the battery charging power supply before the device can power on.** Until the battery gets fully charged for the first time, the battery charge level indicators will be inaccurate. Therefore, it is recommended to fully charge the battery until the amber LED stops blinking before operating the device. Charging a completely drained battery takes approximately 4 hours.

NOTE: *When the battery charge is low, charging for approximately 20 minutes should provide enough battery life to run a typical test.*

WARNING!
If the device has been recently subjected to low temperatures below 0 °C or high temperatures above 40 °C, let the device sit at room temperature for two hours before charging the battery.

WARNING!
The electrode cable assembly should not be attached to a patient while the battery is being charged.

CAUTION:
Only use the ELITechGroup provided battery charging power supply and power cord to charge the battery.



1. Connect the AC power cord to the battery charging power supply.
2. Plug the AC power cord into a 100 VAC to 240 VAC power source.
3. Connect the cable from the battery charging power supply into the DC power connector on the Macroduct Advanced top panel.
4. When DC power is connected, the device powers on and runs through an initialization process (unless it is already on). A battery charging screen displays the battery charging icon and the battery charge level for approximately 10 seconds and then the display turns off. To observe the battery charge screen, press the power switch for 1-2 seconds.

2.2 Charging the Battery

5. While charging, the amber LED within the power switch blinks, indicating that the battery is charging. The LED continues to blink until the battery is fully charged.
6. When the battery is fully charged, the unblinking amber LED remains on.
7. Disconnect the battery charging power supply from the device. The Home screen displays. Refer to Section 5.5, Batteries, Charging, and Calibration for additional information.

When connected to power, the iontophoresis related circuitry is disabled for safety purposes and iontophoresis is not possible.

2.3 Powering the Device On/Off

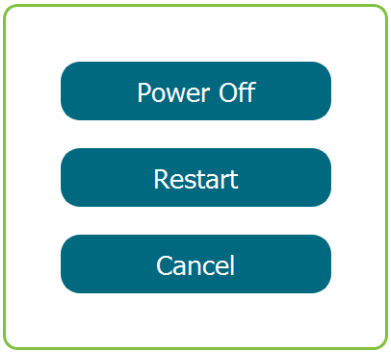
Powering the Device On

Turn the device **On** by pressing and holding down the power switch located on the top panel of the Macroduct Advanced for 1-2 seconds.

The device powers on, turning on the green LED located within the power switch. The device initializes and displays the ELITechGroup logo. A progress bar displays the progress of additional self-tests and the loading of the application.

After initialization, the Home screen appears. Total start-up time is approximately 30 seconds or less.

Powering the Device Off



To power the device **Off**, press and hold the power switch for 2-3 seconds.

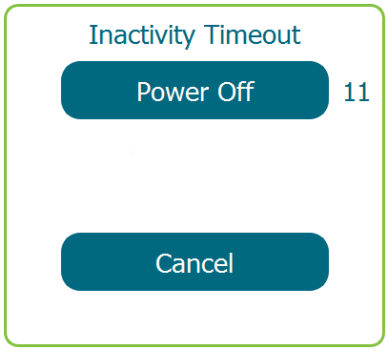
A pop-up window shows three options:

- **Power Off** – performs an orderly power-off process. Tap **Power Off**, a screen displays the power-off progress, the display turns off, the green LED turns off, and the device powers off.
- **Restart** – performs an orderly power-off process and then performs a software restart. Tap **Restart**, a screen displays the power-off progress, the display turns off and the green LED turns off momentarily. The restart process turns the green LED on and continues the normal initialization process.
- **Cancel** – cancels Power Off.

NOTE: *If the power switch is held down for 4-5 seconds, the system resets and the device turns off.*

NOTE: *When the device is off, there is very little power drain. However the battery will eventually run down over several weeks or months.*

2.3 Powering the Device On/Off

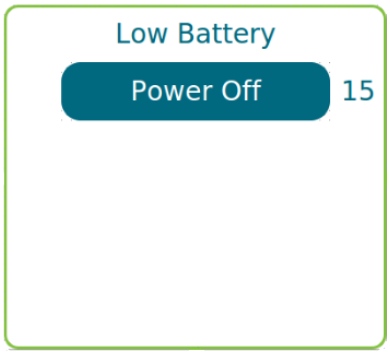


Automatic Power Off – Inactivity Timeout

An automatic power-off process occurs after 15 minutes if there is no operator interaction with the touchscreen (except when the sweat collection timer is running). At that point, a pop-up window shows the Power Off button with a 15-second count down timer and a Cancel button. A beep also sounds every second to notify the operator that the device is about to power off.

- **Power Off** – waiting for 15 seconds or tapping Power Off performs an orderly power-off process. A screen displays the power-off progress, the display turns off, and the device powers off.
- **Cancel** – cancels Power Off.

When Power Save is enabled, the automatic power-off process dims the display after 1.5 minutes of inactivity to conserve power (tap the screen to reactivate the backlight). Later, it turns the display and touchscreen off (press the power switch for 1-2 seconds to reactivate the display and touchscreen), and then powers the device off after 15 minutes of inactivity.



Automatic Power Off – Low Battery

Automatic power-off occurs when the battery reaches a low battery power-off threshold.

When the battery reaches the threshold level, a pop-up window displays a 15-second count down timer. Waiting for 15 seconds or tapping Power Off performs an orderly power-off process. The power-off progress displays until the device powers off.

2.4 Home Screen

The Home screen allows operator access to the settings and context-sensitive help screens, and the step-by-step iontophoresis procedure. The Home screen also displays the battery charge level, the date, and time.

The 100% icon displays the current charge level of the battery.

Tap to access the Settings screen.

Tap ? to access context-sensitive Help screen.

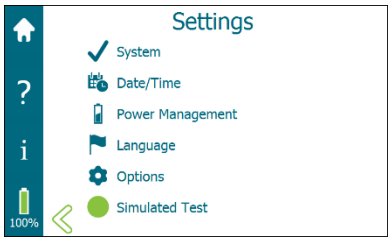
Tap to begin the step-by-step iontophoresis procedure.

SECTION 2: MACRODUCT ADVANCED SYSTEM SETUP

2.5 Settings Screen

The Settings screen is the gateway for most of the user-selectable settings, testing, and other options available with the Macroduct Advanced. The Settings screen is accessed from the Home screen by tapping . Refer to Figure 15: Diagram of the Settings Screen, (on the following page), for a description of the settings and options available under the Settings Screen menu.

Settings Screen



The Settings screen provides access to the following:

- System activities such as functional tests and viewing summary information for recent tests
- Setting the Date/Time
- Selecting Power Management options
- Selecting a Language
- Selecting the Options settings
- Selecting the Simulated Test mode of operation

Tap on the desired settings selection to access a specific screen.

Tap or to return to the Home screen.

Settings Screen Task Bar

The Settings Screen Task Bar provides access to the following:

- Home screen
- Help
- Information
- Battery charge level

Information Screen

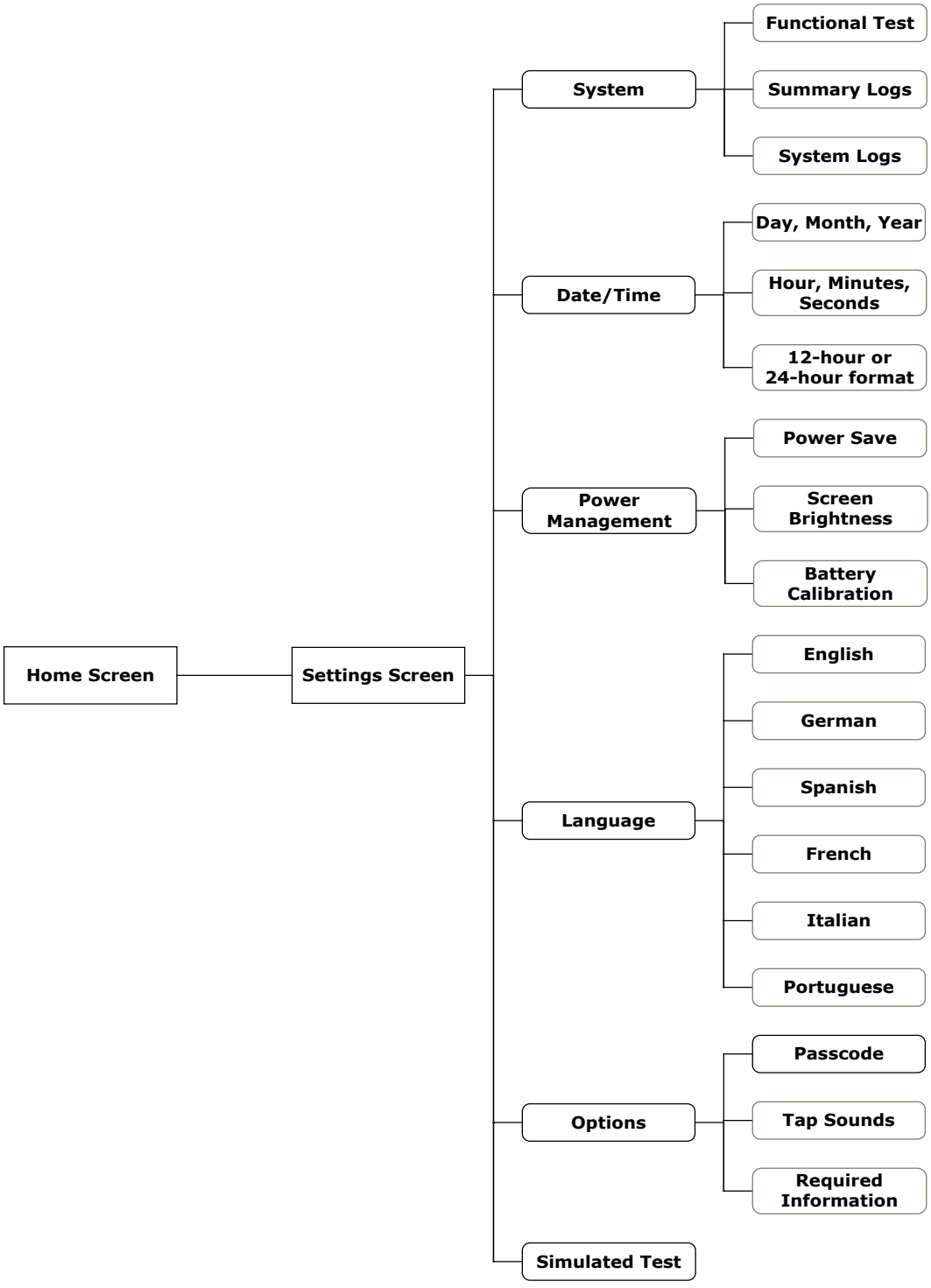
From the Settings screen, tap to access the Information screen. From the Information screen, the operator can view device related information such as: Device Model Number, Serial Number, and Software Version. The Information screen is a view only screen.

Tap to return to the Settings screen.

Tap to return to the Home screen.

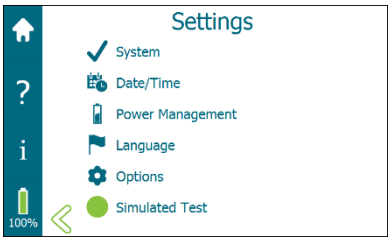
2.5 Settings Screen

Figure 15: Diagram of the Settings Screen



2.5 Settings Screen

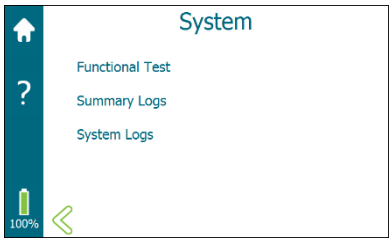
System Screen



Select System from the Settings screen.

From the System screen, the operator can do the following:

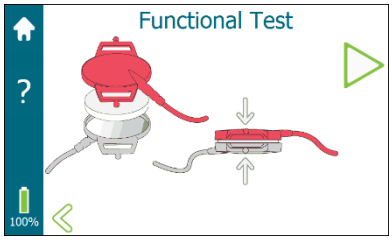
- Perform a Functional Test
- View Summary Logs
- View System Logs



Tap the desired selection to access that particular screen.

Tap to return to the Settings screen.

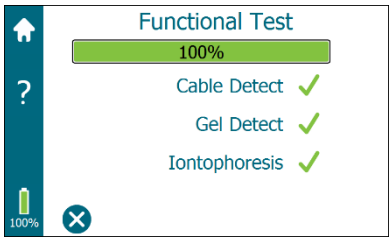
Tap to return to the Home screen.



The Functional Test

The Functional Test combines the testing of the electrode cable assembly with the cable detect circuitry, Pilogel detect circuitry, and iontophoresis circuitry of the device.

See Section 5.1 Troubleshooting for instructions on performing the Functional Test.



SECTION 2: MACRODUCT ADVANCED SYSTEM SETUP

2.5 Settings Screen

Summary Logs

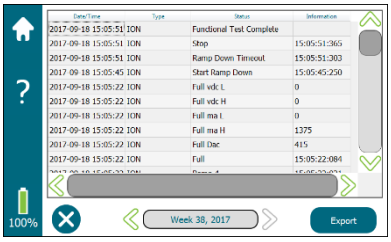
Tap ‹ or › to navigate through the summaries of the 20 most recently performed iontophoresis tests. A summary log will only be created after successfully starting iontophoresis.

The Summary screen displays the following:

- The Operator, Test, and Kit LOT information (grayed out if no entry was made).
- Whether iontophoresis was completed and if there was an error.
- The limb where sweat was collected (based on operator selection).
- Elapsed sweat collection time (based on when the operator started and stopped the sweat collection timer – grayed out if the sweat collection timer was not started).
- The sufficient sweat rate (grayed out if the sweat rate was not selected).
- Date and time of when iontophoresis started.

Tap ⊗ to return to the System screen.

Tap ⌂ to return to the Home screen.



System Logs

System Logs includes device information recorded in addition to the Summary Logs, such as:

- Settings changes
- Iontophoresis current
- Voltage measurements
- Gel-detect measurements and errors

Logs are grouped on a weekly basis.

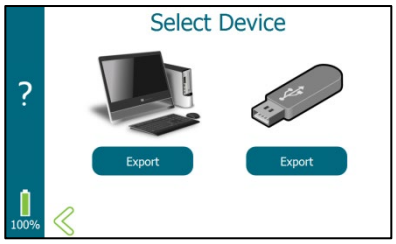
Use navigation arrows to scroll through the logs.

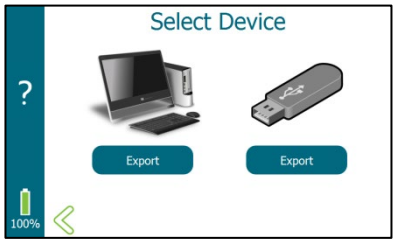
Tap ⊗ to return to the System screen.

Tap ⌂ to return to the Home screen.

Tap Export to export the logs.

2.5 Settings Screen





Select Device

To export the system logs via the micro USB port to the USB drive do the following:

1. Plug a USB drive into the micro USB port on the device.
2. Tap **Export**. 

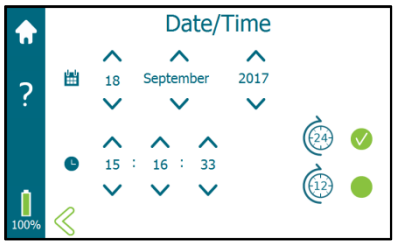
   The System Logs files are exported to the USB drive. After the files are exported, a message prompts that the export has completed.
3. Remove the USB drive from the device.

To export the system logs via the micro USB port to a computer do the following:

1. Plug a USB drive into the micro USB port on the device.
2. Tap **Export** . 

   The System Logs files are shown on a computer as a USB drive. A message prompts that the files are ready to copy when connected to the computer.
3. Copy or View the System Logs files using the computer.
4. Eject the USB drive using the computer.
5. Remove the USB drive from the device.
6. Tap to return to the System screen.

Date/Time Screen



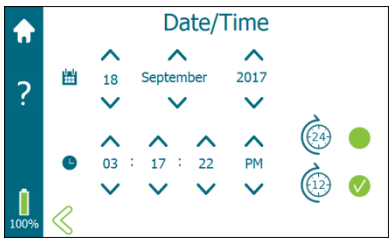
Select Date/Time from the Settings screen.

Tap **Date/Time** to set date and time.

Setting the date:

Set the day, month, and year by tapping ^ or v in the appropriate area.

Setting the hour format:



Tap ● next to the 12-hour or 24-hour format icons to set the format for how the time is displayed. (Default is 24-hour.)

Setting the time:

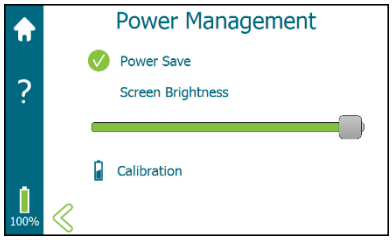
Set the hours, minutes, seconds, and AM/PM (12-hour format only) by tapping ^ or v in the appropriate area.

When finished, tap ⌂ or < to save the date and time settings and return to the Home screen or Settings screen respectively.

Power Management Screen

Select Power Management from the Settings Screen.

Power Save



Select or deselect Power Save by tapping ●.

Power Save selected is the default setting.

With Power Save selected:

After a few minutes of no operator interaction, the device gradually begins to power down. The display dims and eventually turns off.

This process can be reversed by touching the display in the first few minutes, or later by pressing and holding the power switch for several seconds.

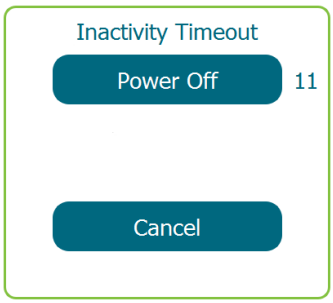
After 15 minutes of no input the device powers down. Press the power switch for a couple seconds to power the device up.

- At the Iontophoresis screen, the display and backlight remain on.
- At the Start Timer screen, the display and backlight remain on.
- At the Collection Time screen, the display eventually dims. The display and touchscreen turn off after 5 minutes. At 28.5 minutes, the display and touchscreen automatically turn on. The operator may also turn the display and touchscreen on by pressing the power switch for 1 to 2 seconds.

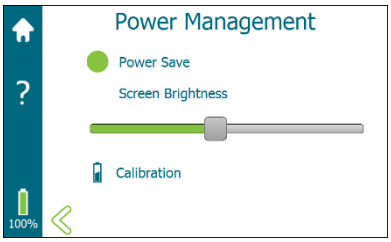
Information continues on the following page

2.5 Settings Screen

Power Management Screen (continued)

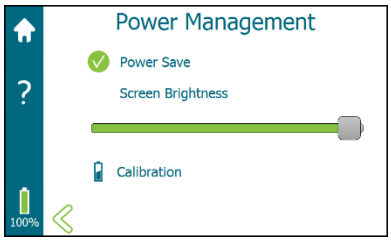


If Power Save is NOT selected, and the operator ignores the Inactivity Timeout warnings, the device powers down.



Screen Brightness

Use the slide bar to adjust the screen brightness. Dimming screen brightness extends the time between battery charges.

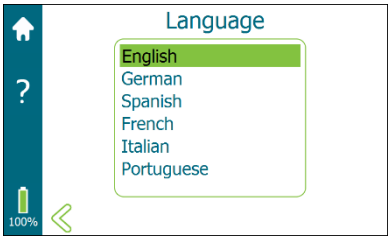


Calibration

Battery Calibration is used to calibrate the battery indicator that displays the percent of battery charge level.
Refer to Section 5.5 for complete information.
When finished, tap  or  to save the power management settings and return to the Home screen or Settings screen respectively.

Language Screen

Select Language from the Settings Screen.



To select a language:

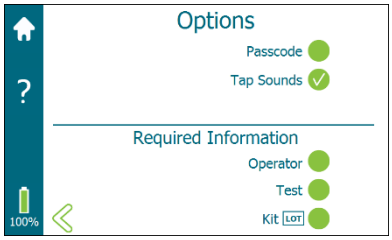
1. Tap  on the Settings screen and then tap the desired language, which highlights the language.
2. Tap  or  to save the selected language and return to the Home screen or Settings screen respectively.

Language selections are shown on the display. The default language is English.

SECTION 2: MACRODUCT ADVANCED SYSTEM SETUP

2.5 Settings Screen

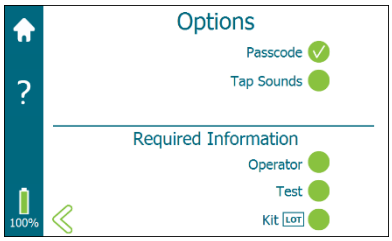
Options Screen

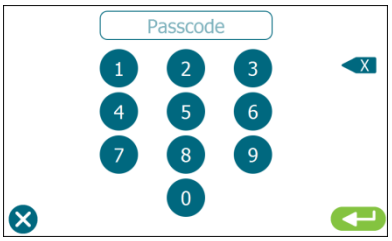


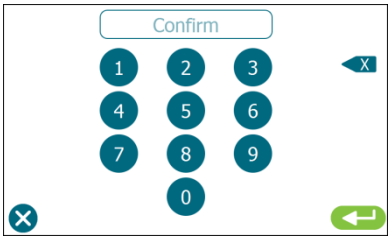
Select Options from the Settings Screen.

The Options screen allows the operator to:

- Set a passcode
- Enable or disable tap sounds
- Define required operator input fields





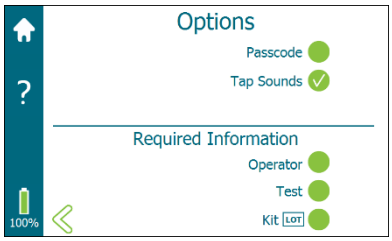


Passcode Setup

1. Tap Passcode ● or ✓ to enable or disable passcode protection. Selecting Passcode advances to the Passcode screen.
2. From the Passcode screen, enter a passcode by tapping on the desired sequence of keys. The passcode must be a minimum of 4 digits and a maximum of 8 digits. After entering the passcode, tap ↵.
3. Enter the passcode a second time to confirm. Enter the passcode and tap ↵. The passcode is saved and the display returns to the Options screen. **Do not forget the passcode**.

   Once the passcode is selected, changes cannot be made to any selection on the screen without entering the correct passcode.
4. To disable the passcode, tap ✓ next to Passcode, enter the passcode, and tap ↵. The passcode is then disabled and returns the operator to the Options screen.

Contact ELITechGroup Technical Service for assistance if the passcode is forgotten.



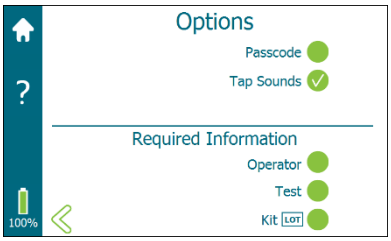
Tap Sounds

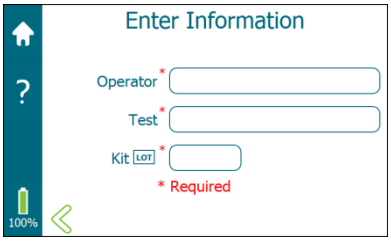
Tap ✓ or ● next to Tap Sounds to toggle the touch sounds on and off. The default setting is touch sounds selected (enabled).

2.5 Settings Screen

Options Screen (continued)

Required Information



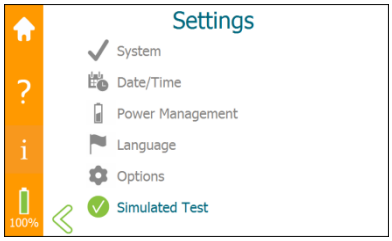


Select or deselect the required information input fields by tapping ● or ✓ next to the required information (Operator, Test, Kit LOT). The default is that none of the fields are required. Any combination of the fields can be selected to be required.

***NOTE**: The operator enters information from the Enter Information screen (shown at left) when preparing to run iontophoresis. Required information is marked by an asterisk (*).*

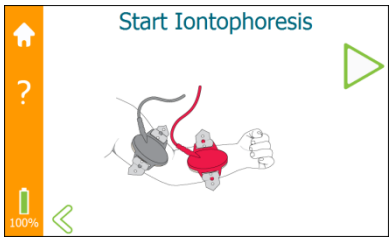
2.5 Settings Screen

Simulated Test



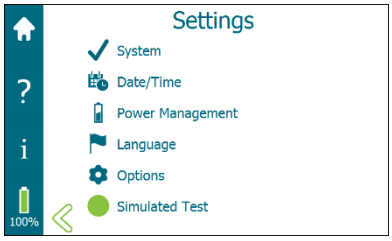
Tapping Simulated Test from the Settings Screen switches to the Simulated Test mode of operation. Simulated Test simulates the iontophoresis sweat test without delivering current. This can be useful for demonstrating device functions or training.

In Simulated Test mode, the Settings are not accessible and are grayed out. Upon selecting Simulated Test, the task bar color, along the left side of the display, changes from blue to **orange**.



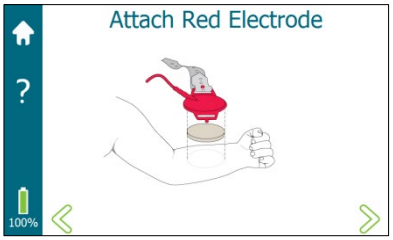
CAUTION:
Never attempt actual iontophoresis on a patient while in Simulated Test mode. Verify that the device is in iontophoresis mode (with blue task bar showing) when performing an actual test.

When simulating a sweat test, the device functions much like it would during a test on a patient. The display screens, selections, and navigation are the same as during an actual test. The operator can access all of the functions of the sweat test without enabling the iontophoresis current. Iontophoresis and sweat collection timers are also simulated, with reduced execution times. During simulated iontophoresis the electrode cable assembly and Pilogel discs are not required.



From the Settings screen tap Simulated Test to switch out of the Simulated Test mode. The task bar color changes from orange back to **blue** and Settings become accessible.

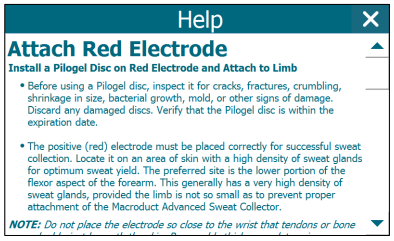
2.6 The Help Menu



Help is a comprehensive on-screen context-sensitive help function.

From any screen that displays the help icon, tap ? to access the context-sensitive help for that specific screen. Depending upon the amount of information, a scroll bar on the right side of the display is used for scrolling up and down.

Tap × to exit the Help screen and return to the previous screen.

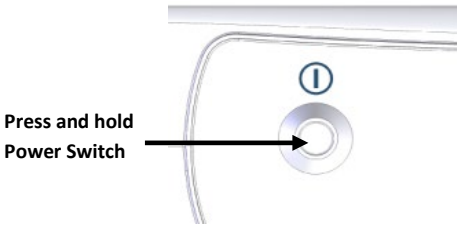


SECTION 3: SWEAT INDUCTION AND COLLECTION

3.1 Preparing for Sweat Induction

WARNING!

Due to the possibility of an explosion, never attempt iontophoresis on a patient receiving oxygen-enriched respiratory therapy in an enclosed space, such as an oxygen tent (nasal cannula is acceptable). With medical approval, remove the patient from that environment during iontophoresis.



1. Turn the Device On

Turn the device on by pressing and holding down the power switch located on the top of the Macroduct Advanced for 1-2 seconds.

2. Advance to the Iontophoresis Procedure

From the Home screen, tap to begin the iontophoresis step-by-step setup procedure.

3. Iontophoresis Supplies

Make certain the device and all supplies are on hand for the complete sweat induction procedure:

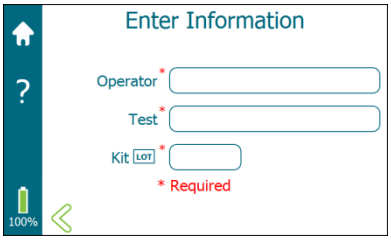
- Macroduct Advanced Model 3710
- Electrode cable assembly
- Electrode and collector straps
- Pilogel discs
- Collector
- Nippers
- EasyDuct needle and syringe
- Sweat dispenser or sweat collection container
- Supply of deionized water
- Alcohol
- Powder-free gloves
- Cotton balls, gauze pads or KimWipes

NOTE: *The operator should wear powder-free gloves throughout the iontophoresis and sweat collection processes.*

Tap to advance to the next screen, or tap to go back to the previous screen.

CAUTION:

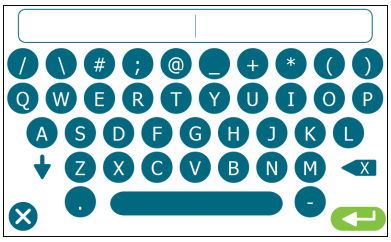
Never attempt actual iontophoresis on a patient while in Simulated Test mode. Verify that the device is in iontophoresis mode (with blue task bar showing) when performing an actual test.



4. Enter Information (optional based upon system settings). See information under Settings Screen in Section 2.5.

Enter Information allows the operator to input Operator, Test, and Kit LOT numbers.

NOTE: *Required fields (marked with an asterisk) must be entered before advancing to the next screen is permitted (is not displayed until information in all required fields is entered).*

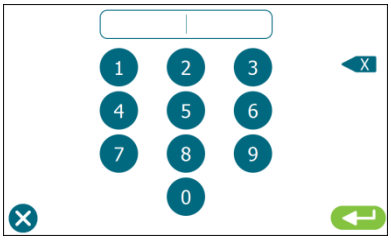


a. Tap inside the Operator field to access the keyboard.

Using the keyboard, enter the Operator identification. When finished, tap to save the entry and return to the Enter Information screen. The maximum number of characters for the Operator is 20.

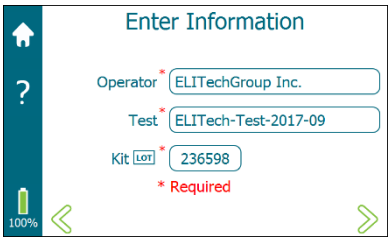
b. Tap inside the Test field to access the keyboard.

Using the keyboard, enter the Test identification and when finished, tap to save the entry and return to the Enter Information screen. The maximum number of characters for the Test identification is 20.



c. Tap inside the Kit LOT field to access the numeric keypad. Using the keypad, enter the 6-digit Kit LOT number, which is located on the Macroduct Advanced Supply Kit box label (SS-268).

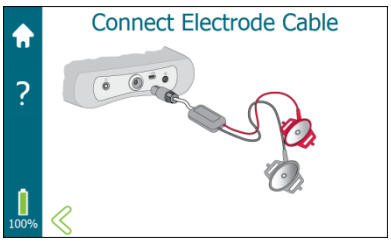
When finished, tap to save the entry and return to the Enter Information screen. Verify that the Kit LOT number is entered correctly and that the supply kit is within the expiration date.

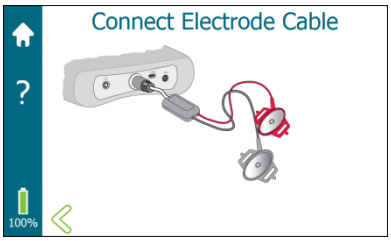


d. Tap to advance to the next screen, or tap to go back to the previous screen.

SECTION 3: SWEAT INDUCTION AND COLLECTION

3.1 Preparing for Sweat Induction





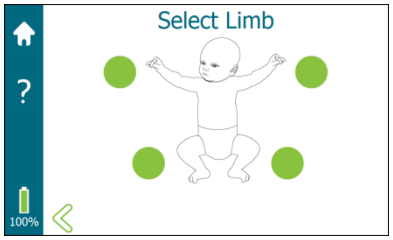
5. Inspect Electrodes and Connect to Macroduct Advanced

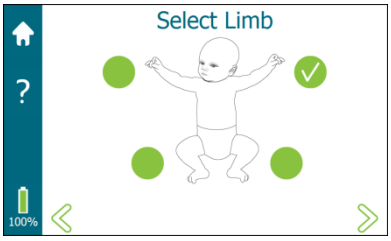
a. Clean the electrodes if necessary.

b. Check wires and insulation for cracks or fraying. Replace electrode cable assembly if wires, insulation, or plastic housing are cracked or frayed.

The device automatically detects if an electrode cable assembly is connected. If already connected, it automatically advances to the next screen. If the electrode cable assembly is not connected, the display prompts to connect the electrode cable.

c. To connect, push the electrode cable assembly plug into the connector on the top panel of the device.





6. Select Limb

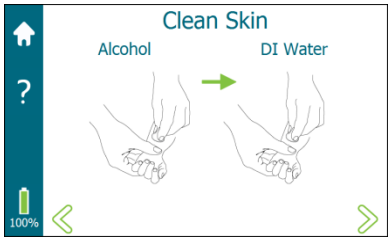
The skin at selected locations for attaching the electrodes must be free from breaks, cuts, observable abnormalities, or signs of inflammation to prevent contamination of the sweat by serous exudates. The skin in this area must be as wrinkle-free and hairless as possible.

a. Tap nearest the limb where the electrodes will be attached. A limb must be selected before being able to advance to the next screen. The icon indicates the selected limb location.

b. After the limb is selected, tap to advance to the next screen, or tap to go back to the previous screen.

WARNING!
Never place electrodes across the chest or on opposite limbs. Even though the DC iontophoretic current is extremely low, there is a remote risk of interference with cardiac rhythms.

3.1 Preparing for Sweat Induction



7. Clean the Selected Skin Areas

Clean the skin at the selected location to remove dirt and loose dead cells to minimize the electrical impedance of the skin. To do this:

a. Swab the area vigorously with alcohol, then rinse the area with a generous amount of deionized water.

b. Leave the skin wet where the Pilogel disc is to be attached,

(Or)

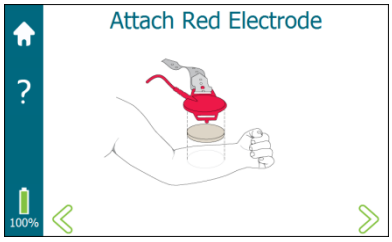
Place a drop of deionized water on the skin or on the surface of the Pilogel disc just before attachment. This ensures uniform contact over the area and reduces the possibility of a burn.

c. Tap ❯ to advance to the next screen, or tap ❮ to go back to the previous screen.

WARNING!
Follow the precautions found in Section 1.5.

SECTION 3: SWEAT INDUCTION AND COLLECTION

3.1 Preparing for Sweat Induction



8. Install a Pilogel Disc on Red Electrode and Attach to Limb

- Before using a Pilogel disc, inspect it for cracks, fractures, crumbling, shrinkage in size, bacterial growth, mold, or other signs of damage. Discard any damaged discs. Verify that the Pilogel disc is within the expiration date.
- The positive (red) electrode must be placed correctly for successful sweat collection. Locate it on an area of skin with a high density of sweat glands for optimum sweat yield. The preferred site is the lower portion of the flexor aspect of the forearm. This generally has a very high density of sweat glands, provided the limb is not so small as to prevent proper attachment of the Macroduct Advanced Sweat Collector.

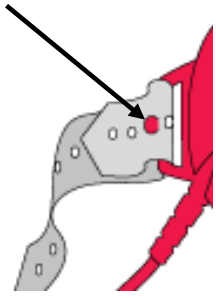
NOTE: *Do not place the electrode so close to the wrist that tendons or bone are palpable just beneath the skin. Reasonably thick musculature is necessary for a proper interface with the Macroduct Advanced Sweat Collector.*

- If the limb is tiny, place the red electrode on the upper portion of the flexor aspect of the forearm (nearer the elbow) or even the upper arm. If the entire arm is too small to attach the electrode, use the inner thigh, placing the red electrode on the inner thigh and the black electrode on the calf. In this case, constrain the infant from flexing the knee to avoid a loss of interface between the skin and the electrode.

WARNING!
Never attach an electrode to the skin without a Pilogel disc. Direct electrode-to skin contact will burn the patient. Refer to Section 1.5 for additional information.

WARNING!
Never place electrodes across the chest or on opposite limbs. Even though the DC iontophoretic current is extremely low, there is a remote risk of interference with cardiac rhythms.

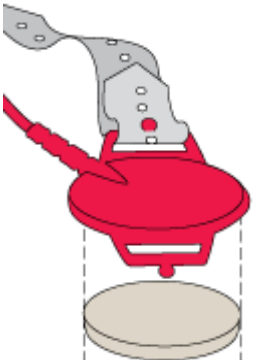
Attach strap to one side of the electrode as shown.



a. Attach the strap to one side of the red electrode by inserting the strap from below the electrode and up through the slot. Align one of the holes in the strap with the protruding attachment knob. Press the hole in the strap down over the knob to lock it in place.

SECTION 3: SWEAT INDUCTION AND COLLECTION

3.1 Preparing for Sweat Induction



b. Fit a Pilogel disc in the red electrode. Pilogel discs are slightly larger than the inside of the electrode skirt to provide a snug fit. Press firmly around the entire perimeter of the disc to achieve uniform, air-free contact with the electrode. This may separate small slivers of gel from the outside of the disc as it is seated against the electrode, which is normal.

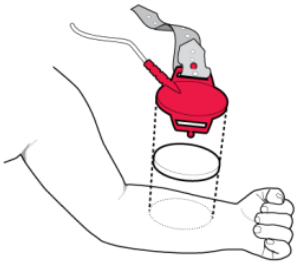
   Do not be concerned if the Pilogel disc bulges somewhat away from the stainless steel electrode at the center. Attachment to the limb flattens it against the electrode.

c. Place a drop of deionized water on the skin where the electrode is to be placed or on the surface of the Pilogel disc just before attachment. This helps with the connection between the Pilogel disc and skin.

d. Position the red electrode, with a Pilogel disc, on the limb.

e. Run the free end of the strap around the limb and through the opposite slot on the electrode from the bottom, through the slot, and then down, aligning a suitable hole in the strap with the attachment knob. Press the selected hole in the strap down over the knob to lock it in place.

f. Grip the electrode and lift it briefly above the skin to equalize strap tension on each side of the electrode, and then position the electrode back on the skin surface. Adjust strap tension on either side, as needed, to ensure even contact.



NOTE: *Attach the strap firmly, but avoid excessive tightness. Correctly applied, the electrode should grip the skin firmly enough to resist moderately forceful attempts to change its position. The surrounding skin areas should move with the electrode when it is moved.*

g. Draw the skin back away from the electrode to remove any underlying wrinkles.

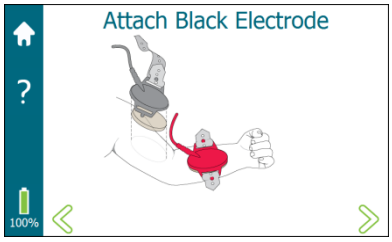
h. Tap ❯ to advance to the next screen, or tap ❮ to go back to the previous screen.

⚠ **WARNING!**

Watch for any signs of interference with blood circulation in the limb, such as cyanosis, swelling, or unusual pallor, and discontinue the test on that limb if any of those conditions should occur.

SECTION 3: SWEAT INDUCTION AND COLLECTION

3.1 Preparing for Sweat Induction



9. Install a Second Pilogel Disc on Black Electrode and Attach to Limb

a. Attach the strap to one side of the black electrode following the same process used in Step 8a.

b. Fit a second Pilogel disc into the black electrode. Before attaching, place a drop of deionized water on the skin where the electrode is to be placed, or on the surface of the Pilogel disc to enhance the connection between the Pilogel disc and skin.

c. Position the black electrode, with a Pilogel disc, at a suitable location on the same limb as the red electrode.

d. Attach the strap to the other side of the black electrode following the same process used for the red electrode.

e. Grip the electrode and lift it briefly above the skin to equalize strap tension on each side of the electrode and then position the electrode back on the skin surface. Adjust strap tension on either side, as needed, to ensure even contact.

f. Draw the skin back away from the electrode to remove any underlying wrinkles.

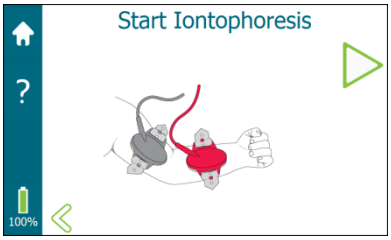
g. Tap ❯ to advance to the next screen, or tap ❮ to go back to the previous screen.

3.2 Inducing Sweat

1. Start Iontophoresis

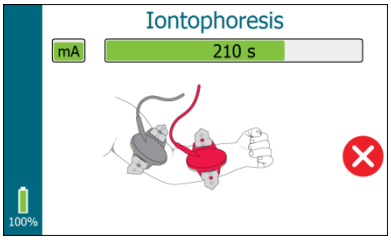
NOTE: *Individuals vary in their sensitivity to iontophoretic current. Most subjects feel nothing more than a slight prickling or tingling sensation during iontophoresis. If the patient complains or shows signs of distress, ensure that the Pilogel disc is pressed tightly against the skin. This may reduce the patient's discomfort.*

NOTE: *Do not start iontophoresis if the battery indicator is red.*



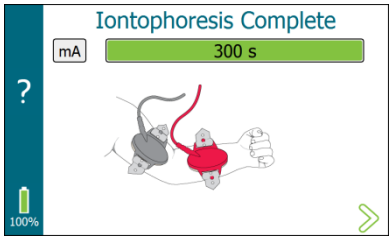
a. Tap ▷ to start iontophoresis. If all safety conditions are met, iontophoresis starts.

- The iontophoresis current slowly ramps to full current. A vertical bar on the left of the screen shows the progress of the increasing current (labeled mA).
- After full current is reached, the horizontal progress bar displays the progress of full current in seconds from 1 to 300 (5 minutes).
- After iontophoresis full current has finished, current ramps down to zero (displayed in the mA bar) and the iontophoresis process is complete.



NOTE: *Iontophoresis takes approximately 5½ minutes. The operator should remain with the patient during iontophoresis.*

2. Iontophoresis Complete

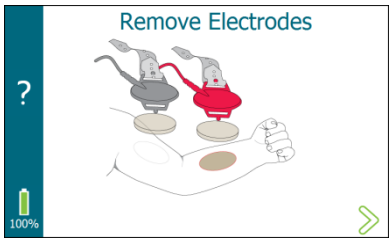


After iontophoresis completes, an audible tone sounds briefly and **Iontophoresis Complete** is displayed. At 15 second intervals, an audible tone sounds and repeats 10 times or until » is tapped.

Tap » to advance to the next screen.

NOTE: *If an error condition, such as a broken connection, occurs during iontophoresis, current flow ceases and the operator is notified.*

3.2 Inducing Sweat



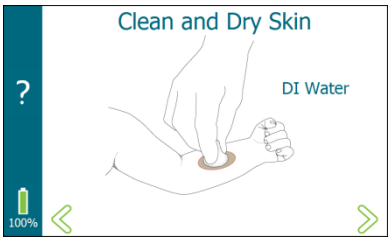
3. Remove Electrodes

a. Remove the black electrode.

b. Remove the red electrode.

c. Immediately dispose of Pilogel discs and straps.

d. Tap ❯ to advance to the next screen.



4. Clean and Dry Skin

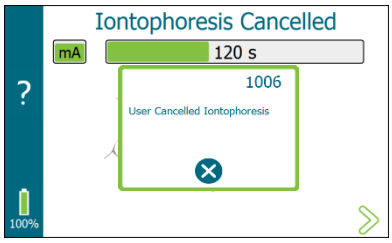
a. Clean the stimulated skin and the surrounding area thoroughly with deionized water to remove salt, then blot dry. There should be a distinct redness under the red electrode.

b. Proceed to the next step immediately by tapping ❯ to advance to the next screen; or tap ❮ to return to the previous screen.

⚠ **WARNING!**
Pilogel is considered harmful. Do not ingest. Consult the SDS sheet for more information.

⚠ **WARNING!**
Pilogel discs are a potential choking hazard. Make sure they are disposed of properly.

Iontophoresis Cancelled – Manually or by Error

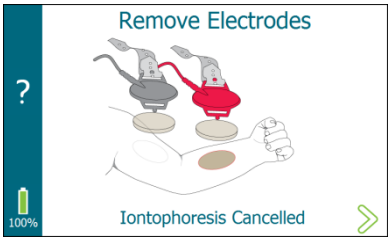


If the iontophoresis is manually cancelled or an error condition occurs, an audible tone sounds and **Iontophoresis Cancelled** is displayed and a pop up display will appear.

1. Tap ⊗ to exit from the pop-up.

2. Tap › to advance to the next screen.

NOTE: *If iontophoresis is cancelled, the iontophoresis procedure must be repeated to completion before proceeding to sweat collection.*

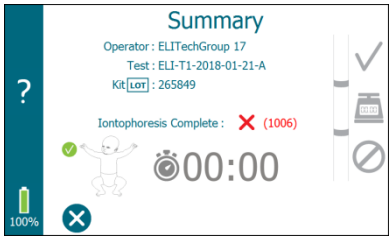


3. Remove the electrodes and discard the Pilogel discs.

   Tap › to advance to the next screen.

4. Clean the skin with deionized water and dry the skin.

5. Tap › to advance to the next screen . or tap ‹ to go back to the previous screen.



A Summary screen displays the operator-entered information up through the time iontophoresis was manually stopped or the error condition occurred. Information not entered or completed displays in gray.

6. Tap ⊗ to return to the Home screen.

SECTION 3: SWEAT INDUCTION AND COLLECTION

3.3 Collecting Sweat

1. Assemble Collection Supplies

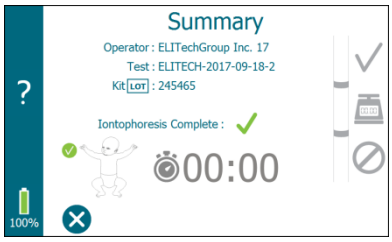
Gather the necessary sweat collection supplies and prepare for collecting sweat.

After successful iontophoresis:

a. Using powder-free gloves to prevent contaminating the collector, open one end of the plastic wrapper and slide the Macroduct Advanced Sweat Collector slightly out of the package.

b. From the bottom of the collector, thread a strap up through one slot, aligning a suitable hole in the strap with the knob and then pressing the hole around and over the knob to lock it in place. DO NOT TOUCH THE COLLECTION SURFACE.

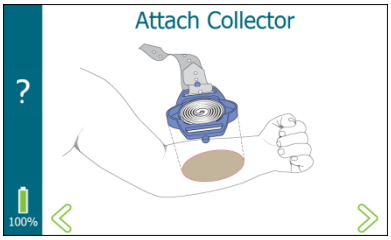
c. Tap ❯ to advance to the next screen, or tap ❮ to go back to the previous screen.



NOTE: *Gather the collection supplies while waiting for the iontophoresis cycle to complete.*

NOTE: *The test can be cancelled from the Collection screen; however, once the test is cancelled there is no way to return to this screen and continue the test. Tap* ☒ *to exit and return to the Home screen.*

If ☒ is tapped, a summary screen displays the information entered and shows that iontophoresis is complete. From the Summary screen tap ⊗ to return to the Home screen.



2. Attach Collector

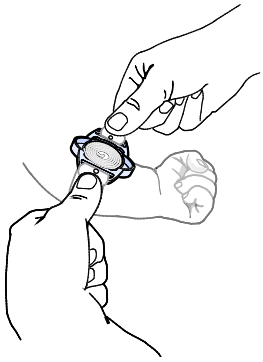
a. Place the concave surface of the collector precisely over the area of skin contacted by the Pilogel disc that was under the red electrode.

b. While applying slight pressure to the collector, wrap the strap around the limb and thread it up through the slot on the opposite side of the collector. Pull the free end out and then down, aligning a suitable hole in the strap with the attachment knob. Press the selected hole in the strap down over the knob to lock it in place.

c. Verify that the collector is firmly attached.

d. If necessary, grip the collector and lift it briefly above the skin to equalize strap tension on each side of the collector. Then lower the collector to the skin surface, ensuring that the collector is still positioned over the sweat-stimulated area. Adjust strap tension on either side, as needed, to ensure even contact.

e. **For neonate sweat collections where the limbs are extremely small:** Overwrap the collector firmly with a 5-8 cm (2 or 3 inch) wide elastic bandage. This ensures continuous and firm contact between the collector and the skin, and greatly improves the probability of successful collection.

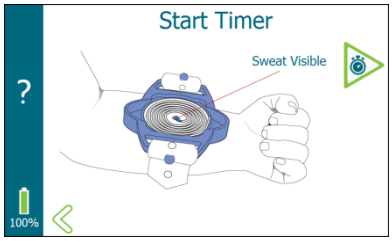


WARNING!
Watch for any signs of interference with blood circulation in the limb, such as cyanosis, swelling, or unusual pallor, and discontinue the test on that limb if any of those conditions should occur.

f. Tap ❯ to advance to the next screen, or tap ❮ to go back to the previous screen.

CAUTION:
Dropping the collector or handling it improperly may cause contamination. The collector should be discarded if the collector surface is touched, dropped, or comes in contact with another surface.

3.3 Collecting Sweat



3. Start Timer

a. Observing the center of the collector, watch for sweat (blue) to emerge into the tube.

b. When sweat is visible, or within four minutes, tap to start the sweat collection count-up timer.

NOTE: *Detect inadequately tightened collector straps by pressing the collector very firmly against the skin. If the advancing meniscus of sweat in the spiral tube moves by more than 2-3 mm (1/16-1/8 inch), attach the strap more firmly.*

c. The sweat collection timer continues until is tapped.

The sweat collection duration should not exceed **30 minutes**.

4. Stop sweat collection timer

a. Tap to stop the timer when it reaches 30 minutes or when the sweat collector is close to being full of sweat, which is indicated by blue dye on the outer edge of the tubing. The timer must be stopped before advancing to the next screen.

The icon indicates the timer has stopped.

b. After the timer is stopped, tap to advance to the next screen.

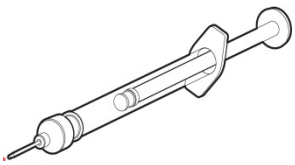
NOTE: *After 30 minutes the time indicator changes to blue. A reminder tone sounds and continues at 30-second intervals until the timer is stopped manually or until the timer reaches 45 minutes. At 45 minutes, the timer automatically turns off, displays a message, and waits for the operator to tap .*

NOTE: *If the timer is started before sweat is visible or inadvertently started before intended, record the time that sweat becomes visible. Then, stop sweat collection 30 minutes after the sweat appears.*

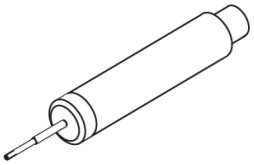
The maximum time for sweat collection is 30 minutes according to CLSI sweat collection guidelines.

5. Extract Tube

CAUTION:
The following procedure should be performed in its entirety while the Macroduct Advanced Sweat Collector is still firmly strapped to the limb. Removing the collector before detaching the tubing may create a vacuum that will draw the collected sweat from the tubing and significantly reduce sample volume.



Syringe with EasyDuct Needle (AC-193)



Sweat Dispenser (RP-065)

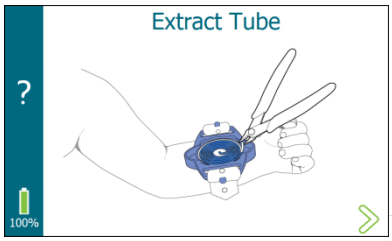
NOTE: *There are two tools available for harvesting and storing a sweat sample, (1) the syringe with the EasyDuct needle (REF: AC-193), or (2) the Sweat Dispenser (REF: RP-065, which is included but should NOT be used with the Sweat-Chek Analyzer). A standard 22-gauge blunt needle, such as those included in SS-045, may be used instead of the EasyDuct needle if disposability is desired.*

If using the Sweat Chek analyzer, only the syringe with the EasyDuct needle can be used. Either the syringe or the sweat dispenser can be used to remove sweat sample for storage or analysis by any other method than the Sweat-Chek analyzer. Do not attempt to use the Sweat Dispenser with the Sweat-Chek analyzer.

WARNING!
If any sweat from the patient is drawn into the syringe or the dispenser, or if any sweat contaminates the needle of either tool, they must be cleaned to prevent contamination of any following samples.

SECTION 3: SWEAT INDUCTION AND COLLECTION

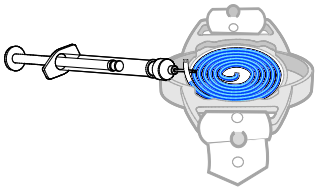
3.3 Collecting Sweat



FOLLOW THESE INSTRUCTIONS CLOSELY:

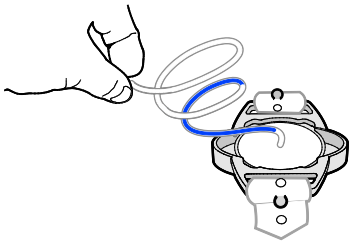
a. Remove the protective transparent cover from the collector. Insert a pointed tool into one of the cut-out sections and pry upward. (The nippers supplied with the Macroduct Advanced system work well.) Dispose of the cover immediately after removal.

WARNING!
The protective transparent cover could cause choking if swallowed. Dispose of properly. Keep out of reach of children.



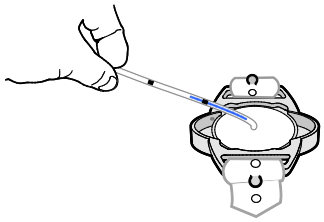
b. Using the EasyDuct needle, dispenser, or the nippers, pry up the end of the tubing enough so the tubing can be grasped by hand. Grasp the tubing and gently pull the tubing away from the collector body until the tubing is completely uncoiled and extending up and outward from the point of attachment.

Do not stretch the tubing.



c. Tap ❯ to advance to the next screen.

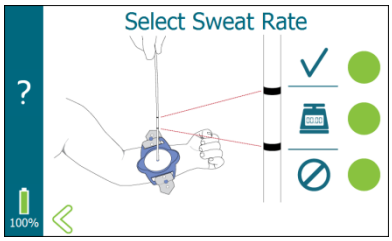
WARNING!
The EasyDuct needle could cause choking if swallowed or may cause injury if not used properly. Keep out of reach of children.



CAUTION:
Although some illustrations, for the sake of clarity, show the Macroduct Advanced Sweat Collector in isolation, these collection procedures must take place while the collector is firmly attached to the patient's limb.

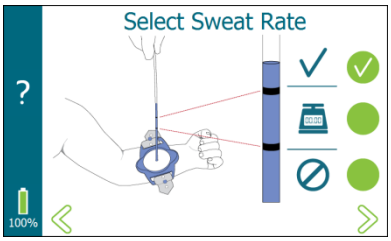
Do Not Stretch Tubing

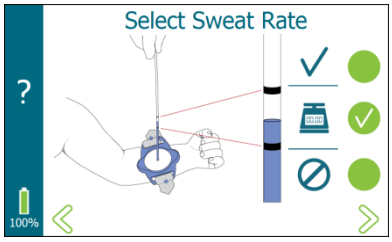
6. Select Observed Sweat Rate

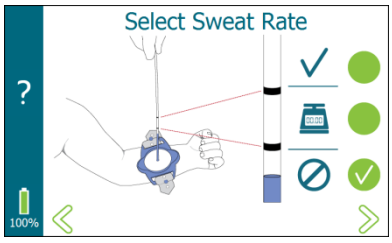


a. With the tubing pulled up and away from the collector, verify actual sweat rate by observing the volume of sweat collected in the tube.

b. On the display, tap the corresponding sweat rate observed on the collector. A selection must be made to continue.







Icon	Sweat Level in Tubing	Sweat Rate Indicated
✓	Above the top black line.	Sufficient sweat rate.*
⚖	Between the two black lines.	Sweat rate inconclusive, weigh the sweat sample to determine if enough sweat was collected to confirm a sufficient sweat rate.
⊘	Below the bottom black line.	**Insufficent sweat rate.

*Sufficient sweat rate is defined as 1g/m^2/min, which in terms of volume equates to approximately 15 µL of sweat collected within 30 minutes.

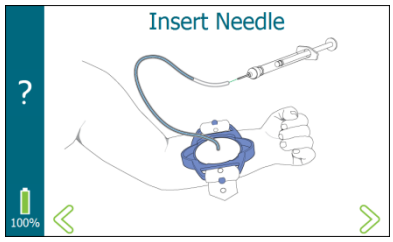
**Sweat samples collected with an insufficient sweat rate should not be recorded as a valid sweat test, because of a risk of false negative results with very slow sweating rates.

c. Tap ● next to the icon ✓, ⚖, or ⊘ that corresponds to the amount of sweat in the tubing. The icon ✓ indicates the selected sweat rate.

d. Tap › to advance to the next screen, or tap ‹ to go back to the previous screen.

NOTE: *If ⊘ is tapped, the Insert Needle and Remove Tube screens are bypassed.*

3.3 Collecting Sweat



7. Insert Needle Using Syringe or Sweat Dispenser

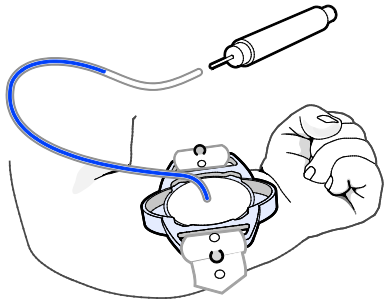
Insert EasyDuct Needle Using the Syringe

a. Position the syringe plunger at mid-point before inserting the EasyDuct needle into the tubing.

b. DO NOT squeeze the syringe body or move the syringe plunger at any time while inserting the EasyDuct needle into the tubing or during the following procedure.

c. Holding the open end of the tubing in one hand, carefully insert the EasyDuct needle approximately 5 mm (¼ inch) into the microbore tubing using a twisting motion.

d. Tap › to advance to the next screen, or tap ‹ to go back to the previous screen.



Insert Needle Using the Sweat Dispenser

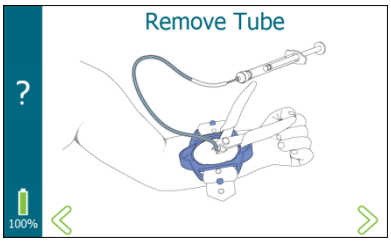
a. DO NOT squeeze the dispenser at any time while inserting the needle into the tubing or during the following procedure. Avoid squeezing the dispenser while manipulating the tool during needle insertion. STRONGLY RECOMMENDED: grasp the dispenser over the black forward end rather than on the flexible middle section.

b. Holding the open end of the tubing in one hand, carefully insert the needle approximately 5 mm (¼ inch) into the microbore tubing using a twisting motion.

c. Tap › to advance to the next screen, or tap ‹ to go back to the previous screen.

⚠ **CAUTION:**
Do not use the Sweat Dispenser to introduce sweat samples into the Sweat-Chek Analyzer.

8. Remove Tube Using Syringe or Sweat Dispenser



Remove Tube Using the Syringe

a. Use the provided nippers to sever the tubing as close as possible to the collector surface.

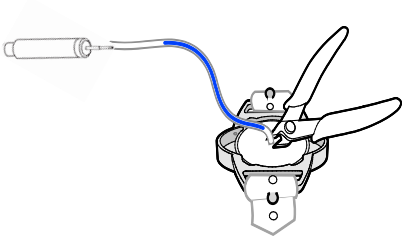
b. Immediately after severing the tubing, pull back the plunger to carefully draw the column of sample sweat further into the tube (towards but not into the syringe) 3-5 cm (one or two inches). This is to prevent any loss of sweat from the cut end due to expansion of air in the syringe body. It also allows for squarely cutting off the tightly-coiled end of the microbore tubing for easier handling.

c. Place the open end of the Macroduct tubing in the small sealable container. Hold the tubing securely in the container and expell the sweat by **slowly** moving the syringe plunger down. The sweat should move smoothly down and out of the tubing.

d. Immediately close the cover to protect the specimen.

WARNING!
The small sealable collection containers are a choking hazard if swallowed. Keep out of reach of children.

e. Tap › to advance to the next screen, or tap ‹ to go back to the previous screen.



Remove Tube Using Sweat Dispenser

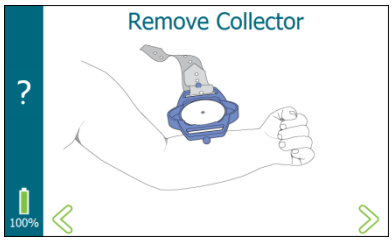
a. Use the provided nippers to sever the tubing as close as possible to the collector surface.

b. Place the open end of the Macroduct tubing in the small sealable container. Hold the tubing securely in the container and expel the sweat by lightly squeezing the center “bulb” area of the dispenser. The sweat should move smoothly down and out of the tubing.

c. Immediately close the cover to protect the specimen.

d. Tap › to advance to the next screen, or tap ‹ to go back to the previous screen.

3.3 Collecting Sweat



9. Remove Collector

a. Remove the collector body from the patient's limb. Discard the strap and the collector body.

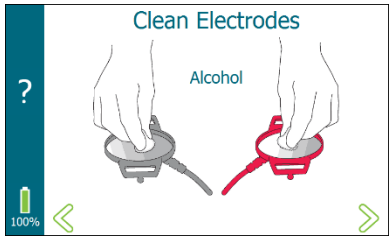
b. Tap ❯ to advance to the next screen, or tap ❮ to go back to the previous screen.

⚠ **CAUTION:**
Due to possible biological contamination, Macroduct Advanced Sweat Collectors are single use only and must be discarded after use. Straps may be reused if they are properly cleaned. See Section 5.4.

10. Clean and Dry Skin

a. Clean the skin and the area surrounding where the collector was attached thoroughly with deionized water, then blot dry.

b. Tap ❯ to advance to the next screen, or tap ❮ to go back to the previous screen.



11. Clean Electrodes

a. Remove and discard the Pilogel discs and the straps from the electrodes.

b. Clean the electrodes with isopropyl alcohol and wipe dry. See Section 5.2 for additional cleaning details.

c. Wipe down the exterior of the device. See Section 5.3.

d. Tap ❯ to advance to the next screen, or tap ❮ to go back to the previous screen.

⚠ **CAUTION:**
Avoid cleaning substances that could leave a residue containing chloride.

12. The Summary Screen

The Summary screen reports the following information:

- If entered, the Operator, Test identification, and Kit LOT number.
- If iontophoresis completed or not, and if there was an error.
- The operator-selected limb where sweat was collected.
- Total sweat collection time (based on when the operator started and stopped the sweat collection timer – grayed out if the sweat collection timer was not started).
- Graphic of sufficient sweat rate (based on operator selection – grayed out if the sweat collection process was not followed).

When finished viewing the Summary screen, tap ⊗ to return to the Home screen.

SECTION 3: SWEAT INDUCTION AND COLLECTION

3.4 Risk of Burns

Sweat Testing Poses a Remote Risk of Minor Skin Burns

The pilocarpine iontophoresis sweat test has been an important laboratory tool since the 1950s. It provides a quantitative test result to confirm or exclude a physician's diagnosis of cystic fibrosis. Unfortunately, the test has been accompanied by occasional minor burns.

Minor skin burns have been an unwelcome, adverse side-effect of pilocarpine iontophoresis from the beginning. Fortunately, such burns are extremely rare with ELITechGroup's iontophoretic system. It uses a sophisticated microprocessor current controller and a very low delivery current of only 1.5 mA. Pilocarpine is contained in unique Pilogel gel reservoirs that are 96% water. These features substantially reduce, but do not totally eliminate, the possibility of skin burns.

Burn descriptions vary from "tiny black pinholes in the skin" to "crater-like, third-degree burns two to three millimeters in diameter." In most of the incidents reported, the patients have exhibited no sign of pain or discomfort during iontophoresis, and the burn was not discovered until the electrodes were removed.

Most individuals exhibit sensitivity to pilocarpine that is typically manifested as mild erythema (redness) of the skin at the electrode locations. In some cases, one or more blister-like welts may also form. These are often mistaken as burns, but they are simply a reaction of the skin to pilocarpine. Such "blisters" invariably disappear within 2 to 3 hours, leaving no after-effects.

Based on current data, the reported burn rate is less than 1 in 50,000 procedures. ELITechGroup prescribes proper test procedures which minimize the risk of burns. It is highly unlikely that a patient will suffer a burn during the sweat test.

ELITechGroup recommends informing patients (or parents of young patients) of this slight risk and following all approved procedures. See DOC-00987 for more information. If a burn should occur, follow the appropriate procedures to determine any treatment needed and notify ELITechGroup immediately. ELITechGroup will gather information related to the burn and will ask that a qualified professional fill out a short form to determine whether the burn is reportable to the US FDA or other regulatory authorities. ELITechGroup will also help determine whether the burn could be related to a malfunction.

SECTION 4: SWEAT ANALYSIS

4.1 An overview of Sweat Analysis

The procedures described up to this point in the manual provide the laboratory technician with an undiluted sweat sample. By virtue of the specific safeguards against condensation and evaporation error, the sample is fully representative of the patient's secretion and is therefore a valid specimen for analysis as long as the sweat rate exceeded 1g/m^2/min, or a sweat sample of at least 15 µL in 30 minutes of collection. Results for samples less than 15 µL should not be recorded as valid sweat tests, nor should insufficient sweat samples be pooled to achieve the volume required.

Chloride Analysis

Sweat samples collected with the Macroduct Advanced can be analyzed for the sweat chloride level. ELITechGroup provides the ChloroChek Chloridometer as an operator friendly method to measure chloride levels in sweat. The ChloroChek Chloridometer is a coulometric titrator designed to determine chloride ion concentrations in sweat samples in less than 20 seconds with just 10 µL of sweat.

Electrical Conductivity

ELITechGroup's Sweat-Chek Sweat Conductivity Analyzer was designed to measure conductivity of Macroduct collected samples. Field testing in clinics in the U.S. and in many other countries testifies to its simplicity, economy, and accuracy in the diagnosis of cystic fibrosis.

SECTION 5: TROUBLESHOOTING AND MAINTENANCE

5.1 Troubleshooting

Aside from electrode cleaning, there is no regular periodic maintenance required for the Macroduct Advanced. If the system appears to malfunction, use the following information to identify and remedy the problem**. Contact ELITechGroup if the information below does not resolve a problem.**

Table 5: General Troubleshooting and Diagnosis

Symptom	Probable Cause/Solution
Nothing happens when the power switch is pressed. (No indication that the device is turning on and the green LED does not light.)	Probable Cause: Low battery. Possible Solutions: Charge the battery. If the battery cannot be charged (amber LED not blinking during charge or battery charge screen does not appear), contact ELITechGroup for further instructions.
Iontophoresis will not start.	Probable Causes: Before iontophoresis can begin, the electrode cable must be plugged into the device and Pilogel discs must be detected. Possible Solutions: Check that the Macroduct Advanced cable is securely connected. Check both electrodes ensuring that a Pilogel disc is present and securely positioned inside both electrode housings. Ensure both electrodes are secured with adequate tightness to the patient's limb. If the problem persists, **with electrodes not attached to a patient**, try checking the electrodes from the System screen. (From the Home screen, tap , tap System, tap Functional Test.)
Iontophoresis begins increasing current but does not reach full current.	Probable Causes: High skin or electrode-to-skin resistance. Possible Solutions: Inspect the electrodes and clean if necessary. Place a drop of deionized water between the electrode and Pilogel disc and directly on the clean skin beneath the Pilogel disc. Ensure both electrodes are secured with adequate tightness to the patient's limb. Suggest repeating the test once. If the problem persists, **with electrodes not attached to a patient**, try checking the electrodes from the System screen. (From the Home screen, tap , tap System, tap Functional Test.)

Table 5: General Troubleshooting and Diagnosis (continued)

Symptom	Probable Cause/Solution
Iontophoresis stops prematurely.	Probable Causes: Loose electrode or broken cable. Possible Solutions: Ensure both electrodes are secured with adequate tightness to the patient's limb and that the cable is connected to the device. Inspect the electrodes and clean if necessary. Place a drop of deionized water between the electrode and Pilogel disc and directly on the clean skin beneath the Pilogel disc. Suggested: Repeat the test once. If the problem persists, current control circuitry may be damaged or electrode cable assembly may be damaged. Stop using the device and contact ELITechGroup.
Device immediately shuts off or the device shuts off during a test.	Probable Causes: Low battery or battery is unable to hold a charge. Possible Solutions: Charge the battery and repeat the test if necessary. If after charging the battery the same problem persists, the battery may need to be replaced.
Low battery displayed.	Probable Cause: Low battery or battery might not be able to be charged. Possible Solutions: Charge the battery. If after charging the battery the same problem persists, contact ELITechGroup for further instructions.
Display remains blank when turned on.	Probable Causes: Low battery or potential lock-up condition. Possible Solutions: Charge the battery. Reset the device by pressing and holding down the power switch for 4-5 seconds. The device powers off. Turn the device back on by pressing the power switch for 1-2 seconds.

5.1 Troubleshooting

Table 5: General Troubleshooting and Diagnosis (continued)

Symptom	Probable Cause/Solution
Device appears to be locked up or is inoperable with the display on.	Probable Causes: There are multiple reasons why a lockup may occur ranging from a hardware malfunction to a software problem. Often times it is hard to pinpoint the exact problem or the series of events that may have led to the problem. Possible Solutions: Reset the device by pressing and holding down the power switch for 4-5 seconds. The device powers off. Turn the device back on by pressing the power switch for 1-2 seconds.
Insufficient sweat occurs.	Probable Causes: Insufficient sweat may occur for a variety of reasons and varies depending upon patient physiological factors. Factors such as the patient's age, weight, race, and hydration level may contribute to insufficient sweat, as well as other physiological factors (e.g. anhidrosis, hypohidrosis). If an adequate sweat sample is not obtained, repeat testing should occur as soon as is practical. This could be the same day or the following day. The sweat test should only be repeated once on any given day. Possible Solutions: The patient should be well hydrated and free of acute illness. Check the polarity of the electrodes. Pilocarpine will not be delivered under the black electrode. The collector must be placed precisely over the location of the red electrode and attached securely. Check that the Pilogel is within the expiration date. See Appendix D – Procedure for High Skin Resistance.
Insufficient sweat occurs on a regular basis.	Probable Cause: High skin resistance or possible defect with the device. Possible Solutions: See Appendix D – Procedure for High Skin Resistance. If insufficient sweat quantity occurs on a regular basis, contact ELITechGroup for further instructions.
Date/Time is not maintained.	Probable Cause: The internal back-up battery for the real time clock (RTC) is discharged. Possible Solutions: Back-up battery needs to be replaced by qualified service personnel.

Table 6: Error Code Troubleshooting and Diagnosis

Error Code Message Displayed	Probable Causes/Possible Solutions
Error 1000 No Cable Detected	Probable Causes: Electrode cable assembly is not connected to the device, problem with the electrode cable assembly, or a problem with the cable detect circuit on the device. Possible Solutions: Check that the Macroduct Advanced Electrode Cable is securely connected.
Error 1001 No Gel Detected	Probable Causes: Pilogel is not present in the red electrode, problem with the electrode cable assembly or a problem with the gel detect circuit on the device. Possible Solutions: Check the red electrode ensuring that a Pilogel disc is present and securely positioned inside the electrode housing.
Error 1002 No Gel Detected	Probable Cause: Pilogel is not present in the black electrode, problem with the electrode cable assembly or a problem with the gel detect circuit on the device. Possible Solutions: Check the black electrode ensuring that a Pilogel disc is present and securely positioned inside the electrode housing.
Error 1003 No Gel Detected	Probable Cause: Pilogel is not present in the red and black electrode, problem with the electrode cable assembly or a problem with the gel detect circuit on the device. Possible Solutions: Check both the red and black electrode ensuring that a Pilogel disc is present and securely positioned inside each of the electrode housings.
Before iontophoresis can begin, the electrode cable must be plugged into the device and Pilogel discs must be detected. If the problem persists, **with electrodes not attached to a patient**, try checking the electrodes from the System screen. (From the Home screen, tap  , then tap **System** and then tap **Functional Test**.) If errors persist, contact ELITechGroup for further instructions.	

5.1 Troubleshooting

Table 6: Error Code Troubleshooting and Diagnosis (continued)

Error Code Message Displayed	Probable Causes/Possible Solutions
Error 1004 Low mA	Current was under the minimum limits. Probable Cause: Loose electrode, broken cable, high skin resistance. Possible Solutions: Be sure both electrodes are secured with adequate tightness to the patient's limb and that the cable is connected to the device. Inspect the electrodes and clean if necessary. Place a drop of deionized water between the electrode and Pilogel disc and directly on the clean skin beneath the Pilogel disc. Suggest repeating the test once. If the problem persists, current control circuitry may be damaged or electrode cable assembly may be damaged. Stop using the device.
Error 1005 High mA	Current exceeded the maximum limits. Probable Cause: Hardware problem in the device. Possible Solutions: Contact ELITechGroup.
Event 1006 User Cancelled Iontophoresis	Event happens when the operator cancels the iontophoresis test.
Error 1007 Disconnect Power Supply	Probable Cause: The battery charging power supply was detected when trying to start iontophoresis. Possible Solutions: Disconnect the battery charging power supply before starting a test.
Error 1008 Power Supply Detected	Probable Cause: The battery charging power supply was plugged in during iontophoresis and as a result iontophoresis was cancelled. Possible Solutions: Charge the battery if necessary and then start the test again or disconnect the charging power supply and start the test again.
Error 1009 Electrode Cable Removed, Iontophoresis Cancelled.	Probable Cause: The electrode cable assembly was removed during iontophoresis and as a result the iontophoresis cancelled. Possible Solutions: Connect the electrode cable assembly and start the test again.

If the malfunction has been traced to a faulty electrode cable assembly, a replacement can be ordered from ELITechGroup (Appendix B).

Table 6: Error Code Troubleshooting and Diagnosis (continued)

Error Code Message Displayed	Probable Causes/Possible Solutions
Error 1010 1 Ramp Low mA Error 1011 2 Ramp Low mA Error 1012 3 Ramp Low mA Error 1013 4 Ramp Low mA	Ramp 1, Ramp 2, Ramp 3 or Ramp 4 current is below their respective lower current thresholds. Probable Causes: High skin resistance, high electrode-to-skin resistance, a problem with the electrode cable assembly, or a problem with the device. Possible Solutions: See Appendix D – Procedure for High Skin Resistance. Inspect the electrodes and clean if necessary. Place a drop of deionized water between the electrode and Pilogel disc and directly on the clean skin beneath the Pilogel disc. Make sure the electrodes are secured with adequate tightness to the patient's limb. Suggest repeating the test once. If the problem persists, **with electrodes not attached to a patient**, try checking the electrodes from the System screen. (From the Home screen, tap  , then tap **System** and then tap **Functional Test**.)
Error 1014 Ramp Timeout Low mA	Full current was not reached during ramp. Probable Causes: High skin resistance, high electrode-to-skin resistance, a problem with the electrode cable assembly, or a problem with the device. Possible Solutions: See Appendix D – Procedure for High Skin Resistance. Inspect the electrodes and clean if necessary. Place a drop of deionized water between the electrode and Pilogel disc and directly on the clean skin beneath the Pilogel disc. Make sure the electrodes are secured with adequate tightness to the patient's limb. Suggest repeating the test once. If the problem persists, **with electrodes not attached to a patient**, try checking the electrodes from the System screen. (From the Home screen, tap  , then tap **System** and then tap **Functional Test**.)

SECTION 5: TROUBLESHOOTING AND MAINTENANCE

5.1 Troubleshooting

Table 6: Error Code Troubleshooting and Diagnosis (continued)

Error Code Message Displayed	Probable Causes/Possible Solutions
Error 1015 Charging Error	No Thermistor, Charging Error. Probable Cause: A problem with the device. Possible Solution: Contact ELITechGroup for further instructions.
Error 1016 Battery charging power supply voltage low.	Battery charging power supply voltage is lower than limit. Probable Causes: Problem with the battery charging power supply or trying to use a power supply not provided by ELITechGroup. Possible Solutions: Make sure the power supply provided by ELITechGroup is being used. Check connections from the power supply to the AC outlet and from the power supply to the device.
Error 1017 Charging Error	Battery Charge Timeout. Probable Causes: The maximum charge time allowed by the charger is 12 hours. The battery may be bad or there may be a problem with the charging circuit in the device. Possible Solutions: If the battery cannot be charged within this allotted time, the battery may need to be replaced or the device serviced. High environmental temperature could also cause this to occur.
Error 1018 Charging Error	Probable Cause: Problem with the battery, not allowing it to charge or a problem with the charging circuit in the device. Possible Solution: Contact ELITechGroup for further instructions.
Error 1019 Charging Error	Probable Cause: Battery shorted. Possible Solutions: Contact ELITechGroup for further instructions.

Table 6: Error Code Troubleshooting and Diagnosis (continued)

Error Code Message Displayed	Probable Causes/Possible Solutions
Error 1020 Calibration Failed	Battery calibration capacity is too low. Probable Cause: Bad battery. Possible Solutions: Run the battery calibration one more time to verify the error. Battery may need to be replaced or the device serviced. Contact ELITechGroup for further instructions.
Error 1021 Calibration Failed	Battery calibration capacity is too high. Probable Cause: Bad battery. Possible Solutions: Run the battery calibration one more time to verify the error. Battery may need to be replaced or the device serviced. Contact ELITechGroup for further instructions.
Error 1022 Clean Red Electrode	Probable Cause: Red Electrode has a Pilogel film buildup. Possible Solutions: Clean Red Electrode with isopropyl alcohol. If problem persists, clean Red Electrode using Electrode Cleaning Pads.
Error 1023 Clean Black Electrode	Probable Cause: Black Electrode has a Pilogel film buildup. Possible Solution: Clean Black Electrode with isopropyl alcohol. If problem persists, clean Black Electrode using Electrode Cleaning Pads.
Error 1024 Clean Electrodes	Probable Cause: Both Red and Black Electrode have a Pilogel film buildup. Possible Solutions: Clean Red and Black Electrode with isopropyl alcohol. If problem persists, clean Red and Black Electrodes using Electrode Cleaning Pads.

If a malfunction has been traced to the electronics or cannot be isolated following the above procedures, the Macroduct Advanced and electrode cable assembly should be returned to ELITechGroup for inspection and repair.

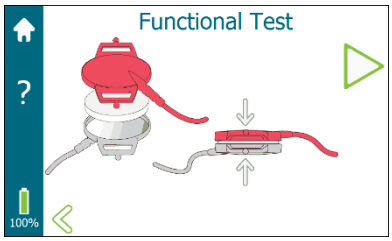
SECTION 5: TROUBLESHOOTING AND MAINTENANCE

5.1 Troubleshooting

WARNING!

DO NOT OPEN the case and attempt repairs without specific authorization by ELITechGroup Inc. To do otherwise voids the Macroduct Advanced warranty and might also pose a significant risk. It is strongly recommended that any malfunctioning device be returned to ELITechGroup for service even after the warranty has expired. Repairs made by electronic technicians who are not completely familiar with the fail-safe features of this device may render such features inoperable.

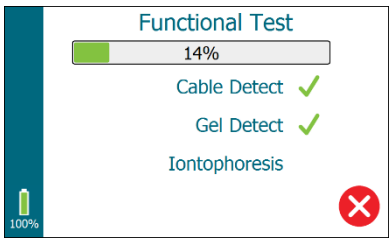
Using Functional Test for Troubleshooting

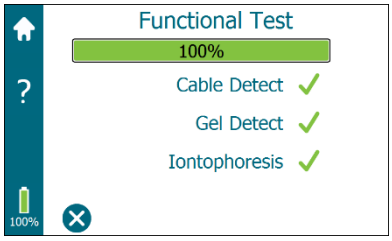


The Functional Test combines the testing of the electrode cable assembly with the cable detect circuitry, Pilogel detect circuitry, and iontophoresis circuitry of the device.

To execute a Functional Test:

1. From the Home screen, tap . From the System screen, tap Functional Test.
2. Connect the electrode cable to the device.
3. Place a single Pilogel disc between the two electrodes. Use an electrode strap to hold them together.
4. Tap to begin the test.
5. A progress status bar displays the progress of the test. As specific tests are completed, results display on the screen. If an error occurs, the error code gets displayed, but the error does not stop the test. The test continues until all three tests have been completed.
6. The test can be stopped at any time by tapping .



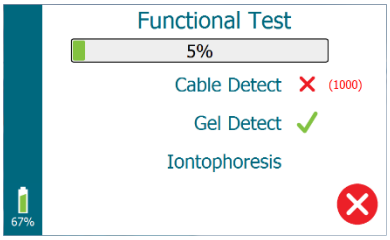
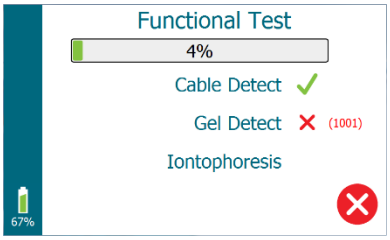


The Functional Test performs the following:

- Verifies that the Macroduct Advanced electrode cable assembly is connected to the device.
- Verifies that a Pilogel disc is in each electrode (two discs are not required for this test).
- Iontophoresis ramps to full current (1.5 mA), verifying that the current is within the specified tolerance. Full current is held for a few seconds and then ramps down to zero mA. Duration of the test is less than one minute.

7. Tap to return to the System screen, or tap to return to the Home screen.

Table 7: Functional Test Troubleshooting and Diagnosis

Functional Test Symptom	Probable Cause/Solution
Cable Detect fails Error 1000 	Probable Causes: The electrode cable assembly was not plugged into the device. Problem with the electrode cable assembly. Problem with the cable detect circuit in the device. Possible Solutions: Ensure the electrode cable assembly is plugged into the device. Try disconnecting and reconnecting the electrode cable. If another electrode cable assembly is available, try using a different cable. Inspect lead wires for breaks or cracks in the insulation. Repeat the functional test multiple times trying the possible solutions. If the problem persists, contact ELITechGroup for further instructions.
Gel Detect fails Errors 1001, 1002, or 1003 	Probable Causes: Pilogel discs are not in the electrodes. Problem with the electrode cable assembly. Problem with the Pilogel detect circuit in the device. Possible Solutions: Ensure a Pilogel disc is placed between the electrodes and that the electrodes are held firmly together. Try using a new Pilogel disc. If another electrode cable assembly is available, try using a different cable. If the problem seems to be intermittent, try wiggling and pulling gently on the wires and cable during the test. Inspect lead wires for breaks or cracks in the insulation. Repeat the functional test multiple times trying the possible solutions. If the problem persists, contact ELITechGroup for further instructions.

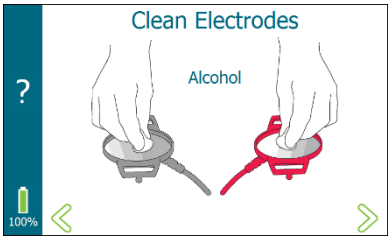
5.1 Troubleshooting

Table 7: Functional Test Troubleshooting and Diagnosis (continued)

Functional Test Symptom	Probable Cause/Solution
Gel Detect fails Errors 1022, 1023, or 1024	Probable Causes: Electrode surfaces have a Pilogel film buildup as a result of not cleaning the electrodes with isopropyl alcohol after every use. Problem with the electrode cable assembly. Problem with the Pilogel detect circuit in the device. Possible Solutions: Clean the electrodes with isopropyl alcohol. Clean the electrodes using Electrode Cleaning Pads. Ensure a Pilogel disc is placed between the electrodes and that the electrodes are held firmly together. Try using a new Pilogel disc. If another electrode cable assembly is available, try using a different cable. Inspect lead wires for breaks or cracks in the insulation. Repeat the functional test multiple times trying the possible solutions. If the problem persists, contact ELITechGroup for further instructions. If the problem seems to be intermittent, try wiggling and pulling gently on the wires and cable during the test. If this helps, discard the electrode set. Inspect lead wires for breaks or cracks in the insulation. Repeat the functional test multiple times trying the possible solutions. If the problem persists, contact ELITechGroup for further instructions.
Iontophoresis fails Errors 1004, 1005, 1009, 1010, 1011, 1012, 1013, or 1014	Probable Causes: Pilogel discs are not in the electrodes. Problem with the electrode cable assembly. Problem with the iontophoresis circuit in the device. Possible Solutions: If a low current error occurs or a ramp error occurs, ensure the Pilogel disc if firmly sandwiched between the electrodes. Inspect lead wires for breaks or cracks in the insulation. If the problem seems to be intermittent, try wiggling and pulling gently on the wires and cable during the test. Repeat the functional test multiple times trying the possible solutions. If the problem persists, contact ELITechGroup for further instructions.

5.2 Cleaning the Electrodes

Electrodes must be cleaned following each iontophoresis procedure.

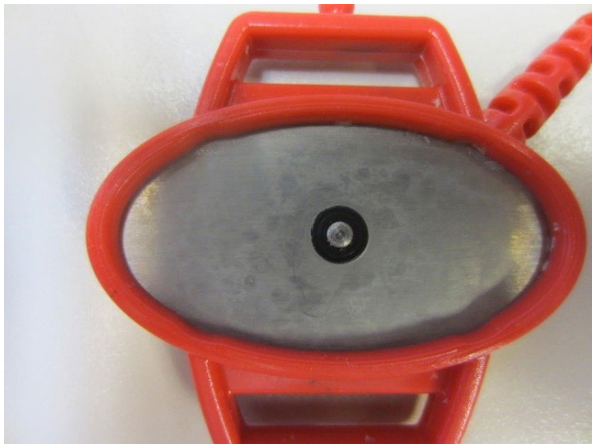


1. Completely remove any remaining Pilogel disc material from the electrodes.
2. Use a cotton ball or swab with isopropyl alcohol or an alcohol wipe to thoroughly clean each electrode.

⚠ **CAUTION:**
Avoid cleaning substances that could leave a chloride residue.

3. Wipe each electrode dry.
4. When using a new Macroduct Advanced Supply Kit (SS-268), or if the electrode appears dirty after an extended idle period, use the Electrode Cleaning Pads (SS-271) to clean and buff the electrode surface.

View of the (un-cleaned) Red Electrode after multiple uses



⚠ **CAUTION:**
Never use harsh abrasives such as steel wool, sandpaper or emery cloth to clean electrodes. Never scrape electrodes with metal tools. If the electrode surface is scratched or pitted, it will not perform as specified and must be replaced.

5.3 Cleaning the Device

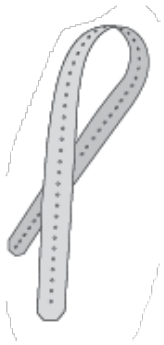
Clean the device after using it with a patient.

Wipe down the exterior of the device using any of the following methods:

- Disinfecting laboratory wipes.
- Isopropyl alcohol, 70% ethanol, or alcohol wipes.

⚠ **CAUTION:**
Avoid cleaning substances that could leave a chloride residue.

5.4 Caring for the Macroduct Straps



The Macroduct Advanced straps are designed to be disposable and it is recommended that they be discarded after use. New straps may be purchased from ELITechGroup (SS-269 or SS-270). See Appendix B.

In the event that the operator desires to reuse the straps, do the following to clean the straps.

1. Soak the straps in 70% Isopropyl alcohol for 1-5 minutes.
2. Rinse soaked straps thoroughly 2 to 3 times in deionized water.
3. Allow to air-dry (high heat may damage straps).

After each cleaning, check for rigidness, brittleness, discoloration, or any other abnormality. Discard strap if damaged beyond usefulness.

WARNING!
Always discard straps that have been contaminated by blood or other bodily fluids.

CAUTION:
Avoid cleaning substances that could leave a chloride residue.

SECTION 5: TROUBLESHOOTING AND MAINTENANCE

5.5 Batteries, Charging and Calibration

Primary (Non-rechargeable) Battery

The Macroduct Advanced has an internal lithium coin cell battery to power the internal clock. Estimated life of this battery is greater than five years. When this battery is discharged, the date/time will not be maintained through power cycles and the battery must be replaced by qualified service personnel. Refer to Replacing the Batteries later in this section.

Secondary (Rechargeable) Battery

The Macroduct Advanced is powered by a main battery consisting of lithium-ion cells. A battery indicator reports the charge status to the operator. When new, a fully-charged battery should adequately power the device for several tests. The number of possible tests will vary based on factors such as the total time it takes to perform each test, the display brightness setting, and whether or not Power Save is enabled.

The Battery Indicator appears in the bottom left-hand corner of the display. Just below  , the approximate % of remaining battery charge is displayed.

Normally, the device is not connected to the battery charging power supply and the following conditions are monitored:

- Battery charge level displays, along with the % of charge remaining.
- When the battery charge level is low, the color of the battery indicator changes to red.
- Do not start iontophoresis if the battery indicator is red.

While the device is connected to the battery charging power supply, the following conditions are controlled:

- Iontophoresis related circuitry is electromechanically disabled. In addition, software prevents using the device.
- The device is in charging mode only.
- While charging, the amber LED on the power on/off switch blinks. When charging is complete, the amber LED stops blinking and remains on for as long as the power supply is connected.

NOTE: *Only charge the battery while the device is within the operating temperature range (15 °C to 30 °C).*

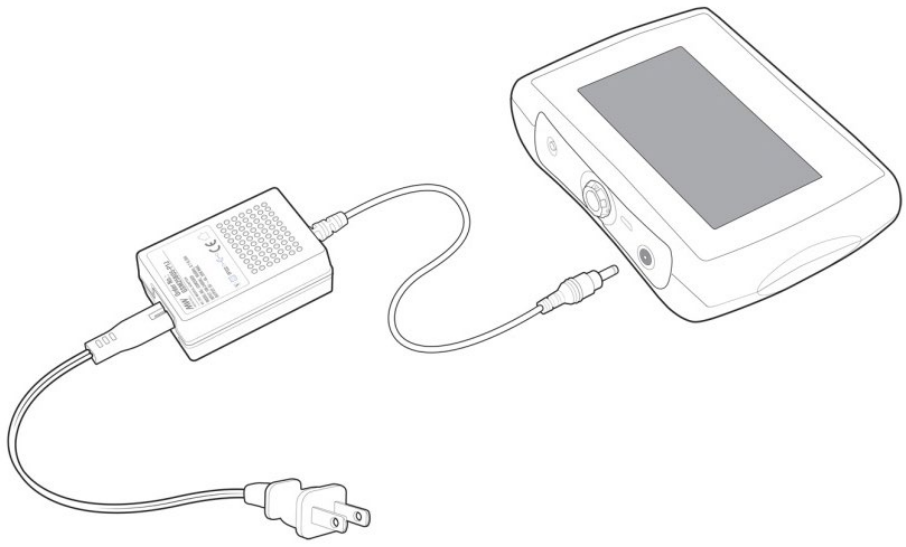
Charging the Battery

For safety, the device is shipped from the factory with the battery partially charged and in a shipping mode. **At first use, the device must be plugged into the battery charging power supply before the device can power on.** Until the battery gets fully charged for the first time, the battery charge level indicators will not be accurate. **Fully charge the battery until the amber LED stops blinking before operating the device.** Typical charge time is approximately 4 hours for a fully discharged battery. Higher environmental temperatures will extend battery charging time.

NOTE: *When the battery is low, charging for approximately 20 minutes should provide enough battery to run a typical test.*

WARNING!
If the device has been recently subjected to low temperatures below 0 °C or high temperatures above 40 °C, let the device equilibrate to room temperature for two hours before charging the battery.

CAUTION:
The electrode cable assembly should never be attached to a patient while the battery is being charged. Only use the ELITechGroup provided power cord and battery charging power supply to charge the battery

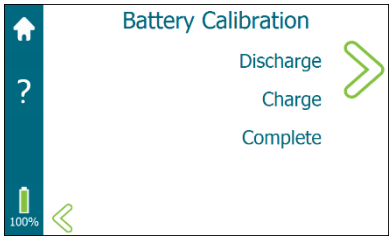


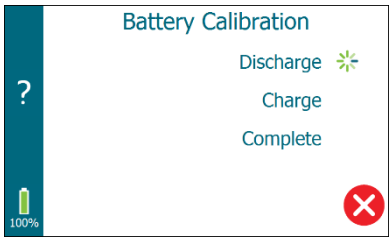
SECTION 5: TROUBLESHOOTING AND MAINTENANCE

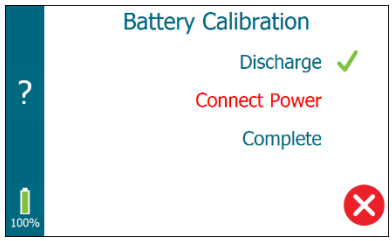
5.5 Batteries, Charging and Calibration

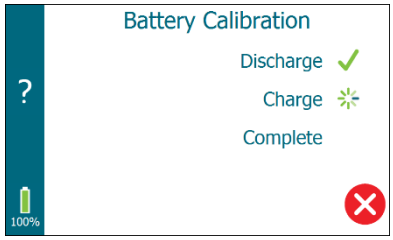
Battery Calibration

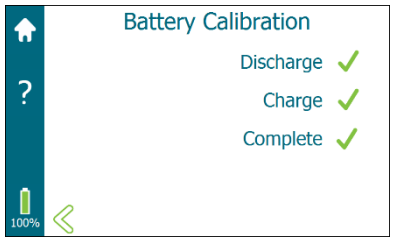
Battery Calibration is used to calibrate the battery indicator that displays the battery charge level. Over time and use, battery capacity decreases, and the displayed charge level becomes less accurate. To improve accuracy, periodically perform this two-step calibration procedure. (1) completely discharge the battery and (2) fully charge the battery.











To perform a battery calibration:

1. From the Home screen, tap .
2. From the Settings screen, tap Power Management.
3. From the Power Management screen, tap Calibration.
4. From the Battery Calibration screen, tap to begin battery calibration.

The battery is discharged by keeping the device operating with the backlight and touchscreen continuously enabled.

Depending upon capacity and current charge level of the battery, discharge can take up to 13.5 hours. After complete discharge, if the display is on, **Connect Power** is displayed. If the display is off, connect the power supply or press the Power Switch to turn the device on and return to the Battery Calibration screen.

5. Connect the power supply to the device to begin charging the battery.

6. Charge the battery until the amber LED stops blinking and remains on (while the LED is blinking, calibration will not occur). This step may take up to 4-6 hours. While charging, with the display off, pressing the Power Switch turns the display on and returns to the Battery Calibration screen (the screen remains on for 10 seconds and then turns off).

7. When charging is completed, a check icon next to Charge indicates that charging is complete and a check icon next to Complete indicates that the calibration is complete.

NOTE: *At any point in the calibration, tap to stop the battery calibration. If the battery calibration is stopped, the calibration must be restarted to calibrate the battery indicator.*

8. Tap to return to the Power Management screen.

Replacing the Batteries

The main battery lithium-ion cells and the lithium coin cell battery are not accessible to the operator and should only be replaced by qualified service personnel.

When the lithium coin cell battery is discharged, the date/time will not be maintained through power cycles and the battery will need to be replaced.

The point at which the main battery should be considered for replacement is somewhat variable and relates to the particular operator needs. As the battery ages, it will hold less charge and will be able to run fewer tests between charges.

WARNING!
Replacement by inadequately trained personnel and/or substituting incorrect cells could result in a hazard (such as excessive temperatures, fire or explosion).

Battery Care

The Macroduct Advanced main battery, like all rechargeable batteries, has a limit to the number of times it can be recharged. The useful life will depend on the environmental temperature during use and charging, calendar age, and how it is used. Only use the device and charge the battery within the operating temperature range (15 °C to 30 °C).

CAUTION:
Do not leave the battery discharged. The battery will naturally discharge over an extended period of time. If not using the device for a prolonged period (a week or more) store the device with the battery partially charged.

5.6 Device Disposal

This device should be completely decontaminated and disposed of as follows:

Under Directive 2012/19/EU (WEEE), this equipment cannot be disposed of in municipal waste. Instead, the equipment must be disposed of either by:

1. Routing to an authorized local facility approved for handling hazardous materials. (Or)
2. Returning the equipment to ELITechGroup or an authorized service center.

5.7 Shipping or Long-Term Storage of the Device

The device and any accessory items such as the electrodes must be cleaned and disinfected before being stored or returned to an authorized service center.

1. Clean the electrodes as described in Section 5.2.
2. Wipe down the exterior of the device as described in Section 5.3.
3. Discharge battery to approximately one-half or less of the full charge by leaving the device on as needed. Battery should NOT be fully charged when transporting the device.

Shipping the device to ELITechGroup:

1. Enclose the device in a container comparable to its original packaging.
2. Include the RMA number along with details describing the reason for the return.

SECTION 5: TROUBLESHOOTING AND MAINTENANCE

5.8 Customer Service Information

ELITechGroup is dedicated to assisting in every aspect of sweat testing theory and practice. ELITechGroup is the acknowledged world leader in the development of innovative systems for cystic fibrosis diagnosis by sweat testing.

This manual contains basic maintenance, troubleshooting, and service information. ELITechGroup is prepared to help resolve any difficulty with the operation or performance of the Macroduct Advanced Sweat Collection System. If a problem cannot be solved using the procedures described in this manual, please contact ELITechGroup's Service Department to help resolve any questions about the operation or performance of your Macroduct Advanced system.

Customers in the United States should contact us by telephone. Outside the U.S., our authorized dealers offer full local service and support.

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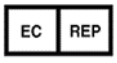

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The Summary of Safety and Clinical Performance (SSCP) for the Macroduct Advanced Sweat Collection System is available upon request by contacting ELITechGroup Inc. using the information above.

APPENDIX A
Pilogel Information

The following information identifies the critical chemicals of each reagent used in this device.

PILOGEL® DISCS (Contained in SS-268 Macroduct Advanced Supply Kit)
Proprietary Name:
Pilogel® Discs

Single Use Only: possible biological contamination; pilocarpine exhaustion.

Indications:

Pilogel/pilocarpine is used under iontophoresis to induce sweating for sweat analysis for the laboratory confirmation of a physician's diagnosis of cystic fibrosis.

Contraindications:

- Do not apply to broken or damaged skin surface.
- Do not use on patients that have a known sensitivity or allergy to any ingredient.

Identification:
Translucent off-white gel disc.

Side Effects and Special Precautions:

The typical and well known side effects associated with pilocarpine use during iontophoresis onto the skin are adverse skin reactions and minor burns. Based on current data and reported events, the incidence of such skin burns is very rare (less than 1 in 50,000 tested patients). See Section 3.4 Risk of Burns.

Consult a physician before performing multiple tests on a patient within a 24-hour period.

Storage Instructions:
Refrigerate at 2 °C to 10 °C. Do not freeze. Keep locked up and out of reach of children.

Registration Number:
SS-268

Name and Business Address of Manufacturer:
ELITechGroup Inc.
370 West 1700 South
Logan, Utah 84321
USA

APPENDIX A
Pilogel Information

Table 8: Critical Components of Pilogel

Product(s)	Critical Components
SS-268 Pilogel Discs contain:	Pilocarpine Nitrate (USP grade) = 0.5 % Other Preservatives < 0.10%

Table 9: Hazard and Precautionary Statements

SS-268 Pilogel Discs are associated with the following Hazard and Precautionary statements. The associated signal word is: Warning.

Hazard	Precautionary Statement
H302	Harmful if swallowed.
P102	Keep out of reach of children.
P264	Wash hands, forearms and face thoroughly after handling.
P270	Do not eat, drink or smoke when using this product.
P301+P312	IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell.
P330	Rinse mouth.
P501	Dispose of contents/container to an authorized waste collection point.

APPENDIX B
Replacement Parts and Supplies

Table 10: Replacement Parts and Supplies

Only replacement parts supplied by ELITechGroup should be used with this device. The use of non-approved parts may affect the performance and safety features of this product.

Replacement Parts and Accessories	Reference Number
EasyDuct Needle/1cc Syringe Set (Pack of 3)	AC-193
Sweat Dispenser	RP-065
Nippers	RP-066
Macroduct Advanced Model 3710 SYS User's Manual	RP-510
Electrode Cable Assembly, Macroduct Advanced	AC-203
USB Cable	RP-538
Medical Grade Power Supply and Power Cord for Battery Charging	
Power Supply and 120 V Power Cord	RP-539
Power Supply and EU Power Cord	RP-540
Power Supply and UK Power Cord	RP-541
Power Supply and AU Power Cord	RP-594
Power Supply and 240 V Power Cord (bare wire end)	RP-542
Supplies	**Reference Number**
Macroduct Advanced Supply Kit (enough for 6 sweat tests) Containing: 12 ea. Pilogel Discs 6 ea. Macroduct Advanced Sweat Collectors 6 ea. Small Sealable Containers	SS-268
Electrode/Collector Strap Set (package of 18)	SS-269
Electrode/Collector Strap Set (package of 180)	SS-270
Electrode Cleaning Pads (package of 10)	SS-271

APPENDIX C
Specifications

Table 11 – General Specifications, Macroduct Advanced Model 3710

Category	Characteristics
Display/Backlight/Touchscreen	Screen Type: Color TFT-LCD (Thin-Film-Transistor Liquid-Crystal Display) Screen Size: 5 inch Wide –VGA Backlight: White LED Touchscreen: Projected Capacitive (PCAP)
Electrical – Power	Rechargeable battery consisting of lithium-ion cells Replaceable only by qualified service personnel
Electrical – Back-up	Lithium coin cell for the real-time clock Replaceable only by qualified service personnel
Iontophoresis Current (nominal)	1.5 mA (automatic)
Iontophoresis Time and Current Control	Current profile-controlled, approximately 20 second rise time, approximately 5 second fall time.
Operating Temperature Operating Humidity Operating Atmospheric Pressure	15 °C to 30 °C (59 °F to 86 °F) ≤ 85%, non-condensing ≥ 79.5 kPa (2000 m)
Storage Temperature	2 °C to 40 °C (36 °F to 104 °F)
Transportation Temperature	-10 °C to 50 °C (14 °F to 122 °F)
Audible Indicator	Magnetic Buzzer, 2.4 KHz (typical)
Electrode Cable Assembly	Elliptically shaped electrodes to fit elliptical Pilogel discs Detect pin for detecting the presence of Pilogel discs
Electrode Connection	6-pin push-pull locking medical connector
Straps	Polyurethane straps are non-latex and non-allergenic
USB Connection	USB Micro B Connector
Charge Connection	Device, DC receptacle, center positive
Power On Indicator	Green LED (power switch)
Battery Charging Indicator	Blinking Amber LED (power switch), graphical battery charge icon
Battery Charged Indicator	Solid Amber LED (power switch), graphical battery charge icon
Device Size (Length x Height x Depth)	17.1 cm x 12.7 cm x 4.4 cm (6.7 in x 5 in x 1.7 in)
Device Weight	0.6 kg (1.4 lbs)
Carrying Case (Length x Height x Depth)	34.3 cm x 24.1 cm x 11.4 cm (13.5 in x 9.5 in x 4.5 in)
Carrying Case Weight (Including device and accessories)	2.3 kg (5 lbs)
Instrument Powered-on Time	8 hours

APPENDIX C
Specifications

Table 12 – Battery Charging Power Supply Specifications

Category	Characteristics	
EMC Compliance	IEC 60601-1-2 4th Edition or later	
Safety Compliance	IEC/EN 60601-1 3.1 Edition or later	
Input Voltage Range	100 VAC to 240 VAC ± 10% @ 50-60 Hz	
Input Connector	2 pin, IEC 60320 C8	
Output Power (typical)	20-30 Watts	
Output Voltage	4.5 VDC (min.) @ full load	6.0 VDC (max.) @ no-load
Output Current (full load)	4 Amps (min.)	
Output Connector	2.1mm x 5.5mm x 11mm length, center positive barrel plug	

APPENDIX D

Procedure for High Skin Resistance

Almost all of the electrical resistance in an iontophoretic circuit is provided by the two skin areas involved, and is due to the relatively dry dead cell layer of the epidermis, which varies in thickness according to location and also between individuals. When iontophoresis begins, the resistance is high, but rapidly reduces as the ducts begin to carry salt-containing sweat to the skin surface. In the majority of cases, the standard pre-cleaning procedure will suffice:

- Rub skin briskly with isopropyl alcohol and water to remove excess skin oils.
- Wash skin vigorously with deionized water to remove as much dead cell material as possible.
- Finally, wet the site under the planned iontophoresis location with deionized water just before applying Pilogel to lower resistance to satisfactory levels.

APPENDIX E
Electromagnetic Compatibility (EMC)

Medical Electrical Equipment, in general, needs special precautions regarding EMC and needs to be used according to the EMC information provided in the accompanying documents. Portable and mobile RF communications equipment can affect Medical Electrical Equipment.

The Macroduct Advanced system is not susceptible to some types of electrical interference, because it is battery-powered. However, it could be affected by radio emissions from other devices. Like all digital electronic equipment it also emits some radio frequency energy when it operates. Use of accessories or cables other than those supplied with the Macroduct Advanced system or supplied by the manufacturer as replacement parts could result in increased emissions or decreased immunity of the Macroduct Advanced Model 3710 and result in improper operation.

The tables below show the test results for both EMC emissions and immunity.

Guidance and Manufacturer's Declaration – Electromagnetic Emissions		
The Macroduct Advanced Sweat Collection System (specifically Model 3710) is intended for use in the electromagnetic environment specified below. The customer or the operator of the Macroduct Advanced Sweat Collection System should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic Environment - guidance**
RF Emissions CISPR 11	Group 1	The Macroduct Advanced system uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class A	The Macroduct Advanced system is suitable for use in all establishments other than domestic. It is battery-powered and does not connect to the public power supply network except for the charging of the battery.

The Macroduct Advanced system should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the Macroduct Advanced system should be observed to verify normal operation in the configuration in which it will be used.

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The Macroduct Advanced system is intended for use in the electromagnetic environment specified below. The customer or the operator of the Macroduct Advanced system should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment - Guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 2, 4, 8, 15 kV air	± 8 kV contact ± 2, 4, 8, 15 kV air	The Macroduct Advanced system is isolated from ground. Any typical flooring may be used.

APPENDIX E

Electromagnetic Compatibility (EMC)

Guidance and manufacturer's declaration – electromagnetic immunity

The Macroduct Advanced system is intended for use in the electromagnetic environment specified below. The customer or the operator of the Macroduct Advanced system should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level			Compliance Level			Electromagnetic Environment - Guidance
	Frequency (MHz)	Level (V/m)	Modulation	Frequency (MHz)	Level (V/m)	Modulation	
Radiated RF Immunity IEC 61000-4-3	800 – 2700	3	1 KHz 80% Amplitude Modulation	800 – 2700	3	1 KHz 80% Amplitude Modulation	Recommended minimum separation distance (m) $1.2\sqrt{P}$ (80 – 800 MHz) $2.3\sqrt{P}$ (800 MHz – 2.7 GHz). Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey [a], should be less than the compliance level in each frequency range. [b] Interference may occur in the vicinity of equipment marked with the following symbol: 
	385	27	Pulse Modulation 18 Hz	385	27	Pulse Modulation 18 Hz	
	450	28	FM ± 5KHz deviation 1 KHz sine	450	28	FM ± 5KHz deviation 1 KHz sine	
	710 745 780	9	Pulse Modulation 217 Hz	710 745 780	9	Pulse Modulation 217 Hz	
	810 870 930	28	Pulse Modulation 18 Hz	810 870 930	28	Pulse Modulation 18 Hz	
	1720 1845 1970	28	Pulse Modulation 217 Hz	1720 1845 1970	28	Pulse Modulation 217 Hz	
	2450	28	Pulse Modulation 217 Hz	2450	28	Pulse Modulation 217 Hz	
	5240 5500 5785	9	Pulse Modulation 217 Hz	5240 5500 5785	9	Pulse Modulation 217 Hz	

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a]Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Macroduct Advanced system is used exceeds the applicable RF compliance level above, the Macroduct Advanced system should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Macroduct Advanced system.

[b]Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

APPENDIX E

Electromagnetic Compatibility (EMC)

Recommended separation distances between portable and mobile RF communications equipment and the Macroduct Advanced System			
The Macroduct 3710 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the operator of the Macroduct 3710 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Macroduct 3710 as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter (Watts)	**Minimum separation distance (m) between portable and mobile RF communications equipment and the Macroduct Advanced system**		
	150 kHz to 80 MHz $d(m)= 1.2\sqrt{P}$	**80 MHz to 800 MHz** $d(m)= 1.2\sqrt{P}$	**800 MHz to 2.7 GHz** $d(m)= 2.3\sqrt{P}$
.01 Watts Maximum	.1 m	.1 m	.2 m
.1 Watts Maximum	.4 m	.4 m	.7 m
.5 W Maximum (typical mobile phone)	.8 m	.8 m	1.6 m (mobile phone)
1 Watts Maximum	1.2 m	1.2 m	2.3 m
10 Watts Maximum	3.7 m	3.7 m	7.4 m
100 Watts Maximum	11.7 m	11.7 m	23.3 m

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