

MEDICAL TECHNOLOGY SRL

EPOREX K69 HEALTH & BEAUTY STATION



EPOREX K69

The deep Blu

Deep blu, beyond the surface.

this is not just our slogan, it also represents the aim we set ourselves and the goal finally reached after a reasoned mix of various synergies and types of co-operation. In fact, modern research in the electromedical field at the moment offers various tools for medical professionals using machines with varying degrees of innovative technological contents.

Nowadays, much is being said regarding how skin and intracellular absorption takes place and there are various theories, even if they are not all sustainable. Here we will only discuss scientifically tested theories.

Medical Technology has optimised a **system of cutaneous transport** on the basis of a large number of accredited studies and research, in particular the research in the field of physical mechanisms that increase the penetration and spread of active principles into the epidermis:

EPOREX K69

With **EPOREX K69** we are creating a new generation **of transdermal delivery system**, bringing about the synergy of already known techniques such as Ionophoresis, Iontophoresis, Electroporation through an innovative method for "active" molecular transcutaneous transport that we call:

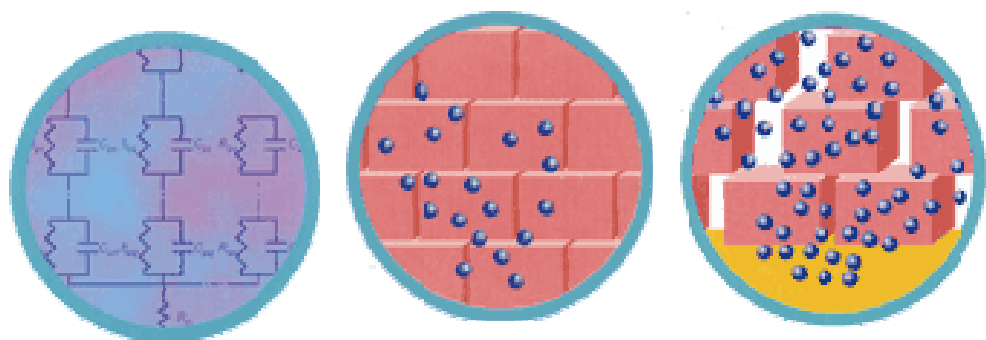
"ISOPHORESIS"

The electronic transdermal method has been used for decades, beginning with the first uses in the medical field for the administration of painkilling drugs and for rehabilitative therapy, but recently it was seen it could be applied in the dermatology and professional aesthetics fields.

The main difficulty for the liberation of substances through the human skin is the external layer, i.e. the corneal layer that is a tough barrier to the transport of substances; its lipid-corneocyte matrix has been the subject of studies regarding:

- variations of impedance of the dermis subject to impulse charges and the consequent variation of its permeability;
- determination of the wave shapes useful for transport purposes;
- creation of a wave shape generator

SKIN BARRIER FUNCTION- HYDROPHYLIC KERATINOCYTES



With ISOPHORESIS an attempt has been made to optimise the transport method to avoid the limits posed by techniques used in the past, i.e. the poor concentration of active principle, the limited depth reached in the tissues, the damage of the tissues due to the intense currents induced.

For these reasons, the isophoretic method represents the avant-garde in skin treatments and in particular the cure of cellulite: new research has already been carried out in various countries with outstanding results representing the future of this new needle-free technique.

TECHNICAL NOTESIONOPHORESIS, IONTOPHORESIS, ELECTROPORATION

Ionophoresis was first described by A. Volta and A. Galvani in the XIX century and laws were formulated about 1900 by Leduc.

This technique exploits the electrical principle by which electrically charged "ions" move at variable speeds in an electrical field generated by a continuous galvanic current but its **limits** are to be found in:

- poor penetration for fixed frequency use (max 5 mm.)
- need for polarised products
- high concentration of active principle
- "saponification" of the skin and burns due to the use of energy over 0.1 mA/cm²
- formulation of substance: pH, viscosity, presence of other ions

Iontophoresis uses the same electrical principles as ionophoresis, in as much as the substance is ionised by means of a continuous galvanic current using however a developed wave no longer continuous but modulated in impulse trains with a lowering of the incidence of surface burns but same capacity of penetration due to non-variation of the wave frequency.

The **limits** are the same as for ionophoresis, especially in the need to use products that are already polarised but, above all, the limit is that only a low quantity of active principle can be carried and the depth reached in the corneal layer is quite limited.

With iontophoresis however, the importance was recognised of using the electronic transdermal method for the administration of drugs in the medical therapy of various specialties, first of all in genetic-molecular therapy as demonstrated by more than 1400 U.S. patents and more than 5,600 articles in scientific journals and magazines.

ELECTROPORATION

This methodology is employed in medical therapy by exploiting its invasive feature, leading to an increase in the permeability of the skin tissue: electroporation of the skin occurs when, by the art of an electric pulse, between 0,5 and 1,5 Volt, a transmembrane potential is generated within an epithelial cell structure .

As a result, the lipid layer of the cell membrane is subjected to an alteration : the formation of the well known aqueous vessels, hence called "electropores".

The creation of electropores occurs at a subsequent time, after the induction of the electric pulse, and takes only a few minutes, thus leading to a diffusive permeability of the molecules, even of high weight, that enables them to penetrate through the entire tissue "targeted" by the electric pulse.

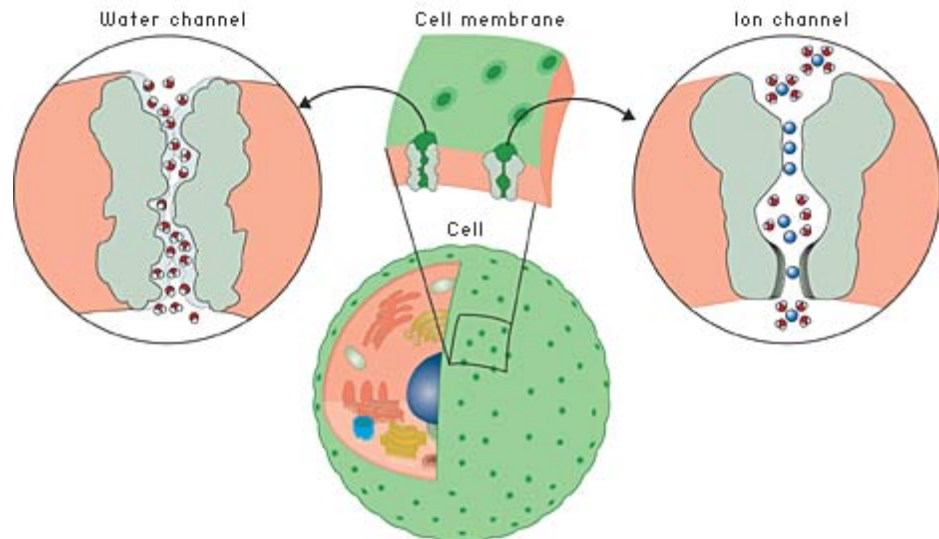
The aqueous vessels will preserve themselves for a period directly proportional to the wave length of the pulse itself: this span ranges from few seconds to about ten minutes.

In particular, takes place, what has been recently established by chemical-biological field researches, in the well known study on "*vessels dedicated to transport of water into cells*".

This study was awarded in the year 2003 with the Nobel prize for chemistry, which went to two eminent american researchers, Roderick MacKinnon and Peter Agre.

In fact, thanks to this study, it was possible to discover the existence of **molecular vessels** which enable the cellular membrane to let in or out vital substances as water and salts (membrane proteins).

SKIN BARRIER FUNCTION - HYDROPHYLIC KERATINOCYTES



the control of the crossing-over of ions and molecules through these structures is regulated by chemical impulses that allow cell-cell contacts.

These impulses appear to be ions or small molecules that induce a series of " **cascade reactions** " inside the cell, this event leading to the emergence of a macroscopic effect, such as, muscular tension or biochemical or metabolic reactions in our body or in the brain.

In consideration of the above, thanks to the methodology developed with the EPOREX K69, i.e. the ISOPHORESIS, it is possible to transport water-soluble molecules through the epidermal barrier, which, it is known, shows an extremely low permeability to water-soluble substances, due to its extracellular lipid matrix (cholesterol, fatty acids), thereby allowing the introduction of active pharmacological principles at varied depths.

EPOREX K69 AND ISOPHORESIS

With the method we have tested called *ISOPHORESIS*, a *pulsed and modulated current is used*: i.e. a low frequency wave with *elastomodulated wave shape* and with a modulated intensity which is variable by the operator. Its shape and particular trend is able in this way to electronically activate molecules with both low and high molecular weight and allows them to pass into the extra-cellular compartment at depths never reached before: up to 9 to 10 cm, while introducing 90% of the active substance necessary for the treatment.

In this way a double objective is achieved: the increase in the permeability of skin tissue even at the deepest levels of the dermis and the capacity of introducing active hydrosoluble substances with a high molecular weight (e.g. hyaluronic acid, collagen, Vitamin C etc.)

EPOREX K69 differs considerably from other systems in two essential features:

1) THE WAVE MODULARITY: non continuous negative/positive or alternate constituted by a pulse train with a sinusoidal mode separated by intervals that can be modified in frequency that, according to the wave equation

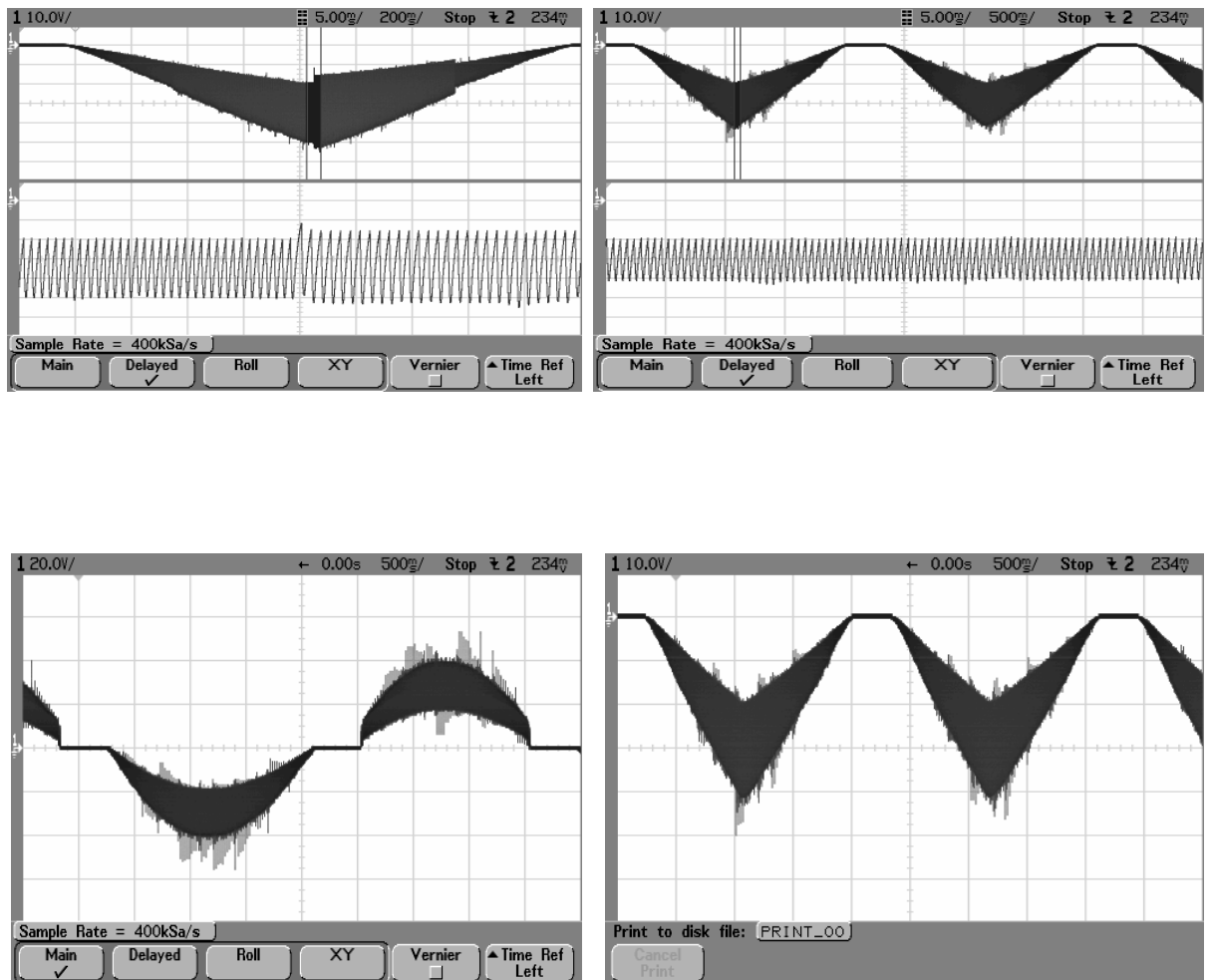
$$Y=X - 180 + 2000$$

where Y is the frequency in HZ and X the depth in cm, enables the product to be carried without thermal damage for several centimetres: in fact, the

wave modulation avoids us the absorption of too much energy into tissue (maximum for human tissue is $0,1\text{mA}/\text{cm}^2$) in the time of phase "off".

The system makes it possible to automatically vary the wave length frequency in relation to the set penetration depth.

WAVE FORM



2) THE PRESENCE OF A IONIZATION CHAMBER in the handpiece that polarises and prepares molecules electrically and no ions, with the possibility of thereby carrying any hydrosoluble substance through the opening of the so called "electropores" and easier intracellular penetration: the "indissociated" molecules actively brought to into the cells will modulate the metabolism in relation to their characteristics and concentration and they will move towards the dermal matrix by electrosmosis.

In brief in ISOPHORESIS the transmission process occurs according to a synergy of steady processes:

1) IONIZATION OF THE SUBSTANCE

The elastopulsated current meets the molecule then it ionises it and makes it "active" ready for transport.



2) TRANSMISSION

The ionised molecule is transferred to the optimal depth.



3) ELECTROPORATION

After around 12 – 13 minutes, electropores are created: the molecules transfer the substances from one cell to the other by osmosis.



EPOREX K69

HANDPIECE AND THE IONIZATION CHAMBER

The ionization chamber is a structure inside the handpiece and is a true innovation, here the osmotic and conductive processes of the substances gradually take place.

In the handpiece a bottle of a conductive gel is mixed with the dehydrated powder immediately before the use. This ensures the freshness of the product.

It makes the active principles that can be ionised soluble and carries them. Also, the conductive gel is free of preservatives, which might create allergies.

EPOREX K69 is supplied with its specifically prepared Gel and Powders.

In the ionization chamber, structured with regular metal armatures, the mix is subjected to fixed and constant induction by the elasto-modulated current. The handpiece is in fact structured in such a way that the armature of the ionisation chamber is fixed and constantly in contact with the mix and ensures a constancy of ionisation of the active principle for later transmission.



The Eporex K69 handpiece , thus studied , can carry out:

- **Constant and graduated transmission of active substances, as its steel roller carries out the electroporation on the skin, with constant release of the mix, with perfect adhesion to the skin and at steady distance.**
- **No dispersion or concentration gradients is created. It ensures a constant quantity of electric power and thereby, of ionised substance.**
- **Furthermore, the handpiece ensures all sanitary standards , in compliance with health regulations. In fact, its special stainless steel parts are removable and can be cleaned and sterilized .**



Methodology 's objective

- **Transmission of the active principle directly and in depth, to the target tissue**
- **Extended action of active principles**
- **Reduced quantity of active principle used**
- **Higher concentration on treated site**
- **Less systemic absorption and toxicity**
- **Total absence of any pain or discomfort during treatment**
- **Hygiene**



We have successfully succeeded in combining Eporex K69 with a different methodology that is able to enhance the efficacy of Isophoresis treatments : ultrasound waves combined with galvanic current by means of

BRIGHT SKIN.

This technological device is patented and supported by registered protocols.

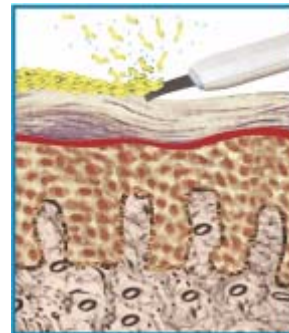
BRIGHT SKIN ultrasound device promotes the rejuvenation of the skin and the prevention of cutaneous ageing through the use of Ultrasound waves : It consists of a metal strip in the shape of a spatula, oscillating at a frequency of 25,000 Khertz . The spatula is bent to 45° at its end, and allows to spread the ultrasonic waves along the whole surface , exploiting the principle of CAVITATION.

This phenomenon occurs when a liquid is subject to a significant depression. When the absolute pressure becomes less than the "tension" of the liquid, a force field is created which transforms, copiously, the liquid into vapour, in the form of micro-bubbles of gases contained in the liquids.

This enables the removal of dead skin cells and residues of make up and impurities deposited in the sebaceous follicles.

Furthermore, on the Bright SKIN handset it is possible to combine, in relation to the selected programme, the emission of galvanic micro-current for transdermal delivery or electric peeling, exploiting the synergy between the action of ultrasound (sonic thrust) and galvanic micro-current (ionic thrust).

CAVITATION PHASES



BRIGHT SKIN device carries out :

- **Peeling/Exfoliation** of dead cells from the cutaneous surface and deep cleansing of the skin from various polluting factors (smog, make up, bacterium, etc.): sonic cavitation allows the removal of the corneal layer and the superficial cell layer, realising a younger layer of corneocytes (cellular turn-over); when combined with the simultaneous emission of galvanic micro-current, that adds an important ionic action, improves tone and luminosity of the skin.

- **Skin toning and cellular stimulation** through electric peeling protocols , by means of galvanic current combined with ultrasound waves
- **Exogenous and endogenous moisturization:** micronized active principles are delivered by means of ultrasound waves in depth , thanks to the osmotic phenomenon made active by the compression and decompression of the interstitial liquids; as a result , an optimal, deep, skin moisturization is achieved.
- **Rebalancing of the metabolism, clearing action:** improves micro-circulation , increases oxygen in the tissue , promotes the production of collagen and elastin through a micro-massage carried out by the elastic pulsed wave. Furthermore, in combination with a specific substance, it reduces melaninic dyschromia, aids and potentiates antioxidant mechanisms.

The Bright Skin device utilized as a pre-treatment phase, prior to the Eporex K69, prepares the skin clean and aseptic, ready to receive active principles for each specific treatment.

The BRIGHT SKIN software offers several different treatment programmes, based on the different skin types (3 typologies), combining, when required, the ultrasound waves to the galvanic currents.

Below, the " programmes range" chart.



<i>PROGRAM</i>	<i>WAVE</i>	<i>TREATMENT</i>
<i>Dermopurification</i>	Continuous	Exfoliation and cleanse
<i>Deep dermo-purification</i>	Continuous combined with galvanic current	Exfoliation and deep cleanse
<i>Deep purification and Tone-up</i>	Pulsating wave with galvanic current	Exfoliation, cleanse and tone-up with mechanical massage
<i>Tone-up action</i>	Pulsating wave	Toning with deep moisturization (active principles penetrate into the skin)
<i>Skin reactivation</i>	Continuous wave with galvanic current	Cellular stimulation with deep moisturization (active principles penetrate into the skin)
<i>Reactivation and Tone -up</i>	Pulsating wave with galvanic current	Cellular stimulation and toning with deep moisturization

OUR SINERGIC TECHNIQUE :
ULTRASOUND + ISOPHORESIS

In conclusion, applications with EPOREX K69 in combination with ultrasounds are particularly effective:

ULTRASOUND=Bright Skin In the first phase, for cleaning treatment by sonic waves that remove skin greases and oils from the surface as well as a portion of corneal layer in a method similar to that of a slight microabrasion of the skin.

WAVE FORM=EPOREX K69 In the second phase, in terms of skin penetration in which the sequenced wave shapes are able to penetrate 90% of the substance but also in terms of the depth reached.

The wave shapes are used in combination with a conducting current in gel, thus permitting the treatment of the active agents at the depth required. In the applied clinical studies it is shown that a range of depth from 0.5 cm to 10 cm might be carried in the tissue.

The key for optimum transmission in aesthetic treatments is the EPOREX K69 patented handpiece incorporating a dispenser with 60 ml of conductive gel.

The handpiece, made with a "roller" mechanism, distributes the mix of conductive gel and the important activated ingredients to be transferred, over the surface of the tissue.

The treatment time is approximately 10 minutes per facial treatment and around 20 minutes for treatments where there is cellulite in the thigh and buttock areas.

The operator can select the treatment parameters according to the special needs of the patient.

Furthermore, no visible sign of the treatment remains on the surface of the skin and the patient's experience is totally painless and pleasant.

SOME EXAMPLES OF THE TREATMENTS CARRIED OUT WITH EPOREX K69.



Patient who undertook rejuvenation and skin resurfacing treatments with EPOREX K69

PHOTO – BEFORE : shows the structure of the skin and the dyschromia on cheeks and neck. The forehead skin appears rough and uneven.

PHOTO - AFTER : the skin is smooth and even.

Significant improvement of the forehead with less dyschromia and lines.

Note the excellent result on the cheeks and the whole neck area.

EPOREX K 69
APPLICATION FIELDS AND ACTIVITIES

MEDICINE	ANALGESIC
	ANAESTHETIC
	ANTI-INFLAMMATORY
	ANTIPHLOGISTIC
	MUSCLE RELAXANT
	ANTIEOEDEMATOUS
AESTHETIC MEDICINE	ACNE
	CELLLULITE
	STRETCH MARKS
	MODELLING AND TONE UP
	ANTI AGING/WRINKLES
	FACE LIFT
	BALDNESS

FINAL CONSIDERATIONS

- ❖ **IT IS THE FIRST TRANSDERMAL DELIVERY, COMPUTER-DRIVEN, CARRYING DEVICE THAT CAN PERFORM, SIMULTANEOUSLY, DIFFERENT TYPES OF TREATMENTS.**
- ❖ **ITS MICROPROCESSOR ALLOWS THE SETTING OF DELIVERY TREATMENTS WITH DIFFERENT FREQUENCIES AND PRODUCTS, TO THE DEPTH REQUIRED.**
- ❖ **EACH OPERATION IS VISIBLE ON THE CONTEMPORARY DESIGNED CONTROL PANEL, WHERE ALL THE ELECTRONIC FUNCTIONS ARE SET.**
- ❖ **EASY TO USE AND HANDY : THANKS TO ITS PORTABILITY AND ITS STREAMLINED SOFTWARE, ENABLES A CLEAR AND SIMPLE EMPLOYMENT.**
- ❖ **ITS INNOVATIVE HANDPIECE, FEATURED BY A CONSTANT CAPACITY OF CARRYING PERFORMANCE, ENSURES OPTIMAL SANITARY STANDARDS, IN COMPLIANCE WITH HEALTH REGULATIONS, SINCE ITS PARTS ARE REMOVABLE, AND THEREFORE CAN BE CLEANED AND STERILIZED.**

*We would like to thank for the kind cooperation and for the clinical applications
on EPOREX K69 :
Dr. M. KARGIN – London, U.K.*

TECHNICAL SPECIFICATIONS
EXTERNAL VOLTAGE: 110/220/240 V. C.A. 50-60 Hz
INTERNAL VOLTAGE: 24 V.C.C.E
ABSORBED POWER (CAPACITY): 40 VA
PROTECTION: FUSE TYPE R 250 MA
SAFETY CLASS: I/BF
DIMENSIONS: 550 x 260. x 230 MM
NET WEIGHT: 6 KG
COMMUNITY POLICY COMPLIANCE
ELECTROMAGNETICAL COMPATIBILITY: 89/336 CEE
LOW VOLTAGE POLICY: 73/23 CEE
SPECIAL REGULATIONS: CEI 62/39 – CEI 61/150



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