

SKIN-BREATH®

Export Version
www.c2p-healthcare.com
www.skin-breath.com

SkinBreath Version 3

Portable Carboxytherapy Device

Instructions for Use



SKIN-BREATH is a registered trademark in Europe and others countries

SKIN-BREATH is a registered model in Europe and Other countries

Skin-Breath is copyrighted

CE approval is delivered by TÜV

CE 1936

I. Introduction

The device was designed for dermatological treatments that stimulate the superficial vascularization of adult skin, for use by physicians, nurses or other approved providers. SkinBreath is a carboxytherapy device designed to be portable and easy to use. The device uses specific medical-quality CO2 cartridges that free you from the traditional large CO2 tank. The adjustment control dial provides precise control of CO2 outflows, and the push button delivers the proper amount of CO2 with limited losses. You can perform all of the same procedures as with a traditional carboxytherapy device using a fraction of the space.

Indications:

- **Angiology:** Raynaud's syndrome, lower limb ischemia, stimulation of ischemic or diabetic ulcer scarring, lymphedema
- **Dermatology:** Raynaud's syndrome, atrophic scars, scars from injury or burns, psoriasis, skin irregularities after liposuction
- **Rheumatology:** Joint pain
- **Neurology:** Specific neurological pain
- **Aesthetic Medicine:** Scars, loss of skin elasticity, dark circles due to venous stasis

Contraindications:

The contraindications for carboxytherapy are the same as those for mesotherapy:

- Scarring problems
- Coagulation problems
- Uncontrolled diabetes or immune deficiency (risk of infection)
- Recent venous thrombosis in the area to be treated
- Pregnancy (as a precaution; temporary contraindication)
- Current dermatological disease (bacterial, viral, fungal) (temporary contraindication)
- The SkinBreath device should never be used for liposuction purposes.

Side effects:

Temporary hematoma at the injection site

Vaso-vagal syndrome, as with any mesotherapy

Pain upon injection (like that for mesotherapy)

Temporary hypesthesia (<3 minutes) when upper or lower extremities are treated.

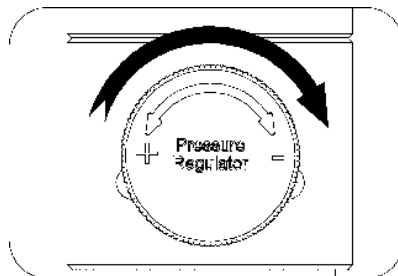
II. Parts Diagram

See web site

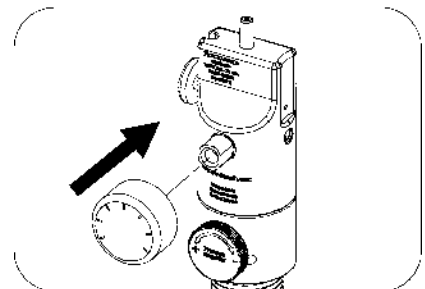
III. Device Set-Up

Please follow the set-up steps carefully to understand how each SkinBreath component works.

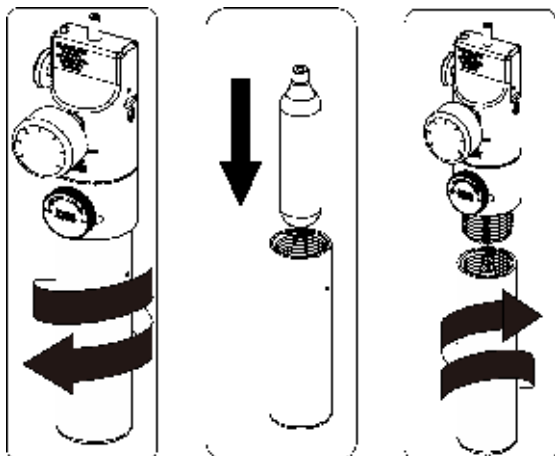
1. Close the pressure wheel dial by slowly turning it clockwise until it stops in the closed position. If you do not close the gas inlet before inserting a cartridge, you risk damaging the pressure gauge with overly high initial pressure.



2. Screw the pressure gauge onto the device. Be careful not to attach the pressure gauge too tightly to avoid crushing the gasket. This could lead to a loss of air tightness and leaks, wasting cartridge gas.



3. Remove the lower section of the device and insert the recommended medical-quality CO2 cartridge as shown in the graphic below.



Fully screw the SkinBreath body on; the cartridge is pierced once the body is completely screwed together. Make sure it is completely screwed on to avoid leaks. We recommend that the device be screwed together rapidly so that the CO2 cartridge is pierced quickly. Screwing it on too slowly can allow some CO2 gas to escape.

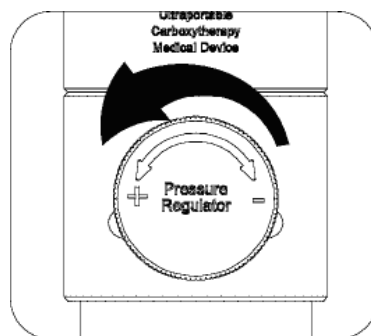
Be sure to only use SkinBreath brand medical CO2

cartridges.

Other CO2 cartridges may damage the device and create a risk for patients or practitioners.

You may need to press the push button while activating the pressure regulator (simultaneous action on the regulator and the push button releases the gas). This will properly equalize the pressure with the needle in the green area of the pressure gauge.

4. Slowly turn the pressure control dial counterclockwise to regulate flow, so that the pressure gauge needle appears in the pink, blue or green area of the dial, depending on the desired flow. Be sure to check that the filter and needle are properly sealed to avoid any gas leaks.



✓ **35 Psi = 120mL/min**

✓ **20 Psi = 70mL/min**

✓ **10 Psi = 30mL/min**

The SKIN BREATH pressure gauge is graduated in PSI and BAR.

It allows the physician to obtain a therapeutic flux estimate in the ranges usually considered as effective.

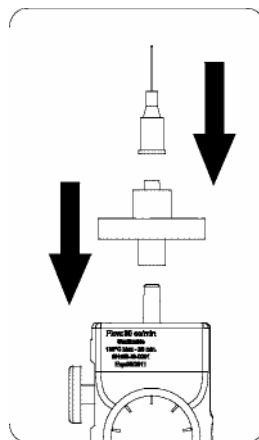
In all cases, the physician should refer to the visual control of the treatment effect to adjust the flow. The values of the gauge should be regarded as a landmark.

In practice, the clinical observation leads the physician to adjust to his diagnosis around these basic values.

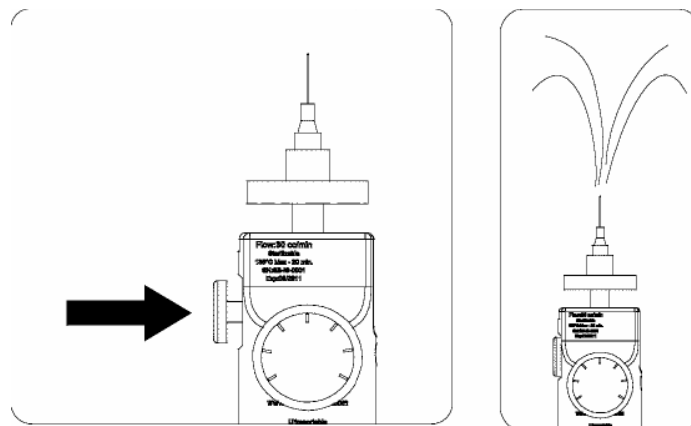
The CO2 meter MUST be closed when the pressure gauge is installed to avoid causing an abrupt pressure spike, which could damage the needle and lead to false pressure readings. We recommend closing the CO2 inlet, installing the pressure gauge, then opening the CO2 inlet to gradually adjust the pressure.

5. Install a recommended 0.22 µ filter and a 30 gauge Luer needle.

(The filter and needle are single-use.)



6. Press the on/off button down to release the desired amount of gas. Release the button to stop the release of gas.



Reminders:

1. ALWAYS use a SkinBreath brand medical CO2 gas cartridge.
2. ALWAYS use a new 0.22 µ filter and a new needle for each patient.
3. NEVER ATTEMPT TO REFILL A GAS CARTRIDGE.

IV. SkinBreath Cleaning Instructions

The SkinBreath must be cleaned and disinfected after each use. It must also be cleaned and disinfected prior to first use after being removed from its packaging.

Note: The cartridge is single-use only and must not be re-used.

Empty cartridges can be thrown away and processed as recyclable metal waste.

The 30 G needle and the 0.22 µ anti-bacterial filter are also single-use only. Never re-use them for another patient. The needle and filter must be disposed of as infectious medical waste products. Yellow containers and special disposal.

You must also comply with all current legal measures in your country as well as with your country's health standards and good practice regulations. This is your responsibility.

The SkinBreath device itself can be re-used. The lifetime of the device depends on how often it is used, whether it is used properly, and on proper, regular maintenance. The user is responsible for inspecting the SkinBreath prior to each use, and should not use it if the device appears to be damaged or dirty. The user is responsible for non-compliant use of the SkinBreath. The user should not loosen or remove screws fitted with leak-prevention gaskets. Unauthorized loosening or removal is not covered by the warranty and may damage the product or cause gas leaks. Pressure gauge gaskets may wear out and age through normal use. The user should be sure to change them if there is a leak or signs of wearing.

Remove residue and spots from the instrument immediately after use with a clean, soft, single-use cloth.

Cleaning Preparation:

1. The device must be open when cleaned.
2. Only use cleaning products recommended by the manufacturer.

Cleaning and Disinfection:

1. Use a spray or wipe disinfectant (fungicide, bactericide, or virucide) for medical products such as **Isorapid® spray, Aniospray® ddsh disinfectant virucide, fungicide, Dentiro® disinfectant wipes, or Wip'Anios® disinfectant wipes.**

2. Follow the product manufacturer's instructions.

Storage and Transport:

1. Put the device away after use to avoid contamination.

Inspection and Testing:

1. Carefully inspect the device for any damage and/or obvious wearing (especially gaskets).

2. Check that moving parts are working correctly for proper operation of the device.

3. Check that there are no leaks or unstable measurement readings in the pressure display.

4. If a problem is detected, do not use the device and contact your reseller.

Storage:

Store the clean device in a clean, dry, dust-free area at room temperature.

Additional Information:

The device should be examined closely to be sure it is completely clean before use.

Important Note Regarding Pressure and Flow Rate Regulation



Important note to users: The SkinBreath® device is designed to operate in the range of 10 to 40 PSI. The materials are fine-tuned in the factory to produce a maximum flow of 120 cc/min, for a pressure gauge reading of 35 PSI.

The materials are not designed to operate at pressures greater than 40 PSI. Exceeding this pressure range may damage the product and/or the pressure gauge, and produce a CO2 flow higher than normally recommended values.

The pressure range must therefore be maintained between 0 and 40 PSI maximum to ensure the proper use of the materials.

The product you have just purchased is made with high-quality materials and components that can be recycled. As noted on the label on the back of the device, this product is covered by European Directive 2002/96/CE (CE dated January 27,

2003), and should not be discarded with household waste at the end of its product life. Instead it should be selectively recycled to protect our environment.

Client Service:

Contact your local representative:

The above instructions were validated by medical device manufacturers as usable for a medical device. It is up to the user to make sure that they are effectively carried out using the appropriate equipment, materials and personnel to ensure a risk-free treatment for patients. This requires that the process be validated and monitored. Any changes by the user to the process thus established are his/her sole responsibility. Likewise, any intentional improper use of the SkinBreath is the user's sole and complete responsibility.



V. Warning!

- Store the CO2 cartridges in a cool, ventilated area.
- Never put cartridges near a source of heat or in the sunlight.
- Never put the CO2 cartridge in an autoclave; this will cause the cartridge to explode.
- The pressure gauge is a precision instrument. Change it if it is dropped to ensure proper operation of the device.
- Never put the pressure gauge in an autoclave. This may damage the pressure gauge.
- Check that the needle and its sterile packaging are intact before use. If they are not, do not use the needle.
- If the device is dropped during use, clean it, check for leaks and malfunctions, then replace the needle and filter to avoid contaminating the patient.
- After use, the needle and filter must be processed as infectious medical waste.
- If there is a leak after inserting a CO2 cartridge, stop using the device and contact your reseller.
- The device's flow rate varies according to the pressure displayed on the pressure gauge. Therapeutic flow is selected by adjusting the pressure.
- The needle and filter are single-use only. Do not use them twice, as they can be a source of blood-borne infection and/or disease.
- Only use recommended needles, filters and cartridges.
- **ATTENTION!** We use specific cartridges. We cannot ensure the device's warranty if other products are used, the SkinBreath is used improperly, or the instructions in this manual are not followed.

- Use of the SkinBreath is reserved for authorized persons according to regulations in effect in the country.
- Improper or non-compliant use of the product may cause injury.
- Make sure the device is maintained on a regular basis. Contact your reseller for maintenance every two years.

The SkinBreath is made of aluminum and stainless steel. This device is never normally used in direct contact with the skin.

VI. Important Notice

C2P Healthcare SARL. All rights reserved. No portion of this publication may be reproduced in any form whatsoever without written authorization from the owner. The manufacture, reproduction, use and sale of rights related to the SkinBreath device are expressly reserved. By accepting this document, the recipient agrees that the information contained herein will not be copied or reproduced, in whole or in part, nor will its contents be revealed, except for the purposes for which this document was prepared and delivered, without the express authorization of C2P Healthcare SARL.

VII. Warranty

C2P Healthcare SARL warrants that every new device is free of material and manufacturing defects. This warranty is not transferrable. This warranty is valid for a period without interruption of one year after the initial shipping date on the original billing document of the original purchaser. This warranty covers parts and labor if the device is deemed defective after testing by the manufacturer. For repairs under warranty to be carried out, the purchaser must inform his/her reseller of presumed defects, and, if these are proven, ship the instrument to the designated address, properly packaged in an appropriate container, for testing and repair.

VIII. Limits and Exclusions

This warranty does not cover repairs required for damage to the equipment caused by improper handling, negligence, abuse or modifications by the client, or user non-compliance with the procedures described in the Instructions for Use. Repaired devices are guaranteed for a 30-day period and are subject to the limitations and exclusions described in this document.

C2P Healthcare reserves the right to change, at any time, the design of its products, its technical specifications, or the content of this manual without obligation to integrate these changes into products that have already been delivered.

Known Problems and Troubleshooting

Audible gas leak during cartridge installation

Check that the body is properly screwed onto the instrument head. If necessary, screw on tightly to eliminate the leak.

Check that the pressure indicated on the pressure gauge is within normal operating values.

Overpressure may cause leaks in the device and changes to flow rate.

Check that the pressure gauge gasket is not crushed, and thus nonfunctional.

Check that the filter and needles are properly attached to the SkinBreath device.

If these actions do not resolve the problem, contact the reseller.

Pressure gauge pressure not returning to zero after use

The pressure indicated on the pressure gauge is not zero when the gas inlet is closed. This is due to remaining CO₂ in the device head. This pressure has no practical consequences. The pressure gauge can be reset to zero by closing the CO₂ inlet and pressing the CO₂ release button to purge the device.

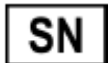
Pressure gauge pressure at maximum after a period of non-use

The pressure gauge may indicate overpressure after a period of non-use. This is due to micro-injections of CO₂ gas from the cartridge to the device head. These small injections end up increasing the internal pressure of the SkinBreath device. To reduce this problem, be sure to completely close the SkinBreath CO₂ inlet. If the pressure gauge shows high pressure, you are advised to purge the head by pressing the gas release button before operating the device again. For long periods of non-use, removal of the cartridge from the medical device is recommended.

IX. Symbols



Caution



Serial number



Consult the Instructions for Use



Manufacturer :

Made in France



1936: number of notified body authorizing the placing on the market, according to the provisions of the European Directive 93/42/EC