



onda

FAQ

Frequently Asked Questions

May 2019

DEKA
Innate Ability

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1. Please explain the Onda mechanism of action in detail.

Microwave technology is very popular in the modern society and it is not a new comer in medical applications either. It has been widely used in many branches of medicine up to now including Oncology. The reason why **Coolwaves™** target fat cells in a safe, effective and non-invasive way depends on the frequency **Coolwaves™** works at.

In fact, from physics, skin behaves differently when submitted to different frequencies (technically: dielectric behavior). The skin allows the passage of energy with high frequencies, but it does not allow it anymore when the frequency of the same energy gets lower.

In other words, **frequency discriminates the passage properties in the skin.**

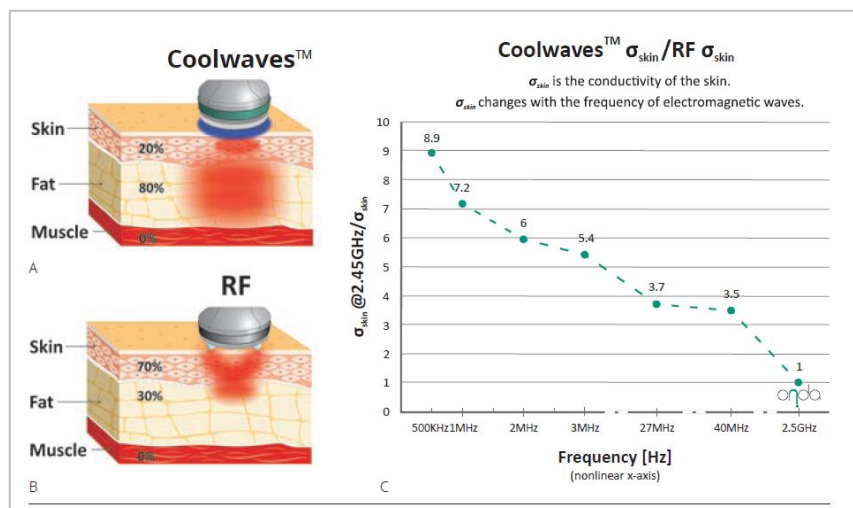
Technically speaking, “Skin Conductivity” is a physic characteristic (parameter) that identifies the property of a biological tissue to transfer the energy received from an outer source (microwave handpiece) to surroundings tissues.

Conductivity is correlated to the applied frequency. Simply speaking, skin offers more resistance (less conductivity) to low frequency energies (from KHz to MHz) instead skin offers less resistance (more conductivity) to higher frequency energies (from MHz to GHz).

The selective microwave frequency **Onda** works at, is 2.45GHz. At such a high frequency, skin tissue is almost “transparent” to the passage of the energy that is almost totally lead over the subdermal fat layer specifically. This makes the superficial layers of the dermis to be preserved from unwanted heating and to stay cool. For this reason, the microwaves **Onda** works with, are now denominated **Coolwaves™**.

In numbers (A):

- 80% **Coolwaves™** energy targeting the **fat cells**.
- 20% Energy absorbed by the epidermal and dermal layers (this is in any case counterbalanced by the cooling system integrated in the handpiece that limits the effects of such heat and protects the epidermis).



The situation is quite different with RF handpieces (B). For **Coolwaves™**, the conductivity of the outermost layers of skin is at least 3.5 times higher than that of the commonly-used RF irradiation systems in aesthetic medicine (Graph C). That means that most of the RF energy gets stuck in the epidermis and dermis, heating them up to such an extent that there is a risk of tissue damage. Moreover, as the RF energy remains close to the surface, it fails to reach the hypodermis where the fat cells are located, and whose membranes must be broken for the treatment to be effective.

2. What's the difference between Radio Frequency (RF) and Microwaves in terms of Hz?

Briefly, according to Radio Society of Great Britain (RSGB) Radiofrequency ranges from 30kHz to 1GHz and, immediately next, Microwaves ranges from 1GHz and 100GHz.

However, even if in some cases the boundary between microwaves and RF is fairly arbitrary and it can change considering different fields of study, 2.45GHz falls plenty in the Microwave domain. Besides, it conserves all the advantages of microwaves including its selectivity and depth of action properties when dealing with biological tissues.

3. How does ONDA (CoolWaves™) compare to all of those products claiming to have magnetic therapy alongside RF?

RFs, with or without magnetic field delivery, are not able to stimulate the collagen, reach a temperature of 50-55°C in fat and properly treat any stage of cellulite. For a more detailed explanation, please refer to the answer to the question nr 1.

4. What's the difference between Onda and a microwave oven if both use 2.45GHz frequency?

The microwave oven is a very popular device utilized in the daily life. It emits at 2.45GHz throughout a free emission antenna. The generated electromagnetic (e.m.) field is of "Radiative Type" (free air emission) and it is free to run everywhere just bouncing back and forth over the oven metallic walls (that's why when you open the microwave oven door the emission suddenly stops to avoid any possible danger). In this condition the food, absorbing microwaves thanks to its water molecules, dissipates and converts into heat the e.m. radiation that is not recalled back by any return electrode (uncontrolled emission).

Differently from the microwave oven, Onda emission is highly controlled instead. First, this kind of emission starts from the central emitting electrodes and it is "recalled back" by the peripheral circular "return electrode". This modality allows to have a controlled limit in the depth of action and to avoid any random, uncontrolled transmission or propagation in the body. Thus, no organs or other tissues than the one we want to treat, are invested by the e.m. radiation. This makes Onda a very safe system!

Moreover, the two patent pending handpieces allow to work only when they are in contact with the skin. Therefore, if the handpiece is not in full contact, it will stop the emission. This will ensure a complete control of the delivery power.

5. What about the Onda 'focal depth', correlated to the penetration depth, of the 2 handpieces?

Focal depth of Onda handpieces depends on their design (Patent Pending) that allows different level of penetration. Particularly speaking, the deep handpiece induces a larger and deeper heating, inducing lipolysis of the fat cells, solubilisation of deeper collagen fibres with consequent remodelling with newer and more elastic younger collagen fibres produced by fibroblasts stimulation. The shallow handpiece instead, carries out a more concentrate and superficial heating action right to produce a controlled hyperthermia that contributes either to a fibrous collagen solubilization and to induce some shrinkage of the most superficial collagen fibres. In this way both tightening and remodelling effect on the superficial connective tissue are obtained.

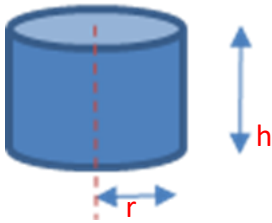
Deep handpiece in brief
6.6 cm large
LED indicators: Green = optimal coupling Yellow = less 70% of coupling Red = no coupling (microwaves stop delivery)
1.2 cm deep heating focalization
Integrated cooling (till 5°C)
Recommended for localised fat & deep cellulite

Shallow handpiece in brief
5.6 cm large
LED indicators: Green = optimal coupling Yellow = less 70% of coupling Red = no coupling (microwaves stop delivery)
0.7 cm deep heating focalization
Integrated cooling (till 5°C)
Recommended for skin tightening & superficial cellulite

6. Can we estimate what volume of tissue is being treated during every passage?

For simplicity, let's assume to refer a single cylinder section on each and every passage (without considering dispersions, inductions and other scattering effects that may contribute to enlarge the volume).

If the volume (V) of a cylinder is: $V = \pi \times r^2 \times h$



We will have the following results for each handpiece:

Shallow (Small) handpiece:

$h = 0.7$ cm (deepest focalization)

$r =$ half of diameter = half of 5.6 cm = 2.8 cm

Volume affected = $\pi \times r^2 \times h = 3.14 \times (2.8 \times 2.8) \times 0.7 = 17.23$ cm³

Deep (Big) handpiece:

$h = 1.2$ cm (deepest focalization)

$r =$ half of diameter = half of 6.6 cm = 3.3 cm

Volume affected = $\pi \times r^2 \times h = 3.14 \times (3.3 \times 3.3) \times 1.2 = 41$ cm³

HOWEVER, heat diffuses all around the theoretical cylinder volume, affecting districts not in direct contact with the field emitted by the probe....so the volume becomes even wider than what above.

7. How can 2.45 GHz work on all three main body contouring blemishes localize fat, cellulite and skin tightening.

Coolwaves™ Action on the Fat.

Coolwaves™ targeted action on the adipose tissue produces the following effects:

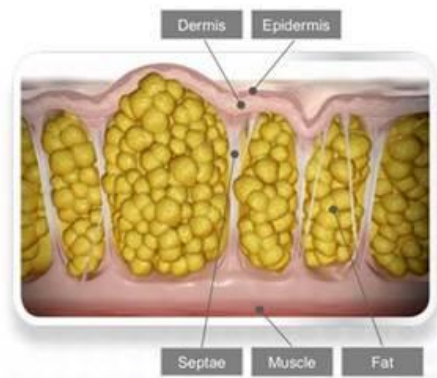
1. Remodeling of the connective tissue matrix by means of the thermal modification of the adipocytes metabolism which leads to the step nr.2;
2. The adipocytes release a quantity of lipids much higher than their physiological capacity in the outer environment through a mechanism called "blebbing".
3. Blebbing gets so intense that induces a process of lysis of fat cells with adipocyte membrane rupture.

4. The large number of droplets of fat that are poured into the interstitial connective, stimulates the recall of the macrophages from the blood that have the task of “cleaning” the cellular interstitium from the excess of fatty acids, engulf the excess free fat.
5. When the condition of normality is restored, the macrophages migrate into the lymphatic system.

Coolwaves™ Action on Cellulite.

Introduction:

The female hypodermis consists of small ‘recesses’ (lobules) separated by parallel walls (septa). Cellulite results from both a build-up of fat in the adipose tissue (the hypodermic fat cells) and water retention around them (in the dermis and hypodermis). Due to fat (when the adipocytes increase their volume) and water which accumulate in these recesses (the edema is due to poor drainage), the walls are compressed, damaging the microcirculation and the natural form of the cell. Because these walls are attached to the dermis (in the anchor points) they pull at the skin surface while fat cells push towards the dermis. In other words, when the adipocytes get bigger or the edema increases too much, the ‘envelopes’ containing them change shape and pull on their anchor points on the skin. The result is a skin surface that takes on a bumpy (‘orange-peel’ appearance). Over time, as the condition worsens, fat and water become wholly enclosed in a prison of always hardened septa composed of fibrous connective tissue.



This is the most common condition, at least for Caucasian patients, where cellulite is very often associated with an increase in the volume of adipocytes, being of a mixed type (cellulite + fat). In this case it is possible to act in two ways:

- 1) Through a direct action on the collagen septa, in particular in the upper part towards the dermis, nearby the anchor points. As the septa (which, due to cellulite, are fibrotic and therefore less elastic) gets solubilized, these are regenerated with new and more elastic fibers of collagen. The final result is a visible improvement of the orange peel appearance and also the "constriction" within the fat lobule itself.
- 2) Through reducing the volume of adipocytes, with a targeted action on them, which is ended to reduce their compression on the hypodermis vessels. In addition, the total volume of the lobules gets reduced, with a consequent lower traction on the anchor points of the septa.

Considering the introduction above, **Coolwaves™** targeted action on Cellulite is carried out on:

1-Subdermal fat layer

In the same way of what explained previously in the “**Coolwaves™ Action on the Fat**” section.

2- Fibrous collagen septae

The typical “orange peel” texture of cellulite is determined by the consistent presence of large fibrous collagen septae (vertical walls in the connective tissue) that lead to a constriction of the natural lobulation of adipose tissue, as well as adipocyte hypertrophy and water retention.

The energy of the **Coolwaves™**, absorbed by fibrous connective branches, causes the solubilization of the old collagen to take place, with consequent debridement of the tight non-elastic weft that strangled the lobules.

The solubilization of collagen, in addition to producing the loss of the pitted appearance of the skin, also makes it possible to reactivate the fibroblasts which are stimulated to produce new, more elastic collagen.

The visible result is the orange-peel effect disappearance. The **Coolwaves™** action also favors the improvement/restoration of the physiological conditions of the tissues that have been compromised by the onset of cellulite.

Coolwaves™ Action on Flabbiness.

The heat produced by the **Coolwaves™** causes either an immediate collagen fiber shrinking in the dermis with a consequent tightening. The final effect is the improvement of skin laxity.

8. What about the mechanism of action on both skin tightening and cellulite reduction, when using the deeper applicator (Big handpiece) which deposits 80% of its energy in the fat and only 20% in the upper layers of the skin? It seems that skin tightening, and cellulite reduction are a by-product or secondary effect when 80% of the energy is being deposited in the fat.

It is by using the proper handpiece (either more superficial or deeper ones) as well as to adjust the emission parameters, that users may "enhance" & "optimize" the **Coolwaves™** action aiming each time, in a more selective way, the specific target of interest like fat, cellulite or tightening.

As already mentioned in this document, the Onda protocol establishes to use the deep handpiece when the main target is localized fat or mixed cellulite reduction (cellulite where also adipocytes have increased size), while we recommend the shallow handpiece for edematous cellulite reduction and skin tightening.

It is clear that, in case of deep handpiece use, it is also present a secondary effect on the more superficial layers due to the 20% of energy here concentrated. This effect can improve skin laxity or superficial cellulite aspect, but this is a “collateral” and “soft” action compared to the main effect on the adipose tissue that represent the main targets!

Otherwise, when the major problems to treat are superficial cellulite and/or skin laxity, the use of shallow handpiece allows to concentrate all the **Coolwaves™** energy on the specific targets and not only the 20%. In this way the treatment achieves a stronger action for melting the collagen septa during cellulite treatment and for shrinking collagen fiber in the dermis with a consequent tightening. Even in this case it is very important to stress the attention on the complete safety of the treatment thanks to the special design of Onda handpieces (patent pending) with integrated skin cooling system.

For a more detailed explanation about mechanism of action of **Coolwaves™** on fat, cellulite and laxity, please refer to the answer to the question nr 7.

9. What is ONDA's strongest feature? I.e. which body regions/areas ONDA gets best results with the least amount of treatments and, on the contrary, which areas have limited improvements?

As every patient is different, is not easy to define in an absolute regime which specific parts are or not more responsive in terms of number of treatments and/or results. We can surely say that cellulite and skin tightening treatments, as a whole, are the best indications from the same stand point, while to appreciate results with fat reduction (especially on a wide abdomen) takes just a little longer.

10. What skin conditions (fat, cellulite and laxity) are ONDA's stronger result giver? I.e. is ONDA best for fat more than cellulite or skin tightening or equally effective in fat as it is in cellulite or tightening?

See the answer to the question nr. 9.

11. How to choose the correct protocol when the patient presents more than one blemish? (e.g. localized adiposity together with cellulite, cellulite together with laxity and so on...).

A very popular case is represented by patients with either mixed cellulite, where the increase in the lobules volume in the hypodermis is given by an increase in both fluids and in the size of the adipocytes. In these cases, it will be necessary to hit different targets at different depths: the adipocytes in the hypodermis and the fibrotic septa, especially their anchor points that are more superficial (for more details, see the answer to question nr. 7). The treatment cycle therefore involves the use of both handpieces to act at different depths.

In the clinical practice it has been observed that the treatment of an advanced very fibrotic cellulite can be more difficult if, in the first sessions, the Deep handpiece (which would act on the

fat cells of the hypodermis) is immediately used. In practice, using the Deep handpiece in the presence of considerable subcutaneous fibrosis, this acts as a shielding action and it is likely that the light on top of the handpiece turns either yellow or red due to a non-optimal coupling.

This is the reason why it is more efficient to spend the first sessions using the Shallow handpiece which, lowering its depth, finds less resistance. **Coolwaves™** can, thus, effectively act on the fibrotic septa at their anchor points close to the dermis (note: septa are usually less fibrous at the ending, close to their anchor point, than in the central part which is much harder and less elastic).

The heat produced spreads towards the lower part of the septa, thus triggering the solubilization process which has been histologically observed.

Once the septa have been "softened", it is possible to use of the Deep handpiece which will be able to penetrate more easily in depth, no longer finding that strong resistance by the fibrous branches.

The following is a summary with the indications of which handpiece is recommended to be used for the treatment of patients according to their conditions:

- Patient LOCALIZED ADIPOSITY as a dominant problem: Deep handpiece.
- Patient with CELLULITE as a dominant problem (understood as cellulite is in the early stages of a predominantly oedematous type): Shallow handpiece.
- Patient with LAXITY as a dominant problem (such as the abdomen after pregnancy): Shallow handpiece.
- Mixed LOCALIZED ADIPOSITY + CELLULITE patient: the first sessions are performed with Shallow handpiece and then continue with the Deep (as explained above).
- Mixed CELLULITE + LAXITY: Shallow handpiece.
- Mixed patient LOCALIZED ADIPOSITY + LAXITY: the first sessions are carried out with a Deep handpiece followed by the Shallow. The initial action of the Deep handpiece acts on fat but also has a secondary action on laxity. When the volumes have been reduced, it will be possible to focus more on laxity with a more superficial targeted action.
- Patient LOCALIZED ADIPOSITY + CELLULITE + LAXITY: the patient should be well assessed considering which components are most important to decide whether to start with the Deep handpiece or with the Shallow according to the rational explained above.

12. Safety: We need more information/details on how microwaves at that particular frequency are proven to be a safe modality.

As per the investigations carried out in our labs (and as already discussed in the answer to the question nr 3), we have designed both handpieces to reach effective depths in a completely safe way:

- Shallow (Small) handpiece comes with a 0.7 cm max deep focalization of the heating;
- Deep (Big) handpiece has a 1.2 cm max deep focalization of the heating that is fully absorbed by the fat (not the visceral one so we are sure that is not interaction with muscles or other vital organs).

Moreover, about the safety of epidermal layer, both Onda handpieces have an integrated cooling system to protect it.

13. Which is the temperature that the body reaches during treatment?

50°C-53°C are reached in the subdermal fat layer that contributes to melt the fat in the proper physiological way.

14. How to measure the temperature in deep layer (fat layer)?

As measuring inner layers temperature during the treatment it's impossible from the outside, it is possible instead to measure the temperature on skin layer. At the end of the session it should be around 38°C-39°C with the deep handpiece and/or 39°C-42°C with the shallow handpiece that are a sign of the 50°C - 53°C in the inner layer. During Onda studies though, some intradermal thermal probes were used to have an exact detection of the real induced temperature in the fat layer as this it is not a data we can easily get from outside.

15. What are the contraindications?

Contraindications

After the preliminary interview with the patient, the physician should assess whether the treatment is appropriate or whether to postpone or exclude it completely. In order to correctly identify the treatment inclusion criteria, it is advisable to also do blood tests for the contraindications given below.

1. Absolute Contraindications

- Cardiac insufficiency or disorders;

- Severe vascular diseases;
- Heart implants/pacemakers;
- Neoplasia in progress or in the past 5 years;
- Kidney and liver failure/dysfunction;
- Active phlebitis, thrombophlebitis, phlebothrombosis;
- Pregnancy and breast-feeding (until 10 months after delivery);
- Infectious diseases (especially hepatitis B and C);
- Subjects with clotting disorders/ haemorrhagic diathesis;
- Patients with a transplanted organ;
- Subjects with decompensated diabetes type I and II;
- Patients with deep brain stimulation implants;
- Recognised sensitivity to the device.

2. Relative contraindications

Listed below are conditions and/or diseases which, based on their specific anatomic position, severity and characteristics, may be a reason to exclude the patient from treatment. Patients with the following conditions have to consult their physician prior to undergoing Onda treatment.

- Skin pathologies;
- Skin disorders stimulated by heat, such as recurrent Herpes Simplex in the treated area (assess the use of a prophylaxis);
- Neoplasia more than 5 years before;
- Anticoagulant and antiaggregant treatments (possibility of persistent erythema);
- Use of anti-inflammatory drugs with steroids one week before the treatment (it is advised against taking these drugs also in the week after the treatment);
- Use of retinoids, antioxidants, skin nutrition supplements within a month from the treatment;
- History of phlebitis or thrombosis;
- Presence of telangiectasias in the area to be treated;
- Presence of lipomas in the area to be treated;
- Subjects with autoimmune diseases;
- Breast-feeding (beyond 10 months after delivery);
- Varicose veins;
- Diabetes;
- Predisposition for formation of keloids or abnormal healing;
- Patients with unrealistic expectations;
- Patients with BMI >30 (**Onda treatment is recommended only for localised adiposity and not for obesity**);
- Hypertriglyceridemia and hypercholesterolemia;

- Alteration of blood pressure;
- History of paradoxical adipose hyperplasia;
- Presence of fibrotic tissue and particularly lax tissue;
- Under-age patients;
- Menstruation.

In the case of patients undergoing pharmacological therapy, always check for the possible contraindications and side effects to evaluate, if appropriate, to stop the therapy before treatment with the **Onda** system.

3. Areas to be excluded from the treatment

- Head and neck;
- Cardiac, décolleté and breast areas;
- Tattoos or permanent make-up in the treated area;
- Genitalia;
- Mucous membranes;
- Bone protrusions;
- Fractures (even if in the process of healing);
- Tissue with limited thickness of the subdermal fat layer (< 1cm);
- Varicose veins;
- Areas with acute inflammatory processes (as rashes, inflammation, infection, hematoma, wounds, etc.)
- Open wounds;
- Permanent implant in the treated area, such as metal/plastic plates, prosthesis and screws or injected chemical or autologous substance, fat injections or prosthesis;
- Subjects with any body piercing in the treatment area;
- Lymph nodes stations;
- Femoral, subclavian and brachial arteries and veins;
- Pharmacologically anaesthetised areas (absence of patient feedback on pain);
- Areas with sensibility reduced or absent;
- Ischaemic tissues of patients with vascular disorders whose blood circulation is insufficient to cover increased metabolic requirements (risk of necrosis);
- Spine areas subjected to laminectomy;
- Hernias;
- Lipomas;
- Fibrotic tissue and particularly lax tissue.

16. "What are the potential side effects (immediate in the days following and longer term if any)?"

Possible Side Effects

Mild side effects including itching, numbness, hardness, warmth, tenderness, redness, swelling, burns, bruising, nodules and blisters at the treatment area are usually transient and resolve within a few days from the treatment.

Adverse effects at the treatment area such as skin and fat tissue necrosis, skin contour irregularities and asymmetry could occur after improper use of the system, such as excessive energy levels or incorrect fat tissue evaluation.

17. Any risk of nodules/irregularities forming?

No, providing the handpieces are kept moving and stay with treatment protocols.

18. What about the treatment's long-term impact over either blood or lipid profile?

From blood test carried out during our studies no significant alteration on lipids and blood were recorded. See the published white paper "*Results on Subdermal Fat Tissue Reduction Using a Novel Microwave Based Body Contouring System*", P.Bonan et al. – Oct 2018

19. What about the pre-treatment instructions?

Pre-Treatment Procedure

1. Recommendations

Given the high degree of absorption of microwaves by water, it is recommended to suspend the use of moisturizing and softening creams in the area to be treated at least one week before the session with Onda. In this way it is avoided to have a greater absorption of the **Coolwaves™** in the superficial layers of the skin and, at the same time, the penetration to the adipose tissue is increased. The patient should drink 2 liters of water a day to facilitate the drainage of interstitial fluids. It is recommended to start this the day before the treatment and continue the following day.

2. Photographic Monitoring

Acquiring photographic images of patient, before and after every treatment session, helps to monitor the effectiveness of the treatment. For ensuring the best photographic quality it is

necessary to standardise the shots in order to reproduce the same position of the patient, the same lighting conditions and biometric reference points.

3. Just Before Starting with the Treatment

- Before starting the treatment, the area concerned must be cleansed of any impurities that could interact with the **Coolwaves™** or obstruct handpiece sources. Remove any make up, lotions, deodorants or ointments with a gentle soap, then rinse with plenty of water.
- Shave any dense hair on the area to be treated to improve the coupling between handpiece and skin.
- Divide the treatment area into sub-areas of 15 cm x 15 cm.
- In case of localized fat, take the measure of skinfold inside the square sub areas with the standing patient.
- The patient should lie on the bed in the appropriate position. To increase the adipose tissue thickness and move away from the muscle surface in treatment of the abdomen, it is advisable to position the patient with the torso slightly bent forward.
- Spread a thin film of pure vaseline oil (pharmaceutical grade) over the entire treatment area for proper contact of the handpiece with the skin, better coupling and greater fluidity of the movements. Use minimal quantity! During the treatment, it may be necessary to repeat application of the product.

NOTE: For more detailed indications about “how to use the system”, “warning” and “safety recommendations” please refer to the Onda Operator’s Manual received with the system.

20. What about the post-treatment instructions?

Post-Treatment Recommendations

- It is suggested to perform a lymphatic drainage massage immediately after the Onda treatments.
- It is advisable not to treat again the same area before 15 days.
- The patient should avoid direct exposure to the sun after the treatment (for erythema ab igne) for 2 days.
- If the skin is slightly pink or red in areas following the treatment, the patient must avoid hot water when washing until any erythema has subsided.
- It is suggested, for the patient, to follow an appropriate healthy diet and do a moderate physical activity.

21. What is the interval in between sessions?

The minimum interval is 4 weeks for fat and 3 weeks for cellulite and skin laxity treatments.

22. Can the interval between session be shortened to 2 weeks? What is the risk in this case? If not, why not?

The minimum interval between Onda sessions is 3 weeks for cellulite and tightening treatments as well as 4 weeks for fat sessions. The reason is that the body needs some time to remove the lysate generated by ONDA treatment. Under this light, it does not make sense to have bi-weekly, or shorter, treatments: they surely represent an unnecessary overlapping.

23. What are the body anatomical parts treatable with Onda?

Abdomen:	from 1 to 4 15 cm x 15 cm areas
Flanks:	1 15 cm x 15 cm area per side
Buttocks:	1 15 cm x 15 cm area per side
Anterior Tight:	2 15 cm x 15 cm area per side
Posterior Tight:	1 15 cm x 15 cm area per side (excluding buttocks)
Bra Line:	1 15 cm x 15 cm area per side
Under Arm:	1 15 cm x 15 cm area per side
Trocanteric Area:	1 15 cm x 15 cm area per side

24. How many 15 cm x 15 cm areas are allowable to be treated in one session?

Users can treat up to 8 “15 cm x 15 cm” areas. It must be considered that, in this case, results may appear a little later vs the expected timings because of lymphatic system overcharge that results in a slower eliminating process.

25. Can we perform two different protocols on same area...one after the other? If not, how many days after is advisable?

Once you treat a part with a protocol it is not recommendable to insist again with another one on the same part in the session. You would wait till the next session to operate in the same area with other values. The minimum interval between sessions is 4 weeks for fat and 3 weeks for cellulite and skin laxity treatments.

26. Typically, how soon do results occur?

The patient can note an initial improvement just after the first session but to consolidate the results a few more sessions are needed.

For fat treatments, for instance, 2 to 4 sessions are usually necessary for good results (depending on baseline and if patient sticks with post TX suggestions) while for both cellulite and tightening they might be noticed earlier in reason of 2 sessions (patient depending).

27. What about adverse conditions that may prevent Onda to achieve the desired result?

As water is very likely to absorb microwaves, avoid to applying Onda over hyper hydrated tissues. For this reason, patients are suggested to stop hydrating the area to be treated some time before the treatment.

Once at the treatment venue, Onda users put some vaseline oil (pharmaceutical degree, no water inside) over the skin to better couple the handpiece and spread cooling effect over the moving area. In this condition **Coolwaves™** energy, is not either wasted and it can be absorbed by the subdermal fat tissue in a volumetric way (please refer to the answer to the question nr 6).

In case of some water retention, it is recommended to perform a draining massage before ONDA treatment.

28. What about the approach when dealing with stage 1 and 2 cellulite? How many sessions are typically recommended, and can you indicate suitable pre/post recommendations you encourage patients to undergo with?

To treat 1st/2nd cellulite stage (with edematous/water content) it is recommendable to drain the legs by a lymphatic massage (other draining treatments are suitable too) just before the Onda treatment. It's also important to perform some draining massages sessions in between Onda sessions.

Lymphatics massages are strongly recommended in order to have further enhancements in these kind of cases.

29. Concerning lymphatic massage of the treated area, what is advisable? When and how frequent?

Usually a 1 - 2 minutes lymphatic massage immediately after the end of Onda session is recommended, as well as 1 or 2 massages per week (manual or machine assisted as you like) in between the sessions to help fat and liquid elimination.

30. We know that is advisable for the patient consume a quantity of drinking water before and after the treatment. If not, does this influence the results?

Water stimulates a faster fluid drainage and decrease fluid retention especially after the treatment.

31. Can you pass the applicator over bone and, if not, what is the consequence of doing this?

It is not suggested to pass the handpiece over bones otherwise pain is perceived immediately due to both the limited thickness of the tissue and lack of fat.

32. What is your protocol-application in conjunction with other surgical procedures in same area?

If you combine other surgical procedures, you must wait for the complete healing of the surgical intervention and then you may deliver ONDA.

33. Application suitability/protocol as corrective such as post Lipo or CryoLipolysis irregularities?

ONDA can be used 6 months post-lipo surgery to smooth odds, while to improve Cryolipolysis irregularities users must wait for the complete healing (that means no pain, swelling etc.).

34. What about diabetic patients. Can we use Onda in such as patients?

As the clinical manual says diabetic patients falls down into a relative evaluation. This means the physician will decide based on their specific condition and this, in some cases, may be a reason to exclude the patient from treatment. In any case, patients with that condition should consult their physician prior to using the device.

35. Can Onda treat over an area with vascular lesions?

Onda is selective for fat and not for Oxihemoglobin, so vascular lesions, like capillaries, usually don't represent a problem for the treatment, if not in a severe condition. In some cases was observed a temporary worsening of superficial telangiectasias present in the treatment area. This is due to the heat produced by Coolwaves™.

Different it is the situation in case of varicose veins instead, that would be a contraindication.

Remark: In some cases, pressing on an area with capillaries can be a little bit painful. If the patient complains about pain reduce the pressure of the handpiece during the treatment of that area.

36. Can Onda treat over a tattoo area?

No, it can't. Because of it is not possible to know exactly the kind of pigment used in the tattoo, it is strongly recommended to avoid to treat the area over a tattoo or a permanent make-up. Possible metallic components inside the pigment can interact with Coolwaves™ causing problems.

37. Can we treat a patient with a past “breakage in the stomach”? Can we treat that area?

It is never recommended to treat over the stomach. As the major part of the fat is usually concentrated in the lower abdominal part, the treatment must be carried out over that part and the subsequent heating diffusion will cover the upper parts too.

38. When we treat belly area, is there a need to treat also at both side areas?

As it is never recommended to treat over the stomach, belly button falls into the indications too. For this reason, belly might be left on the edges of the 15 cm x 15 cm area in order not to be directly invested by the handpiece being used.

As the major part of the fat is usually concentrated in the lower abdominal part, the treatment must be carried out over that part and the subsequent heating diffusion will cover the upper parts too.

Concerning other parts, as Onda wants to eliminate visible dissimilarities and get to body to reacquire whole harmony, treatments on additional areas must be evaluated case by case following Onda harmony target criteria.

39. What about treatment in presence of a metal implant? Is this a contraindication?

Treatment areas where a metal implant is present will be contraindicated to treatment.

40. Can a pregnant user perform Onda treatment?

Yes, they can. They may find that she feels tired after completing session/sessions.

41. Can Onda treat a new mother (just 40 days after giving birth)?

Well, if the patient is breastfeeding the lymphatic drainage capacity is getting SLOWER, so it is better to postpone till the mother has finished breastfeeding. Instead, if the patient is NOT breast feeding the lymphatic drainage capacity is ok BUT it is recommended to wait at least for two months to allow uterus to restore.

42. What about cooling fluid with Onda?

As Onda cooling fluid is not distilled water but it is a special cooler fluid, then this should be ordered from DEKA. As per our present data, the replacement interval is quite long.

43. Since there are no consumables what are the typical components or items which may break up during the use?

As no disposable item comes with the unit, care in handling the handpieces must be carried out as they are the only part able to break if dropped or knocked.

44. Is ONDA FDA approved?

Not yet.

To have more detailed information we suggest to read the Clinical User's Manual and the published Whitepapers or ask DEKA directly at deka.webcontacts@deka.it

DEKA
Innate Ability

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