Ural State Medical University of the Ministry of Health of the Russian Federation

ULTRASONIC CAVITATION FOR THE ENT-ORGANS PREVENTION AND TREATMENT

Guidelines for Physicians





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The guidelines are dedicated to the use of low frequency ultrasound in combination with antiseptics and medicines for the prevention and treatment of inflammatory diseases of ENT-organs. The method application efficiency has been assessed in different clinical situations (including sinusitis, children's acute sinusitis). Techniques of ultrasonic cavitation "FOTEK" devices application in outpatient and inpatient conditions are given for treating diseases of the pharynx, nasopharynx, outer ear.

The guidelines are meant for ENT specialists, residents, and interns. It is recommended for continuing medical education.

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Introduction

So far, diseases of upper respiratory tract are the most widespread complications of prior virus infections progressing due to compromised immunity. In most cases, these diseases are inflammatory ones, since the ENT-organs coarctate and constantly interact with the environment.

Treating chronic purulent-inflammatory diseases with a variety of clinical manifestations is the most important problem of applied medicine. In modern conditions of changes in pathogens virulence, increase in their resistance to antibacterial drugs, allergization of the macroorganism, and decrease in the immunological status of patients, searching for new pathogenetically justified sparing treatment methods is a priority. In our opinion, the use of ultrasonic cavitation therapy is very promising for increasing the effectiveness of treatment compared to conventional therapy, for reducing the number of tonsillectomies and adenoidectomies [20, 67]. The studies proved the maxillary sinuses treatment with "sonic" solutions to improve the condition of sinusitis patients faster than the conventional treatment [6, 37, 67].

The use of ultrasonic cavitation for therapeutic purposes helps to intensify the processes of microcirculation in tissues, as well as the permeability of cell membranes. Exposure to a "sonic" therapeutic solution leads to a sharp increase in the sensitivity of bacteria to antibiotics and antiseptics. It allows us to significantly reduce the pill burden on the patient, to diminish the hazards of complications due to medicaments [2,9,24].

1 ULTRASONIC EFFECTS

1.1 Ultrasonic cavitation (USC) potentials for the complex therapy of ENT disorders

In the past decade, various methods of physical medicine were successfully introduced into the complex of immunoreabilitation measures [9,24]. Low frequency ultrasound (LFUS) is known to have a positive effect and accelerate the recovery process of the patient while treating acute and chronic pathology of the lymphoid tissue of Waldeyer's tonsillar ring, of the nasopharyngeal and oropharyngeal mucosa by causing mobilization and effector reactions in the system of local anti-infective protection. Therefore, the subject of its application as an independent physiotherapy treatment has become relevant.

Applying ultrasonic therapy for nonoperative therapy results in reducing the number of relapses, increasing the effectiveness and shortening the duration of treatment, herein life quality of the patient being improved [6,9,20,24,31,37,38,60,67]. In case of adenoiditis, it is possible to reduce inflammation and, sometimes, to avoid tonsillectomy.

In case of maxillary sinusitis, the tissue swelling can be reduced and the affected sinus aspiration through the natural sinus ostium can be regained. The gentle therapeutic effect on the tissues of cavitated solutions allows the irrigation procedure to be performed for relieving the inflammatory process in its acute period, for example, in case of tonsillitis. During remission periods, it is effective to perform the lavage of the palatine tonsils by cavitation bubbling in combination with suction-vacuum exposure to remove plugs from lacunae. To prevent infections of the nasopharyngeal and oropharyngeal mucosa, cavitation irrigation with medications is recommended both for people having recurrent respiratory infection in autumn-winter period [20,37,60] and for those whose upper respiratory tract mucosa is constantly exposed to harmful factors (smoking, harmful dusty industry, extreme climatic conditions) [20].

The use of the low-frequency USC method in the complex of prevention and treatment of ENT-organs inflammatory diseases and their complications contributes to pathogen eradication and improves regeneration of the ciliated layer of nasal and paranasal sinuses mucosae. Consequently, it improves the clinical, functional, and morphological parameters [20,34,60].

1.2 Ultrasound applications in medicine

Ultrasound consists of mechanical vibrations of particles in a solid, liquid, and gases at the frequency range from 16 kHz to 100 MHz. Low-frequency ultrasonic devices operating in the range from 16 to 80 kHz are used for the irrigation and lavage of an infection site, for the wound surface treatment and tissue destruction.

The complex mechanism of ultrasonic effect has been studied by many authors [50, 63]. By activating an intermediate medicinal medium, sound vibrations impact on the tissues in different (physical, biological, and biochemical) ways.

Most of ultrasonic biological effects are associated with the **cavitation** process [11, 68], wherein microscopic cavities (or bubbles) carrying an electric charge on the boundary surface [47] are formed in the "sonic" liquid.

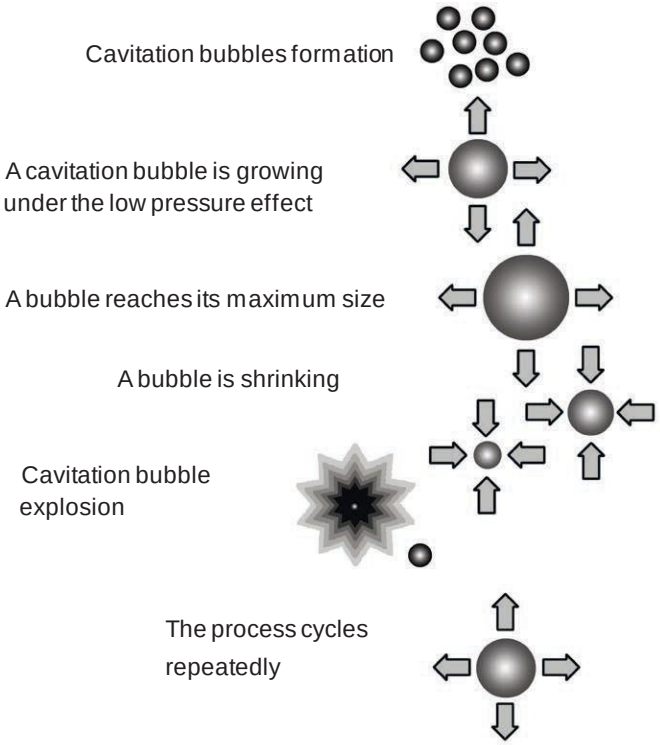


Fig. 1. The process of cavitation bubbles formation and “explosion”

Cavitation bubbles “shrinking” results in shock waves, which mechanically destroy bacterial films and damage the cell membranes of microorganisms [43, 72]. Water molecules in cavitation cavities dissociate into H+ and OH– ions having a bactericidal

effect on pathogenic microorganisms [2, 23]. Due to their microscopic size, cavitation bubbles penetrate into the areas of the affected region, being inaccessible for conventional treatment, and perform a thorough and gentle lavage.

Low-frequency USC has a bactericidal and bacteriostatic effect, and improves antibiotics penetration into the deep layers of tissues [27]. In addition, LFUS increases the microflora responsiveness to medicines [57].

The biological and physical properties of LFUS having been studied, it began to be widely used for the treatment of inflammatory processes of various localizations. Currently, the methods of ultrasound treatment have been developed and put into practice for a number of diseases.

Including LFUS into the complex therapy of **surgical site infection** allows to faster relief the inflammation, to accelerate the process of **wounds debridement** from purulent necrotic contents, to reduce microbial content, and to improve microcirculation in the area [23]. Both in Russia and abroad, physicians of the departments of purulent, abdominal, thoracic, vascular surgery, and combustiology actively use LFUS for treating purulent wounds of different origins [3, 22, 23, 48, 62].

Ultrasonic technologies have opened up new opportunities in **dentistry**. The capability of cavitation bubbles to penetrate into difficult-to-reach areas allows dentists to perform high-quality lavage of a complex root canal system before filling, implant placement, treating inflammatory-destructive periodontal lesions, etc. Due to the ability of removing dental plaque and calculus with no damage to the enamel, ultrasound is widely used for professional oral hygiene [21, 51].

In **obstetrics and gynecology**, the clinical use of LFUS results in significant acceleration of the patients recovery from infectious and inflammatory diseases of the vulva, vagina, cervix and uterine cavity. LFUS application for prevention significantly reduce the complication rate of infections in the postpartum and postoperative periods [28, 38].

LFUS is a well established practice in **ENT**. Most modern ENT offices are equipped with LFUS technologies. In case of inflammatory diseases (including children) of the oropharynx, nasopharynx, and ear, ultrasound is prescribed as a method of quick reverse of an inflammatory process [33, 35]. For instance, LFUS method application in combination with suction-vacuum exposure of chronic tonsillitis results in reliable reduction of the number of tonsilectomies [20,60]. Special attention should be paid to this method application for treating children adenoiditis. LFUS impact allows to painlessly relieve inflammation and swelling of the pharyngeal tonsil. It helps to improve the patient's breathing. In some cases, there is no more need for an adenoidectomy [6, 37, 46, 67].

Therapeutic tactics of LFUS application has undeniable advantages over the conventional treatment. It is well confirmed by both immediate and long-term results of ultrasound exposure: the duration of treatment reduces, the remission period increases, and the pill burden decreases [2,8, 53,63, 66].

1.3 LFUS effects on biological tissues

LFUS physical and chemical effects

There are the following **physical and chemical LFUS effects** on medicinal solutions:

- **US-cavitation;**
- **cavitation bubbling;**
- **acoustic streaming;**
- **decomposition of water molecules, formation of free radicals [24].**

Ultrasonic cavitation

When the US-wave of sufficient power (the power above the so-called "**cavitation threshold**") passes through the liquid, pulsating micro-bubbles (caverns, cavities) are formed in it. They carry an electric charge on the boundary surface and are filled with steam, gas or mixture of them. This process is called **ultrasonic cavitation** (from the Latin word *cavita* — void) [2, 26].

The formation and subsequent expansion of bubbles in the liquid medium happens within the half-periods of the ultrasonic wave rarefaction. Within the half-period of compression, the bubbles immediately "shrink" (explode), Fig. 1, forming a shock wave of microscopic scale, as well as micro-regions, wherein the pressure and temperature sharply increase [66].

The shock waves destroy bacterial films and damage the cell membranes of microorganisms mechanically [10, 43, 72].

In the cavities, water molecules dissociate into H+ and OH–ions having bactericidal and bacteriostatic effect on pathogenic bacteria and viruses [2, 23]. LFUS cavitation also improves antibiotics penetration into the deep layers of tissues [27]. Besides, LFUS increases the microflora responsiveness to medicines [57]. Due to their microscopic size, cavitation bubbles penetrate into the areas of the affected region, being inaccessible for conventional treatment, and perform a thorough and gentle lavage on the microlevel.

Cavitation bubbling

The process of intensive liquid mixing by the flows of cavitation bubbles, formed by an ultrasonic wave, is called **cavitation bubbling**. When exposed to a bubbled medicinal solution, intensive processes of mass exchange and mass transfer occur: apart from the penetration of medicinal substance into the underlying tissues, the treated surface is cleaned of pus, detritus, fibrin, and other overlayers [61].

Acoustic currents (acoustic wind) are eddy currents existing in intense sound field in liquids and gases.

Decomposition of water molecules, formation of free radicals

In the cavities, electric charges, causing medium ionization, are formed. The result of water molecules dissociation into H+ and OH– is hydrogen peroxide formation. And in presence of nitrogen, nitric and nitrogenous acids having bactericidal properties are formed [26]. Free radicals H+ and OH- immediately enter into redox reactions, destroying and annihilating pathogenic microorganisms and viruses [26].

LFUS biological effects

LFUS biological effects depend on frequency, power, exposure of US effect, the mode of "sonification" and properties of the biological tissue. Both stimulation and inhibition of functions are possible [18, 23]. There are the following biological effects of LFUS [24]:

- bactericidal;
- phonophoretic;
- thermal;
- necrolytic;
- tissue-destroying;
- neuroreflectory;
- micro-massage;
- anti-inflammatory;
- immunomodulatory.

Bactericidal effect

According to the opinion of most researchers, the bactericidal effect is determined by several contributory reasons:

- mechanical effect of USC — the direct destruction of **cell membranes** of bacteria and fungi, **breaking up of bacterial films** created by pathogenic and conditionally pathogenic microorganisms;
- cavitation bubbles "shrinking" — due to it, a thorough cleaning of the surface from purulent and pathological plaque, as well as from pathogenic microorganisms and their waste products, occurs [7];
- direct bactericidal properties of free radicals and hydrogen peroxide [7, 14, 56, 71].

Currently, **microorganisms have not yet developed any mechanisms of adaptation** to the effects of cavitated solutions [10, 62]. The LFUS bactericidal effect has been proven for many types of bacteria: Staphylococcus, Proteus, Pseudomonas aeruginosa, and Escherichia coli [27, 65]. The number of pathogens after a 5-minute exposure to the cavitated solution is repeatedly reduced. For example, the number of Pseudomonas aeruginosa reduces from 3×1011 to 5×106 CFU/ml, and the number of Streptococcus appears to be 300 times less [18]. Experimental "sonification" of cultures of Trichomonas vaginalis, Escherichia coli, and Proteus vulgaris, make

irreversible changes in the structure of microorganisms causing their death [28].

LFUS has a significant impact on **medicine-resistant strains** of mycobacteria. There was a further growth of the number of bacteria (on the 15th-20th days) and a decrease in the number of new colonies (by 3-4 times). A decrease in the medicine resistance of microorganisms is also described [18, 52, 55].

While cavitation, the cell membranes of microorganisms are damaged and the cultures of pathogens are weakened. As a result, their **responsiveness** to antibiotics and disinfectants **increases** [14, 50]. Under these conditions, conventional therapeutic dosages of medicines result in a more considerable therapeutic effect [19].

The use of ultrasound in combination with antiseptics has been reported. Exposure of Staphylococcus aureus culture to hydrogen peroxide for 10 minutes reduces the number of microbial cells by 5-6%, and in combination with ultrasound — by 80% [41]. Exposure of medicines to ultrasound increases their antibacterial effect by 1.7-10.8 times. So, **the combinational effect** of the antibiotic and LFUS is not just their sum, but exceeds their total effect by several times [18].

The LFUS bactericidal effect depends on its intensity: the microorganisms annihilation takes place in case the intensity exceeds the cavitation threshold [28, 62].

Phonophoretic effect

Most researchers recommend to combine LFUS with various medicinal solutions. Liquid antiseptics, antibiotics, or immunomodulators are used **to potentiate the therapeutic effect** [10, 15, 23].

The medicine penetrates into deep layers of the tissue with the help of LFUS. The degree of penetration depends on the functional state and type of the tissue, on the exposure and intensity of US effect, the type and amount of the medicine [28].

The increase in tissue permeability is due to LFUS capability to actively stimulate the liquid movement in capillary-porous structures (skin, mucous membranes, etc.). Due to ultrasonic phonophoresis, the medicine **penetrates** much **deeper**; for subcutaneous fat, the penetration depth is up to 6.3 mm, for muscles — up to 4 mm [24]. In case of inflammation, LFUS provides the medicine penetration up to 9 mm [23]. By initiating the decomposition of water molecules, LFUS affects the number of ions surrounding the cell membrane. The active diffusion of substances from the extracellular environment into the cell increases. In addition, ultrasonic vibrations change the permeability of biological structures: an alternating electric potential, similar to the potential of cell membranes, is generated. It causes their depolarization and changes the permeability for some ions [53, 74]. This **contributes to the therapeutic effect potentiation of medicines** introduced by ultrasound (US) [9].

Another important aspect of the LFUS biological effect is **the formation of micro-flows** within cells [66]. Acoustic currents, arising in the microscopic volume of the cell, move the intracellular formations, changing their spatial orientation, and exposing the enzymatic centers. Such changes **stimulate the functional activity of the cell** and its

responsiveness to physical and chemical factors.

Effective relief of the inflammatory process and tissue purification also takes place due to favorable metabolic changes, in particular due to the rapid normalization of the medium pH [54, 70].

Thermal effect

In biological objects, US being absorbed, acoustic energy is transformed into thermal energy. A small local heating of tissues (for fractions and units of degrees), as a rule, contributes to the vital activity of biological objects, increasing the intensity of metabolism. However, a stronger and longer exposure can cause overheating and destruction of biological structures (by proteins denaturation, etc.) [62].

Necrolytic effect

Ultrasound is applied for stringently dosed **necrectomy under control**. It enables to debride purulent wounds of necrosis causing little blood loss and minimal damage to viable tissues [23].

During cavitation, the cellular elements of the wound exudate are annihilated, wherein lysosomal enzymes, chemotactic factors, bactericidal cationic proteins, and biogenic stimulators are released. These substances fragment and exfoliate the necrotic layer, and **increase the proteolytic activity of the exudate**. Then, the number of phagocytic neutrophils increases in the site, the phagocytic and antibacterial properties of leucocytes are activated. Undoubtedly, it accelerates the process of tissue regeneration [4, 73].

The result of selective impact on tissues

LFUS of certain intensity is able to destroy soft and hard biological tissues or cause their fragmentation. This takes place both during direct contact of the US tip with the tissue and when loose tissues exposed to the flows of cavitated liquids. Exposure parameters setting enables selective destruction of tissues (tissue selectivity) by ultrasound: some structures are destroyed, while others are not [23, 62].

Neuroreflectory effect

The effect of US vibrations on nerve fibers **disrupts their conductivity** and blocks nerve synapses. As a result, analgesic and hyposensitization effects are observed [2, 28].

Micro-massage effect

USC and microvibrations arising in the liquid perform a kind of micro-massage of the tissues. Favorable changes occur in the macro- and microvasculature. LFUS expands the blood vessels, which causes regional blood flow increase by 2-3 times, and collateral blood circulation development [15, 23]. Acoustic flows and diffusion

improve blood and lymph circulation, microcirculation, and stimulate reparative processes [27].

Anti-inflammatory effect

LFUS has a significant anti-inflammatory effect. It is a result of various aspects: bactericidal properties, rapid tissue purification from purulent-necrotic and pathological masses, normalization of microcirculatory disorders in inflammatory sites [16, 23].

Immunomodulatory effect

LFUS helps to normalize the functional activity of phagocytes, as well as their qualitative and quantitative composition US-cavitation, as part of infectious and inflammatory diseases therapy, improves the phagocytic, killing, and secretory functions of granulocytes [9].

Multiple LFUS clinical effects resulted in its effective use for treating wound infection, ENT-organs pathology, as well as in urology, gynecology and abdominal surgery.

The important advantages of the method are its versatility and simplicity, the possibility of its use in outpatient and inpatient conditions.

The LFUS impact on the tissues of ENT-organs provides:

- complete cleaning of the treated surfaces from bacterial films and pathological plaque;
- deep medicine penetration into the tissues;
- reduction of microbial content of tissues, decrease in the absorption of toxins;
- improvement of microcirculation and metabolic processes in the tissues (micro-massage).

2 TECHNICAL IMPLEMENTATION FOR THE USE OF THE ULTRASONIC CAVITATION METHOD FOR TREATING AND PREVENTING INFLAMMATORY ENT DISEASES

2.1 Instruments and consumables

To perform the procedure using LFUS, the following equipment and instruments are required:

- ENT chair (preferably with adjustable height);
- ENT instruments: nasal speculum, Kulikovsky's needles, cannulas and syringes for tonsils lavage, ear speculum;
- low-frequency ultrasonic “FOTEK” device AK101M (ACTITON-A) with a set of instruments (or AK102M (ACTITON), distinguished by the absence of subsystem for liquid aspiration);
- therapeutic solution for ultrasonic cavitation and treatment of a pathological site;
- cotton and gauze pads;
- containers for disinfection of instruments;
- containers for disposal of consumables and instruments;
- equipment for sterilization and sterility preservation.



Fig. 2. “FOTEK” device of AK100M (ACTITION) series

2.2 Description of the ultrasonic cavitation “FOTEK” device of AK100M (ACTITON) series

“FOTEK” devices of AK100M series (models AK101M (ACTITON-A) and AK102M (ACTITON)) are applied in ENT to impact on biological tissues by means of LFUS vibrations and "sonic" (cavitated) solutions during manipulations aimed at lavage of infection sites and impregnation the medicine into the mucous membranes. The devices allow you to

perform irrigation of the nasal and oropharynx with medicinal solutions, washing of the tonsils with intense flows of cavitation bubbles together with aspiration-vacuum action, phonophoresis of the drug in the tissues of the tonsils and the posterior pharyngeal wall, washing of the maxillary sinuses.

The device are easy to handle. It is supplied with a trolley (Fig. 2) and a set of ultrasonic handpieces for different applications (Fig. 3).



Fig. 3. Ultrasonic handpieces applied in ENT

Operating principle of the device

The device control unit converts the electric current of the industrial network with a frequency of 50 Hz into the electric current of ultrasonic frequency of 25 kHz (Fig. 4), which is supplied to the piezoceramic elements of the ultrasonic handpiece.



Fig. 4 The operating principle of the control unit of “FOTEK” device of AK100M (ACTITION) series

The piezoelectric elements of the ultrasonic handpiece (UH) transform supplied electric current into mechanical reciprocating oscillatory movements of the ultrasonic waveguide instrument with a frequency of 25 kHz (Fig. 5). The ultrasonic (US) tip is either a part of the ultrasonic handpiece, or is to be fixed with a key for fixing (depending on the handpiece model).

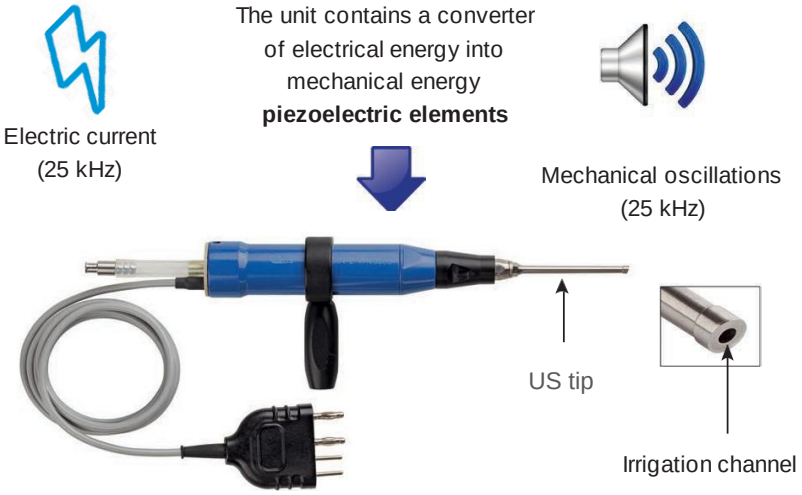


Fig. 5. The operating principle of the ultrasonic handpiece

The amplitude of mechanical vibrations of the US waveguide instrument is several dozens of micrometers. This oscillatory process is invisible. But high mechanical energy is concentrated at the tip of the instrument, and its direct contact with the tissues can cause damage to them. In this regard, for most ultrasonic handpieces, protective covers are provided. They are put on the ultrasonic instrument and prevent it from direct contact with the tissue (Fig. 6).

Inside the ultrasonic handpiece there is an irrigation channel designed for delivering the solution to the treated area, as well as for effective cooling down of the ultrasonic handpiece by the flowing solution during the manipulation. The solution is supplied to the handpiece by means of an infusion system connected with the handpiece through a special adapter (Fig. 6).

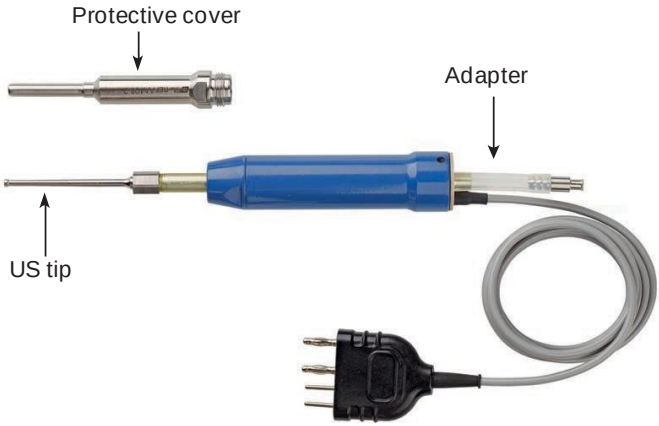


Fig. 6. Elements of ultrasonic handpiece

After passing through the channel of the ultrasonic handpiece, the solution turns into a directed fine-dispersed jet of "sonic" (cavitated) liquid (Fig. 7). The required liquid supply rate is set by a roller clamp on the infusion system.

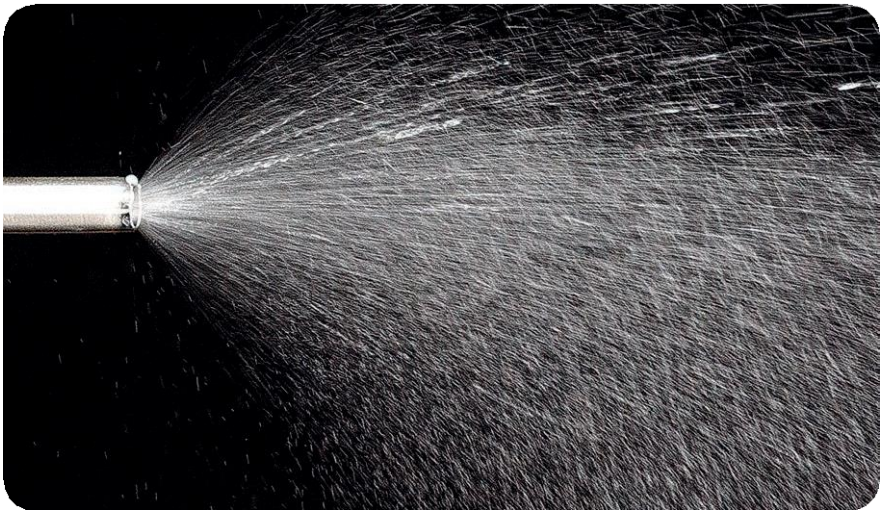


Fig. 7. Cavitation jet

The level (power) of ultrasonic vibrations is regulated in the range from 1 to 100 nominal units and determines the amplitude of the ultrasonic tip vibrations, as well as the intensity of solution spraying and its impact on the tissue.

The device is switched on by a single-pedal footswitch or double-pedal footswitch. Holding the footswitch pedal for more than one minute (unless the "TIMER" option is on (Fig. 8, pos.5)) results in automatic stop of ultrasonic vibrations. They can be resumed after releasing and pressing the pedal again only. This option is designed for

the facility of marking time of ultrasonic exposure without additional setting of the "TIMER" option (Fig. 8, pos. 5). The device operation peculiarities under the "TIMER" option are described in Appendix A. p. V

See device components assembly and setting-up procedures in Appendix A.
See device components disinfection and sterilization procedures in Appendix B.



Video tutorial on using ultrasonic surgery cavitation ACTITON and ACTITON-A devices : https://goo.su/2BkQ

2.2.1 Operating modes of the device

The ultrasonic cavitation "FOTEK" devices of AK100M (ACTITION) series provide the following modes:

- for ultrasonic exposure: "BASIC" (basic) and "SELECTIVE" (selective).
- for using liquid: for the device AK102M (ACTITION) model there is the liquid supply mode "IRRIGATION", for AK101M (ACTITION-A) model there are the liquid supply mode "IRRIGATION" and the liquid suction mode "SUCTION" (see Table 1).

The mode selection buttons are located on the touch panel of the device (Fig. 8).



Fig. 8. Front and rear panel of the ultrasonic cavitation “FOTEK” device (ACTITION-A model): 1 — "ULTRASOUND" button to enable US modes; 2 — button to enable "SUCTION" mode; 3 — button to enable "IRRIGATION" mode; 4 — display of the US vibrations level; 5 — button to enable "TIMER" option; 6 — buttons to adjust the US vibrations level; 7 — view information on the enabled UH; 8 — irrigation control valve; 9 — information on the connected footswitch, the footswitch function; 10 — brief information on the device operation; 11 — screen color, sound level, interface language settings; 12 — "STB" button ("Stand-by" — sleep mode); 13 — "ULTRASOUND" socket for an ultrasonic handpiece; 14 — socket for a footswitch; 15 — "SUCTION" connector for the suction tubing; 16 — mains switch button; 17 — socket for the mains cable

Tab.1: Operating modes of the "FOTEK" device of AK100M series: models AK101M (ACTITON-A) and AK102M (ACTITON)

OPERATING MODES OF THE DEVICE	ACTITON-A MODEL	ACTITON MODEL
Modes of ultrasonic exposure:		
BASIC (basic) — a mode for intensive impact on the tissue due to the continuous supply of US vibration energy to the tip. **It is used for:** • oro- and nasopharynx irrigation; • tonsils lavage; • maxillary sinuses lavage; • external auditory canal irrigation;	●	●
SELECTIVE (selective) — a mode for a gentle, selective effect on the tissue due to the pulsed supply of ultrasonic vibration energy to the working tool. **It is used for:** • phonophoresis delivery of the medicine to the tissue of the tonsils, to the posterior pharyngeal wall	●	●
Modes for operating with liquid:		
IRRIGATION — a mode for automatical supply of medicinal solution to the internal irrigation channel of the ultrasonic instrument with the simultaneous activation of the ultrasonic exposure	●	●
SUCTION — the mode for removing liquid from the treated area. It is used in case of treating palatine tonsils by the device	●	—

2.2.2 Types of the device ultrasonic impact on the tissues

The instruments and techniques used determine two main types of exposure that can be implemented:

1) Exposure with no transfer of ultrasonic vibrations (non-contact) — there is no direct ultrasonic impact on the tissues, but there is a combination of mechanical effect of a liquid jet and a solution activated by cavitation (Fig. 9, a). Cavitated ("sonic") liquid is characterized by the presence of cavitation bubbles and active chemicals: hydrogen peroxide, hydrogen ions, and oxygen. This method is used for local lavage of inflammatory sites.
2) **Exposure with transfer of ultrasonic vibrations (contact)** is the effect of ultrasonic vibrations on the tissue through an intermediate medium, for example, a liquid (Fig. 9, b), or directly with an ultrasonic tip (Fig. 9, c). It can be used for the lavage of cavities filled with a medicinal solution, as well as for the debridement of purulent wounds from fibrin plaque and necrotic tissues.

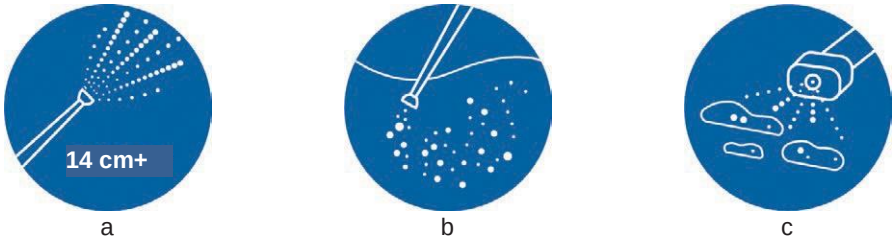


Fig. 9. Types of the device ultrasonic impact on the tissues
a — exposure with no transfer of US vibrations (non-contact); b — exposure of tissues through an intermediate medium (liquid); c — direct exposure of tissues by an ultrasonic instrument

2.2.3 Exposure of tissues with no transfer of ultrasonic vibrations (non-contact)

It is implemented with the help of instruments for tissues processing with a jet of cavitated liquid. The solution supplied by the working instrument is transformed by means of ultrasonic vibrations into a directed fine-dispersed jet of “sonic” liquid (Fig. 9, a) containing many cavitation bubbles filled with gas and/or steam.

Exposure to ultrasonic waves results in the change of the aqueous solution structure. The following active chemicals having bactericidal properties are formed in it: hydrogen ions, oxygen, hydrogen peroxide, etc. The lifetime of these substances is limited, so the closer the ultrasonic instrument is located to the treated surface, the stronger the bactericidal effect is.

The cavitation bubbles move in jet space at a high speed. Multiple bubbles shrinking at the boundary of the surface of the tissues, results in a high-quality cleaning of the inflammatory site from pathological secretions, pus and bacteria, and causes bacterial films destruction. At the same time, the medicinal solution penetrates into the deep layers of the tissues with the help of a shock wave of bursting bubbles. Due to the micro-massage of tissues by the cavitated jet, local microcirculation improves, and reparative processes are stimulated. The active chemicals formed in the sprayed liquid have a bactericidal effect on the pathogens of wound infection, and normalize the redox processes in the tissues.

For the selected instrument, the power and dispersity of the cavitation jet is determined by the level of ultrasonic vibrations, by the adjusted liquid supply rate, as well as by the level of hydrostatic pressure of the liquid flowing through the irrigation channel of the instrument. In its turn, the value of hydrostatic pressure of the liquid depends on the installation height of the container with the supplied medicinal solution. The recommended parameters of non-contact ultrasonic exposure for treating different pathologies are given in Chapter 3.

In ENT, the non-contact method of exposure is applied for irrigation of the naso- and oropharynx in case of infectious and inflammatory diseases of ENT organs, as well as for treating tissues in the postoperative period (after adenoidectomies, tonsillectomies, nasal septum operations, polysinusotomies, maxillary sinusotomies).

2.2.4 Exposure of tissues with transfer of ultrasonic vibrations (contact)

Exposure of tissues through an intermediate medium (liquid)

While exposure of tissues through an intermediate medium (liquid), the enabled ultrasonic instrument is immersed in a cavity filled with a solution (Fig. 9, b). Herewith, cavitation flows are formed in the liquid (mainly, along the axis of the instrument). The cavitation flows effectively mix the liquid. It is the method of cavitation bubbling of the solution in the cavity.

Ultrasonic vibrations are partially transferred to the tissues through the liquid. It results in a micro-massage of the tissues, in separation of necrotic plaque from living tissues, as well as in mechanical destruction of bacteria. It is also provided by other factors of ultrasonic bubbling of the solution in the cavity. In particular, these are the acoustic streaming, flows of cavitation bubbles, variable sound pressure, the effect of forming free radicals and hydrogen peroxide. The combination of all the factors results in gentle cleansing of tissues, normalization of microcirculation processes and acceleration of reparative processes.

The reason for this method ENT application is tonsils lavage. In this case, the solution is mixed in a funnel placed on the tonsil by means of the ultrasonic instrument in a special protective cover.

Direct exposure of the tissues by means of ultrasonic instrument

In case of direct exposure of the tissues by means of ultrasonic instrument, the working area of the tool touches the treated surface, as shown in Fig. 9, c.

Herewith, instruments including irrigation channel provide a combinational contact effect on the tissues of the very ultrasonic instrument, making reciprocating movements (like a hammer) with an amplitude of several tens of micrometers, and the "sonic" liquid containing cavitation bubbles and active chemicals in the form of hydrogen peroxide and free radicals.

This type of effect causes mechanical destruction of soft tissues, fat emulsification, fragmentation of necrotic tissues having increased water content, due to the cavitation mechanism of ultrasonic effect. Herewith, dense tissues reflecting ultrasound well (nerves, large blood vessels, connective tissue) are hardly destructed by ultrasonic impact. So, the effect of tissue selectivity takes place. It enables to make a gentle necrectomy with minimal blood loss and minimal damage to viable tissues.

In surgery, wounds are debrided of necrosis by means of contact US effect.

Another kind of contact effect is the exposure of a large area tip with no liquid supply (Fig. 18). In this case, the phonophoretic effect of LFUS increases: medicinal substances (solutions, gels) applied to the ultrasonic instrument through gauze are "driven" into the deeper layers of tissues. As a result, the effect of these medicines is prolonged. Intensive micro-massage of tissues improves blood circulation and tissue trophism. In ENT, this method of exposure is used for phonophoresis delivery of medicines to the tissue of the tonsils and the posterior pharyngeal wall
Fig 26.

2.2.5 Ultrasonic handpieces of the device

For ultrasonic impact on the tissues, several ultrasonic handpieces (UH) having different functional purposes and construction, are applied:

Table 2. Types of ultrasonic handpieces and their ENT applications

AA208.5 unit **<u>Using AA108-2 cover:</u> irrigation of the naso- and oropharynx, external auditory canal** **<u>Using AA108-4 cover:</u> maxillary sinuses lavage**	 using AA108-2 cover using AA108-4 cover
AA202.5* unit **tonsils lavage** *AA202.5 unit includes ultrasonic handpiece AA202. 6, ultrasonic instrument AA123, protective cover AA124, replaceable applicators of three standard sizes	
AA202.6* unit (assembled with US instrument AA122.1) **phonophoresis delivery of the medicine to the tonsillar tissue** * AA202.6 unit is used for tonsils lavage as a part of AA202.5	 

The internal irrigation channel passes through the entire length of ultrasonic handpiece. Through the irrigation channel a medicinal solution is supplied to the treated area. The solution is supplied by infusion systems connected to the “Luer-lock” pipe of the ultrasonic handpiece through an adapter and a back-check valve (see Appendix A, Fig. A.8). All the elements and accessories are sterilized by autoclaving (at T = 134 °C, 5 min).

2.2.5.1 Ultrasonic handpiece AA208. 5 is the ultrasonic handpiece with replaceable protective cover (Fig. 10)

Scope

The unit is designed for non-contact treatment of the naso-, oropharynx, external auditory canal with cavitated medicinal solutions to treat and prevent rhinitis, sinusitis, pharyngitis, laryngitis, tonsillitis, otitis. It can be used for debriding the wound surface after vasotomies, tonsillectomies, adenotomies, polysinusotomies, maxillary sinusotomies, operations for snoring treatment, and operations of the nasal septum to stimulate regenerative processes and disinfect tissues.



Fig. 10. Ultrasonic handpiece AA208.5 supplied with the instrument and replaceable protective cover

Scope of the ultrasonic handpiece AA208.5 with different types of covers:

Application of the handpiece with AA108-2 cover	Application of the handpiece with AA108-4 cover
Ultrasonic exposure of the organs of the oro-, nasopharynx, and external auditory canal for treating and preventing infectious and inflammatory diseases of the ENT organs	Exposure of maxillary sinuses to treat sinusitis

Peculiarities of using AA208.5 handpiece with AA108–2 cover:

AA108-2 cover (Fig. 11) is put on top of the **irreplaceable** ultrasonic instrument and screwed to the body of the ultrasonic handpiece AA208.5 (Fig. 12). For each ultrasonic treatment procedure, a **sterile** protective cover is used.



Fig. 11. AA108–2 cover

The purpose of AA108-2 cover:

1) It prevents the tissues from accidental contact with the enabled ultrasonic instrument;
2) It prevents contamination of the ultrasonic instrument in case of **non-contact exposure** enabling to use the ultrasonic handpiece AA208.5 more than once after sterilization if the following **conditions** are met while the procedure:
    - exposure of tissues is carried out by the non-contact method;
    - for each procedure, a sterile protective cover is used;
    - during the procedure, ultrasonic handpiece does not touch the patient's tissues and contaminated instruments, and is not immersed in the liquids having contacted with the patient;
    - after each procedure, the covered US instrument (Fig. 12) and the body of the ultrasonic handpiece are wiped with a disinfectant (one should use disinfectant wipes applicable for treating the

skin);

- after wiping the instrument and the ultrasonic handpiece with a disinfectant solution, it is recommended to remove the solution remnants from the instrument and handpiece by wiping with a cloth moistened with distilled water, otherwise chemical burns of the tissues are possible.

If these conditions are not met while treating patient's tissues, then the ultrasonic handpiece is to be disinfected and sterilized in parts after the procedure (as shown in Fig. 12).

When using AA108–2 cover, the tissues lavage is carried out by a fine-dispersed jet of cavitated medicinal solution (Fig. 7).

AA108–2 cover is a part of AA208.5 unit with **irreplaceable** ultrasonic instrument, and is also supplied separately.

For the detailed description of the algorithms of procedures carried out using this cover, and treatment schemes, see Sections 3.2, 3.5, 4, 5, 6.

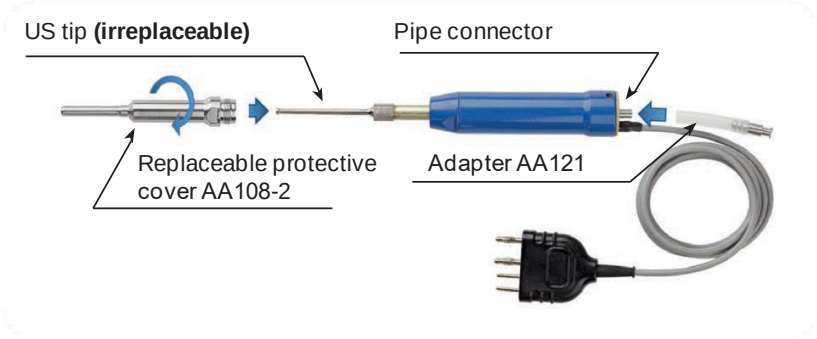


Fig. 12. Ultrasonic handpiece AA208.5 with AA108-2 cover in parts

Peculiarities of using AA208.5 handpiece with AA108–4 cover:

AA108-4 cover is put on top of the ultrasonic instrument and screwed to the body of the ultrasonic handpiece AA208. 5 (Fig. 15). This cover has a taper connector of the "record" type (Fig. 13).



Fig 13. AA108–4 cover

Kulikovsky's needle is installed on the "record" connector of the cover (Fig. 14 and 15).



Fig 14. Kulikovsky's needle

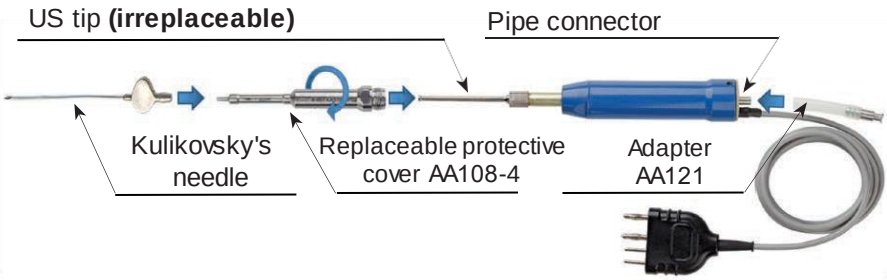


Fig 15. Ultrasonic handpiece AA208.5 with AA108-4 cover and Kulikovsky's needle in parts

The purpose of AA108-4 cover:

- It prevents the tissues from accidental contact with the enabled ultrasonic instrument;
- it facilitates the delivery of the "sonic" solution to the maxillary sinus cavity.

After the procedure, the ultrasonic handpiece, as well as disconnected adapter and Kulikovsky's needle, and unscrewed cover (Fig. 15) are disinfected and sterilized.
AA108–4 cover is not a part of AA208.5 unit. It is supplied separately. For the detailed description of the algorithms of procedures carried out using this cover, and treatment schemes, see Sections 3.5, 5.3.

2.2.5.2 Ultrasonic handpiece AA202.5 (Fig. 16)

Scope

The handpiece is designed to make tonsils lavage by means of a combination of a cavitated solution and suction-vacuum exposure. It consists of **ultrasonic handpiece AA202.6**, ultrasonic instrument AA123, a replaceable protective cover AA124 and replaceable applicators of three standard sizes: small AA125.3, medium AA125.2 and large AA125.1 (Fig.17).



Fig 16. Ultrasonic handpiece AA202.5 supplied with replaceable ultrasonic instrument, replaceable cover, applicator for the treatment of palatine tonsils, and suction tubing

Peculiarities of the ultrasonic handpiece:

- the handpiece is used with a replaceable ultrasound instrument AA123, which is screwed with a *sterile* key to fix the instruments AA102, and a replaceable AA124 cover with an applicator for treating palatine tonsils (Fig. 17);
- the appropriate applicator is selected with regard to the size of the tonsils (small AA125.3, medium AA125.2, or large AA125.1);
- it is necessary to use the device with built-in suction, ACTITON-A; it is allowed to use the device without built-in suction, ACTITON, if there is an external aspirator;
- when connecting the ultrasonic instrument to the ultrasonic handpiece, do not allow any distortion of threaded connection and apply excessive force;
- it is more convenient to replace the instrument using the handle AA116 (Fig. 17), which is attached to the body of the ultrasonic handpiece;
- if the instrument fixation is not stable, it is necessary to tighten the threaded connection of the tool with the ultrasonic handpiece;
- after the procedure, the cover is to be removed, the ultrasonic instrument is unscrewed from the ultrasonic handpiece by means of a key for fixing. All the accessories used for the procedure are disinfected and sterilized in parts (Fig. 17).

For the detailed description of the algorithms of tonsils lavage procedures carried out using this instrument, and treatment schemes, see Sections 3.3, 4.4.

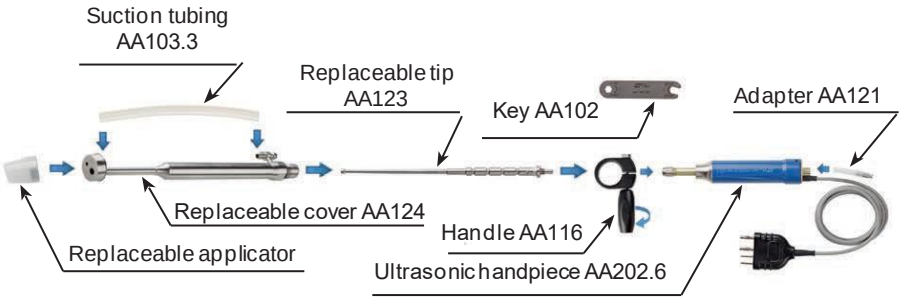


Fig. 17. Device for tonsils lavage in parts (handle AA116 is used for easy assembly/disassembly)

2.2.5.3 Ultrasonic handpiece AA202.6 (Fig. 17 and Fig. 19)

Scope

The application of handpiece with accessories for tonsils lavage (Fig. 16)	The application of handpiece with an ultrasonic tip for phonophoresis AA122.1 (Fig. 18)
Tonsils lavage for treating chronic tonsillitis	Phonophoresis delivery of the medicine to the tonsillar tissue for treating chronic tonsillitis, to the posterior pharyngeal wall for treating chronic pharyngitis

Peculiarities of the ultrasonic handpiece:

- the handpiece is used with replaceable ultrasonic instruments A122.1, AA123, which are screwed to it by a key for fixing the tools AA102 (Fig. 17, Fig. 19);
- when connecting the ultrasonic instrument to the ultrasonic handpiece, do not allow any distortion of threaded connection and apply excessive force;
- it is more convenient to replace the instrument using the AA116 handle, which is attached to the body of the ultrasonic handpiece (the AA116 handle is a part of the supply package of ACTITON-A device);
- if the instrument fixation is not stable, it is necessary to tighten the threaded connection of the tool with the ultrasonic handpiece;
- after the procedure, the ultrasonic instrument is unscrewed from the ultrasonic handpiece, the adapter is removed. All the accessories used for the procedure (handpiece, instrument, key for fixing, handle for the

handpiece, and adapter) are disinfected and sterilized in parts (Fig. 17 and Fig. 19).

The medicine is impregnated into the tissues of the tonsils and of the posterior pharyngeal wall by mechanical micro-massage of the tissues using ultrasonic instrument AA122.1. For a detailed description of the method, see Section *4.4.*

For details on the application of the AA202.6 ultrasonic handpiece with accessories for the tonsillectomy procedure, see sections 3.3 and 4.4.



Fig 18. Ultrasonic handpiece AA202.6 assembled with ultrasonic instrument AA122.1



Fig. 19. Ultrasonic handpiece AA202.6 and its accessories in parts

3 Peculiarities of ultrasonic cavitation procedures for the local treatment and prevention of inflammatory diseases of the ENT organs

3.1 Indications and contraindications. Medical support. Infectious safety

Indications for the use of the LFUS method:

- treatment of infectious and inflammatory diseases of the pharynx and larynx (tonsillitis, pharyngitis, laryngitis);
- respiratory diseases
- postoperative recovery (adenotomies, tonsillectomies, nasal cavity operations, reconstructive and sanitizing ear operations);
- purulent-septic wounds of the soft tissues of the face and neck.
- treatment of infectious and inflammatory ear diseases (otitis externa and media).

Contraindications:

- allergic reactions to the medicines used for treatment;
- the presence of mature granulations (in the case of contact treatment of the wound surface);
- acute period (for contact exposure).

Medications recommended for ultrasonic cavitation:

- sodium chloride solution 0.9% (sterile saline solution);
- water solution of chlorhexidine 0.05%;
- octenisept solution in 1:10 dilution with sterile saline solution;
- dioxydine solution 0.5% without dilution;
- 1% dioxydine solution in 1:1 dilution with sterile saline solution;
- furacin solution 0.02%;
- miramistin solution 0.01%.

Infectious safety

Infectious safety of the procedure of cavities and external surfaces lavage by cavitated liquids is achieved by meeting all the requirements of asepsis and

antiseptics:

- treatment in the procedure room;
- medical clothing and shoes for the staff;
- the use of personal protective equipment (sterile gloves, shields, glasses) by personnel;
- the use of sterile instruments and consumables: tongue spatulas, ultrasonic handpieces, ultrasonic instruments, protective covers, key for fixings for fixing ultrasonic instruments, applicators, Kulikovsky's needles, suction tubings, nasal mirrors;
- instruments disinfection, pre-sterilization and sterilization in autoclave (chemical disinfection and sterilization in solutions that do not contain peroxide are allowed).

3.2 Peculiarities of the irrigation procedure for the organs of the pharynx and nasopharynx, as well as the outer ear, by cavitated solutions

The procedure is performed in the ENT office or in the manipulation room.
The patient is seated on the ENT chair.

For the irrigation procedure of the pharyngeal, nasopharyngeal organs, or the external ear, ultrasonic handpiece **AA208.5** is used supplied with a replaceable protective cover (Fig. 10). The adapter AA121, the back-check valve Infuvalve, REF 4094000N (item number AA118), and then the infusion system Infusomat Space Line REF 8700036SP (item number AA120), produced by B. Braun, are connected to the ultrasonic handpiece (see Appendix A, Fig. A.8). The system is connected to a container filled with medicine. The container is placed on a tripod stand of the trolley.

Before the procedure of ENT organs irrigation, the "ULTRASOUND" and "IRRIGATION" modes are to be enabled on ACTITON-A and ACTITON units. The power of ultrasonic exposure is set at the level of **30-40 nominal units.**

To get a fine-dispersed cloud of the drug solution, it is necessary to set the medium-drop liquid supply rate using the roller clamp on the infusion system (see Appendix A, Figure A. 7), and to get the intensive jet one should set the maximum-drop liquid supply rate. The container with the solution should be located on the infusion trolley above the patient's head. To increase the intensity of spraying, it is recommended to set the container at the maximum possible height.

When the yellow footswitch pedal is pressed, the ultrasonic mode "BASIC" and the liquid supply mode "IRRIGATION" are enabled: a cavitated jet is formed at the output of the ultrasonic instrument. When using a single-pedal footswitch, switching the modes of ultrasonic exposure ("BASIC" or "SELECTIVE") is done by pressing the button with the footswitch image of the corresponding color on the touch panel of the

device. For this manipulation, one must select the yellow footswitch ("BASIC" mode) and enable it using a single-pedal footswitch.

3.3 Peculiarities of the tonsils lavage procedure by the cavitated solution in combination with suction-vacuum exposure

The procedure is performed in the ENT office or in the manipulation room. The patient is seated on the ENT chair.

For the tonsils lavage procedure, ultrasonic handpiece **AA202.5** is used (Fig. 16), supplied with a replaceable ultrasonic instrument, a cover for treating palatine tonsils, and applicators of three sizes (the size of the tonsils defines which size of applicator, small, large or medium, is used). The adapter AA121, the back-check valve Infuvalve, REF 4094000N (AA118), and then the infusion system Infusomat Space Line REF 8700036SP (AA120), are connected to the ultrasonic handpiece (see Appendix A, Fig. A.8). The system is connected to a container filled with medicine. The container is placed on a tripod stand. Then one should connect the AA202.5 handpiece to the suction tract by means of suction tubing (see Appendix A, Fig. A.11). When using the ACTITON-A device with a built-in liquid removal function, it is necessary to install the suction jar in the holder strictly below the level of the patient's head to avoid the infected liquid getting back into the patient's tubing. The container with the solution should be placed above the level of the patient's head, and back-check valve AA118 should be connected to the ultrasonic handpiece AA202.5 (see Appendix A, Figure A.8) to prevent the waste liquid from draining into the patient's area (Fig. 20). The ACTITON device is admitted to be used with the external aspirator.



Fig. 20. The correct position of the suction jar and the container with the therapeutic solution during the tonsils lavage procedure:
1 — container with a solution, 2 — suction jar

Before the procedure, anesthesia is performed (with 10% lidocaine spray) to block the pharyngeal reflex.

One should select the modes "ULTRASOUND", "IRRIGATION", "SUCTION" of the ACTITON-A unit; and modes "IRRIGATION", "ULTRASOUND" on the ACTITON unit; then connect to an external aspirator (connect the suction tubing to the cover of the ultrasonic handpiece AA202.5 (Fig. A.11)). The power of ultrasonic exposure is set at the level of **60-80 nominal units.** Before the procedure, it is necessary to **check the flow of the solution into the system** (the liquid supply must be jet one). For this manipulation, 250-300 ml of the medicine is required.

The applicator of the ultrasonic handpiece is put on the tonsilla palatina. By pressing the yellow footswitch pedal, the ultrasonic exposure mode "BASIC", liquid supply mode "IRRIGATION", and suction control mode "SUCTION" is enabled. To pump out the solution, the hole for vacuum relief is closed with a finger (Fig. 21a). To stop pumping out, the finger is removed from the hole (Fig. 21b).

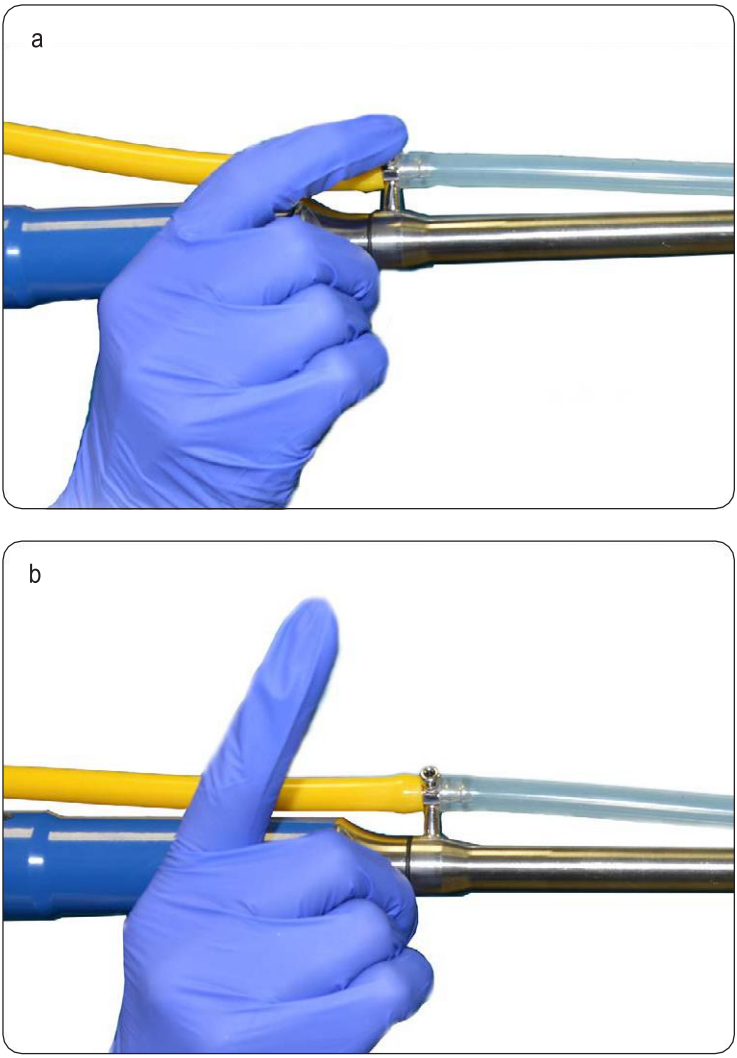


Fig. 21. Suction control by means of the vacuum relief hole of ultrasonic handpiece AA202.5:
a) when the hole is closed with a finger, vacuum is formed in the suction system;
b) when the finger is removed from the hole, the vacuum is relieved

At the end of the procedure, by withdrawing the finger from the hole, the vacuum is released instantly, so there is no need to use a spatula to detach the applicator from the tonsil. It is important to watch the position (inclination angle) of the ultrasonic handpiece when it is removed from the tonsil (to prevent the waste liquid flowing down to the irrigation channel of the ultrasonic handpiece and its infecting):

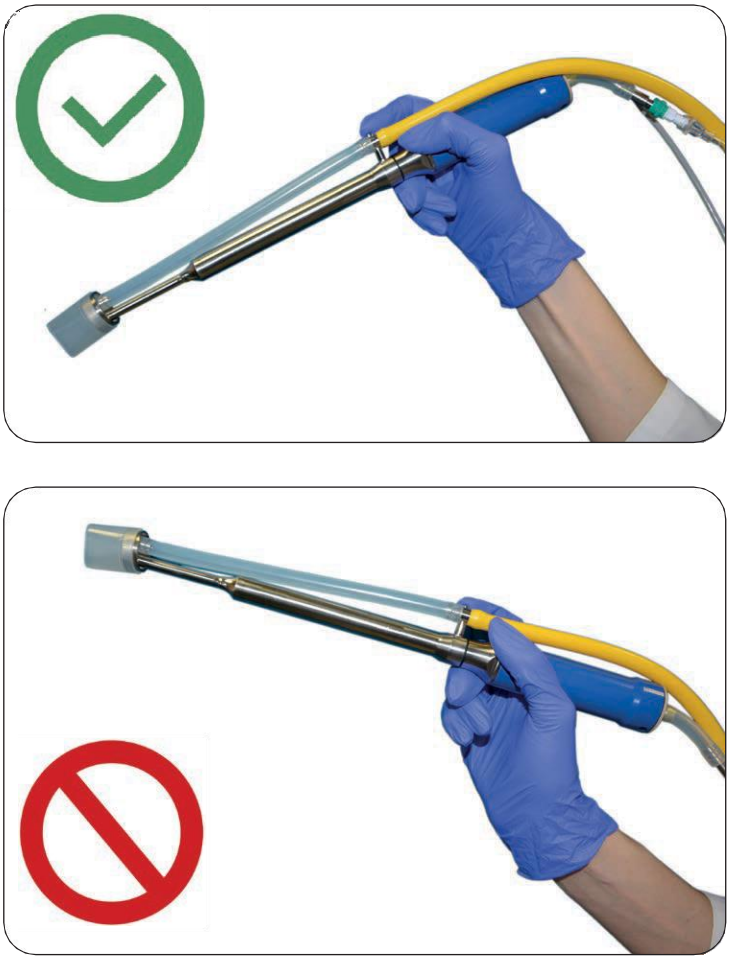


Fig. 22. The correct (upper picture) and incorrect (lower picture) position of the ultrasonic handpiece when detached from the tonsil

3.4 Peculiarities of the phonophoresis medicine delivery

The procedure is performed in the ENT office or in the manipulation room. The patient is seated on the ENT chair.

The "ULTRASOUND" mode is to be selected on the ACTITON-A and ACTITON units. The power of the ultrasonic exposure is set at the level of **3 nominal units.**

For the procedure of phonophoresis delivery of medicine to the tissue of the palatine tonsils and of posterior pharyngeal wall, ultrasonic handpiece **AA202.6** with ultrasonic instrument **AA122.1** is used (Fig. 18). A gauze pad (12 layers of gauze) with the medicine is put on the tip of ultrasonic instrument.

The instrument is applied to the tissue. By pressing the **blue** footswitch pedal, the ultrasonic mode "SELECT" is enabled.

3.5 Peculiarities of the maxillary sinuses lavage procedure

The procedure is performed in the ENT office or in the manipulation room.
The patient is seated on the ENT chair.

For the procedure of maxillary sinuses lavage, ultrasonic handpiece **AA208.5** and **a cover having a "record" connector AA108–4** (Fig. 15) with Kulikovsky's needle installed, are used. The adapter AA121, the back-check valve Infuvalve, REF 4094000N (AA118), and then the infusion system "Infusomat" AA120, are connected to the ultrasonic handpiece (see Appendix A, Fig. A.8). The system is connected to a container filled with medicine. The container is placed on a tripod stand.

Before the procedure of maxillary sinuses lavage, the "ULTRASOUND" and "IRRIGATION" modes are to be enabled on ACTITON-A and "ACTITON" units. The power of ultrasonic exposure is set at the level of **70-80 nominal units.**

Herewith, it is necessary to set the jet liquid supply rate using a roller clamp on the infusion system (see Appendix A, Figure A.7). The container with the solution should be located on the infusion trolley at a level above the patient's head. It is recommended to set the container at the maximum possible height for this procedure. It is important to watch the outflow of waste liquid to avoid air embolus. 100-150 ml of the solution is required.

When the yellow footswitch pedal is pressed, the ultrasonic mode "BASIC" and the liquid supply mode "IRRIGATION" are enabled: a cavitated jet is formed at the output of the ultrasonic instrument (Fig. 23).

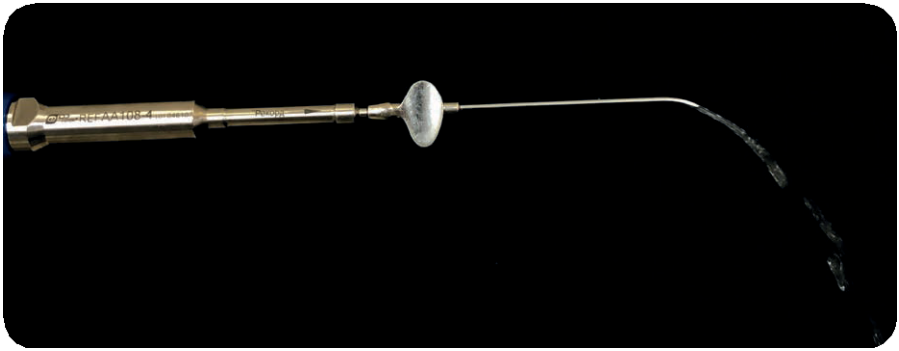


Fig. 23. Cavitated solution at the output of the Kulikovsky's needle

4 Treatment of inflammatory diseases of the pharynx and larynx with medicinal solutions cavitated by LFUS

4.1 Treatment of laryngitis

While treating laryngitis, it is necessary to eliminate inflammation of the mucous membrane of the posterior pharyngeal wall, as well as inflammation of the larynx in the area of the false and true vocal cords and the subglottic space. Under the control of direct vision or optics, pharynx and nasopharynx irrigation is carried out for 30-60 seconds (with a break of 3-5 seconds after each 5-7 seconds) at the power of 30-40 nominal units (see p. 3.2) 100-150 ml of medicinal solution (furacin 1:5000, miramistin, octinisept or saline solution). The liquid supply rate is a medium-drop one. It is recommended to perform 3-5 procedures (daily or alternate days). If necessary, the course can be repeated after 6 months.

4.2 Treatment of pharyngitis

Acute pharyngitis with symptoms of ARVI is most effectively treated in the first days of the disease. The oropharynx and nasopharynx are irrigated (see p. 3.2) by medicinal solution (octenisept, miramistin, saline solution, dioxydine 1%, dioxydine 0.5%, furacin 1:5000) at the power of 30-40 nominal units. It takes about 100 ml of solution per procedure. Mostly, 3-5 procedures are enough (daily or alternate days). The liquid supply rate is a medium-drop one. If the patient is admitted a few weeks after disease exacerbation, a longer treatment course will be required: 3-7 procedures.

4.3 Treatment of nasopharyngitis

For treating nasopharyngitis, the inflamed nasal mucosa is irrigated with "sonic" solutions of medicinal substances (octenisept, saline solution, dioxydine 1%, furacin (1:5000)) for 30-60 seconds (5 seconds each, with a break of 2-3 seconds) at the power of ultrasound exposure of 30-40 nominal units. The liquid supply rate is a medium-drop one. A daily repetition of the procedure is required. In general, 5-7 procedures are necessary. If necessary, it is recommended to repeat the course after 6 months.

4.4 Treatment of chronic and acute tonsillitis

The incidence rate of **chronic tonsillitis** among the working-age population reaches 11-16% (Popa V. A., 1984; Soldatov I. B., 1994; Palchun V. T., 1998; Izvin A. I., 2004). Subject to relapse, tonsillitis can provoke metatonsillar complications of various organs and systems in case of incorrect and non-systematic treatment.

The introduction of gentle, nonoperative methods, making it possible to avoid tonsillectomy, into ENT practice, (Konstantinova N. P., 1999), allows a more rational approach to treating chronic tonsillitis.

One of the most common methods of nonoperative treatment is the lavage of the palatine tonsils lacunae by various medicinal solutions (Belogolov N. V., Ermolaev V. G., 1929, cited according to Soldatov I. B., 1969; Popa V. A., 1984; Soldatov I. B., 1994; Tsvetkov E. A., 2003; Izvin A. I., 2004).

Treatment of chronic tonsillitis of compensated and decompensated forms is carried out in the phase of clinical remission and is aimed at eliminating infectious inflammation of the tonsils. Ultrasonic exposure of the tonsils can accelerate their cleansing, reduce pain, decrease the inflammatory process and accelerate patient's recovery [20,34,60].

Depending on the state of the tonsils and doctor's preferences, the methods described below are used.

First of all, it is necessary to perform a thorough palatine tonsils lavage. The conventional method of lacunae cleansing from tonsilloliths and pus is lavaging with a syringe through a special curved cannula (Fig. 24). The latter is introduced into the tonsil lacuna, the solution is released from the syringe: as a result, under the pressure of the liquid jet, the plugs and food residues are washed out. It is worth remembering that this method has a number of disadvantages: it is difficult to wash out deep plugs (especially from small lacunae), the introduction of a cannula into lacuna causes injury to the tonsillar tissue, which contributes to scarring and reduces natural self-cleaning. Therefore, it is important to carefully perform this manipulation.

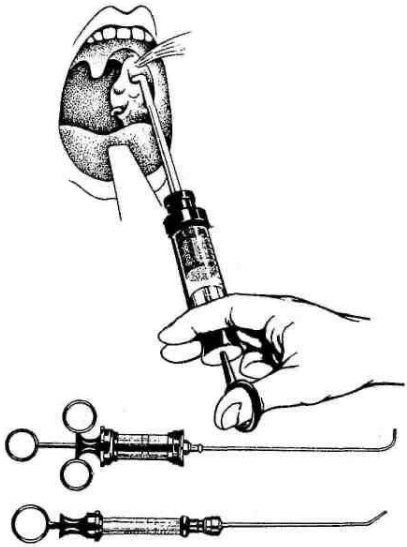


Fig. 24. The conventional method of the tonsils lacunae lavage by a cannula connected to a syringe

In the presence of deep plugs in the lacunae, when the conventional method of treating chronic tonsillitis is ineffective, **the method of tonsils lavage by the cavitated solution in combination with vacuum exposure is used.**

For this purpose, the ultrasonic handpiece AA202.5 is used (see p. 3.3).

The pharyngeal reflex is blocked by anesthesia (10% lidocaine spray). The tonsils lavage by the "sonic" solution (saline solution, furacilin, miramistin, etc.) is carried out using jet liquid supply in combination with suction-vacuum exposure. The resulting intense flows of cavitation bubbles contribute to the qualitative tonsils lavage to remove pathological plaque, to disinfect and improve tissues trophism. Vacuum exposure makes deep plugs come out of lacunae and are removed together with the waste liquid.

During manipulation, it is important to watch the patient's experience and quickly relieve vacuum (Fig. 21), if necessary. During the procedure, alternating the phases of pumping out and negative pressure relief can result in a better drainage effect and additional massage of the tonsils. Each tonsil is to be exposed to ultrasound for 25-30 seconds. Usually, it takes about 5 procedures and 250-300 ml of the solution (liquid supply rate is a jet one).

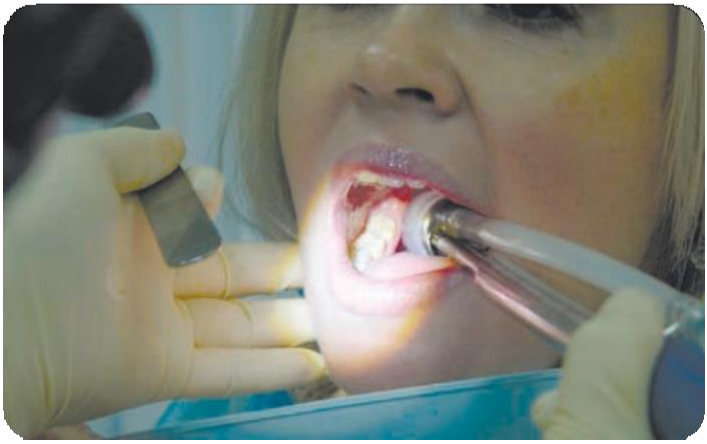


Fig. 25. Procedure of tonsils lavage

The 3rd procedure of the course of tonsils lavage is complemented by the phonophoresis delivery of the medicine. For this purpose, the ultrasonic handpiece **AA202.6** with ultrasonic tip **AA122.1** is used **(Fig. 18).** One should fix a strip of **12 layers of gauze** on the cup-shaped end of the ultrasonic instrument. A gel (viferon, colegel, hydrocortisone ointment, etc.) or a medicinal solution (furacin, dioxydine 0.5%, miramistin, octenisept, etc.) is applied to the gauze. In circular motions, the activated ultrasonic tip is to be moved along the treated surface. But one should not press the tip

hard. The exposure time is 10 seconds for each tonsil at the power of ultrasonic exposure of **3 nominal units**.



Fig. 26. The phonophoresis delivery of medicine to the tonsil tissue

In an acute form of tonsillitis, any contact effect is contraindicated. A safe method of treatment is ultrasonic irrigation by 100-150 ml of a "sonic" solution (saline solution, dioxydine 0.5%, furacin 1:5000, novocaine 0.5%, miramistin, octenisept) by means of ultrasonic handpiece **AA208.5** (see p. 3.2). Each amygdala is exposed for 20-30 seconds at the power of 30-40 nominal units (Fig. 27). The liquid supply rate is a medium-drop one. The course duration is determined individually. The average course is 5-7 procedures (1-2 irrigations per day). This method of treatment allows to accelerate the cleansing of the palatine tonsils without injuring the mucosa and bloodstream, to reduce pain and swelling, microbial content of tissues. The activity of the inflammatory process decreases, and the patient recovers faster. If necessary, the course is repeated after 6 months.



Fig. 27. Tonsils irrigation by the cavitated solution

5 Treatment of inflammatory nose diseases with medicinal solutions cavitated by low-frequency ultrasound

Currently, the most frequent ENT pathologies are nose and paranasal sinuses diseases. This group includes up to 52% of patients treated in ENT hospitals (Piskunov G. Z., Lopatin A. S., 1992, Abdulkerimov Kh. T., 2001, 2015). Sinusitis of outpatients with upper respiratory tract diseases makes even larger percentage.

The reasons for changes in the incidence of diseases are considered: polygenicity of sinusitis, the complexity of its pathogenesis, peculiarities of the anatomical and physiological structure of the nose and paranasal sinuses, a decrease in the immunoreactive properties of the body, allergies, insufficient effectiveness of existing treatment methods, as well as the nature and intensity of changes in the state of the nasal mucosa and paranasal sinuses on the cellular and molecular levels. Most often, sinusitis occurs after influenza and acute respiratory viral infections. They are often accompanied by the development of ocular and intracranial complications [37,45,46,49].

Therefore, rhinosinusitis treatment is and remains one of the most urgent ENT problems. Due to increase in the frequency of nose and paranasal sinuses diseases, and imperfections of diagnosis and treatment of this pathology and the complications, the introduction of advanced methods of diagnosis and treatment of paranasal sinus pathology in clinical medicine is necessary. In this regard, treating sinusitis with various antiseptics and saline solution, cavitated ("sonic") by LFUS, is advantageous.

5.1 Treatment of rhinitis

For treating rhinitis, the nasopharynx lavage is carried out by the “sonic” solution of the medicine (see p. 3.2). The warm solution (t=36-37 °C) is used, since it is important not to compromise the function of the ciliated epithelium. The irrigation is carried out at the power of ultrasonic exposure of 30-40 nominal units for 30-60 seconds (5-10 seconds sets, with 2-3 seconds break). The liquid supply rate is a medium-drop one. About 100 ml and at least 5 daily procedures are required.

For treating **chronic rhinosinusitis,** the nasal cavity is treated with octenisept or saline solution daily for 30-60 seconds each nasal meatus (5-10 seconds sets, with 2-3 seconds break) at the power of ultrasonic exposure of 30-40 nominal units. The liquid supply rate is a medium-drop one, about 100 ml is needed. 5-10 daily procedures are required. The second course is prescribed after 6 months.

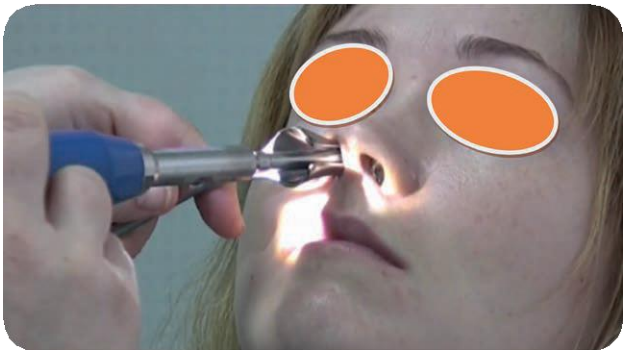


Fig. 28. Ultrasonic irrigation of the nasal mucosae

For treating purulent chronic rhinosinusitis, it is necessary to lavage nasal passages by 100-150 ml of a cavitated solution of dioxydine 1% (0.5%), furacin (1:5000), or another antiseptic solution for 10-20 seconds (5-10 seconds sets, with 2-3 seconds break) at the power of ultrasonic exposure of 30-40 nominal units. The liquid supply rate is a medium-drop one. At least 5 daily procedures are required. If necessary, it is recommended to repeat the course after 6 months.

In case of **polypous chronic rhinosinusitis**, after removing polyps, the nasal passages are lavaged by 100-150 ml of a "sonic" solution of an antiseptic or antifungal drug (amphotericin) for 10-20 seconds (5-10 seconds sets, with 2-3 seconds break) at the power of ultrasonic exposure of 30-40 nominal units. The liquid supply rate is a medium-drop one. 5-15 daily procedures are recommended.

In case of ***atrophic rhinitis (ozena)***, ultrasonic exposure of the nasal passages is carried out daily for 30–40 seconds. (5 seconds sets, with 2–3 seconds break) at the power of ultrasonic exposure of 30–40 nominal units. For both sides 100–150 ml of antiseptic solution, herbal infusion, saline solution, etc. are required. The liquid supply rate is a medium-drop one. 10–15 procedures are required.

5.2 Treatment of chronic adenoiditis

Ultrasound irrigation (see p. 3.2) of the inflamed tonsilla pharyngea helps to remove purulent plaque and fibrin overlays located in the crypts of inflamed lymphoid tissue. A large surface of interaction is created at the "rich-in-gas liquid, — crypt walls" boundary, which contributes to the intensification of physico-chemical and metabolic processes, mechanical destruction of bacteria, and micro-massage of the underlying tissues. As a result, normal breathing is restored without surgery [20,60]. The procedure is especially good for children, as it is painless and effective. Irrigation of each nasal passage with cavitated medicinal solutions (octenisept, saline solution, dioxydine 1%, dioxydine 0.5%, furacin 1:5000) is performed for 30-40 seconds (5-10 seconds sets, with 2-3 seconds break) at the power of ultrasound exposure of 30-40

nominal units. 100-150 ml of the solution are required. The liquid supply rate is medium-drop one. 5–10 procedures are required.

5.3 Treatment of sinusitis

For treating catarrhal maxillary sinusitis, the nasal cavity is irrigated daily (see p. 3.2) with medicinal solutions (dioxydine 1% (0.5%), furacin (1:5000) , etc.) for 10-20 seconds (5-10 seconds sets, with 2-3 seconds breaks) on both sides of the nasal passages at the power of 30-40 nominal units. About 5 procedures are required.

In case of purulent maxillary sinusitis, when the natural ostium is inflamed and impassable, a puncture of the maxillary sinus is required. There are three stages of the cavity lavage. At the first stage, the purulent content of the sinus is pumped out (evacuated) with a syringe through Kulikovsky's needle. The substance is taken for bacterial culture test. At the second stage, the sinus is lavaged with a saline solution, supplied to the sinus through a syringe till clean washing water. At the third stage, a "sonic" solution is delivered to the sinus through Kulikovsky's needle (installed on the AA108–4 cover of the ultrasonic handpiece AA208.5) (Fig. 29) in order to disinfect the cavity, destroy bacterial films preventing the penetration of drugs into the tissues (see p. 3.5).

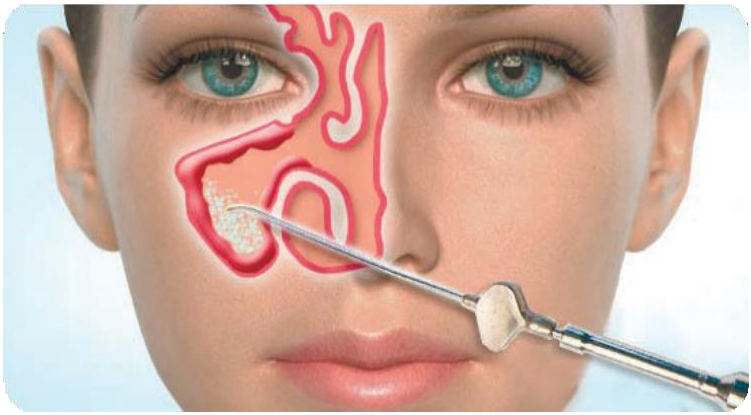


Fig. 29. The maxillary sinus lavage with a cavitated solution

The exposure is carried out at the power of 70-80 nominal units under the condition of jet supply of a solution (saline solution, dioxydine 1% (0.5%), furacin (1:5000), etc.) for 10-30 seconds. 100-150 ml of the solution are required. The treatment course is 3–5 procedures (daily or alternate days).

5.4 Post-operation states

Ultrasonic nose and oropharynx irrigation with medicinal solutions (octenisept, miramistin, dioxydine 1% (0.5%), furacin (1:5000)) improves the condition after polysinusotomies, septum operations, adenotomies, tonsillectomies, maxillary sinusotomies, helps to remove crusts, fibrinous plaque, wound exudate, and inhibits the microflora growth. Irrigation of the nasal cavity (see p. 3.2) is carried out for 10-20 seconds per each nasal passage; irrigation of the oropharynx takes 30-60 seconds (5-10 seconds in sets, with 2-3 seconds break) at the power of ultrasonic exposure of 30-40 nominal units. It requires 5-7 procedures (daily or alternate days, or once per 3 days). The manipulation is carried out one day after the nasal septum operation, 7-10 days after adenoidectomy and tosylectomy, on the second day after polysinusotomy and maxillary sinusotomy.

6 Treatment of inflammatory ear diseases

In case of acute otitis externa and media, the use of cavitated solutions is effective in combination with the conventional treatment scheme. This makes it possible to perform a non-invasive care and cleaning of the external auditory canal and gently remove the epidermal masses. It reduces edema in the membranous-cartilaginous and bony parts of the auditory canal, accelerates the repair processes, which contribute to the rapid recovery of patients, and prevents chronification of the disease [15, 19]. Irrigation of the wound surface with "sonic" solutions after middle ear operations also contributes to the faster healing of injured tissues [15, 19].

6.1 Treatment of acute otitis externa and media

The auxiliary therapy of irrigation of the external auditory canal with cavitated solutions (aqueous solution of chlorhexidine 0.05%, dioxydine 0.5%, miramistin solution 0.01%, bacteriophages, sodium chloride solution 0.9% (sterile saline solution), etc.) allows to relieve the inflammatory process in a shorter time. The procedure is carried out for 30-60 seconds in 3 sets (10-20 seconds each) at the power of 30 nominal units. The liquid supply rate is a medium-drop one. It requires 3-5 procedures (daily).

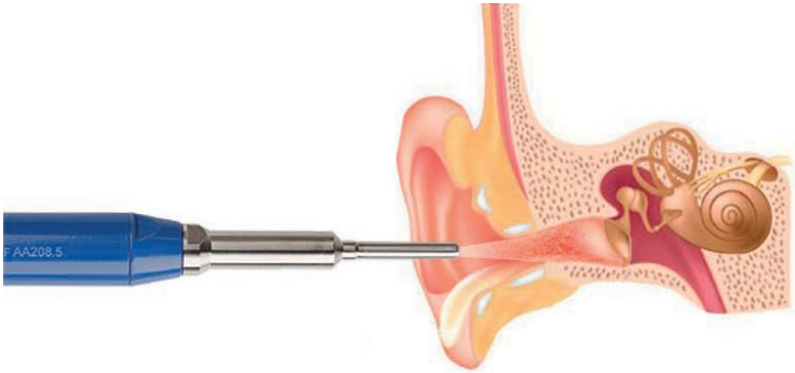


Fig. 30. External auditory canal irrigation procedure with a "sonic" solution

6.2 Post-operation states

Ultrasonic irrigation of the external auditory canal with "sonic" LFUS solutions of medicines (aqueous solution of chlorhexidine 0.05%, dioxydine 0.5%, miramistin solution 0.01 %, bacteriophages, sodium chloride solution 0.9% (sterile saline solution), etc.) contributes to a softer debridement of the postoperative area (wound). And the disinfecting effect of LFUS provides rapid healing of tissues after reconstructive and sanitizing ear operations.

After removing the ear tampon, the procedure is performed for 15-30 seconds in 2-3 sets (5-10 seconds each) at the power of ultrasonic exposure of 30 nominal units. The liquid supply rate is a medium-drop one. 3 procedures are required.

7 Experience of ultrasonic cavitation use in the complex treatment of sinusitis

At the main clinical base of the Department of Surgical Dentistry, ENT and Maxillofacial Surgery of the Ural State Medical University of the Ministry of Health of the Russian Federation (ENT Department of Municipal clinical hospital No. 40, Ekaterinburg city), the method of irrigation with a cavitated solution of the maxillary sinus was applied for patients with chronic maxillary sinusitis [67].

More than 250 patients (the average age is 36.8 years) were treated (inpatient stay) with a diagnosis of chronic maxillary sinusitis, exacerbation. The main group (200 individuals) was treated with "sonic" solutions (124 male patients and 76 female patients). The reference group consisted of 50 individuals who were treated using conventional (generally accepted) methods.

For all patients of the main group, maxillary sinus cavity was treated with a "sonic" medicine solution for 30-60 seconds, with 5-10 seconds break. The ultrasonic exposure was at the power of 70-80 nominal units with a jet supply of a solution (saline solution or antiseptic solutions). The treatment course was 3-5 daily procedures. During the procedure, the patients assessed their sensations as comfortable.

On average, on the second or third day after the beginning of procedures, nasal discharge reduced subjectively, and patients' well-being improved. The positive dynamics was confirmed by the objective examination, laboratory studies, as well as decrease in the pathogens titer during treatment.

Bacterial culture tests of punctate from maxillary sinuses and washing waters were carried out for all the patients in the bacteriological laboratory of the Municipal clinical hospital No. 40. The microbial landscape before treatment is shown in Fig. 31.

Fig. 31 shows the main pathogens of the inflammatory process in maxillary sinuses and nasal cavity are Str. pneumonia and H. Influenza (more than 50%). For other pathogens (11 microorganisms), a significantly lower titer was detected.

In cases of the patients treated with a cavitated solution, the pathogen titer had a fast-decreasing dynamics. After the 3rd procedure, the pathogen was not detected. While in cases of the patients treated with conventional methods, the pathogen titer decreased more slowly.

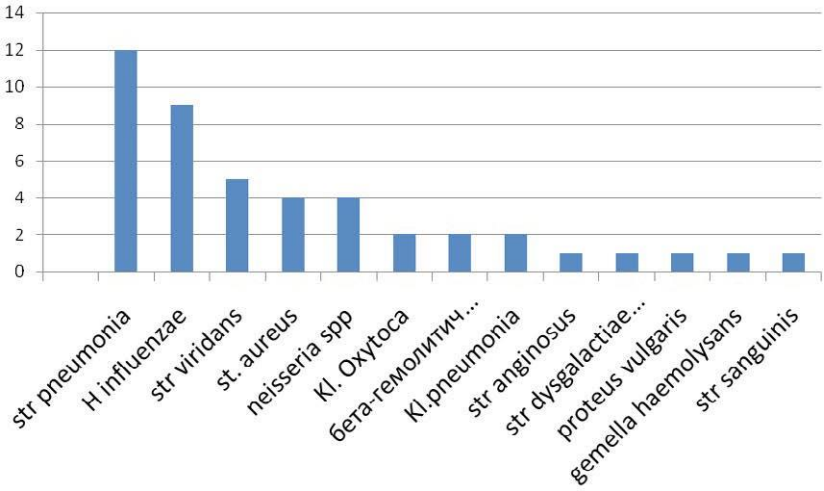


Fig. 31. Microbial landscape before treatment, all the patients under study

So, according to our observations, when using LFUS for treating, inflammatory changes improved on the 3rd day, while conventional treatment gave the same result on the 5th-6th day.

The use of LFUS for treating chronic purulent sinusitis made it possible to reduce the number of punctures to achieve recovery, in comparison with conventional therapy, to accelerate recovery, to decrease the frequency of exacerbations, the cost of medicines, and to significantly reduce the period of patients' disability.

8 Experience of ultrasonic cavitation use in the complex treatment of children acute rhinosinusitis

For treating children acute bacterial rhinosinusitis in the children's hospital "Edkarik", Kaliningrad city, and in the clinical bases of ENT Department of the Ural State Medical University of the Ministry of Health of the Russian Federation, Ekaterinburg, the method of the nasal cavity lavage with a cavitated solution was applied [6,31,32,33].

109 patients with acute bacterial rhinosinusitis were treated. Among them, 54 patients (29 boys (53.7%) and 25 girls (46.3%)) got the complex treatment including the nasal cavity lavage with a solution cavitated by LFUS. The age of the patients under study ranged from 5 to 17 years, the average age was 10.6 years. Patients of the reference group (55 children) got the complex treatment including the nasal cavity lavage with saline solutions according to the conventional method.

In both groups, therapy efficiency was assessed by the dynamics of nasal symptoms intensity. The treatment period was 6 days, while the follow-up period was 1 month.

All the patients were examined, including:

- complaints survey and anamnesis;
- visual examination and ENT organs endoscopy;
- clinical studies;
- the microbial landscape of the middle nasal meatuses discharge;
- rhinocytogram;
- radiation diagnostics (CT imaging of the paranasal sinuses).

The assessment of the patient's subjective sensations was carried out by using a special SNOT-20 questionnaire in the form of a cross-poll (researcher — parent of the patient under study — the patient under study). The intensity of subjective symptoms was assessed by the patients (or their parents) on a 5-point scale. The value of 0 points corresponded to the absence of symptoms; 1 point — mild periodically occurring symptoms; 2 points — mild constantly observed symptoms; 3 points — moderate symptoms, not affecting daily activities; 4 points — obvious symptoms, affecting daily activity; 5 points — significant symptoms. The disease severity was assessed using a 10-centimeter visual analog scale. Values from 0 to 3 cm (points) corresponded to the mild disease severity, from 4 to 7 points — a moderate one, from 8 to 10 points — a severe form of disease.

According to the SNOT-20 scale, before treatment, nasal breathing difficulty was

3.0 points in the main group of patients, and 2.9 points in the reference group; the presence of nasal discharge — 3.0 and 2.9 points, respectively, the discharge flow from the nose to the throat (postnasal drip syndrome) — 3.0 and 2.9 points, respectively; cough — 2.4 and 2.6 points, respectively. Unilateral inflammation of the maxillary sinus was observed for 24 (44.4%) patients in the main group, and for 22 (40%) patients in the reference group; two-lateral inflammation of the maxillary sinus was observed for 17 (31.5%) and 19 (34.5%) individuals, respectively; hemisinusitis — for 13 (24.1%) and 14 (25.5%) patients, respectively.

Before the beginning of treatment, in the microbial landscape of discharge from the middle nasal meatuses there dominated (Fig. 32):

- Str. pneumonia — 49 (45%) cases;
- H. influenzae — 27 (24.8%) cases
- association of H. influenzae+Str.pneumonia microbes —17 (15.6%) cases;
- Staph. aureus — 12 (11.0%) cases;
- Str. pyogenes — 4 (3.7%) cases.

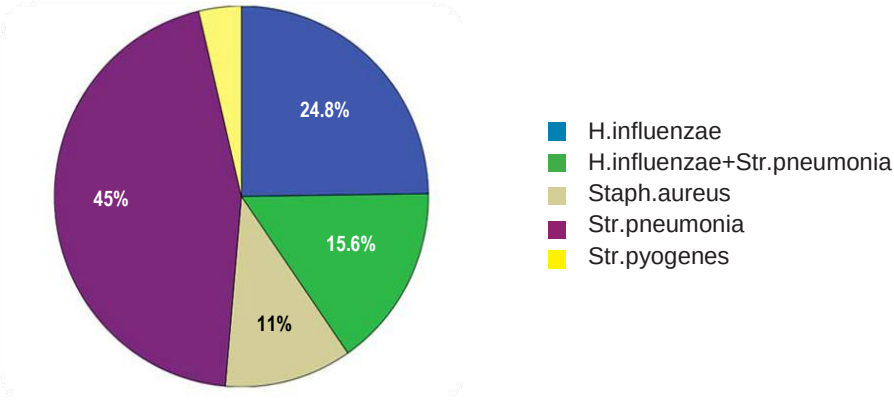


Fig. 32. Microbial landscape before treatment, all the patients under study

For the patients with acute bacterial rhinosinusitis, monoflora prevailed in 84% of cases, and associative flora was detected in 16% of cases.

For all the patients of the main group, the complex treatment included nasal cavity lavage with the solutions cavitated by LFUS. The protective cover enables the nasal cavity lavage with the maximum approach of the tip to the middle nasal meatus, where the natural ostium of the maxillary sinus is located. The nasal cavity treatment was carried out for 30-60 seconds with 5-10 seconds breaks. The power of the ultrasonic exposure reached up to 80-90 nominal units, using jet supply of the solution. Saline solution, 0.9% sodium chloride, was used. The treatment course was 4-5 procedures. Pediatric patient tolerated the procedure well.

The assessment of the patients' condition dynamics, of changes in complaints

indicators, and of the study results was carried out on the 1st, 3rd and 6th days of treatment, 14 days and 1 month after treatment.

By the 3rd day, for the patients treated with the nasal cavity lavage with cavitated solutions, a faster positive dynamics of the main clinical symptoms was observed: nasal breathing improved (1.8±0.7 points), the amount and nature of nasal discharge decreased (1.5±0.8 points), the flow of discharge into the throat stopped (0.9±0.8 points) and cough sharply decreased (0.4±0.7 points). According to the laboratory tests results, a decrease in the elevated level of leucocytes in the clinical blood analysis, and a decrease in serum IgA and M, neutrophil cells in rhinocytograms was determined. The concentration of class A immunoglobulins was 1.71 g/l after the 3rd day of therapy (on the 1st day it had been 4.20 g/l; $p<0.001$) for the patients of the main group. There was a significant improvement of the time of mucociliary transport of the nasal mucosa: the parameters of the saccharin test changed from 17.47±0.13 minutes to 6.19±0.1 minutes.

In the reference group, these changes were less significant by the 3rd day: the improvement of nasal breathing was 2.6±0.7 points, the reduction of nasal discharge was 2.04±0.9 points, the discharge flowing into the throat — 1.6±0.1 points, cough — 0.5±0.8 points, the concentration of class A immunoglobulins decreased from 4.33 g/l on the 1st day of therapy to 2.83 g/l after the 3rd day of treatment ($p<0.001$). The improvement of mucociliary transport time of the nasal mucosa was significant (from 17.42±0.1 minutes to 5.05±0.1 minutes).

At the end of the treatment course, by the 6th day, the patients of the main group had a complete recovery of nasal breathing, nasal discharge disappearance, the absence of discharge running into the throat and cough. The laboratory indicators returned to their normal values. The patients of the reference group also had the recovery of nasal breathing, the disappearance of nasal discharge, but the positive dynamics of the postnasal drip syndrome was detected in 2 cases (3.6%) only. On the 6th day of therapy, there was a more significant reduction in the time of the saccharin test for the patients of the main group ($p=0.009$; Mann-Whitney test), compared to the patients of the reference group ($p<0.001$).

There was a more significant recovery of the paranasal sinus mucosa in the main group than in the reference group. According to the paranasal sinuses CT imaging performed 1 month after treatment, their pneumatization was completely recovered for 50 (92.6%) patients of the main group and for 44 (80.0%) patients of the comparison group; parietal darkening of the maxillary sinuses was detected in 2 (3.7%) and 5 (9.1%) cases, respectively; the maxillary sinuses darkening — in 2 (3.7%) and 6 (10.9%) cases, respectively.

The patients treated with cavitated solutions had the best long-term results of the treatment, with regard to the symptoms of the disease (relapse) and to recovery of the function of the ciliated epithelium of the nasal mucosa. A month after the end of therapy, the number of patients having worse clinical symptoms was observed to increase in the reference group compared to the 6th day of the treatment course. In the

main group, it happened only in 1 (1.9%) case in the form of mucosal discharge flowing along the posterior pharyngeal wall.

Therefore, the use of LFUS for treating children acute rhinosinusitis gave positive results by the 3rd day of treatment, while the recovery process was slower for the patients conventionally treated. In addition, the use of cavitated solutions allowed to reduce the number of relapses compared to the conventional treatment scheme.

CONCLUSION

Taking into account the above facts, the use of low-frequency ultrasound for treating chronic sinusitis, diseases of the pharynx and nasopharynx, acute otitis media externa and media can reduce the severity of clinical symptoms faster than in case of conventional therapy. As a result, the terms of hospitalization are reduced. It makes the method economically effective and reasonable. The simplicity and ease of ACTITON and ACTITON-A devices use allow to apply them in outpatient conditions as well.



Video demonstration of the use of devices of the AK100M series in ENT:
https://https://goo.su/2b2i

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Appendix A. Installation of “FOTEK” ultrasonic cavitation device of AK100M series



Fig. A.1 Device assembled on trolley

I. Initial step of installation

1. Install **the device control unit** on the top shelf of the trolley (Fig. A.1).

2. Plug **the footswitch** in the socket for a footswitch on the rear side of device control unit (Fig. A.3, pos. 14).

3. Plug **the mains cable** first in the socket for the mains cable on the rear side of device control unit (Fig. A.3, pos. 17), and then in a socket outlet with **grounding pins** (Fig. A.2).

4. Tap the **ultrasonic handpiece** plug into **the "ULTRASOUND" connector** on the front side of the device control unit (Fig. A.3, pos. 13).

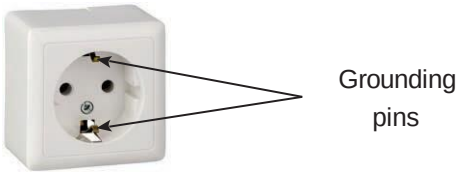


Fig. A.2. Socket outlet with grounding pins



Fig. A.3. Front and rear sides of “FOTEK” device of AK100M series (ACTITON-A model):
1 — "ULTRASOUND" button to enable US modes; 2 — button to enable "SUCTION" mode; 3 — button to enable "IRRIGATION" mode; 4 — display of the US vibrations level; 5 — button to enable "TIMER" option; 6 — buttons to adjust the US vibrations level;
7 — view information on the enabled UH; 8 — irrigation control valve; 9 — information on the connected footswitch, the footswitch function;
10 — brief information on the device operation; 11 — screen color, sound level, interface language settings; 12 — "STB" button ("Stand-by" — sleep mode);
13 — "ULTRASOUND" socket for an ultrasonic handpiece; 14 — socket for a footswitch; 15 — "SUCTION" connector for the suction tubing; 16 — mains switch button; 17 — socket for the mains cable

5. The ultrasonic handpiece (UH) can be placed in a special holder on the trolley shelf, if there are no requirements for the unit sterility maintenance (Fig. A.4).

6. Turn on the device by pressing **the mains switch** (Fig. A.3, pos. 16), the device will be in stand-by mode. First, press **“STB” ("Standby") button** on the front side of the device (Fig. A.3, pos.12). The indicator next to the button will go off, and the screen will light up. To put the device to stand-by mode, press **“STB” button** again (Fig. A.3, pos. 12). The indicator next to the button will light up, and the device screen will go off.



Fig. A.4. UH holder on the trolley shelf

II. Installation of the device irrigation tract

The main elements of the device irrigation tract are shown in Fig. A.5:



a b c

Fig. A.5. The main elements of the device irrigation tract:
a — container with a medicinal solution (pack or vial); b — infusion system; c — ultrasonic handpiece.

To switch on the "IRRIGATION" mode, it is necessary to use special infusion systems **Infusomat Space Line REF 8700036SP** (produced by B. Braun). A pack of infusion systems (100 pcs.) is supplied with the device, item number **AA120** (Fig. A.6).

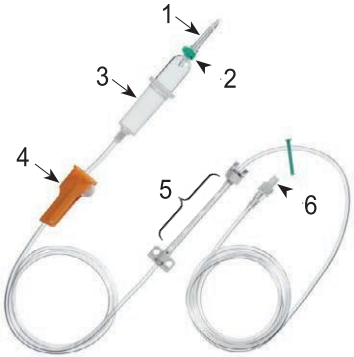
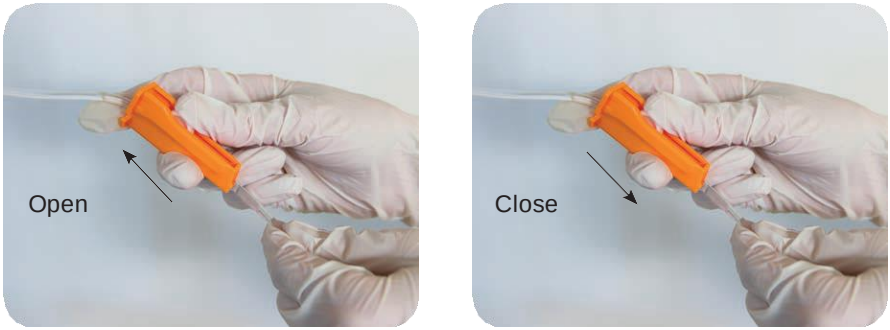


Fig. A.6. Infusion system Infusomat Space Line REF 8700036SP, produced by B.Braun (AA120):
1 — piercing spike;
2 — air valve; 3 — drip chamber; 4 — roller clamp; 5 — silicone pump segment;
6 — distal end with “Luer-lock” adapter

1. Close the roller clamp of the infusion system (Fig. A.7, b).



a b

Fig. A.7. Opening (a) and closing (b) of the roller clamp of the infusion system

2. Introduce **the piercing spike of the infusion system** (Fig. A.6, pos. 1) into the container with the medicinal solution until it stops. Hang **the container with the solution** on the infusion trolley. The height of the infusion trolley can be varied by means of a regulator located on the tripod stand (Fig. A.1). Put **the adapter AA121** (Fig. A.8, pos. 2), supplied with each handpiece, on the pipe connector of the ultrasonic handpiece (Fig. A.8, pos. 1). Screw **the back-check valve Infuvalve, REF 4094000N,** produced by B. Braun (the item number AA118) (hereinafter referred to as the Infuvalve) in the adapter, Fig. A.8, pos. 3, after removing the protective cap from the valve. The device is supplied with a pack of Infuvalves (50 pcs.). Connect **the distal end** of **the infusion system** to the Infuvalve (Fig. A.8, pos. 4), after removing the protective cap from it.

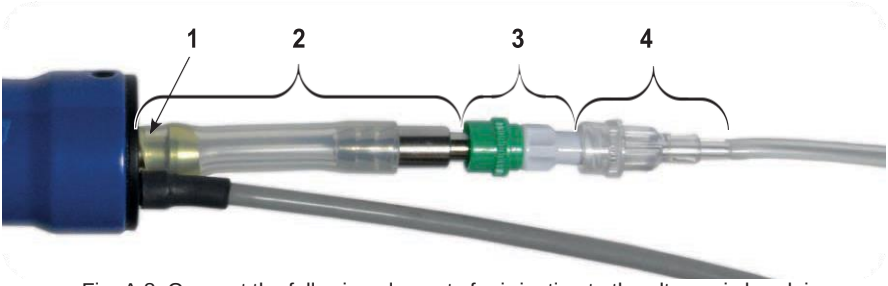


Fig. A.8. Connect the following elements for irrigation to the ultrasonic handpiece:
1 — pipe connector; 2 — adapter (AA121); 3 — back-check valve (AA118); 4 — distal end of the infusion system (AA120)

IMPORTANT! If the back-check valve AA118 is not connected to the handpiece, the liquid can be "pumped out" from the cavity into the irrigation channel of the ultrasonic handpiece and the infusion system when putting the distal end of the ultrasonic handpiece into the cavity filled with liquid. The Infuvalve does not allow the liquid to rise through the handpiece channel in the opposite direction and prevents the liquid from the patient's cavity from entering the handpiece irrigation channel and the infusion system.

It is allowed to use the device without Infuvalve if a sterile handpiece and a sterile infusion system is used for each procedure. Open **the air valve of the infusion system** (Fig. A.6, pos. 2). **Fill the drip chamber of the infusion system** (Fig. A.6, pos. 3) half-full with a therapeutic solution by squeezing it with your fingers on both sides simultaneously. Install the container under the ultrasonic handpiece to check the operation of the device irrigation tract. **Open the roller clamp of the infusion system** (Fig. A.7, a). Then the system will begin to fill with the therapeutic solution. When the solution fills the system and begins to flow out of the ultrasonic handpiece channel, close the roller clamp of the infusion system (Fig. A.7, b). **Install the silicone segment of the infusion system** (Fig. A.6, pos. 5) into the irrigation control valve lash on the front side of the control unit by pressing the button in the center of the valve (Fig. A.9, a). Release the button and make sure the gap of the silicone tube is blocked by the valve (Fig. A.9, b).



a b

Fig. A.9. Connect the infusion system to the irrigation control valve:
a — pressing the valve button; b — releasing the valve button

3. Open **the roller clamp** of the infusion system (Fig. A.7, a). On the touch screen of the device, **turn on the "IRRIGATION" mode** by pressing the same-name button (Fig. A.3, pos. 3). Make sure the "ULTRASOUND" and "SUCTION" modes are disabled (i.e. the buttons with the names of these modes (Fig. A.3, pos. 1 and 2) are

not highlighted on the display). Otherwise, it is necessary to disable them by clicking on them. **Enable the "IRRIGATION" mode** by pressing any pedal on the double-pedal or single-pedal footswitch. Make sure the solution flows out of the ultrasonic handpiece channel in the form of a thin jet. Using the roller clamp (Fig. A. 6, pos. 4) set the required liquid supply rate (for most applications, it should be maximum). When you release the footswitch, the solution supply to the handpiece will stop.

NOTE: the irrigation control valve (Fig. A.9) performs the function of automatic closing/opening of the solution supply to the ultrasonic handpiece. At the moment of enabling the "IRRIGATION" mode by the footswitch, the valve opens, the system tube is opened, and the solution flows to the handpiece. At the moment of disabling the "IRRIGATION" mode (releasing the footswitch), the valve squeezes the system tube (Fig. A.9, b), and solution supply to the handpiece stops.

IMPORTANT! The "IRRIGATION" mode can only be used in case the infusion system Infusomat Space Line REF 8700036SP, produced by B. Braun, is used to supply the solution. This system contains **a silicone segment** (Fig. A.6, pos. 5), which can be inserted into the irrigation control valve lash, which allows to automatically close/open the solution supply to the handpiece. **When using the standard infusion system (without a silicone segment)**, it is necessary to manually close/open the solution supply to the handpiece by the roller clamp, available on each system. The "IRRIGATION" mode should be **turned off** in this case. The tube of standard infusion system should not be inserted into the valve, because it will not be completely squeezed by it.

lll. INSTALLATION OF THE ASPIRATION TRACT OF THE DEVICE (for the "FOTEK" device of AK100M series (ACTITON-A model)

The main elements of the device aspiration tract are given in Fig. A.10:



Fig. A.10. The main elements of the device aspiration tract are:
a — a set of suction tubings (short 0.9 m and long 2 m); b — suction jar; c — ultrasonic handpiece AA202.5 for the treating palatine tonsils

1. Connect **elbow connectors** supplied with the jar to the jar unions (Fig. A.10, b). Install the jar to the holder located on the rear side of the trolley column.

2. **A short, 0.9 m, suction hose** (Fig. A.10a, left) is used to create vacuum in the suction jar. Connect one end of the suction hose to the "SUCTION" connector on the rear side of the control unit of the device (Fig. A3, pos. 15), and the second end — to the jar union "TO THE DEVICE" ("VACUUM") through the elbow connector.

3. **A long, 2 m, suction hose** (Fig. A.10a, right) is designed to remove the liquid from the treated area. Connect one of its ends to the jar union "TO THE INSTRUMENT" ("PATIENT") through the elbow connector. Connect the second end of the hose to the jar with the vacuum relief hole of the ultrasonic handpiece AA202. 5 cover (Fig. A.11).

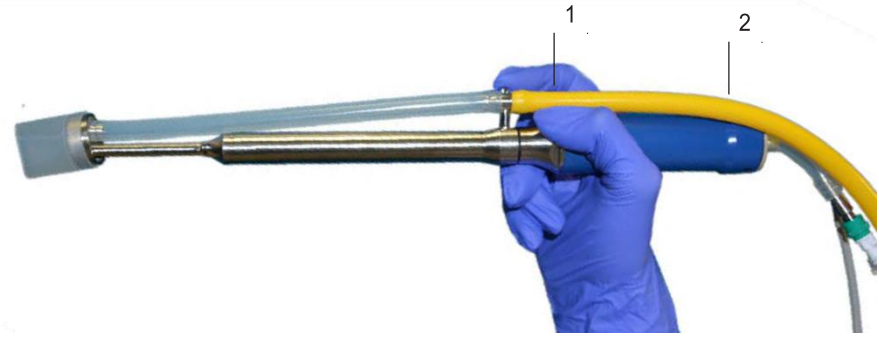


Fig. A.11. Connection of the suction hose to the ultrasonic handpiece AA202. 5:
1 — jar with the vacuum relief hole; 2 — suction hose

IMPORTANT! Incorrect connection of the hoses can result in liquid supply to the pump of the device control unit and the failure of the device.

4. **Turn on the "SUCTION" mode** by pressing the same-name button on the display of the device (Fig. A3, pos. 2). **Enable the "SUCTION" mode** by pressing **any** pedal on the double-pedal or single-pedal footswitch.

ATTENTION! The "IRRIGATION" and "SUCTION" modes can be enabled simultaneously. Therefore, when the "SUCTION" mode is enabled, liquid will start to flow out of the ultrasonic handpiece channel, if the "IRRIGATION" mode is also enabled.

5. Put the applicator of the ultrasonic handpiece AA202.5 to the palm of your hand in a sterile glove, and make sure that the vacuum is developed, the solution bubbled in the applicator is pumped out.

6. When you release the footswitch, the liquid suction stops after 3 seconds delay.

IV. ACTIVATION OF THE ULTRASONIC MODES

1. On the device display, **press the "ULTRASOUND" button** (Fig. A.3, pos. 1).

The level of ultrasonic vibrations (Fig. A.3, pos. 4) is controlled by the "+"/"-" buttons on the device display (Fig. A.3, pos. 6).
Set the vibration level recommended for the procedure.

2. **Activation of "BASIC" ultrasonic mode** is carried out by pressing the yellow pedal of the double-pedal footswitch, "SELECT" mode - by pressing the blue pedal (the description of the modes is given in Table 1).

If a single-pedal footswitch is used, there are two images of a single-pedal footswitch at the bottom of the device screen — one of a yellow pedal, the other one of a blue pedal (Fig. A.12). If the image of footswitch with a yellow pedal is highlighted in the background, the footswitch will enable the "BASIC" mode, Fig. A.12. If you select a footswitch with a blue pedal on the screen (by clicking its image), the footswitch will enable "SELECTIVE" mode.

If all the previous steps of the device installation are completed correctly, then after pressing the footswitch, a cavitation jet in the form of directed fine-dispersed cloud comes from the irrigation channel of the ultrasonic handpiece, Fig. 7 (except for the cases when the AA208.5 handpiece with the AA108–4 cover is used).

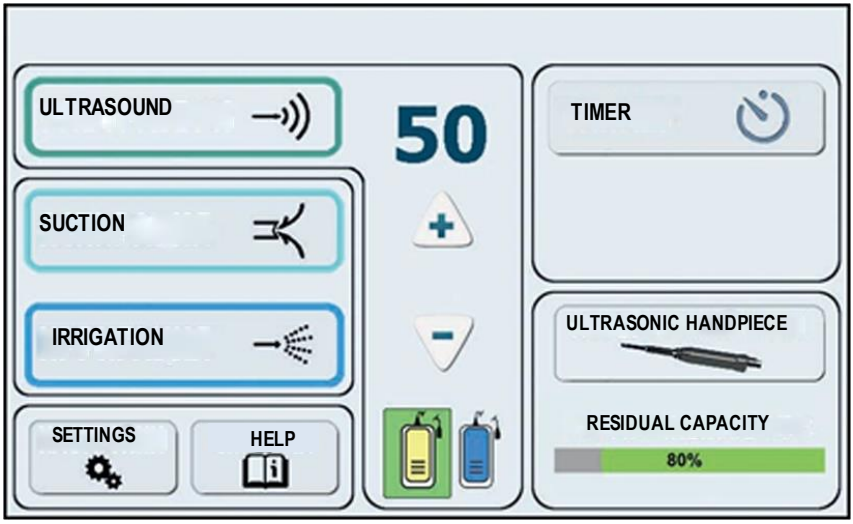


Fig. A.12. Screen view of single-key footswitch and ultrasonic handpiece connection

NOTE: "IRRIGATION", "SUCTION" and "ULTRASOUND" device modes can be enabled both simultaneously and separately.

IMPORTANT! When the ultrasonic modes are enabled, the solution **is to pass** through the irrigation channel of the ultrasonic handpiece, otherwise the handpiece will not cool down and can overheat. To provide this, the infusion system and the irrigation channel of the ultrasonic handpiece are to be **completely filled with the medicinal**

solution before enabling the ultrasound modes (see Section "Installation of the device irrigation tract").

3. **The power and dispersity of the cavitation jet** depend on the selected level of ultrasonic vibrations, the preset liquid supply rate of the medicine solution, as well as the level of hydrostatic pressure of the liquid flowing to the irrigation channel of the instrument. In its turn, the value of hydrostatic pressure of the liquid depends on the installation height of the container with the supplied medicinal solution. The higher the container with the solution is, the more powerful the cavitation jet formed by the device is, and the stronger it hits the tissues.

V. AUXILIARY OPTIONS OF THE DEVICE

1. Timer

The timer option is used to set the time of ultrasonic exposure. To do this, press **the "TIMER" button** on the device display (Fig. A.3, pos. 5) and set the required time period of ultrasonic vibrations generation. To resume them, you need to press the footswitch again. If the timer has not expired and you need to start it again, then click **the "RESET" button**, and the timer will be updated.

2. Viewing information on the connected ultrasonic handpiece

When connecting an ultrasonic handpiece, information on the residual capacity of the handpiece will appear on the screen under **the "ULTRASONIC HANDPIECE" button** (Fig. A.3, pos. 7). When you click on the button, reference information on the connected ultrasonic handpiece will appear.

3. Adjustment of screen brightness and volume level

By clicking on the **"SETTINGS" button** (Fig. A.3, pos. 11), one can change the screen brightness and the volume level of the device sonic signal.

4. Background information

By clicking on **the "HELP" button** (Fig. A.3, pos. 10), one can view a summary on the use of device.

Appendix B. Disinfection and sterilization of elements of the “FOTEK” ultrasonic cavitation device of AK100M series (ACTITON and ACTITON-A models)

1. **The device control unit, the double-pedal footswitch, the device table with accessories** are to be subjected to chemical disinfection by double wiping with a squeezed-out disinfectant wipe.

2. **The suction jar** is subjected to steam disinfection (110 °C, 20 min), pre-sterilization cleaning with the solutions recommended for treating medical products made of plastic and rubber by the manufacturer. The jar can be subjected to steam disinfection (121 °C, 20 min). Since the jar does not contact with the patient's tissues, it is allowed to carry out its disinfection only.

3. Back-check valve AA118, infusion system A120 are to be disposed after their use.

4. Ultrasonic handpieces and their accessories (adapters with connectors, protective covers, replaceable ultrasonic instruments, keys for fixing instruments, handles), suction tubings and applicators (hereinafter referred to as accessories) are subjected to disinfection, pre-sterilization cleaning and sterilization in parts (see Fig. 12, 15, 17, 19) according to the recommendations below.

ATTENTION! It is forbidden to sterilize ultrasonic handpieces with hot air in a dry-air sterilizer.

ATTENTION! The use of ultrasonic washing and disinfecting machines is forbidden.

ATTENTION! Disinfection, pre-sterilization cleaning and sterilization of accessories with solutions containing hydrogen peroxide are forbidden.

Disinfection

It is recommended to carry out disinfection by the steam method (autoclaving) in the mode of **110 °C, 20 minutes.** If the steam disinfection method recommended is not available, it is allowed to carry out chemical disinfection by the means recommended for treating medical products made of metal, plastic and rubber by their manufacturer. Chemical disinfection is carried out according to the instructions for the product used.

For manual disinfection, accessories must be completely immersed in the solution. The inner channels of the accessories are to be filled with a solution without air locks Be sure to wash the channels with a disinfectant solution from the proximal end using a syringe (Fig. B.1) or other device.

After chemical disinfection, **the solution is to be thoroughly washed** from the

accessories. Special attention should be paid to washing the internal channels of ultrasonic handpieces. The accessory channels are washed out with a syringe (Fig. B.1) or a water jet pump for 3–5 minutes.



Fig. B.1. Washing out internal channels of the accessories

Remaining dirt is thoroughly washed using mechanical means (badgers, brushes, gauze or coarse calico wipes, etc.).

Pre-sterilization cleaning

Pre-sterilization cleaning is carried out manually or by machine according to the instructions for the product used. Pre-sterilization cleaning can be combined with disinfection, if it is allowed by the instruction for the product used.

After pre-sterilization cleaning, **the solution is to be thoroughly washed** from the accessories. Special attention should be paid to washing out the internal channels of the ultrasonic handpieces. The accessory channels are washed out with a syringe or water jet pump for 3-5 minutes.

Next, the washing water is to be removed from the internal channels of the accessories (using a syringe or air gun), the accessories are to be completely dried.

Sterilization

It is recommended to carry out sterilization by **the steam method** (autoclaving) in the mode of **134 °C, 5 minutes.**

If the steam sterilization method recommended is not available, it is allowed to carry out chemical sterilization by the means recommended for treating medical products made of metal, plastic and rubber by their manufacturer. Chemical sterilization is carried out according to the instructions for the product used.

In case of manual chemical sterilization, all the manipulations are to be performed in aseptic conditions, using sterile water containers, sterile water and instruments, as

well as sterile gloves to protect the hand skin.

The accessories are to be completely immersed in the sterilization solution. The internal channels of ultrasonic handpieces and instruments are to be filled with a solution without air locks. Be sure to wash the accessory channels with a disinfectant solution from the proximal end using a syringe

After chemical sterilization, the accessories are to be **thoroughly washed from the solution with sterile water.** The accessories channels are washed out with sterile water using a syringe or other device for 3-5 minutes, and the water having passed through the channel is not to fill the container with the washed elements.

After washing the accessories, the remains of washing water in the channels are to be removed using a sterile syringe or other device, and the accessories are to be completely dried.

Purchase of equipment for ultrasound therapy and surgery

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