

Operating Manual Art.-Nr. 101719-V02

SONIC VITAL XTcolor

ULTRASOUND THERAPY DEVICE

chiroform®

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General

Purpose of Use

The SONIC vital XTcoloR is intended for use by qualified therapists for low intensity, non-invasive, external pulsed ultrasound therapy on persons. The aim of the treatment is to re-establish normal functioning of skin and muscle tissue, tendons and joints and to exert a positive influence on the pain relief process. The SONIC vital XTcoloR is particularly well suited for use in orthopaedic, trauma and sports medicine disciplines. The SONIC vital XTcoloR is furthermore suitable for use for sonophoresis for the comparable spectrum of indications as outlined above.

Precautionary Measures

- » The SONIC vital XTcoloR may only be used in compliance with this instruction manual and in relation to the medical contra-indications.
- » The SONIC vital XTcoloR may only be operated by qualified and trained personnel.
- » Never use adapters or extension leads of any sort. Such use can cause increased emissions or a reduction in the stability of the SONIC vital XTcoloR.
- » Damaged cables or plugs must be replaced immediately.
- » If the SONIC vital XTcoloR is damaged in any way, it must be returned to the manufacturer for testing before re-use.
- » Always disconnect the mains plug and all other cables before cleaning and servicing the device.
- » All maintenance and inspection work must be performed by qualified professionals who have been trained in the functioning of the SONIC vital XTcoloR and using suitable and properly calibrated measuring equipment.
- » Never use in close proximity to combustible anaesthetics or gases. Explosion hazard!
- » Vessels containing liquids must be kept well away from the SONIC vital XTcoloR. The penetration of liquids into the SONIC vital XTcoloR is to be avoided. But if such penetration into the SONIC vital XTcoloR has occurred, the device must be subjected to a technical safety check before being re-used.
- » Before connecting to the mains power supply, check that the mains voltage and frequency are in compliance with the values stated on the rating plate.
- » The SONIC vital XTcoloR may only be operated in ambient temperatures of 10 °C to 40 °C and a relative humidity factor of less than 90 %. Devices which have

been stored in cold places must have attained ambient temperature before being switched on to avoid condensation. The SONIC vital XTcolor must not be used in damp rooms.

- » Any deviations from these precautionary measures are the sole responsibility of the operator.

Safety Instructions

- » Only those articles listed under „Accessories“ in this instruction manual may be used in conjunction with the SONIC vital XTcolor.
- » Operating in the proximity of short wave or microwave therapeutic devices can cause fluctuations in the output values of the SONIC vital XTcolor.

To avoid such undesirable effects please observe the following recommendations:

- » The output level should be set as low as possible for the purpose involved.
- » The interferences generated through the use of the SONIC vital XTcolor may affect the functioning of other electronic devices. Portable and mobile HF communication equipment may interfere with the functioning of electronic medical devices. Please observe the start-up instructions.
- » We exhibit, on request of, a manufacturer explanation with respect to the electromagnetic compatibility for the SONIC vital XTcolor.
- » The operator of the device is responsible for checking all accessories at regular intervals. The cables in particular must be inspected for potential damage to the insulation.

Contra-Indications

Therapeutic Ultrasound Contra-Indications

General Contra-Indications

- » Serious cardiovascular and circulatory diseases, in particular with the treatment directed at areas with large autonomous nerves and nerve centres.
- » Serious systemic diseases.
- » Malignant diseases in the area of treatment.
- » Bacterial, viral or fungal infections in the area of treatment.

- » Hypaesthesia in the treatment area and in patients with loss of autonomic function.
- » Patients with dementia.
- » Children under five years old.
- » Application in the area of active epiphyseal cartilage.
- » Application to female and male gonads and glandular tissue.
- » During pregnancy.
- » Application in the area in the vicinity of the eyes.
- » Implants, including all electronic implants (for example, pace makers).
- » Advanced circulatory disorders, with the exception of low intensity wound treatments.
- » Serious bleeding disorders, for example such as haemophilia and patients on anti-coagulants.
- » Serious vascular damage and danger of bleeding.
- » Deep venous thrombosis.
- » Application in the area of the unprotected brain and spinal cord, e. g. after laminectomy.
- » Unhealed fractures (with the exception of low intensity application) and stress fractures.
- » Application where osteoporosis is present.
- » Around the pelvis during menstruation.
- » Application where osteonecrosis is present.
- » Application in the facial area (1 MHz).
- » Application in the cardiac area where serious cardiac disease is present.

Additional Contra-Indications Related to Thermal Applications

- » All diseases where heat treatment is contra-indicated, as, for example Serious injuries.
- » Infections within the treatment area.
- » Thrombophlebitis.

Additional Contra-Indications Related to Ultrasonophoresis

- » Specific contra-indications of substances and auxiliary substances.

Side Effects of Therapeutic Ultrasound

- » Worsening of infections.
- » Increase in pain levels.
- » Wound healing complications.
- » Tissue trauma caused by incorrect application and overdosing.
- » Reactions of the autonomous nerve system, for example circulatory haemostasis caused by stationary waves resulting from insufficient ultrasound head movement.

Additional Side Effects Related to Ultrasound Phoresis

- » Specific substance and auxiliary substance side effects.
- » Skin irritation.



Programs and Indications











All statements are to be regarded as treatment suggestions which, as and when necessary should be adapted according to the case under treatment.












The treatment times relate to a treatment area twice the size of the ultrasound head, that is a maximum of 8 cm² with the large surface ultrasound head and 2 cm² with the smaller ultrasound head.












Partly modified parameters according to Tim Watson, „Therapeutic Ultrasound“ (www.electrotherapy.org).

Program Listing / Indications








Program / Indication	Type of indication	Frequency in MHz	Min.	Duty Cycle As a %	Watt per cm ²	Treatment Frequency	Graphics
1 Rheumatoid Arthritis Fingers	Other	3	3	10	0.5	Every day	
2 Osteoarthritis of the Wrist	Other	1	7	100	0.5	3 times a week	

Program / Indication	Type of indication	Frequency in MHz	Min.	Duty Cycle As a %	Watt per cm ²	Treatment Frequency	Graphics
3 Cervical Osteoarthritis	Other	1	7	100	0.5	3 times a week	
4 Bursitis (with chronic calcification)	Chronic	1	7.5	100	1.5	3 times a week	
5 Hypertrophic Scar	Other	3	15	100	2	Every day	
6 Post-Surgical Scar Tissue (new)	Other	3	10	20	0.5	Every day	
7 Frozen Shoulder	Other	1	7	100	2	3 times a week	
8 Dupuytren's Contracture	Other	1	6	100	1.5	3 times a week	
9 Coxarthrosis	Other	1	7	100	1.5	3 times a week	
10 Decubitus Ulcers	Other	3	1	20	0.5	Every day	
11 Knee Distortion (acute)	Acute	1	5	10	1	Every day	
12 Interphalangeal Joints Distortion (acu.)	Acute	3	3	10	1	Every day	
13 Interphalangeal Joints Distorsion (chr.)	Chronic	3	7	100	1	Every day	
14 Ankle Joint Distorsion (acute)	Acute	3	3	10	1	Every day	
15 Ankle Joint Distorsion (chronic)	Chronic	3	7	100	1	3 times a week	
16 Epicondylitis Type 1 (subacute)	Subacute	3	5	30	0.5	Every day	

Program / Indication	Type of indication	Frequency in MHz	Min.	Duty Cycle As a %	Watt per cm ²	Treatment Frequency	Graphics
17 Epicondylitis Type 1 (chronic)	Chronic	3	7	100	1	3 times a week	
18 Epicondylitis Type 2 (subacute)	Subacute	3	5	30	0.5	Every day	
19 Epicondylitis Type 2 (chronic)	Chronic	3	7	100	1	3 times a week	
20 Epicondylitis Type 3 (subacute)	Subacute	3	5	30	0.5	Every day	
21 Epicondylitis Type 3 (chronic)	Chronic	3	7	100	1	3 times a week	
22 Epicondylitis Type 4 (subacute)	Subacute	3	5	30	0.5	Every day	
23 Epicondylitis Type 4 (chronic)	Chronic	3	7	100	1	3 times a week	
24 Plantar Fasciitis	Other	1	6	100	2	3 times a week	
25 Periarthritis Scapulohumeralis	Other	1	15	100	2	3 times a week	
26 Gonarthrosis	Other	1	7	100	1	3 times a week	
27 Chronic Haematoma	Chronic	3	7	100	1.5	3 times a week	
28 Lumbar Disc Herniation	Other	1	5	20	1.5	Every day	



Program / Indication	Type of indication	Frequency in MHz	Min.	Duty Cycle As a %	Watt per cm ²	Treatment Frequency	Graphics
29 Lumbago (acute)	Acute	1	5	20	1	Every day	
30 Lumbago (chronic)	Chronic	1	7	100	1.5	3 times a week	
31 Spondylarthritis (general)	Other	1	7	20	1.5	3 times a week	
32 Spondylarthritis (sacroiliac joints)	Other	1	7	20	1.5	3 times a week	
33 Thromboangiitis Obliterans (lo. ext.)	Other	1	7	100	0.3	Every day	
34 Thromboangiitis Obliterans (up. ext.)	Other	1	7	100	0.3	Every day	
35 Raynaud's Disease (lower extremities)	Other	1	7	100	0.3	Every day	
36 Raynaud's Disease (upper extremities)	Other	1	7	100	0.3	Every day	
37 Sudeck's Dystrophy (lower ext.)	Other	1	7	100	0.3	Every day	
38 Sudeck's Dystrophy (upper ext.)	Other	1	7	100	0.3	Every day	
39 Myalgia (e.g. M. vastus lateralis)	Other	1	7	20	0.5	Every day	
40 Low Back Pain (discs)	Other	1	5	100	1.5	Every day	

Program / Indication	Type of indication	Frequency in MHz	Min.	Duty Cycle As a %	Watt per cm ²	Treatment Frequency	Graphics
41 Phantom Pain	Other	1	5	100	1	Every day	
42 Search For Painful Points	Other	1	10	100	1		
43 Rheumatoid Arthritis (finger joints)	Chronic	1	7	100	0.5	3 times a week	
44 Stress Fracture	Other	1	10	100	1		
45 Subluxation (acute)	Acute	1	5	10	1	Every day	
46 Subluxation (chronic)	Chronic	1	7	100	1	3 times a week	
47 Achilles Tendinitis (subacute)	Subacute	3	5	30	0.5	Every day	
48 Achilles Tendinitis (chronic)	Chronic	3	7	100	0.5	3 times a week	
49 Adductor Tendinitis (subacute)	Subacute	3	5	30	0.5	Every day	
50 Adductor Tendinitis (chronic)	Chronic	3	7	100	0.5	3 times a week	
51 Tendinitis M. Infraspinus (subacute)	Subacute	3	5	30	0.5	Every day	
52 Tendinitis M. Infraspinus (chronic)	Chronic	3	7	100	0.5	3 times a week	

Program / Indication	Type of indication	Frequency in MHz	Min.	Duty Cycle As a %	Watt per cm ²	Treatment Frequency	Graphics
53 Patellar Tendinitis (subacute)	Subacute	3	5	30	0.5	Every day	
54 Patellar Tendinitis (chronic)	Chronic	3	7	100	0.5	3 times a week	
55 Tendinitis M. Subscapularis (subacute)	Subacute	3	5	30	0.5	Every day	
56 Tendinitis M. Subscapularis (chronic)	Chronic	3	7	100	0.5	3 times a week	
57 Supraspinatus Tendinitis (subacute)	Subacute	3	5	30	0.5	Every day	
58 Supraspinatus Tendinitis (chronisch)	Chronic	3	7	100	0.5	3 times a week	
59 Trigger Finger	Chronic	3	6	100	2	3 times a week	
60 Leg Ulcer	Chronic	3	10	50	0.5	Every day	








Programs Sorted According to the Type of Indication (Program Group)




Acute Indications

Program / Indication	Frequency in MHz	Min.	Duty Cycle as a %	W/ cm ²	Treatment Frequency	Comments	Graphics
11 Knee Distortion (acute)	1	5	10	1	Every day	Gentle; Athermic	
12 Interphalangeal Joints Distortion (acu.)	3	3	10	1	Every day	Gentle; Athermic	







Program / Indication	Frequency in MHz	Min.	Duty Cycle as a %	W/cm ²	Treatment Frequency	Comments	Graphics
14 Ankle Joint Distorsion (acute)	3	3	10	1	Every day	Gentle; Athermic; Option: Underwater treatment	
29 Lumbago (acute)	1	5	20	1	Every day	Gentle; Athermic effect	
45 Subluxation (acute)	1	5	10	1	Every day	Gentle; Athermic	








Subacute Indications

Program / Indication	Frequency in MHz	Min.	Duty Cycle as a %	W/cm ²	Treatment Frequency	Comments	Graphics
16 Epicondylitis Type 1 (subacute)	3	5	30	0.5	Every day	Gentle; Athermic	
18 Epicondylitis Type 2 (subacute)	3	5	30	0.5	Every day	Gentle; Athermic	
20 Epicondylitis Type 3 (subacute)	3	5	30	0.5	Every day	Relatively Gentle; Slight thermal effect	
22 Epicondylitis Type 4 (subacute)	3	5	30	0.5	Every day	Relatively Gentle; Slight thermal effect	
47 Achilles Tendinitis (subacute)	3	5	30	0.5	Every day	Relatively Gentle; Slight thermal effect	
49 Adductor Tendinitis (subacute)	3	5	30	0.5	Every day	Relatively Gentle; Slight thermal effect	
51 Tendinitis M. Infraspinatus (subacute)	3	5	30	0.5	Every day	Relatively Gentle; Slight thermal effect	










Program / Indication	Frequency in MHz	Min.	Duty Cycle as a %	W/ cm ²	Treatment Frequency	Comments	Graphics
53 Patellar Tendinitis (subacute)	3	5	30	0.5	Every day	Relatively Gentle; Slight thermal effect	
55 Tendinitis M. Subscapularis (subacute)	3	5	30	0.5	Every day	Relatively Gentle; Slight thermal effect	
57 Supraspinatus Tendinitis (subacute)	3	5	30	0.5	Every day	Relatively Gentle; Slight thermal effect	












Chronic Indications


Program / Indication	Frequency in MHz	Min.	Duty Cycle as a %	W/ cm ²	Treatment Frequency	Comments	Graphics
4 Bursitis (with chronic calcification)	1	7.5	100	1.5	3 times a week	Intensive; Thermal effect	
13 Interphalangeal Joints Distorsion (chr.)	3	7	100	1	Every day	Intensive; Thermal effect	
15 Ankle Joint Distorsion (chronic)	3	7	100	1	3 times a week	Intensive; Thermal effect	
17 Epicondylitis Type 1 (chronic)	3	7	100	1	3 times a week	Intensive; Thermal effect	
19 Epicondylitis Type 2 (chronic)	3	7	100	1	3 times a week	Intensive; Thermal effect	
21 Epicondylitis Type 3 (chronic)	3	7	100	1	3 times a week	Intensive; Thermal effect	
23 Epicondylitis Type 4 (chronic)	3	7	100	1	3 times a week	Intensive; Thermal effect	
27 Chronic Haematoma	3	7	100	1.5	3 times a week	Intensive; Thermal effect	

Program / Indication	Frequency in MHz	Min.	Duty Cycle as a %	W/cm ²	Treatment Frequency	Comments	Graphics
30 Lumbago (chronic)	1	7	100	1.5	3 times a week	Intensive; Thermal effect	
43 Rheumatoid Arthritis (finger joints)	1	7	100	0.5	3 times a week	Intensive; Thermal effect	
46 Subluxation (chronic)	1	7	100	1	3 times a week	Intensive; Thermal effect	
48 Achilles Tendinitis (chronic)	3	7	100	0.5	3 times a week	Intensive; Thermal effect	
50 Adductor Tendinitis (chronic)	3	7	100	0.5	3 times a week	Intensive; Thermal effect	
52 Tendinitis M. Infraspinatus (chronic)	3	7	100	0.5	3 times a week	Intensive; Thermal effect	
54 Patellar Tendinitis (chronic)	3	7	100	0.5	3 times a week	Intensive; Thermal effect	
56 Tendinitis M. Subscapularis (chronic)	3	7	100	0.5	3 times a week	Intensive; Thermal effect	
58 Supraspinatus Tendinitis (chronisch)	3	7	100	0.5	3 times a week	Intensive; Thermal effect	
59 Trigger Finger	3	6	100	2	3 times a week	Relatively Gentle; Slight thermal effect	
60 Leg Ulcer	3	10	50	0.5	Every day	Gentle; athermic effect	

Other Indications

Program / Indication	Frequency in MHz	Min.	Duty Cycle as a %	W/ cm ²	Treatment Frequency	Comments	Graphics
1 Rheumatoid Arthritis Fingers	3	3	10	0.5	Every day	Gentle; Athermic; Option: Underwater treatment	
2 Osteoarthritis Of The Wrist	1	7	100	0.5	3 times a week	Intensive; Thermal effect	
3 Cervical Osteoarthritis	1	7	100	0.5	3 times a week	Intensive; Thermal effect	
5 Hypertrophic Scar	3	15	100	2	Every day	Intensive; Thermal effect	
6 Post-Surgical Scar Tissue (new)	3	10	20	0.5	Every day	Gentle; Athermic	
7 Frozen Shoulder	1	7	100	2	3 times a week	Intensive; Thermal effect	
8 Dupuytren's Contracture	1	6	100	1.5	3 times a week	Intensive; Thermal effect; Option : Underwater treatment	
9 Coxarthrosis	1	7	100	1.5	3 times a week	Intensive; Thermal effect	
10 Decubitus Ulcers	3	1	20	0.5	3 times a week		
24 Plantar Fasciitis	1	6	100	2	3 times a week	Intensive; Thermal effect	
25 Periarthritis Scapulo-humeralis	1	15	100	2	3 times a week	Intensive; Thermal effect	
26 Gonarthrosis	1	7	100	1	3 times a week	Intensive; Thermal effect	

Program / Indication	Frequency in MHz	Min.	Duty Cycle as a %	W/cm ²	Treatment Frequency	Comments	Graphics
28 Lumbar Disc Herniation	1	5	20	1.5	Every day	Relatively Gentle; Slight thermal effect	
31 Spondylarthritis (general)	1	7	20	1.5	3 times a week	Relatively Gentle; Slight thermal effect	
32 Spondylarthritis (sacroiliac joints)	1	7	20	1.5	3 times a week	Relatively Gentle; Slight thermal effect	
33 Thromboangiitis Obliterans (lo. ext.)	1	7	100	0.3	Every day	Intensive; Thermal effect	
34 Thromboangiitis Obliterans (up. ext.)	1	7	100	0.3	Every day	Intensive; Thermal effect	
35 Raynaud's Disease (lower extremities)	1	7	100	0.3	Every day	Intensive; Thermal effect	
36 Raynaud's Disease (upper extremities)	1	7	100	0.3	Every day	Intensive; Thermal effect	
37 Sudeck's Dystrophy (lower ext.)	1	7	100	0.3	Every day	Intensive; Thermal effect	
38 Sudeck's Dystrophy (upper ext.)	1	7	100	0.3	Every day	Intensive; Thermal effect	
39 Myalgia (e.g. M. vastus lateralis)	1	7	20	0.5	Every day	Relatively Gentle; Slight thermal effect	
40 Low Back Pain (discs)	1	5	100	1.5	Every day	Intensive; Thermal effect	
41 Phantom Pain	1	5	100	1	Every day	Intensive; Thermal effect	

Program / Indication	Frequency in MHz	Min.	Duty Cycle as a %	W/cm ²	Treatment Frequency	Comments	Graphics
42 Search For Painful Points	1	10	100	1		Intensive; Thermal effect	
44 Stress Fracture	1	10	100	1		Intensive; Thermal effect	

Ultrasonophoresis

- » In cause of better coupling, gels are more convenient for sonophoresis than ointments.
- » Before use, the skin can be heated to increase the absorption.
- » Dosage 0.5 – 1 W/cm²
- » The pulsed ultrasound seems to have better results than continuous ultrasound.

Special indications

Program / indication	frequency	min.	duty cycle	W/cm ²
61 Ultrasonophoresis	1	5	30	0.5 – 1.0

4. Device Description

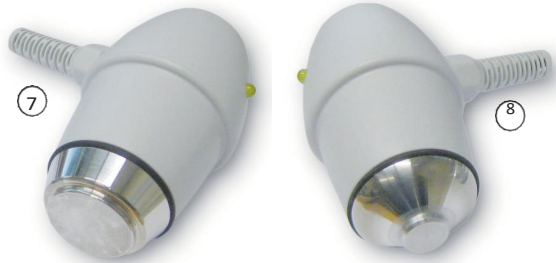
1. Display
2. Pressure rotating button



3. Ultrasound Connection, Channel 2
4. Ultrasound Connection, Channel 1
5. ON/OFF Switch
6. Mains Power Connecting Cable



7. Ultrasound Head SVDF 4 (large) 4 cm² (Standard Accessory)
8. Ultrasound Head SVDF 1 (small) 1 cm² (Optional Accessory)



9. Ultrasound gel
10. Transport Case (Optional accessory)



Set-Up and Starting






The following describes the setting up and the starting of the SONIC vital XTcoloR.

1. The device should be placed on a smooth, even surface.
2. Please ensure that the SONIC vital XTcoloR is not placed immediately adjacent to other devices and neither should it be stacked on other devices. This is to avoid reciprocal interference. If this is not possible, the function of the respective devices must be kept under observation to ensure that proper operation is not compromised.
3. **Voltage supply connection**
The connection for the mains power cable is located on the reverse side of the device. It must be checked that the mains voltage supply values are in compliance with the values stated on the rating plate. Once this has been checked, the mains cable is to be connected to the device and plugged into the mains socket.
4. **Connecting the ultrasound heads**
Connect the required ultrasound head(s) to any of the connectors on the reverse side of the device. When removing the ultrasound head from its socket never pull on the cable: always grasp the plug casing! Otherwise, the ultrasound head could be damaged or ruined.
5. The device is switched on with the ON/OFF switch which is located on the reverse side of the device.
6. The start video screen will appear after a few seconds.
7. Once the main menu appears in the display, the device is ready to operate.

Main Menu



The following menu points can be selected in the main menu:

-  Program Listing
All programs of the SONIC VITAL XTcoloR are available for selection.
-  User Programs
Your freely definable user program.
-  Favourites
Listing of favourite programs as specified by you.
-  Program Group
Programs ordered according to the type of indication: acute, subacute, chronic or other.
-  Settings
Edit user programs, delete all favourites and system settings.

Using the rotating button, select the required menu point. The menu point selected will be displayed down in the foreground. Selection is confirmed by depressing the rotating button.

Program Listing

Here are displayed all programs available in the device for all indications.

Use the rotating button to select the required program (Indication) and confirm by depressing the rotating button. You now arrive in the treatment menu.

User Programs

Here you can select from the ten freely definable user programs. These can be executed under the menu point Settings / User Programs.

Using the rotating button, select the required user program. Selection is confirmed by depressing the rotating button and you arrive in the treatment menu.

Favourites

Here you have quick access to your favourite programs (Indication). You define favourites by flagging them in the treatment menu. The complete favourite listing can be deleted under Settings / Delete Favourites. After confirming the selected indication you arrive back in the treatment menu.

Program Listing	11:05
1 Rheumatoid Arthritis Fingers	
2 Osteoarthritis Of The Wrist	
3 Cervical Osteoarthritis	
4 Bursitis (with chronic calcification)	
5 Hypertrophic Scar	
6 Post-Surgical Scar Tissue (new)	
7 Frozen Shoulder	
8 Dupuytren's Contracture	

programmes user	14:23
Programme 1 - 3 MHz, 30% DC, 08:00	
Programme 2 - 1 MHz, 100% DC, 12:00	
Programme 3 - 1 MHz, 100% DC, 10:00	
Programme 4 - 3 MHz, 100% DC, 03:30	
Programme 5 - 1 MHz, 100% DC, 10:00	
Programme 6 - 1 MHz, 10% DC, 15:00	
Programme 7 - 1 MHz, 100% DC, 10:00	
Programme 8 - 1 MHz, 100% DC, 10:00	

Favourites	11:53
2 Osteoarthritis of the wrist	
8 Dupuytren's contracture	
11 Knee distortion (acute)	
15 Ankle joint distorsion (chronic)	
16 Epicondylitis type 1 (subacute)	
17 Epicondylitis type 1 (chronic)	
19 Epicondylitis type 2 (chronic)	
21 Epicondylitis type 3 (chronic)	

Program Groups

In this menu you can select the required indication type (Acute, Subacute, Chronic or Other Indication). Once you have selected and confirmed the type of indication, a listing with the respective programs will be displayed. After selecting the program, you will get back to the treatment menu.



Caution

Before starting ultrasound treatment, ultrasound gel must first be applied to the treatment area. Move the ultrasound head during the treatment continually over the skin to avoid exposure to excessive intensities. These can cause burning on certain parts of the skin.

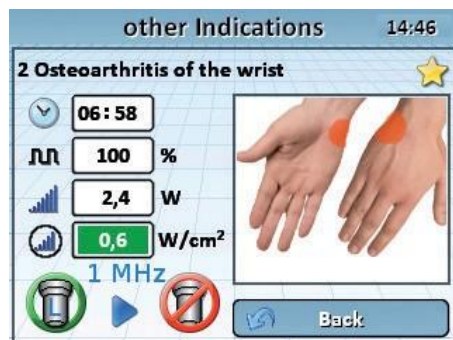


Treatment with SONIC vital XTcolor

Display of the selected therapy

The example here is Programm 2 Osteoarthritis of the wrist.

The following parameters are displayed in the treatment menu of the SONIC vital XTcolor:






Identification for the favourite




★ Program is filed as a favourite (in the example: flagged)

☆ Program is not flagged as a favourite





🕒 Display of the remaining therapy time for the selected therapy in minutes : seconds

-  Display of the duty cycle as a percentage
 -  Power output in Watts, related to 100 % duty cycle
 -  Display of the set output intensity per surface (power density) in W/cm^2 (Watts per square centimetre), related to 100 % duty cycle
 - 1 MHz** or **3 MHz** Display of the ultrasound frequency
-

Display of the connected ultrasound heads

-  No head is connected
 -  Connected, selected ultrasound head with large size surface
 -  Connected, non-selected ultrasound head with small size surface
-


Treatment status

-  No treatment is running
-  Treatment break
-  Contact control (the ultrasound head does not have adequate contact with the skin, no coupling)
-  Treatment running

Ultrasound Head

When the coupling is proceeding correctly, the LED in the ultrasound head will illuminate permanently during treatment. If coupling fails, the LED will begin to flash and the intensity reduced to a minimum (0.2 W/cm^2). Do not disconnect nor change the ultrasound head during a running treatment.

Channel Selection

When two ultrasound heads are connected to the SONIC VITAL XTcolor you can use the rotating button to select the required channel (ultrasound head). Briefly depressing the rotating button will confirm the selection and this selected output will be shown in the display with a green ring  (example for selected ultrasound head with large size surface).

If only one ultrasound head is connected, this will be selected automatically.

Starting Treatment

To start treatment, use the rotating button to select the input field for the output intensity per surface (power density)  and confirm by depressing the button. The input field will now appear in green and the required intensity can be set.

Intensity Selection

When the program has started (the input field appears in green), the required output intensity per surface can be set with the rotating button in steps of 0.1 W/cm^2 . Once the treatment time has elapsed, the intensity is reset to „0“. The running treatment can be terminated at any time by depressing the rotating button.

This symbol  shows the ultrasound power.

This symbol  shows the ultrasound power effective on a surface.

While the intensity per surface is being set with the rotating button, the display for the ultrasound power (W) also changes.

Where inadequate skin contact is involved, the LED in the ultrasound head and also in the illumination of the rotating button begins to flash and the treatment time counter is halted.

Caution

- » Before starting the ultrasound treatment, apply sufficient ultrasound gel to the surface to be treated.
- » The ultrasound heads must be continually moved around so as to avoid exposure to excessive intensity on the skin because this can result in burning.

Settings



Creating User Programs

Use the rotating button to select the program to be programmed. The value to be changed are flashing. Set the required value with the help of the rotating button and save the change by depressing the rotating button.

With regard to frequency selection (1 MHz or 3 MHz) it is sufficient to simply confirm either the field 1 MHz or 3 MHz by depressing the rotating button.



Deleting Favourites

Select this menu point if you wish to delete the complete favourite listing. After a prompt with confirmation that you really want to delete all favourites, the favourites listing will contain no further indications. To create new favourites, select one of the menu points Program Listing, User Programs or Program Group, select a program and flag this in the treatment menu as a favourite.

(★ - Flagged as favourite)

In this way individual programs can also be deleted from the favourite listing.



System Settings



The system setting menu allows selection of menu points date, time and language or possible software updates.

Date / Time

Use the rotating button to select the field to be changed. Depress the button to enter the selected value. The field to be changed flashes and you can now change to the desired value by turning the rotating button. Renewed depressing of the rotating button will finalise the change. Depress on "OK" to confirm the date and time values. Depress on "Cancel" to return to the previous menu without having effected a change.



Language

To select another language, use the rotating button to move to the language required and confirm by depressing the rotating button.

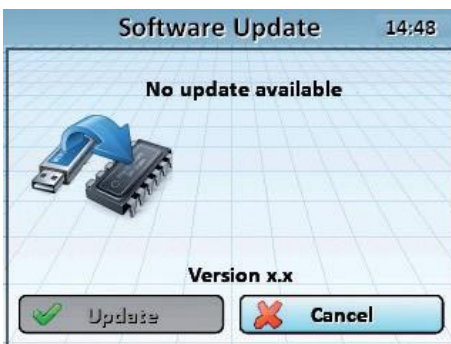


Software Update

Software Updates for the SONIC VITAL XTcolor may only be processed by authorised technicians or by the manufacturer.

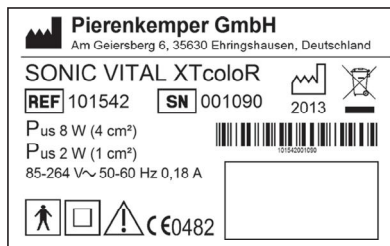
Standby

If the device is not operated for approximately 10 minutes, it will change to standby mode. In this case both the illumination of the display and the ventilator will be switched off. The luminosity of the rotating button continually changes to signal that the device is still switched on. As soon as the device is again operated it will revert to operating mode.



Technical Informations

Rating Plate



Symbols



Attention: Read accompanying documents, especially user manual!



Type BF applied part



Manufacturer



Date of manufacture



Catalogue number



Serial number



Batch code



Environment

Do not dispose of the appliance with the normal household waste at the end of its life, but hand it in at an official collection point for recycling. By doing this you will help to protect the environment.

CE0482 By labelling with CE mark, the manufacturer asserts that the product fulfills all relevant requirements of the respective EC Directives. A conformation assessment process has been successfully completed. The identification number in respect of the conformation assessment process is given in accordance with the CE labelling of the relevant notified body.



Class II equipment

Technical Data

Protection Class	II
Application Parts	Type BF 2 pieces
Operations Type	Continuous operation
Dimensions	43 cm x 24 cm x 10 cm
Weight	1.7 kg (only the device)
Voltage Supply	100 - 240 VAC
Power Take-Up	0.18 A
Duty Cycle (Tact Ratio)	10 - 50 % in 5 Steps (Step Width 10 %), 100 %
Maximum Power	2 W/cm ² (duty cycle = 100 % = continuous operations) and 3 W/cm ² in duty cycle operations
Pulse Frequency	100 Hz.
Number of Programs	60 Fixed and 10 User Programs
Treatment Duration	0 - 59 Min.

Ultrasound Head	SVDF 1 (small size)
Acoustic Working Frequency	1 and 3 MHz
Power Density	2 W/cm ² and 3 W/cm ² in duty cycle operations
ERA	1 cm ²
BNR	< 4.0
Bundle Type	Collimating

Ultrasound Head	SVDF 4 (large size)
Acoustic Working Frequency	1 and 3 MHz
Power Density	2 W/cm ² and 3 W/cm ² in duty cycle operations
ERA	4 cm ²
BNR	< 4.0
Bundle Type	Collimating

Classification

The SONIC vital XTcoloR has been classified as a Class IIa device in compliance with the classification criteria of the Medical Device Directive 93/42/EU, Appendix IX, Rule 9.

Maintenance and Safety Technical Controls

The SONIC VITAL XTcolor may only be serviced by authorised technicians or by the manufacturer.

All repairs may only be carried out by qualified, professional technicians. Maintenance work must be carried out with suitable measuring equipment with validated calibration. The responsibility for service work carried out rests with the personnel involved with this activity. Unauthorised servicing endangers the guarantee and the safe function of the device.

The SONIC VITAL XTcolor including any connected accessories must be tested at least once annually as part of the safety technical controls in accordance with § 11 MPBetreibV, This is to be carried out only by authorised persons.

Authorised persons are those persons who, by virtue of their training, knowledge and experience gained from their practical activities are qualified to carry out such controls in a proper manner and who have been trained in respect of the function of the device and are not subject to instructions relating to this control activity.

The safety technical controls comprise:

Visual Inspection

- » Completeness of the documentation.
 - Instruction manual
 - Medicine product book
- » Check completeness of the delivery content (please see „Delivery Content“).
- » That the labelling is correct and complete:
 - Inscriptions
 - Information signs
 - Labelling on the front panel
- » Mechanical damage to the device

Testing Functional Capability

- » Operating field: Rotating button and display
- » Functional testing commensurate with the instruction manual

The device is to be checked for mechanical damage and proper condition. The cables are to be inspected for mechanical faults or damage and also for correct insulation.

Electrical Safety Testing in accordance with EN 62/353

- » Substitute for device discharge current.
- » Substitute for patient discharge current.

With regard to recurring safety technical controls, the measured values must not exceed 1.5 times the values first measured or 0.9 times the limit values in accordance with EN 62/353.

Measuring the output value.

Subsequently, the results together with date and name of the person or company who has carried out the testing are to be documented in the medicine product book or to be extended. If the device is not functionally or operationally in order, it is to be repaired or the operator of the device is to be informed with regard to the danger emanating from the device.

Attention

If failures or defects occur during testing and which could cause possible danger to patients, employees or third persons, the device must no longer be operated.

Regular Ultrasound Head Checks

The ultrasound head must be checked at least once a month with regard to function. During the check and in particular, the ultrasound head must be examined for possible damage, for example cracks, otherwise liquids could penetrate the ultrasound head. In addition, the connecting cable insulation should be checked for damage. All contacts for the connecting plug must be intact and present.

The SONIC vital XTcoloR must not be operated if the ultrasound head, the connecting cable or the connecting plug are defective.

Cleaning and Checking the Ultrasound Head

The SONIC vital XTcoloR must be cleaned at regular intervals. For this purpose use a soft, fluff-free cloth with, if necessary, a mild cleaning agent or Isopropanol. Do not use cleaning agents containing grinding additives. When cleaning, ensure that no fluids penetrate the interior of the device. Combustible cleaning agents must have completely evaporated before the device is re-started. When cleaning, please disconnect the mains electricity plug. The ultrasound heads may only be cleaned with a slightly moistened cloth.

Warranty

Legal right of warranty is applied according to the German Civil Code.

Guarantee

The device carries a warranty of 1 year, valid from the date of handover.

The warranty does not apply in the following cases:

- » for wear and tear parts and consumables
- » damage due to improper handling
- » defects the customer is aware of on the date of purchase
- » damage caused by the customer

Disposal

The manufacturer undertakes to accept the SONIC VITAL XTcoloR for disposal in accordance with the regulations.

Delivery Content

The SONIC VITAL XTcolor delivery comprises the following:

Quantity	REF	Description
1	101542	SONIC VITAL XTcolor
1	450810-0043	Mains Power Connecting Cable
1	106359	Ultrasound Head 4 cm ² (large size) SVDF 4
(1)	106358	Optional: Ultrasound Head 1 cm ² (small size) SVDF 1
1	101719	Instruction manual
1	104749	Ultrasound Gel (250 ml)

Accessories

Only the following accessories are permissible for use with the SONIC VITAL XTcolor:


REF	Description	Type
450810-0043	Mains Power Connecting Cable	
106358	Ultrasound Head 1 cm ² (small size)	SVDF 1
106359	Ultrasound Head 4 cm ² (large size)	SVDF 4
104749	Ultrasound Gel	250 ml
104752	Ultrasound Gel	1 l
104753	Ultrasound Gel	5 l
450980-0166	Transport Case	

Manufacturer's declaration for the medical product Sonic VITAL XTColor

Guidelines and manufacturer's declaration – electromagnetic emission		
The product device is designated for operation in an environment as stated below. The customer or the operator of the product should ensure that it is operated in such an environment.		
Measurement of emitted interference	Compliance	Electromagnetic environment - guideline
RF emissions as per CISPR 11	Group 1	The product needs to emit electromagnetic energy in order to perform its intended function. Neighbouring electronic devices may be affected by this.
RF emissions as per CISPR 11	Class B	The product is suitable for use in all establishments, including residential ones and those connected directly to a power supply that also supplies buildings used for residential purposes.
Emission of over-tones as per IEC 61000-3-2	Class A	
Emissions of voltage fluctuations/ flicker as per IEC 61000-3-3	Complies	

Guidelines and manufacturer's declaration – electromagnetic interference resistance			
The product is designated for operation in the electromagnetic environment stated below. The customer or the operator of the product should ensure that it is operated in such an environment.			
Testing for interference resistance	IEC 60601 test level	Compliance level	Electromagnetic environment - guidelines
Electro static discharge (ESD) as per IEC 61000-4-2	± 6 kV contact discharge ± 8 kV air discharge	± 6 kV contact discharge ± 8 kV air discharge	Floors should be made from wood or concrete, or covered with ceramic tiles. If the floor is comprised of synthetic materials, the relative humidity must be at least 30 %.
Rapid transient interference / bursts as per IEC 61000-4-4	± 2 kV for mains supply ± 1 kV for input and output supply	± 2 kV for mains supply ± 1 kV for input and output supply	The quality of supply voltage should correspond to that of a typical commercial or hospital environment.
Surges as per IEC 61000-4-5	± 1 kV Push-pull voltage ± 2 kV Push-push voltage	± 1 kV Push-pull voltage ± 2 kV Push-push voltage	The quality of supply voltage should correspond to that of a typical commercial or hospital environment.
Drops in voltage, short-term disruption and fluctuations in supply voltage as per IEC 61000-4-11	< 5 % U_T (> 95 % drop in U_T) for ½ period 40 % U_T (60 % drops in U_T) for 5 periods 70 % U_T (30 % drop in U_T) for 25 periods < 5 % U_T (> 95 % drop in U_T) for 5 s	0 % U_T for 10 ms 40 % U_T for 100 ms 70 % U_T for 500 ms 0 % U_T for 5 s	The quality of supply voltage should correspond to that of a typical commercial or hospital environment. If the operator of the product requires continued function even after the occurrence of a disruption in energy supply, it is recommended that the product is supplied from a power source free of disruption, or a battery
Magnetic field at supply frequency (50/60 Hz) as per IEC 61000-4-8	3 A/m	3 A/m	Magnetic fields at mains frequency should correspond to the typical values found in a commercial and hospital environment.
NOTE U_T is the mains a.c. voltage prior to application of the test level			

Guidelines and manufacturer's declaration - electromagnetic interferences resistance

The product is designated for operation in the electromagnetic environment stated below. The customer or the operator of the product should ensure that it is operated in such an environment.			
Testing of interference resistance	IEC 60601 test level	Compliance level	Electromagnetic environment - guidelines
Conducted RF interference as per IEC 61000-4-6	3 V _{eff} 150 kHz to 80 MHz	3 V _{eff}	Portable and mobile communication devices should not be used in a closer proximity to the product or its cable than the protective distance calculated according to the equation calculated for the transmission frequency. Recommended protective distance: $d = 1,2\sqrt{P}$ $d = 1,2\sqrt{P}$ for 800 MHz to 2,5 GHz $d = 2,3\sqrt{P}$ for 80 MHz to 800 MHz
Emitted RF interference as per IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	with P as nominal output of the transmitter in Watt as per the specifications of the transmitter manufacturer and d as recommended protective distance in metres [m] The field strength of stationary radio transmitters should be lower than the compliance level ^a , determined in the course of an inspection on site. ^b Disturbance is possible in the vicinity of devices bearing the following symbol. 
NOTE 1 At 80 MHz and 800 MHz the higher frequency range applies.			
NOTE 2 These guidelines may not be applicable in all cases. The spread of electro-magnetism is influenced by absorption and reflection from buildings, objects and people			
^a The field strength of stationary transmitters, such as base stations for mobile telephones and mobile land lines, amateur radio stations, AM- and FM radio and television stations cannot be previously determined, in theory. In order to specify the electro-magnetic environment with regard to the stationary transmitters a study of the location should be considered. If the field strength measured on the site on which the product is operated exceeds the compliance level detailed above, then the product should be monitored in order to provide evidence of its operation in accordance with regulations. If unusual characteristics are observed, then additional measures may prove necessary, such as a change in alignment or a different location of the Product .			
^b Above the frequency range of 150 kHz to 80 MHz the field strength should be less than 3 V/m.			

Recommended protective distances between portable and mobile RF telecommunications devices and the Product

The **product** is designated for operation in an electromagnetic environment in which RF interference is controlled. The customer or operator of the **product** can help to avoid electromagnetic interference by maintaining a minimum protective distance between portable and mobile RF telecommunication devices (transmitters) and the **product** – dependent upon the output power of the communication device, as stated below.

Nominal output of transmitter W	Protective distance dependent upon transmission frequency m		
	150 kHz to 80 MHz $d = 1,2\sqrt{P}$	80 MHz to 800 MHz $d = 1,2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2,3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters with a maximum nominal output not listed in the table above the recommended protective distance d can be calculated in metres (m) using the equation for the respective column, whereby P is the maximum nominal output in Watt (W) as per the specifications of the transmitter manufacturer.

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

NOTE 2 These guidelines may not be applicable in all cases. The spread of electro-magnetism is influenced by absorption and reflection from buildings, objects and people.



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