




Mixing Device - OPERATING INSTRUCTIONS



MANUFACTURED AND DISTRIBUTED BY	
 	<p>ATS DENTAL srl Via Vecchia Provinciale Lucchese, 49/F 51034 SERRAVALLE PISTOIESE – Italy Tel: +39 0573 518137</p>
	<p>Regulation UE2017/745 has been used as a basis in the design and manufacture of this medical product. A product with this mark meets the requirements of the relevant EC directives, i.e. the applicable standards in Europe.</p>
<p>EN 61010-1 - EN61010-2-81-EN61326-1 - EN61000-3-2 EN6100-3-3 - ISO 7488 :1991 EN ISO 13485</p>	<p>This equipment is manufactured according to current regulations and standard and according to the EN ISO 13485 quality control certification system.</p>

DIRECTION FOR USE

INTENDED USE

TAC UltraMix is a universal mixer for amalgam, glass ionomer cements and other pre-dosed dental materials in capsules and syringes.

The apparatus has been developed solely for use in dentistry. Liability cannot be accepted for damage resulting from misuse or failure to observe the Operating Instructions.

The user is responsible for testing the TAC UltraMix for its use and suitability for the intended purposes. The intended use also includes the observation of the notes and regulations in these Operating Instructions. The TAC UltraMix has been shipped from the manufacturer in a safe and technically sound condition.

The apparatus is built according to: Regulation 2017/745 UE and in compliance with the Directive Rule 89/336/CEE, 92/31/CEE and 98/68/CEE and the following harmonized standards have been applied: EN 61010-1 - EN61010-2-81-EN61326-1 - EN61000-3-2 – EN61000-3-3 - ISO 7488

SAFETY



CAUTION !

Please read these instructions carefully before you set up and start the device. As with all technical equipment, this unit will function properly and be safe to operate only if both the general safety regulations and the specific safety instructions laid out in these Operating Instructions are followed.

1. The unit must be operated in accordance with the following instructions. We accept no liability for any damage arising from use of the unit for any other purpose.
2. Prior to setting-up the device, ensure that the voltage stated on the rating plate is identical to the available main voltage. Use of the device at different voltages may lead to the destruction of the unit.
3. The unit must be operated with the cover intact and closed, otherwise, there is a risk of injury.
4. The cover must not be opened until the capsule holder has come to a complete stop.
5. Only the capsule to be mixed but no other objects may be present in the space below the cover prior to initiating the mixing cycle.
6. Placement or operation of the unit on non-level surfaces is not permissible.
7. For operation of the unit, connect the main plug to an adequate electrical socket with grounded lead. If an extension cable is used, ensure that the grounded lead is not interrupted.
8. In order to prevent electrical shock hazards do not insert any objects into the unit with the exception of replacement parts properly installed in accordance with the present instructions.
9. The device should be opened and repairs be carried out only by qualified personnel.
10. Only adequately labelled original ATS DENTAL replacement parts may be used in the repair and maintenance of this unit. Any damage resulting from the use of third-party replacement parts voids the liability of ATS DENTAL.
11. Do not expose the device to solvents, flammable liquids, and strong heat sources as these may damage the plastic housing.

DENTAL MATERIALS USED

The corresponding instructions for use of the material suppliers have to be observed.

ASSUMPTION OF IMPAIRED SAFETY

If it has to be assumed that safe operation is no longer possible, the power must be disconnected to avoid accidental operation. This may be the case, for example, if the apparatus is visibly damaged or no longer works correctly. A complete disconnection from the power supply is only ensured when the power cord is disconnected from the power source.

REMOVAL OF TRANSIT SCREWS



BEFORE USING REMOVE TRANSIT SCREW FROM UNDERSIDE OF UNIT. (Fig A)

For safety during transit the amalgamator has been fitted with a transit screw prior to shipping. It is essential to remove this screw prior to using the amalgamator.

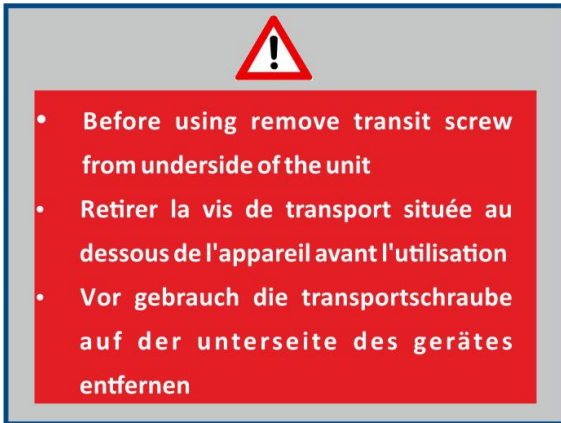
- a) Place the unit on its side on a soft surface
- b) Using the supplied 3mm allen key, turn the transit screw anti-clockwise until it is loosened. Remove screws.
- c) Place the amalgamator correct side up on a flat surface in a easily accessible location.

SET UP

Packaging part list: Electronic Control Console -Power Cord – Allen Key – DFU (Fig. D)

1. Connect the power supply output cord with the socket at the rear of the apparatus and subsequently with the mains socket.
2. Switch on the apparatus at the rear.

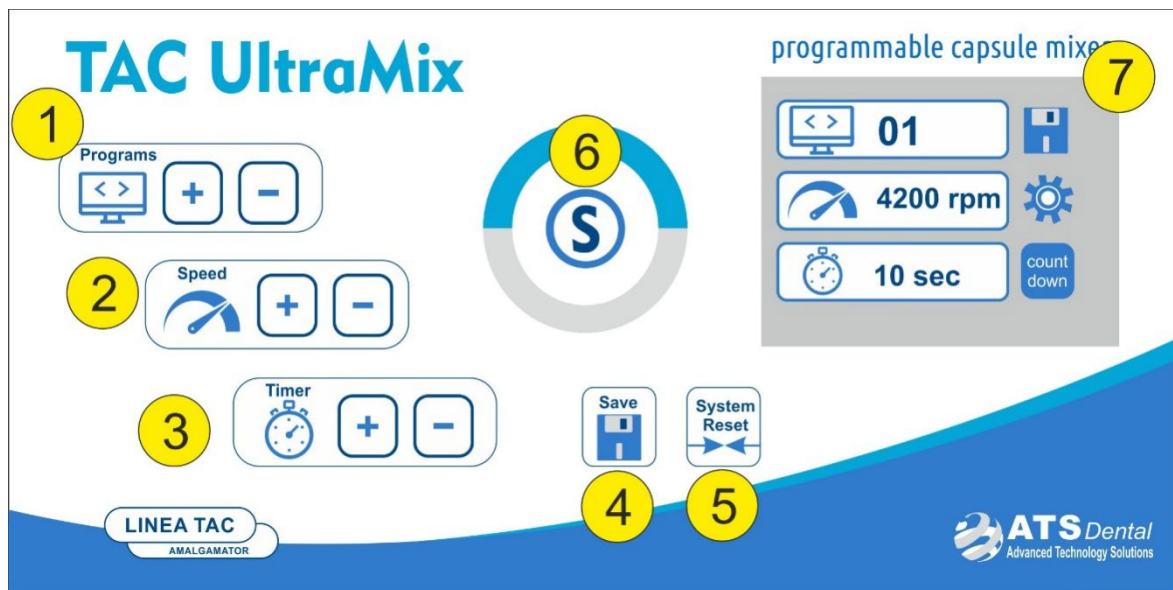
If the red screws have not been removed, the unit switch on, but it doesn't work. The display writes as the follow:



3. Raise the safety cover and place the mixing capsule in the mixing fork (Fig. C)

- Insert the capsule in the right cap of plastic fork (Fig. C-1)
- Open the fork moving the left part (max 8 mm) (Fig. C-2)
- Turn the capsule inside the plastic fork (Fig. C-3)
- Check the capsule is clamp correctly.

CONTROL PANEL FUNCTIONS



1. With "Programs" buttons, the operator can easily switch from 0 to 9 programs
2. Set Mixing Speed (RPM) from 3600 to 5600 rpm
3. Set Mixing Time (Sec.) from 1 to 99 Sec.
4. Save in programs 1-9 the set Speed and Time
5. Restore all the Programs to Default Parameters
6. Start Mixing
7. Graphic Display

USE

Working with program “0”

In this program, the default parameters are: Time = 0 and Speed= 0

1. Plan the wished time with the buttons Time “+” and “-”
2. Plan the wished speed with the buttons Speed “+” and “-”
3. Push the bottom “S” (Start). On display you will see the decreasing time. When the operation is finished, it will remain planed.

Working with programs 1-9.

The machine is supplied with 9 different planed times of mixing and speed.

Program	Speed (RPM)	Time(Sec.)	Material
1	4200	6	IQC Valiant / Dispersalloy / IQC Palladium/ Contour
2	4200	10	Axia Glass / Amalcap/ Axia Base/ Axia Silver Memory
3	4200	7	Duralloy / Ana2000 / Permite C
4	4200	8	Astralloy PD/45
5	5200	10	GC/Axia Glass/Voco
6	5200	8	3M Espe
7	2000	15
8	5600	6
9	5600	5

1. Choose the Program with button “Programs”.
2. Using the default Speed and Time. icon on display is GREY.
3. Press the button “S” to start the mixing
4. Changing the values with the buttons Speed “+” and “-” and the buttons Time “+” and “-” the icon became BLUE.
5. Press “Save” to store the new values in the current program. The icon on Display become GREY.
6. Press the button “S” to start the mixing.
7. If you do not press button “Save”, you can mix with the new parameters (Press button “S”), but at the end the icon become GREY with the old parameters stored in the programs
8. Press the button “System Reset” for at least 5 Sec. to restore default parameters.
9. During the mixing, you can see decreasing time.

If the safety cover is opened during the mixing process, the motor and count down stops automatically. The mixing process might be finished by closing the safety cover. When you turn off the main switch, the amalgamator remains set on the last operation executed. TAC UltraMix fits capsules between 30 and 36 mm of length and with 14/18 mm of diameter.

CLEANING



Switch off the apparatus by disconnecting the mains cord. Clean housing, keypad and safety cover with a soft cloth and customary aldehyde-free disinfecting solution. Do not clean with highly aggressive disinfecting solutions (e.g. solutions based on orange oil or with an ethanol content of more than 50%), solvents (e.g. acetone), or pointed instruments, which may damage or scratch the plastic. Make sure that no disinfectant, other liquid or foreign object enters the apparatus.



It is necessary for the user to report to the manufacturer and the competent authority of his state any serious accident that occurs in relation to the device.

WARRANTY PERIOD / WARRANTY CONDITIONS














ATS DENTAL., the Manufacturer, extends a 2 years warranty against defects in materials or workmanship to the original purchaser of this product. The Manufacturer agrees to correct any defects which develop within the warranty period, either by repair or replacement, at its option. This warranty is valid providing factory inspection indicates that any such defect developed during normal and proper use subject to the conditions below.

- Please attach your invoice as proof of purchase.
- Claims for damage in shipment should be filed promptly with the transportation company.
- All shipments claimed defective can only be returned to the Manufacturer with the written consent of the Manufacturer.
- All returned products must be accompanied by a full description of discrepancy or malfunction.
- Only ATS DENTAL srl authorized service personnel are allowed to carry out repairs to the unit.
- The Manufacturer shall be released from all obligations under this warranty if repairs or modifications are made by persons other than the Manufacturer’s own or authorized service personnel.
- Use only ATS DENTAL parts exclusively to replace defective components.
- The product warranty does not cover any damage resulting from the use of third-party replacements parts.

- The Manufacturer shall be released from all obligations under this warranty in the event of improper installation; damage due to casualty; or obvious misuse including but not limited to damage from liquids.
- The Manufacturer shall in no event be liable for any consequential damages arising from the misuse of the product. Only the above stated warranty shall be applicable, and all other warranties, expressed or implied, are hereby excluded.

All correspondence concerning the product should specify the model and serial number.

TECHNICAL DATA			
Manufacturer	ATS DENTAL – Pistoia – Italy	Nominal Power	60 VA
Model	TAC UltraMix	Class MD	I
Dimensions	300x220x170	Console	IP21
Materials	Plastic	7488 Classification	Type 2
Noise	< 65 dBA	Operating Mode	30" ON – 180" OFF
Supply Voltage	AC 100/240 V	Max Working Time	30'
Frequency	50/60 Hz	Power supply output	DC 24V
Conditions of use: Dental Practice			
Shipping and Storage conditions: Not critical			

SYMBOLS			
	2017/745 UE		Supply Voltage
	Manufacturer		Model - Code
	Intermittent Operations		This symbol reminds to consult the present Operating and Maintenance Instruction Manual.
	Production year		Double insulation
	Indicates a hazardous situation		Important Information
	This symbol on the product or on its packaging indicates that this product may not be treated as household waste. Instead it shall be handled over the applicable collection point for the recycling of electrical and electronic equipment. By ensuring this product is disposed correctly, you will help prevent potential negative consequences for the environment and human health, which could otherwise be caused by inappropriate waste handling of this product. For more detailed information about recycling of this product, please contact your local city office, your household waste disposal service or the shop where you purchased the product.		
	High Voltage Inside. This equipment operates from A.C mains. Only authorized personnel to open unit.		
	MEDICAL DEVICE		

LIMITATION OF LIABILITY

Except where prohibited by law, ATS DENTAL srl will not be liable for any loss or damage arising from this product, whether direct, indirect, special, incidental or consequential, regardless of the theory asserted, including warranty, contract, negligence or strict liability.

Information valid as of Sept 21

Fig.: A – C

FIG "A"

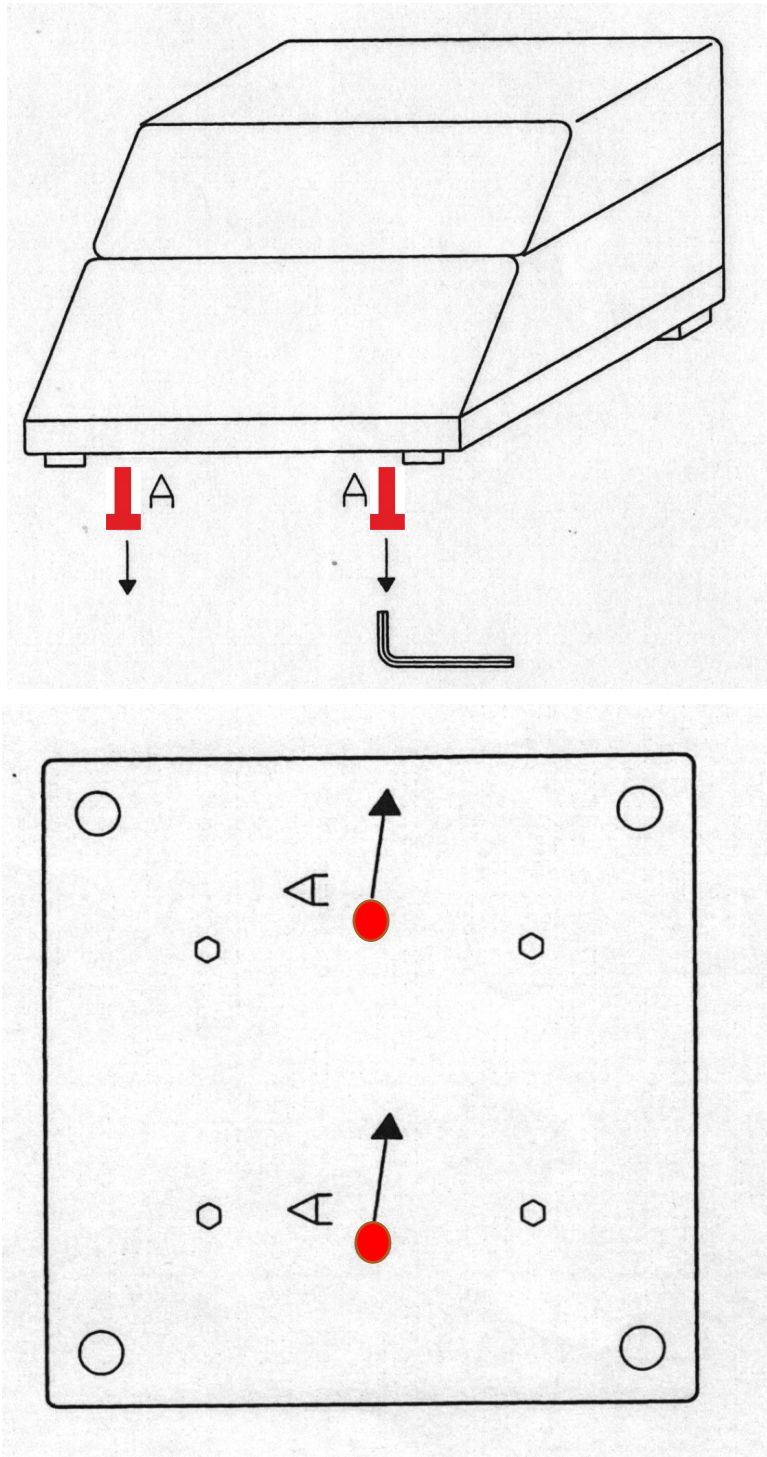


FIG "C"

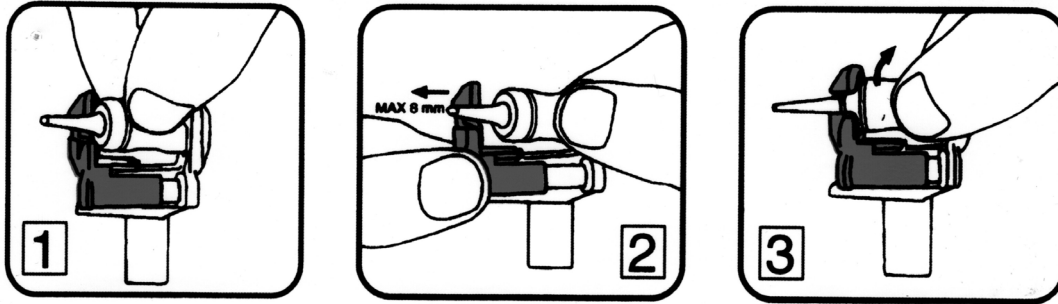
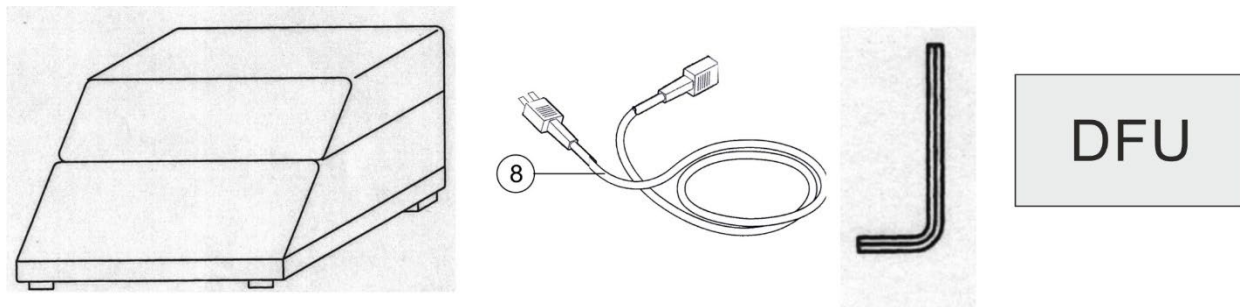


FIG "D"



ATS DENTAL SRL reserves the right to modify the present DFU without prior notice.



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