DECLARATON OF CONFORMITY „CE“

In accordance to the following directives

97 / 23 / EG for equipment under pressure
used modul: A

Type and model of products;

Autoclave Type : KL – 5 - 3
Autoclave Type : KL – 7 - 3
Autoclave Type : KL – 12 - 2

It is declared that the above mentioned products in conception and type of construction, also in the mode of design traded by us, meet the above directives.
This declaration is going to loose its validity in case of changes not agreed by us.

Used harmonised regulations:

DIN EN 10028 - 7

Used national regulations/technical specifications:

AD – Merkblatt A 2

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Bad Überkingen , 07.01.2003

Adolf Wolf .

Directing Manager

Table 8: Survey of the inspection, maintenance and cleaning work

	Inspection	Maintenance	Cleaning
Rubber gasket of the vessel lid	Visual inspection befor each sterilization process: **Ensure that the gasket is intact before starting!**	The rubber gasket is a wearing part. **It must be renewed in the event of damage or wear.**	Carefully remove grime with water.
Valves	Visual inspection befor each sterilization process: **Watch for grime!**	For safety reasons **the lid must be returned to the manufacturer** when the valve has become clogged.	**Do not try to clean yourself!**
Heater	Monthly visual inspection: **Watch for scaling!**	Eco-friendly descaling with vinegar at a moderate temperature.	_____
Autoclave	**The autoclave must be checked every 2-3 years by the manufacturer!** **Recalibrate the temperature and pressure indicator yearly.**	After sterilization autoclaves must be **stored in an open condition.**	Monthly cleaning of the inside depending upon the frequency of use. **Do not use a scouring agent!**
Sterilization-process	**Check effectiveness* in conformity with DIN 58946-8 every 6 month.**		

* Please contact us in the event of uncertainty. We will be happy to supply you with any information required.

Check of Temperature and pressure indicator:
The autoclave is to heat up to 1 bar and 2 bar. Than the following data have to appear:
Pressure: 1bar Temperature: 121°C
Pressure: 2bar Temperature: 134°C
If there are any deviations the autoclave has to be checked by the manufacturer or, pressure -, respectively temperature-indicator has to be replaced.

4 Optional extras: Media sensor

The media sensor can only be used in conjunction with the MCS control (see fig.2 page 23)

WARNING: Do not open the exhaust steam valve after the sterilization of liquids (media) due to the danger of delayed boiling. Allow the autoclave to cool down naturally.

Only open the autoclave, when
⇒ the chamber temperature has cooled down to at least 70°C
⇒ the autoclave has no remaining pressure (0 bar)

The media sensor is used to establish the actual temperature of a liquid (medium) that is to be sterilized during the heating-up and cooling-down stages. The sensor is directly immersed in the medium (reference container).

1. Activation of the media sensor (see fig. 2 page 23)

a) To activate the media sensor press the "E" key before the autoclave is started with the "F" key. The LED indicator (6) lights up to confirm that the media sensor has been switched on.

b) Press the "E" key to call the media temperature during the sterilization process.

c) **NOTE:** When a media sensor is being used the sterilization time only commences when the medium has reached the setpoint temperature.
An additional sterilization time as described under chapter 2.6.2 therefore is not necessary.

1 Safety Instructions

„SANOclav" stands for state-of-the-art small-batch autoclaves (small sterilizers). All safety-technical aspects, in so far as they are within the manufacturer's sphere of control, have been taken into account.

The series KL and TKL autoclaves are insufficiently equipped for sterilisation of medical products within the meaning of the European Guideline 93/42/CCE and are therefore not suitable.

For causes outside the manufacturer's sphere of control, no responsibility is accepted for consequential damage, injury to the sterilization product, device, appliance or the surrounding area.

The basic prerequisite for operation ensuring freedom of hazard to a great degree is that:

- the devices are only used by persons who can offer the guarantee for proper handling on the basis of their training or their knowledge and practical experience.
- These Operating Instructions, as well as any other appropriate additional documents, must be made available to the operating personnel at all times for their work. Operating personnel are obliged to observe these Operating Instructions and other documents.
- Unqualified personnel are not allowed to work at the autoclaves or be in their vicinity.
- The autoclaves most not be technically changed in any manner without previously consulting the manufacturer.

These safety instructions do not claim to be complete. In the event of queries and problems please consult our specialists who will be happy to help you and supply corresponding information.

2.7.1 Trouble shooting for the MCS control

Table 7: Reason for error message and possible cause

Display	Description	Cause
Err 1	Operation was aborted during the heating-up stage	for example: Power failure
Err 2	Operation was aborted during the sterilization period	for example: Power failure
Err 3	Operation was interrupted	Defective (broken) chamber sensor
Err 4	Operation was interrupted	Defective (broken) media sensor
Err 5	Operation was interrupted	The chamber or media temperature dropped by more than 2°C below the setpoint temperature during a sterilization period of more than 2 minutes
F---	Arises when the device is switched on or after Err 3 and Err 4	Broken chamber sensor
F___	Arises when the device is switched on or after Err 3 and Err 4	Short-circuited chamber sensor

Table 8: Action after an error message

Display	Action
Err 1	Repeat sterilization. Consult manufacturer if message reappears.
Err 2	Repeat sterilization. Consult manufacturer if message reappears.
Err 3	Autoclave must be repaired by the manufacturer
Err 4	Autoclave must be repaired by the manufacturer
Err 5	Check rubber gasket for proper seat in the lid and then repeat sterilization. Consult manufacturer if message reappears.
F---	Autoclave must be repaired by the manufacturer
F___	Autoclave must be repaired by the manufacturer

All error messages must be confirmed with the "F" key. This resets the autoclave to its initial state. The messages "Err 3", "Err 4" and "F---" cannot be followed by another operation. The messages "F---" or "F___" appear when the "F" key (device ON/OFF) is depressed.

WARNING: Transport and installation:

1. Ensure that the room is well illuminated (at least 300 Lug). Incorrectly read measured values can result in damage to the sterilization product or inadequate results.

2. To avoid damage due to radiated heat, autoclaves of the KL and TKL series must be spaced by at least 0.5 m from heat sensitive walls. The base must be heat-proof.

3. Unsuitable (sensitive to heat) wall panelling can be damaged in the event of uncontrolled emission of hot steam. We recommend the use of our condense collecting container (see Chapter 3 "Accessories").

4. There is a danger of autoclaves toppling over if they are placed on a sloping or soft base.

5. The risk of short circuits is greatly increased if moisture-sensitive devices (PC, meters, etc.) are set up in the same room as the autoclaves.

6. The vapours of aggressive media (e.g. acids, lees, various solvents, etc.) can corrode the autoclaves.

1. Fill the vessel with at least 1½ litre of water, but never more than ¾ of the specified maximum vessel volume. The autoclave must never run dry.

2. Charge and close the autoclave in the manner described in Chapters 2.6.1-1.

3. Open the exhaust steam valve right up to its stop point to ensure proper venting during the heating-up stage. The autoclave can now be switched on with its mains switch.

4. Setting the sterilization temperature ("C" key) and time ("D" key): Press the given setpoint key (see fig. 1) and adjust the required value with the edit keys. The actual temperature is displayed after the settings have been completed.

5. Start the sterilization process by pressing the "F" key. **WARNING:** Renewed depression of the "F" key terminates the sterilization process (e.g. in the event of an incorrect entry).

B: During operation

WARNING: Please observe the "Safety Instructions" and "Acceptable Risks" (Chapters 1. and 1.2), but particularly the section "During Operation".

6. The autoclave is adequately vented when a strong jet steamis emitted by the pressure control valve (approx. 4 minutes at 99-100°C thermometer display). Close the exhaust steam valve.

8. **In case of sterilization of adhesive fluids an Operating Test of the Safety Valve has do be made before and after the sterilization (see chapter 6.2)**

9. In case of sterilization of fluids (in open containers) we recommend the use of a media sensor (see chapter 4)

WARNING: During operation:

1. An autoclave without MCS control must be constantly supervised during the sterilization process. It may be necessary to readjust the steam pressure control valve to avoid a short-fall or transgression of the operating pressure.

2. Inadequate venting of the autoclave prior to sterilization will result in inadequate sterilization results. Please refer to the corresponding details in these Operating Instructions.

3. A short-fall of the operating temperature will result in inadequate sterilization, while an excessive operating temperature can damage the product being sterilized. Consequently, it must be ensured that autoclaves that do not feature an MCS control must never be operated unattended.

4. The autoclave lid and walls become very hot during operation. Contact with the autoclave in this condition can result in burns (except for the plastic handles).

5. To achieve the required sterilizing effect, the sterilization period for liquids must be extended by the additional time listed in table 6 page 19.
6.

2.7 Operation of small-batch autoclaves, type „TKL-MCS“

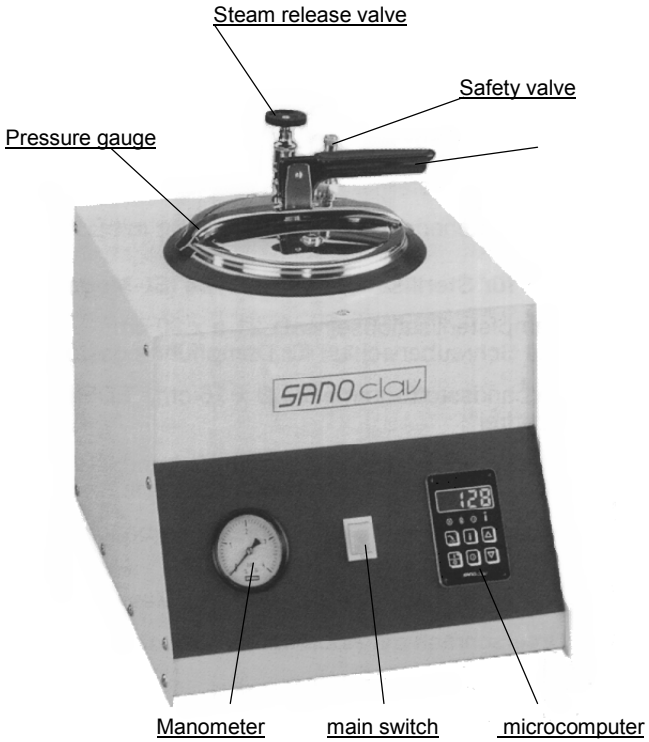

Fig. 1 TKL – Autoclave with MCS-controller

B: After sterilizing liquids:

1. **Let the autoclave cool down to at least 70°C chamber temperature.**

   Liquid sterilization products will boil over on account of **delayed boiling** and cause serious burns if the steam pressure is vented instead of allowing the autoclave to cool down slowly.

   Only open the autoclave, when

   ⇒ **the chamber temperature has cooled down to at least 70°C**
   ⇒ **the autoclave has no remaining pressure (0 bar).**

2. In case of sterilizing adhesive fluids an Operating Test of the Safety Valve is necessary before and after the sterilization.(see chapter 6.2)

   After a result of delayed boiling adhesive fluid can clog up the valves. In such an event the autoclave lid must be sent to the manufacturer so that the valves can be checked.
   Continued operation with clogged valves can result in the explosion of the pressure vessel.

   ⇒**Risk to Life !**

C: After sterilization

WARNING: Please observe the "Safety Instructions" and "Acceptable Risks" (Chapters 1. and 1.2), but particularly the section "After Sterilization".

1. Do not vent the steam when sterilization has been completed but rather allow the autoclave to cool down slowly to at least 70°C. Liquid sterilization products will boil over on account of delayed boiling if the steam pressure is vented. In unfortunate circumstances such effect can gravely scald attending operators.

2. Consequently, as a result of the delayed boiling effect, the autoclave must only be opened after
   ⇒ it has cooled down to below 70°C.
   ⇒ there is no remaining pressure in it (0 bar)

3. In case of sterilizing adhesive fluids an Operating Test of the Safety Valve is necessary before and after the sterilization. (see chapter 6.2)

After a result of delayed boiling adhesive fluid can clog up the valves. In such an event the autoclave lid must be sent to the manufacturer so that the valves can be checked.
Continued operation with clogged valves can result in the explosion of the pressure vessel.
⇒ **Risk to Life!**

WARNING: Electromagnetic compatibility:
0

1. To guarantee proper sterilization after a mains failure, the sterilization must be repeated for the set time when the power has returned.

2. Do not complete any changes (e.g. a different power supply cable) without previously consulting the manufacture as this can adversely influence the autoclave's immunity to malfunctions.

2 Details concerning use

2.1 Fields of application

The autoclaves of type „**KL + TKL**..“ are for:

Sterilization in high-pressure steam

Do not sterilize in those autoclaves:

⇒ **packed solids**
⇒ **liquids in closed containers**
⇒ **further the following dangerous liquids:**

- **explosive**
- **high inflammatory**
- **easy inflammatory**
- **inflammatory (if the maximum allowed temperature is above the flamepoint)**
- **very toxic**
- **toxic**
- **effective for burning**

C: After sterilization

WARNING: Please observe the „Safety Instructions“ and „Acceptable Risks“ (chapter 1 and 1.2), but particularly the section „After Sterilization“.

- Turn off the heater when the sterilization time has ended
- The steam pressure control valve can now be carefully opened and the pressure slowly vented until there is no remaining pressure in the chamber (manometer = 0 bar)
- Let the autoclave cool down to at least 80°C
- Before opening the lid check again if there is no pressure remaining in the chamber
- Now you can open the autoclave and take off the sterilization products.

2.6.2 Sterilization of liquids

A: Preparation for operation

WARNING: Please observe the "Safety Instructions" and "Acceptable Risks" (Chapters 1. and 1.2), but particularly the section "Preparations for Operation".

The same preparations are required as described in Section 2.6.1 A, except that the following additional and modified preparatory work is necessary:

1. Do place the container holding the liquid to be sterilized deep but not directly on the autoclave base.

CAUTION: **Do not use closed containers.** Closed containers may lead to a **retardation of ebullition (delayed boiling).**

2.2 Transport and installation

WARNING: Please observe "Safety Instructions" and "Acceptable Risks" (Chapters 1. and 1.2), but particularly the section "Transport and Installation".

The following ambient conditions must be fulfilled to ensure optimal autoclave operation:

- Ensure *good lighting conditions*.
- The base must be *level, firm and resistant to heat*.
- Ensure *effective ventilation*.
- TKL-MCS autoclaves must be connected to a *socket with earthed conductor* (see Table 3 "Technical Data").
- Maintain the following ambient parameters for TKL-MCS autoclaves:

Table 2: Ambient conditions

Ambient conditions	only indoors
Altitude for operation	up to maximum 2000 m mean sea level
Ambient temperature	from 5°C to 40°C
Voltage fluctuations	maximum ±10% of rated value
Pollution	maximum Pollution Severity Degree 2 acc. to IEC 664

2.6.1 Sterilization of solids

A: Preparations for operation

WARNING: Please observe the "Safety Instructions" and "Acceptable Risks" (Chapters 1. and 1.2), but particularly the section "Preparations for Operation".

1. The autoclave's lid must only be opened when the device is in a pressureless state.
   • If necessary, open the steam pressure valve. The closing ever can be raised to a vertical position as soon as no more steam is being emitted by the valve. This releases the lid as it is lowered into the vessel.
   • Turn the lid by 90° with its closing lever and then tilt towards the valve side. The lid can then be removed.

2. Fill the vessel with at least 1,5 litre of water, but never more than 3/4 of the specified maximum vessel volume.
   The autoclave must never run dry.
   The inserts are selected according to the products that are to be sterilized: Sieve tray, sieve basket and test tube rack (see Chapter 3 "Accessories").

3. The pressure vessel is closed by returning the lid in the same manner.
   • Turn the lid by 90° so that the **cross bracing is inserted precisely in the recessions in the edge of the vessel**.
   • Adjust the closing lever to its horizontal closing position. An accurately inserted lid must be uniformly seated on the vessel opening.

Do not complete any changes (e.g. a different power supply cable) without previously consulting the manufacture as this can adversely influence the autoclave's immunity to malfunctions.

Table 4a

Field of application	Requirements	
concerning	Emitted interference	Interference immunity
Living area*	EN 55011	EN 50082-1
Industrial area	EN 55011	EN 50082-2

** Living area: Office rooms, workshops and laboratories, small enterprises*

Table 4b: Details concerning severity with regard to interference immunity

Details on electromagnetic compatibility	Inspection values
Interference immunity towards static electricity discharges Tested acc. to IEC 801-2, EN 61000-4-2	Air discharge: 8 kV Contact discharge: 4 kV
Interference immunity towards transientinterference voltage (burst) Coupling to the power supply line of the device: Tested acc. to IEC 801-4, prEN 61000-4-4	2 kV
Interference immunity towards surge voltage Coupling to the power supply line of the device: Tested acc. to IEC 801-5, draft VDE 0843-5	L - N: 2 kV L - PE: 4 kV N - PE: 4 kV
Interference immunity towards voltage dip, brief interruptions and voltage fluctuations Voltage dip with 60% reduction for more than 100 ms; angle in 45° increments Voltage dip with 30% reduction for more than 10 ms; angle in 45° increments Voltage reduction ±10% for more than 30 s Tested acc. to IEC 801-11, EN 61000-4-11:	No interference No interference No interference
Interference immunity towards high-frequency radiation Acc. to IEC 801-3, prEN 55024-3	3 V/m

2.5 General details concerning sterilization with high-pressure steam

WARNING: Always check whether sterilization with high-pressure steam is suitable and which temperature and sterilizing time is required to determinate the given product.

Prior to each sterilization process it is necessary to check whether the selected sterilization method is suitable to kill off the germs. It is also necessary to establish whether the product that is to be sterilized will withstand the sterilization conditions. For instance, instruments with rubber or plastic parts can be significantly damaged by a temperature of e.g. 143°C (3 bar).

The subsequent Table 5 can function as a guideline for the operation of an autoclave. The specified values are purely for orientation and merely relate the sterilization time to temperature and pressure.

Table 5: Ratio between sterilization time and steam pressure and steam temperature

Sterilization time* in minutes	20	15	12	10	6	3	1
Stream pressure: bar	0,5	1,0	1,5	2,0	2,5	3,0	(4)
Stream temperature: °C	110	120	127	133	138	143	(151)

The steam temperature depends upon the steam pressure. The temperature display is significant for sterilization, and pressure display for the operating conditions inside the autoclave.