



# *Operators Manual*

## **Portaclave (STxx35) Thermostatically controlled electric autoclave 40 and 50 litres**

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**This manual should be read carefully before any attempt is made to use this autoclave**

## **SECTION ONE**

### **INTRODUCTION**

The **Rodwell Portaclave (STxx35)** range is a bench top, top loading portable laboratory autoclave with a chamber volume of 40 or 50 litres. The autoclave is simple to use and meets all the current U.K. safety requirements. The development of the **Rodwell Portaclave (STxx35)** has resulted in an autoclave that is both easy to use and service, if used and serviced in accordance with the manufacturers' instruction it should provide years of trouble free operation.

**NOTE This machine has no automatic control and requires operator intervention to ensure correct and safe operation DO NOT LEAVE THIS MACHINE UNATTENDED**

**SAFETY NOTE:** We recommend that a copy of the Health and Safety Executive Guidance Note PM 73 (UK) or other similar document relevant to the country of use be read carefully and implemented before the autoclave is put into service.

### **HANDOVER OF YOUR NEW MACHINE**

Once your machine has been installed and commissioned you must be trained in the correct and safe operation of the machine. You should read this manual carefully and be sure that you and all personnel that will use this machine fully understand how it operates and all aspects of safety.

## **SECTION TWO**

### **INSTALLATION AND SET-UP PROCEDURES**

This information is intended as a brief installation instruction. This machine must only be installed and set up by qualified personnel.

### **POSITIONING THE MACHINE**

Position the **Portaclave (STxx35)** on a solid table. Ensure there is sufficient room to allow the lid to be opened fully and easy access to machine supply socket

Ensure that the chamber drain valve is shut tight.

***For health and safety compliance, connections for to the mains supply MUST be within 1m of the machine and easily accessible by the operator***

### **ELECTRICAL SUPPLY**

The autoclave is supplied with heating elements and is designed to operate from a 220V. 1ph. 50/60hz 13amp supply. The electrical supply must be from an R.C.D isolator and connects to the IEC socket on the autoclave.

### **WATER SUPPLY**

In hard water areas, the supply should be treated to avoid chamber, element and pipe scaling. Distilled water, water softening units that use salts, reverse osmosis systems or de-ionised water supplies, are ***not*** recommended. (A water treatment device can be supplied and fitted by Rodwell Scientific Instruments). Sodium Chloride within the water supply should not exceed a level greater than 1000 parts per million. ***Failure to comply may result in damage to the autoclave and the invalidation of any warranty.*** (For further information on water quality, please contact your local Water Authority.)

### **WASTE CONNECTION**

There is no true waste connection required with this machine, if sterilising Dressings instruments or apparatus then the water must be drained off manually at the end of the sterilising period to ensure a dry load

## INITIAL CHECK OPERATION PROCEDURE



- A) Draw-off Cock
- B) Aircock
- C) Pressure gauge
- D) Safety valve
- E) Thermometer
- F) Wing nut (6)
- G) Drop bolt (6)
- H) Switch

### Parts supplied with Autoclave

- Autoclave body and lid complete with all fittings as per the picture
- Inner liner
- Pair of liner Carrying Handles.
- White silicone gasket in lid.
- Pack of TST indicator strips.
- Power lead with IEC connector
- USB stick containing:
  - Declaration of conformity (On USB stick)
  - Test certificate.
  - Operators manual.

- Remove all external protective covers
- Unscrew the 8 wing nuts (F) and swing down the Drop bolts (G)
- Twist the lid anti-clockwise until the locking lugs disengage
- Remove the lid
- Remove all packaging from inside the autoclave
- Check that all external parts are correct and undamaged Paying special attention to the Pressure gauge (C) and Thermometer (E)
- Check that all parts are included (as listed above)
- Connect the autoclave to a power supply using the supplied IEC lead **DO NOT SWITCH ON**
- Remove the inner liner
- PAT Test machine and enter detail into your Equipment register
- Fill the chamber with water to the height of the studs
- Ensure the lid gasket is correctly seated in its groove on the underside of the lid
- Place the lid onto the autoclave and rotate clockwise until it hits the stops
- Lift up the 8 drop bolts and lightly tighten in opposite pairs – Normal finger tightness is adequate
- Close the draw-off cock (A) and open the aircock (B) approximately 6 turns
- Switch on the mains supply – The green indicator will come on
- Switch on the power switch (H) the red light indicates the autoclave is running
- When the water begins to boil, steam will start to emit from the Aircock. It will splutter at first
- Close the Aircock once it has stopped spluttering and a clean jet of steam is visible.

*It is imperative that a clean jet of steam is visible before closing the Aircock as this ensures all the air in the autoclave is expelled. Air pockets in the autoclave will cause sterilisation to be incomplete*

- The temperature will now continue to rise until it reaches the preset level
- Allow the autoclave to run for 5 minutes
- Check constantly for any leaks of steam or water
- Turn off the red switch
- Place a suitable receptacle beneath the Draw-off Cock and open the Draw-off Cock to release water and steam under pressure from the autoclave. When steam ceases to emit, close the Draw-off Cock

**Warning - The water and steam that is released from the autoclave at this stage is extremely hot. Wear suitable protective equipment at this stage.**

- Wait until temperature falls to 80°C or less
- Open the aircock approximately 6 turns
- When the pressure gauge is reading zero it is safe to release the lid
- Open the lid by releasing the wing nuts in opposite pairs two full turns at a time
- Once all wing nuts have been released by these two turns it is safe to release them all fully
- Swing down the drop bolts
- Twist the lid anti-clockwise until the locking lugs disengage and lift off the lid

**THE AUTOCLAVE IS NOW READY FOR USE.**

#### **SAFETY NOTE**

Operators must wear a visor, heat protective gauntlets, a laboratory coat with sleeves, suitable footwear and a heavy apron before opening the lid or unloading the autoclave.

## SECTION THREE

### MACHINE OPERATION

*This is a very basic machine and has no automatic control the heating, free steaming and sterilise periods have to be controlled by the operator Never leave the machine unattended*

The autoclave is factory set to run at 121°C. This is the maximum setting, which is suitable for most purposes. A lower setting can be used if required.

Many materials can be autoclaved at 121°C. These include most metals, glass, silicone rubber and many plastics. If in doubt, consult the manufacturer of the instrument or equipment concerned as the manufacturer of the autoclave does not accept liability for damage of this nature.

#### Operating Instructions

- Remove the Inner Liner. Fill the chamber of the autoclave with water up to the height of the studs.
- Articles to be sterilised should be placed into the Inner Liner, a Wire Mesh Basket or a Bottle Rack. To sterilise porous loads (i.e. dressings and drapes) it is recommended that a Dressing Drum be used. The container should not be packed tightly, especially when dressings are being sterilised. It is important that steam can circulate freely. Place the Inner Liner / Wire Mesh Basket / Bottle Rack / Dressing Drum inside the autoclave
- Check that the Lid Gasket is correctly seated in its groove on the underside of the lid. Place the lid on the autoclave and rotate clockwise until it hits the stops and the slots for the Drop Bolts line up in the lid and body ring. The 8 Wing Nuts and Drop Bolts should now be lifted up and lightly tightened in opposite pairs. This should be done - one in each hand - until the slack is taken up. Now tighten up in opposite pairs. Normal finger tightness is adequate.
- Close the Draw-off Cock (A)
- Open the Aircock (B) approximately 6 turns.
- Plug the power lead into the autoclave. Plug the lead into the mains (the green light will show connection to the mains).
- Turn on the red Switch (H) (the red light will show power on).
- When the water begins to boil, steam will start to emit from the Aircock. It will splutter at first

Close the Aircock once it has stopped spluttering and a clean jet of steam is visible.

*It is imperative that a clean jet of steam is visible before closing the Aircock as this ensures all the air in the autoclave is expelled. Air pockets in the autoclave will cause sterilisation to be incomplete. It is advisable to use some form of sterilisation test e.g. the TST indicator strips supplied*

- The temperature will now continue to rise until it reaches the preset level
- It is at this time that the sterilisation period begins.
- Start a timer unit or stopwatch to time the required sterilisation period
- When the sterilisation period is complete, turn off the red Switch.
- Depending on the materials being sterilised
  - Bottles or other sealed vessels containing liquid - **Do not, under any circumstances, open the Draw-off Cock or the Aircock or release pressure from the autoclave in any manner. To release pressure from the autoclave at this point could cause the containers to explode.** Allow the autoclave to cool until the Thermometer shows 80°C or less

- Dressings, instruments and apparatus - (providing the apparatus does not have sealed glass containers holding liquid). **Warning - The water and steam that is released from the autoclave at this stage is extremely hot. Wear suitable protective equipment at this stage.** Place a suitable receptacle beneath the Draw-off Cock and open the Draw-off Cock to release water and steam under pressure from the autoclave. When steam ceases to emit, close the Draw-off Cock and allow the autoclave to cool until the Thermometer shows 80°C or less. During the cooling period a partial vacuum will form inside the autoclave. This will help in drying the contents
- Open the aircock approximately 6 turns
- When the pressure gauge is reading zero it is safe to release the lid
- Open the lid by releasing the wing nuts in opposite pairs two full turns at a time
- Once all wing nuts have been released by these two turns it is safe to release them all fully
- Swing down the drop bolts
- Twist the lid anti-clockwise until the locking lugs disengage and lift off the lid
- Remove the sterilised contents

#### Suggested program configurations

Typical settings for average loosely packed loads are detailed here and can be used as a starting point for the majority of applications. Dressings in particular should not be packed tightly as steam will not penetrate. Wire Mesh Baskets or Dressing Drums are recommended for this application.

| Load type                                 | Temperature | Time       |
|---|-------------|------------|
| Instruments and Equipment                 | 121°C       | 15 Minutes |
| Dressings and Drapes                      | 121°C       | 30 Minutes |
| Liquid in Sealed Containers (0ml - 200ml) | 121°C       | 20 Minutes |
| Culture Media (up to 1 litre)             | 121°C       | 15 Minutes |

#### Notes on sterilisation of Culture Media:

1. Always follow the manufacturer's instructions.
2. Use volumes up to 1 litre.
3. Use similar volumes in the same load.
4. After cycle test for sterility.
5. Check microbiological performance before use.

***NOTE These are suggested settings and should be used as a starting point, it is essential that you ensure that the autoclave is loaded and the time and temperatures are set to ensure that the entire load is fully sterilised.***

## **SECTION FOUR**

### **BASIC FAULT FINDING**

#### **Power interruption**

If the mains supply to the machine is interrupted during a program cycle then when the power is restored the machine will continue to operate. If the power failure was short then it may be safe to continue with the sterilisation period as the unit temperature may not have dropped significantly. Under certain circumstances it may also be adequate to extend the sterilise period to compensate for any time the load spent below temperature.

If in doubt the load should be allowed to cool and the cycle started again from scratch.

#### **FAULT FINDING CHART**

| <b>FAULT</b>                            | <b>CAUSE</b>   | <b>REMEDY</b>  |
|---|--|--|
| <b>Cycle fails to reach temperature</b> | Heating element fault<br>Faulty Safety valve<br>Leak from lid seal<br>Lid seal fault<br>Aircock not closed or leaking<br>Draw-off cock not closed or leaking<br>140°C Internal cut out tripped | Contact service engineer<br>Contact service engineer<br>Clean the seal<br>Replace seal<br>Close/Replace aircock<br>Close replace draw-off cock<br><br>Contact service engineer |
|   |  |  |

If your problem cannot be corrected by the use of the above information, a service engineer should be called.

## SECTION FIVE

### ROUTINE MAINTENANCE

#### Cleaning procedures and equipment

The external surfaces of the machine can be cleaned using a soft cloth and mild detergent. ***Do not use abrasive cleaners on painted surfaces as these may scratch the surface.***

The internal parts of this machine are constructed from stainless steel because of its inherent corrosion resistance, strength and aesthetic appeal. However, dependent on the conditions of use stainless steel will stain and discolour due to surface deposits and so cannot be assumed maintenance free. In order to maintain maximum corrosion resistance and long service life the surface of the stainless must be cleaned regularly. To ensure long life and ease of cleaning the surface should not be allowed to be in contact with non-stainless steel metallic items during operation nor should ferrous metal products be used for cleaning. Regular washing with soap or mild detergent and warm water will often be sufficient to maintain a good finish. ***Excessive use of abrasive cleaners will remove the natural protective surface of the metal and will increase the tendency to discolour so do not use abrasive products for routine cleaning. DO NOT use the same cleaning items on the stainless steel parts to any other machine parts as particles on the cleaning cloths could cause re-staining of the stainless steel***

| Problem   | Suggested method  | Comments   |
|---|---|--|
| Routine cleaning of light soiling   | Soap, detergent or dilute (1%) ammonia solution in warm water. Apply with a clean sponge, soft cloth or soft fibre brush then rinse with clean water  | Satisfactory for most light deposits   |
| Stubborn spots, stains and light discolouration. Water marking. Light rust staining | Mild, non-scratching creams or polishes. Apply with a soft cloth or soft sponge, rinse off residues with clean water  | Avoid cleaning pastes with abrasive additions. Suitable cream cleansers are available with soft calcium carbonate additions or with the addition of citric acid. Do not use chloride solutions |
| Localised rust stains caused by carbon steel contamination                          | Proprietary gels, or 10% phosphoric acid solution (followed by ammonia and water rinses), or oxalic acid solution (followed by water rinse). Small areas may be treated with a rubbing block comprising fine abrasive particles in a hard rubber or plastic filler (see recommended spares list, Rodwell part number <b>891-0044</b> ). | A test should be carried out to ensure that the original surface finish is not damaged. Carbon steel wool, or pads previously used on carbon steel should not be used                          |
| Burnt on food products or carbon deposits   | Pre-soak with hot water with detergent or ammonia solution. Remove deposits with nylon brush and fine scouring powder if necessary. Repeat if required, finish using 'routine cleaning' above   | Abrasive scouring powders can leave scratch marks.   |
| Tannin stains   | Wash with a hot solution of washing soda (sodium carbonate). Apply with a soft cloth or soft sponge, rinse off residues with clean water  | Satisfactory for most light deposits   |
| Oily deposits   | Wash with a hot solution of baking soda (sodium bicarbonate). Apply with a soft cloth or soft sponge, rinse off residues with   | Satisfactory for most light deposits   |

|  |  |   |
|--|--|---|
|  | clean water  |   |
| Adherent hard water scales                               | 10-15% by volume solution of phosphoric acid. Use warm, neutralise afterwards with dilute ammonia solution. Rinse with clean water. Alternatively wash with a 25% vinegar solution and use a nylon brush to remove deposits. | Proprietary formulations are available with surfactant additions.   |
| Heating or heavy discolouration                          | a) Non-scratching cream or metal polish<br>b) Nylon type pad, (see recommended spares, Rodwell part number <b>891-0043</b> )<br>c) Nitric acid-hydrofluoric acid pickling pastes or a nitric acid passivation solution.      | Suitable for most deposits<br><br>Use along the grain the grain<br><br>Changes in surface appearance usually result after cleaning with these acids |
| Badly neglected surfaces with accumulated grime deposits | A fine, abrasive car body refinishing paste. Rinse clean afterwards to remove all paste  | May brighten dull finishes. To avoid a patchy appearance, the whole surface may need to be treated  |

### **Maintenance procedures**

UK users - this autoclave comes within the scope of 'The Pressure Systems and Transportable Gas Containers Regulations 1989' and should be inspected and maintained accordingly. General maintenance should be carried out by a competent person only, as and when deemed necessary. In other countries you should check the appropriate legislative procedures

### **Daily Maintenance by Operator**

- 1) Check the white silicone Lid Gasket for distortion or wear and tear. The Lid Gasket is located in the groove on the underside of the lid. Check that it has not become brittle. Replace the Lid Gasket with a new one if necessary.
- 2) Check the rim of the body where the Lid Gasket seats for damage to the metal rim which would cause the lid seal to leak. If the damage is only minor, then the rim can be repaired by filing and smoothing with emery cloth. Major damage should be referred to the manufacturer or a qualified service engineer.
- 3) Clean all foreign matter from the chamber. The surface of the chamber should be washed with water containing a mild detergent; the baskets should be cleaned in a similar way. (Materials that will leave deposits such as cotton wool should not be used for cleaning) SEE ABOVE
- 4) Keep the autoclave clean and free from dust and dirt.

### **Weekly Maintenance**

- 1) Check the calibration of the temperature and pressure gauges
- 2) Check the Draw-off Cock for signs of leaking around the seals and from the valve. Replace the seals or complete Draw-off Cock with a new one if necessary.
- 3) Check all fittings for signs of leaks.

- 4) Check the Switch and light for damage. Replace if necessary. See that the IEC connector fits firmly in the socket

### **Monthly Maintenance**

- 1) Check that the daily and weekly maintenance has been carried out.
- 3) Check lid bolts and hinges for wear

### **Annual Maintenance**

- 1) PAT test autoclave and enter into Equipment register.
- 2) Check calibration and operation of safety valve

### **Safety Valve Adjustment and Maintenance**

The Safety Valve is factory set using a test rig to release pressure at 1.3 bar (18 psi). It should be replaced or returned to The Rodwell Autoclave company for test and calibration

**Do not attempt to service or repair this device it is safety critical and could result in serious damage if not calibrated correctly.**

### **Electrical Maintenance**

One element is internally fitted - 3.0kW - requiring a minimum 10A fuse. Check that the terminals on the elements are tight and that the elements are securely mounted in the base.

### **Overheat Cutout**

To avoid damage to the element, should the autoclave boil dry, it is fitted with an automatic overheat cutout. This is clamped to the base of the chamber. If the device should cutout it must be manually reset. Before doing this switch off the mains to the autoclave and remove the plug. Allow the autoclave to cool down. To reset the cutout turn the autoclave upside down and remove the perforated protection plate from the bottom. The cutout will now be visible. It is a round black unit approximately 15mm in diameter with a red button protruding from the middle. To reset the cutout press this red button. You should hear an audible 'click' as the cutout is reset. Refit the protection plate and turn the autoclave the right way up. The autoclave will now work as before

### **Thermostat Adjustment**

The autoclave is controlled by an electronic thermostat mounted in the base. The working temperature is adjusted using a potentiometer mounted on the skirting band. Remove the protective cap to the left of the rating plate to access the potentiometer adjuster. The adjuster is a blue fluted shaft. Bring the autoclave up to working temperature. To increase the working temperature turn the adjuster clockwise and to decrease the set temperature turn the adjuster anti-clockwise. A turn of 30° equates to approximately 5°C. The autoclave

should be left to settle for about 2 minutes after each adjustment. When the desired setting is reached replace the protective cap. The maximum setting allowed is 121°C

Your maintenance engineers should be fully conversant with the function of the Autoclave, so that notwithstanding any service contract, emergency maintenance can be affected if necessary. In the event of a major breakdown, **The Rodwell Autoclave Company service engineer (or their recognised Distributor service engineer for your area)** should be called in.

A log book should be kept adjacent to each Autoclave. Every incident or irregularity in performance, leak etc., and maintenance checks should be recorded in it. Incidents of irregularity should be reported to the engineer by the operating staff as soon as it is discovered. It is often found that complaints about performance occur because a known fault has not been reported. (If the machine is fitted with USB logging then any faults occurring during a cycle are automatically recorded.)

Section 14 (Service record) Must be completed by the service engineer when the service is completed.

**The Rodwell Autoclave Company (or their recognised Distributor) can, if requested, carry out periodic maintenance visits, which can be arranged in the form of a Preventative Maintenance Contract along with Rodwell or NAMAS Calibration Services.**

**For details of Service/Calibration Contracts, contact The Rodwell Autoclave Company Service Department, +44 (0) 1268 286646 (or the recognised Distributor in your area).**

#### **Note**

If a service engineer has to be called in, then a clearance note, stating that the unit is free from biological or bacteriological contamination and signed by the **Head of Department**, must be handed to the service engineer before he commences work. If the above is not possible, then he must be completely informed of the dangers involved and fully instructed with regards to the necessary precautions, any overalls or protective clothing must then be supplied by the laboratory and must **NOT** be brought away.

Under **NO** circumstances must contaminated clothing or equipment be returned to the factory.

**NOTE: BEFORE ATTEMPTING SERVICING OF THE ELECTRICAL CIRCUIT, ISOLATE THE AUTOCLAVE FROM THE MAINS SUPPLY.**

**SAFETY NOTE: We strongly recommend that a copy of the Health and Safety Executive Guidance Note PM73 and Safe Working and the Prevention of Infection in Clinical Laboratories or other documents relevant to the country of operation be carefully read and implemented before this autoclave is put into service.**

## **SECTION SIX**

### **TECHNICAL INFORMATION**

| Model                        | Portaclave<br>(ST4035) | Portaclave<br>(ST5035) |
|------------------------------|------------------------|------------------------|
| Weight                       | 31kG                   | 33kG                   |
| Height                       | 630mm                  | 735mm                  |
| Width                        | 440mm                  | 440mm                  |
| Depth                        | 460mm                  | 4600mm                 |
| Power rating                 | 3kW                    | 3kW                    |
|                              |                        |                        |
| SAFE DESIGN OPERATING LIMITS |                        |                        |
| Maximum working temperature  | 121°C                  | 121°C                  |
| Minimum working temperature  | 7°C                    | 7°C                    |
| Maximum hydraulic pressure   | 2.0Bar                 | 2.0Bar                 |
| Maximum working pressure     | 1.3Bar                 | 1.3Bar                 |
|                              |                        |                        |

SODIUM CHLORIDE WITHIN WATER SUPPLY MUST NOT EXCEED A LEVEL GREATER THAN 1000 PARTS PER MILLION.

#### **ELECTRICS:**

220 Volts 1 ph 50/60hz

## **SECTION SEVEN**

### **Recommended spare parts for 2 years**

|       |           |                              |
|-------|-----------|------------------------------|
| 2 off | STS18     | Lid Seal                     |
| 1 off | STS33     | Temperature gauge            |
| 1 off | STS02     | Pressure Gauge               |
| 1 off | STS01-13  | Safety valve 1.3bar          |
| 1 off | STS75     | Element kit                  |
| 1 off | STSxx-240 | 3kW element                  |
| 1 off | 891-0043  | Abrasive cleaning pad (pack) |
| 1 off | 891-0044  | Rubbing block                |
| 1 off | 890-0034  | Service label                |

## **SECTION EIGHT**

### **RISK ASSESSMENT AND SAFETY**

| <b>HAZARDS</b>  | <b>COMMENTS</b>   |
|---|---|
| Burns and Scolds from Liquid Loads.                         | Protective Clothing must be worn.   |
| Burns and Scolds from hot steam when opening the autoclave  | Care should always be taken.  |
| Liquid Spillage when loading or unloading.                  | Clean Up and Dry.   |
| Burns and Scolds from opening manual drain valve.           | Ensure there is no pressure in the chamber and the temperature is below 80°C before opening any manual valves |
| Burns and Scolds from failing to close manual drain valves. | Ensure all manual valves are securely closed after use, servicing or maintenance                              |
|   |   |
|   |   |

## **SECTION NINE**

### **USERS RESPONSIBILITIES**

The User is responsible for ensuring that

- The load contents will be compatible with the materials used to construct this vessel
- The chamber is free from stress corrosion cracking; this is foreseen by the use of excessive sodium chlorides, from the load or from the water used to fill the vessel.
- The operator carries out routine maintenance checks as stated in this manual.
- The operator is fully trained before using this equipment.
- A full service record is kept up to date of this equipment and a yearly routine inspection of the pressure vessel carried out by a Notified Body.
- The contents of the autoclave are correctly sterilised before releasing the lid
- All necessary precautions are taken to prevent the possible release of harmful pathogens or chemicals into the environment both through the atmosphere and through any discharge to the waste system
- any leaks or operational malfunctions rectified immediately
- UK Customers must have a written scheme of examination (See Appendix 2 or contact The Rodwell Autoclave company for additional information) In other countries you should check the appropriate legislative procedures

## **SECTION TEN**

### **A Guide to the Planning and Implementation of your Health & Safety Control Measures.** **Are the following Control Measures in place?**

- Method Statements.
- Autoclave Risk Assessment.
- Operator Risk Assessment
- Periodic Maintenance, by an authorised Rodwell Engineer.
- Operator Training.
- Pressure Vessel annual Inspection.
- Autoclave Log Book for Daily Records.
- Earth Continuity Test on all metal panels recorded. **This is a Safety Critical Operation.**
- Insulation Type Class1 for Insulation Resistance Test.
- Safety Critical Components adjusted and maintained in working order to the Manufacturers tolerances.
- Health & Safety Guidance note PM73. Implemented?

**Ref:** Low Voltage Directive 93/68/EEC.

Pressure Equipment Directive 97/23/EC.

Insulation Type Class 1.

**For further information contact:**  
**The Rodwell Autoclave Company**  
**Quality Assurance Department.**  
**Advice Line. +44 (0) 1268 286646.**  
**Or your Local Health & Safety Executive.**

## **SECTION ELEVEN**

### **DISPOSAL – CARING FOR THE ENVIRONMENT**



Please consider the environment when disposing of your Autoclave.

Disposal of the Autoclave should be carried out by a professional disposal company, after decontamination of any bacteriological or microbiological waste. A clearance note must be issued by the end user.

You are responsible for financing and arranging treatment in accordance with the WEEE Regulations, and existing waste management legislation, including the Duty of Care and the Hazardous Waste Regulations or any other regulations appropriate to your country.

If the Autoclave is to be permanently demolished and/or scrapped, divide the material to be disposed of according to type and composition, as follows:

- 1). Iron or ferrous materials, composed of metal alone, are secondary raw materials, so they may be taken to an iron foundry for re-smelting after having removed the contents (classified in point 3).
- 2). Electrical components, including the cable and electronic material (magnetic cards, etc.), fall within the category of material classified as being assimilated to urban waste according to the laws of your local, state or federal government.
- 3). Old greases are considered hazardous or special refuse, so they must be collected, transported and disposed of at a special waste disposal service.
- 4). In the UK Appliances bearing the WEEE symbol must not be disposed of with domestic rubbish or sent to landfill

**NOTE: The standards and legislation concerning refuse are in a constant state of evolution and therefore are subject to change. The user must keep informed of the regulations at the time of disposal as these may differ from those described above.**

## **SECTION TWELVE**

### **DISCLAIMER**

This manual represents a supplement to any legislation and guide-lines currently in force.

It is the responsibility of responsible persons within the user's organisation to ensure that all current legislation's and guide-lines relevant to the country in which the equipment is to be used are obtained and adhered to for the safety of personnel and the safe operation of the equipment.

Whilst every effort has been made to ensure the information in this manual is correct and relevant. The Rodwell autoclave company and its associated companies will not accept any liability for errors omissions or inaccuracies.



## Customer Care Sheet- End User

We trust you have received your Rodwell Autoclave in the condition you would expect. If you have any comments please use this sheet to notify us of these.

Please complete the topic boxes below to identify the related details and return either

by fax to: **+44 (0) 1268 287799** or by e.mail to: [andrew.rodwell@rodwell-htb.com](mailto:andrew.rodwell@rodwell-htb.com)

We treat all comments as valuable to improve our current service and will notify you of any actions as a result of your comments, thank you.

### 1.0 Documentation

|  |
|--|
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### 2.0 Packaging

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### 3.0 Paint finish

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### 4.0 General assembly

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### 5.0 Electrical assembly

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### 6.0 Performance

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### 7.0 Other (please state)

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|  |
|--|

Model: \_\_\_\_\_ Serial No: \_\_\_\_\_ Commissioning date: \_\_\_\_\_

**Organisation Name** \_\_\_\_\_

Contact Name \_\_\_\_\_ Contact Fax no./ E.mail: \_\_\_\_\_

## Service Interval Record

### Machine serial No. ....



It is recommended that your Autoclave is serviced regularly and that the appropriate service record below is completed.

**Service Engineer.** Before completing the Service Interval Record below please ensure that you have carried out the service as described as per the manufacturers instructions to validate the warranty. Always use manufacturers specified spare parts only.

#### **Service 1 Date:**

Engineer's Name: \_\_\_\_\_

Company Name: \_\_\_\_\_

Rodwell certification No.: \_\_\_\_\_

Certification expiry date: \_\_\_\_\_

Comments: \_\_\_\_\_  
\_\_\_\_\_

Signature: \_\_\_\_\_

#### **Service 2 Date:**

Engineer's Name: \_\_\_\_\_

Company Name: \_\_\_\_\_

Rodwell certification No.: \_\_\_\_\_

Certification expiry date: \_\_\_\_\_

Comments: \_\_\_\_\_  
\_\_\_\_\_

Signature: \_\_\_\_\_

#### **Service 3 Date:**

Engineer's Name: \_\_\_\_\_

Company Name: \_\_\_\_\_

Rodwell certification No.: \_\_\_\_\_

Certification expiry date: \_\_\_\_\_

Comments: \_\_\_\_\_  
\_\_\_\_\_

Signature: \_\_\_\_\_

#### **Service 4 Date:**

Engineer's Name: \_\_\_\_\_

Company Name: \_\_\_\_\_

Rodwell certification No.: \_\_\_\_\_

Certification expiry date: \_\_\_\_\_

Comments: \_\_\_\_\_  
\_\_\_\_\_

Signature: \_\_\_\_\_

#### **Service 5 Date:**

Engineer's Name: \_\_\_\_\_

Company Name: \_\_\_\_\_

Rodwell certification No.: \_\_\_\_\_

Certification expiry date: \_\_\_\_\_

Comments: \_\_\_\_\_  
\_\_\_\_\_

Signature: \_\_\_\_\_

#### **Service 6 Date:**

Engineer's Name: \_\_\_\_\_

Company Name: \_\_\_\_\_

Rodwell certification No.: \_\_\_\_\_

Certification expiry date: \_\_\_\_\_

Comments: \_\_\_\_\_  
\_\_\_\_\_

Signature: \_\_\_\_\_

#### **Service 7 Date:**

Engineer's Name: \_\_\_\_\_

Company Name: \_\_\_\_\_

Rodwell certification No.: \_\_\_\_\_

Certification expiry date: \_\_\_\_\_

Comments: \_\_\_\_\_  
\_\_\_\_\_

Signature: \_\_\_\_\_

#### **Service 8 Date:**

Engineer's Name: \_\_\_\_\_

Company Name: \_\_\_\_\_

Rodwell certification No.: \_\_\_\_\_

Certification expiry date: \_\_\_\_\_

Comments: \_\_\_\_\_  
\_\_\_\_\_

Signature: \_\_\_\_\_

**Service 9 Date:** \_\_\_\_\_

Engineer's Name: \_\_\_\_\_

Company Name: \_\_\_\_\_

Rodwell certification No.: \_\_\_\_\_

Certification expiry date: \_\_\_\_\_

Comments: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Signature: \_\_\_\_\_

**Service 10 Date:** \_\_\_\_\_

Machine cycle count: \_\_\_\_\_

Engineer's Name: \_\_\_\_\_

Company Name: \_\_\_\_\_

Rodwell certification No.: \_\_\_\_\_

Certification expiry date: \_\_\_\_\_

Comments: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Signature: \_\_\_\_\_

**Service 11 Date:** \_\_\_\_\_

Engineer's Name: \_\_\_\_\_

Company Name: \_\_\_\_\_

Rodwell certification No.: \_\_\_\_\_

Certification expiry date: \_\_\_\_\_

Comments: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Signature: \_\_\_\_\_

**Service 12 Date:** \_\_\_\_\_

Engineer's Name: \_\_\_\_\_

Company Name: \_\_\_\_\_

Rodwell certification No.: \_\_\_\_\_

Certification expiry date: \_\_\_\_\_

Comments: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Signature: \_\_\_\_\_

**Service 13 Date:** \_\_\_\_\_

Engineer's Name: \_\_\_\_\_

Company Name: \_\_\_\_\_

Rodwell certification No.: \_\_\_\_\_

Certification expiry date: \_\_\_\_\_

Comments: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Signature: \_\_\_\_\_

**Service 14 Date:** \_\_\_\_\_

Engineer's Name: \_\_\_\_\_

Company Name: \_\_\_\_\_

Rodwell certification No.: \_\_\_\_\_

Certification expiry date: \_\_\_\_\_

Comments: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Signature: \_\_\_\_\_

**Service 15 Date:** \_\_\_\_\_

Engineer's Name: \_\_\_\_\_

Company Name: \_\_\_\_\_

Rodwell certification No.: \_\_\_\_\_

Certification expiry date: \_\_\_\_\_

Comments: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Signature: \_\_\_\_\_

**Service 16 Date:** \_\_\_\_\_

Engineer's Name: \_\_\_\_\_

Company Name: \_\_\_\_\_

Rodwell certification No.: \_\_\_\_\_

Certification expiry date: \_\_\_\_\_

Comments: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Signature: \_\_\_\_\_

**Service 17 Date:** \_\_\_\_\_

Engineer's Name: \_\_\_\_\_

Company Name: \_\_\_\_\_

Rodwell certification No.: \_\_\_\_\_

Certification expiry date: \_\_\_\_\_

Comments: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Signature: \_\_\_\_\_

**Service 18 Date:** \_\_\_\_\_

Engineer's Name: \_\_\_\_\_

Company Name: \_\_\_\_\_

Rodwell certification No.: \_\_\_\_\_

Certification expiry date: \_\_\_\_\_

Comments: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Signature: \_\_\_\_\_

## **SECTION FIFTEEN**

### **CONTACT DETAILS**

If you have a service contract with a third party company then you should in the first instance contact them regarding any problems or additional requirements. However, The Rodwell Autoclave Company can provide full backup and support for your machine so please feel free to contact us using, in the first instance, the appropriate Email address listed here.

|                                     |  |
|-------------------------------------|--|
| Technical support with an Autoclave | <a href="mailto:support@autoclaveservice.co.uk">support@autoclaveservice.co.uk</a>             |
| Spares parts                        | <a href="mailto:spares@autoclaveservice.co.uk">spares@autoclaveservice.co.uk</a>               |
| Consumable products                 | <a href="mailto:consumables@autoclaveservice.co.uk">consumables@autoclaveservice.co.uk</a>     |
| UK machine service department       | <a href="mailto:ukservice@autoclaveservice.co.uk">ukservice@autoclaveservice.co.uk</a>         |
| Global machine service department   | <a href="mailto:globalservice@autoclaveservice.co.uk">globalservice@autoclaveservice.co.uk</a> |
| Sales of new/replacement machines   | <a href="mailto:autoclavesales@rodwellgroup.co.uk">autoclavesales@rodwellgroup.co.uk</a>       |
| Complaints                          | <a href="mailto:complaints@autoclaveservice.co.uk">complaints@autoclaveservice.co.uk</a>       |

# Safety requirements for autoclaves

Guidance Note PM73(rev3)



## Introduction

- 1 Autoclaves are pressure vessels with lids or doors, arranged for regular access. They are used in a variety of processes, where products are placed inside the vessel and subjected to greater than atmospheric pressures and, in most cases, elevated temperatures.
- 2 This guidance covers industrial autoclaves used in workplaces. It is aimed at all employers, supervisors and managers responsible for the safe operation and maintenance of these devices. It specifically addresses the risks associated with safeguarding, training and maintenance.
- 3 The guidance can also help Notified Bodies (responsible for conformity assessment) and Competent Persons (devising written schemes of thorough examination) to assess the autoclave and identify measures for risk reduction.
- 4 This guidance has been prepared in response to two fatalities in the UK since 2008. One incident involved a walkway collapsing while production staff were loading the autoclave. In the other incident, an employee was struck by the vessel door when it opened, while still under pressure.

## Risks from autoclaves

- 5 Autoclaves are high-risk equipment. Their use is covered by the Provision and Use of Work Equipment Regulations 1998 (PUWER)<sup>1</sup> and the Pressure Systems Safety Regulations 2000 (PSSR).<sup>2</sup>
- 6 The most serious risks come from the uncontrolled release of stored energy, which happen when safety critical parts fail. This can cause violent ejection of:
  - components/pieces of equipment;
  - the pressurising medium;
  - the vessel contents.

## What you need to do

- 7 You must reduce the risks outlined above by taking appropriate safety measures. What is required depends largely on the size of the autoclave, its operating pressure and the kind of pressurising medium.
- 8 You can determine the measures appropriate for your particular situation by weighing up the risk factors described in this guidance.

9 The starting point is to identify the safety critical parts of the autoclave system, including those where a single fault leads to total disengagement or loss of system integrity.

10 The nature of the autoclave, how it is installed and what it is used for may highlight other hazards such as:

- inadvertent opening/failure of the lid/door mechanism while under pressure;
- overloading the supporting framework;
- corrosion/erosion;
- fragile containers, in autoclaves for sterilising, shattering if exposed to a sudden temperature change.

## **Determining risk factors**

11 You must assess the following key issues:

- control of automated and manual systems;
- inadvertent pressurisation with a person inside the autoclave;
- inadvertent pressurisation of blowdown, drain and transfer lines;
- a door or lid opening violently under pressure;
- verifying nil pressure before opening the vessel;
- location;
- instruction and training;
- thorough examination;
- maintenance and inspection.

## **Control of automated and manual systems**

12 Autoclave control can be fully manual but programmable electronic systems (PESs) are becoming increasingly commonplace in autoclave control. The monitoring and control facilities these systems provide may be very sophisticated. They can allow for automatic shutdown and remote monitoring, as well as a facility to indicate that a fault has been detected, at a remote location away from the autoclave. You must have the following control safeguards in place.

13 In automated autoclave systems, you must configure all safety devices so that, in the event of a dangerous situation, the autoclave will fail-safe with a means of dissipating residual energy (ie the pressurising medium within the autoclave). These dangerous situations include:

- loss of power;
- loss of pressure;
- over-pressure;
- over-temperature;
- emergency stop activation;
- interlock/sensor discrepancy.

14 When any automated system is placed in a safe condition, the inlet valves should close and the exhaust valves open, which is established industry practice. There must be gauge points on or near the valves to allow verification that there is no longer pressure in the lines.

15 There must also be isolation of pressure to the autoclave. This should normally be achieved with fail-to-safe automated valves or manually-operated valves, using

double isolation valves when transferring and isolating relevant fluids, which is the established industry standard.

16 To prevent risks from interlock/sensor discrepancy on automated process controls, you should verify the function of the interlock or safety device. Established industry practice for this is to continually monitor interlock and safety devices with independent sensors so that, in the event of a discrepancy, the autoclave is placed in a safe condition and a fault condition is reported immediately.

17 Manually-operated autoclaves rely on operator procedure to verify the safe condition of the plant and that interlocking and safety devices are functioning correctly. Visible door position indicators and additional gauge points are also advisable, to further reduce the risk, by allowing the operator to cross-check the status of the autoclave.

### **Inadvertent pressurisation with a person inside the autoclave**

18 If the autoclave is large enough for an operator to enter, fit the autoclave door with a device to prevent the door from closing and the cycle from starting with the operator inside.

19 Where full-body access inside the autoclave is possible, it is also advisable, depending on the process, to reduce the risk further by providing a safety alarm or pull cord inside the vessel to automatically engage the emergency stop circuit.

### **Inadvertent pressurisation of blowdown, drain and transfer lines**

20 To prevent inadvertent pressurisation or scalding at adjacent autoclaves, you must install independent drain and blowdown lines wherever possible. Where this is not possible, there must be additional safety devices to make sure only one autoclave blowdown valve can be in the open position at any one time.

21 Where the exhaust of relevant fluid from one autoclave is reused in another autoclave, it is essential to provide a valve in the transfer line. This must be interlocked with the door-locking mechanism of the autoclave that the relevant fluid is being supplied to.

### **Door/lid opening violently under pressure**

22 You should take several factors into account when you are assessing the suitability of door/lid opening and closing mechanisms, especially those fitted with a mechanism that allows rapid opening (called quick-opening doors), where exposure can occur quickly.

23 This can also apply to smaller vessels if the initial 'cracking' of the door seal is likely to lead to dangerous emissions of vapour, scalding liquid or fragments of product container, which have shattered in the autoclave. Paragraphs 24-29 explain the precautions you must take.

24 The autoclave should not be capable of being pressurised unless the door/lid is completely closed, the securing mechanism fully engaged and the chamber sealed. This is normally achieved by interlocking between the door-securing mechanism and the pressurising system. Where pressure is applied:

- from an external source, eg steam, air or other gas, the interlock should be between the door-securing mechanism and the pressurising fluid inlet valve;
- by boiling liquid in the vessel, the interlocking arrangement should be between the door-securing mechanism and the source of heat;
- by a pump, the pump should not be able to pressurise the system unless the door-securing mechanism is fully engaged.

25 As part of any automated door-opening system, the door position monitoring must be verified. You can ensure this by installing more than one position sensor. It is also advisable to include a visual indicator to allow the operator to physically check the door position.

26 The autoclave should be vented to reduce the internal pressure to atmospheric conditions before the door-securing mechanism can be disengaged.

27 Take care to make sure the door/lid does not open violently due to any residual pressure in the vessel. A suitable device for this purpose is a safety catch robust enough to prevent single component failure of the normal door-locking assembly and which has to be released independently after:

- the door-securing mechanism has been disengaged; and
- the door seal has been broken.

The purpose of a safety catch is to prevent risk from residual pressure inside the vessel. However, as the extent of residual pressure cannot be determined, it is recommended that the safety catch is capable of withstanding energy release from catastrophic failure (ie normal working pressure). Safety catches can be automatically or manually engaged.

28 Where there is a danger of the door seal sticking, with residual pressure remaining, the door mechanism should break the seal before the locking device is disengaged in such a way that the door remains captive. Where this is not possible, movement should be restricted, so the door opens not more than 8 mm after it has been partially released. A suitable device for this is a safety catch that:

- has to be released independently of the door being unlocked; and
- may not be fully released until the door has been 'cracked' open and the seal broken.

29 To further reduce the risk of harm from hot product, it is advisable to prevent the door/lid from being opened until the temperature of the autoclave contents have been reduced to a safe level. This may be achieved by using an interlocking arrangement, incorporating temperature-sensing devices located in the parts of the vessel expected to remain at the highest temperature at the end of the cycle.

## **Verifying nil pressure before opening the vessel**

30 All autoclaves must include a correct and suitable pressure indicator installed where the operator can see it easily. This should usually be on or near the autoclave.

31 On larger autoclaves the residual pressure may not be enough to register on an indicator gauge. But, acting over the surface area of a large door, this residual pressure can exert a considerable force that is released violently, if the door is opened suddenly. Normal industry practice is to prevent this by installing a vent

valve (also referred to as a test cock) to verify there is nil pressure. The test cock may be manually operated, or form part of the automated process control.

32 On automated systems the vent valve is opened with a 'test sequence' button. This must be a hard-wired circuit, with independent sensors used to confirm nil pressure in the autoclave. Integration with the door position interlocks (as part of the door-opening sequence) is also established practice.

33 On manual systems, there is a reliance on hearing the pressure release (air systems) from the vent valve and/or visual means, eg steam. The vent valve outlet should always be arranged, so that any discharge will not injure someone carrying out the test.

## **Location**

34 Several aspects of location of the autoclave are important. These include:

- access;
- control position;
- outlets;
- loading arrangements.

Paragraphs 35-39 explain the action you need to take.

35 The operator needs safe access, taking account of relevant general hazards, such as:

- working at height;
- hot surfaces;
- poor visibility;
- awkward reaches.

36 To reduce risks to other people besides the operator further, install the autoclave so its door/lid faces away from main thoroughfares wherever possible.

37 Position controls for the autoclave so they are remote from potential energy release created from failure of the door and from pressure relief, blowdown or drain outlets.

38 Situate the outlets remotely or install additional pipework to the discharge from these devices, to a place where it will not be a hazard.

39 Where trolleys are used to load product into the autoclave, avoid using pedestrian access platforms for this purpose. Provide dedicated trolleys and rails strong enough to support the product's weight. In all circumstances, do not exceed the maximum load of the trolley, rails and access platforms.

## **Instruction and training**

40 The training and instruction given to operators should cover all the procedures and information they need to operate the system safely. It should also cover any special procedures to follow in an emergency. You also need to give existing staff regular refresher training.

41 Do not allow anyone to enter the confined space of an autoclave, unless you have assessed the risks to health and safety, put a suitable safe system of work in place and provided training in confined space entry for the people involved. There is further information on work in confined spaces in the HSE leaflet *Safe work in confined spaces*.<sup>3</sup>

42 Supervisors are crucial in making sure operators follow agreed safe systems of work. They also need to be competent to carry out their duties effectively and may themselves require refresher training, if there are changes to the way you work.

## **Thorough examination**

43 A competent person should examine autoclaves containing a 'relevant fluid' (as defined under PSSR), periodically, under a Written Scheme of Examination (WSE).

44 Under PSSR, it is the autoclave user's responsibility to make sure the WSE is prepared and in place before the autoclave is put into use. The WSE should include:

- those parts of a system that must be formally examined;
- the nature of examination required;
- details of any preparatory work required;
- the maximum interval between examinations;
- details of those certifying the WSE and when it was completed.

See *Written schemes of examination: Pressure Systems Safety Regulations 2000* for more information.<sup>4</sup>

45 The autoclave user must provide information, such as operating and maintenance records, to enable the competent person to establish how the autoclave is being used and target their examination accordingly.

46 You should adopt a similar regime of examination under PUWER for vessels containing a non-relevant fluid.

## **Maintenance and inspection**

47 Do not confuse the need for maintenance with the requirement for thorough examination under the written scheme. They are two separate issues, although problems identified during an examination under the WSE may require maintenance to correct.

48 Under PSSR, the user must inform the competent person of any significant repairs or modifications to the system.

49 Make suitable and effective arrangements to make sure the autoclave is properly maintained. Where the manufacturer or supplier has provided maintenance instructions for all or part of the system, these will form the basis of the maintenance programme. If they are not comprehensive enough to cover the on-site operating conditions, they should be supplemented as appropriate. Paragraphs 50–57 explain the arrangements you need to include.

50 You need planned preventive maintenance on the autoclave system, carried out at regular intervals by an experienced person, properly trained and competent to recognise defects.

51 There should be an appropriate monitoring scheme to keep all safety-critical parts of the autoclave, including all those where a single component failure can lead to danger, in efficient working order. This will normally include daily (or shift) checks to ensure that all the critical safety devices are working effectively, carried out by operators who have had the necessary training.

52 Keep a comprehensive maintenance history, with suitable and sufficient records of maintenance inspections, tests, faults, repairs and modifications to help identify and address problems before they develop and to inform the competent person of any significant repairs or modifications to the system.

53 Take appropriate actions arising from problems identified during operation of the system and assessed for their impact on the safety of the system. For example: make frequent checks in processes where accumulations of deposits of process waste materials may cause protective devices and other safeguards to become ineffective. This applies particularly to door interlock devices, tap-in points and vent lines.

54 Where the vent line requires regular rodding to clear the build-up of detritus:

- you need to provide safe access to the rodding point; and
- the rod should be long enough to clear the bore through to the autoclave chamber.

55 Make sure that door-locking assemblies are in good working order, regularly check that all securing bolts are tight, welds are not cracked and that the tightening mechanism (eg wedge or castellations) is to the correct tolerance. It is widely believed that vibration causes bolt loosening (referred to as self-loosening). In such applications, use a suitable thread locking device (also referred to as free spinning, friction locking, or chemical locking devices) to prevent self-loosening.

56 On three-part door-locking assemblies, the rotating ring is a safety critical part (as it is a single component used to retain the door against the vessel rim). You must target maintenance to ensure the ongoing integrity of this connection. Dimension checks, in combination with close visual inspection, should form part of periodic inspection, to make sure that the ring is not running eccentrically.

57 Ensure that door assemblies are adequately greased. Consult the manufacturer about any particular recommendations, eg use of high-temperature grease to the injection points and manually applying graphite paste to the door seal face.

## **References**

- 1 *PUWER 1998: Provision and Use of Work Equipment Regulations 1998. Open learning guidance* (Second edition) HSE Books 2008 ISBN 978 0 7176 6285 2
- 2 *Safety of pressure systems. Pressure Systems Safety Regulations 2000. Approved Code of Practice L122* HSE Books 2000 ISBN 978 0 7176 1767 8 [www.hse.gov.uk/pubns/books/l122.htm](http://www.hse.gov.uk/pubns/books/l122.htm)
- 3 *Safe work in confined spaces* Leaflet INDG258 HSE Books 1997 (Priced pack ISBN 978 0 7176 1442 4) [www.hse.gov.uk/pubns/indg258.pdf](http://www.hse.gov.uk/pubns/indg258.pdf)
- 4 *Written schemes of examination: Pressure Systems Safety Regulations 2000* Leaflet INDG178(rev1) HSE Books 2002 (Priced pack ISBN 978 0 7176 2269 6) [www.hse.gov.uk/pubns/indg178.htm](http://www.hse.gov.uk/pubns/indg178.htm)

## Further reading

HSE's pressure systems web pages: [www.hse.gov.uk/pressure-systems/index.htm](http://www.hse.gov.uk/pressure-systems/index.htm)

## Further information

For information about health and safety, or to report inconsistencies or inaccuracies in this guidance, visit [www.hse.gov.uk/](http://www.hse.gov.uk/). You can view HSE guidance online and order priced publications from the website. HSE priced publications are also available from bookshops.

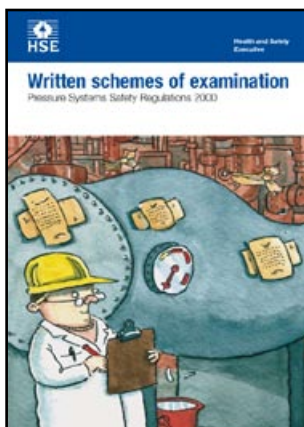
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# Written schemes of examination

## Pressure Systems Safety Regulations 2000



This is a web-friendly version of leaflet INDG178(rev2), published 11/12

**Under the Pressure Systems Safety Regulations 2000, users and owners of pressure systems are required to demonstrate that they know the safe operating limits (principally pressure and temperature) of their systems, and that they are safe under those conditions.**

**They need to ensure that a suitable written scheme of examination is in place before the system is operated. They also need to ensure that the system is actually examined in accordance with the written scheme of examination.**

**This publication complements the HSE leaflet *Pressure systems: A brief guide to safety*. It provides guidance on drafting written schemes of examination, but it cannot cover all relevant aspects of the Regulations. The 'Find out more' section at the end of the leaflet lists detailed guidance.**

### What is a written scheme of examination?

A written scheme of examination is a document containing information about selected items of plant or equipment which form a pressure system, operate under pressure and contain a 'relevant fluid'.

The term relevant fluid is defined in the Regulations and covers compressed or liquefied gas, including air, at a pressure greater than 0.5 bar (approximately 7 psi) above atmospheric pressure; pressurised hot water above 110 °C; and steam at any pressure. Typical contents of a written scheme of examination include:

- identification of the items of plant or equipment within the system;
- those parts of the system which are to be examined;
- the nature of the examination required, including the inspection and testing to be carried out on any protective devices;
- the preparatory work needed for the item to be examined safely;
- where appropriate, the nature of any examination needed before the system is first used;
- the maximum interval between examinations;
- the critical parts of the system which, if modified or repaired, should be examined by a competent person before the system is used again;
- the name of the competent person certifying the written scheme of examination; and
- the date of certification.

## How do I draw up a written scheme of examination?

First, look around your workplace and decide which items of plant or equipment operate under pressure and form a pressure system.

Next, follow the steps described in the HSE leaflet *Pressure systems: A brief guide to safety* (see the 'Find out more' section at the end of the leaflet).

Then check the exceptions to the Regulations, as you may find your particular pressure system does not require a written scheme of examination at all. For example, you don't normally need to include the compressor associated with an air receiver in the scheme of examination.

To see if any of your plant or equipment is an exception under the Regulations, the best place to look first is *Safety of pressure systems. Pressure Systems Safety Regulations 2000. Approved Code of Practice* (see 'Find out more' for details).

## Which items of plant should I include in the written scheme of examination?

An item of plant from the pressure system should be included in a written scheme of examination if its failure could unintentionally release pressure from the system and the resulting release of stored energy could cause injury.

Each system is likely to be unique, but the following questions may help users to arrive at some decisions:

- Do the manufacturers of the plant or equipment forming the pressure system give guidance, instruction and the precautions to take for safe operation of the system?
- Could failure of any part of the pressure system cause someone in the vicinity to be injured by the release of pressure, fragments or steam?
- Does the pressure system contain any protective devices?

If the answer to any of these questions is 'Yes', then those items of plant may need to be included in the written scheme of examination.

## What types of typical pressurised systems might require a written scheme of examination?

The following pressurised systems are likely to require a written scheme of examination:

- a compressed air receiver and the associated pipework, where the product of the pressure in bars multiplied by the internal capacity in litres of the receiver is equal to or greater than 250 bar litres;
- a steam sterilising autoclave and associated pipework and protective devices;
- a steam boiler and associated pipework and protective devices;
- a pressure cooker;
- a gas-loaded hydraulic accumulator;
- a vapour compression refrigeration system where the installed power exceeds 25 kW;
- a narrow-gauge steam locomotive;
- the components of self-contained breathing apparatus sets (excluding the gas container); and
- a fixed liquefied petroleum gas (LPG) storage system, supplying fuel for heating in a workplace.

The following pressurised systems are exempted from the Regulations and will not require a written scheme of examination:

- a machine tool hydraulic system;
- any pipeline and its protective devices in which the pressure does not exceed 2 bar above atmospheric pressure;
- a portable fire extinguisher with a working pressure below 25 bar at 60 °C and having a total mass of no more than 23 kg; and
- a tyre used on a vehicle.

The following pressurised systems are not likely to require a written scheme of examination:

- an office hot water urn (for making tea etc);
- a pneumatic cylinder in a compressed air system;
- a handheld tool;
- a combustion engine cooling system;
- a portable compressed air receiver and the associated pipework, where the product of the pressure in bars multiplied by the internal capacity in litres of the receiver is less than 250 bar litres; and
- a portable LPG cylinder.

These are typical examples for guidance purposes only. You must decide whether your pressurised system is covered by the Regulations in practice.

### **Do I need written schemes of examination for portable gas welding sets?**

A written scheme of examination is not required for the following:

- regulators;
- pressure gauges;
- hoses;
- torches; and
- other components that form part of conventional gas welding sets (portable, twin cylinder, oxyacetylene or oxypropane sets used for welding, cutting and burning).

### **Who decides which items of plant are included in the written scheme of examination?**

Users of pressure equipment which is not mobile, or owners of mobile systems (eg hired pressure plant), have a legal responsibility to define the items of plant that form a pressure system and, within that system, the items of plant which need to be included in the written scheme of examination.

To arrive at a properly informed decision, users or owners may need to seek advice from other sources, such as in-house engineering staff, inspection bodies or consultants, but the legal responsibility for defining the scope of the scheme rests with users or owners.

The written scheme should generally cover all items within a self-contained pressurised system which may give rise to danger. If you have more than one self-contained pressure system, you will probably need more than one written scheme, ie one system, one scheme.

## What happens when the scope of the written scheme has been decided?

The user or owner of the pressure system should:

- contact a person with sufficient knowledge and expertise about the system, ie one who is capable of offering informed advice on the subject;
- discuss the scope of the written scheme with them; and
- if necessary, modify the scope accordingly.

The written scheme of examination should then be submitted to a competent person (as defined in the Regulations), who may or may not be the same competent person who advised the user or owner on the scope of the written scheme.

The competent person will normally advise on the nature and frequency of examination and any special safety measures necessary to prepare the system for examination. If requested by the user, the competent person may draw up a suitable written scheme of examination, or they may certify a written scheme of examination, prepared by the user or owner, as being suitable.

## Which competent person should I choose?

Guidance on the selection of competent persons is given in the HSE publications *Pressure systems: A brief guide to safety* and *Safety of pressure systems. Pressure Systems Safety Regulations 2000. Approved Code of Practice* (see 'Find out more' at the end of this leaflet).

Users (or owners) of pressure systems are free to select any competent person, but they should take all reasonable steps to ensure that the person selected can actually demonstrate competence, ie the necessary breadth of knowledge, experience and independence.

To help users or owners judge levels of competence, a national accreditation scheme has been developed by the United Kingdom Accreditation Service (UKAS) for bodies that provide such services. Further details are given in 'Find out more'.

## Does the written scheme of examination need to be reviewed periodically?

It must be 'suitable' throughout the lifetime of the plant or equipment, so it should be reviewed and, when necessary, revised. For example, as the age of some plant increases you may need to carry out more frequent examinations or change their content or type.

It is the user's responsibility under the Regulations to ensure the content of the written scheme is reviewed at appropriate intervals by a competent person to determine whether it remains suitable, but clearly the competent person should be in a position to give advice on this aspect.

## What should I do next?

The users and owners of pressure systems covered by a written scheme of examination have a legal responsibility to ensure that those systems are examined by a competent person in accordance with the scheme.

## **Find out more**

*Safety of pressure systems. Pressure Systems Safety Regulations 2000.  
Approved Code of Practice L122* HSE Books 2000 ISBN 978 0 7176 1767 8  
[www.hse.gov.uk/pubns/books/l122.htm](http://www.hse.gov.uk/pubns/books/l122.htm)

*Pressure systems at work: A brief guide to safety* Leaflet INDG261(rev2)  
HSE Books 2012 [www.hse.gov.uk/pubns/indg261.htm](http://www.hse.gov.uk/pubns/indg261.htm)

The Pressure Systems Safety Regulations 2000 SI 2000/128  
The Stationery Office 2000 ISBN 978 0 11 085836 4

## **The Stationery Office publications**

Available from The Stationery Office, PO Box 29, Norwich NR3 1GN  
Tel: 0870 600 5522 Fax: 0870 600 5533 email: [customer.services@tso.co.uk](mailto:customer.services@tso.co.uk)  
Website: [www.tsoshop.co.uk/](http://www.tsoshop.co.uk/) (They are also available from bookshops.) Statutory  
Instruments can be viewed free of charge at [www.legislation.gov.uk/](http://www.legislation.gov.uk/).

## **UKAS**

For advice on bodies with relevant accreditation for providing competent persons:  
UKAS, 2147 High Street, Feltham, Middlesex, TW13 4UN Tel: 020 8917 8400  
Website: [www.ukas.com](http://www.ukas.com)

## **Further information**

For information about health and safety, or to report inconsistencies or inaccuracies in this guidance, visit [www.hse.gov.uk/](http://www.hse.gov.uk/). You can view HSE guidance online and order priced publications from the website. HSE priced publications are also available from bookshops.

This guidance is issued by the Health and Safety Executive. Following the guidance is not compulsory, unless specifically stated, and you are free to take other action. But if you do follow the guidance you will normally be doing enough to comply with the law. Health and safety inspectors seek to secure compliance with the law and may refer to this guidance.

This leaflet is available at: [www.hse.gov.uk/pubns/indg178.htm](http://www.hse.gov.uk/pubns/indg178.htm).

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# Pressure systems

## A brief guide to safety



This is a web-friendly version of leaflet INDG261(rev2), published 11/12

### Introduction

If pressure equipment fails in use, it can seriously injure or kill people nearby and cause serious damage to property.

This leaflet describes what employers need to do to minimise the risks when working with systems or equipment which contain a liquid or gas under pressure. It will also be useful to employees and their safety representatives.

As an employer or self-employed person, you have a duty to provide a safe workplace and safe work equipment. Designers, manufacturers, suppliers, installers, users and owners also have duties.

The leaflet does not cover gas cylinders (now called transportable pressure receptacles or transportable pressure vessels), or tanks and tank containers.

The main regulations covering pressure equipment and pressure systems are the Pressure Equipment Regulations 1999 and the Pressure Systems Safety Regulations 2000.

Employers have a further duty to consult any safety or employee representatives on health and safety matters. Where none are appointed, employers should consult the workforce direct.

Examples of pressure systems and equipment are:

- boilers and steam heating systems;
- pressurised process plant and piping;
- compressed air systems (fixed and portable);
- pressure cookers, autoclaves and retorts;
- heat exchangers and refrigeration plant;
- valves, steam traps and filters;
- pipework and hoses; and
- pressure gauges and level indicators.

Principal causes of incidents are:

- poor equipment and/or system design;
- poor maintenance of equipment;
- an unsafe system of work;
- operator error, poor training/supervision;
- poor installation; and
- inadequate repairs or modifications.

The main hazards are:

- impact from the blast of an explosion or release of compressed liquid or gas;
- impact from parts of equipment that fail or any flying debris;
- contact with released liquid or gas, such as steam; and
- fire resulting from the escape of flammable liquids or gases.

### **Reduce the risk of failure**

The level of risk from the failure of pressure systems and equipment depends on a number of factors including:

- the pressure in the system;
- the type of liquid or gas and its properties;
- the suitability of the equipment and pipework that contains it;
- the age and condition of the equipment;
- the complexity and control of its operation;
- the prevailing conditions (eg a process carried out at high temperature); and
- the skills and knowledge of the people who design, manufacture, install, maintain, test and operate the pressure equipment and systems.

To reduce the risks you need to know (and act on) some basic precautions, some of which are contained in the Pressure Systems Safety Regulations 2000 and the Pressure Equipment Regulations 1999.

### ***Provide safe and suitable equipment***

- When installing new equipment, ensure that it is suitable for its intended purpose and that it is installed correctly. This requirement can normally be met by using the appropriate design, construction and installation standards and/or codes of practice. Since 2002, most pressure equipment placed on the market has had to meet the requirements of the Pressure Equipment Regulations 1999. For pressure equipment not covered by the Pressure Equipment Regulations 1999, the more general requirements of the Pressure Systems Safety Regulations 2000 apply.
- The pressure system should be designed and manufactured from suitable materials. You should make sure that the vessel, pipes and valves have been made of suitable materials for the liquids or gases they will contain.
- Ensure the system can be operated safely – without having to climb or struggle through gaps in pipework or structures, for example.
- Be careful when repairing or modifying a pressure system. Following a major repair and/or modification, you may need to have the whole system re-examined before allowing the system to come back into use.

### ***Know the operating conditions***

- Know what liquid or gas is being contained, stored or processed, for example is it toxic/flammable?
- Know the process conditions, such as the pressures and temperatures.
- Know the safe operating limits of the system and any equipment directly linked to it or affected by it.
- Ensure there is a set of operating instructions for all the equipment and for the control of the whole system including emergencies.
- Ensure that appropriate employees have access to these instructions, and are properly trained in the operation and use of the equipment or system (see the section on training below).

***Fit suitable protective devices and ensure they function properly***

- Ensure suitable protective devices are fitted to the vessels, or pipework (eg safety valves and any electronic devices which cause shutdown when the pressure, temperature or liquid or gas level exceed permissible limits).
- Ensure the protective devices have been adjusted to the correct settings.
- If warning devices are fitted, ensure they are noticeable, either by sight or sound.
- Ensure protective devices are kept in good working order at all times.
- Ensure that, where fitted, protective devices such as safety valves and bursting discs discharge to a safe place.
- Ensure that, once set, protective devices cannot be altered except by an authorised person.

***Carry out suitable maintenance***

- All pressure equipment and systems should be properly maintained. There should be a maintenance programme for the system as a whole. It should take into account the system and equipment age, its uses and the environment.
- Look for tell-tale signs of problems with the system, eg if a safety valve repeatedly discharges this could be an indication that either the system is over-pressurising or the safety valve is not working correctly.
- Look for signs of wear and corrosion.
- Systems should be depressurised before maintenance work is carried out.
- Ensure there is a safe system of work, so that maintenance work is carried out properly and under suitable supervision.

Further guidance on regulation 11 (Operation) and regulation 12 (Maintenance) of the Pressure Systems Safety Regulations 2000 is given in the Approved Code of Practice *Safety of pressure systems*. (See 'Find out more'.)

***Make provision for appropriate training***

Everybody operating, installing, maintaining, repairing, inspecting and testing pressure equipment should have the necessary skills and knowledge to carry out their job safely – so you need to provide suitable training. This includes all new employees, who should have initial training and be supervised closely.

Additional training or retraining may be required if:

- the job changes;
- the equipment or operation changes; or
- skills have not been used for a while.

***Have the equipment examined***

Under the Pressure Systems Safety Regulations 2000, a written scheme of examination is required for most pressure systems. Exempted systems are listed in the Regulations. Generally speaking, only very small systems are exempted.

- The written scheme should be drawn up (or certified as suitable) by a competent person. It is the duty of the user of an installed system and the owner of a mobile system to ensure that the scheme has been drawn up. You must not allow your pressure system to be operated (or hired out) until you have a written scheme of examination and ensured that the system has been examined.

- The written scheme of examination must cover all protective devices. It must also include every pressure vessel and those parts of pipelines and pipework which, if they fail, may give rise to danger.
- The written scheme must specify the nature and frequency of examinations, and include any special measures that may be needed to prepare a system for a safe examination.
- The pressure system must be examined in accordance with the written scheme by a competent person.
- For fired (heated) pressure systems, such as steam boilers, the written scheme should include an examination of the system when it is cold and stripped down and when it is running under normal conditions.

The key steps are:

- Decide what items of equipment and parts of the plant should be included in the scheme. This must include all protective devices. It must also include pressure vessels, and parts of pipework, which if they failed could give rise to danger.
- The scheme must be drawn up (or certified as suitable) by a competent person. It must specify whether the examination is in-service or out-of-service and how often the system is to be examined.
- The system must be examined by a competent person in accordance with that scheme.

Remember, an examination undertaken in accordance with a written scheme of examination is like an MOT for your car. It is a statutory examination that is designed to ensure that your pressure system is 'roadworthy'. It is not a substitute for regular and routine maintenance.

### ***Choose a competent person***

- You must assure yourself that the competent person has the necessary knowledge, experience and independence to undertake the functions required of them.
- The competent person carrying out examinations under a written scheme does not necessarily need to be the same one who prepares or certifies the scheme as suitable.

A competent person may be:

- a company's own in-house inspection department;
- an individual person (eg a self-employed person); or
- an organisation providing independent inspection services.

Bodies that have United Kingdom Accreditation Service ([www.ukas.com/](http://www.ukas.com/)) accreditation to the British, European and international standard BS EN ISO/IEC 17020: 2004, for the scope of in-service inspection of pressure equipment, can provide competent persons meeting the appropriate criteria.

The competent person undertaking an examination of a pressure system in accordance with the written scheme of examination takes the responsibility for all aspects of the examination.

For example, on systems where ancillary examination techniques (eg non-destructive testing) are undertaken, the competent person must assume responsibility for the results of these tests and their interpretation even though the tests may have been carried out by someone else.

## Find out more

For further practical advice see the 'Pressure systems' web pages at [www.hse.gov.uk/pressure-systems/index.htm](http://www.hse.gov.uk/pressure-systems/index.htm) or the following publications:

*Safety of pressure systems: Pressure Systems Safety Regulations 2000. Approved Code of Practice L122* HSE Books 2000 ISBN 978 0 7176 1767 8  
[www.hse.gov.uk/pubns/books/L122.htm](http://www.hse.gov.uk/pubns/books/L122.htm)

*Written schemes of examination: Pressure Systems Safety Regulations 2000* Leaflet INDG178(rev2) HSE Books 2012 [www.hse.gov.uk/pubns/INDG178.htm](http://www.hse.gov.uk/pubns/INDG178.htm)

*Pressure Equipment Regulations 1999* (SI 1999/2001) The Stationery Office (as amended) [www.legislation.gov.uk/](http://www.legislation.gov.uk/)

*Pressure Systems Safety Regulations 2000* (SI 2000/128) The Stationery Office [www.legislation.gov.uk/](http://www.legislation.gov.uk/)

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(They are also available from bookshops.) Statutory Instruments can be viewed free of charge at: [www.legislation.gov.uk/](http://www.legislation.gov.uk/).

## Further information

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## Rodwell AUTOCLAVE Products

For use in monitoring steam sterilisation processes.



### Bowie & Dick Tests

A Bowie & Dick test is a test for steam penetration in dynamic air removal steam sterilisers. A daily steam penetration test should be run in every autoclave. The colour of the indicator test sheet changes from Blue to Pink which will confirm that the steam penetration has been effective up to the centre of the sterilisation pack.

B&D test Steam: 134°C, 3,5min.  
Conforms to EN-867-4, ISO 11140-1, class 2  
**Catalogue No. AC980** (Case of 20)

### Chemical Indicators

Chemical Process Indicators are self-adhesive labels suitable for application on various types of autoclave load. The label colour indicates at a glance whether or not the product has gone through the sterilisation process, making it easy for sterilisation facilities to ensure that products have been exposed to the sterilisation process. Labels turn from blue to pink after exposure to 121°C for 3-10 mins, or 134°C for 0.5—2 mins.

**Catalogue No. AC986**



### Biological Indicators



Fast and no fuss. Excelsior Scientific offers regular biological indicators as well as self contained biological indicators. Simply place the SCBI into the autoclave, remove after cycle end, crush the cap (or squeeze the side for Mini SCBIs) and incubate for 24 hours. A negative result ensures the micro-organism within has been destroyed and guarantees sterility of the process.

**Catalogue No. AC982 (Regular), AC984 (Mini)**  
**Catalogue No. AC983 (Glass Ampoules)**



ISO 11140-1 Class 4

### Reference:

Acceptable if indicating square is equal to or darker in color than reference arrow

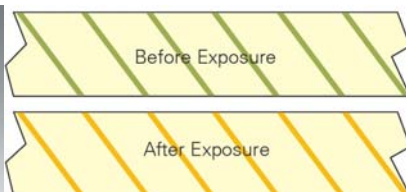


### Autoclave TST Strips:

The TST (Time, Steam and Temperature) Steriliser Control is the most sophisticated Chemical device produced, being an

integrated control system that registers a Pass only when it has been subjected to the required heat and time ratio in saturated heat steam. when exposed to steam for 15 minutes at 121°C. Can be placed throughout the load for thorough checking.

**Catalogue No. AC981**



### Autoclave Tape

White adhesive tape, for use in standard autoclaves. Transitions from green to Orange after 15 mins at 121° C. Provides clean removal from autoclaved object. Can be written on. Tape Size: 18mm x 55m,

**Catalogue No. AC985**

For Further information please contact The Rodwell Autoclave Company.



The Rodwell Autoclave Company, Bentalls, Pipp's Hill Industrial Estate, Basildon, Essex SS14 3SD, United Kingdom  
Tel: +44 (0)1268 286646 Fax: +44 (0)1268 287799  
E-mail: [autoclavesales@rodwellgroup.co.uk](mailto:autoclavesales@rodwellgroup.co.uk)  
Site: [www.rodwell-autoclave.com](http://www.rodwell-autoclave.com)

## Rodwell AUTOCLAVE Products Cleaning products



An abrasive pad designed to help remove stubborn stains from the Autoclave chamber and other stainless steel parts

**Catalogue No. 891-0043**



A medium grit rubbing block for removing localised stains from the chamber and other stainless steel parts

**Catalogue No.891-0044**

For Further information please contact The Rodwell Autoclave Company.



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Site: [www.rodwell-autoclave.com](http://www.rodwell-autoclave.com)