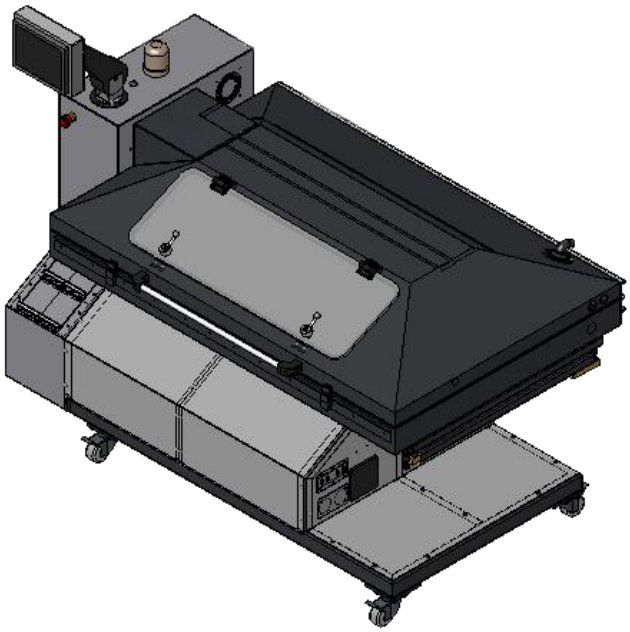
GE Healthcare

WAVE Bioreactor System 200EH

Safety Handbook



WAVE™
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Important user information

All users must read this entire manual to fully understand the safe use of WAVE Bioreactor System 200EH.

Important!

WAVE Bioreactor System 200EH is intended for research use only, and should not be used in any clinical or in vitro procedures for diagnostic purposes.

Safety notices

This manual contains warnings and cautions concerning the safe use of the product. See definitions below.

WARNING! The WARNING symbol and notice highlight instructions that must be followed to avoid personal injury. Do not proceed until all stated conditions are clearly understood and met.

CAUTION! The CAUTION notice highlights instructions that must be followed to avoid damage to the product or other equipment. Do not proceed until all stated conditions are met and clearly understood.

***Note**: A Note is used to indicate information that is Important for trouble-free and optimal use of the product.*

Recycling

This symbol indicates that the waste of electrical and electronic equipment must not be disposed as unsorted municipal waste and must be collected separately. Please contact an authorized representative of the manufacturer for information concerning the decommissioning of equipment.

WARNING! This is a Class A product. In a domestic environment, it might cause radio interference, in which case the user might be required to take appropriate measures.

WARNING! All repairs should be done by personnel authorized by GE Healthcare. Do not open any covers or replace parts unless specifically stated in instructions.

CE-certification

This product complies with the European directives listed below, by fulfilling corresponding standards. A copy of the Declaration of Conformity is available on request.

- 2006/95/EC, Low Voltage Directive
- 2004/108/EC, EMC, Electromagnetic Compatibility Directive

The **CE** symbol and corresponding declaration of conformity, is valid for the instrument when it is:

- used as a stand-alone unit, or
- connected to other CE-marked GE Healthcare instruments, or
- connected to other products recommended or described in this manual, and
- used in the same state as it was delivered from GE Healthcare except for alterations described in this manual.

***Note:** The Declaration of conformity is valid only for systems that are marked with the **CE**-logo:*

CE

Contents

1 Introduction

1.1 About the Safety instructions

The Safety instructions are valid for all variants of standard Wave Bioreactor™ System 200EH. The purpose of the Safety Instructions is to describe safety precautions and emergency procedures for the WAVE Bioreactor System 200EH. Note that the Safety Instructions only addresses items relating to safety issues and that for most parts is an excerpt from WAVE Bioreactor System 200EH User Manual. Please refer to the User Manual for information about the general handling and operation of the system.

If you have any questions or require further information, please contact your local GE Healthcare sales office or service department. Contact information is listed on the back cover of this book.

1.2 Associated documentation

Apart from the Safety Instructions additional, associated documentation is provided with the bioreactor. The system will be delivered with a full set of System Documentation. Table 1-1 describes the complete documentation.

Table 1-1. Associated documentation

Document	Contents
WAVE Bioreactor System 200EH Operator Manual	How to use the system, including concepts, methodology, operation, troubleshooting and maintenance. This document is also available as online help.
WAVE Bioreactor System 200EH Safety Handbook	Safety instructions that must be followed for use of WAVE Bioreactor System 200EH, in 6 languages: English, German, Spanish, French, Italian and Swedish.
WAVE Bioreactor System 200EH Maintenance Manual	Contains detailed troubleshooting methods, replacement procedures and spare part lists.

2 Safety precautions

The Safety handbook contains our recommendations about precautions and handling procedures for the WAVE Bioreactor System 200EH from GE Healthcare Wave Biotech, especially for

- Transport and Installation
- Setting up the System
- Operation
- Troubleshooting
- Maintenance and Service

These safety instructions are meant exclusively for the equipment as delivered. They are not valid for other equipment. However, the level of risk is highly dependent on the application and environment in which the bioreactor is operated. In order to secure the safe operation of the equipment a risk assessment must be made. This risk assessment, in combination with local regulations and policies, will result in specific safety instructions for installation, operation and maintenance, use of proper personal protective equipment, or other arrangements that are needed to operate your process safely. The warnings required and cautions in this Safety Handbook shall in no way in your facility take precedence over more restrictive local regulations and policies.

2.1 Personal protection

For your personal safety it is important that you have a proper knowledge of the entire system that the bioreactor is part of. Study any complementary safety instructions and use appropriate personal protection equipment for the specific application and operation environment.

During the operation and during other work with the bioreactor, it is always each individual operator's responsibility to consider:

- Their own and other's personal safety
- The safety of the equipment through correct use in accordance with the descriptions and instructions given in this Safety Handbook and other parts of the System Documentation.

IMPORTANT! Always keep the Safety Handbook on hand when using the bioreactor.

2.1.1 Miscellaneous warnings

WARNING! This is a class A product, input power > 1kW, intended for Professional use. In a domestic environment it may cause radio interference, in which case the user might be required to take appropriate measures.

Note: This device complies with FCC part 15 (2004): radiofrequency device subpart B: Unintentional radiators, Class A. operation is subject to the following two conditions:

1. *This device may not cause harmful interference.*
2. *This device must accept any interference received, including interference that may cause undesired operation.*

WARNING! The end user must ensure that all installation, maintenance, operation and inspection is carried out by qualified personnel who are adequately trained, understand and adhere to local regulations and the operating instructions and have a thorough knowledge of the entire system and process.

WARNING! The bioreactors should not be used for any application other than specified by the manufacturer.

WARNING! Only WAVE approved Cell Culture Bags shall be used on this equipment.

WARNING! The bioreactors are not designed to handle flammable fluids.
The bioreactor is not approved for work in a potentially explosive atmosphere.

WARNING! Always use protective glasses and other personal protective equipment appropriate with the current application to ensure personal safety during operation.

WARNING! Inspect all connections and tubing before start and replace any defective parts.

WARNING! Ensure that all tubing, hoses and cables are placed so that the risk for tripping accidents is minimized.

WARNING! Remove any spillage on the floor immediately to minimize the risk for slipping accidents.

WARNING! Make sure no one enters the hazardous area while the system is operating with the rocker in motion.

WARNING! Ensure that no body parts are caught between the base enclosure and the tray while rocking.

CAUTION! Disconnect all tubing, hoses and cables before moving the base unit.

CAUTION! Base unit equipped with wheels must be leveled properly with the wheels removed before the system is used.

CAUTION! Only use chemicals that have been proven not to be harmful to the cellbag and the system.

3 Labels, indicators and controls

3.1 System labels

This section describes the labels on the WAVE Bioreactor System 200EH.

Labels for safety, product no., CE, and rating are located on the rear panel.

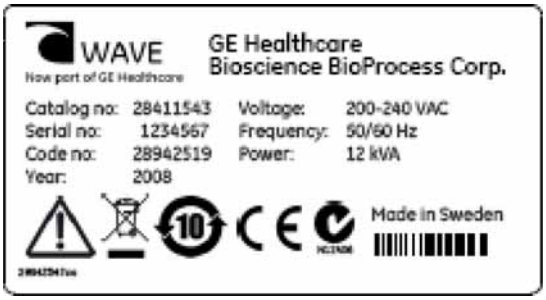
A system no. label is located on the marking plate.

The safety label warns the user of risk to personal injury. Do not proceed until the instructions are clearly understood and all stated conditions are met.

System 200EH is labeled with the following information:

- Product Catalog Number
- Serial Number
- Code no.
- Line Power (Voltage required)
- Line Current Frequency
- Power Consumption
- Maximum limited Current (Fuse or breaker)
- Manufacturing Year

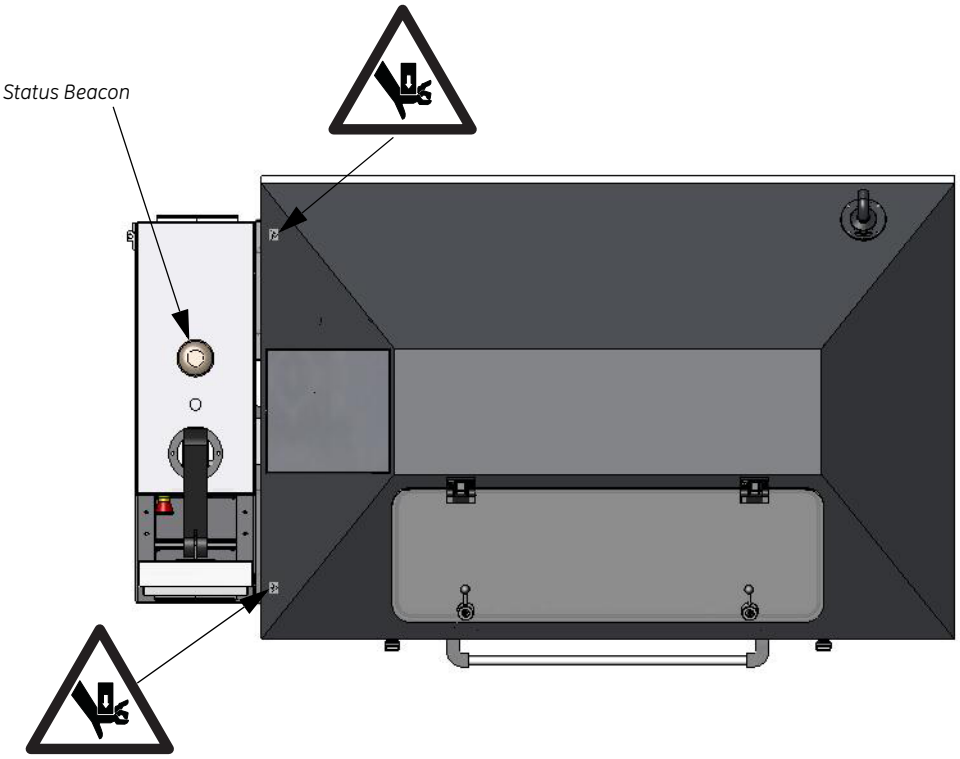
Fig 3-1. Safety label



3.2 Safety labels

Safety labels are located on the system as illustrated below. The labels warn the user of risk of personal injury.

Fig 3-2. WAVE Bioreactor System 200EH – top view



In Table 3-1, the safety labels are described. Make sure you fully understand the potential hazards indicated by the labels.

Table 3-1. Safety labels.

Label	Description
	Danger of pinch injury. This sign is located near the rocker.
	Read the user documentation before using the system. Do not open any covers or replace parts unless specifically stated in the user documentation.
	The system complies with the requirements for electromagnetic compliance (EMC) in Australia and New Zealand.
	This system meets all the essential requirements of applicable EU directives and applicable conformity assessment procedures have been applied.
	This symbol indicates a hazardous electrical potential exists and care must be exercised to prevent electrical shock.
	This symbol indicates the product contains hazardous materials in excess of the limits established by the Chinese standard SJ/T11363-2006 Requirements for Concentration Limits for Certain Hazardous Substances in Electronic Information Products. The number in the symbol is the Environment-friendly Use Period (EFUP), which indicates the period during which the toxic or hazardous substances or elements contained in electronic information products will not leak or mutate under normal operating conditions so that the use of such electronic information products will not result in any severe environmental pollution, any bodily injury or damage to any assets. The unit of the period is "Year".

3.3 Emergency stop

This section describes the emergency shutdown of the System 200EH.

3.3.1 Emergency shutdown

In a situation where there is risk of physical injury:

Step	Action
1	Press the **EMERGENCY STOP** switch. Pressing the switch will stop the rocking motion and remove power from the motor and heaters.

Step	Action
2	If required, switch off the power supply to the system by setting the main circuit breaker to the **OFF** (down) position. The main circuit breaker is located at the bottom right side of the rear panel.

3.4 Alarm settings

Alarms when they occur are displayed on the System Touch screen.

Two types of alarms are available. Critical alarms, such MOTOR OVERTEMP, TEMP PROBE FAIL and secondary alarms record deviations from the set point.

3.4.1 Beacon/audible alarm logic

The beacon alarm is a large, top mounted light on the control panel that changes color depending upon the type of alarm. Table 3-2 describes the various alarms.

Table 3-2. Alarms

Beacon	Audible buzzer	Alarm	Contact condition
Green	No sound	OFF	No alarms
Yellow steady	No sound	ON	Acknowledged alarms present
Red	Flashing sound	ON	Unacknowledged alarm
Red steady	No sound	ON	Silence pressed but not acknowledged

WARNING! Pressing the ***SILENCE AUDIBLE ALARM*** only stops the buzzer sound. It does not acknowledge the alarm condition. The beacon will turn from flashing red to steady red.

CAUTION! Press ***ACKNOWLEDGE ALL ALARMS*** to acknowledge the new alarms. The beacon will turn yellow to indicate that alarms still exist but have been acknowledged. If new alarms occur the beacon will flash red and the audible alarm will sound. If the acknowledged alarm condition no longer exists then the beacon will go green and the external alarm contact will turn off.

3.5 Product safety

International standards and regulatory conformance to CE.

The WAVE Bioreactor System 200EH complies with the International Standards for product safety according to WTO's TBT agreement.

IEC/UL/EN 61010:2001 safety requirements for electrical equipment for measurement control and laboratory use.

IEC/EN 61326-1:1997 Electrical equipment for measurement, control and laboratory use, EMC requirements.

The WAVE Bioreactor System 200EH complies with the harmonized standards (EN) according to the New and Global Approach for conformance with the European product safety directives.

The above mentioned harmonized standards are conformance to the LVD 2006/95/EC and EMC 2004/108/EC directive.

For the Machinery Directive 98/37EC following harmonized standards conform compliance.

EN ISO 12100-1:2003 Safety of machinery - Basic concepts, general principles for design - Part 1: Basic terminology, methodology.
EN ISO 12100-2:2003 Safety of machinery - Basic concepts, general principles for design Part 2: Technical principles and specifications.
EN ISO 14121-1 Safety of machinery - Risk assessment - Principles.

The system complies in accordance with ANSI/NFPA 70, National Electrical Code™ (NEC) and UL 61010-1; Canadian Electrical Code (CEC), Part I, CSA C22.1, and CSA C22.2 No. 0. FCC Part 15 Electromagnetic compatibility for the US and Canada.

Complies with the complementary test stated in IEC 61010-1 UL 61010-1 is similar with South Korean requirement.

The chosen International Standards result in a comprehensive liable framework in line with the Bioreactor business area.

4 Installation

Use the information from Appendix A in the WAVE Bioreactor System 200EH Operator manual.

4.1 Overall Dimensions

For specific measurements, see following overall drawings for Base 200.

Fig 4-1. Base 200 front dimensions

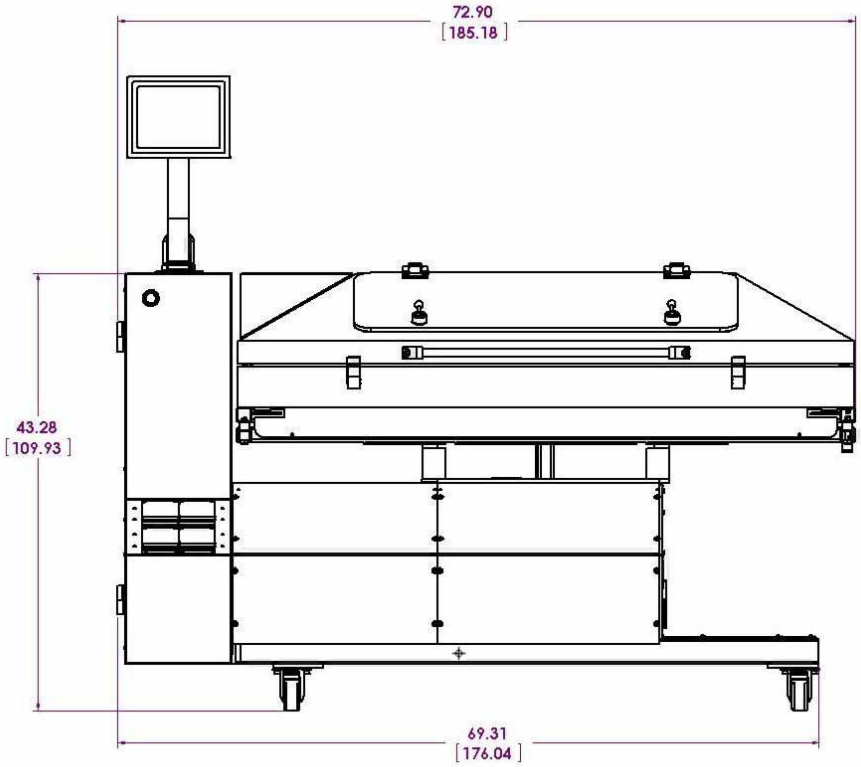
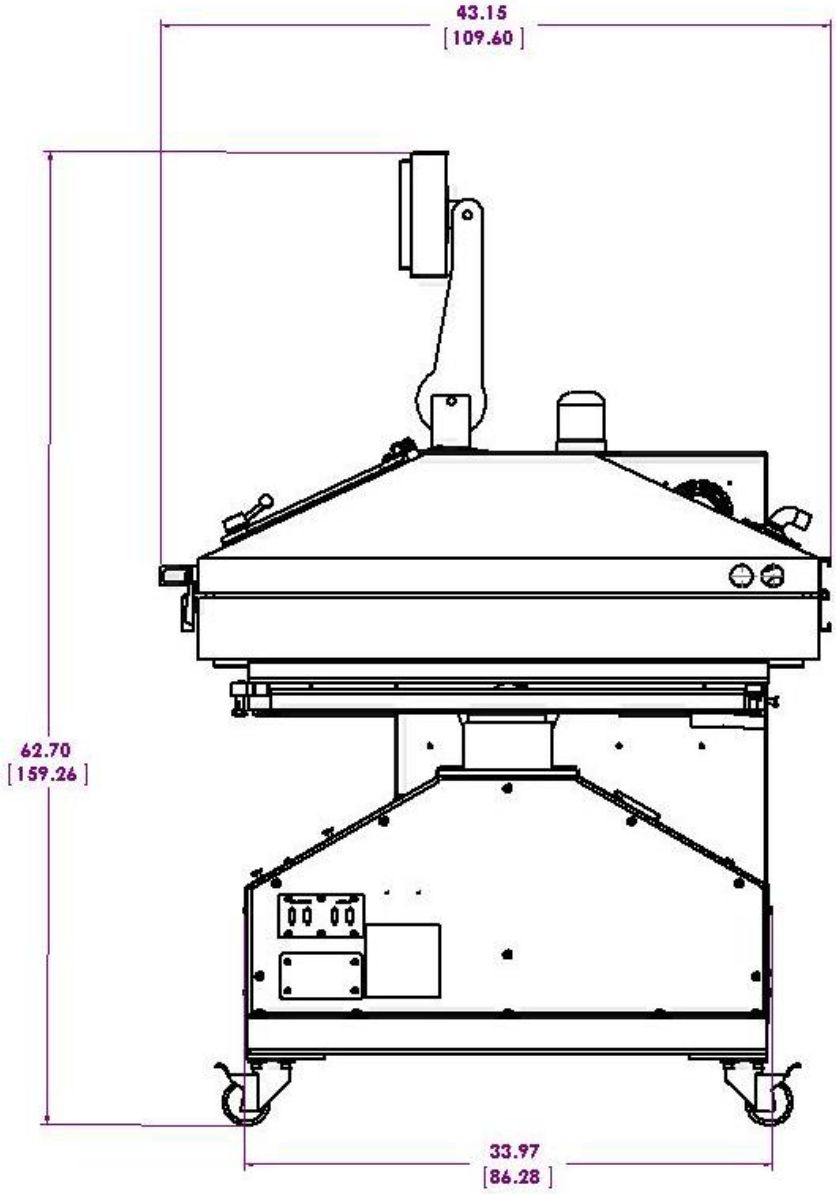


Fig 4-2. Base 200 side dimensions

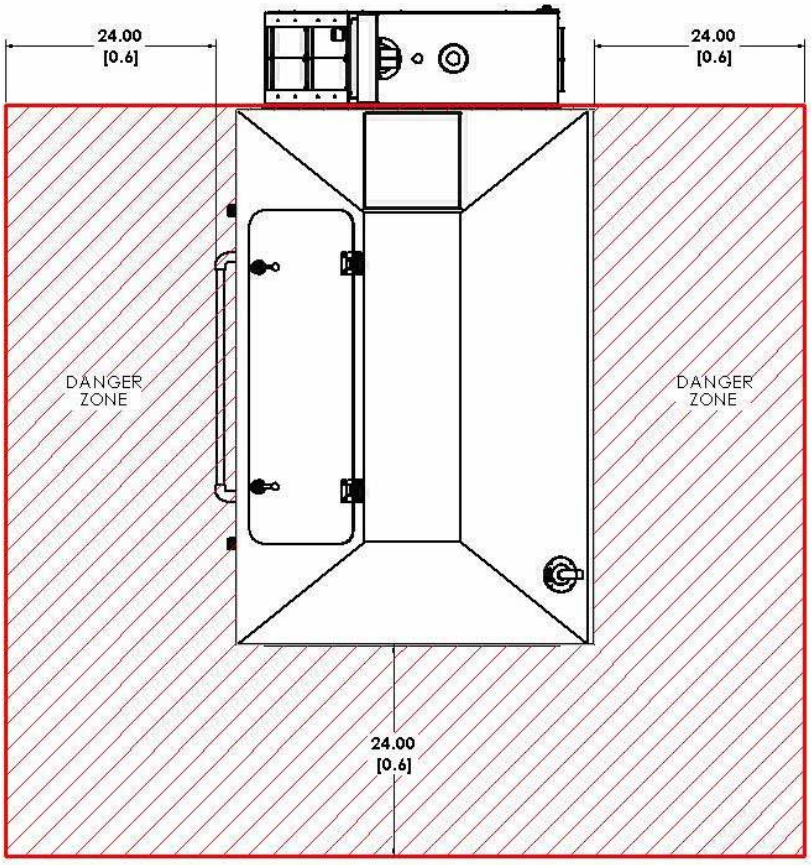


4.2 Working place requirements

- The weight of the WAVE Bioreactor System 200EH must not exceed the maximum load of the installation floor.
- There should be enough space left for easy access to the whole equipment, both for normal operation and maintenance and service operations. At least 0.6 m workspace around the base unit.
- Possible to isolate the working area of the fermentation plant from common areas.
- The danger zone should be kept clear of obstructions. Clean spills immediately to not cause a slip hazard which could lead to injury.

A Danger zone exists around the WAVE Bioreactor System 200EH. 0.6 meter, 24 inches from each side of the rocking tray and the area between the cabinet and the rocker.

Fig 4-3. Danger zone areas around the Bioreactor



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