INTEGRA Declaration of conformity

INTEGRA Biosciences AG – 7205 Zizers, Switzerland

declares on its own responsibility that the devices

<table>
<thead>
<tr>
<th>Description</th>
<th>Models</th>
</tr>
</thead>
<tbody>
<tr>
<td>FLAMEBOY</td>
<td>145000, 145003</td>
</tr>
</tbody>
</table>

comply with:

<table>
<thead>
<tr>
<th>EU Regulations</th>
<th>Scope</th>
<th>Date effective</th>
</tr>
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<tbody>
<tr>
<td>1907/2006</td>
<td>Registration, evaluation, authorisation and restriction of chemicals (REACH)</td>
<td>01.06.2007</td>
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</table>

<table>
<thead>
<tr>
<th>EU Standards</th>
<th>Scope</th>
</tr>
</thead>
<tbody>
<tr>
<td>EN 9001:2015</td>
<td>Quality Management</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>USA Regulations</th>
<th>Scope</th>
</tr>
</thead>
<tbody>
<tr>
<td>17 CFR Parts 240 &amp; 249b Dodd frank “Conflict minerals”</td>
<td></td>
</tr>
<tr>
<td>27 CCR Parts 25102-27001</td>
<td>Proposition 65: The safe drinking water and toxic enforcement act</td>
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</tbody>
</table>

Zizers, February 19, 2021

Urs Hartmann
CEO

Thomas Neher
Quality Manager

www.integra-biosciences.com
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Imprint

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These operating instructions have the part number 465051; the version is V06.

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Further information and other languages are available on www.integra-biosciences.com or on request (info@integra-biosciences.com).
1 Introduction

These operating instructions contain all information required for the commissioning, operation and maintenance of the flame-sterilizer FLAMEBOY. This chapter informs about the symbols used in these operation instructions, the intended use of the FLAMEBOY and the general safety instructions.

1.1 Symbols used

The operating instructions specifically advise of residual risks with the following symbols:

- **WARNING**
  This safety symbol warns against hazards that could result in injury or death. It also indicates hazards for machinery, materials and the environment. It is essential that you follow the corresponding precautions.

- **CAUTION**
  This symbol cautions against potential material damage. Follow the instructions.

- **NOTE**
  This symbol identifies important notes regarding the correct operation of the device and labor-saving features.

1.2 Intended use

The FLAMEBOY is a portable, hand-held and automatic laboratory flame burner for propane/butane, natural- or town gas. It provides piezo-electric ignition at the push of a button. It is intended for laboratory use. Any use of this instrument in a medical or IVD setting is under the sole responsibility of the user.

The FLAMEBOY is used for surface sterilization. It is especially convenient for sterilizing contamination-prone ports or contacts, drying wet surfaces of bioreactors or fermenters, or for heating up objects. If FLAMEBOY is used in a manner not specified by INTEGRA, the protection provided by the FLAMEBOY may be impaired.
1.3 Safety notes

1.3.1 Operation of the FLAMEBOY

The FLAMEBOY corresponds to state of the art, complies to the recognized safety regulations and is safe to operate. The FLAMEBOY may be operated only in flawless condition while observing these operating instructions. The device may be associated with residual risks if it is used or operated improperly by untrained personnel.

Any person charged with the operation of the FLAMEBOY must have read and understood these operating instructions, and particularly, the safety notes, or must have been instructed by the supervisors so that safe operation of the device is guaranteed. Regardless of the listed safety notes, additionally applicable regulations and guidelines of trade associations, health authorities, trade supervisory offices, etc. must be observed.

Please visit our website www.integra-biosciences.com on a regular basis for up to date information regarding REACH classified chemicals contained in our products.

1.3.2 General safety notes

FLAMEBOY may not be altered in design or in any of its safety aspects. If alterations are made, INTEGRA Biosciences will be relieved from all liability for any resulting damage.

- Do not carry out any conversions and alterations on the device.
- Defective parts may only be replaced with original INTEGRA Biosciences spare parts.
- Do not open the FLAMEBOY. Repairs may only be performed by INTEGRA Biosciences or an authorized after-sales service member.
- The device may be operated only under constant supervision.
- Always wear protective goggles when working with the FLAMEBOY.
- Work only in well ventilated areas.
- Do not use the FLAMEBOY near inflammable material or in explosive areas.
- Use only approved and tested safety gas tubing with threaded or hose connectors and inspect the device regularly for damage.
- Firmly tighten all gas connections and verify gas tightness using test equipment.
- Never remove the gas cartridge adapter while it is connected to the gas cartridge.

The gas supply must be closed off when:
- the device is being transported or installed
- the gas adapter for gas hose is being changed
- extended breaks are taken and after the work has been completed
- cleaning and repair work is being performed
2 Description of the device

2.1 Scope of delivery

Part No. 145 000:
- FLAMEBOY device
- Adapter for standard gas hose with inner diameter 10 mm
- Threaded adapter for ¼” gas hose, left hand thread
- 3 nozzles for propane/butane (P80), town gas (M250) and natural gas (N110)
- Operating instructions

Part No. 145 003:
- FLAMEBOY device
- Adapter for gas cartridge Campingaz CV 360
- 3 nozzles for propane/butane (P80), town gas (M250) and natural gas (N110)
- Operating instructions

CAUTION
Verify the scope of delivery when unpacking the device and check for potential transportation damage. Do not operate a device that is damaged, instead contact your local dealer.

2.2 Overview of the FLAMEBOY

1 Gas-flow control valve
2 Brass screw for replacing the nozzle
3 Air-flow control valve
4 Threaded adapter for gas hose
5 Threaded connector of gas tubing
6 Adapter latch
7 Handle
8 Trigger
9 Burner tube
3 Installation

3.1 Operating environment

The FLAMEBOY has been designed for use in a laboratory. It shall be operated in a dry and dust-free location with a temperature of 5-40 °C and a maximal (non-condensing) relative humidity of 80%.

3.2 Connecting the FLAMEBOY to the gas supply

The FLAMEBOY is appropriate for use with natural gas (gas mixture, >85% methane, further alkanes), commercial propane/butane gas (mixture 20%-40% propane, 65%-10% butane) and town gas (mixture of methane and other gases).

3.2.1 Fitting the nozzle for the gas in use

The P80 nozzle for propane/butane gas is fitted ex-factory for FLAMEBOY. If necessary, the nozzle must be fitted for the gas in use.

<table>
<thead>
<tr>
<th>Type of gas</th>
<th>Gas input pressure</th>
<th>Inscription</th>
<th>Nozzle</th>
</tr>
</thead>
<tbody>
<tr>
<td>Natural gas (methane)</td>
<td>20 mbar</td>
<td>N110</td>
<td></td>
</tr>
<tr>
<td>Propane/butane gas (e. g. gas cartridge)</td>
<td>50 mbar</td>
<td>P80</td>
<td></td>
</tr>
<tr>
<td>Town gas</td>
<td>8 mbar</td>
<td>M250</td>
<td></td>
</tr>
</tbody>
</table>

The nozzles are marked on the lower surface with the appropriate designation.

**CAUTION**

*FLAMEBOY may only be operated with the nozzle that corresponds to the gas type in use. Only use the nozzles supplied. Prior to every nozzle installation, inspect the O-ring in the brass screw for damage and if necessary replace it.*

When replacing the nozzle, proceed as follows:

1. Turn gas-flow control valve (1) to appropriate position to have access to the brass screw (2). Remove the brass screw.
2. Turn over the device and allow the nozzle to drop out.
3. Insert the desired new nozzle and retighten the screw (2).
3.2.2 Connecting to central gas supply or a gas cylinder

Connecting to gas tubing with 1/4” threaded connector:

- Insert the threaded adapter (b) into the gas adapter opening of the FLAMEBOY (a). Making sure it audibly clicks into position. Check the connection for tensile strength.
- Screw the threaded connector (left-hand thread) of the gas tubing (c) onto the adapter and tighten it with a 17 mm fork wrench.
- Screw the other end of the hose to the gas supply.
- Turn on the gas supply.
- The FLAMEBOY is ready to use.

Connecting to standard gas hoses (inner diameter 10 mm):

- Insert the adapter for standard gas hoses (b) to the gas adapter opening of the FLAMEBOY (a). Make sure it audibly clicks into position. Check the connection for tensile strength.
- Connect one end of the gas hose (c) to the adapter and fix it with a tubing clamp.
- Attach the other end of the gas hose to the gas supply and fix it with a tubing clamp.
- Turn on the gas supply.
- The FLAMEBOY is ready to use.
3.2.3 Connecting to gas cartridges

**Connecting gas cartridge CV 360:**

- Hold the brass knurled wheel (b) of the gas cartridge adapter and close the valve by unscrewing the black cap (c) clockwise.
- Insert the gas cartridge adapter (b, c) to the gas adapter opening of the FLAMEBOY (a). Make sure it audibly clicks into position. Check the connection for tensile strength.
- Press the gas cartridge (d) into the adapter (b, c).
- Hold the knurled wheel (b) and open the valve by screwing the black cap (c) counterclockwise to the stop.
- The gas cartridge is now open and ready to use.

**Connecting gas cartridge Express 444:**

- Insert the gas cartridge adapter (b) to the gas adapter opening of the FLAMEBOY (a). Make sure it audibly clicks into position. Check the connection for tensile strength.
- Hold the knurled wheel (b) and connect the gas cartridge by screwing it clockwise to the gas cartridge adapter.
- The gas cartridge is now open and ready to use.

3.2.4 Replacing the gas cartridges

- **CV360:** Hold the knurled screw of the gas cartridge adapter (see above) and unscrew the black cap clockwise.
- Remove the empty gas cartridge by pulling (CV360) or screwing it out (EXPRESS 444). Insert a new gas cartridge.
- **CV360:** Hold the knurled screw of the gas cartridge adapter and screw the black cap counterclockwise to the stop.
- The gas cartridge is now open and ready to use.
3.2.5 Replacing the adapters

**WARNING**
When replacing the adapters, always close off gas supply completely or remove the gas cartridge, respectively.

- In order to remove the adapter, use a pointed tool (a) to press the adapter latch (6) inward and pull out the adapter.
- Insert the requested new adapter until it audibly clicks into position.
- The adapter is replaced.
4 Operation

**WARNING**
When using the FLAMEBOY, always point away from yourself and do not point in the direction of other persons or inflammable products.
Risk of burns! Even after the FLAMEBOY is switched off, the burner tube (9) may still be hot.

4.1 Igniting FLAMEBOY

Turn the gas-flow control valve (1) counterclockwise to the left. The FLAMEBOY is ignited by slowly pulling the trigger (8). The flame burns only as long as the trigger is pulled.

4.2 Adjusting the flame

The gas-flow control valve (1) is used to adjust the gas flow (flame size). Rotating its knob clockwise reduces gas supply, rotating it counterclockwise increases it.

The air-flow control valve (3) is used to regulate the air supply (flame temperature). Moving its knob to the left reduces air supply, moving it to the right increases it.

**WARNING**
Close off gas supply completely when your work with the FLAMEBOY has been finished.
5  Maintenance

5.1 Cleaning and decontamination

WARNING

Allow the burner tube (9) to cool off before cleaning and disinfecting. Disconnect the device from the gas supply. Allow the device to dry before operating it again.

Use a cloth moistened with soapy water or a 70% ethanol solution to clean the FLAMEBOY. The stainless steel burner tube (9) can be cleaned with commercially available cleaning or disinfecting agents.

If the housing of the FLAMEBOY have been in contact with biohazardous material, it must be decontaminated in accordance to good laboratory practice. Do not spray directly on the instrument but use a lint-free cloth, lightly soaked with a disinfectant and wipe dry directly after decontamination. Never use bleach (sodium hypochlorite), acetone or other solvents! Follow the instructions provided by the disinfectant manufacturer.

5.2 Disposal

The FLAMEBOY must not be disposed of with unsorted municipal waste. Do not dispose it in a fire.

Dispose of FLAMEBOY in accordance with the laws and regulations in your area governing disposal of devices.
# Technical data

<table>
<thead>
<tr>
<th>Device</th>
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<tbody>
<tr>
<td>Type</td>
<td>Automatic flame pistol FLAMEBOY</td>
</tr>
<tr>
<td>Dimensions (W x D x H)</td>
<td>200 x 40 x 200 mm</td>
</tr>
<tr>
<td>Weight</td>
<td>608 g</td>
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</table>

<table>
<thead>
<tr>
<th>Temperature</th>
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</tr>
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<tbody>
<tr>
<td>Max. flame temperature</td>
<td>1350 °C on propane/butane gas, 1300 on natural gas</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Nominal thermal rating</th>
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<tbody>
<tr>
<td>Propane/butane gas</td>
<td>1.6 kW</td>
</tr>
<tr>
<td>Natural gas</td>
<td>1.0 kW</td>
</tr>
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</table>

<table>
<thead>
<tr>
<th>Nominal gas input pressure</th>
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</thead>
<tbody>
<tr>
<td>Propane/butane gas</td>
<td>50 mbar</td>
</tr>
<tr>
<td>Natural gas</td>
<td>20 mbar</td>
</tr>
<tr>
<td>Town gas</td>
<td>8 mbar</td>
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</table>

<table>
<thead>
<tr>
<th>Materials</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Burner tube</td>
<td>Stainless steel</td>
</tr>
<tr>
<td>Housing</td>
<td>Polyamide</td>
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</table>
## 7 Accessories

A variety of accessories are available, which adapt FLAMEBOY to the respective application requirements and work environments.

<table>
<thead>
<tr>
<th>Accessories</th>
<th>Part No.</th>
</tr>
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<tbody>
<tr>
<td>Gas cartridge adapter for Campingaz CV 360</td>
<td>145 010</td>
</tr>
<tr>
<td>Gas cartridge adapter for EXPRESS 444.</td>
<td>145 120</td>
</tr>
<tr>
<td>Adapter for standard gas hose with inner diameter 10 mm</td>
<td>143 550</td>
</tr>
<tr>
<td>Threaded adapter for 1/4” gas hose, left-hand thread</td>
<td>143 220</td>
</tr>
<tr>
<td>Gas tubing, 2 m length with double-sided threaded connector 1/4”, DVGW approved¹</td>
<td>140 068</td>
</tr>
<tr>
<td>Nozzle N110</td>
<td>145 220</td>
</tr>
<tr>
<td>Nozzle P80</td>
<td>145 225</td>
</tr>
<tr>
<td>Nozzle P250</td>
<td>145 230</td>
</tr>
</tbody>
</table>

¹ DVGW: German Technical and Scientific Association for Gas and Water (e.V. for conformity assessment of products in gas and water supply).

<table>
<thead>
<tr>
<th>Consumables</th>
<th>Part No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>O-rings for the brass screw, 10 pack</td>
<td>144 330</td>
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