

## Risk Assessment Form

<b>Procedure</b>	Use of Bio-Rad CFX384 Touch Real-Time PCR Detection system
------------------	--

<b>Name(s) of person performing the work</b>	Users (Lab manager & Lab Technician & Tenants & Licensee's)		
<b>Name &amp; position of assessor</b>	Khwaja Islam & Laboratory Manager	<b>Signature</b>	
<b>Date of assessment</b>	03/07/2020	<b>RA Number</b>	BioE 0041

### Outline of procedure / activity:

The CFX384 touch real-time PCR detection system (or quantitative PCR) is located in Innovation lab 1 (696.10.14) which is used performing rapid, accurate polymerase chain reaction (PCR) in combination with real-time, online detection enabling quantification of a target nucleic acid, as well as post-PCR analysis of the amplified nucleic acid by melting curve analysis.

The CFX384 touch real-time PCR detection system is an electromechanical instrument; it consists of an enclosed thermal cycler and detection system and a laptop (HP Business note book). The system comes with precision melt analysis software.

CFX384 has two components:

- **Optical reaction module.** This module includes an optical system to collect fluorescent data and a thermal cycler block.
- **C1000 thermal cycler base.** The C1000 base includes a user interface to control the system when running in stand-alone mode, the power button, and ports (both on the back panel) to connect to the laptop.

Operator must be trained in CFX384 touch real-time PCR detection system to guarantee safe daily use. Untrained Personnel are not be allowed to operate the CFX384 touch real-time PCR detection system. Users should operate the CFX384 touch real-time PCR detection system according to instructions in the manual. User must always ensure that power cable is in good condition, no wires exposed.

#### Loading the block:

- Click the open lid button located on software's start run tab or press the lid button on front of the system to start opening the motorized lid.
- Place 0.2ml microplate or tube strips with sealed lids in the block. Check that the tubes are completely sealed to prevent leakage. For optimal results load sample volumes of 5-20ul.

- Be sure nothing is blocking the lid when it closes. Although there is a safety mechanism to prevent the lid from closing if it senses an obstruction, do not place anything in the way of closing the lid.
- After run, click open the lid button front of the instrument and remove the samples from the block and click the close lid button to close the lid.
- Press the Power switch on the back panel of the instrument to power down the system.

#### Instrument maintenance:

CFX384 touch real-time PCR detection system includes a sensitive optical shuttle system that moves quickly during data collection and a sample block that must heat and cool very fast. Contamination of these components can interfere with thermal cycling and data collection.

**Warning:** Never allow a reaction to run with an open or leaking sample lid. The reagents could escape and coat the block, inner lid, and optical head in the shuttle system. Excessive dirt can dim the signal and fluorescent contamination can create excessive background signal. The shuttle system cannot be cleaned, except by trained Bio-Rad service engineer.

Avoid contamination of the instrument by following suggestions:

- Always clean the outside of any before placing them in the block.
- Never run a reaction with a seal that is open, loose, punctured, or otherwise damaged because you could contaminate the block, inner lid, and optical system.
- Never run a PCR or real-time PCR with volatile reagents that could explode and contaminate the block, inner lid, and optical system.
- Clean the block, and inner lid periodically to prevent build-up of dirt or biohazardous materials.
- Never clean or otherwise touch the optical system behind the heater plate holes in the inner lid.
- Cleaning the outer lid and C1000 base on a regular schedule.

Cleaning the optical reaction module:

The block of the optical reaction module should be cleaned on a regular basis to remove any debris or dirt that might interfere with proper function. Clean soon as you discover debris and spilled liquids with a soft lint-free cloth that is dampened with water.

**Warning:** never use cleaning solutions that are corrosive to aluminium. Avoid scratching the surface of the C1000 reaction module bay. As scratches and damages to this surface interfere with precision thermal control.

**Warning:** Never pour water down or other solutions into the C1000 reaction module bay. Wet components can cause electrical shocks when the thermal cycler is plugged in.

Clean the optical reaction module as soon as you discover debris, dirt, or contamination in the block or inner lid. Any dirt can interfere with the ability of the block to change temperature quickly and collect accurate fluorescent data.

To clean the reaction module. Follow the following suggestion:

- Clean the outer surface. Use a damp cloth or tissue to clean spills off the outside case.
- Clean the cooling fins. Remove the dust with a soft brush or damp cloth. Remove any heavy dust that is deep in the vents with a vacuum cleaner. Use water and a soft, lint-free cloth to remove debris that is stuck to the fins. Cleaning the fins improves precise sample heating and cooling.
- Clean the wells in the block. Clean spills immediately to prevent them from drying. Use disposable plastic pipettes with water. Also use a soft, lint-free cloth or paper towel and water to clean the block. Always rinse the wells with water several times to remove all traces of cleaning reagent.

- Clean the inner lid. Use a soft, lint-free cloth and water to remove debris and solutions from the inner lid surface.

Warning: Never clean the block with strong alkaline solutions. Never use corrosive or abrasive cleaning solutions.

Warning: To prevent electrical shock remove the reaction module from the thermal cycler base or unplug the base before cleaning the instrument.

Warning. Never touch or allow solutions to touch the optical system that is located behind the heated plate holes in the inner lid.

Safety precautions:

- Do not operate the device in areas where work is completed with explosive substances.
- Do not use this device to process any explosive or highly reactive substances.
- Do not use this device to process any substances which could create an explosive atmosphere.
- Do not use this device to process any highly flammable liquids.
- The use of accessories and spare parts other than those recommended by Bio-rad may impair the safety, functioning and precession of the device.
- Condensate can form in the device after it has been moved from a cool environment to a warmer environment. Wait 12 hours before connecting the device to the mains/power line.
- Avoid touching the inner block or lid. These services can be hot.
- Prevent contamination of instrument by spills, and never run a reaction with an open lid or leaking sample lid.
- Avoid contact with back panel of the cycler during operation.
- Inner lid with heater plate. The heater lid maintains temperature on top the consumable to prevent evaporation. Avoid touching and never poke anything through the holes as it will damage the optics shuttle system.
- The sample blocks can become hot enough during the course of normal operations to cause liquids to boil and explode.

### Potential hazards

Substance or item handled	Associated Hazard (s)	Existing Control Measures	Risk (L/M/H)	Further Action required	Risk (L/M/H)
Hot surfaces on block and inner lid with heater plate	Skin Burns due to hot surfaces	Wear proper PPE; gown (lab coat and gloves and safety specs). Users will have a risk assessment / SOP in place before work begins. Avoid touching the inner lid with heater plate or block. Always allow the sample block to return to idle temperature before opening the lid and removing the sample. Always allow maximum clearance to avoid accidental skin burns.	M	No further action required if the existing control measures are adhere to.	M
Mains connection socket with power switch	Electrical hazard - Electrical shock – danger of death	Only switch on the device if the device and power cable are undamaged. Only trained personal are allowed to use the machine. Instrument is earthed, protective earth connection for the machine is provided using 13A plug fitted to the machine (RCD protected). Make sure it has been PAT tested. Regular visual checks of power cords for fault, fraying or wear and regular electrical safety check. Any faults	L	No further action required if the existing control measures are adhere to.	L

		reported and repaired before use. Always handle any components of the system with care and with clean, dry hands. Do not clean, open the housing, or access any electrical parts while the instrument is connected to the mains.			
Biohazard – unsuitable vessels, plates and lids	Biohazard-unsuitable reaction vessels, plates and lids get damage in the cycler and release sample material.	Only use reaction vessels, plates and lids that meet the requirements specified in the operating manual. Do not fill sample material directly into the block. When handling biohazard samples adhere to SOP and COSHH.	L	No further action required if the existing control measures are adhere to.	L
Lifting the instrument	Risk of injury when lifting and carrying the heavy device (weight is 21kg)	If the device is moved using the lid, the lid may break, causing the device to fall. Only lift the device by holding it at the bottom of the housing. Use both hands to carry the device. Only lift and transport the device with a sufficient number of helpers. Use a transport aid for transporting the device. Do not lift the device using the lid. MHO training is required by personal before lifting and carrying the heavy load.	L	No further action required if the existing control measures are adhere to.	L

**Persons potentially at risk:**

Only the user or others near by

**Action in event of an accident or emergency:**

1. **Fire:** raise the fire alarm and evacuate the area.

**Arrangements for monitoring effectiveness of control:**

Daily inspection of equipment by lab technician.

Annual preventative maintenance carried by external contractor.

Instruction and training given to all operators which is reviewed annually.

Existing operators receive annual refresher training.

Annual pat testing by external contractor.

**Arrangements for monitoring effectiveness of control:****Review of the Risk Assessment:**

Date of review		Name of reviewer	
Date of next review		Signature	

Have the control measures been effective in controlling the risk?

Yes	No
-----	----

Have there been any changes in the procedure or in the information available which affect the estimated level of risk from the listed substances

Yes	No
-----	----

What changes to the control measures are required?

--



