## **TECHNICAL MANUAL** Cellbox Flight 2.0





### **PRODUCED BY**



An der Bahn 5 22844 Norderstedt Germany T +49 40 226316410 cellbox-solutions.com Englische Planke 8 20459 Hamburg Germany T +49 40 226316410 office@cellbox-solutions.com

# **TECHNICAL MANUAL**

### Cellbox Flight 2.0 21 CFR Part 11 Data Security Software License

DISCLAIMER

The manual is intended as a guideline and that Cellbox Solution GmbH shall in no event be held liable for any direct, or incidental damages that arises out of, or are related to the use of this manual. Version 1.4, February 2023, Author: Robin Sieg

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#### 1 SAFEKEEPING OF THE MANUAL

The technical manual belongs to the Cellbox Flight 2.0 -21 CFR Part 11 Data Security Software License - and must be downloaded digitally. This ensures that persons operating the device can refer to the content of the manual as required

The latest version of the technical manual can be opened by scanning the code on the type plate of the Cellbox 2.0 or below:



https://cellbox-solutions.com/downloads

#### 2 DEVICE DESCRIPTION

The Cellbox 2.0 is an electronic device developed by Cellbox Solutions GmbH for the safe and documented transport of living cells. The living cells, which can be transported in various cell culture vessels, are enclosed within the incubation chamber of a robust transport trunk. This creates a controlled environment wherein the physical parameters, such as the temperature and  $CO_2$  concentration can be defined and stably maintained for a period of at least 32 hours without an external power source.

In order to achieve the optimal conditions for the transport of living cells, the Cellbox 2.0 is able to control the ambient temperature around the cell culture vessels with precision. This function is further supported by the continuous circulation of air around the cell culture vessels, resulting in an even temperature distribution. The device also maintains a constant internal CO<sub>2</sub> concentration by automatically dispensing pure gaseous CO<sub>2</sub>. This sustains the vitality of the in vitro cell cultures by providing a source of environmental CO<sub>2</sub> that stabilizes the pH. To ensure that an adequate supply of gaseous CO<sub>2</sub> is available for the entire period of transport, the device has been fitted with a thermally-insulated container for the storage of dry ice. Through the process of sublimation gaseous CO<sub>2</sub> is produced for the conditioning of the transport compartment. A complete fill with dry ice can maintain a 5%  $CO_2$  environment for up to 32 hours.

The Cellbox 2.0 can be operated from its built-in rechargeable Lithium-Ion Battery packs, an external power supply or even an automotive/vehicle power adapter (see chapter 6.1). This provides the user with various options to ensure an uninterrupted power supply during transport. Sensors within the transportation compartment of the device log data of the conditions that the cells (living cargo) experience during transport. These data logs can easily be transferred to a mobile device using Bluetooth connectivity to the CELLBOX 2.0 – LIVE CELL SHIPPER App.

#### 3 LIST OF USED SYMBOLD

Symbols used on Cellbox		
	Direct Current	
$\mathbf{S}$	Read the manual	
	Use cold protection gloves when han- dling dry ice	
X	This product is subject to the European Community Directive 2002/96/EG on waste electrical and electronic equip- ment (WEEE).	
FC	This product has been tested for electro- magnetic radiation below the limits spec- ified by the Federal Communications Commission.	
CE	This product satisfies European harmoni- sation legislation. (CE Marking)	
Symbols	used on the Technical Manual	
i	Additional information for the user	
	Warning: Warning of situations that may result in personal injury or property dam- age	
	Critical Warning: Prohibition of misuse that may result in personal injury or prop- erty damage	

#### 4 INTENDED USE

#### 4.1 Purpose

This device is intended to serve as a protective environment that can sustain living cells, in various cell culture vessels, for a defined period of time, with the purpose of transport. In this context transport can refer to carrying the device or moving the device with the aid of a vehicle. When in operation the device can be configured to automatically maintain a set internal temperature and  $CO_2$  concentration.

Power can be supplied to the device by means of an external power supply or in a portable manner from the internal battery packs.

The following cell culture vessels are compatible with the Cellbox Flight 2.0:

- Multiwell-plates with 6, 12, 24, 48, 96 and 384 wells
- Multiwell-plates with standard ANSI/SBS footprint.
- Various chip formats
- Various cell culture bags
- Various cell culture flasks

#### 4.2 Restrictions on the Use of this Device

It is strictly forbidden to use the device for the transport of infectious substances as classified within Class 6.2 of the ADR (European Agreement concerning the International Carriage of Dangerous Goods by Road, applicable as from 01.01.2015) as well as Class 3.6.2 of the IATA (International Air Transport Association - Dangerous Goods Regulations, applicable as from 01.01.2021).

Use of the device for any purpose other than the intended purpose described in section 4.1 is classified as misuse and can result in danger or damage.

The device may not be used for the transport of materials and substances that could produce toxic vapors or explosive fumes at the set temperature. Furthermore, materials and substances that pose a risk of exploding, bursting or igniting may not be transported in this device. If any doubt arises about the composition of the materials or substances to be transported, they must not be loaded in the device.

Potentially explosive gas-air mixtures may not be formed in the transportation compartment, nor may the device be operated in their immediate vicinity.

#### **5 SAFETY INSTRUCTIONS**

The device may only be operated in a good working order. When the user identifies any irregularities, disturbances or damage before or during the operation of the device, it should immediately be decommissioned. After decommissioning the device, the user should contact the manufacturer.

The device may not be rebuilt, modified or altered in any way without the authorization of the manufacturer. In the event of any unauthorized modification or alteration, the declaration of conformity is declared invalid and the device must be decommissioned.

During the transport of unsuitable goods, the possibility exists that toxic vapors or explosive fumes may be formed. This may cause the device to explode and result in serious injury or poisoning. The device is only intended for the transport of goods that do not form any toxic vapors or explosive fumes when heated (also see section 4)

The device must not be sprayed with or submerged in water. As the device is only resistant to low quantities of dripping water, larger quantities of water could reach the internal electronics and cause damage.

As a result of partial disassembly or damage to the casing of the trunk, electrical wires could be exposed and pose a risk of electric shock to the user. Repairs and maintenance of the electric components must only be performed by the manufacturer and authorised partners. The use of the device in potentially explosive areas (containing flammable substances, gases, fumes or mixtures of gas and air) is strictly forbidden. The device does not have any measure of explosion protection.

Only use the Cellbox Flight 2.0 in well ventilated areas when filled with dry ice. Due to the sublimation of dry ice an increase of the CO<sub>2</sub> concentration can ensue in the environment around the device. Depending on the CO<sub>2</sub> concentration inhaled and exposure duration, toxicological symptoms in humans could range from headaches increased respiratory and heart rate, dizziness, muscle twitching, confusion, unconsciousness, coma and death.

#### 6 PRODUCT SPECIFICATION

#### 6.1 Scope of Delivery

Besides the Cellbox Flight 2.0 the following items are included in the scope of delivery:

- 1x multi-well holder
- 3x spacers for multi-well holder
- 1x power adapter for operation of the device or for charging the battery packs
- 1x car adapter\*
- Technical Manual (Online)
- Power plugs with wall socket compatibility for EU, Japan, UK, USA, Switzerland and Australia.
   \*not in compliance with cULus



#### 6.2 Installation

Place the polystyrene carton overpack for best ergonomics onto a clean floor. Open the carton as well as the isolating polystyrene lid. Pull the lid handle and lift the Cellbox 2.0 out of its isolating overpack with care and place on to an even and clean surface. Remove the protective plastic bag and discard it.

Operate (Charge & Power On/Off) the device as described in Chapter 7.

 $\Delta$  Do not use the Cellbox 2.0 inside of the plastic bag! Please make sure that the plastic bag is also not placed into the bottom of the polystyrene housing to avoid CO<sub>2</sub> build up by blocking the integrated CO<sub>2</sub> overflow tube.

The Cellbox 2.0 is a heavy load. Lifting and carrying loads for many years can lead to serious damage to the musculoskeletal system and especially to the intervertebral discs. In general, therefore, always use a carrying or pulling aid if possible or carry the Cellbox preferably together with another person.

#### 6.3 Features

The Cellbox Flight 2.0 has the following features:

- Protective environment for the temporary storage and transport of cells and culture media within a variety of cell culture vessels.
- Mechanical protection of goods when the device is carried or transported in a vehicle, train, ship, airplane or during stationary application.
- Simple-to-use touch screen interface for the operation of the device.
- Incubation range 3°C above ambient temperature and programmable between 28°C and 38°C.
- Programmable CO<sub>2</sub> concentration between 0% and 18%.
- Display that is updated with the internal CO<sub>2</sub> concentration and temperature in real-time.
- The Cellbox 2.0 logs the history of the internal set and actual temperature, actual ambient temperature\*, internal set and actual CO<sub>2</sub> concentration, incubation lid status, actual ambient pressure, remaining CO<sub>2</sub> in the dry ice compartment as well as the maximum tilt, acceleration and impacts within the last minute as events and the battery percentage.
- Additional device events such as technical settings are logged in the event log (Audit Trial) as well.
- Bluetooth connection for communication with smart devices.
- Cellbox 2.0 App for data and event log export and graphical presentation of logged environmental conditions.

\*The ambient temperature is not representing the actual ambient temperature of the environment. It represents the internal chassis / device temperature but is not connected to the incubation space temperature.

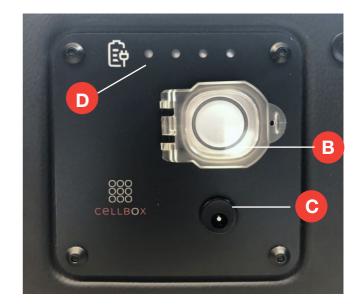
#### 6.4 Device Overview

The outer case of the Cellbox is a robust transport box made to withstand mechanical impact. It is therefore the ideal device for the transport of biological material by road, sea, rail and air.

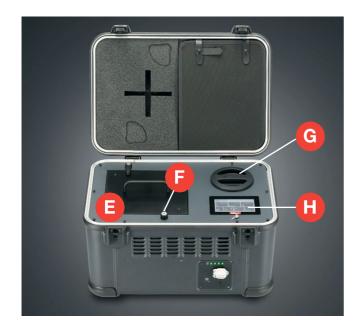
The following device elements have been highlighted for the user:



#### A Locking mechanism



- **B** Main power switch with protective lid and LED for device status
- C Connection/socket for external power supply
- **D** 4 LEDs for indication of the battery level



- E Incubation chamber lid
- F Lid locking mechanism
- G Chamber for dry ice with lid
- H Display

#### 6.5 Display Elements

The touch screen of the Cellbox Flight 2.0 indicated the conditions inside the incubation chamber and allows the user to adjust incubation parameters as well as access to the logging feature.



The Cellbox 2.0 Homescreen becomes visible when the device is switched on. The following is displayed:

- Internal actual temperature in °C
- Internal set (user-defined) temperature in °C
- Internal actual CO2 level in %
- Internal set (user-defined) CO<sub>2</sub> level in %
- Elapsed episode logging time in hh:mm:ss
- Bluetooth toggle on/off
- Remaining CO<sub>2</sub> (dry ice) level in %
- Battery Management and level in %

Tap the respective field to enter its sub menu.

#### 6.5.1 User Management

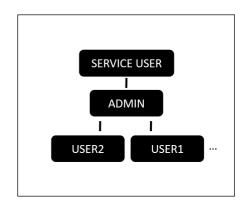
The CBS 21 CFR Part 11 Data Security Software is a license version of the Cellbox Flight 2.0 which is in

conformity with regulations for electronic records and signatures specified in FDA 21 CFR Part 11. This license enables the option for creating users with their own login information to privatize their data if needed. To use the Cellbox Flight 2.0 in this mode, it is mandatory that the user logs only into their assigned account to track any changes made to the Cellbox 2.0 e.g., changing parameters.

In 21 CFR Part 11 data security software mode, simply every user action on the Cellbox is constantly logged by into the audit trail and can be verified. The audit trail can be downloaded via the Cellbox 2.0 App in its entirety and partwise over the defined period of an episode. User management structure:

The admin is the most responsible person for the Cellbox 2.0. He has the capability of the general functionalities of the Cellbox 2.0 and is allowed to add new user accounts, edit existing accounts or to delete user accounts. Additionally, he has the exclusive rights to determine which log parameters are being exported.

A user is assigned to an admin and is able to operate the general functionality of the Cellbox 2.0 like defining values for target conditions (CO<sub>2</sub> and Temperature), "Start Episodes", "Stop Episodes", "Create Episodes", "Plot Episodes" and to choose if the episode shall be public or private creation. Private Episodes can only be seen by the user him-/ herself. Public Episodes can be seen, plotted and downloaded via the Cellbox 2.0 App by all users. Additionally, a user is capable to change its own password.



6.5.1.1 User Management Setup

When you start the Cellbox 2.0 CFR for the first time you will be asked to log in with the default information of the admin.



Touch the text field to let the keyboard appear and enter following default information:

Default Username: Admin Default Password: AdminDev123

You can switch between the input lines by touching them. To leave the line and let the keyboard disappear press "OK".



When information is entered and "Login" button is pressed you will be asked to change the password.



After successfully changing your password, you need to enter a new username for the admin which has to differ from the default name and only contains letters and numbers.



Now the initialization process for the admin is done and by navigating to the service menu (button with the gear) you will have access to the user management as shown below.

OOO OOO CELI OOO Admin	_BOX		
Set Local Time		Cellbox Flight 2.0 Serial No.: CBX1071000 21 CFR Part 11 Data Security Software License	
Change Password	User Management	Cellbox Solutions GmbH An der Bahn 5 22844 Norderstedt www.cellbox-solutions.com	
Shutdown	Login	office@ceilbox-solutions.com Mainboard Firmware Version: 1.0 Battery Firmware Version: 1.0 Butedoth Firmware Version: V20.2 UTC: 2022-01-01.09:00:00 Local Time: 2022-01-01 10:00:00	

To enter the user management menu, tap the "User Management" button. The next screen will give you access to the different sub menus to add new users ("Add User" button), edit existing users ("Edit User" button) or delete all users ("Delete All Users" button).



To add a new user, navigate in the submenu as described above. You need to enter the full name of the person you want to add, a username and a default password and then touch the "Confirm" button. The recently added user is now able to login with this defined login information in the exact same way as it was described for the admin before.

Name :	
Username :	
Password :	
Confirm	

When you like to change the password of an existing user or delete a user navigate to the "Edit user" submenu. A list of existing users will appear and you can select a user by touching its username.



When you tap the user, you want to edit a window will pop-up as shown.



To change the user's password, press the "Change Password" button and in the next screen you will be asked to enter the new password twice and confirm it.



To delete a user completely press the "Delete User" button and a list of existing users will appear where you can select a user by tapping its username. In a pop-up window you will get asked if you want to delete the selected user with the option to confirm or deny your decision. The option to delete all users simultaneously can be accessed by taping the "Delete All Users" button. When pressing the button, a pop-up window will appear and you will get asked to confirm or cancel your decision.

Delete all users ?	
Confirm Cancel	

To exit the User management menu, tap "C" to return.

When you want to log out as an admin (or as a basic user) just navigate to the main menu, press the logout button and confirm the logout.



The active user is also being logged out after three minutes of inactivity.

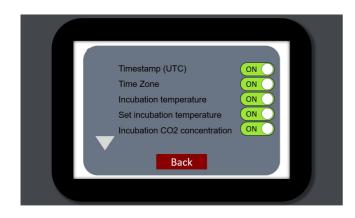
000 000 <mark>CELLB</mark> OX 000 Admin	
37.0 °C Set 37.0 °C Set 37.0 ℃ CO2	

#### 6.5.1.2 Select Logging Parameters:

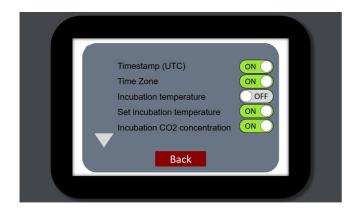
As an admin you have the option to define the parameters which shall be logged from the Cellbox 2.0. To enter the submenu, navigate to the data logging menu.



The button "Data Recording Parameters" will lead you inside the parameter's selection pop-up window.



In this window you have the option switch parameters on and off for logging just by touching the toggle switch. After touching the toggle, the selected parameter will be turned off and the green "on" indication will switch to a grey "off" indication.



By pressing the arrow down on the lower left corner you have the option to navigate between the screens of parameters.

The admin does additionally have the rights to delete all episodes. For that use the "Delete All Episodes" button within the data-logging menu and confirm.

#### 6.5.2 Setup - Temperature

000 000 CELLBOX	1 2 3
max. 38°C Set min. 28°C Set ℃	4 5 6
С	< 0 .

Use the keypad to define the target temperature in the incubation chamber. A value in the range of 28.0°C to 38.0°C is possible and can be defined in increments of 0.1°C. Use the "<" key to correct your entry. Confirm your entry with "OK" (green field).



The user is returned to the Homescreen. Tap "C" to return to the Homescreen without modifying the set value.

If a value lower than 28.0°C or higher than 38.0°C is entered and confirmed, the system will automatically default to the closest minimum or maximum temperature.

It is strongly recommended that the initial heating of the incubation chamber is performed with the Cellbox Flight 2.0 connected to a wall power socket to reserve the fully charged batteries for transport. Depending on the ambient temperature the initial heating stage can take up to 30 minutes.

#### 6.5.3 Setup - CO<sub>2</sub> Concentration



Use the keypad to define a target  $CO_2$  concentration between 0.0% and 18% in the incubation chamber. The target  $CO_2$  concentration can be defined in increments of 0.1%. Use the "<" key to correct your entry. Confirm an entry with "OK" (green field).



The user will be returned to the Homescreen. Tap "C" to return to the Homescreen without modifying the set value.

If a  $CO_2$  concentration higher than 18% is entered and confirmed, the system will automatically default to the maximum value.



The initial CO<sub>2</sub> equilibration may take up to 5 minutes.

#### 6.5.4 Setup – CO<sub>2</sub> Dry Ice Timer



Reset the remaining  $CO_2$  (dry ice) level timer by tapping the blue button and confirm that the dry ice container has been refilled.



The timer will start to count backwards from 32 hours.

Tap "C" to return to the Homescreen.

The remaining dry ice level is displayed by a timer that counts backwards from 32 hours as well as via percentage indication.

# It is recommended to refill the dry ice container before each transport. Re-icing can also be performed more frequently if needed.

When the timer reaches zero it is very likely that there is little to no dry ice left to condition the transport compartment.

During long transport periods the dry ice may completely sublimate inside the container and be replaced by gaseous  $CO_2$ . Therefore, it is not advised to open the dry ice compartment without re-icing the device, because this could lead to a loss of the remaining gaseous  $CO_2$  and compromise the incubation functionality.

**i** Be aware that leaving the transport compartment opened for longer periods of time or increasing the CO<sub>2</sub> concentration above 5% leads to faster sublimation of dry ice which results in significant shorter runtimes.

#### 6.5.5 Setup – Data Logging

The Cellbox Flight 2.0 continuously logs data on the internal storage drive when the device is turned on. Due to the continuous data stream feature, the Cellbox 2.0 offers two options for creating data logging episodes:

#### Immediate Episode Creation (Start / Stop)

To start a log episode at any time, also shortly before a transport.

<u>Historical Episode Creation (Create Episode)</u> To create a log episode of a time-period in the past.

When the battery level is below 5% a nonconfirmable popup screen appears on the Cellbox display. Please be aware that the Cellbox 2.0 stops its internal recording due to storage safety! Please recharge the Cellbox 2.0 to at least 5% to enable logging capabilities!

6.5.5.1 Immediate Episode Creation



To start a log, tap "Start Episode Recording".

Enter the episode name in the pop-up window using the on-screen keyboard. Choose if the episode is public or access is private and confirm your entry by first tapping "OK" and then "Confirm".

Episode Name: Access: Public	
Confirm Cancel	



The Cellbox 2.0 is now writing the continuous data stream into the current episode log.



To stop the episode log, tap "Stop Episode Recording". Tap "C" to return to the Homescreen.

#### 6.5.5.2 Historical Episode Creation



Episode Name:
Episode Start:
Episode End: (YYYY/MM/DD) (HH:MM/SS)
UTC Time: YES Access: Private
Confirm

To create a historical episode, tap "Create Episode".

Enter the episode name in the pop-up window using the on-screen keyboard. Additionally enter the "Episode Start" and "Episode End" date as well as the respective times in the required formats:

Date: YYYY/MM/DD Time: HH/MM/SS

Select either "YES" or "NO" on the switch slider as you wish to select the episode time either from the UTC or the local timeline.

To load a log from the local timeline, make sure to set the time zone correctly within the Service menu.

Confirm your entry by first taping "OK" and then "Confirm".



Tap " C" to return to the Homescreen.

#### 6.5.5.3 Plot Episode

In order to plot episodes in the plot menu, the episode must have been either created by "Immediate Episode Creation" or by "History Episode Creation".



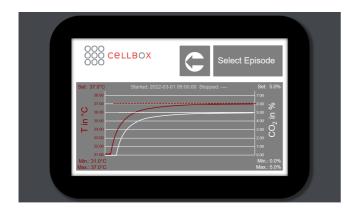
Tap "Select Episode" to open a list of created episodes. Use the up  $\blacktriangle$  and down  $\blacktriangledown$  arrows to navigate between the episodes. Tap onto the respective Episode to load the plot or use the "Back" button to navigate back and cancel the plot creation.

#### i

The time required to create the on-screen plot is dependent on the length of the episode and might take up to 5 minutes.



Once the plot has been created, it should contain internal actual temperature in °C as well as the internal actual  $CO_2$  level in % for the duration of the episode. The axes are self-adjusting to display all log values.



Tap "C" to return to the Homescreen.

#### 6.5.6 Data Export

To export data, install the "Cellbox 2.0 - LIVE CELL SHIP-PER" - App on your smart device. Activate Bluetooth and location services on your smart device and open the Cellbox 2.0 App.

Tap the Bluetooth button on the Cellbox Homescreen to activate the internal Bluetooth module of the Cellbox. If active, the Bluetooth symbol becomes blue. The Cellbox will attempt to pair with your smart device via the Cellbox App.



Follow the on-screen instructions in the App to access the data logs.

To learn more about the function of the Cellbox 2.0 App, please refer to our video tutorials and separate Cellbox 2.0 App Instruction Manual accessible at: www.cellbox-solutions.com/downloads

# Only pair the Cellbox and the smart device via the Cellbox App and not by the smart device internal pairing function.

#### 6.5.7 Service



Tapping the gear icon will open the service window where further device information can be found. Information displayed includes the current Mainboard Firmware Version, Battery Firmware Version and Bluetooth Firmware Version of the device. The service menu also shows the actual time, both in UTC and local time, as well as contact details of your Cellbox Solutions Service team.

Tap "Set Local Time" and set your desired local time by using the up  $\blacktriangle$  and down  $\checkmark$  arrows. Tap the green "Confirm" button to accept the entry or "Cancel" the entry.



Tap "C" to return to the Homescreen.

The shutdown button will be explained in Chapter 7.1 Power On / Power Off.

#### 6.5.8 Battery Management

#### 6.5.8.1 Storage Mode

Proper storage of batteries can help to maintain the battery's health over time, reflected by ability to provide voltage and capacity as specified, while ensuring optimal performance when the battery is needed. The Cellbox is therefore equipped with an integrated Storage Mode which should be activated whenever the Cellbox will not be in use for a period of several weeks or more.



To enter Storage Mode, tap the battery symbol on the main menu and then "Storage Mode" and the "Confirm" button. The Cellbox device needs to be charged to at least 60% to enter the Storage Mode. Switch off the device by pushing the main switch at the front panel of the device. The device will afterwards bring the battery charging level to the optimum for long-term storage.

Contract the second sec
Enter Storage Mode? After confirming the device will set itself into storage mode to maintain battery health. The only way to exit storage mode is to connect the device to main power. The device can not be operated while the storage mode is active.
Confirm Cancel

In order to wake the Cellbox out of Storage Mode after storage is to connect it to main power by pluggin in the external power supply. Without that, the device cannot be turned on! It is therefore important to bring the power adapter along! After the device can be either unplugged or the batteries can be charged to 100% charging level by leaving the power supply plugged in.

#### 6.5.8.2 Battery Reset / Disconnection

Certain regulations might require a complete battery restart / disconnection from the Cellbox. This can internally be achieved by activating the battery reset function.

Perform battery reset?
Confirm Cancel

After tapping the battery symbol in the main menu, tap "Battery Reset", followed by "Confirm" and use the front main switch to shut the Cellbox off. The batteries will immediately become physically disconnected.



In order to wake the Cellbox up after Battery Reset is to connect it to main power by

pluggin in the external power supply. Without that, the device cannot be turned on! It is therefore important to bring the power adapter along!

#### 7 OPERATION OF THE DEVICE

#### 7.1 Power On / Power Off

To power on the Cellbox 2.0, press the main power switch. The white LED ring will light up and the Cellbox display and software initializes.

To power off the Cellbox 2.0, go into the Service Menu and tap the "Shutdown" Button.



Confirm by tapping the green confirm button or tap cancel to abort the shutdown process. The Software is now being shut down. Lastly press the Main power switch to power off the Cellbox 2.0.



The Cellbox 2.0 display with reduce its light intensity and goes into sleep mode after 1 minute.

The Cellbox 2.0 indicated when the battery level is below 10% via a confirmable popup window. Make sure to charge the device if you want to increase runtime.



When the battery level is below 5% a nonconfirmable popup screen appears on the Cellbox display. Please be aware that the Cellbox 2.0 stops its internal recording due to storage safety! Please recharge the Cellbox 2.0 to at least 5% to enable logging capabilities!

Battery Level Critical (< 5%) Logging disabled

#### 7.2 Charging the Device

The Cellbox is fitted with four lithium-lon battery packs that each have a capacity of 99.4Wh. These battery packs provide an uninterrupted power source for the operation of the device during transport for more than 32 hours.

(MeanWell GST120A20-P1M, 20 VDC, 6 A, 120 W Max)

It is recommended to connect the Cellbox to a power supply when heating up the device for transport. This ensures that all battery packs are fully charged before the transport



10 hours will be required to fully charge the bates.

To charge the device during transportation, ensure that the automotive/adapter is set to 20V.



The power cable, power adapter and car adapter can be found in the lid compartment.



Securely plug the power cable into the socket below the power button.



One of the four LEDs on the front panel of the device will start to blink after connecting a partially or fully discharged Cellbox to an external power source.

Each of the LEDs represents a 25% charge value. A continuously blinking LED indicates that the Cellbox is being charged. When all four of the LEDs are steadily lit in green, the device is fully charged. It is possible to charge the device both when in operation or switched off.

The white LED ring around the power button increases in brightness when an external power source is connected.

- 4 LEDs are steadily lit 100% charged
- 3 LEDs are steadily lit 75% charged
- 2 LEDs are steadily lit 50% charged
- 1 LED is steadily lit 25% charged

During discharge of the battery packs each LED light will shortly blink before switching off. When only one light is blinking, the device needs to be connected to a power supply as soon as possible to ensure that incubation conditions are maintained.

Please be aware that more time is required to fully charge the Cellbox when it is in operation. The available current is preferentially used to power the device, while the smart charging system only diverts a portion of the current to recharge the batteries.

#### 7.3 Refilling the Dry Ice Container

The Cellbox Flight 2.0 uses gaseous  $CO_2$  to condition the internal environment for the transport of living cells. In this model of the Cellbox, dry ice generates gaseous  $CO_2$  through the process of sublimation. The Cellbox is fitted with a thermally-insulated container for the storage of approximately 0,5 kg of dry ice pellets. An electronically managed system ensures that the  $CO_2$  is distributed accurately as required.

Always handle dry ice with the appropriate personal protective equipment (PPE). We recommend using goggles or a face shield, a lab coat or a similar protective coat and loose fitting thermally-insulated gloves.

Never handle dry ice with bare hands. Store dry ice in a well-ventilated area. Wear appropriate PPE.





Open the Cellbox and gain access to the dry ice container by unscrewing the lid in an anti-clockwise motion and pulling out the polystyrene lid on its appropriate handle.



Use a small dry ice scoop or dry ice shovel to fill the dry ice container up so that the polystyrene lid can still be easily placed on top of the dry ice. Do not squeeze the polystyrene lid in too far to avoid issues in retrieving.



# The lid for the dry ice container needs to be securely tightened to reduce the risk of a leakage into the incubation chamber

The container is designed to hold approximately 0,5kg of dry ice pellets / nuggets with a diameter of 10mm. Avoid overfilling the container to ensure that the polystyrene lid can be replaced and the dry ice lid can be tightened securely at least to its minimum marking.





Tap the  $CO_2$  dry ice timer window in the Cellbox Homescreen and reset the  $CO_2$  dry ice timer, as described in section 6.5.4.

A completely filled  $CO_2$  dry ice container can sustain a 5%  $CO_2$  concentration in the incubation chamber for at least 24 hours.

If the incubation chamber is frequently opened or left open for long periods during operation, there is a risk that the dry ice may be depleted prematurely.

It is recommended to refill the dry ice container and start the timer shortly before transport.

#### 7.4 Preparing the device for transport

- Switch on the Cellbox.
- Verify the battery status and if necessary, charge the device (observe the status of the 4 LEDs on the front panel). Please keep in mind that 10 hours will be needed to fully charge the batteries.
- If necessary, refill dry ice before use as described in section 7.3.
- It is essential to provide the device with sufficient time to reach a stable internal temperature before being used for the transport of living cells. The lid of the incubation chamber has to be closed and latched down before the device is switched on. Approximately 30 minutes are required for the internal temperature to reach 37°C.
- The device can reach an internal CO<sub>2</sub> concentration

#### All preparations should be performed using an external power source to ensure that the battery packs remain fully charged for transport.

For more advises, tips and tricks on the procedure check our shipping checklist which can be found at:



https://cellbox-solutions.com/downloads

#### 7.5 Transporting and packing the Cellbox

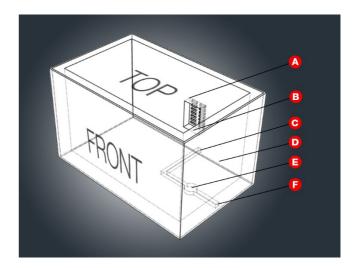
The lid of the main power switch should be securely closed before the device is transported. This prevents access to the main power switch, ensuring the device is not accidentally powered off during transport.

Open the carton overpack to access the polystyrene housing within.



Lift the polystyrene lid and place the Cellbox inside.

The polystyrene housing has been specially designed for effortlessly inserting and removing the Cellbox. Should the Cellbox not fit, do not force it, simply rotate the Cellbox until it slides into the polystyrene housing with the power button facing to the front. The polystyrene housing additionally has a port hole at its bottom leading through a channel to the back / or right side of the polystyrene housing. It is mandatory to align the CO<sub>2</sub> overflow tube coming out of the **Cellbox Flight 2.0 bottom with the respective hole** in the polystyrene to let free CO<sub>2</sub> gas escape from the package. Do not block this port or the outlet at the back/ right side! If the alignment is not correct or the CO<sub>2</sub> overflow is blocked, excess CO<sub>2</sub> will build up within the polystyrene housing to the level of the incubation chamber, resulting in an unwanted and uncontrolled  $CO_2$  increase. The Cellbox Ground 2.0 does not come with the above-mentioned  $CO_2$  overflow tube, hence this information can generally ben unattended for Cellbox Ground 2.0 users but have been included into this manual for completion and if the same polystyrene / carton overpack housing is alternating been used with both, a Cellbox Flight 2.0 and Cellbox Ground 2.0.



- A Ventilation opening
- **B** Polystyrene housing
- C Polystyrene CO<sub>2</sub> overflow channel and port to the back (old configuration)
- **D** Carton overpack
- E Polystyrene port hole that needs to be aligned to the Cellbox Flight 2.0 overflow tube
- **F** Polystyrene CO<sub>2</sub> overflow channel and port to the right side (new configuration)

The polystyrene housing has been specially designed for improving the Cellbox runtime by additionally improving its temperture isolation, expecially during the cold months of the year. The ventilation opening at the back is a cruicial part of the internal temperature regulation and may never been blocked, closed or taped! Proper ventilation is important to prevent overheating of the device! The polystyrene housing should not be used when the outside ambient temperature during the transport is expected be higher than 35°C for more than 2 hours or when the expected outside ambient temperature is higher than 3°C below the set temperature. If the Cellbox is supposed to be transported at higher temperatures please consider to transport the Cellbox in its unpacked configuration or within the non-isolating CBS Transport Protection Inlay.



To protect the contents of the Cellbox, the device should only be transported in an upright position.

It is strongly recommended that the Cellbox case, and more importantly the incubation chamber, remains closed during transport. The incubation chamber should only be opened if absolutely necessary because this jeopardizes the internal environment and subsequently the cell viability.

If the possibility exists, the device should be connected to an external power source during transport. Dry ice can also be refilled as required. This way the maximum transport period can be extended.

#### 7.6 Safe Removal of live cells from the device

- Unlatch the outer locks and open the Cellbox device lid.
- Unlatch the incubation chamber locks and remove the incubation lid.
- Remove the adapter containing the transport vessels and place it on the work bench.
- Remove the spacers when taking the vessels from the adapter.
- Use good sterile technique when handling biological material.

#### 7.7 Cleaning the device

The device must be switched off and disconnected from the external power supply before any attempts at cleaning are made.

The incubation chamber is constructed from hard anodized aluminium. It can therefore be cleaned using a soft cloth and appropriate detergents (e.g., 70% ethanol). The outer surface of the device can be wiped clean with a dry cloth.

Further information can be found in the CLEANING IN-STRUCTIONS in chapter 13.

#### 8 LABELS ON THE DEVICE

#### 8.1 Type plate

Detailed information about each device can be found on the type plate located at the back of the Cellbox.



### 8.2 Labeling requirements for dangerous goods

According to the guidelines of the ADR (European Agreement concerning the International Carriage of Dangerous Goods by Road, applicable as from 01.01.2015), as well as the IATA (International Air Transport Association - Dangerous Goods Regulations, applicable as from 01.01.2021) the Cellbox has to be labelled to indicate that its operation requires dry ice for the conditioning of the internal environment as well as that the Cellbox is containing lithium-ion batteries.

CELLBOX FLIGHT 2.0 <u>WITH</u> DRY ICE	
ROAD (ADR)	
Labels on cardboard overpack	UN 3481 label indicating the use of lithium-ion batteries with Cellbox Solution's phone number in the indication field: +49 40 226316410
	DRY ICE AS CONDITIONER
	TROCKENEIS ALS KONDITIONIERUNGSMITTEL
	Dry ice as conditioner label indicating the use of dry ice
	Text on cardboard: UMVERPACKUNG / OVERPACK
Information in transport documents (optional)	Lithium-Ion batteries contained in equipment
Indication on <b>Cellbox</b> (if transported without the overpack)	When the set of lithium is the set
	TROCKENEIS ALS         KONDITIONIERUNGSMITTEL         Dry ice as conditioner label indicating the use of dry ice
Information in transport documents (optional)	Lithium-ion batteries contained in equipment

CELLBOX FLIGHT 2.0 <u>WITH</u> DRY ICE	
AIR (IATA)	
Labels on <b>cardboard overpack</b>	UN 3481 label indicating the use of lithium-ion batteries with Cellbox Solution's phone number in the indication field: +49 40 226316410
	Please add amount of dry ice in kg as well as shippers and consignees' information on UN 1845 Dry Ice label. It is recommended to place both dangerous goods labels on the same
	side of the cardboard overpack. It is recommended to place both dangerous goods labels on the same side of the cardboard overpack. DRY ICE AS CONDITIONER
	TROCKENEIS ALS KONDITIONIERUNGSMITTEL
	Dry ice as conditioner label indicating the use of dry ice
	Text on cardboard: UMVERPACKUNG / OVERPACK
Information on airwaybill (AWB)	Lithium-Ion batteries contained in equipment in compliance with section II of PI967.

CELLBOX FLIGHT 2.0 WITHOUT DRY ICE	
ROAD (ADR)	
Labels on cardboard overpack	UN 3481 label indicating the use of lithium-ion batteries with Cellbox Solution's phone number in the indication field: +49 40 226316410
	Text on cardboard: UMVERPACKUNG / OVERPACK
Information in transport documents (optional)	Lithium-Ion batteries contained in equipment
Indication on <b>Cellbox</b> (if transported without the overpack)	UN 3481 label indicating the use of lithium-ion batteries with Cellbox Solution's phone number in the indication field: +49 40 226316410
Information in transport documents (optional)	Lithium-ion batteries contained in equipment

CELLBOX FLIGHT 2.0 <u>WITHOUT</u> DRY ICE	
AIR (IATA)	
Labels on cardboard overpack	UN 3481 label indicating the use of lithium-ion batteries with Cellbox Solution's phone number in the indication field: +49 40 226316410 Text on cardboard: UMVERPACKUNG / OVERPACK
Information on airwaybill (AWB)	Lithium-Ion batteries contained in equipment in compliance with section II of PI967.

This overview is intended as a guideline for the labelling of dangerous goods. Cellbox Solutions GmbH shall in no event be held liable for damages / unsuccessful transports resulting from inappropriate labelling. Please consult your speciality logistics provider for final approval.

#### 8.3 Packaging of biological materials

Cellbox devices used to ship biological materials, need to be packaged according to Packing Instruction of the ADR and IATA.

Biological Substance shipments must comply with local, state, federal and international laws governing identification, classification, packaging and package markings (which may be in label form).

Cellbox recommends adhering to a three-layer packaging system, consisting of:

- leak proof primary culture vessel
- leak proof secondary packaging
- absorbent material
- outer packaging of adequate strength

The Cellbox provides a fourth sturdy outer layer packaging. Affix the appropriate label(s) to the outer package, either on the surface of the Cellbox 2.0, or on the carton overpack.

Cellbox Solutions GmbH shall in no event be held liable for damages/unsuccessful transports resulting from inappropriate labelling.

Please consult your specialty logistics provider for final approval.

### 9 ENVIRONMENTAL CONDITIONS FOR THE USE OF THE DEVICE

The Cellbox 2.0 may only be operated under the following environmental conditions:

- Environmental temperature range of 0°C to 40°C. Please take note that continuous operation at temperatures below 20°C and above 30° C will drastically affect the battery life.
- The device must be protected from being sprayed with water or submerged in water. Larger quantities of water could reach the internal electronics and cause damage.
- The operation of the device in an environment containing explosive substances, gases, fumes or mixtures of gas and air is strictly forbidden. The device does not have any measure of explosion protection.

When the Cellbox is powered from a wall socket and the battery packs are being charged, the device should only be used indoors with the following environmental conditions:

- Environmental temperature range of 0°C to +40°C
- Relative humidity max. 80% (no condensation)

#### 10 STORAGE AND DISPOSAL

#### 10.1 Storage

Storage of the device is possible in a dust-free and frostfree room. During storage the device should not be connected to an external power source.

#### 10.2 Disposal

This product is subject to the European Community Directive 2002/96/EG on waste electrical and electronic equipment (WEEE). This device may not be disposed of along with general waste at public collection points. Please contact your distributor or manufacturer for the disposal of this device. Devices that are contaminated with infected, infectious or any other substances that pose a health hazard are excluded from being returned to the manufacturer or distributor.

#### **11 TECHNICAL SPECIFICATIONS**

- Dimensions of the Cellbox 2.0: 535 mm x 380 mm x 340 mm (21.0" x 15.0" x 13.4")
- Cellbox carton overpack dimensions: 670 mm x 490 mm x 470 mm (26.4" x 19.3" x 18.5")
- Dimensions of the transport compartment: 155 mm x 200 mm x 135 mm (6.10" x 7.87" x 5.31")
- Electrical supply of the power adapter: 100–240 V AC, 50/60 Hz, 1.4 A
- Electrical supply of the Cellbox (only to be operated or charged using the provided power adapter): 20 V DC, 6,0 A, 120 W max.
- Net weight: 17 kg; 37.5 lbs
- Packed weight: 23 kg; 50.7 lbs
- Maintenance interval: 12 months
- Warranty: 1 year

More information can be found on the Technical Datasheets which can be downloaded by scanning the code on the type plate of the Cellbox 2.0 or below:



https://cellbox-solutions.com/downloads

#### 12 MAINANANCE & WARRANTY

The maintenance interval for the Cellbox 2.0 as well as its warranty are 12 months. To ensure proper functionality of the device make sure to get your service on an annular bases and request your maintenance offering from Cellbox Solutions GmbH or their respective partners.

#### **13 CLEANING INSTRUCTIONS**

#### General Advice

Clean the Cellbox before every use. Wear clean gloves for cleaning. Use an appropriate detergent (e.g., 70% ethanol or Bacillol® AF). Avoid spray disinfection.

#### Immediate Measure



#### Regular Measure

The <b>outer surface</b> of the device can be wiped clean with a dry cloth.
The device must be <b>switched off and disconnected</b> from the external power supply before any attempts at cleaning are made.



The **incubation chamber** is constructed from hard anodized aluminum. It can therefore be cleaned using a soft cloth and appropriate detergents.

#### 14 EC DECLARATION OF CONFORMITY

Hereby, Cellbox Solutions GmbH declares that the radio equipment type

Cellbox Flight 2.0

is in compliance with Directive 2014/53/EU.

The full text of the EU declaration of conformity is available at the following internet address: <a href="https://cellbox-solutions.com/downloads">https://cellbox-solutions.com/downloads</a>

Norderstedt, April 2022,

N. Vintral

Cellbox Solutions GmbH Wolfgang Kintzel CEO



An der Bahn 5 22844 Norderstedt I Germany

Englische Planke 8 20459 Hamburg | Germany

T +49 40 226316410 office@cellbox-solutions.com cellbox-solutions.com