TECHNICAL MANUAL Cellbox Ground 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 Ground 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 Ground 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 CO₂ 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_2 concentration by automatically dispensing pure gaseous CO_2 . This sustains the vitality of the in vitro cell cultures by providing a source of environmental CO_2 that stabilizes the pH. To ensure that an adequate supply of gaseous CO_2 is available for the entire period of transport, the device is equipped with a disposable CO_2 cartridge. Each disposable cartridge can maintain a 5% CO_2 environment for up to 72 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 SYMBOLS

Symbols	Symbols used on Cellbox			
===	Direct Current			
	Read the manual			
7	This product is subject to the European Community Directive 2002/96/EG on waste electrical and electronic equipment (WEEE).			
FC	This product has been tested for electromagnetic radiation below the limits specified by the Federal Communications Commission.			
CE	This product satisfies European harmonisation legislation. (CE Marking)			
Symbols	used on the Technical Manual			
	Additional information for the user			
	Additional information for the user Warning: Warning of situations that may result in personal injury or property 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 $\rm CO_2$ 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 Ground 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 transport a device in operation by aircraft if a mini CO₂ cartridge is inserted.

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.

6 PRODUCT SPECIFICATION

6.1 Scope of Delivery

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

- 1x multi-well holder
- 3x spacers for multi-well holder
- 3x spare disposable CO₂ cartridges
- 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.

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_2 build up by blocking the integrated CO_2 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 Ground 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 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 CO₂ concentration between 0% and 18%.
- Display that is updated with the internal CO₂ 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 CO₂ concentration, incubation lid status, actual ambient pressure, remaining CO₂ in the CO₂ mini cartridge 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.

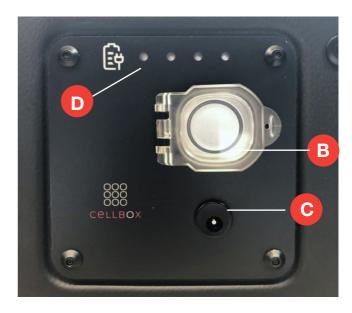
6.4 Device Overview

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 and rail.

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 CO₂ mini cartridge with lid

6.5 Display Elements

The touch screen of the Cellbox Ground 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) CO2 level in %
- Elapsed episode logging time in hh:mm:ss
- Bluetooth toggle on/off
- Remaining CO₂ level in CO₂ mini cartridge in %
- Battery Management and level in %

Tap the respective field to enter its sub menu.

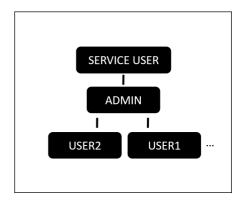
6.5.1 User Management

The CBS 21 CFR Part 11 Data Security Software is a license version of the Cellbox Ground 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 Ground 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 $_2$ 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 <u>User Management Setup</u>

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.



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.



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.



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.

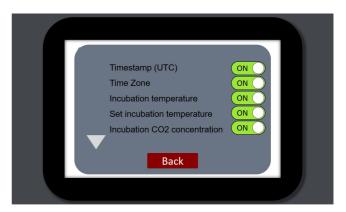


6.5.1.2 Select Logging Parameters:

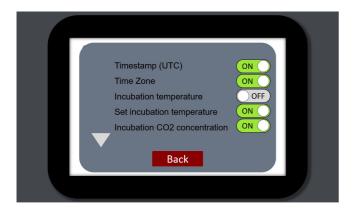
As an admin you have the option to define the parameters which shall be logged from the Cellbox 2.0. To enter the submenu, navigate to the data logging menu.



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



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 Ground 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 – CO₂ 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 CO₂ equilibration may take up to 5 minutes.

6.5.4 Setup – CO₂ Cartridge Level



Reset the remaining CO_2 mini cartridge level by tapping the blue button and confirm that disposable CO_2 cartridge has been replaced.



The counter will start to count backwards from 100%. Tap "C" to return to the Homescreen.

The remaining cartridge level is being calculated internally by counting the opening intervals and opening times of the CO₂ inlet valve.

Due to unavoidable CO₂ leakage of the system, it is mendatory to replace the CO₂ cartidge before each transport.

Be aware that leaving the transport compartment opened for longer periods of time or increasing the CO₂ concentration above 5% leads to faster idle and significant shorter runtimes.

6.5.5 Setup - Data Logging

The Cellbox Ground 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.

Historical Episode Creation (Create Episode)

To create a log episode of a time-period in the past.

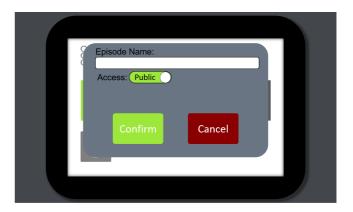
When the battery level is below 5% a non-confirmable popup screen appears on the Cellbox display. Please be aware that the Cellbox 2.0 stops its internal recording due to storage safety! Please recharge the Cellbox 2.0 to at least 5% to enable logging capabilities!

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".





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

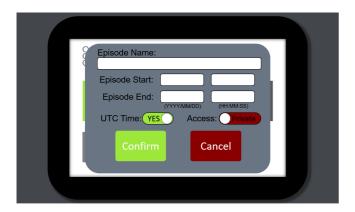


To stop the episode log, tap "Stop Episode Recording". Tap "C" to return to the Homescreen.

6.5.5.2 <u>Historical Episode Creation</u>



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.

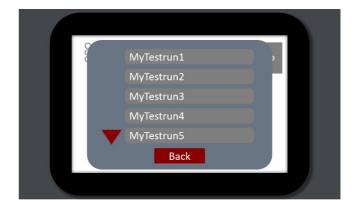
6.5.5.3 Plot Episode

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".

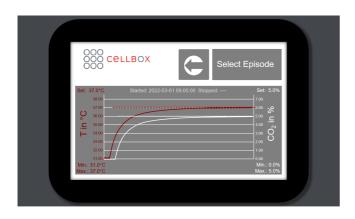


Tap "Select Episode" to open a list of created episodes. Use the up ▲ and down ▼ arrows to navigate between the episodes. Tap onto the respective Episode to load the plot or use the "Back" button to navigate back and cancel the plot creation.

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 $^{\circ}$ C as well as the internal actual CO₂ level in % for the duration of the episode. The axes are self-adjusting to display all log values.

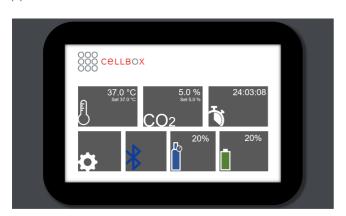


Tap "C" to return to the Homescreen.

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 \blacktriangledown 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 7.17.1 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.



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.



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 non-confirmable 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!



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.

Use only the supplied power supply unit!
(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 batteries.

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 Exchange of CO₂ mini cartridge

The Cellbox Ground 2.0 uses gaseous CO_2 to condition the internal environment for the transport of living cells. In this model of the Cellbox, gaseous CO_2 is dispensed through a disposable CO_2 mini cartridge. An electronically managed system of valves and fans ensures that the CO_2 is distributed accurately as required.

Up to three spare cartridges can be stored in the lid compartment.



Lift the CO_2 compartment lid to gain access to the cartridge thread. Start by aligning the cartridge with the thread and carefully screwing it clockwise. Once the cartridge has entered the thread, quickly tighten the carticles as a set of the cartridge has entered the thread, quickly tighten the carticles as a set of the car

tridge securely.



The cartridge needs to be tightened quickly to avoid excessive loss of CO₂ when punctured by the system.

The cartridge needs to be securely tightened to reduce the risk of a leak. The system is now pressurized!

Do not remove the disposable cartridge during operation if not replaced immediately. It serves as the gas reservoir for the incubation chamber.

Removing the disposable cartridge may lead to a rapid release of remaining CO₂, which could cause a static charge as well as ice formation in and around the thread. Please wait for several minutes before reinstalling a new cartridge.

Replace the circular lid securely on top of the disposable cartridge.

Tap the reset button within the CO_2 level menu which can be found in the Cellbox Homescreen and reset the CO_2 cartridge level, as described in section 6.5.4.

A disposable CO_2 cartridge can sustain a 5% CO_2 concentration in the incubation chamber for more than 72 hours.

If the incubation chamber is frequently opened or left open for long periods during operation, there is a risk that the CO₂ from the cartridge may be depleted prematurely.

It is mandatory to use a fresh CO₂ cartridge before every transport, since slight leakage of the system could reduce the transport time damatically.

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.
- Replace the CO₂ mini cartridge 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 CO₂ concentration of 5% within a few minutes of operation.

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

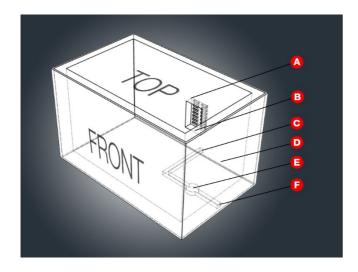
The lid of the main power switch should be securely closed before the device is transported. This prevents access to the main power switch, ensuring the device is not accidentally powered off during transport.

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 CO₂ overflow tube coming out of the Cellbox Flight 2.0 bottom with the respective hole in the polystyrene to let free CO₂ 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 CO2 overflow is blocked, excess CO₂ will build up within the polystyrene housing to the level of the incubation chamber, resulting in an unwanted and uncontrolled CO₂ increase. The Cellbox Ground 2.0 does not come with the above-mentioned CO₂ 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 CO₂ 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 CO₂ 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 to be transported at supposed 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. The CO_2 mini cartridge can also be exchanged as desired. In 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 CO_2 for the conditioning of the internal environment as well as that the Cellbox is containing lithium-ion batteries.

It is strongly forbidden to carry the Cellbox Ground 2.0 within an air plane when loaded with a open CO₂ cartridge! The Cellbox Ground 2.0 can only be carried switched OFF or by using the temperature control function only!

Labels on Cardboard Overpack / Cellbox during Ground and Flight Transport with CO_2 mini cartridge

CELLBOX GROUND 2.0 WITH CO ₂ CARTRIDGE				
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			
	CO ₂ AS CONDITIONER CO ₂ ALS KONDITIONIERUNGSMITTEL CO ₂ as conditioner label indicating the use of a CO ₂ mini cartridge			
	Text on cardboard: UMVERPACKUNG / OVERPACK			
Information in transport documents (optional)	Lithium-lon batteries contained in equipment			
Indication on Cellbox (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			
	CO ₂ AS CONDITIONER CO ₂ ALS KONDITIONIERUNGSMITTEL CO ₂ as conditioner label indicating the use of a CO ₂ mini cartridge			
Information in transport documents (optional)	Lithium-ion batteries contained in equipment			

CELLBOX GROUND 2.0 WITHOUT CO₂ CARTRIDGE				
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-lon batteries contained in equipment			
Indication on Cellbox (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			

Please be aware that the air cargo transport is only permitted in the respective overpack. Cellboxes without the overpack do not conform to the IATA regulations and may not be transported.

CELLBOX GROUND 2.0 WITHOUT CO₂ CARTRIDGE				
AIR (IATA)				
Labels on cardboard overpack	UN 3481 Left on cardboard: UMVERPACKUNG / OVERPACK			
Information on airwaybill (AWB)	Lithium-lon 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 frost-free 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: 18 kg; 40.0 lbs
- Packed weight: 24 kg; 53.0 lbs

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

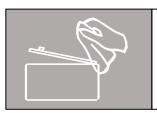
Clean the Cellbox before every use.
Wear clean gloves for cleaning.
Use an appropriate detergent (e.g., 70% ethanol or Bacillol® AF).
Avoid spray disinfection.

Immediate Measure



Please remove any spills immediately.

Regular Measure



The **outer surface** of the device can be wiped clean with a dry cloth.



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 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 Ground 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: https://cellbox-solutions.com/downloads

Norderstedt, April 2022,

M. Wintel

Cellbox Solutions GmbH

Wolfgang Kintzel

CEO

