INTEGRA



D-ONE Single Channel Pipetting Modules Operating Instructions for ASSIST PLUS

CEUR Declaration of conformity INTEGRA Biosciences AG – 7205 Zizers, Switzerland declares on its own responsibility its user

Description	Models	
VIAFLO Pipettes	4011, 4012, 4013, 4014, 4015, 4016, 4621, 4622 4626, 4631, 4632, 4633, 4634, 4636, 4641, 4642	
VOYAGER Pipettes	4721, 4722, 4723, 4724, 4726, 4731, 4732, 4736 4763, 4764	6, 4743, 4744,
D-ONE Module	4531, 4532	
Accessories	3214, 3215, 3216, 3217, 3218, 4200, 4205, 4210 4221), 4211, 4215,
comply with:		
EU Directives	Scope	Date effective
2014/35/EU	Low voltage directive (LVD)	20.04.2016
2014/30/EU	Electromagnetic compatibility (EMC)	20.04.2016
2012/19/EC	Waste electrical and electronic equipment (WEEE)	14.02.2014
2011/65/EC	Restriction of hazardous substances (RoHS)	03.01.2013
2006/66/EC	Battery directive	26.09.2008
EU Regulations	Scope	Date effective
1907/2006	Registration, evaluation, authorisation and restriction of chemicals (REACH)	01.06.2007
2019/1782	External power supply efficiency	01.04.2020
1103/2010	Capacity labelling of portable batteries	30.11.2010
EU Standards	Scope	
EN 9001:2015	Quality Management	
EN 61010-1:2020	Safety general laboratory equipment	
EN 61326-1:2013	Electromagnetic compatibility laboratory equipme	ent
EN 60950-1:2013	Safety information technology equipment	
EN 62368-1:2021	Safety information technology equipment	
EN 62133-2:2017	Batteries containing non-acid electrolytes	

GBR Regulations	Scope	Date effective
S.I. 2016/1101	Electrical equipment safety	08.12.2016
S.I. 2016/1091	Electromagnetic compatibility (EMC)	08.12.2016
S.I: 2008/2164	Batteries and accumulators regulations	26.09.2008
S.I. 2013/3113	Waste electrical and electronic equipment (WEEE)	01.01.2019
S.I. 2012/3032	Restriction of hazardous substances (RoHS)	02.01.2013
GBR Standards	Scope	
BS 61010-1:2010	Safety general laboratory equipment	
BS 62368-1:2020	Safety information technology equipment	
BS 63000:2018	Restriction of hazardous substances (RoHS)	

USA Regulations	Scope	Date effective
47 CFR Part 15 (FCC)	Electromagnetic compatibility (EMC)	
10 CFR Part 430	External power supply efficiency (CEC VI)	
17 CFR Parts 240 & 249b	Dodd frank "Conflict minerals"	
27 CCR Parts 25102- 27001	Proposition 65: The safe drinking water and toxic enforcement act	
TSCA 40 CFR Part 751	Toxic substances control act	
20 CCR Parts 1601-1608	CEC BCS, Battery charging efficiency	01.01.2017
USA Standards	Scope	
UL 61010-1:2012	Safety general laboratory equipment	

CAN Standards	Scope
CSA-C22.2 No. 61010-1	Safety general laboratory equipment

CHN Regulations	Scope	Date effective
AQSIQ Order 5 /2001	(CCC) safety and EMC requirements for electrical equipment	01.08.2003
Order 32/2016	Restriction of hazardous substances (RoHS)	01.07.2016
CHN Standards	Scope	
GB4943.1-2011	Information technology equipment safety	
GB9254-2008	Information technology equipment radio disturbance	
GB17625.1-2012	EMC limits for harmonic current emissions	
GB31241-2014	Safety for Lithium-ion batteries	
SJ/T 11364-2014	Restriction of hazardous substances (RoHS)	

JPN Regulations	Scope	Date effective
PSE (Denan) Law	Electrical appliance and material safety law	01.01.2014

ЕАС Технический регламент Таможенного союза			
TP TC 004/2011	О безопасности низковольтного оборудования		
TP TC 020/2011	Электромагнитная совместимость технических средств		

International Standards		
ISO 8655-2	Piston pipettes	

Zizers, May 2, 2022

Urs Hartmann CEO

1). Rau

Daniel Bächi Head of Corporate Quality

Table of Contents

Chapter 1	Introduction	
	1.1 Symbols used1.2 Intended use1.3 Safety notes	7
Chapter 2	Description of the device	
	 2.1 Scope of delivery 2.2 Overview of D-ONE module 2.2.1 Module parts 2.2.2 Back view 2.2.3 Display 2.2.4 Touch wheel 2.2.5 PURGE button (only calibration) 2.2.6 RUN button (only calibration) 2.2.7 Tip ejector 2.2.8 Reset button 	11 12 12 13 13 13 13
Chapter 3	Installation	
	 3.1 Operating environment	14 15 16 17 18 19 20 20
Chapter 4	Operation	
	 4.1 Turn on/off the device	22 22 23 23

Chapter 5 Maintenance

5.1	Maintenance schedule	25
	5.1.1 Daily	25
	5.1.2 Periodical	
	5.1.3 Yearly Maintenance	25
5.2	Cleaning	25
5.3	Decontamination	
5.4	Leak test	
5.5	Servicing	27
	5.5.1 Shipping to INTEGRA Biosciences	27
	5.5.2 Changing O-rings of tip fittings	
5.6	Equipment disposal	

Chapter 6 Technical data

6.1	Environmental conditions	29
6.2	Specification of the device	29
6.3	Pipetting speed	30
6.4	Intellectual Property	31
6.5	D-ONE Specifications	32

Chapter 7 Accessories

7.1	Acces	ssories		
7.2	Consumables			
7.3	GRIP	TIPS		
	7.3.1	INTEGRA pipetting device		
	7.3.2	Package options		
		GRIPTIP properties		
Imp	rint			

1 Introduction

These operating instructions contain all the information required for installation, operation and maintenance of the D-ONE modules. This chapter informs about the symbols used in these operating instructions, the intended use of D-ONE and the general safety instructions.

1.1 Symbols used

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



WARNING

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



CAUTION

This symbol cautions against potential material damage or the loss of data in a microprocessor controller. Follow the instructions.



Νοτε

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

1.2 Intended use

This is a general-purpose laboratory instrument for use in research only. Any use of this instrument in a medical or IVD setting is under the sole responsibility of the user.

This product may only be operated in a secure, protected network with validated, trustworthy clients. The operator must ensure that network security measures are always up-to-date and state-of-the-art. This product may not be directly exposed to the internet.

If the D-ONE modules are used in a manner not specified by INTEGRA Biosciences, the protection provided by the D-ONE may be impaired.

D-ONE are microprocessor controlled and stepper motor driven pipetting modules with two channels, one of which can be used at a time. They are used on the ASSIST PLUS pipetting robot for aspirating and dispensing aqueous liquids in the volume range of 0.5 – 1250 µl using GRIPTIP[™] pipette tips only. Each D-ONE module is compatible with two different GRIPTIP sizes and provides pressure-based liquid level detection.

1.3 Safety notes

D-ONE comply to the recognized safety regulations and are safe to operate. D-ONE should only be operated when in perfect condition and while observing these operating instructions.

The device may be associated with residual risks if it is used or operated improperly by untrained personnel. Any person operating D-ONE must have read and understood these operating instructions, and particularly, the safety notes, or must have been instructed by supervisors so that safe operation of the device is guaranteed.



WARNING

- Use only an original INTEGRA Li-ion battery (#4205) and charging device.
- Old Li-ion batteries may cause a safety risk. We recommend to replace the battery after 3 years of use. Also replace the battery if the charging intervals are unusually short or if the charging takes much longer than usual (4 hours or more). – These are indicators that the battery has reached the end of its life-cycle.

If a lithium battery is never deep discharged and is always stored and operated in the recommended temperature range and stored at 40-80% charge level during long standby periods, it may live much longer than 3 years. If it shows no signs of physical damage or change, see <u>5.1.3</u>, it is a strong indication that you may continue to use the battery.

 Li-ion technology bears the risk of thermal runaway and cell rupture if the battery was damaged. Do not expose the battery to heat (> 60 °C) and avoid mechanical stress. Batteries which were subject to deep discharges may develop internal short circuits, leading to an increased selfdischarge rate and heating during battery charging. This may also result in thermal runaway and cell rupture.



CAUTION

 To extend the battery life-cycle, it is recommended to charge the battery every 2 months if D-ONE is not used regularly. If D-ONE is not used for more than 6 months, unplug the battery.



WARNING

- Do not use D-ONE near flammable material or in explosive areas. Also, do not pipette highly flammable liquids such as acetone or ether.
- When handling dangerous substances, comply with the material safety data sheet (MSDS) and with all safety guidelines such as the use of protective clothing and safety goggles.



CAUTION

- Do not immerse D-ONE in liquid. The fluid can damage internal parts. Avoid pipetting of liquids whose vapors could attack the materials PA (polyamide), POM (polyoxymethylene), FPM (fluor-rubber), NBR (nitrilerubber), CR (chloroprene), silicone. Corrosive vapors could also damage metallic parts inside the device.
- Do not modify D-ONE in any way. Repairs may only be performed by INTEGRA Biosciences or by an authorized after-sales service member.
- · Parts may be replaced with original INTEGRA Biosciences parts only.



Νοτε

Prolonged exposure of D-ONE to UV-light can cause discoloration and/or yellowing of D-ONE housing. However, this will not affect the performance of the device in any way.

Regardless of the listed safety notes, additional applicable regulations and guidelines of trade associations, health authorities, trade supervisory offices, etc. must be observed.

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

2 Description of the device

2.1 Scope of delivery

- D-ONE single channel pipetting module
- Rechargeable battery (located inside the module, Li-ion, 3.7 V, 1050 mAh)
- Bag of spare O-rings
- · O-ring removal tool
- Certificate of performance
- Trial pack 25 ml SureFlo™ reagent reservoir
- Quick start guide



CAUTION

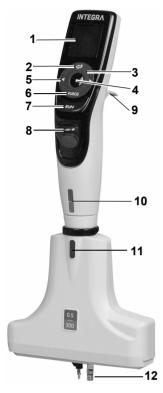
Verify the scope of delivery when unpacking the device and check for potential transportation damage. Do not operate a device that is damaged, instead contact your local INTEGRA representative.

Νοτε

The pipette communication module (#4221) is mandatory to use the D-ONE module with the ASSIST PLUS and has to be ordered separately.

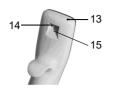
2.2 Overview of D-ONE module

2.2.1 Module parts



- 1 Display
- 2 Back button, to navigate backward
- 3 Touch wheel, spin to scroll and move the cursor
- 4 OK button, to make a selection
- 5 Left and right arrow buttons, for selections
- 6 **PURGE button**, to empty GRIPTIPS, for calibration only
- 7 RUN button, to start operations
- 8 Tip ejector
- 9 Finger hook
- 10 Volume indicator label (purple/green or yellow/ blue), colors match GRIPTIP rack inserts
- 11 Tip ejector
- 12 Tip fittings, for 0.5/300 μl or 5/1250 μl GRIPTIPS

2.2.2 Back view



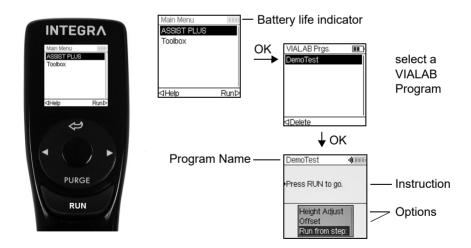
- 13 Power connector
- 14 Reset button
- 15 Communication/charging cable interface



16 Battery

2.2.3 Display

The Display shows under ASSIST PLUS all available VIALAB programs.



2.2.4 Touch wheel

The **touch wheel** is fully operational with only one hand. Rotational finger movements translate into up and down cursor movement on the display. The **touch wheel** is fully functional with the use of latex gloves.

2.2.5 PURGE button (only calibration)

During pipetting, you can interrupt the current pipetting protocol and purge all remaining liquid currently in the GRIPTIPS. To do so, press **PURGE** (6).



The module will display a prompt:

To proceed, press and release **RUN** (<u>7</u>). Upon completion of the dispense, the first step in the current program will be displayed.

2.2.6 RUN button (only calibration)

Press and release the **RUN button** $(\underline{7})$ to initiate pipetting operations. This button is centrally located for left- or right-handed actuation.

During dispense, you can press and hold **RUN** to perform a two-step blowout, see <u>"4.4</u> Troubleshooting/FAQ" on page 23.

2.2.7 Tip ejector

The Tip Ejector easily ejects tips from the tip fitting.



The serial number can be found beneath the tip ejector. Press and hold the tip ejector in the down position to see the 7-digit serial number.

2.2.8 Reset button

The **reset button** (<u>13</u>) is located on the back of D-ONE. It is used to reset the RAM in the module. The programs stored in memory are maintained. Once pressed, the startup screen will be displayed.

Press any key to continue and allow the instrument to initialize and home. The routine ends by displaying the Main Menu.

3 Installation

3.1 Operating environment

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

3.2 Charging the battery

D-ONE contains a rechargeable Li-ion battery. Charge the battery completely before first use. A full charge takes 2.5 hours (max. 4 hours) and will provide approximately 1500 cycles.

A battery indicator is provided on D-ONE display (2.2.3) indicating different states:

- Blinking red icon: Battery is low and needs to be recharged. If not connected to the mains adapter, the D-ONE module will turn off soon.
- · Green icon: D-ONE module is connected to the mains adapter.
- Blinking bars: D-ONE module is recharging.
- Two static and one blinking bar on the right: D-ONE module is recharging and battery is 80% charged.
- Three static bars: Battery is fully charged.

Use the charging/communication stand (#4211), the USB cable (#4226) or the charging cable (#4549) to charge the battery, see <u>"7.1 Accessories" on page 33</u>).



Place the D-ONE module on the charging/communication stand by fitting the power receptacle (<u>15</u>, on the top back of the module) over the four pin prong connector on the top of the stand.

Plug the power cable of the adequate power supply to the socket.

CAUTION

Use only the approved INTEGRA battery, charging cable or stand with the correct mains adapter. Use of an incompatible power transformer can damage the D-ONE module.

The D-ONE module will turn on when placed on the stand and turn off when the Turn Off Time is reached. The display may dim or show the start up screen, but it will continue to show the battery life indicator. When the Standby Time is reached, the display is turned off. When the Turn Off Time is reached, the instrument will shut off.

For disconnecting simply lift the D-ONE module up from the stand.

3.3 Exchanging the battery



To exchange the battery, loosen the screw to detach the D-ONE module backing. Disconnect the power plug of battery (<u>16</u>). Connect the power plug of the new battery to the D-ONE module's socket and reassemble the D-ONE module backing.

After exchanging the battery, a protective switch is active. The D-ONE module can only be started after connecting it to the mains power supply.



WARNING

D-ONE module use Li-ion batteries, see <u>"1.3 Safety notes" on page 8</u>.

3.4 Tip deck for D-ONE

The D-ONE module requires its own tip deck (#4535) on ASSIST PLUS. Insert the tip deck and place two GRIPTIP racks on the deck.

D-ONE 0.5–300 μl : pink 12.5 μl and green 300 μl tip rack.

D-ONE 5 – 1250 μl : yellow 125 μl and blue 1250 μl tip rack.



Left side: pink 12.5 µl or yellow 125 µl rack.

The 192 tips on the right half of the rack can be loaded. Then rotate the rack 180° to use the tips on the left half.

Right side: green 300 µl or blue 1250 µl rack.

The lid on the right side must be removed manually prior to tips loading.

Attach the second stage to lift the 12.5 or 125 μ l tip rack so that both racks are the same height when using 300 μ l LONG or 1250 μ l GRIPTIPS.

The second stage can be removed by tilting it to the right (see arrow).

3.5 Toolbox - adapt your D-ONE module

The Toolbox provides options to adapt the device to appropriate applications, setting personal preferences, calibration, computer connectivity and storing device information.

Toolbox mode	Description	
ASSIST PLUS	Options to adapt the D-ONE module in combination with ASSIST PLUS.	
Preferences	Customizes the system parameters.	
Calibration & Service	Sets calibration and service history options.	
Communications	Enables communication between your D-ONE module and a PC.	
Device Information	View your D-ONE module's serial number and set a personal ID.	
Language	Sets language.	
Write Protect	Protects programs or menu options from modification.	
Time/Date	Sets current time and date.	

Help information is available for each mode.

3.5.1 Preferences

Preferences customizes your system parameters. Select a preference and press $\ensuremath{\text{OK}}$ to access.

Preference	Description	Range
Sound	 Simple tones indicate completion of operations and errors. Select an option and press OK to change the status of the beep tone between On and Off: Program Complete: At program completion PURGE button: When PURGE is pressed. Messages: When a message appears. Error Message: When an error message appears or when illegal data entry is attempted. Touch Wheel: When using the touch wheel. 	✓/x (On/Off)
Display	 Customizes your display. Press OK to select an option, use the touch wheel to display the desired value. Start up Screen: Select the startup display at one of the following: None or Custom (up to two, uploaded with VIALINK). Press ▷ to save your selection. Brightness: Use the touch wheel to change the brightness: 1 (dim) to 10 (bright). Press OK. Dim Time: The display will dim after a set number of minutes. A shorter dim time helps preserve battery life. Press OK to save your selection. Standby Time: The display will turn off after a set number of minutes and allows you to continue working where you have left. A shorter standby time helps preserve battery life. Turn Off Time: The D-ONE module will turn off after a set number of hours. You can change this setting. Press OK to save your selection. 	None, Custom 1 or 2 1-10 Never, 1-20 min 5-60 min (default 5 min) 1-24 hours (default 8 h)
Touch Wheel	Adjust your touch wheel sensitivity. Press ▷ to save.	Low, Medium, High

After changing desired settings, press \triangleright to save.

3.5.2 Calibration & Service

These options enable you to set calibration features, review service history and check the number of pipetting moves performed.

Calibration & Service	Description	Range
Calibration	 Allows for re-calibration of the D-ONE module to restore accuracy (calibration has to be performed by INTEGRA). Choose the channel. The calibration factors for Pipette and Repeat type are displayed. To edit the calibration volumes, press < Edit. Target Volume: This is the volume you are interested in using for the calibration. Actual Volume: This is the measured volume obtained when dispensing the target volume. Current Factor: Displays the factor currently in use. Factory Reset: Resets the correction factor back to the original factory setting. Press < to apply the factory setting. 	-
Calibration Reminder	 Sets a calibration reminder based on a specified time frame or number of pipetting cycles. When the calibration reminder is displayed, press any key to confirm. However, the reminder will reappear every time the D-ONE module is turned on until you change the reminder time or use the reset option. Reminder: Press OK to turn the reminder timer On or 	√/x
Cycles	 Off. Days/Cycles: Use the touch wheel to set a reminder interval for calibration (time in days or in thousands of cycles). Press ⊲ to set the timer to the defined calibration interval. Remind in/Total Cycles: Displays the residual time or amount of cycles respectively before calibration is required. Reset: Resets the timer to the defined calibration interval. Press ⊲ to enable. 	(On/Off) 1-365 days or 1k - 240k cycles
Service History	Displays notes of any service that took place on the D- ONE module listed newest entry first.	-

Calibration & Service	Description	Range
Move Counter	 Displays the number of completed moves. Piston Moves: One piston move is defined as one full start and stop cycle of the piston. Y Moves: One tip spacing move is defined as one full start and stop cycle of the spacing motor. 	-

After changing desired settings, press \triangleright to save.

3.5.3 Communications

D-ONE must be programmed from a PC via a charging/communication stand (#4211), the USB cable #4226 or charging/communication station for linear stand (#3218).

VIALAB is a pipetting automation software for the PC. It allows to create automated pipetting programs for a variety of applications on ASSIST PLUS. It can be downloaded from the INTEGRA website in the product section. A detailed description of the software, along with the operating instructions, can be found on the website as well.

Communi- cations	Description
USB	Place the D-ONE module on a charging/communication stand (#4211), or connect the device to the USB cable (#4226) and connect it to the USB port of your PC.
ComModule	Each D-ONE module needs its own pipette communication module (#4221). Using the communication module enables a communication with an open field connectivity of about 10 meters. If a paring code is required: 12345.
Via ASSIST PLUS	Activate this communication for live position teaching on ASSIST PLUS. ASSIST PLUS needs to be connected with USB to the PC.
PC Control (A+)	To control the D-ONE module by an external device, e.g. laptop or PC. This allows to start a VIALAB program directly from VIALAB itself.

Select one connection type and press **OK** to allow communication with the PC. VIALAB will detect the D-ONE module automatically.

Updating firmware

Connect the pipette to the to the USB port of your PC. From the VIALINK software on your PC go to the Firmware tab and install the latest firmware. This will create backup copies of all existing VIALAB programs on your D-ONE module, which will be displayed in gray. When selecting one of these programs, you are prompted to convert it. Press **RUN**. The newly converted program is displayed in black and can be executed on ASSIST PLUS.



NOTE Check the converted program before first use. Once it is found OK, delete the backup program.

3.5.4 Device Information

This menu displays information about your D-ONE module, such as volume range, number of channels, serial number, firmware (FW) and hardware (HW) version.

Device Information	Description
Edit Owner	 Press < Edit Owner to enter the user name for your D-ONE module. Use the touch wheel to highlight a character and press OK. You can press < to Delete the last character entered. After entering the desired text, press > to Save.

Go to the next pages with Next \triangleright .



The last page displays the compliance screen, which is also shown during start up. It lists the standards the D-ONE modules comply with.

3.5.5 Language

Language	Description
	You can choose the language in which all screens are displayed. Scroll to the desired language, press OK and \triangleright to Save.

3.5.6 Write protect

Select this option to protect programs and menu options from inadvertent modification. The pipetting programs can still be used.

Write Protect	Description	Range
	 Select an option and press OK to switch protection on or off: Custom Programs Password Protection: Protect the access to the write protect menu by selecting "✓". Edit Password, if password protect is switched on. To enter a password use the touch wheel to highlight a character and press OK. Press ▷ to save the password. The password must be entered before you can access the write protect menu. 	√/≭ On/Off

Keep the password in a safe place. Should you lose your password, contact INTEGRA Biosciences for assistance in retrieving it.

4 Operation

4.1 Turn on/off the device

Turn on:

Press and release RUN (7) to turn on D-ONE.



CAUTION

Do not touch the **touch wheel** at switch on and during homing, because it is calibrated during the start up process. Make sure the tip fittings (<u>12</u>) are free of any obstacles when D-ONE is switched on.

D-ONE flashes the startup screen and performs a full motor homing routine, ensuring the motor is in the run position. "Home" is the base point for D-ONE. Homing is the process whereby the D-ONE motor moves the piston(s) to a sensor position. This position ensures that no liquid remains in the tips. Homing also includes the tip spacing motor. The tips move to the first tip spacing position. After homing the Main menu is displayed.

Turn off:

To turn off D-ONE, press and hold the **back button** (2) for 3 seconds.



Νοτε

D-ONE will dim and turn off automatically after a preset duration of inactivity. This duration is 5 minutes, by default, and configurable with the Toolbox (see "3.5.1 Preferences" on page 17).

4.2 Programming

Use the VIALAB pipetting automation software to create multi-step programs on a PC and transfer them to the D-ONE module, see VIALAB operating instructions.

4.3 Running a program

D-ONE can only be operated on ASSIST PLUS. For further information, see ASSIST PLUS operating instructions.

Attach the D-ONE module on the ASSIST PLUS pipetting robot. Use the communication module or the communication cable to connect D-ONE with ASSIST PLUS. Scroll with the **touch wheel** ($\underline{3}$) to your desired program and press **OK** ($\underline{4}$). Selected parameters for the action you are about to perform will be displayed on the Run screen. Press **RUN**.

4.4 Troubleshooting/FAQ

4.4.1 General

Problem	Probable cause	Remedy
Leakage.	 Tip incorrectly attached. Foreign particles between tip and tip fitting. Damaged colored O-ring. 	 Attach a new tip. Clean tip fitting. Attach new tips. Change the colored O-ring, see <u>5.5.2</u>. If leak persists, contact service.
Dispense results are inaccurate.	 Unsuitable calibration. Improper pipetting techniques. 	 Send D-ONE to INTEGRA for calibration. Adjust aspiration and dispense speed depending on liquid: High viscosity liquids may require calibration. High vapor pressure liquids may require pre-wetting.
Not dispensing/ aspirating.	 Piston stuck or not connected. Motor not running. Internal O-ring is damaged. 	Contact service.
Droplets on the tips.	 Temperature of liquid differs from that of air inside the tips. Liquid of low viscosity and high vapor pressure. Touch off was not performed. 	 Pre-wet tips up to 3 times. Increase dispensing speed. Perform a touch-off.
Display does not react.	Software frozen.	Press Reset Button on back of D-ONE.

Problem	Probable cause	Remedy
When pressing RUN , a "Low Bat- tery" message appears on the Run screen.	• Low battery.	• Re-charge the battery in order to resume pipetting operation.
Display turns off completely.	• Dead battery.	Charge the battery with a power cord or charge stand.Replace the battery after 3 years, if damaged.
Touchwheel response is erratic and uncontrollable.	 A finger was on the touch- wheel when D-ONE was turned on. 	 Reset D-ONE without touching the touch wheel during reset. Adjust the touch wheel sensitivity with Toolbox, Preferences, touch wheel, see <u>3.5.1</u>.
Displayed charac- ters are scrambled.	• Unknown.	• Reset D-ONE.
Battery charging indicator is not pul- sing while on the stand. D-ONE does not turn on when placed on the charging stand.	• Charge stand pins are out of place.	 Check that both charge stand conductor pins are at the same height. Make sure the charger is plugged in.
Error message "Homing error!" is displayed.	 Indicates too much friction was encountered during operation. Indicates possible motor fail- ure. 	 Reset D-ONE. If problem persists, please contact service for technical assistance.
Tip spacing motor not working.	 Tip spacing motor drive not initialized. 	 Reset D-ONE. Turn D-ONE off. Unplug battery for about 5 seconds. Turn D- ONE on.

4.4.2 Electronic

5 Maintenance



WARNING

D-ONE maintenance should be carried out on a clean and dust free workplace. Always turn off power and disconnect D-ONE from the mains and wear gloves when carrying out maintenance work.

D-ONE modules are precision instruments, therefore a proper maintenance routine must be followed to ensure safe and reliable operation. Cleaning is recommended if D-ONE has been contaminated or if it has come in contact with corrosive liquids.

5.1 Maintenance schedule

5.1.1 Daily

- Inspect D-ONE for visual damages.
- Clean the outer surface of D-ONE (see 5.2).

5.1.2 Periodical

• In case D-ONE is in daily use, perform a leak test every 3 months (see 5.4).

5.1.3 Yearly Maintenance

- Send it for calibration to INTEGRA at least once a year (see 5.5).
- If you operate the battery beyond the recommended 3 year period, visually check the battery for signs of damage, e.g. discoloration, unexpected stains, shrinking of the tube wrapping.

5.2 Cleaning

The materials used on the exterior of D-ONE support regular cleaning intervals. Clean the external components with a lint-free cloth lightly soaked with mild soap solution in distilled water or with a 70 % dilution of Isopropyl or Ethanol. Never use Acetone or other solvents.



WARNING

Do not immerse the entire D-ONE into a cleaning solution or spray cleaning solution directly onto the exterior body of D-ONE as this can potentially damage internal electronics.

If liquid ever enters the internals of D-ONE, please contact your service technician.



CAUTION

D-ONE can only be completely disassembled by trained service personnel.

5.3 Decontamination

If the surface of D-ONE has been in contact with biohazardous material, it must be decontaminated in accordance to good laboratory practice. Wipe the clean surface with a lint-free cloth, lightly soaked e. g. with the following disinfectants:

- Ethanol 70 %
- Microcide SQ 1:64
- Glutaraldehyde solution 4%
- Virkon solution 1-3%

Follow the instructions provided with the disinfectants.

D-ONE may be decontaminated with $\rm H_2O_2$ gas (maximal concentration 35 %) for 60 minutes.



WARNING

D-ONE can NOT be autoclaved!

5.4 Leak test

It is recommended to perform a leak test every 3 months or when errors occur. The following two programs are available in VIALAB under sample programs:

- Leaktest D-ONE 0.5 300 μl
- Leaktest D-ONE 5 1250 µl

Select a program and transfer it to the D-ONE module. Read the program description carefully, start the program and observe the pipetting process.

Signs indicating a leak

- 1) Liquid level in the tip is decreasing while the tip is immersed in liquid during the 30 s wait time.
- 2) During the mix cycle the top aspiration level in the tip is gradually decreasing. This shows in uneven liquid levels across the tips after aspiration.
- 3) The tip show air bubbles at the tip end during the mix cycles.



NOTE A decreasing liquid level at aspiration could be an indication of a slow leak. Performing a retest at 10 mixes may help identify a slow leak.

If a leaking channel is identified, change the colored O-ring on that specific tip fitting (where applicable, see 5.5.2) or contact your service technician.

5.5 Servicing

An annual maintenance service including calibration is recommended on D-ONE in order to ensure optimal pipetting accuracy/precision, as well as a long life for the device.

If you intend to ship D-ONE to be periodically calibrated, the original packaging can be stored and reused for this purpose. Contact INTEGRA for more information about available calibration services.



WARNING

If liquid ever enters the internals of the D-ONE pipetting unit, please contact your service technician.

Pipetting unit need to be serviced by INTEGRA in the following cases:

- · Liquid has entered the pipetting unit
- · One or more channels did not pass the leak test

5.5.1 Shipping to INTEGRA Biosciences

For any service or repairs, please contact your local service technician.



WARNING

If working with infectious materials, e. g. human pathogens, D-ONE needs to be decontaminated before sending them to service and the declaration on the absence of health hazards must be signed. This is necessary to protect service personnel.

5.5.2 Changing O-rings of tip fittings

D-ONE modules feature a tip fitting with a colored O-ring. This O-ring is used to seal against the inside wall of GRIPTIPS and provides a robust seal.

O-rings are made of durable silicone. If necessary, e.g. in case of a leakage due to damaged O-ring, you can replace these O-rings. A set of spare O-rings and an O-ring removal tool are included and can be ordered separately, see <u>"7 Accessories" on page 33</u>.



WARNING

Avoid mechanical damage of the tip fittings.





Choose the side of the O-ring removal tool corresponding to the size (300 μ I or 1250 μ I) of D-ONE tip fitting (<u>12</u>). Slide the O-Ring removal tool sidewards onto the tip fitting until the O-ring (a) builds a loop. Remove the O-ring with fine plastic tweezers.



Slide a new O-ring over the tip fitting (b).

5.6 Equipment disposal



D-ONE must not be disposed of with unsorted municipal waste. Do not dispose of D-ONE in a fire.

D-ONE contains a Li-ion battery. Do not modify the battery in any way. Dispose of D-ONE and the batteries separately in accordance with the laws and regulations in your area governing disposal of devices containing Li-ion

batteries. In certain regions and countries, e.g. in EU member states, the distributor is obliged to take back this product free of charge at the end of life. Please contact your local distributor for more details.

6 Technical data

6.1 Environmental conditions

	Operation
Temperature range	5–40°C
Humidity range	Max. rel. humidity 80% for temperatures up to 31°C, decreasing linearly to 50% rel. humidity at 40°C.
Altitude range	< 2000 m

6.2 Specification of the device

Battery	Type: rechargeable, Li-ion, 3.7 V, 1050 mAh Typical charging time: 2.5 hours Charging cycles: 500–1000 (when charging as indi- cated) Running time: approx. 1500 pipetting cycles
Electricity supply	Mains adapter input: 100–240 V, 50/60 Hz Device input: 5.7–6.4 V, 3 W
Pipetting channels	2 x 1
Pipetting speed	10 steps, in μl/s
Pipetting technology	Air displacement
User interface	Touch wheel, color display

6.3 Pipetting speed

Default pipetting speed (μl/s)					
	D-ONE Size				
Speed	20 µl	125 µl	300 µl	1250 µl	
1	0.52	4.9	11.6	47	
2	1.04	9.8	23.3	93	
3	2.58	24.3	57.8	232	
4	3.12	29.4	70.1	281	
5	3.81	35.8	85.5	343	
6	5.16	48.5	115.7	464	
7	7.30	68.7	163.8	657	
8	9.72	91.5	218.2	875	
9	10.94	102.9	245.5	985	
10	12.51	117.7	280.8	1126	

The speeds apply to firmware version 5.01 or higher.

6.4 Intellectual Property

Patent Number	Country	Title	Apply to
7,662,343	USA	Locking Pipette Tip And Mounting Shaft	All pipettes
7,662,344	USA	Locking Pipette Tip And Mounting Shaft	GRIPTIP/Tip fitting
5261392	JAPA	Locking Pipette Tip And Mounting Shaft	GRIPTIP/Tip fitting
8,033,188	USA	Pipettor Software Interface	All pipettes
2192985	EPC/ FRAN/ GBRI/ SWIT	Pipettor Software Interface	All pipettes
602008010945	GERM	Pipettor Software Interface	All pipettes
D596,754	USA	Pipette	All pipettes
7,540,205	USA	Electronic Pipette Assembly	All pipettes
8,122,779	USA	Electronic Pipettor With Improved Accuracy	All pipettes
D596,755	USA	Multi-Channel Voyager	VOYAGER
8,029,742	USA	Multi-Channel Pipettor With Reposi- tionable Tips	VOYAGER
8,128,892	USA	Programmable Multi-Channel Pipet- tor with Repositionable Tips	VOYAGER
D599,030	USA	Multi-Channel Pipette	Multichannel pipettes
7,811,522	USA	Sample Reservoir Kits With Dispos- able Liners	Reservoirs
D599,031	USA	A Liquid Sample Or Liquid Reagent Reservoir Kit	Reservoirs
8,277,757	USA	Pipette Tip Mounting Shaft	GRIPTIPS
8,501,118	USA	Disposable Pipette Tip	GRIPTIPS

The D-ONE modules are covered under the following patents:

6.5 D-ONE Specifications

The specifications apply to neat transfers only when the D-ONE module is used together with INTEGRA GRIPTIPS.

Precision = coefficient of variation

D-ONE modules						
Channel	Part No.	Volume Range (µl)	Volume Increments (µl)	Test Volume (μl)	Accuracy (±%)	Precision (≤%)
				2	10.00	6.00
		0.5–20	0.01	10	4.00	1.60
1	4531			20	2.00	0.80
				30	4.00	1.20
		10-300	0.5	150	2.00	0.60
				300	1.60	0.35
				12.5	3.75	1.50
		5–125	0.1	62.5	2.50	0.70
1	4532			125	1.60	0.35
		50-1250	1	125	6.00	1.10
				625	2.40	0.50
				1250	1.20	0.30

7 Accessories

7.1 Accessories

Charging options and communication	Part no.
Short linear stand, holds up to 2 charging stations	3214
Linear stand, holds up to 4 charging stations	3215
Mains adapter for up to 4 stations and carousel charging stand	3216
Charging station for linear stand, incl. connection cable	3217
Charging/communication station for linear stand, incl. connection cable and USB cable	3218
Battery, Li-ion, for VIAFLO, VOYAGER, D-ONE	4205
Charging/communication stand for 1 VIAFLO, VOYAGER, D-ONE, incl. mains adapter and USB cable	4211
Communication module for VIAFLO, VOYAGER, D-ONE	4221
Charging/communication cable for VIAFLO, VOYAGER, D-ONE to ASSIST PLUS	4548
Charging cable for VIAFLO, VOYAGER, D-ONE to ASSIST PLUS	4549

General	Part no.
ASSIST PLUS pipetting robot	4505
O-ring removal tool for 300 µl and 1250 µl pipettes	161916

7.2 Consumables

Colored O-rings for tip fittings	Part no.
O-ring for 200/300 μl tip fittings, pack of 2	161 192
O-ring for 1000/1250 μl tip fittings, pack of 2	161 193

Reservoirs 10 ml, disposable inserts		Part no.
INTEGRA	Reservoir base 10 ml, pack of 10	4306
SureFlo™,	Trial pack, sterile (3 reservoirs, 1 base)	4370
polystyrene	Sterile, pack of 30 (30 individually wrapped, 1 base)	4371
	Sterile, pack of 200 (4 sleeves, 1 base)	4372
	Sterile, pack of 50	4373
polystyrene	Trial pack, sterile (3 reservoirs, 1 base)	4330
	Sterile, pack of 30 (30 individually wrapped, 1 base)	4331
	Sterile, pack of 200 (4 sleeves, 1 base)	4332
SureFlo™,	Trial pack, sterile (3 reservoirs, 1 base)	4375
polypropylene	Sterile, pack of 30 (30 individually wrapped, 1 base)	4376
	Sterile, pack of 200 (4 sleeves, 1 base)	4377
polypropylene	Trial pack, sterile (3 reservoirs, 1 base)	4335
	Sterile, pack of 30 (30 individually wrapped, 1 base)	4336
	Sterile, pack of 200 (4 sleeves, 1 base)	4337

Reservoirs 10 ml disposable inserts

• SureFlo™ = anti-sealing array

Reservoirs 25 ml, disposable inserts		Part no.
INTEGRA	Reservoir base 25 ml, pack of 10	4304
SureFlo™,	Trial pack, sterile (3 reservoirs, 1 base)	4380
polystyrene	Sterile, pack of 30 (30 individually wrapped, 1 base)	4381
	Sterile, pack of 200 (4 sleeves, 1 base)	4382
	Sterile, pack of 50	4383
polystyrene	Trial pack, sterile (3 reservoirs, 1 base)	4310
	Sterile, pack of 30 (30 individually wrapped, 1 base)	4311
	Sterile, pack of 200 (4 sleeves, 1 base)	4312

Reservoirs 25 ml, disposable inserts		Part no.
SureFlo™, polypropylene	Trial pack, sterile (3 reservoirs, 1 base)	4385
	Sterile, pack of 30 (30 individually wrapped, 1 base)	4386
	Sterile, pack of 200 (4 sleeves, 1 base)	4387
polypropylene	Trial pack, sterile (3 reservoirs, 1 base)	4315
	Sterile, pack of 30 (30 individually wrapped, 1 base)	4316
	Sterile, pack of 200 (4 sleeves, 1 base)	4317

• SureFlo™ = anti-sealing array

un linder and	Reservoir base 25 ml, pack of 10	4304	
INTEGRA		4304	
Arright	Two compartments, 5 + 10 ml		
SureFlo™, divided	Trial pack, sterile (3 reservoirs, 1 base)	4350	
(5 + 10 ml),	Sterile, pack of 30 (30 individually wrapped, 1 base)	4351	
polystyrene	Sterile, pack of 200 (4 sleeves, 1 base)	4352	
	Sterile, pack of 50	4353	
SureFlo™, divided	Trial pack, sterile (3 reservoirs, 1 base)	4355	
(5 + 10 ml),	Sterile, pack of 30 (30 individually wrapped, 1 base)	4356	
polypropylene	Sterile, pack of 200 (4 sleeves, 1 base)	4357	
	Sterile, pack of 50	4358	
INTEGRA	Twelve 3 ml compartments with 9 mm well spacing		
SureFlo™, divided	Trial pack, sterile (3 reservoirs, 1 base)	4360	
(12 x 3 ml), polystyrene	Sterile, pack of 30 (30 individually wrapped, 1 base)	4361	
SureFlo™, divided (12 x 3 ml), polypropylene	Trial pack, sterile (3 reservoirs, 1 base)	4365	
	Sterile, pack of 30 (30 individually wrapped, 1 base)	4366	

SureFlo[™] = anti-sealing array

Reservoirs 100 mi, disposable inserts	
Reservoir base 100 ml, pack of 10	4305
Trial pack, sterile (3 reservoirs, 1 base)	4390
Sterile, pack of 30 (30 individually wrapped, 1 base)	4391
Sterile, pack of 200 (4 sleeves, 1 base)	4392
Sterile, pack of 50	4393
Trial pack, sterile (3 reservoirs, 1 base)	4320
Sterile, pack of 30 (30 individually wrapped, 1 base)	4321
Sterile, pack of 200 (4 sleeves, 1 base)	4322
Trial pack, sterile (3 reservoirs, 1 base)	4395
Sterile, pack of 30 (30 individually wrapped, 1 base)	4396
Sterile, pack of 200 (4 sleeves, 1 base)	4397
Trial pack, sterile (3 reservoirs, 1 base)	4325
Sterile, pack of 30 (30 individually wrapped, 1 base)	4326
Sterile, pack of 200 (4 sleeves, 1 base)	4327
	Reservoir base 100 ml, pack of 10 Trial pack, sterile (3 reservoirs, 1 base) Sterile, pack of 30 (30 individually wrapped, 1 base) Sterile, pack of 200 (4 sleeves, 1 base) Sterile, pack of 50 Trial pack, sterile (3 reservoirs, 1 base) Sterile, pack of 30 (30 individually wrapped, 1 base) Sterile, pack of 200 (4 sleeves, 1 base) Sterile, pack of 200 (4 sleeves, 1 base) Sterile, pack of 200 (4 sleeves, 1 base) Trial pack, sterile (3 reservoirs, 1 base) Sterile, pack of 30 (30 individually wrapped, 1 base) Sterile, pack of 200 (4 sleeves, 1 base) Trial pack, sterile (3 reservoirs, 1 base) Sterile, pack of 200 (4 sleeves, 1 base) Sterile, pack of 30 (30 individually wrapped, 1 base) Sterile, pack of 30 (30 individually wrapped, 1 base)

Reservoirs 100 ml, disposable inserts

Part no.

SureFlo™ = anti-sealing array

7.3 GRIPTIPS

INTEGRA offers a wide range of GRIPTIPS in the volume ranges from $12.5 \ \mu\text{I} - 5000 \ \mu\text{I}$.



Visit the GRIPTIP Selector Guide (<u>www.integra-biosciences.com/griptips</u>) to find the correct tips and set a filter by available volumes, packaging and properties.

7.3.1 INTEGRA pipetting device

The GRIPTIPS selection depends on which pipetting device you work with:

• **GRIPTIPS for automation**: for MINI 96, VIAFLO 96, VIAFLO 384 and ASSIST PLUS. These GRIPTIPS have undergone straightness testing and were engineered to resist the shear forces of automated tip loading on benchtop pipetting systems. For 384 configuration GRIPTIPS, extra sturdy antistatic XYZ-racks are used.



NOTE Autoclaving of GRIPTIPS for automation is not recommended as they may warp during the process, which can lead to incorrect tip loading and obstruct precise well targeting.

7.3.2 Package options

- Automation friendly racks (6xxx series): for automated tip loading, refillable with GREEN CHOICE inserts.
- **GREEN CHOICE** (64xx series): environmentally friendly refills allowing the reuse of existing racks and thus reduces plastic waste.

If recycling is available in your region, fill the outer carton in which your GRIPTIPS are delivered with the empty racks for pickup by a parcel service.

7.3.3 GRIPTIP properties

According to our cleanroom standards, all GRIPTIPS (non-sterile, pre-sterilized and sterile) comply with our VIAPURE claims. This states that all product are RNase, DNase, endotoxin and pyrogenic free.

- Sterile/pre-sterilized: the products are gamma irradiated within the minimum and maximum dosage range specified for INTEGRA sterile products. Racks are individually vacuum sealed in a bag and are considered sterile until opened. The entire case of 5 presterilized GREEN CHOICE inserts is sealed.
- Non-sterile: the items are manufactured in the same cleanroom and packed in a carton case.
- · Long: longer design allows easy access into deep laboratory vessels
- · Short: shorter design allows easy access in 1536 well plates or improves ergonomics
- Wide bore: large opening at the tip end, reduces shear forces
- · Low retention: low liquid retention, for liquids with low surface tension

Imprint

© 2023 INTEGRA Biosciences AG

All rights to this documentation are reserved. In particular the rights of reproduction, processing, translation and the form of presentation lie with INTEGRA Biosciences AG. Neither the complete documentation nor parts thereof may be reproduced in any way, or stored and processed using electronic media or distributed in any other way without the written consent of INTEGRA Biosciences AG.

This operating instruction manual has part number 128966, the version is V01. It applies as of (see Toolbox - Device information):

Serial number	7 000000 or higher
(Firmware) FW version	5.04 or higher

of D-ONE single channel pipetting modules until a newer revision is released.

VIALAB and GRIPTIPS are trademarks of INTEGRA Holding, Switzerland.

Manufacturer and customer service

Your local INTEGRA Biosciences representative, further information, and operating instructions in other languages can be found at <u>www.integra-biosciences.com</u> or are available on request <u>info@integra-biosciences.com</u>.

INTEGRA Biosciences AG	INTEGRA Biosciences Corp.
Tardisstrasse 201	22 Friars Drive
CH-7205 Zizers, Switzerland	Hudson, NH 03051, USA
T +41 81 286 95 30	T +1 603 578 5800
INTEGRA Biosciences Ltd	INTEGRA Biosciences Nordic ApS
2 Rivermead Business Park	Vallensbækvej 22A 3TV
Thatcham, Berks, RG19 4EP, UK	Brøndby 2605, DK
T +44 1635 797 00	T +45 3173 5373
INTEGRA Biosciences KK	INTEGRA Biosciences (Shanghai) Co., Ltd.
Higashikanda 1-5-6, Chiyoda-ku	Room 1110, No. 515 Huanke Road
Tokyo, 101-0031, JP	Shanghai 201315, CN
T +813 5962 4936	T +86 21 5844 7203
INTEGRA Biosciences SAS	INTEGRA Biosciences Deutschland GmbH
8 avenue du Fief	An der Amtmannsmühle 1
95310 Saint Ouen l'Aumône, FR	35444 Biebertal, DE
T +33 1 34 30 76 76	T +49 6409 81 999 15