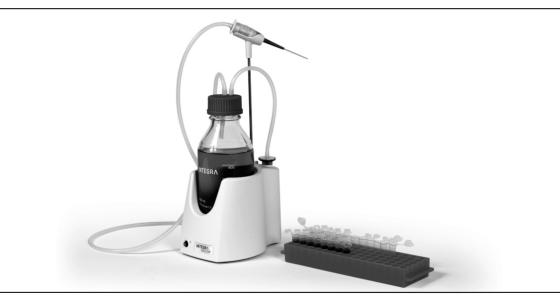
## **INTEGRA**



**VACUSIP** Operating instructions

159950\_V08

# **CEUR** Declaration of conformity INTEGRA Biosciences AG – 7205 Zizers, Switzerland declares on its own responsibility in the

Description	Models	
VACUSIP	159000, 159010	
Accessories	156631, 156632, 156633, 156634, 156635, 1550	)66
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	

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	
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	

Zizers, April 11, 2022

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Urs Hartmann CEO

n. Rave

Daniel Bächi Head of Corporate Quality

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	Description of the device Installation Operation Maintenance Technical data

#### Imprint

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#### 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 info@integra-biosciences.com.

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## 1 Introduction

These operating instructions contain all the information required for installation, operation and maintenance of the VACUSIP aspiration system.

#### 1.1 Intended use

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

VACUSIP is a vacuum-based system for aspiration of non explosive aqueous solutions, such as biological buffers and media.

If the VACUSIP is used in a manner not specified by INTEGRA Biosciences, the protection provided by the VACUSIP may be impaired.

#### 1.2 Safety notes



#### WARNING

Read these operating instructions carefully before use and pay particular attention to sections containing this symbol.

#### 1.2.1 General

- 1) Do not carry out any conversions and alterations on the device.
- 2) Defective parts may only be replaced with original INTEGRA Biosciences spare parts according to the INTEGRA Biosciences operating or service instructions.
- 3) Do not use or charge VACUSIP in an atmosphere with danger of explosion. Also, do not aspirate highly flammable liquids such as acetone or ether.
- 4) 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.
- Prolonged exposure of VACUSIP to UV-light can cause discoloration and/or yellowing of the plastic housing. However, this will not affect the performance of the device in any way.
- 6) Excess spare parts, accessories and consumables (e.g. tubings, lids, plastic parts, rubber products, O-rings, filter) should be stored in a light protected place at ambient temperature to prevent premature material aging caused by prolonged exposure to UV-light.

Regardless of the listed safety notes, additionally applicable regulations and guidelines of trade associations, health authorities, trade supervisory offices, etc. must be observed. Please visit our website <u>www.integra-biosciences.com</u> on a regular basis for up to date information regarding REACH classified chemicals contained in our products.

#### 1.2.2 Battery (model 159 000)

- 1) Charge the VACUSIP device using only the charger supplied by INTEGRA Biosciences.
- 2) 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 (6 hours or more). These are indicators that the battery has reached the end of its life-cycle.

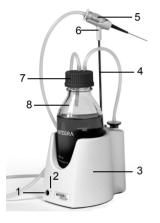
If a lithium battery is never deep discharged and is always stored and operated in the recommended temperature range and stored at 40-80% charge level during long standby periods, it may live much longer than 3 years. If it shows no signs of physical damage or change, see 5.1, it is a strong indication that you may continue to use the battery.

- 3) 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 self-discharge rate and heating during battery charging. This may also result in thermal runaway and cell rupture.
- 4) To extend the battery life-cycle, it is recommended to charge the battery every 2 months if the VACUSIP is not used regularly. If the VACUSIP is not used for more than 6 months, unplug the battery, see <u>3.3.5</u>.
- 5) If despite all safety measures the VACUSIP Li-ion battery catches fire and toxic (typically dense, white) fumes emanate from the VACUSIP device, immediately evacuate the working area. The VACUSIP housing is made of special flame retardant material that has proven its capability to contain a battery fire. During a battery fire the housing surface may become very hot. Do not touch the housing by hand and wait at least 20 minutes after fumes have disappeared before approaching the device. Do no longer use the VACUSIP device.

#### 2 Description of the device

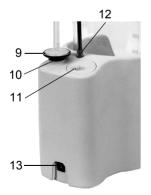
#### Scope of delivery

- VACUSIP base unit without battery (model 159 010) or with battery (model 159 000)
- · Mains adapter
- · INTEGRA glass bottle 500 ml with standard GL 45 lid
- · GL 45 lid with tube fittings
- · Tubing and hydrophobic filter with an additional spare filter
- VACUSIP hand operator
- · 8-channel stainless steel tips
- 1-channel stainless steel tip
- · 1-channel adapter for disposable tips



- 1 On/off switch
- 2 Indicator LED
- 3 Base unit
- 4 Stainless steel rod
- 5 VACUSIP hand operator
- 6 Hand operator mount
- 7 Lid with tube fittings
- 8 500 ml bottle for liquid collection

**Rear view** 



- 9 Hydrophobic filter
- 10 Silicone filter adapter
- 11 Air outlet
- 12 Opening to insert stainless steel rod
- 13 Mains connection socket

#### 3 Installation

#### 3.1 Power supply

Insert the mains adapter cable into the VACUSIP mains connection socket  $(\underline{13})$  and plug it into the power source.



#### WARNING

Use an original INTEGRA Biosciences mains adapter only (see <u>"6.1</u> Specifications" on page 14 for voltage requirements)

#### 3.2 Charging of VACUSIP battery model

A full charge takes 5 hours. Before the first use, VACUSIP should be charged for at least 5 hours.

When the LED (2) starts to blink green, the battery needs to be recharged immediately to prolong battery life. VACUSIP has an integrated overcharge protection.

VACUSIP can be used while it is being charged.

#### 3.3 Set-up

#### 3.3.1 Installing the VACUSIP hand operator mount

Find the enclosed stainless steel rod (4) and push it into the opening (12).

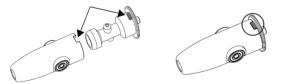
Attach the hand operator mount  $(\underline{6})$  to the top of the stainless steel rod  $(\underline{4})$ .



#### WARNING

Do not carry VACUSIP by holding the rod or the hand operator mount. Always grab the instrument at the back to carry it around.

#### 3.3.2 Assembling the hand operator



Insert the inner part in the silicone cover, as shown on the picture beside.

#### 3.3.3 Connecting the filter

Attach the shorter silicone tubing to the filter (9) and then plug the filter into the silicone filter adapter with the blue side facing the instrument.

VACUSIP should never be used without a filter.

#### 3.3.4 Connecting the silicone tubing

Place the bottle in the instrument and screw on the green lid with tube fittings  $(\underline{7})$ .

Attach the silicone tubing coming from the filter to the fitting on the lid named "FILTER".

Attach the longer silicone tubing to the fitting in the lid named "LIQ" (liquid) and the other end to the VACUSIP hand operator ( $\underline{5}$ ).

#### 3.3.5 Replacing the battery



Unscrew the 5 screws on the bottom of the device with a Phillips screwdriver nr. 1 and remove the bottom lid.



Unplug the old battery and replace it with an original INTEGRA Biosciences rechargeable battery, see <u>"7</u> <u>Accessories and consumables" on page 16</u>. Make sure that it is inserted with the correct polarity (+/-).

Place back the battery in the battery compartment with the wire facing to the inside of the instrument.

Close the bottom lid and fix it with the 5 screws.

#### 4 Operation

#### 4.1 Vacuum activation and notes on use

Switch on VACUSIP to start the vacuum pump (the LED lights up green).



Attach a suitable adapter to the hand operator.

To aspirate press the soft buttons on both sides of the VACUSIP hand operator.

Once the vacuum is reached, the pump stops until the vacuum falls below threshold.

VACUSIP switches off automatically after the pump has not been running for 10 minutes or 40 minutes after initial switch-on. This feature can be temporarily deactivated by pressing the power button for at least 4 seconds when switching on the instrument. The power-off function is automatically restored after turning off VACUSIP.

Check the level of liquid in the bottle frequently. The liquid level should never reach the lid.

Prevent liquid or foam overflow from the collection bottle into the filter. In case the filter gets accidentally wetted or soiled, exchange it immediately or otherwise the retention of further liquid cannot be guaranteed. Note that the hydrophobic filter holds back aqueous solutions, whereas retention of apolar liquids is limited.



#### WARNING

When working with dangerous substances, you must comply with the material safety data sheet (MSDS) and the additionally applicable regulations of trade associations, health authorities, supervisory offices, etc. In addition, when working with hazardous volatile substances or biohazardous agents, either place the VACUSIP inside a biosafety cabinet or connect the instrument's air outlet (11) to a safety ventilation by means of a tube (ID=4 mm) and an aspiration needle (Part. No. 155 502).

LED code	Meaning
Constantly green	Unit is powered on and no errors occurred.
Blinking green	Battery level low.
Blinking red once per second	Leakage detection. Pump turns off if end vacuum has not been reached after 5 minutes.
Blinking red 5 times per second	Vacuum generation is too fast (~100 mbar/s). Indicates a clogged part.
Constantly red	Battery error. Press the power button to continue using the mains power supply.
Blinking red and green	Error in vacuum sensor calibration. Please contact your supplier.

#### 4.2 Code of indicator LED

	)	
Problem	Probable cause	Remedy
Device is not running.	No electrical power.	Check if mains adapter cable is plugged in or if battery (model 159000) is discharged. Check indicator LED light.
	Unit automatically switched off.	Switch on the unit (LED lights up green). VACUSIP automatically switches off if it is not used or 40 minutes after initial switch-on.
Aspiration speed is low.	Aspiration speed is low. Leak in the vacuum system.	Close the bottle lid tightly and attach tubing firmly. Check tubing, filter and hand operator for leaks. If the maximum vacuum is no reached for 5 min, the pump is turned off.
	Liquid overflowed and blocked the Empty bottle and exchange filter. filter.	Empty bottle and exchange filter.
	Tubing is blocked.	Clean or exchange the tubing.
	Hand operator is clogged.	Take apart the hand operator to clean it. Use an ultrasonic bath to clean it of debris. Replace the hand operator.
VACUSIP turns off after a few seconds or minutes.	VACUSIP turns off after Clogging of a part close to the a few seconds or pump. minutes.	The LED blinks red rapidly. Check if filter is blocked and exchange it, if necessary. Check if the filter adapter is blocked.
	Leak in the vacuum system.	The LED blinks red slowly. The pump automatically stops if the end vacuum is not reached after 5 min. Check for leaks in the system and push the power button again.

4.3 Troubleshooting

#### 5 Maintenance

#### 5.1 Cleaning and servicing



#### WARNING

Always switch off the VACUSIP and disconnect it from the mains when carrying out maintenance work.

Clean the VACUSIP housing 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 bleach (sodium hypochlorite) or other solvents.

It is recommended to change the hydrophobic filter regularly, at least once a year. Exchange the filter immediately if liquid has entered.

When working with solvents and other hazardous materials always rinse the hand operator and tubing with water followed by 70% Ethanol.

Annual inspection: 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 Autoclaving and chemical sterilization

#### 5.2.1 Autoclaving

All parts contacting the liquid can be autoclaved: 500 ml glass bottle, lid with tube fittings, silicone tubing and hand operator. The hand operator should be taken apart for optimal decontamination. To disassemble it, hold the silicone cover and pull out the inner part. Recommendation regarding autoclaving: glass bottle for at least 20 min at 121°C.

The bottle lid has to be always unscrewed and kept loosely on the bottle during autoclaving.

Silicone may become brittle after extensive autoclaving. Replace the tubings if they are damaged.



#### WARNING

The hand operator can be autoclaved sporadically for decontamination, however it is not recommended to autoclave it regularly. The filter and the instrument itself cannot be autoclaved.

#### 5.2.2 Chemical sterilization

Two methods for chemical inactivation of biohazardous agents are commonly used:

- A suitable disinfectant is added to the full collection bottle and left to react for the recommended time.
- The disinfectant is added to the empty bottle so that the aspirated liquid gets sterilized as it accumulates in the bottle. Use disinfectants that are free of chlorine or other corrosive agents, especially when corrosive vapors are generated and aspirated.

VACUSIP and VACUBOY may be decontaminated with  $H_2O_2$  gas (maximal concentration 35 %) for 60 minutes.

#### 5.3 Equipment disposal



The VACUSIP device must not be disposed of with unsorted municipal waste. Do not dispose of the device in a fire.

VACUSIP (159000) contains a Li-ion battery. Do not modify the battery in any way. Dispose of the VACUSIP device and the battery 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 Specifications

Vacuum range	–250 mbar +/- 20%
Flow rate (air)	Pump: 1.5 I/min +/- 30% at ambient pressure
Dimensions (H x W x D)	125 x 120 x 162 mm (base unit) Height: unit with bottle and hand operator mount 345 mm
Weight	Base unit only: 500 g Unit complete: 970 g (with glass bottle, tubing and hand operator)
Electricity supply	Mains adapter input: 100–240 VAC, 50/60 Hz Device input: 8–10 VDC, 6 W
Battery	rechargeable, Li-ion, ANSI 1604 size
Degree of protection	IP 31
Ambient conditions	Altitude: up to 2000 m Temperature: 5 – 40 °C Humidity: max. rel. humidity 80% for temperatures up to 31 °C decreasing linearly to 50% rel. humidity at 40 °C.

#### 6.2 Chemical compatibility

The table below lists VACUSIP parts that come into contact with the aspirated liquid or its aerosols and vapors, and rates the compatibility of these parts to a few of the chemicals commonly used in laboratories. To determine the compatibility of a component to a chemical not listed in the table, please consult one of the several tables available on the internet. Note that the rating refers to soaking in the concentrated chemical; however, more relevant here is the attenuated effect resulting from vapors and the diluted chemical. It is recommended to test the compatibility of relevant components to a specific chemical prior to extensive use.

INTEGRA Biosciences does not warrant that the information in the table is accurate or complete and that any material is suitable for any purpose.

<b>Compatibility ratings:</b> A = Good, no or minor effects. B = Fair, moderate effects, not for continuous use. C = Critical, not recommendec determined by test.	<b>npatibility ratings:</b> Good, no or minor effects. Fair, moderate effects, not recommended for continuous use. Critical, not recommended, suitability to be determined by test.	mmended ability to be	JAVEL (e.g. Nat	Acetic acid Ac	Ethanol E	Isopropyl alcohol	Sodium hydro: Na	Sodium ace (3M, pH	Hydrochloric HCl (20	Nitric acid (20	Dimethyl sulfo: DM	Phenol Ph
Parts		Materials	CIO)	юн	tOH	IPA	xide aOH			)%)	xide 1SO	юH
Hand operator	Inner part	РР	A	A	∢	∢	۲	۲	A	٩	A	۲
	Outer part	Silicone	A	ш	۲	∢	۲	υ	A	ပ	A	ပ
	Adapters	POM	С	С	A	A	A	A	В	ပ	A	A
		NOX	В	ပ	A	A	в	A	ပ	A	A	A
Tubing		Silicone	A	в	A	A	A	υ	A	ပ	A	ပ
Bottle	Single-use	ЪР	A	A	A	A	A	A	A	A	A	A
	Lids	РР	A	A	A	A	A	A	A	A	A	A
	Gasket	EPDM	A	A	A	A	A	A	A	A	A	A
Filter	Membrane	PTFE	A	A	A	A	A	A	A	A	A	A
	Housing	PVC	A	С	В	A	A	A	A	A	С	В
Filter adapter		Silicone	A	В	A	A	A	С	A	ပ	A	ပ
VACUSIP base	Housing	ЪР	A	A	A	A	A	A	A	A	A	A
	Pump housing	POM	С	С	A	A	A	A	В	ပ	A	A
	Pump membrane	NBR	A	В	В	۲	A	A	A	ပ	В	ပ

#### 7 Accessories and consumables

Accessories		Part no.
Adapter	1-channel stainless steel adapter 40 mm	155 502
	1-channel stainless steel adapter 150 mm	155 522
	1-channel stainless steel adapter 280 mm	155 525
	1-channel adapter for disposable tips/GripTips (pack of 5)	159 023
	1-channel adapter with ejector for disposable tips	159 026
Rod	1-channel adapter with ejector for GripTips	159 027
	4-channel stainless steel adapter 40 mm	155 524
	8-channel stainless steel adapter 40 mm	155 503
	8-channel adapter with ejector for disposable tips	159 024
	8-channel adapter with ejector for GripTips	159 025
	for hand operator mount, stainless steel	159 045
Mount	for hand operator VACUSIP	159 046
Mains adapter for PIPETBOY pro,	EU	156 631
	US	156 630
VACUSIP (100 - 240 VAC,	JP	156 634
50/60 Hz)	UK	156 632
- /	AU	156 633

Consumables

Part no.

Filter	For protection of the pump, non sterile, 0.45 µm. For the country specific part number, please refer to our website.	
Silicone tubing	Ø 3/6 mm, 2.5 m	171 023
	Ø 3/6 mm, 25 m bulk roll	171 033
Hand operator set for VACUSIP	Consists of: VACUSIP Hand operator, Silicone tubings Ø 2 mm, 1.2 m and 0.22 m, 1 filter Ø 25 mm, pore size 0.45 μm, non-sterile	159 040
Bottle	500 ml, glass, for VACUSIP, with standard GL 45 blue lid	159 031
	500 ml, polypropylene, for VACUSIP, with GL 45 lid, pack of 10	159 032
	Green lid GL45 with fittings, for VACUSIP, pack of 2	159 035
Battery	Li-ion, for PIPETBOY acu 2, VACUSIP	155 066