WHO Prequalification of Diagnostics Programme
PUBLIC REPORT

Product: Pima CD4 Test
WHO reference number: PQDx 0099-032-00

The Pima CD4 Test with product codes 260100100, 260100025 and 260300003[1], manufactured by Abbott Rapid Diagnostics Jena GmbH[2], Orlaweg 1, D-07743 Jena, Germany, CE-marked regulatory version, was accepted for the WHO list of prequalified diagnostics and was listed on 20 November 2012.

Summary of prequalification status for Pima CD4 Test:

	Date	Outcome
Prequalification listing	20 November 2012	listed
Dossier assessment	30 September 2011	MR
Site inspection(s) of quality management system	01 October 2011	MR
Product performance evaluation	14 September 2012	MR

MR: Meets Requirements

Report amendments and/or product changes

This public report has since been amended. Amendments may have arisen because of changes to the prequalified product for which WHO has been notified and has undertaken a review. Amendments to the report are summarized in the following table, and details of each amendment are provided below.

Version	Summary of amendment	Date of report amendment
1.0-4.0	Correction of typographical errors and change of labelling.	08 April 2014
5.0	Change of manufacturer name and address from Alere Technologies GmbH, Loebstedter Str. 103-105, Jena 07749, Germany to Abbott Rapid Diagnostics Jena GmbH, Orlaweg 1, D-07743 Jena, Germany. Product labelling was revised accordingly, New multi-language IFU with updated warnings and precautions section was issued and list of accessory items was updated.	13 October 2020

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[1] See page 3 for a list of components required to perform the assay.

[2] manufacturer name and address from Alere Technologies GmbH, Loebstedter Str. 103–105, Jena 07749, Germany to Abbott Rapid Diagnostics Jena GmbH, Orlaweg 1, D–07743 Jena, Germany.

6.0	Labelling update to reflect the new manufacturer name and address: Abbott Rapid Diagnostics Jena GmbH, Orlaweg I, D-O7743 Jena, Germany.	09 May 2022

Intended use

According to the claim of intended use from Abbott Rapid Diagnostics Jena GmbH, "*Pima CD4 is an automated, image-based immune hematology test intended for the rapid in vitro quantitative measurement of CD3+/CD4+ T cells (T -helper cells) in capillary or venous whole blood. Pima CD4 determines the absolute count of CD3+/CD4+ cells and is intended to be used for the ongoing monitoring of absolute CD4 lymphocyte counts in patients with documented diagnosis of an immunodeficiency disease. The Pima CD4 test is intended for in vitro diagnostic use.*"

Assay description

According to the claim of assay description from Abbott Rapid Diagnostics Jena GmbH, "*the Pima CD4 test comprises a disposable Pima CD4 test cartridge and the Pima Analyser, and enables the determination of absolute counts of T-helper cells in whole blood. This test may be used for near-patient testing.*
The disposable Pima CD4 test cartridge is equipped with means to take up approximately 25 µL of sample and contains dried reagents needed to perform the test. The Pima CD4 test is performed within the Pima CD4 test cartridge and no part of the Pima Analyser has contact with the sample at anytime in the testing process. This minimises the risk of Analyser contamination and sample carry over between measurements.
After insertion of the Pima CD4 test cartridge into the analyser, peristaltic movement first transports the sample into the incubation compartment where the sample interacts with specific antibodies labelled with two different fluorescent dyes emitting light at two different wavelengths (dye 1 and dye 2).
One antibody is an anti-human CD3 monoclonal antibody conjugated to dye 1.
The second antibody is an anti-human CD4 monoclonal antibody conjugated to dye 2.
After a defined incubation time, the stained sample is transferred into the detection channel of the cartridge. The Pima Analyser is equipped with miniaturized multicolour fluorescence imaging optics. Fluorescence signals are detected by an on-board camera and analysed using proprietary software algorithms on board an embedded computer. T-helper cells carry both CD3 and CD4 surface antigens and therefore emit light at wavelengths specific for both antibody-dye conjugates. This allows the specific differentiation of T-helper cells from other blood cell types carrying only one of the two surface antigens.
Results are displayed by the Pima Analyser as cells/µL. Results are also stored in an on-board archive and are assigned to a sample ID that has been entered into the Pima Analyser by the operator and the date/time the test was carried out. Data can be retrieved and down-loaded by the operator at any time after the test. An external Pima Printer can be attached via USB to the Pima Analyser to print test results."

Test kit contents

- Disposable Pima CD4 cartridge, test kits containing 100 cartridges (260100100) or 25 cartridges (260100025)
- 1 Pima CD4 Cartridge guide

In order to perform the assay, the following components are required:

Items required but not provided

Instrumentation:
- Pima Analyser (260300003)

Software:
- The Pima Analyser has embedded software

Components and consumables

- volumetric or transfer capillaries for venous blood samples
- sterile lancets* (for capillary blood samples)

* recommended:
- Safety-Lancet Super, Sarstedt, Germany
- Prolance Max flow, HTL STREFA, Poland

If other lancets are used, please refer to the specific instructions from the legal manufacturer.
- alcohol swabs
- dry swabs
- band aid

Optional:
- USB Printer (27040R007)
- Pima Analyser bag (260400001)
- Printer paper I (26040R009)
- Printer Paper II (26040R010)

Complete list of items:

Cat. No.	Product Name	Kit Size
260100100	Pima CD4 100X	100 Pima CD4 foil sealed test cartridges
260100025	Pima CD4 25X	25 Pima CD4 foil sealed test cartridges
260300003	Pima Analyser (incl. Bead Standard)	1x Pima Analyser (260300001) 1x Pima Bead Standard (260400011) 1x power transformer 1x EU power cable
260300006	Pima Analyser (CN)	1x Pima Analyser with Chinese user interface 1x Pima Bead Standard (260400011) 1x power transformer 1x CN power cable
260300004	Pima Instrument & Accessories Pack	1x Pima Analyser (260300001) 1x Pima Bead Standard (260400011) 1 x Pima Printer (260400007) 1 x Pima Analyser Bag (260400001) 1 x Pima Printer Paper I (260400009) 1 x Alere Connectivity Pack I (260400015) 1x power transformer 1x EU Power cable
260400001	Pima Analyser Bag	1 instrument bag
27040R007	USB Printer	1 USB Printer incl. 1 roll Printer Paper I
26040R009	Printer Paper I	10 rolls of thermal paper
26040R010	Printer Paper II	10 rolls of thermal paper
260400011	Pima Bead Standard	box incl. 2 bead cartridges " Low" and "Normal"
260400199	Finger Stick Sample Collection Kit	for 100 tests: 1. 4x units of safety lancets (x28) (260400101) 2. 4x units of gauze swabs (x25) (260400104) 3. 1x unit of alcoholic swabs (x100) (260400103) 4x units of plasters (x26) (260400102)
260400059	Connectivity Pack IV	1 Samba3G-G-IV
260400042	Power Transformer & Power Cable (EU)	1 power transformer 1 EU power cable

Storage:
The Pima CD4 cartridge should be stored at 2-30°C temperature range.

Shelf-life:
The shelf life of the Pima CD4 cartridge is 18 months at 2-30°C temperature range.

Prioritization for prequalification

Abbott Rapid Diagnostics Jena GmbH submitted an application for prequalification of Pima CD4 Test. Based on the established eligibility WHO prioritization criteria, Pima CD4 Test was given priority for prequalification assessment.

Dossier assessment

Abbott Rapid Diagnostics Jena GmbH (Formerly called Alere Technologies GmbH) submitted a product dossier for Pima CD4 Test as per the Instructions for compilation of a product dossier. The information submitted in the product dossier was reviewed by WHO staff and external experts (assessors) appointed by WHO in accordance with the internal procedure on the screening and assessment of a product dossier. The product dossier screening and assessment findings met the requirements, a recommendation was made to accept the product dossier for Pima CD4 Test.

Commitment for prequalification:

The manufacturer committed to amend and submit additional documentation for shipping stability at high humidity and variable temperature. The commitment was closed.

Manufacturing site inspection

An onsite inspection of Abbott Rapid Diagnostics Jena GmbH located at Loebstedter Str. 103-105, Thuringia, Jena, 07749 Germany was conducted between 16-18 July 2018. At the time of considering the product application for Prequalification, the Manufacturer of the product had a well-established quality management system and manufacturing practices in place that would support the manufacture of a product of consistent quality. Routine inspections of the Manufacturing site will be conducted with copies of the WHO Public Inspection Report (WHOPIR) published on the WHO Prequalification web page as per Resolution WHA57.14 of the World Health Assembly. Note that a WHOPIR reflects the information on the most current desk assessment performed at a manufacturing site for in vitro diagnostic products and gives a summary of the onsite inspection findings.

The manufacturer's responses to the nonconformities found at the time of the onsite inspection were accepted on 29 December 2018.

Product performance evaluation

The Pima system was evaluated in two WHO collaborating laboratories in Antwerp, Belgium and Dar es Salaam, Tanzania between April and September 2012. The evaluation was conducted using the WHO evaluation protocol which was also approved by in-country ethical review boards in Belgium and Tanzania. A total of 479 fresh blood samples were used to study failure rates, reproducibility (intra-laboratory variation, intra-assay variation and inter-assay) and agreement with the FACSCalibur as the reference method. Lastly ease to use was assessed. The acceptance criteria for reproducibility studies was that the assay should have a percentage coefficient of variation (%CV) of less than 15% for CD4$^+$ T counts less than or equal to 200/µL and less than 10% for CD4 counts more than 200 cells/µL.

In laboratory 1, a total of 32/240 (13.3%) samples failed to run in the instruments while in laboratory B a total of 47/220 (21.4%) samples failed. In both laboratories, there were significant difference in the failure rates when capillary and venous samples were compared. While in laboratory 1 all but 2 failures occurred with capillary samples, in laboratory 2 almost 2/3 of failures occurred with venous samples. Notably, failure rates varied significantly with the operators and could account for the failure rates mentioned above. No detailed analysis was performed to distinguish whether failures operator and device induced. Intra-assay variation studies with samples less than 300 cells/µL showed mean %CV of 13.4% and 13.3% in laboratory 1 and laboratory 2 respectively. This variation includes inter-instrument variability since multiple instruments were used for the 10 repeats per sample. The mean inter-instrument variability among the five Pima^{TM} instruments was 4.6%. The mean inter-assay variability was 9.5%, and 7.7% for CD4 <200/µL and CD4 > 300/µL respectively in laboratory 1. In laboratory 2 the mean inter-assay variability was 12.0%, and 8.0% for CD4 < 200/µL and CD4 > 300/µL respectively. Regarding agreement with the reference method and agreement between capillary and venous samples, the correlation coefficients were high with minimal bias in both laboratories.

1. Labels

Pouch Label Pima CD4

Box Label Pima CD4 100x

Box Label Pima CD4 25x

Box Label Finger Stick Sample Collection Kit

Content for 100 blood collections/ Contenu pour 100 prises de sang/
Contenido para obtener 100 muestras de sangre/ Conteúdo para 100 recolhas de sangue:

1. Safety-Lancet Super:
   Lancets 4 x 28 pcs./ Lancettes 4 x 28 uds/
   Lancetas 4 x 28 pièces/ Lancetas 4 x 28 unidades

2. Alcohol Pads:
   Alcohol pads 1 x 100 pcs./ Tampons alcoolisés 1 x 100 uds/
   Gasas con alcohol 1 x 100 pièces/
   Compressas de álcool 1 x 100 unidades

3. Plastic Bandage:
   Adhesive plasters 1 x 100 pcs./
   Pansement prédécoupés 1 x 100 uds/
   Tiras adhesivas sanitarias 1 x 100 pièces/
   Pensos adesivos 1 x 100 unidades

4. Nonwoven Swabs:
   Nonwoven Swabs 4 x (25x2) pcs./
   Compresses en non-tissé 4 x (25 x 2) uds/
   Compresas no tejidas 4 x (25x2) pièces/
   Compressas não tecido 4 x (25x2) unidades

Distributed by: Abbott Rapid Diagnostics Jena GmbH
          Orlaweg 1
          D-07743 Jena, Germany
          www.globalpointofcare.abbott

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Finger-Stick Sample Collection Kit

4 051892 000490

REF 260400199   ⌛ yyyy-mm-dd

LOT 00000xxxxx

(241)260400199(10)00000xxxxx(17)yyyymmdd

BL 260400199-03

Box Label Pima Bead Standard "Normal" and "Low"

Pima™ Beads [Normal]

Manufacturing range/Plage de mesure pendant la production/ Rango de producción/Intervalo de fábrica: **850 -1150 c/µL** Device specific range/Plage spécifique au dispositif/ Rango específico del instrumento/Intervalo específico do aparelho: Opening date/Date d'ouverture/ Fecha de apertura/Data de abertura:	dpos 00005 **LOT** 02747 Stable up to 6 month upon opening Stable jusqu'à 6 mois à l'ouverture Estable hasta 6 meses al abrir Estável até 6 meses após abertura 180291

BL 260400011N-07

Pima™ Beads [Low]

Manufacturing range/Plage de mesure pendant la production/ Rango de producción/Intervalo de fábrica: **170 -230 c/µL** Device specific range/Plage spécifique au dispositif/ Rango específico del instrumento/Intervalo específico do aparelho: Opening date/Date d'ouverture/ Fecha de apertura/Data de abertura:	dpos 00011 **LOT** 02733 Stable up to 6 month upon opening Stable jusqu'à 6 mois à l'ouverture Estable hasta 6 meses al abrir Estável até 6 meses após abertura 180291

BL 260400011L-07
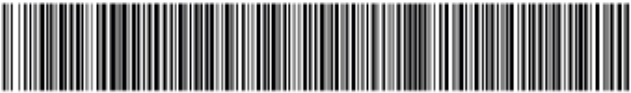
Pouch Label Pima Bead Standard

Pima™ Bead Standard

4 051892 000003

REF 260400011   **IVD**   2°C–30°C   CE

LOT 00158   ⧗ 2020-12

(241)260400011(10)00158(17)202012

Abbott Rapid Diagnostics Jena GmbH
Orlaweg 1
D-07743 Jena, Germany
www.abbott.com/poct

FL 260400011a-08

Pima™ Bead Standard

REF 260400011   2°C–30°C

LOT 00158   CE   **IVD**

2020-12

Stable up to 6 month upon opening
Stable jusqu'à 6 mois à l'ouverture
Estable hasta 6 meses al abrir
Estável até 6 meses após abertura

Abbott Rapid Diagnostics Jena GmbH
Orlaweg 1
D-07743 Jena, Germany
www.abbott.com/poct

(241)260400011(10)00158(17)202012

FL 260400011b-06

Device Label Pima Analyser

Device Label Pima Analyser

Pima™ Analyser

SN PIMA-D-008400

Abbott Rapid Diagnostics Jena GmbH
Orlaweg 1
D-07743 Jena, Germany
www.globalpointofcare.abbott

IVD   CE

Li-Ion

DC Input:
18 V ⎓ 3.3 A

DL 260300001-08

Box Label Pima Analyser

Pima™ Analyser

4 051892 000018

REF 260300003   CE

(241) 260300003

Pima™ Analyser

SN PIMA-D-005864

2021-02-08

(241)260300001(21)PIMA-D-005864

Pima™ Bead Standard

LOT 00158

2022-12

(241)26040011(10)00158(17)202212

BL 260300003-08

Pima™ ANALYSER
Abbott

EN
Pima™ ANALYSER
incl. power transformer (18 V)
and power cord (EU)

incl. Pima™ Bead Standard

ES
Pima™ ANALYSER
incl. transformador de corriente (18 V)
y cable de alimentación (EU)

incl. Pima™ Bead Standard

FR
Pima™ ANALYSER
incl. adaptateur alimentation (18 V)
et câble d'alimentation (EU)

incl. Pima™ Bead Standard

PT
Pima™ ANALYSER
incl. transformador de corrente (18 V)
e cabo de alimentação (EU)

incl. Pima™ Bead Standard

Abbott Rapid Diagnostics Jena GmbH
Orlaweg 1
D-07743 Jena, Germany
www.globalpointofcare.abbott

Pima™ ANALYSER
Abbott

401265-01

Packaging Label Pima Bag

Pima™ Bag	‖‖‖‖‖‖‖‖‖‖‖‖‖‖‖‖‖‖ 4 051892 000056

REF 260400001

LOT 0000009704

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Orlaweg 1
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‖‖‖‖‖‖‖‖‖‖‖‖‖‖‖‖‖‖‖‖‖
(241)260400001(10)0000009704

BL 260400001-01

Device Label USB Printer

Box Label USB Printer

Box Label Connectivity Pack IV

Box Label Pima Instrument & Accessories Pack

Box Label Power Transformer & Power Cable (EU)

Power Transformer & Power Cable (EU)

to Pima™ Analyser

REF   260400042   [📖]   CE   Abbott Rapid Diagnostics Jena GmbH
Orlaweg 1
D-07743 Jena, Germany
www.abbott.com/poct

(241)260400042   BL 260400042-03
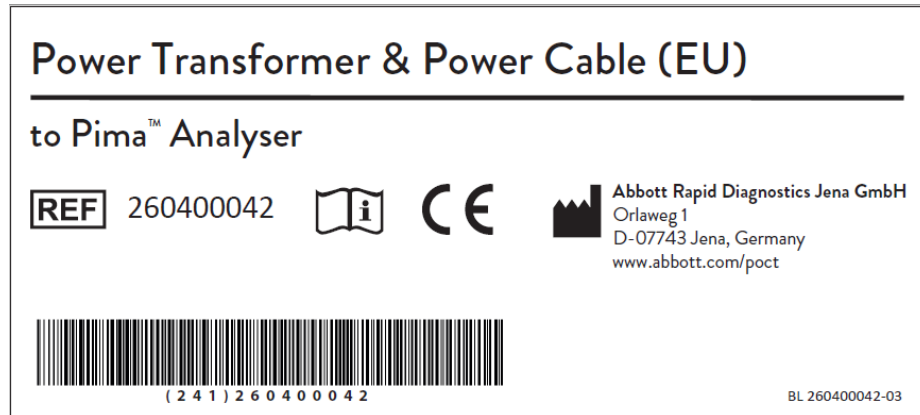
2. Instructions for use[3]

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[3] English version of the IFU was the one that was assessed by WHO. It is the responsibility of the manufacturer to ensure correct translation into other languages.

2.1. Pima CD4 Cartridge Guide
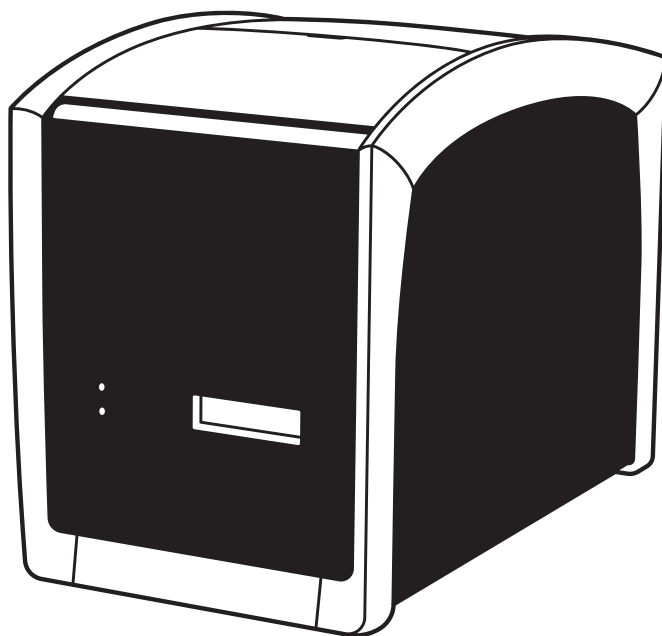
Pima™ ANALYSER
USER GUIDE

EN   C E   IVD

Pima™ Analyser

The Pima Analyser employs the same static image analysis and counting principles as existing cell enumeration technologies, in a compact, portable and robust package. Designed equally to suit the needs of the healthcare professional in the field or in the laboratory the Pima Analyser is an affordable, effective and valuable point-of-care diagnostic tool.
The following cartridges can be used together with the Pima Analyser:

Pima CD4 test cartridges: 25 individually pouched test cartridges
(catalogue no. 260100025) or
100 individually pouched test cartridges
(catalogue no. 260100100)

Pima Bead Standard: box incl. 2 bead cartridges "Low" and "Normal"
(catalogue no. 260400011)

For more information about Pima: www.globalpointofcare.abbott

Index of Symbols

CE	CE Mark	Li-Po	Lithium-Polymer
IVD	In vitro diagnostic medical device	Li-Ion	Lithium-Ion
	Manufacturer	+□	Battery
REF	Catalogue Number	SN	Serial Number
!	Attention symbol. Indicates special problems or important information. Read the accompanying text carefully.		To keep dry
---	Direct current (DC)		This unit must be recycled or discarded according to applicable local and national regulations.

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TABLE OF CONTENTS

1 INTRODUCTION

Intended Use

The Pima Analyser is a portable bench-top fixed volume cytometer used for the processing and analysis of a Pima CD4 test cartridge.
For in vitro diagnostic use. Designed to perform in a laboratory as well as in non-laboratory environments, the Pima Analyser can be operated on external power or by using an on-board rechargeable battery.
The Pima Analyser requires no maintenance.

Test Principle

The Pima test consists of a disposable Pima test cartridge, containing dried reagents, and the Pima Analyser. A low sample volume of approx.
25 microliters (μL) of capillary or venous whole blood is collected into the test cartridge, which is then capped.
The Pima test cartridge is inserted into the Pima Analyser and the sample sealed within the cartridge is processed. During the course of test processing, data is recorded, analyzed and interpreted using software embedded in the Pima Analyser.
Upon completion of the test the cartridge is removed from the Pima Analyser and a test result is displayed.

Data Handling

The Pima Analyser provides for data entry (Operator ID, Sample ID), archiving and connectivity to printers and data storage media.

All results are saved in an on-board archive and may be retrieved and downloaded by the operator at any time after the test.

A Pima Test Report may also be printed using an attached external USB Printer.

Pima Analyser Specifications

Pima Analyser

Dimensions	D 22 cm × W 13 cm × H 16 cm
Weight	2.54 kg
Detection System	LED illumination and CCD-based detection
Controls	sample volume control; reagent control; automatic control of cartridge expiry date; internal process controls; automatic test identification
Display	graphical display, monochrome, 128 × 64 pixel
User Interface	16 button keypad
Languages (Display)	English
Memory	data storage capacity of approx. 1000 tests

Operating Conditions

Operating Temperature	10 - 40 °C
Altitude	0 - 2000 m
Relative Humidity	10 - 95 % (no condensation)
Transport/Storage Temperature	2- 40 °C
Environment	protect from direct sunlight, humidity and dust

Power

Power Supply	DC 18 V/ 3.5 A
Mains Power	100 - 240 V ± 10 % (A/C) at 47 - 63 Hz

Declaration of Conformity

The Pima Analyser complies with the Essential Requirements of the Directive 98/79/EC Annex I and was tested according to EN 61010-1, EN 61010-2-101, EN 61326-1 and EN 61326-2-6.

Pima Analyser Recharging Intervals during Storage

During long term storage below 30 °C, the Pima Analyser should be connected to mains A/C power and the battery recharged overnight at least once per year. During long term storage at 30 - 40 °C the battery needs to be recharged at least once every 6 months. If long term storage temperatures exceed 40 °C, the recharge intervals may need to be considerably shorter.

❶ **Note:** It is not recommended to store the Pima Analyser with an empty battery. Therefore, always recharge the battery before long term storage.

Unpacking, Installation & Transport

Unpack the Pima Analyser and place safely on a clean, flat, level and stable surface. Do not put the Pima Analyser on surfaces that may vibrate, e.g. the top of a freezer or refrigerator or next to a laboratory centrifuge.
Inspect for any obvious sign of damage. Report any damage immediately to your local distributor. Allow temperature equilibration for at least 30 minutes to ensure that the Pima Analyser has reached surrounding temperature.

When using the Pima Bag for transportation, take out the Pima Analyser and place safely on a clean, flat, level and stable surface for testing.
If the Pima Analyser was transported or moved to areas with different climatic conditions, allow temperature equilibration for at least 30 minutes.

❶ **Note:** Keep the original Pima Analyser box in case the instrument needs to be shipped for repair or the like.

Pima Analyser Calibration

The Pima Analyser is factory calibrated and does not require any further calibration and verification operations. However, a daily performance check using Pima Bead Standard is recommended. If the Pima Analyser was transported or moved, a test with the Pima Bead Standard may be run to ensure proper functionality. Please refer to the Pima Bead Standard User Guide (UG-PIMA-03) for more information on this product.

Maintenance & Cleaning

The Pima Analyser is a maintenance free instrument and has no serviceable parts. In the case of encountered Pima Analyser failures or damages, contact your local distributor.
Use cleaning solutions containing alcohol (for example 70 % Ethanol or Isopropanol). Soak a paper towel or clean cloth with cleaning solution and wipe the outside of the instrument. In case of using a liquid reagent, turn off the Pima Analyser and disconnect it from mains A/C power.

❶ Do not try to open the Pima Analyser for cleaning.
Do not spray directly onto or inside of the instrument.
Do not use cleaning solutions containing chlorine bleach or organic solvents other than alcohol.
Follow instructions on clearance certificate included in the Pima Analyser box before shipping the instrument to a third party.

Components and Optional Items

The following items are supplied with your Pima Analyser
(catalogue no. 260300003):
• Power transformer (18 V)
• Power cable (EU)
• Pima Analyser User Guide
• Pima Bead Standard (catalogue no. 260400011)

The following optional items are also available for your Pima Analyser:
• Pima Bag (catalogue no. 260400001)
• USB Printer (catalogue no. 27040R007)
    and Printer Paper I (catalogue no. 26040R009)
    and Printer Paper II (catalogue no. 26040R010)
• Connectivity Pack IV (catalogue no. 260400059)

Safety Warnings

❶ Only use the power transformer and A/C power cable supplied with the Pima Analyser. Any other power supplies can damage the instrument and may cause possible hazards.

❶ Plug in power cable only in grounded power sockets.

❶ Use Pima Analyser indoors when connected to A/C power.
When used outdoors disconnect from mains and avoid direct contact with liquids of any kind.

❶ Do not open the Pima Analyser. Any unauthorized opening of the instrument can cause potential hazards and will invalidate warranty claims.

❶ Only use the Pima Analyser as described in this document.

❶ Only insert USB Printers, USB storage devices or other authorized devices into the USB ports of the Pima Analyser. Do not use USB 3.0 storage devices.

❶ Placement of the Pima Analyser should allow easy disconnection from mains A/C power at any time.

❶ To ensure proper ventilation do not cover the instrument while switched on.

❶ Perform scan on USB storage devices for viruses on a regular basis.

❶ Do not plug in bulky USB devices next to each other since this may damage the USB ports.

❶ When using the Pima Analyser together with the Pima CD4 cartridge follow proper infection control guidelines for handling all blood specimens and related items.

❶ For disposal of the Pima Analyser please contact your local distributor.

Pima Analyser at a Glance

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❶ Display	❹ Power On
❷ Keypad	❺ 2 × USB ports
❸ Cartridge slot door	Both Pima USB ports are designed to be used with USB storage media, USB Printers or other authorized devices only.
	❻ Power connector port

2 GETTING STARTED

Pima Analyser Status Lights
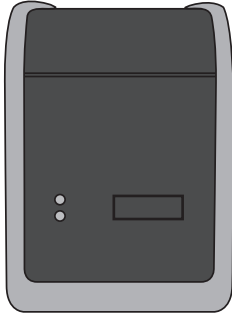
	Symbol	Colour	
Power Status	⏻	Green	⚪
Charging Status	⬚	Yellow	⚪

Pima Analyser Display
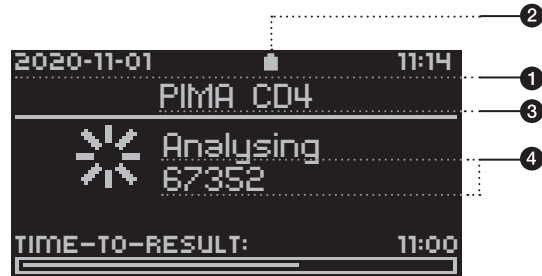
❶ Status Line
Date and time are displayed.

❷ Battery Status
The Battery Status symbol indicates the charging status when the Pima Analyser is not connected to mains A/C power.

❸ Title Line
Display of currently active menu or sub-menu. During analysis and in the result windows, the name of the test is displayed here.

❹ Message Lines
Area to display menu items, test results, Pima Analyser activities and function messages.

Charging the Pima Analyser

Your Pima Analyser is supplied with a partially charged battery secured within the analyzer. To charge the analyzer battery connect the Pima Analyser to mains A/C power as follows:

- Insert the A/C power cable into the power transformer.
- Connect the power transformer to the power connector port located at the back of the Pima Analyser.
- Connect the power cable to the corresponding A/C power socket.

Power connector   Power transformer   A/C power cable
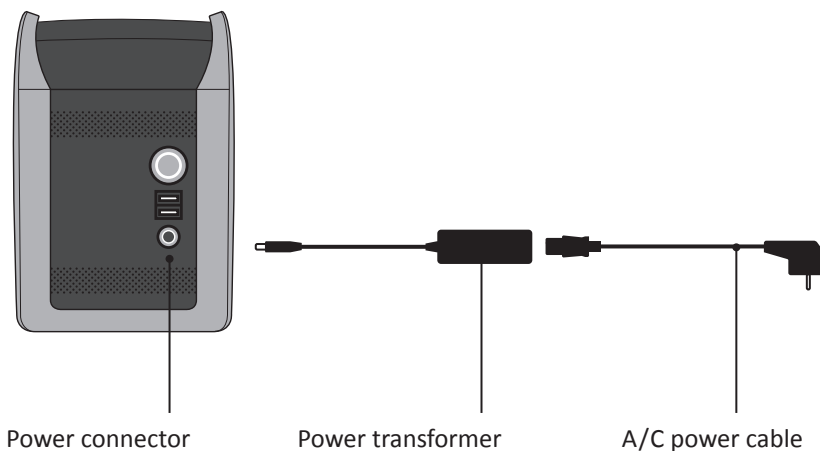
Charging Status Light

Upon connecting to mains A/C power the yellow charging status light located on the front of the Pima Analyser will be illuminated, indicating the charge state of the analyzer battery.

Pima Analyser battery fully charged	Solid	
Pima Analyser battery charging	Flashing	

❶ The charging status light will only be illuminated when connected to main A/C power. It may take several minutes until the correct charging status is displayed.

❶ In order to ensure maximum battery life charge the analyzer battery fully overnight (8 -10 hours) before running the Pima Analyser on battery power.

❶ When running the Pima Analyser on battery power, the battery status is displayed by the battery status symbol within the display status line.

Switching On the Pima Analyser/Power Status Light

The green power status light located on the front of the Pima Analyser displays its power status.

Pima Analyser On	On	⏻ ⬤
Pima Analyser Off	Off	⏻ ◯

Press and hold the Power On button until you hear a triple "beep" and the appearance of «pima™» on the screen confirms that the Pima Analyser is now switched on.
An automated initialization and self-test procedure is activated which may last for approximately two minutes. During this time the screen changes and the function of the cartridge slot door is tested.

If the Pima Analyser fails correct initialization and self-test, an error code is displayed. It may not be possible to turn the Pima Analyser off via the route described in section 7. In such a case press and hold the Power On button on the back of the Pima Analyser until the screen turns black and you hear a single "beep", confirming that the Pima Analyser is now switched off. Restart the Pima Analyser as described above. Refer to section 8 and 9 for details on error codes and contact your local distributor or Technical Support, if necessary.

❶ It is recommended to shutdown the Pima Analyser at least once per month.

User Interface

All operator interactions with the Pima Analyser are performed using the analyzer keypad.
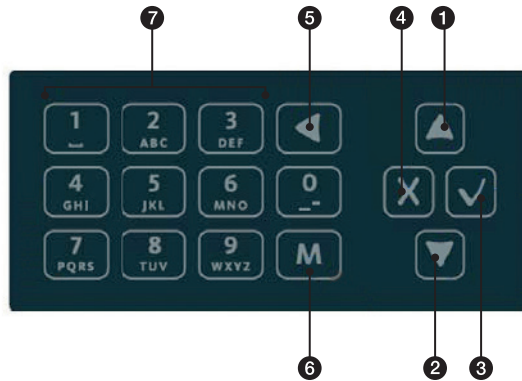
Navigation

❶   ▲ (UP) key to navigate menus, operator and result lists
❷   ▼ (DOWN) key to navigate menus, operator and result lists
❸   ∨ (OK) key to confirm selected menu items and entered text
❹   X (BACK) key to cancel a particular action and to go back to previous screen
❺   ◀ (CLEAR) key to delete entered text
❻   M (MODE) key to switch from numbers to letters and special characters on the keypad
❼   Text edit keys to enter numbers, letters and special characters

Press a number key to enter the respective number. Press M once to switch back and forth between numbers and letters and special characters, respectively. Press respective keys repeatedly until the desired character appears in the order as printed on the keys. If the next letter you want to enter is located on the same key as the present one, wait until the cursor appears and enter the letter.
«Dash» and «Underscore» are located on the (0) key.
«Space» is located on the (1) key.

3 RUNNING A TEST

Initiating a Test

The Pima test consists of a disposable Pima CD4 test cartridge, containing dried reagents, and the Pima Analyser.

Pima test cartridges are supplied in boxes containing a product insert detailing instructions for sample collection as well as the test specific performance characteristics.

❶ Before performing a Pima test, carefully read the Pima CD4 cartridge guide for details on sample application and cartridge handling.

❶ Check correct local date and time before running a test.

• To initiate a test run and open the cartridge slot door press ☑ when prompted by the following screen.


```
2020-11-01          ▊          11:05

         ⬆      Run test
                press OK
```

• The cartridge slot door opens and the Pima Analyser prompts the operator to insert a cartridge.

• The cartridge slot door can be closed by pressing ☒ returning the operator to the «Run test» window.


```
2020-11-01          ▊          11:05

         ⬆      Insert new
                cartridge
```

If no cartridge is inserted within 30 seconds, the cartridge slot door closes automatically and the display returns to the «Run test» window.

Inserting the Pima Test Cartridge

Insert cartridge into the Pima Analyser in the direction indicated by the arrow on the cartridge.

❗ The Pima Analyser is designed to be used in combination with the Pima test cartridge only. No other cartridges, test strips or devices should be inserted into the Pima Analyser.

❗ Do not discard the cartridge pouch until the Pima Analyser has successfully started the analysis. In case of a barcode error, the information printed on the cartridge pouch can be used to enter the barcode manually (refer to p. 40 for Barcode Error message).

• Upon inserting the Pima test cartridge a sensor in the Pima Analyser recognizes that a cartridge has been inserted and automatically starts the analysis process by fully drawing the cartridge into the Pima Analyser and closing the cartridge slot door.
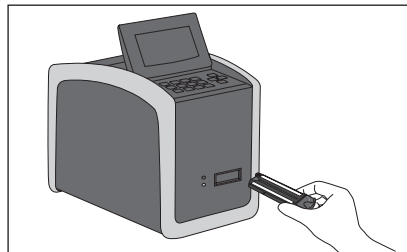
• The display screen changes briefly to «Reading cartridge» at this moment.
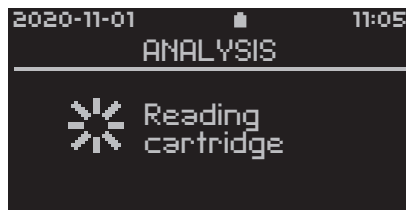
• Once the Pima Analyser has accepted the cartridge it will prompt the operator to enter both the Operator and Sample ID.
During data entry the test analysis continues in the background.

❗ While it is not necessary to enter Operator and Sample ID before starting the analysis, the Pima Analyser will NOT display a result until both Operator and Sample ID have been entered.

Operator ID Entry

The «Operator List» is displayed with all archived operators in alphabetical order.

- Select an operator from the list by using ▲ and ▼ and confirm the selection with ✓.
  Or, if the operator is not yet in the list, select «New Operator» to enter a new operator into the list.

```
2020-11-01              ▯        11:05
           OPERATOR LIST
   <New Operator>
 + Anton
   Chris
   Karin
```
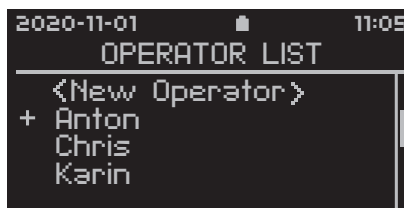
Refer to section 6 for instructions on how to enter a new Operator ID into the Operator List.

Sample ID Entry

After entering an operator, the «Enter Sample» window is displayed on the screen.

- A Sample ID of up to 20 characters may be entered using the keypad. Enter Sample ID and confirm with ✓.

```
2020-11-01              ▯        11:05
           ENTER SAMPLE

 67_
```

Analysis in Progress

- After Operator and Sample ID have been entered successfully, the «Analysis in Progress» window appears.
  The ID of the sample currently analysed and an estimated time to completion are shown.

```
2020-11-01              ▯        11:14
             PIMA CD4
        ✳  Analysing
           67352

TIME-TO-RESULT:               11:00
```
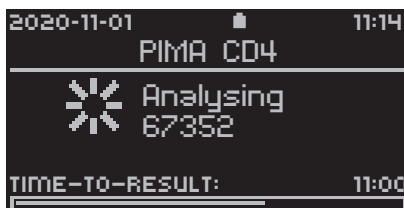
Analysis Complete

- After the analysis has been
  successfully completed, the
  «Analysis done. Remove cartridge»
  window appears and prompts the
  operator to remove the cartridge
  from the Pima Analyser.

```
2020-11-01          🔋           11:25
              ANALYSIS

        ⇩      Analysis done.
               Remove
               cartridge
```

- Once the cartridge has been
  removed, the Pima Analyser
  automatically displays the first of
  four result windows, showing the
  Sample ID and test result.

```
2020-11-01          🔋           11:25
              PIMA CD4

Sample:                      67352
CD3+CD4+:          183c/µl
BACK ✕                    ✓ PRINT
```
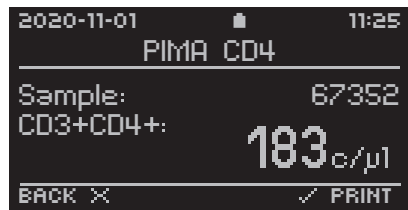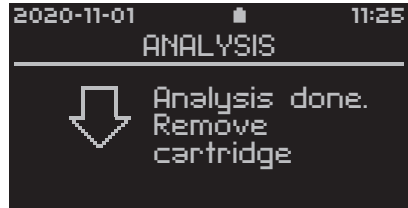
- Additional test related parameters can be viewed using ⬇ and ⬆.

A Pima Test Report may be printed at this time (see "Printing results
immediately after Analysis" for details).

All results data is stored in the data archive. Archived results can be viewed
under «Results» in the «Main Menu». For details see section 5.

- Press ✕ to return to the initial
  «Run test» window and start
  the analysis.

```
2020-11-01          🔋           11:25


        ⇧      Run test
               press OK
```

Printing Results immediately after Analysis

❗ This option is only available if a USB Printer is attached to the Pima Analyser via the USB port. For information on Pima accessories, please view www.globalpointofcare.abbott and refer to the USB Printer User Guide (UG-m-PIMA-02).

• A Pima Test Report can be printed from any of the four Pima test result windows by pressing ☑.

```
2020-11-01            🔋         11:25
            PIMA CD4
Sample:                    67352
CD3+CD4+:
                183 c/µl
BACK ✗                    ✓ PRINT
```
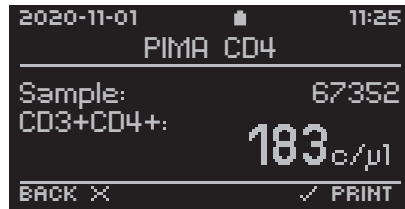
• The «Print» window appears and «YES» is selected by default. Confirm with ☑ and the current result is printed. Press ☒ or select «NO» to exit this window and return tothe Pima test result window.

```
2020-11-01            🔋         11:25
              PRINT
Do you want to
print the
current result?       + YES
                         NO
```
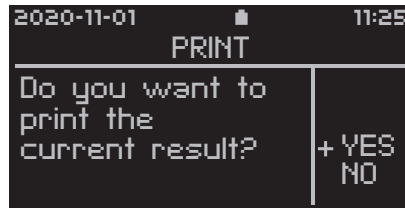
• The printing status is indicated by a progress bar. Printing can be aborted at any time this window is shown on the screen. Refer to section 4 on how to abort printing.

```
2020-11-01            🔋         11:25
          PRINT RESULTS
        ✳   Printing
             results
    TOTAL:   [=========    ]
```

- The «Pima Test Report» (example shown below) contains all information displayed on the result windows of the Pima Analyser.
After successful printing, the Pima Analyser returns automatically to the Pima test result window.


```
        PIMA Test Report
            PIMA CD4

Sample:              123_BA

CD3+CD4+:          829c/µl

Result Date:   2020-11-27
Start Time:         10:56
Operator:             BOB
Test ID:               78
Device:    PIMA-D-001693
Software:          0.43.1

QC
Barcode:             pass
Expiry Date:         pass
Volume:              pass
Device:              pass
Reagent:             pass
```

4 ANALYSIS MENU

Changing Operator and Sample ID during a Test Run

Should the operator discover that an error has been made in the entry of Operator and / or Sample ID, these entries can be changed as long as the cartridge is not removed from the Pima Analyser.

❶ After removal of the cartridge no changes to the selected Operator or entered Sample ID are possible anymore.

Changes to Operator and Sample ID can be made through the «Analysis Menu» which is accessed by pressing ⊠.

Analysis Menu

The «Analysis Menu» can only be accessed while an analysis is in progress and allows the operator to change the Operator and Sample ID as well as abort the test run.

```
2020-11-01              🔋        11:05
          ANALYSIS MENU
      Operator
    + Sample ID
      Abort Analysis
```
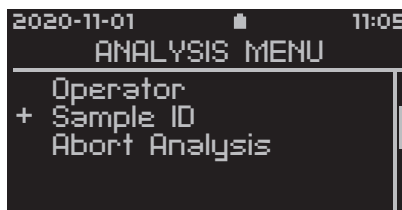
Change Operator ID

• To change the Operator ID during the analysis, select «Operator» from the «Analysis Menu» and confirm with ✅. Select a different operator from the «Operator List» or select «New Operator» to enter a new operator. Any new operator will be automatically added to the «Operator List». Confirming the operator with ✅ will re-open the «Analysis in Progress» window.

Change Sample ID

• To change a Sample ID during the analysis, select «Sample ID» from the «Analysis Menu» and confirm with ✅. This opens the «Enter Sample» window and the Sample ID can be edited. Confirming the edited Sample ID with ✅ will re-open the «Analysis in Progress» window.

Abort Analysis

• Select «Abort Analysis» in the «Analysis Menu» and confirm with ☑.

❶ Note that cartridges CANNOT be re-used after an analysis is aborted.

• The «Abort Analysis» window
appears and «NO» is selected by
default. Press either ☑ or ☒
to exit this window and to return
to the «Analysis Menu».

```
2020-11-01              ▪        11:05
        ABORT ANALYSIS
Do you want to
abort the
analysis ?              YES
                      + NO
```
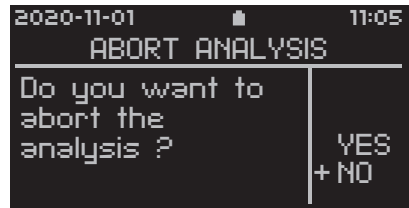
• Select «YES» and confirm with ☑.
The Pima Analyser will abort the
current analysis.

```
2020-11-01              ▪        11:05
        ABORT ANALYSIS
Do you want to
abort the
analysis ?            + YES
                        NO
```
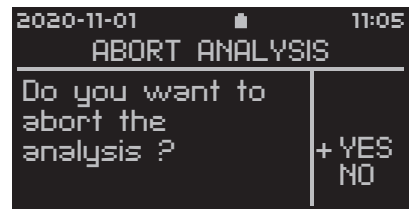
• The operator is prompted to
remove the cartridge. The following
error code is displayed in the first
result window. Press ☒ to return to
the initial «Run test» window and
to start the next analysis.

```
2020-11-01              ▪        11:05
          PIMA CD4
Sample:              67352
      Manual abort
      Error 206

BACK X                  ✓ PRINT
```
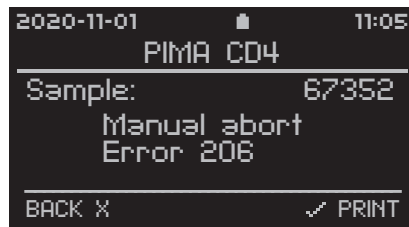
To abort the export, deletion or printing of results, proceed in the same
manner. Press ☒ to open the «Abort process» window. «NO» is selected by
default. Select «YES» and confirm with ☑.
The Pima Analyser will abort the current process.

5 MAIN MENU: RESULTS

The «Main Menu» window can only be selected, if there is no analysis currently in progress.

View Results from Archive

• To view the result options, select «Results» from the «Main Menu» and confirm with ✅.

```
2020-11-01          🔋          11:30
              MAIN MENU
+ Results
  Settings
  Power Off
```
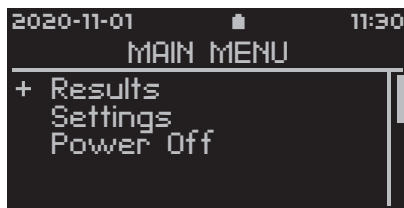
• A list of all available result options is displayed. Use ▲ and ▼ to scroll the complete list. To view Results select «View» from the «Results» window.

```
2020-11-01          🔋          11:30
               RESULTS
+ View
  Print
  Export
  Export and Delete
  Delete
```
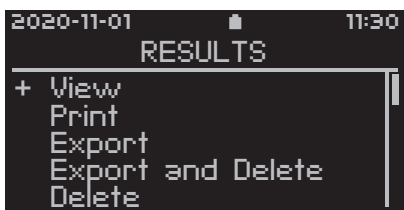
• The «View Results» window with all archived Sample IDs is displayed by Test ID in reverse chronological order. The last archived result is selected by default. Use ▲ and ▼ to select a result of interest and confirm with ✅.

```
2020-11-01          🔋          11:30
            VIEW RESULTS
+ 36 67352
  35 55687
  34 48951
  33 37756
  32 23544
```
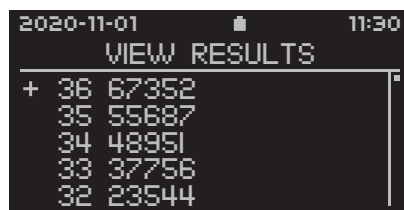
• This opens the first result window for the selected Sample ID. Additional test related parameters can be viewed using ▼ and ▲.

• Press ☒ to return to the «View Results» window.

```
2020-11-01          🔋          11:25
              PIMA CD4
Sample:                  67352
CD3+CD4+:
              183 c/µl
BACK ☒              ✓ PRINT
```
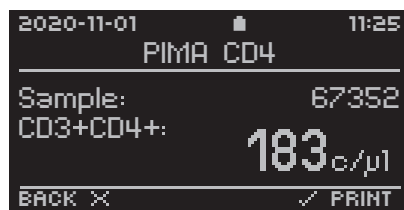
Print Results from Archive

❗ For printing, a USB Printer needs to be attached to the Pima Analyser via the USB port.

• To print results select «Print» from the «Results» window and confirm with ☑.

```
2020-11-01           🔋            11:30
              RESULTS
    View
  + Print
    Export
    Export and Delete
    Delete
```
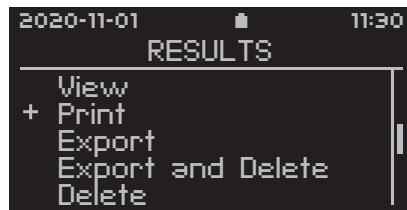
• The «Print Results» window with all archived Sample IDs is displayed by Test ID in reverse chronological order. Select results to be printed and confirm with ☑. Confirmed results are marked by a (x).

```
2020-11-01           🔋            11:30
            PRINT RESULTS
    <Print All>
    <Print Selected>
  + 36 67352
    35 55687
    34 48951
```
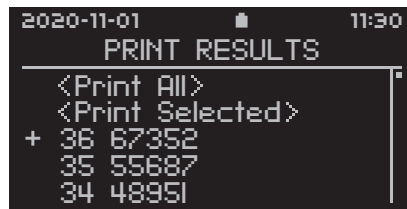
If only one result is selected, printing will start immediately after initial confirmation.

• If more than one result was selected, the «Print» window appears and «NO» is selected by default. Select «YES» and confirm with ☑ to print selected results from the Pima Analyser archive. Press ☒ or select «NO» to exit this window and return to the «Print Results» window.

```
2020-11-01           🔋            11:30
               PRINT
  Do you want to
  print 2
  results ?                    YES
                             + NO
```

The printing status is indicated by a progress bar.
The «Pima Test Report» contains all information displayed on the four result windows of the Pima Analyser.

After successful print, the display automatically returns to the «Results» window.

Export Results from Archive

- To export results select «Export»
  from the «Results» window and
  confirm with ☑.

```
2020-11-01          🔋          11:30
             RESULTS
   View
   Print
 + Export
   Export and Delete
   Delete
```
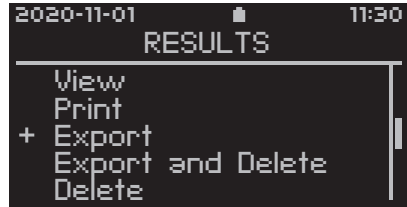
- The Pima Analyser prompts
  the operator to insert a storage
  medium into one of the two USB
  ports on the back of the analyzer.

```
2020-11-01          🔋          11:30


         ⬆       Insert
                 storage
                 medium
```

- The storage medium is recognized
  by the Pima Analyser and
  displayed. This may take up to one
  minute. Use ▲ and ▼ to select a
  storage medium and confirm
  with ☑.

```
2020-11-01          🔋          11:30
          SELECT STORAGE
 + Storage device 2 GB
   Mobile Modem
   LAN Adaptor
```

- In case the USB storage medium is not recognized, please refer to p.42
  for Export Error message. In case a mobile modem is used, please refer to
  "Connectivity Pack IV – Annex to Pima Analyser User Guide UG-PIMA-01".

- The «Export Results» window with all archived Sample IDs is displayed by Test ID in reverse chronological order.

```
2020-11-01          🔋          11:30
       EXPORT RESULTS
  <Export All>
+ <Export Selected>
  36 67352
  35 55687
  34 48951
```

- Either select «Export All» to export all results in the list,
  or use ▲ and ▼ to select a result of interest and confirm with ☑.
  Confirmed results are marked by a (x). After selecting one or more individual results, select «Export Selected» and confirm with ☑ to export results onto the storage medium.

```
2020-11-01          🔋          11:30
       EXPORT RESULTS
  <Export All>
+ <Export Selected>
x 36 67352
  35 55687
  34 48951
```

- If only one result is selected, export will start immediately after initial confirmation. If more than one result was selected, the «Export» window appears and «NO» is selected by default. Select «YES» and confirm with ☑ to export selected results from the Pima Analyser archive. Press ☒ or select «NO» to exit this window and return to the «Export Results» window.

5

- The exporting status is indicated by a progress bar. Exporting can be aborted at any time this window is shown on the screen.

```
2020-11-01          🔋          11:30
        EXPORT RESULTS
        ✳  Exporting
           results
  TOTAL:   [▭▭▭▭▭▭▭▭▭▭▭  ]
```

- Successful export is indicated by this message. Remove storage medium or press ☑ or ☒ to continue.

```
2020-11-01          🔋          11:30



    ⓘ   Remove
        storage
        medium
```

⚠ **Note**: The storage medium does not need to be removed to continue, however, removal is recommended, especially when the Pima Analyser is operated on the integrated battery.

Export and Delete Results from Archive

- To export and delete results at the same time, select «Export and Delete» from the «Results» window and confirm with ☑.
  Select results of interest in the same way as described in the previous section for result export.

```
2020-11-01          🔋          11:30
        RESULTS
   View
   Print
   Export
 + Export and Delete
   Delete
```
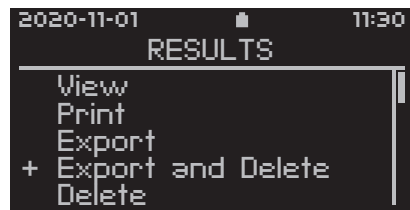
After export, the operator will be prompted to confirm deletion of results.

- The «Delete» window appears and «NO» is selected by default. Press either ☑ or ☒ to exit this window and return to the «Export Results» window.

```
2020-11-01          🔋          11:30
           DELETE
Do you want to    |
delete 35         |
exported          |        YES
results ?         |      + NO
```
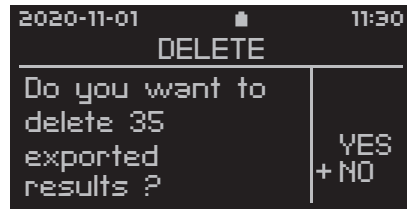
- Select «YES» and confirm with ☑ and selected results are deleted from the Pima Analyser archive after their export onto the storage medium. All other results remain in the archive.
  The process status is indicated by a progress bar.

```
2020-11-01          🔋          11:30
           DELETE
Do you want to    |
delete 35         |
exported          |      + YES
results ?         |        NO
```
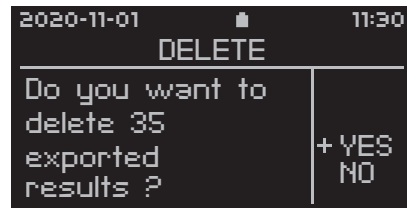
After successful completion, the display automatically returns to the «Results» window.

Delete Results from Archive

- To delete results select «Delete» from the «Results» window and confirm with ☑.

```
2020-11-01          🔋          11:30
           RESULTS
   View              |
   Print             |
   Export            |
   Export and Delete |
 + Delete
```
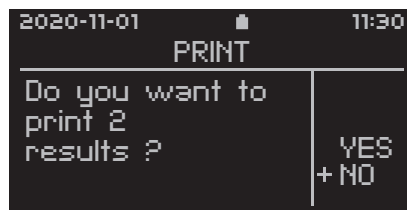
- The «Delete Results» window with all archived Sample IDs is displayed by Test ID in reverse chronological order. Select results to be deleted as described in the section for result export.
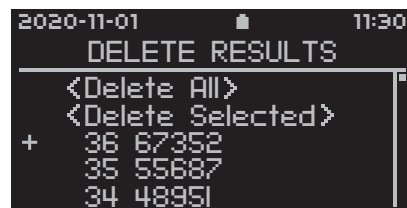
```
2020-11-01          🔋          11:30
       DELETE RESULTS
   <Delete All>       |
   <Delete Selected>  |
 + 36 67352
   35 55687
   34 48951
```

- The «Delete» window appears and «NO» is selected by default. Press either ☑ or ☒ to exit this window and return to the «Delete Results» window.
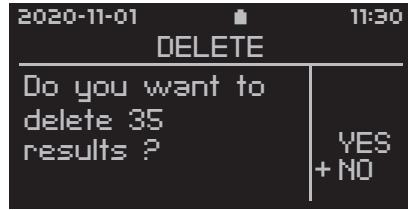
```
2020-11-01          🔋          11:30
              DELETE
Do you want to    │
delete 35         │
results ?         │    YES
                  │  + NO
```

- Select «YES» and confirm with ☑ and selected results are deleted from the Pima Analyser archive. All other results remain in the archive. The deleting status is indicated by a progress bar.

```
2020-11-01          🔋          11:30
              DELETE
Do you want to    │
delete 35         │
results ?         │  + YES
                  │    NO
```
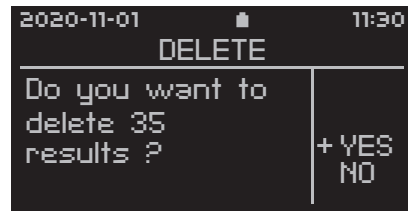
After successful deletion, the display automatically returns to the «Results» window.

6 MAIN MENU: SETTINGS

Settings

- To change general Pima Analyser settings, select «Settings» from the «Main Menu» and confirm with ☑.

- A list of all available settings is displayed. Use ⬆ and ⬇ to scroll the complete list.

```
2020-11-01          🔋          11:05
            MAIN MENU
    Results
+   Settings
    Power Off
```
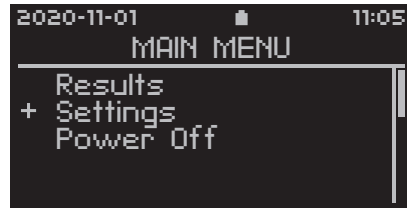
Enter an Operator ID

- Select «Operator» from the «Settings List» and confirm with ☑.

```
2020-11-01          🔋          11:05
           SETTINGS LIST
+   Operator
    Date
    Time
    Service Export
    Device Info
```

- This opens the «Operator List» window. Select «New Operator» to enter a new operator into the list. Confirm with ☑.

```
2020-11-01          🔋          11:05
          OPERATOR LIST
+   <New Operator>
```

- Enter a new operator using the keypad and confirm with ☑. Press ☑ again to save new operator.
  The «Operator List» now contains an operator.
  Continue as described above to enter more operators.

```
2020-11-01          🔋          11:05
           NEW OPERATOR


KARIN_
```
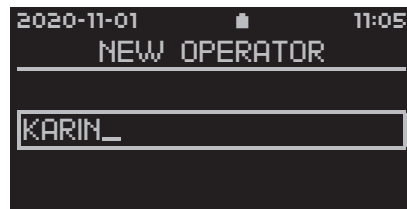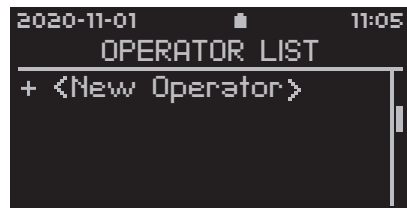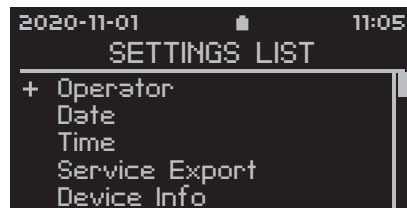
Edit an Operator ID

Editing of existing operators is only possible when no analysis is running. Select «Operator» from the «Settings List » and confirm with ☑ to enter the «Operator List».

- Select the operator that needs to be edited. Confirm with ☑.

```
2020-11-01          🔋        11:05
            OPERATOR LIST
   <New Operator>
   Karin
 + Anton
   Chris
```
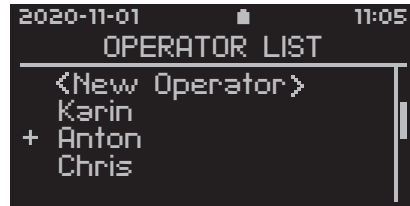
- The «Operator ID» window opens. Select «Edit Operator» and confirm with ☑.

```
2020-11-01          🔋        11:05
            OPERATOR ID
 + Edit
   Delete
```
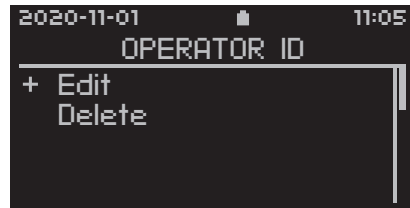
- The «Edit Operator» window opens and the entry can be edited. Confirm with ☑ when finished and the «Edit Operator» Menu is displayed.

```
2020-11-01          🔋        11:05
            EDIT OPERATOR

ANTO_
```
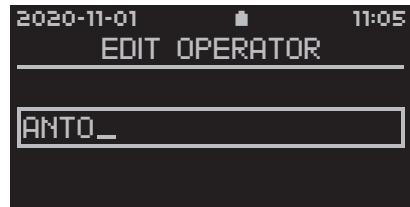
Press ☑ to save edited operator. Selecting «Cancel» and confirm with ☑ re-opens the unchanged «Operator List».

```
2020-11-01          🔋        11:05
            EDIT OPERATOR
 + Save
   Cancel
```
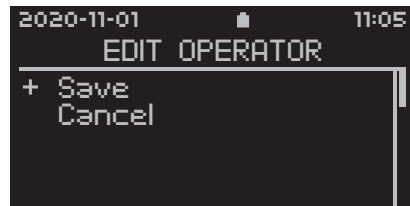
• After confirmation, the edited
  operator is displayed in the
  «Operator List».

```
2020-11-01              ▪         11:05
         OPERATOR LIST
  <New Operator>
  Karin
+ Anto
  Chris
```
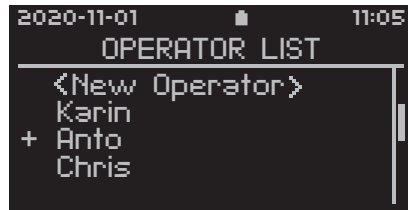
Delete an Operator ID

• Select «Delete» in the «Operator
  ID» window and confirm with ☑.
  The operator is now deleted from
  the «Operator List».

```
2020-11-01              ▪         11:05
         OPERATOR ID
  Edit
+ Delete
```
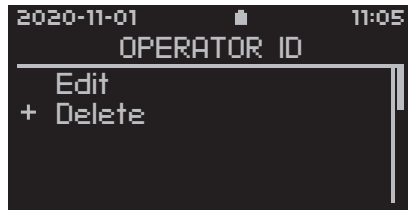
Date

• Select «Date» from the «Settings
  List» and confirm with ☑ to set
  the date on the Pima Analyser.

```
2020-11-01              ▪         11:05
         SETTINGS LIST
  Operator
+ Date
  Time
  Service Export
  Device Info
```
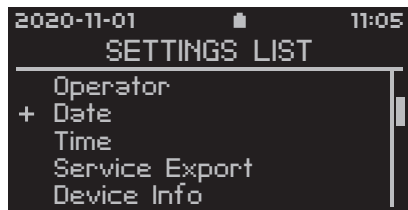
• Use ▲ and ▼ to select the
  desired number and confirm
  with ☑, entering the year first,
  followed by month and day.
  Confirm the correct date with ☑.

```
2020-11-01              ▪         11:05
         SET DATE

         2020-12-04
```
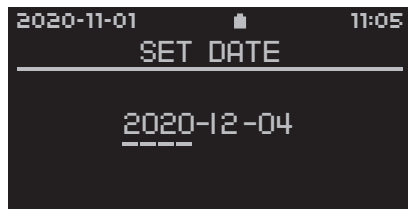
Time

- Select «Time» from the «Settings List» and confirm with ☑ to set the time on the Pima Analyser.

```
2020-11-01           🔋          11:05
            SETTINGS LIST
   Operator
   Date
 + Time
   Service Export
   Device Info
```
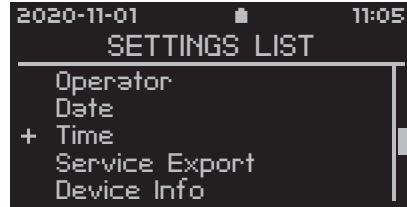
- Use ▲ and ▼ to select the desired number and confirm with ☑, entering the hours first, followed by minutes. Confirm the correct time with ☑.

```
2020-11-01           🔋          11:05
              SET TIME


              13:53
              __
```
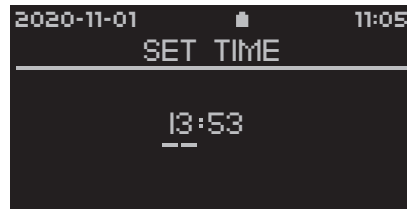
Service Export

- Select «Service Export» from the «Settings List» and confirm with ☑ to export encrypted data from the last analysis or the last 10 analyses. Follow the on-screen instructions and proceed in similar fashion as described for "Export Results from Archive".

```
2020-11-01           🔋          11:05
            SETTINGS LIST
   Operator
   Date
   Time
 + Service Export
   Device Info
```
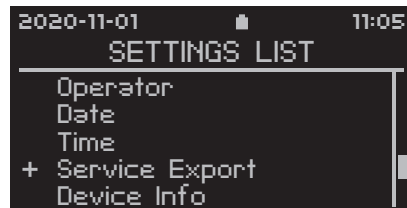
❗ **Note**: The Service Export tool is meant to assist Technical Support in trouble shooting the Pima Analyser. Service Export files can only be read using matching decrypting software. Service Exports may take up to an hour, depending on the number of files needed to be exported and the USB storage medium used.

Device Info

The Device Info window provides a quick overview of some important Pima Analyser characteristics.

- Select «Device Info» from the «Settings List» and confirm with ☑ to view Pima Analyser status data.

```
2020-11-01          🔋          11:05
          SETTINGS LIST
   Operator
   Date
   Time
   Service Export
 + Device Info
```
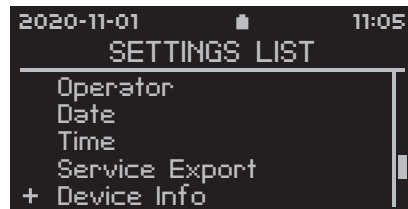
- The following information can be obtained:

```
2020-11-01          🔋          11:30
          DEVICE INFO

 DEVICE:              PIMA-D-000552
 SOFTWARE:                   0.43.1
 BATTERY:                       60%
 ARCHIVE:                37 RESULTS
 CONNECTIVITY:        CP1, CP2, CP4
```

Category	Information
Device:	Serial Number of the Pima Analyser
Software:	Software version installed on the Pima Analyser
Battery:	Current charging status of the internal battery
Archive:	Number of results stored in the archive
Connectivity:	Mobile modems that can be used with this Pima Analyser

6

Connectivity

- This option is only available in combination with the respective hardware and Pima software version 0.43.0 or higher.
  For wireless connectivity please refer to "Connectivity Pack IV – Annex to Pima Analyser User Guide UG-PIMA-01" or contact your local distributor.

```
2020-11-01          🔋          11:05
          SETTINGS LIST
   Date
   Time
   Service Export
   Device Info
 + Connectivity
```
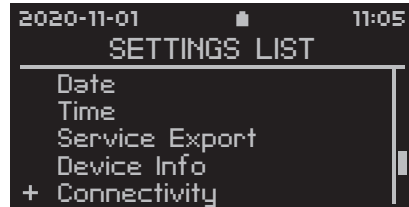
Local Network

- This option is only available in combination with the respective hardware and Pima software version 0.40.0 or higher.

  For more information about LAN connectivity please contact your local distributor.

```
2020-11-01          🔋          11:05
          SETTINGS LIST
   Time
   Service Export
   Device Info
   Connectivity
 + Local Network
```
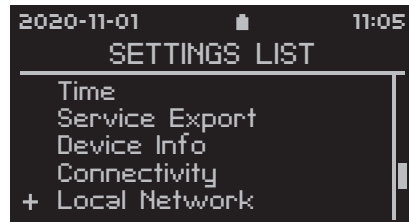
7 MAIN MENU: POWER OFF

Turning Off the Pima Analyser

- To turn off the Pima Analyser select «Power Off» from the «Main Menu» and confirm with ☑.

```
2020-11-01          🔋          11:05
              MAIN MENU
   Results
   Settings
 + Power Off
```
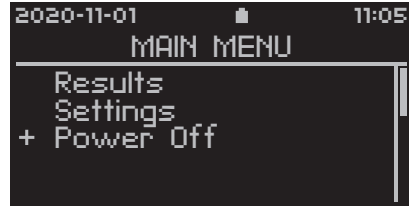
- The «Power Off» window appears and, as a safety measure, «NO» is selected by default.

```
2020-11-01          🔋          11:05
              POWER OFF
 Do you want to
 turn power off ?
                              YES
                           + NO
```
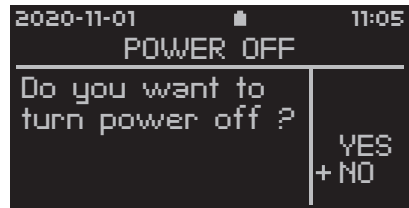
- If «YES» was selected and confirmed with ☑, the screen will indicate that the Pima Analyser is shutting down. This may take up to one minute. After the shutdown sequence is completed, the Pima Analyser will turn itself off, the screen will turn black and a "beep" is audible.

```
2020-11-01          🔋          11:05


        ⧗   Shutdown
            Please wait
```

❗ Remove any storage media from the USB port before shutting down the Pima Analyser.

8 ERROR CODES & TECHNICAL SUPPORT

Note: If the Pima Analyser does not react to any input from the keypad, press and hold the Power On button on the back of the analyzer until the screen turns black and you hear a long single "beep", confirming that the analyzer is now switched off. Restart the Pima Analyser.

Error Code Window

The Pima Analyser performs a series of checks to ensure that all steps of the analysis process are completed successfully.

Should one of these checks discover an error, the test will be aborted automatically, the cartridge ejected and an error code displayed on the screen (an example is shown to the right).


```
2020-11-01              🔋              11:05
                 PIMA CD4
Sample:                        67352
              Invalid Test
              Error 810

BACK X                              PRINT
```
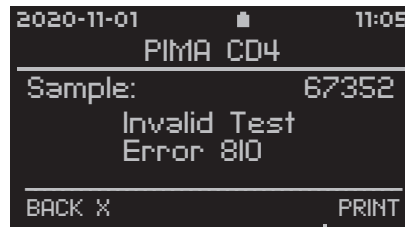
Technical Support

For Technical Support please contact your local distributor or call the respective number for your region:

Europe & Middle East	+44 161 483 9032	EME.TechSupport@abbott.com
Africa	+27 10 500 9700	arcis.techsupport@abbott.com
Asia Pacific	+61 7 3363 7100	AP.TechSupport@abbott.com
Latin America	+57 1 482 4033	LA.TechSupport@Abbott.com
Russia, and the Commonwealth of Independant States (RCIS)	+44 161 483 9032	arcis.techsupport@abbott.com

Error Codes

Error Code	Action
200	Switch off the Pima Analyser via Main Menu and restart. If Error persists contact your local distributor.
201	Check cartridge control window was fully filled. Repeat test with new cartridge.
202	Check cartridge cap was completely closed. Repeat test with new cartridge.
203	Check cartridge expiry date. Check correct date on the Pima Analyser. Repeat test with valid cartridge.
204	Repeat test with new cartridge.
205	Contact your local distributor.
206	Analysis aborted by operator. No further action required.
207	Repeat test with new cartridge. If Error persists contact your local distributor.
210, 220, 230	Repeat test with new cartridge. If Error persists contact your local distributor.
211	Switch off the Pima Analyser via Main Menu and restart. If Error persists contact your local distributor.
300-399	Contact your local distributor.
810	
820	
825	
830	
840	
850	
860	Repeat test with new cartridge. If Error persists contact your local distributor.
870	
880	
910	
920	
930	
940	

8

9 ERROR WARNINGS & MESSAGES

Archive Error

❶ If the storage capacity of the archive is reached, the screen will display the «Archive full» window. No further analyses can be performed by the Pima Analyser until data has been downloaded and the archive emptied.

Even if the storage capacity is reached, all menu functions are still active.

Barcode Errors

In the unlikely event that the Pima Analyser has difficulties reading the cartridge barcode, the «Barcode error» window appears.

- Press ☑ or ☒ and enter the number printed below the barcode on the cartridge pouch (circled in image). Press ☑ to confirm and continue. The barcodes (and their respective numbers) carry important cartridge specific information and may differ from cartridge to cartridge.
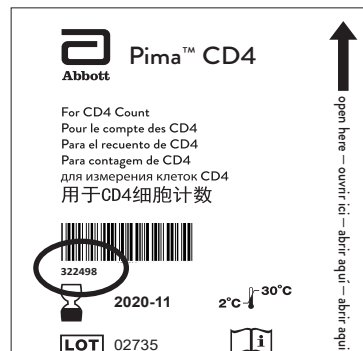
- Press ☒ instead of entering a barcode and the «Abort Analysis» window opens.
❶ Check cartridge barcode for damage or marks.

❶ DO NOT use the barcode from a different cartridge when manually entering the barcode. Manual input of barcodes will be documented on the test result pages.

• If the cartridge barcode does not encode for a test type uploaded onto the Pima Analyser, the following window is displayed.

```
2020-11-01          🔋          11:05
              FAILURE
    ⊗       Invalid
            barcode
```
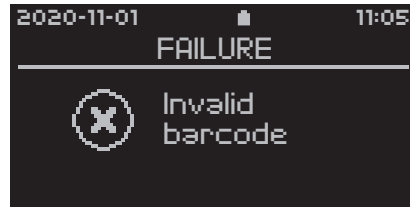
❶ For information regarding available test software please contact your local distributor.

Entry Errors

It is mandatory to enter Operator and Sample ID to view a test result. Attempting to confirm «blank» entry fields for either Operator or Sample ID will trigger the following error messages.

```
2020-11-01          🔋          11:05
            INVALID ENTRY
    ⊗       Operator is
            required
```

• Enter valid Operator and Sample ID to continue.

```
2020-11-01          🔋          11:05
            INVALID ENTRY
    ⊗       Sample ID
            is required
```

Should a new Operator ID be entered into the Operator List, but an operator with the same name / number already exists in the list, the following window is displayed.

```
2020-11-01          🔋          11:05
            INVALID ENTRY
    ⊗       Operator
            already
            exists
```

• Press ☑ or ☒ and pick a different name / number for the new operator.

Export Error

If the «Export failed» window
appears, an unspecified error has
occurred during export of results.
This may have been caused by either
the storage medium or the Pima
Analyser.

```
2020-11-01          🔋          11:05
              FAILURE
   (✕)   Export
         failed
```

- Press ☑ or ☒ and remove the storage medium. Repeat export of results.
  Should this fail a second time insert a different USB storage medium and
  export results.

Power Warning

The «Warning Recharge battery»
window appears indicating that the
Pima Analyser's integrated battery is
low. This warning can appear at any
time, even during an active analysis.
At this point the Pima Analyser is
fully functional and the analysis can
be continued.

```
2020-11-01          🔋          11:05
              WARNING
   (ⓘ)   Recharge
         battery
```
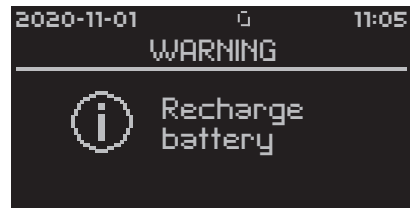
❗ It is recommended to connect the Pima Analyser to A/C power before
   starting another analysis.

- Press ☑ or ☒ to continue.

9

Power Error

The «Recharge battery» window appears if the power level of the integrated battery is too low to conduct another analysis.
No further analyses can be performed by the Pima Analyser until the battery is recharged or the analyzer is connected to A/C power.

```
2020-11-01          ⬚          11:05


       ⊗       Recharge
               battery
```
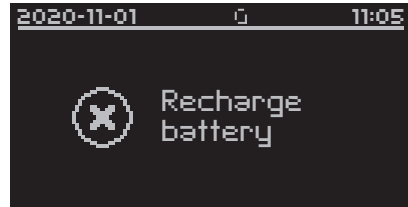
- Menu functions may still be active at this point. Press ✓ or ☒ to continue.

❗ It is recommended to connect the Pima Analyser to A/C power before the integrated battery is completely discharged.

Printer Errors

Should the operator attempt to print results with no USB Printer attached to the Pima Analyser the «Failure» window is displayed.

```
2020-11-01          🔋          11:05
            FAILURE
 Printer error
 Abort printing ?

                        YES
                       + NO
```
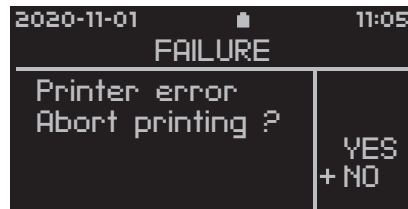
Should the USB Printer run out of paper, the following window is displayed.

After a new roll of paper has been inserted, confirm continuation of printing with ✓. In case the error occurred during the printing of a Pima Test Report, the last report will be printed again.

```
2020-11-01          🔋          11:05
            FAILURE
 Paper required
 Abort printing ?

                        YES
                       + NO
```

9
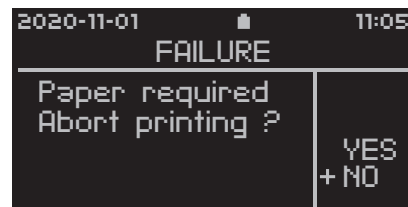
For more information on the USB Printer, please refer also to the USB Printer User Guide (UG-m-PIMA-02).

Selection Error

Should the operator attempt to print, export, export and delete or delete stored test results without selecting a result prior to executing the command the following window is displayed.

```
2020-11-01          11:05
      INVALID SELECTION

   ⊗    No test
        selected
```

- Press X and select one or more tests before pressing ✓.

Storage Errors

If, during export, the storage capacity of the storage medium is reached, the following window appears.

```
2020-11-01          11:05
            FAILURE

   ⊗    Storage
        medium full
```

- Press ✓ or X and remove the storage medium. Insert another storage medium with adequate storage capacity and try to export again.

If, during export, the storage medium is removed from the USB port, the following window appears.

```
2020-11-01          11:05
            FAILURE

   ⊗    Storage
        medium lost
```

- Press ✓ or X, re-insert the storage medium and attempt to export again.

9
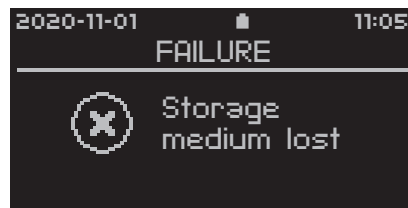
Undeﬁned Errors

It is possible that an undeﬁned error occurs while operating the Pima Analyser.

This error message may appear if the analyzer unexpectedly aborted start up.

- Press and hold the Power On button on the back of the Pima Analyser until the screen turns and remains black. Then restart the analyzer.

2020-11-01   11:05
FAILURE

(X) Unexpected
exception
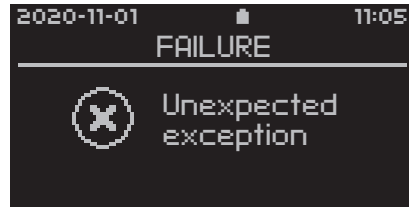
This error message may appear at any time. Depending on what triggered the error, the operator may still be able to navigate through the Pima Analyser menus and to start a new test.

2020-11-01   11:05
FAILURE

(X) Error 0000

- In case the error caused the Pima Analyser to stall, press and hold the Power On button on the back of the analyzer until the screen turns and remains black. Then restart the Pima Analyser.

This error message may appear during the initial booting procedure and will cause the Pima Analyser to stall.

- Press and hold the Power On button on the back of the analyzer until the screen turns and remains black. Then restart the Pima Analyser. If error persists contact your local distributor.

pima™

HARDWARE FAILED

9

Volume Error

Before each analysis, the Pima
Analyser checks the sample volume
loaded on the Pima test cartridge.
If the Pima Analyser detects
insufficient volume the following
window is displayed.

```
2020-11-01          🔋          11:05
              FAILURE
        ─────────────────
   ⊗       No sample
           detected
           Error 201
```
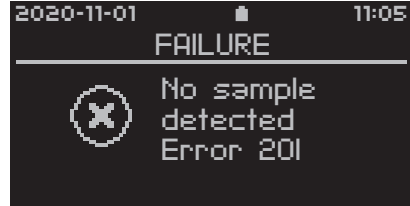
Press ☑ or ☒ and the «Abort
Analysis» window opens.

The operator can overrule this error message by selecting «NO» in the
«Abort Analysis» window and the analysis process will continue.

❗ Overruling Error 201 will be documented on the result pages.

2.2. Pima Bead Standard User Guide

For information on optional peripheral equipment and accessories, please view at **www.abbott.com/poct**

IVD	*In vitro* diagnostic medical device	(hourglass)	Use by
CE	CE Mark	(factory)	Manufacturer
REF	Catalogue number	(umbrella)	To keep dry
LOT	LOT number	2°C – 30°C	Temperature limitation
(book/i)	Consult instructions for use		

Abbott Rapid Diagnostics Jena GmbH
Orlaweg 1
D-07743 Jena, Germany
www.abbott.com/poct

Printed on 100% recycled paper.

Revision date: 21-Jan-2020   UG-PIMA-03-07-EN

Abbott

Pima™ Bead Standard
USER GUIDE

EN

Intended Use

The Pima Bead Standard is an external control material for daily quality control (QC) on the Pima Analyser and controls instrument setup and performance, and data analysis. It comprises two ready-to-use test cartridges, Pima Beads [Normal] and Pima Beads [Low], with set amounts of fluorescent spots. Daily QC should be performed before testing of patient samples or after any relocation of the Pima Analyser. Each test takes approx. 7 minutes. For *in vitro* diagnostic use.

Stability and Storage

The Pima Bead Standard is a re-usable dry standard material that is stable until the expiry date indicated on the pouch label, as long as the sealed foil pouch is not opened. Upon opening the Pima Bead Standard can be used for 6 months.
Store the Pima Bead Standard cartridges in their storage box at ambient temperature and protected from light.

❶ Record the opening date on the label inside the storage box.

How to use the Pima Bead Standard

❶ For daily QC always use one pair of Pima Bead Standard together with one particular Pima Analyser.

The Pima Bead Standard box labels indicate the respective manufacturing ranges for the cartridges (see example page 4).
To establish an individual range for a particular Bead Standard/ Analyser combination perform 10 tests with each cartridge on the same Pima Analyser. The results need to be within the manufacturing range printed on the label.
After these initial tests the individual device specific ranges need to be established and all following measurements need to fall within these new ranges.
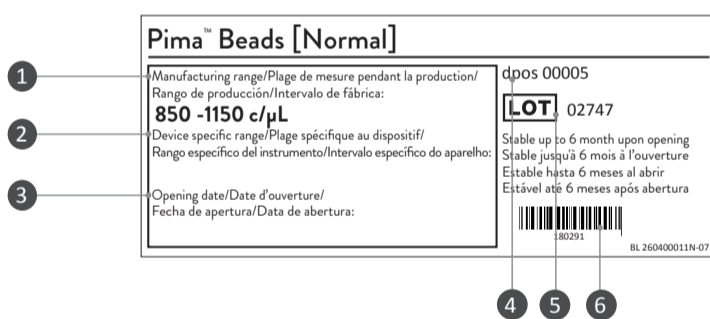
How to calculate the device specific range

The individual ranges for a particular Bead Standard/ Analyser combination are determined by calculating the mean (= sum of all measured values divided by the total number of measurements).
An acceptable deviation from the mean can be calculated by multiplying the mean with 0.05.
The result (= XX c/µL) will determine the individual range for the particular Bead Standard/Analyser combination (= mean ± XX c/µL).

Record the new device specific range on the respective box labels.

Please find respective calculation sheet plus example calculation overleaf.

The Pima Bead Standard Box Label

① Manufacturing range:
Result range for a particular cartridge LOT across all Pima Analysers.

② Device specific range:
Note result range calculated for one particular Pima Analyser/ Pima Bead Standard combination (see calculation sheet overleaf).

③ Opening date:
Note opening date to recognize 6 months expiry.

---

④ dpos number:
Can be used to identify the individual cartridge.

⑤ LOT number:
Can be used to identify the manufacturing LOT of an individual cartridge.

⑥ Barcode:
In the unlikely event that the Pima Analyser has difficulties reading the cartridge barcode you can enter the number printed below the barcode on the cartridge label.
See Pima Analyser User Guide for further details.

Testing the Pima Bead Standard

Dry control material is sealed within each Pima Bead Standard cartridge. No addition of liquid reagent or sample is needed.
To perform a Pima Beads measurement press the ☑ button on the Pima Analyser and insert a Pima Bead Standard cartridge when prompted by the Analyser. The Analyser automatically recognises the cartridge and initiates the Pima Beads test.
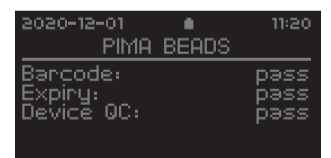
- Once an Operator and Sample ID have been entered into the Pima Analyser the «Analysis in Progress» window appears.
«Pima Beads» is displayed in the status line.

- After successful completion of the analysis, remove the Pima Bead Standard cartridge. Once the cartridge is removed, the Pima Analyser automatically displays the first «Pima Beads» result window, showing the Sample ID and test result in c/µL.

- There are four result windows for every Pima Beads test. Because Pima Bead Standard is a dry material, the QC features for«Volume» and «Reagent» are inactivated and not displayed on the result screen.
All other QC parameters are tested as usual. The test results are stored in the Analyser archive. In case a result falls outside the device specific range clean the detection channel lid with a lint free cloth and repeat the measurement twice. Should the results fall within the range, continue testing patient samples. Should the results again fall outside the range contact your local distributor for support before testing patient samples.

For further information on viewing and printing test results please refer to the Pima Analyser User Guide.
For Technical Support please contact your local distributor or call the respective number for your region:

Europe, Russia & CIS:	+44 161 483 5884	EME.techsupport@alere.com
Africa:	+27 21 5315 999	Afrisupport@alere.com
Asia Pacific:	+61 7 3363 7166	au.techsupport@alere.com
India:	+91 11 45089400	technical.service@alere.com
Latin America:	+57 2 6618916 +57 26618797	la.techsupport@alere.com

Pima Bead Standard
Calculation of device specific ranges - Example

Pima Analyser		Pima Bead Standard	
Serial No.　PIMA-D- _0 0 2 4 1 8_		LOT No.　_0 0 8 2 1_	
		absolute expiry *(YYYY/MM)*　_2 0 2 1 / 0 6_	
		6 months expiry *(DD/MM/YY)*　_1 2 / 0 8 / 2 0_	

Pima Beads [Normal]		Pima Beads [Low]	
LOT No.　_0 2 0 2 5_		LOT No.　_0 2 0 2 7_	
dpos　_0 6 2 6 8_		dpos　_0 8 5 4 7_	
manufacturing range　_699 - 1299_		manufacturing range　_144 - 267_	

	Date	Result	Comment		Date	Result	Comment
Normal 1	12/02/20	837	--------------	Low 1	12/02/20	205	--------------
Normal 2	12/02/20	840	--------------	Low 2	12/02/20	203	--------------
Normal 3	12/02/20	854	--------------	Low 3	12/02/20	201	--------------
Normal 4	12/02/20	841	--------------	Low 4	12/02/20	201	--------------
Normal 5	12/02/20	840	--------------	Low 5	12/02/20	200	--------------
Normal 6	12/02/20	838	--------------	Low 6	12/02/20	206	--------------
Normal 7	12/02/20	849	--------------	Low 7	12/02/20	202	--------------
Normal 8	12/02/20	846	--------------	Low 8	12/02/20	200	--------------
Normal 9	12/02/20	851	--------------	Low 9	12/02/20	205	--------------
Normal 10	12/02/20	843	--------------	Low 10	12/02/20	202	--------------
Mean		844		Mean		203	
Mean times 0.05		42		Mean times 0.05		10	
Device specific range		802 - 886		Device specific range		193 - 213	

Pima Bead Standard
Calculation of device specific ranges

Pima Analyser		Pima Bead Standard	
Serial No.　PIMA-D- _ _ _ _ _ _		LOT No.　_ _ _ _ _	
		absolute expiry *(YYYY/MM)*　_ _ / _ _	
		6 months expiry *(DD/MM/YY)*　_ _ / _ _ / _ _	

Pima Beads [Normal]		Pima Beads [Low]	
LOT No.　_ _ _ _ _		LOT No.　_ _ _ _ _	
dpos　_ _ _ _ _		dpos　_ _ _ _ _	
manufacturing range		manufacturing range	

	Date	Result	Comment		Date	Result	Comment
Normal 1				Low 1			
Normal 2				Low 2			
Normal 3				Low 3			
Normal 4				Low 4			
Normal 5				Low 5			
Normal 6				Low 6			
Normal 7				Low 7			
Normal 8				Low 8			
Normal 9				Low 9			
Normal 10				Low 10			
Mean				Mean			
Mean times 0.05				Mean times 0.05			
Device specific range				Device specific range			