IH-1000

User Manual

BIO-RAD

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Identification

IH-1000 User Manual

Version 2.0 - 01/2022

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3 /

K_lsd_arspcp

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Tcpqgml Fgqrmpw

Bmaskclr Tcpqgml	Qmdru_pc Tcpqgml	B_rc	Kmbgdga_rgml
/,.		07/2010	First edition
/,/	T1,.	03/2011	V3.0 Soft updates
/,0	T2,.	11/2012	V4.0 Soft and troubleshooting updates
/,1		11/2013	Compliance 61010-1 2010, User level and minor updates
/,2	T.2,.2	03/2015	V04.04 Soft updates and minor updates
/,3	T.2,.5	07/2017	New layout Content update according to the software version Revised: • the Glossary on page 12; • the procedures of Managing Liquids and Wastes on page 93; • the description of the Options on page 125; • the Maintenance Operations on page 148; • the list of Examples of Test Execution; • Barcode Exception Mask Filter Option on page 130; Added: • a glossary of abbreviations; • a procedure for Removing Sample Racks on page 88
/,4	T.2,.6	03/2020	Content update according to the software version Revised: • the management of the resources used by the instrument and the tests to be performed; • the flowchart describing a normal test performed by the instrument; • the criterias of the return of gel cards for 2nd reading; • the list of troubleshooting. Added: • a statement about the limitations to install third-party software in the computers of the instrument; • a warning before proceeding to the decontamination procedure.
/,5		01/2021	Revised: • the section describing the clot detection; • the cleaning and the replacement of the needle. Added a statement about overvoltages.
0,.		01/2022	Added complementary information about cleaning solution preparation. User Manual fully revised in accordance to the new European regulation (EU) 2017/746 (IVDR).

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N?EC GLRCLRGML?JJW JCDR @J?L I

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Af_nrcp /. Rpms`jcqfmmrgle ,,,

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1 Generalities

Af_nrcp Mtcptgcu

This chapter contains basic information on the instrument and the document structure.

1.1 Intended Use

The IH-1000 is a fully automated instrument intended for the ID-System used in immunohematology testing for ABO blood grouping (forward and reverse), antigen typing, antibody screening, antibody identification, Direct Antiglobulin Testing (DAT) and compatibility tests in human blood samples.

For in vitro diagnostic use, by trained laboratory personnel. Device for professional user in a laboratory environment only.

Using the IH-1000 is only permitted in conjunction with the corresponding software or in a configuration which is authorized by Bio-Rad.

The use of any material other than the one specified in the User Manual (e.g. non-authorized substances) is forbidden.

0 The instructions contained in the current User Manual must be adhered to with particular reference to the safety instructions.

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1.2 Warranty Limitation

Although the instrument and its software have been tested, it is highly recommended to perform a backup of the computer before any installation and use of the software.

Bio-Rad denies any responsibility in case of:

- wrong use of the instrument;
- unauthorized modification (willingly or unwillingly);
- not complying to the instructions contained in the manuals provided with the instruments and software;
- not complying to the safety instructions contained in the manuals;
- damages linked with the use of the instrument, in particular any data loss or any financial loss which could possibly be attached to the use of the software;
- if the instrument is used in a manner not specified by the manufacturer, the protection provided by the instrument may be impaired.

When the instrument is connected to a host, the user takes the entire responsibility for an error-less transmission of the results (hardware, software, firmware, etc...) to this system.

> ?lw u_pp_lrw ugjj `c bcckcb tmgb gd d_sjr gq dmslb rm f_tc `ccl a_sqcb `w k_jrpc_rkclr* kgqsqc* sl_srfmpgxcb k_glrcl_lac md qcptgac mp lcejgeclac md pcesj_p k_glrcl_lac _lb qcptgac* _aagbclr_j b_k_ec* glamppcar qrmp_ec mp sqc md rfc npmbsarq dmp mncp_rgmlq msrqgbc rfcgp qncagdgcb jgkgr_rgmlq* msrqgbc rfcgp qncagdga_rgmlq* amlrp_pw rm rfc glqrpsargmlq egtcl gl rfgq k_ls_j,

Each Bio-Rad's IH-1000 is tested by the manufacturer before shipping.

1.3 Glossary

The following terms, among others, are used in this manual.

ES6	Graphical User Interface
6B+A_pb	Term which designates the gel card
J?L	Local-Area Network
OA	Quality Control
SB6	Unique Device Identifier
SNQ	Uninterruptible Power Supply
SQ@	Universal Serial Bus

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/,1,/ Ncpqmlq

K_lsd_arspcp

The manufacturer of the IH-1000 is:

DiaMed GmbH
Pra Rond 23
1785 Cressier FR
Switzerland

Mncp_rmp

The operator is the owner of a IH-1000 when using it as its owner and when transferring it to a third-party.

Ncpqmllcj

The term “personnel” includes any person who performs any kind of operation with the IH-1000. These individuals should be qualified in accordance with the manufacturer’s requirement.

Rcaflga_jncpqmllcj

The term «technical personnel» designates the duly trained persons, who are allowed to perform specific tasks on the IH-1000.

For instance, an electrician is designated as technical personnel for the activities linked to wiring the IH-1000 to the electrical network.

Ncpqmllcj os_jgdga_rgmlq

The personnel qualifications define the minimum requirements which must be met by the authorized personnel.

KglmpGlhspw

A Reversible injury that does not require medical treatment.

KmbcpcrcGlhspw

A Reversible injury that does require medical treatment.

K_hmpGlhspw

The damage that is irreversible, causes handicap or death.

/,1,0 Npmbsar

Glqrpskclr

This is the IH-1000 distributed by the manufacturer.

@gm-P_b _srfmpgxcb Ecj A_pb

Gel card based on column agglutination technique including a microtube system consumable where the antigen-antibody binding is fixed in the gel matrix.

- Mljwecja_pbq k_lsd_arspcb `w @gm-P_b k_w `c sqcb glrfc glqrpskclr,

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Q_knjc

Content of any sample tube.

@gm-P_b _srfmpgxcb Pc_eclr

A consumable substance or compound that is added to a system in order to bring about a chemical reaction, or is added to see if a reaction occurs. Such a reaction is used to confirm the presence of another substance.

! Mljw pc_eclrq k_lsd_arspcb `w @gm-P_b k_w `c sqcb gl rfc glqrpskclr,

/,1,1 Q_knjc K_rcpg_j

?@M-Pf Rcqrgle

Centrifuged blood samples are required for tests which involves red cells EDTA is considered an acceptable anticoagulant for patient and donor samples.

Clotted samples (no anti coagulant in the sample) cannot be used when red cell testing is being performed.
Clotted, grossly hemolyzed, grossly lipemic or grossly icteric samples may result in inaccurate typing or increased “not interpretable” results.

Anti-coagulated blood samples can be tested for up to 48 hours after collection. If the samples are not tested within 24 hours of collection, samples should be stored at 2-8 °C.

The samples must return to room temperature prior to analysis. The use of cold samples may cause dispensing errors or non-specific reactions.

Prior testing, samples must be centrifuged according to the local Good Laboratory Practices, e.g. 10 minutes at 1500g, to obtain a distinct separation between cells and plasma/serum.

?lrg`mbw Qapccl Rcqrgle

Plasma or serum can be used for the antibody screening, antibody identification and crossmatch test on the IH-1000. The serum must be in a separate tube without the presence of red cells in the same tube.

1.4 Typographical Conventions

The following styles are used in this manual.

/,2,/ Bcqapgnrgml

This style, used in conjunction with illustration numbers, is preceded with the corresponding numbers:

Cv_knjc

1 First element.

2 Second element.

3 Etc...

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/,2,0 Amk k_lb

Any software command, button, function key, window, icon, option, tab, checkbox, selection box, article, menu, tool bar, field and section used in this document is represented by a bold font.

Cv_knjc

The **EXIT** command allows to quit the software.

/,2,1 Npmacbspc

Each procedure step to be carried out step-by-step by the user is preceded by a letter.

Cv_knjc

A	Open the drawer.
B	Put the gel card into position as shown.
C	Close the drawer.

/,2,2 Npmacbspc Pcqsjr

A procedure result is shown by the following symbol .

Cv_knjc

A	Click on the **Parameters** button. *Rfc n_p_kcrcp qapccl gq bgqnj_wcb,*

/,2,3 Apmqq Pcdcpclac

This style helps the user to find complementary information linked to the current subject.

Cv_knjc

See chapter Cross Reference on page 15.

/,2,4 Jgqr md Grckq

This style is used in order to display a list of elements.

Cv_knjc8

- item 1;
- item 2;
- item 3.

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/,2,5 Rpms`jcqfmmrgle

The complete description along with the error code, the description and the corrective actions as follows:

Cppmp ambc	Cppmp bcqapgnrgml	Amppcargtc _argmlq

/,2,6 Gk_ecq

Versions on screen shots do not necessarily correspond with the current version of software.

/,2,7 U_plgle

The following styles are used in this manual.

Content of software screens and buttons remain in English printed in bold italic type and are followed by their translation in brackets (e.g. click the **VALIDATE** button to confirm).

/,2,7,/ U_plgle

- Rm bcqgel_rc8
  _lgk kglclr_lb b_lecpmsq qgrs_rgml ufgaf*gd lmr_tmgbcb* k_wjc_b rm k_hmpglhspw md rfc sqcp9
  mp_nmrclrg_jjw b_lecpmsq qgrs_rgml ufgaf*gd lmr_tmgbcb* k_wjc_b rm8
  - kmbcp_rc glhspw md sqcp mpgl rfc rcqrq `cgle d_jqc9
  - glhspw md sqcp mpgl gknmpr_lr bcj_wgl bcjgtcpw md rfc rcqr pcqsjrq,

/,2,7,0 Lmrc

0 Indicates:

- a preferred procedure or recommended use,
- a general or informative remark.

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2 Safety and Handling

Af_nrcp amlrclrq

This chapter sets out safety instructions to ensure safe and trouble-free operation of the IH-1000 and its associated softwares. It also describes the handling and storage conditions.

2.1 Introduction

0,/,/ Npglagnjcq

- @cdmpc a_ppwgle msr_lw mncp_rgml uf_rqmctcp ml rfc GF-/...*gr gq g k ncp_rgtc rm pc_b rfgq af_nrcp_lb dsjjw slbcpqr_lb gr,

In case of any doubt, consult your Bio-Rad representative.

0,/,0 Gknmpr_lac md rfc Q_dcrw Glqrpsargmlq

- ?jj rfc q_dcrw glqrpsargmlq gl rfgq Sqcp K_ls_j_lb ml rfc glqrps k clr k sqr `c am k njgcb ugrf gl mpbcp rm npctclr_aagbclrq rm ncpqmlq*b_k_ec rm cosgn k clr mp nmjjsrgml md rfc cltgpml k clr,

In a similar manner, the legal bylaws and the recognized technical rules which apply in the country of use of the IH-1000 must be adhered to.

If during the use of this device or as a result of its use, a serious incident occurs, please report it to Bio-Rad Laboratories and/or its authorized representative and to your national Competent Authority.

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0,/,1 Bgqpce_pbgle rfc Q_dcrw Psjcq

Disregarding the safety rules, as well as existing legal and technical regulations, may lead to accidents, property damages or environmental pollution.

- Bgqpce_pbgle rfc glqrpsargmlq dmp sqc egtcl `w rfc k_lsd_arspcp k_w pcbsac rfc jctcj md npmrcargml mddcpcb `w rfc glqrps k clr,

2.2 Environmental Conditions

- Rfc GF-/... k_w mljw `c sqcb glbmmpq _lb lctcp gl rfc gk k cbg_rc tgaglgrw md n_rgclrq,
  Rfc cjcarpga_j q_dcrw md rfc GF-/... gq es_p_lrccb mljw gd rfc cjcarpga_j glqr_jj_rgml md rfc `sgjbgle amk njgcq ugrf l_rgml_j pcesj_rgmlq _nnjga_`jc rm `sgjbgleq dmp k cbga_j nspnmqcq mp j_`mp_rmpgcq _lb gd rfgq glqr_jj_rgml gq ds largmlgle ncpdcarjw,
  Rfc GF-/... k_w lmr `c sqcb gl npc kgqcq qs`hcar rm pgqiq md dgpc mp cvnjmqgml,

- ?q dmp _lw mrfcp cjcarpga_j bctgac* rfc GF-/... k_w lmr `c jma_rcb lc_p _u_rcp r_n, Bm lmr_jjmu _lw jgosgb rm nclcrp_rc glqgbc rfc fmsqgle md _lw glqrps k clr, Gl a_qc md k_hmp qngjj_ecq md jgosgb glqgbc _lw glqrps k clr* npmaccb gk k cbg_rcjw _q dmjjmuq8
  ?, Qugraf mdd rfc GF-/... _r rfc nmucp qugraf,
  @, Bgqamllcar rfc njse,
  A, Bpw rfc glqrps k clr,
  B, Ajc_l _lb bcamlr_kgl_rc rfc glqrps k clr,
  C, Afcai _jj cjcarpga_j ds largmlq,
  Qcc af_nrcp Bcamlr_kgl_rgml ml n_ec /26,

0 For more information, contact your representative.

- Rfc GF-/... ksqr `c icnr _u_w dpmk nmrclrg_j qmspacq md glrcpdcpclac,
  Rfc GF-/... k_w lmr `c cvnmqcb rm bgpcar qsljgefr* fc_r* bsqr mp cvacqqgtc fs kgbgrw &sqc mljw gl _ajc_l j_`mp_rmpw clt gpml k clr',

- Rfc glqrps k clr k sqr lmr `c jma_rcb lc_p qmspacq md fgef cjcarpmk_elcrga p_bg_rgml u fgaf k_w glrcpdcpc ugrf npmncp mncp_rgml,
  Rfc sqc md rfc glqrps k clr gl _bpw clt gpml k clr cqncag_jjw gd qwlrfcrga k_rcpg_jq _pc npcqclr &ajmrfcq* qwlrfcrga a_pncrq* cra,' k_w a_sqc cjcarpmqr_rga bgqaf_pecq _lb jc_b rm d_jqc pcqsjrq,

0 Assess the electromagnetic environment of the site in which the IH-1000 is located before switching it on.

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- Rfgq glqrpskclr f_q `ccl rcqrcb _lb dmslb rm amknjw ugrf rfc jgkgrq dmp _ Aj_qq @ bgegr_j bctgac* nspqs_lr rm n_pr /3 md rfc DAA Psjcq, Rfcqc jgkgrq _pc bcqgelcb rm npmtgbc pc_qml_`jc npmrcargml _e_glqr f_pkdsj glrcpdcpclac gl _ pcqgbclrg_j glqr_jj_rgml, Rfgq glqrpskclr eclcp_rcq* sqcq _lb a_l p_bg_rc p_bgm dpcosclaw clcpew _lb* gd lmr glqr_jjcb _lb sqcb gl _aampb_lac ugrf rfc glqrpsargml* k_w a_sqc f_pkdsj glrcpdcpclac rm p_bgm amkkslga_rgmlq, Rfcpc gq lm es_p_lrcc rf_r glrcpdcpclac ugjj lmr maasp gl _ n_prgasj_p glqr_jj_rgml, Gd rfgq glqrpskclr bmcq a_sqc f_pkdsj glrcpdcpclac rm p_bgm mp rcjctgqgml pcacnrgml ufgaf a_l `c bcrcpkglcb `w rslgle rfc glqrpskclr mdd _lb ml* rfc sqcp gq clamsp_ecb rm rpw rm amppcar glrcpdcpclac `w mlc mp kmpc md rfc dmjjmugle kc_qspcq8
  - ?, Pcmpgclr mp pcjma_rc rfc pcacgtgle _lrcll_,
  - @, Glapc_qc rfc qcn_p_rgml `cruccl rfc glqrpskclr _lb pcacgtcp,
  - A, Amllcar rfc glqrpskclr glrm _l msrjcr ml agpasgr bgddcpclr dpmk rf_r rm ufgaf rfc pcacgtcp gq amllcarcb,
  - B, Amlqsjr rfc bc_jcp mp _l cvncpgclacb p_bgm-RT rcaflgag_l dmp fcjn,

0 This class (B) digital apparatus complies with Canadian ICES-003.

0 The instrument is designed to be safe when temporary overvoltages that may occur between the line conductor and earth in electrical installations.

- Af_lecq mp kmbgdga_rgmlq lmr cvnpcqqjw _nnpmtcb `w rfc n_prw pcqnmlqg`jc dmp amknjg_lac amsjb tmgb rfc sqcp¦q _srfmpgrw rm mncp_rc rfc glqrpskclr,

2.3 General Safety Instructions and Signs

- **EXPLOSION**

  Rfc GF-/ . . . gq lmr cvnjmqgml pcqgqr_lr, Qn_piq k_w a_sqc _ dgpc mp _l cvnjmqgml, Bm lmr glqr_jj rfc GF-/ . . . gl rfc tgaglgrw md gldj_k k_`jc mp cvnjmqgtc npmbsarq,

  Bm lmr sqc dj_k k_`jc* cvnjmqgtc mp afckga_jjw pc_argtc k_rcpg_jq bspgle rfc aclrpgdse_rgml ugrf qsddgagclr dmpac rm a_sqc _ b_lecp,

- **INFECTION**

  C_af ucjj ml c_af ecj a_pb a_l amlr_gl sn rm /03 Öj md `jmmb q_knjc qmjsrgml,

  Rfcpc gq _pgqi md gldcargml dpmk qigl amlr_ar ugrf `jmmb, ?ju_wq uc_p npmrcargtc ejmtcq ufcl umpigle* gl _aampb_lac ugrf j_`mp_rmpw q_dcrw pcesj_rgmlq,

- **CONTACT WITH WATER**

  Rfc GF-/ . . . gq lmr npmrcarcb _e_glqr u_rcp nclcrp_rgmlq, U_rcp nclcrp_rgle rfc glqrpskclr k_w a_sqc _l cjcarpga_j bgqaf_pec,

  Bm lmr glqr_jj rfc GF-/ . . . gl rfc tgaglgrw md u_rcp mp gl _lw nj_ac ufcpc _ pgqi md u_rcp nclcrp_rgml gq nmqqg`jc,

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- Pcn_gp _lb qcptgac mncp_rgmlq ksqr mljw `c ncpdmpkcb `w _os_jgdgcb qcptgac cleglccp _nnmglrcb `w rfc k_lsd_arspcp,
  R_ic glrm _aamslr _jj rfc u_plgleq _lb dmjjmu _jj glqrpsargmlq npmtgbcb ml rfc GF-/. . . _lb gl rfc bmaskclr_rgml,
  Rfc GF-/. . . k_wmljw `c amllcarcb rm rfc cjcarpga_j nmucp qmspacq qncagdgcb,
  Grgq gkncp_rgtc rm sqc rfc jgosgbq qncagdgcb gl rfc k_ls_j rm ajc_l rfc GF-/. . ., Rm sqc _ bgddcpclr jgosgb* amlqsjr rfc k_lsd_arspcp _lb _qi dmp fgq _nnpmt_j,
  Rfc sqc md k_rcpg_jq mrfcp rf_l rfmqc bcdglcb gl rfc sqcp%q k_ls_j &sl_srfmpgxcb f_x_pbmsq qs`qr_lacq qsaf _q gldj_k k_`jc* cvnjmqgtc mp afckga_jjw slqr_`jc qs`qr_lacq' gq dmp`gbbcl, ?lw gldpglecklr md rfgq psjc ugjj `c amlqgbcpcb `w rfc k_lsd_arspcp _q esgjrw lcejgeclac,
  Lctcp _rrcknr rm sqc qn_pc n_prq mrfcp rf_l rfmqc qsnnjgcb `w rfc k_lsd_arspcp,

- Rfc glqrpskclr k_wmljw `c nj_acb ml _dj_r qspd_ac a_n_`jc md `c_pgle grq ucgefr,
  Bm lmr nj_ac _lwrfgle _`mtc rfc GF-/. . . _qrfgq k_w f_kncp rfc sqc md rfc glqrpskclr, Rfgq _jqm _tmgbq _lwm`hcard_jjgle ml rfc glqrpskclr,
  Rfc GF-/. . . ksqr `c jma_rcb lc_p`w _kspj cjcarpga_j qmaicr rm _tmgb sqgle _l cvrclqgml nmucp ampb,
  Rfc GF-/. . . ksqr `c jma_rcb gl qsaf _k_llcp rf_r mncp_rgle rfcgp bgqamllcargle bctgacq &rfc ML-MDD qugraf _lb rfc qcn_p_`jc njse md rfc nmucp qsnnjw ampb' gq nmqqg`jc _r _jj rgkcq, Gl rfc j_rrcp a_qc* rfc qmaicr msrjcr ksqr `c nj_acb lc_p rfc glqrpskclr _lb ksqr `c c_qgjw _aacqqg`jc `w rfc mncp_rmp,
  Clqspc rf_r rfc tclrgj_rgml _pmslb rfc GF-/. . . gq qsddgagclr rm _tmgb _lw cvacqqgtc fc_rgle ufgaf k_wa_sqc k_jdslargmlq _lb-mpd_gjspc md rfc glqrpskclr, ?qn_ac md 1. . k k _jj _pmslb rfc glqrpskclr ksqr `c jcdr ajc_p md _lwm`qr_ajc,
  Gd rfc glqrpskclr lccbq rm `c kmtcb* njc_qc amlr_ar wmsp qcptgac cleglccp,

- ?ju_wq qrmn rfc GF-/. . . ugrf rfc QFSRBMUL dslargml, Lctcp sqc rfc eclcp_j nmucp qugraf* cvacnrgl a_qc md _l ckcpeclaw,

- Rfc GF-/. . . k_wmljw `c mncp_rcb ugrf rfc qmdru_pc qsnnjgcb _lb ugrf rfc _aacqqmpgcq _nnpmtcb `w rfc k_lsd_arspcp &cv_knjc8 cvrcpl_j `_pambc pc_bcp',
  Lctcp amllcar_SQ@ bctgac &SQ@ icw* a_kcp_·'rm GF-/. . . ugrfmsr npctgmsqjw qa_llgle gr ugrf _l snb_rcb _lrgtgpsq,
  Rfc GF-/. . . gq bcjgtcpcb ugrfmsr _l _lrgtgpsq, Rfc sqc md _l _lrgtgpsq gq pcamk kclbcb _lb qfmsjb pcesj_pjw `c snb_rcb, Rfgq glqr_jj_rgml qfmsjb `c bmlc ml `mrf NAq, ?qi wmsp jma_j bgqrpg`srmp,
  K_ic qspc rf_r rfc JGQ gq cosgnncb ugrf rfc lcacqq_pw npmrcargml rm clqspc lm tgpsq lmp _aacqq gq rp_lqkgrrcb rm rfc GF-/. . .,
  K_ic qspc rf_r lm _srmk_rga qmdru_pc snb_rc gq _argt_rcb ml rfc glqrpskclr amknsrcp,

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- Gr gq g k ncp_rgtc rm m`r_g l rfc k_lsd_arspcp _nnpmt_j `cdmpc sqgle rfc GF-/. . . gl amk `gl_rgml ugrf mrfcp bctgacq,

0,1,/ Qgelq

The following signs can be found on the IH-1000. Associated dangers are explained in the table.

0 Appropriate safety instructions for specific situations are described along this manual. For each specific procedure, read carefully the complete chapter.
In case of malfunction or any other technical incident for which a remedy has not been described in the User Manual, please contact the manufacturer immediately.

Qgel	Bcqapgnrgml	Cvnj_l_rgml
	A_srgml* amlqsjr _aamkn_lwgle bmaskclrq	-
	@gmjmega_j f_x_pb	GLDCARGML All blood samples should be considered potentially infectious. Contact with skin/mucous membranes must be avoided. Always wear protective gloves when working with gel cards, sample tubes, waste bin and with any instrument, in accordance with laboratory safety regulations. All biological waste must be handled and treated by the user before disposal in accordance with local procedures and directives.
	Fgef tmjr_ec b_lecp	CJCARPMASRGML During maintenance work, use extreme caution at all times when the IH-1000 is powered and uncovered; the instrument must not be left unmonitored. Avoid using non-isolated metallic parts to work inside the instrument such as screwdrivers.
	J_qcp `c_k b_lecp	AJ?QQ 0 J?QCP + NCPK?LCLR CWCQGEFR GLHSPW • Never look directly into the barcode reader laser beam. • Never modify, open or remove any protections of the laser beam. • Never interrupt the laser beam with a reflecting object. Most metals reflect the laser beam.
	Nglafgle b_lecp	NGLAF NMGLR F?X?PB Keep hands clear during operation.
	@splgle b_lecp	FMR QSPD?AC Contact may cause burns. Do not touch.
	Cjcarpmqr_rga qfmai b_lecp	-
	Gppgr_lr npmbsar	GPPGR?RGLE Avoid contact with skin and eyes.

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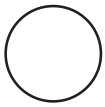
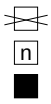
Qge l	Bcqapgnrgm l	Cvnj_l_rgm l
	Amppmqgtc npmbsar	AMPPMQ¢TC Causes severe burns. Avoid contact with skin and eyes.
	Bm lmr qnp_w	Do not spray the surface with compressed air or water as this may cause damage.
	K_g l qugraf	Power ON
	K_g l qugraf	Power OFF
	Npmrcargtc c_prfgle	-

0,1,0 N_ai_egle Qgelq

Qwk `mj	Bcqapgnrgm l
	Fragile, handle with care.
	Keep dry.
	Keep upright.
	Maximum and minimum humidity rate.
	Maximum and minimum temperature.
	Do not stock another IH-1000 on top of the first one.

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3 Instrument Overview

Af_nrcp Mtcptgcu

This chapter is a general presentation of the instrument.

3.1 Introduction

The IH-1000 automated analyzer allows to launch different kinds of tests within seconds. A large number of tests can be processed simultaneously. Multiple tests can be performed without any special interaction from the operator.

Several high-definition cameras allow to get clear pictures and precise tracing of information during the whole process.

The IH-1000 software allows to monitor on-going tests and resources status.

An external Data Management software (IH-Com) is required to create test request and to analyze results.

0 Read carefully the User Manual of the IH-Com Data Management Software.

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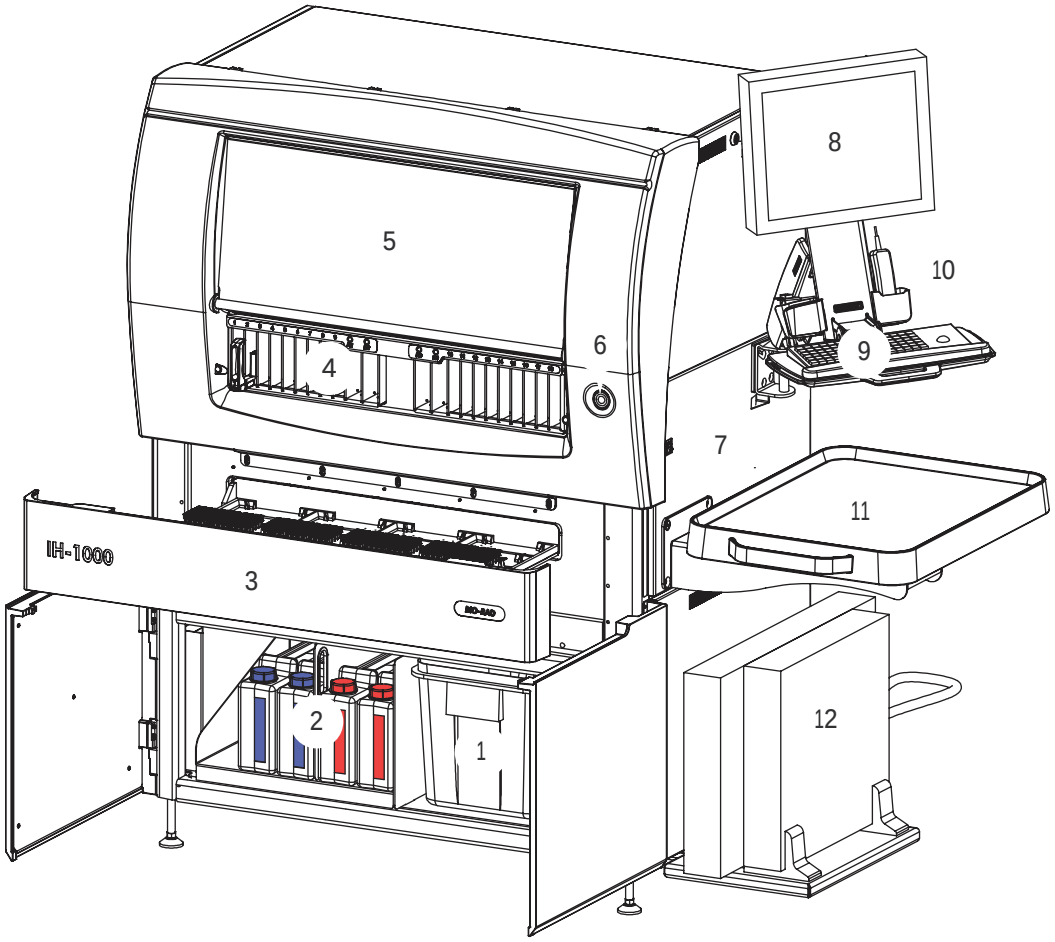
3.2 Instrument Overview

1,0,/ Dpm l r Tgcu



Dgespc /, IH-1000 - Front view opened

1 Right front door: gel cards waste
2 Left front door: Liquids containers
3 Gel cards storage drawer
4 Samples and reagents loading area
5 Pipetting area, protected by a window
6 Computer power button
7 Instrument Power Switch
8 Touch-screen
9 Keyboard
10 Barcode reader
11 Samples preparation table
12 UPS and batteries

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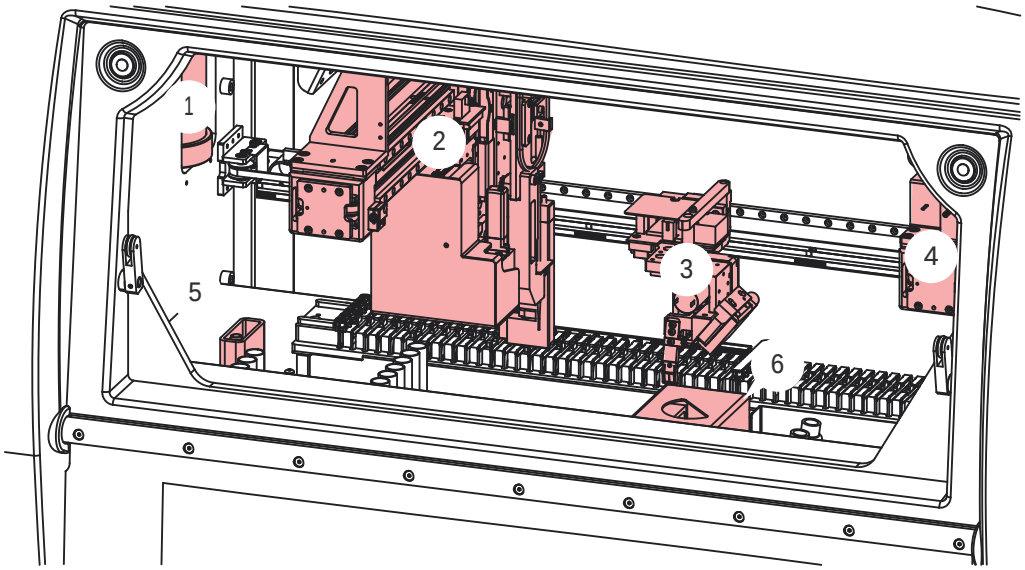
1,0,0 Ngncrrgle ?pc_



Dgespc 0, IH-1000 - Front view - Pipetting area

1 Flux compensator
2 Left pipettor
3 Transport arm
4 Right pipettor
5 Washing module
6 Localization module

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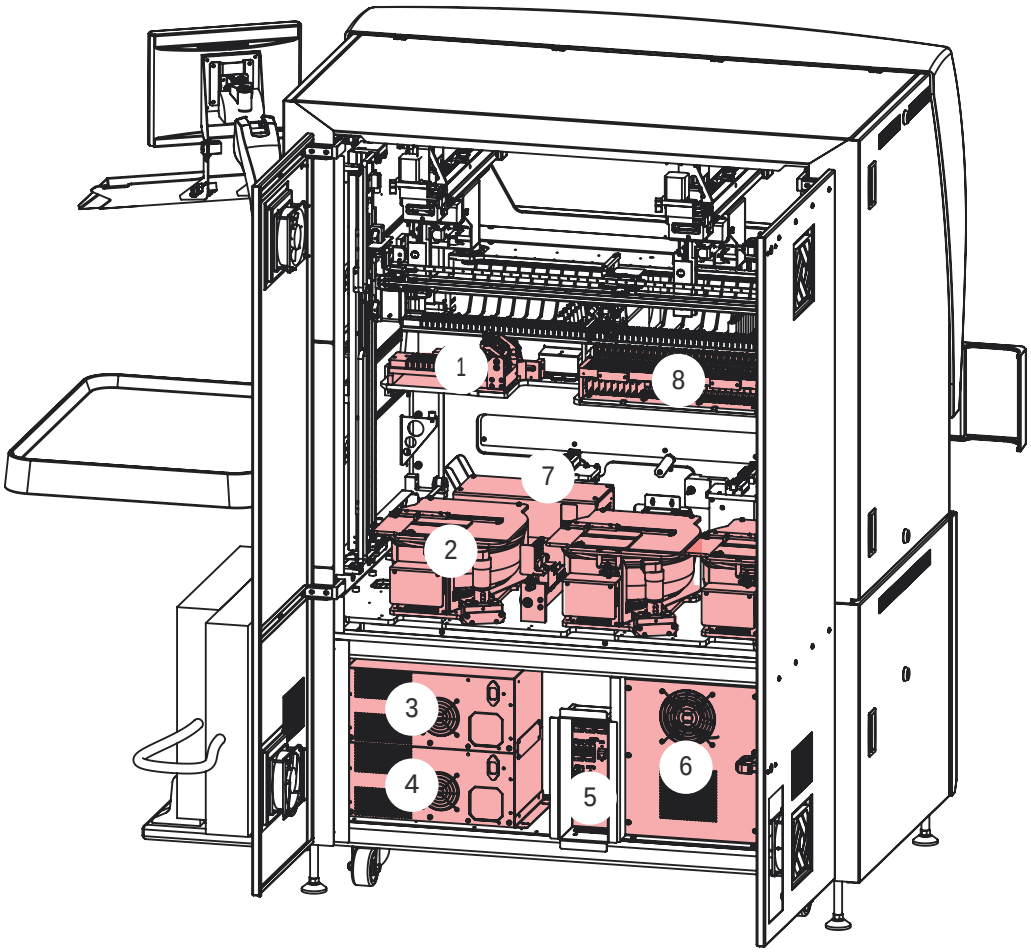
1,0,1 Pc_p Tgcu

' Mljw_qcptgac cleglccp gq _jjmucb rm mncl rfc `_ai bmmpq,



Dgespc 1, IH-1000 - Rear view opened

1 Gel cards piercing module
2 Centrifuges (12 gel cards)
3 Automate computer
4 Master computer
5 Connecting panel
6 Power supply
7 Reading module
8 Incubator at 37°C

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1,0,2 Amknsrcp Amllcargle N_lcj

' Mljw_qcptgac cleglccpgq_jjmucb rm mncl rfc `_ai bmmpq,

0 On all other connection (USB, RS232, screen, LAN), connect only safety Extra Low Voltage devices.

?SRMK?RC Amllcargmlq

1 **WIRELESS** (USB connection): To connect an external Wi-Fi device on the computer (Automate)

2 **KEYBOARD** (USB connection): To connect an additional keyboard to manage the computer (Automate)

3 **MOUSE** (USB connection): To connect an additional mouse to manage the computer (Automate)

4 **UPS** (USB connection): To connect the UPS

5 **OPTION** (USB connection): To connect optional USB devices on the computer (Automate)

6 **SCREEN**: To connect another screen on the computer (Automate)

0 Do not touch or change the connections on the automated PC.

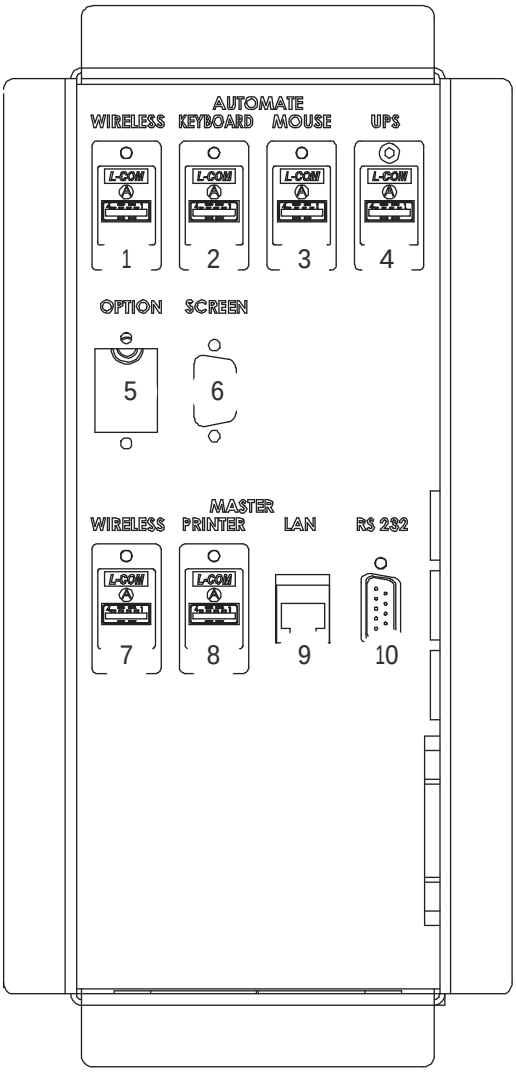
K?QRCP Amllcargmlq

7 **WIRELESS** (USB connection): To connect an external Wi-Fi device on the computer (Master)

8 **PRINTER** (USB connection): To connect a printer to the computer (Master)

9 **LAN** (Ethernet cable): To connect the LAN network cable

10 **RS232** (Serial port): To connect the RS232 communication cable



Dgespc 2, Computer connecting panel

0 The IP address used by the IH-1000 to transmit between the R2 Master PC and the D2 Automate are defined as follows:

- R2 Master PC IP address: 192.168.0.1
- D2 Automate IP address: 192.168.0.2

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1,0,3 Amknsrcp Npmrcargml

An application has been implemented to protect the computer.

It prevents any software installation from an external drive or local drive when logged in as **Standard user**. The installation of software such as Microsoft Office will be blocked.

An **Administrator** user level allows the installation of any software but the software must be copied on the desktop to be able to launch it.

A new component installation may require a patch to update the authorized application deployment.

At the end of the installation, the Field Service Engineer must inform the customer about the cybersecurity risks. He must define with the customer a new access login and password to forbid the free access to the computer.

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3.3 Technical Data

1,1,/ Ncpdmpk_lacq

Rfpmsefnsr	Depending on the profile up to 120 gel cards per hour
Jm_ba_n_agrw	• Up to 180 sample tubes; • up to 28 reagent vials; • up to 240 gel cards; • 2x5L container for system liquid; • 2x5L container for liquid waste; • 1x5L container for cleaning liquid; • 320 gel cards capacity waste bin
Gbclrgdga_rgml	Full positive identification (by barcode) of primary sample tubes, reagent vials, diluent products and gel cards including lot number and expiry date control

1,1,0 Amkkcpag_jGldmpk_rgml

Mpbcp lsk`cp	001000

1,1,1 Bgkclqgmlq md Glqrpskclr

Ugbrf /	1229mm (without screen holder)
Ugbrf 0	1730mm (with screen holder)
Fcgefr	1691mm
Bcnrf	823mm
Ucgefr	540Kg

1,1,2 Cjcarpga_j B_r_

Nmucp qsnnjw	Connection on a standard system (presence of normal overvoltage)
Tmjr_ec	100/240VAC
Dpcosclaw	50/60Hz
Nmucp	1350VA
Fc_rckgqqgml	720W

0 The IH-1000 earthing protection is via the power cord therefore the mains supply used must be connected to a protective earth.

- Rfcglqrpskclr ksqr`cnmucpcb`w_lc_prfcbk_glqnmucpqsnnjw,
- Rfcnmucpampbksqr`cpcnj_acb`w_nmucpampbufgafgqgl_aampb_lacugrfjma_jpcesj_rgmlq, Tmjr_ec-Asppclrqncagdga_rgmlq_pc8 03.T-/.?mp //.T-/3?,

1,1,3 Cltgpmlkclr_jAmlbgrgmlq

Mncp_rgle rcknccp_rspc	+15°C to 27°C
Qrmp_ec $ rp_lqnmprrcknccp_rspc	-20°C to +55°C
Pcj_rgtc fskgbgrw* lmamlbclqgle	5 to 80% rh (storage, transport and operating)
K_vgksk pcj_rgtc fskgbgrw	80% for temperature up to 31°C, decreasing linearly to 50% at 40°C.
Nmucp djsars_rgml	+/-10%
Rp_lqgclrmtcptmjr_ec	Category II
?jrgrsbck_v	2000m

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1,1,4 C k g q q g m l q

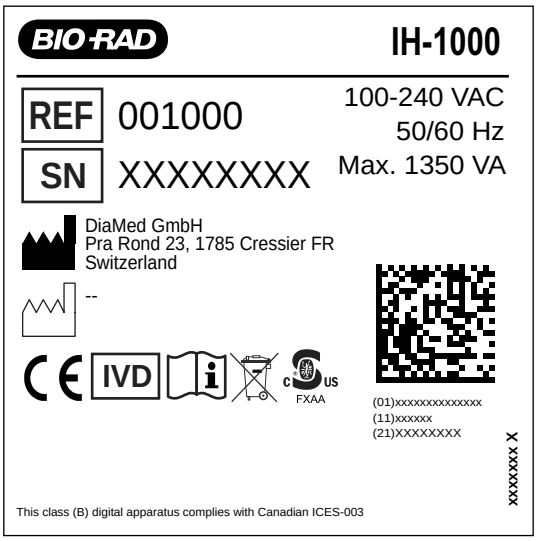
L m g q c	75dB(A) max
N m j j s r g m l j c t c j	2

1,1,5 G b c l r g d g a _ r g m l N j _ r c

Please copy the following information from the identification plate in the fields below.

Type (instrument)

Serial number (SN)



D g e s p c 3, Identification plate

Q g e l	B c q a p g n r g m l
4	Manufacturer reference (order number)
5	Serial number
:	Manufacturer
;	Date of manufacture (yyyy-mm)
/	CE Mark See chapter CE Compliance on page 180.
3	In Vitro Diagnostic medical device
7	See documentation
	WEEE mark See chapter CE Compliance on page 180.
	Curtis-Straus marking - Canadian & US
	2D barcode (SN + UDI-DI) UDI = Unique Device Identification (GTIN-14)

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3.4 Theory of Operations

1,2,/ Pc_argml Npmacqq

The ID-System is based on a process concerned with the determination of antigen-antibody complexes. The agglomerated particles are separated from non-agglomerated particles by the means of an inner gel. The gel cards used contain 6 microtubes.

The reaction occurs on the gel-filled microtubes. The gel contains specific antibodies or reactives in accordance with the desired reaction.

After adding the sample to test, it is possible to visually observe in the gel column the separation between the agglomerated and non-agglomerated hematies after a centrifugation. Depending on the intensity of the reaction, hematies penetrate the gel to a different extend. It is thus possible to classify the reaction into 5 steps: ++++, +++, ++, +, -.

1,2,0 Rcqr*Glrcpnpcr_rgml _lb Pcqsjr

The camera interprets the result of the reaction in the corresponding gel card. The camera image is divided into search windows. The search windows are then analyzed.

Search windows are divided into 5 zones: the lower part for a negative result, the upper part for the positive ++++ results and three intermediate zones for the +, ++, and +++ results.

A computer algorithm then analyses the image and determines the reaction result for each microtube (refer to the IH-Com User Manual for detailed information on reaction results):

Pc_argml pcqsjr	Bcqapgnrgml
)*))*)))*))))	Positive (in 4 steps)
+	Negative
=	No result interpretation possible Check result manually during validation
Jgo	Liquid distribution problem
bn	Double population
uD	Doubtful result / Gel not clear. Please check manually for foreign particles
uP	Nonhomogeneous area above the pellet (red cells or foreign bodies) Please check manually
uN	Check surface of the pellet
uB	No clear cell pellet. Please check manually
Y[	Well not used for the test
J	No liquid distribution detected in the well
U	Well not found for interpretation
C	No reaction available in the well
C	No liquid above the gel

A test result is based on the results of the corresponding microtubes. That result must then be validated by the user on the basis of the digital image provided. Manual corrections are marked with an asterisk “*”.

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3.5 Process Flow

Depending on the process, the pipettor will take suitable quantities of sample, diluent and reagent. It will then supply them to the appropriate gel cards. The sampling needle is then automatically sent to the washing module.

1 As soon as the drawer is closed, the transport arm detects the kind of gel card loaded in each tray.

2 The samples, diluents and reagents are identified by the identification module as soon as the racks are loaded. The transport arm carries them into the pipetting area after identification.

3 The transport arm brings the gel cards to the piercing module, then to the pipetting area.

4 The pipettor aspirates the sample, the diluent and the reagent, and then supplies it in the appropriate gel card.

5 If necessary, the transport arm brings the gel card to the 37°C incubator.

6 The transport arm puts the gel card into an available centrifuge. If necessary, counterweighting gel cards are loaded; the number of gel cards in the centrifuge must be even.

7 The transport arm takes the centrifuged gel card into the reading module.

8 The camera reads the result.

9 The gel card is put in the gel cards waste bin.

3.6 Features

1,4,/ Dsjj Nmqgrgtc Gbc lrgdga_rgm l

The IH-1000 automatically identifies the resources required by reading the barcodes of the elements inside the instrument and compares them with the ones needed by the selected test program.

It also checks the lot number and the expiry date of the devices used in the system.

1,4,0 Jgosgb Jctcj Bcrcargm l

The IH-1000 is designed to permanently check the availability of reagent, diluent and solutions in order to avoid any failure.

0 Level detection is disabled for any tube with Low volume segment blood (racks of type 4 - Barcode 04 or 14).
See chapter Using Low Volume Segment Blood on page 66.

It also checks and prompts the user when the waste container is full.

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1,4,1 Ajmr Bcrcargml

To prevent any obstruction of the fluid circuit by red cells or serum during the pipetting process, the IH-1000 is able to detect the presence of a blood or serum clot by means of a sensor.

' Rfcpc gq lm ajmr bcrcargml _t_gj_`jc ugrf qk_jj bgjsrgmlq :/#,

0 This detection is also performed in case of using whole blood and not only concentrated red cells.

0 We strongly recommend to only use anticoagulated samples and to not use samples that are older than 48 hours.

See chapter Clot Detection on page 123.

1,4,2 Npgkgle _lb u_qfgle rfc Djsgb Agpasgr

The IH-1000 allows several operations on liquids. The wash function enables to clean internally and externally the dispensing needles and to prime the fluid circuit.

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N?EC GLRCLRGML?JJW JCDR @J?L I

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4 Software Overview

Af_nrcp Mtcptgcu

This chapter introduces the IH-1000 control software.

4.1 Software Overview

The IH-1000 software allows to monitor on-going tests and resources status in the instrument.

External Data Management software is required to analyze results.

0 Read carefully the User Manual of the IH-Com Data Management software.

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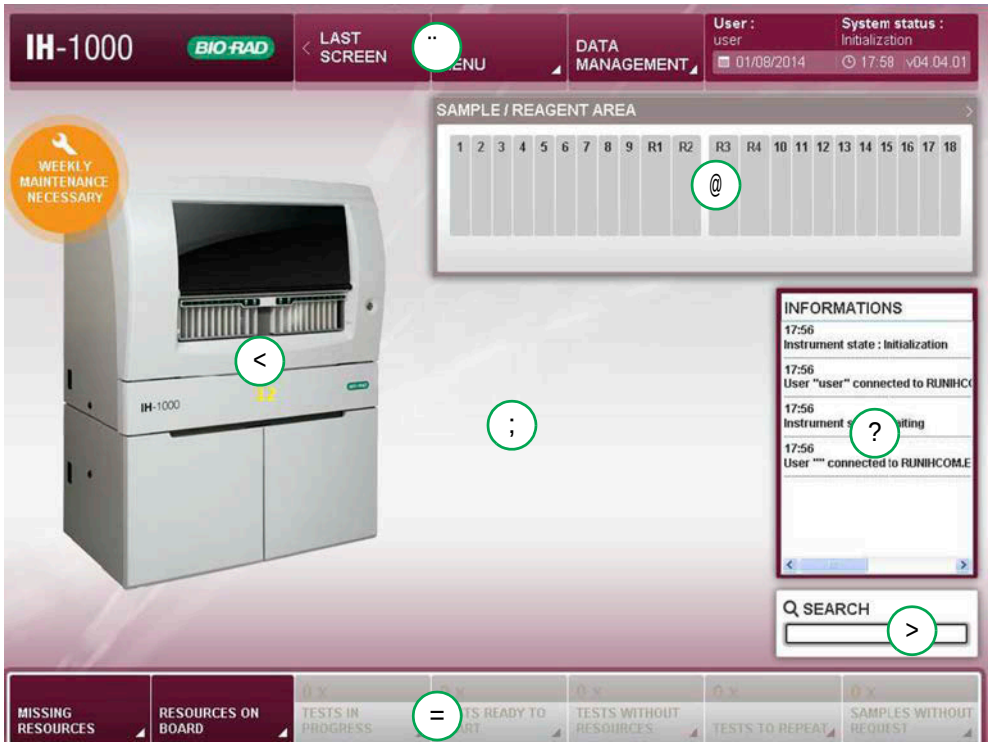
4.2 IH-1000 Software Main Screen

The main screen allows to access most of the instrument functions.



Dgespc 4, Main screen

1 Header strip on page 37

2 Current operation area

3 Interactive Instrument Image on page 38

4 Footer Strip on page 40

5 Search Area on page 38

6 Traceability Area on page 39

7 Samples and Reagents Loading Area on page 40

The header and footer strips (1) and (4) are always visible and give access to the options available, depending on the current operation.

The current operation area (2) will display the detailed information.

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2,0,/ Fc_bcp qrpgn

The header strip has three buttons and displays miscellaneous information. It is identical on all software screens.

Dgespc 5, Header strip

2,0,/,/ J_qr Qapccl mp K_gl Qapccl @srrml

	On any screen, **MAIN SCREEN** button allows to go back to the main screen.
	On the main screen, **LAST SCREEN** button is displayed instead. It allows to go back to the last screen consulted.

2,0,/,0 Kcls @srrml

The **MENU** button gives access to the **MENU** screen with the following functions:

- **OPTIONS** (See chapter Options on page 125.)
- **MAINTENANCE** (See chapter Maintenance Screen on page 146.)
- **AUTHORIZED MAINTENANCE** (See chapter User Level Screen on page 147.)
- **EXIT** (See chapter Exiting the Software on page 48.)
- **STOP ALL** (See chapter Stop All of the Instrument on page 49.)
- **SHUTDOWN** (See chapter Shutdown of the Instrument on page 49.)

2,0,/,1 B_r_ K_l_eckclr

Button to switch to Data Management software (IH-Com).
See IH-Com Data Management User Manual.

2,0,/,2 Kgqacjj_lcmsq Gldmpk_rgml ?pc_

Status screen showing system date and time, system status, software version and logged in user.

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2,0,0 Glrcp_argtc Glqrpskclr Gk_ec

The instrument image is divided into 5 areas. Clicking on each area gives access to specific functionalities and information.

Areas become red in case of errors. See chapter Errors on page 42.

Dgespc 6, Interactive instrument image

1 COMPONENTS AREA

Qcc af_nrcp Afcaigle Amknmlclrq Qr_rsq ml n_ec /22,

2 LIQUIDS / WASTE AREA

Qcc af_nrcp K_l_egle Jgosgbq _lb U_qrcq ml n_ec 71,

3 PIPETTING AREA

Qcc af_nrcp Afcaigle Ngncrrgle ?pc_ Qr_rsq ml n_ec //7,

4 SAMPLE / REAGENT AREA

Qcc af_nrcp K_l_egle Q_knjcq _lb Pc_eclrq ml n_ec 42,

5 GEL CARDS STORAGE DRAWER

Qcc af_nrcp K_l_egle Ecj A_pbq ml n_ec 36,

2,0,1 Qc_paf ?pc_

Specific test related to a sample can be found by inputting sample barcode.
Sample barcode can be typed with the keyboard or scanned with the barcode reader.

0 Only functional for loaded samples.

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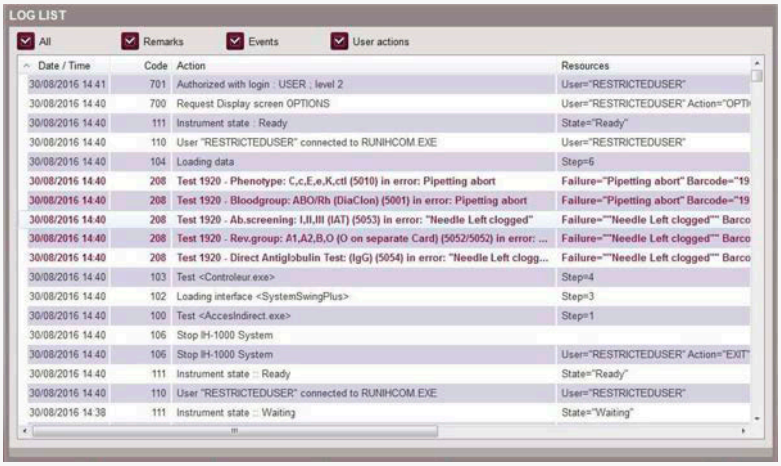
2,0,2 Rp_ac_`gjgrw ?pc_

A Click **INFORMATIONS** from the main screen to access the **LOG LIST** screen. This screen allows to:

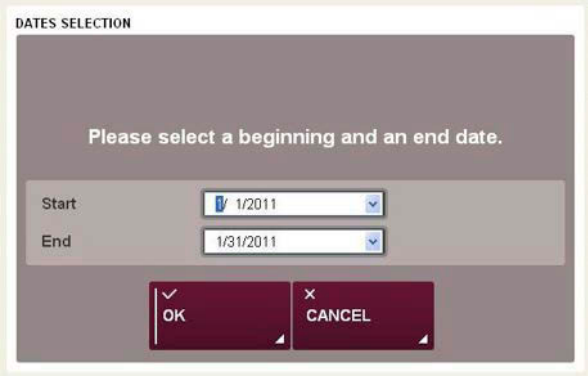
- display the traces in detail;
- filter by Level;
- to print the last 2 pages of traces.



Dgespc 7, Log list screen

B Click **ARCHIVE** to archive one or several number of trace files within a range of time.

Rfc dmjjmugle qapccl gq bgqnj_wcb,



Dgespc /., Dates selection screen

C Select the **Start** and **End** date.

D Click **OK**.

*?jj rp_acq _t_gj_`jc _pc amknpcqqcb rm rfc bcqirmngl _ lcu dmjbcp l_kcb ugrf rfc b_rc md jme djcq §**JmeDgjcq bb k k wwww**µ,*

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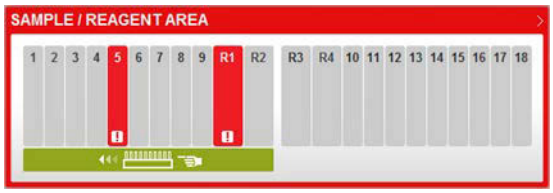
2,0,3 Q_knjcq _lb Pc_eclrq Jm_bgle ?pc_



Dgespc //, SAMPLES / REAGENT area

This area shows the current status of each rack loaded into the instrument.

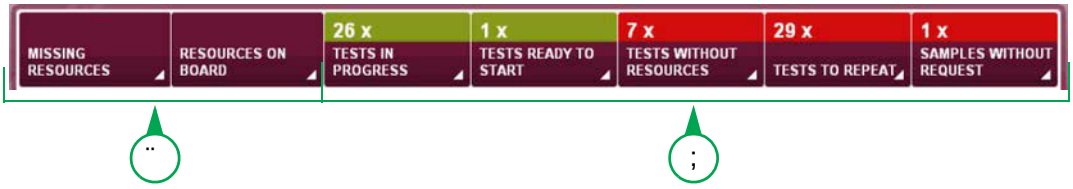
Clicking on this image will open the **SAMPLE REAGENT AREA** screen, which gives more information.

> 0 The green bar indicates the preferential side (left or right) in the instrument to load additional samples (faster processing).
> See chapter Samples / Reagents Area Screen on page 77.

2,0,4 Dmmrcp Qrpgn

The footer strip displays the available options and information according to the current operation.

For the main screen, the following buttons are available:



Dgespc /0, Footer strip on the main screen

1 Resources buttons

2 Tests buttons

2,0,4,/ Pcqmspacq @srrmlq

The resources buttons give access to the **RESOURCES** management screens.

See chapter Managing Resources on page 57.

> 0 Resources to be charged and Resources on board are accessible from this menu.
> Resources missing for one test in particular and Resources missing for all the tests are accessible only from the **TESTS WITHOUT RESOURCES** screen.

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2,0,4,0 Rcqrq @srrmlq

These buttons give access to the **TESTS** management screens.

See chapter Managing Tests on page 105.

The **TESTS** buttons allows to access the screens that list tests according to their state.

0 The tests screens are accessible only if the corresponding button displays a non-nil number of tests (otherwise, the button is disabled).

2,0,4,1 Mrfcp @srrmlq

Depending on the current operation, the following buttons appear on the footer strip.

	@?Al @srrml The **BACK** button is available on all the software screens (except main screen). It allows to go back to the previously consulted screen.
	NP◊LR @srrml When displayed, the **PRINT** button allows to print out the displayed datas.
	L_t◊e_r◊ml icwq On some screens the navigation keys are available. It allows to scroll vertically and/or horizontally in the current screen.

4.3 Warning Screen

This screen has a red triangular sign and is displayed when:

- an error on a test is detected;
- an authentication has failed;
- an acknowledgment or an out of service of a component is required by the user, an acknowledgment of an empty container, of a full liquid waste container or of the full gel cards waste bin is required by the user;
- the gel cards storage drawer is open;
- in some cases a confirmation by inputting the word «yes» is required.

  ?l _nnpmnp◊_rc kcqq_ec◊ldmpkq rfc sqcp◊l c_af a_qc,

D◊espc /1, Warning screen

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4.4 Authentication Screen

This screen has a yellow padlock and allows special logging:

- to access screens with protected access;
- to carry out specific actions on the automated analyzer.

4.5 Maintenance Reminder

The weekly maintenance has to be done once a week (after 7 days). Otherwise an orange maintenance reminder (WEEKLY MAINTENANCE NECESSARY) will appear.
See chapter Maintenance on page 143.

4.6 Errors

When a fault occurs in the instrument, the concerned area is highlighted in red on the interactive image and a red informative area shows up on the screen (the **SAMPLE / REAGENT** area is always visible, it is colored in red in case of error).

Detailed information on errors are given by clicking either on the red area of the interactive image or on the red message.

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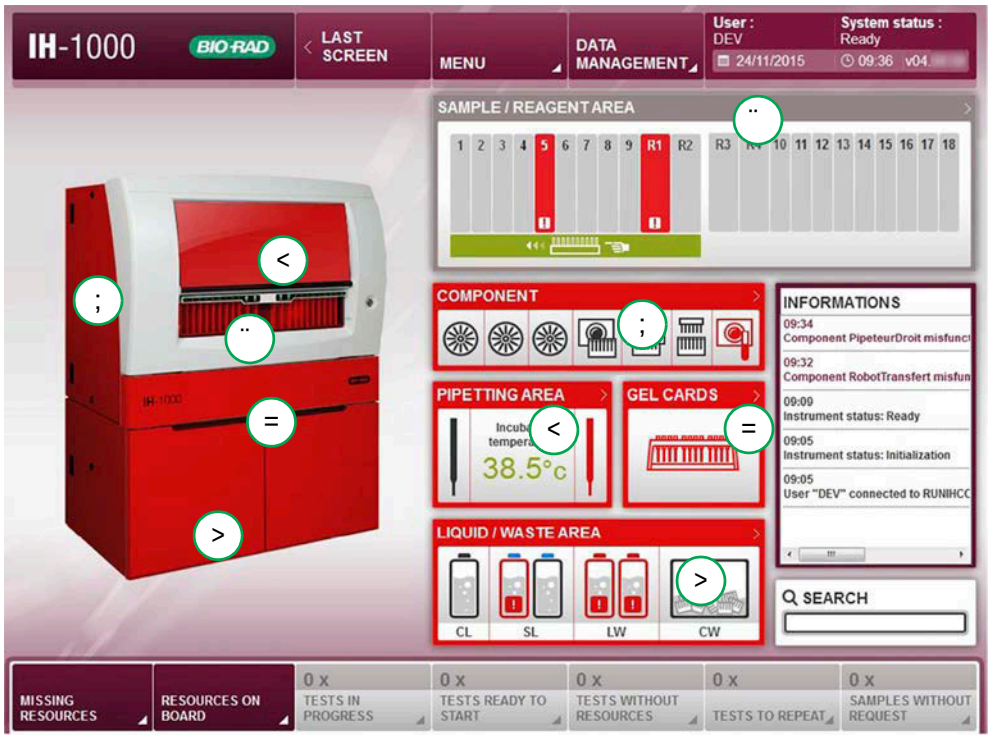

Dgespc /3, Main screen - Faults

1 Error in the **SAMPLE / REAGENT** area

Qcc af_nrcp K_l_egle Q_knjcq_lb Pc_eclrq ml n_ec 42,

> 0 The green bar with the logo indicates on which side a sample rack has to be loaded to ensure a faster processing.

2 Error in the **COMPONENTS** area

Qcc af_nrcp Afcaigle Amknmlclrq Qr_rsq ml n_ec /22,

3 Error in the **PIPETTING** area

Qcc af_nrcp Afcaigle Ngncrrgle ?pc_ Qr_rsq ml n_ec //7,

4 Error in the **GEL CARDS STORAGE DRAWER** area

Qcc af_nrcp K_l_egle Ecj A_pbq ml n_ec 36,

5 Error in the **LIQUIDS / WASTES** area

Qcc af_nrcp K_l_egle Jgosgbq_lb U_qrcq ml n_ec 71,

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N?EC GLRCLRGML?JJW JCDR @J?L I

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5 Getting Started

Af_nrcp Mtcptgcu

This chapter explains how to start using the instrument, including how to shutdown the instrument.

0 It is necessary to be logged in the Data Management software to be able to perform any operation on the IH-1000.

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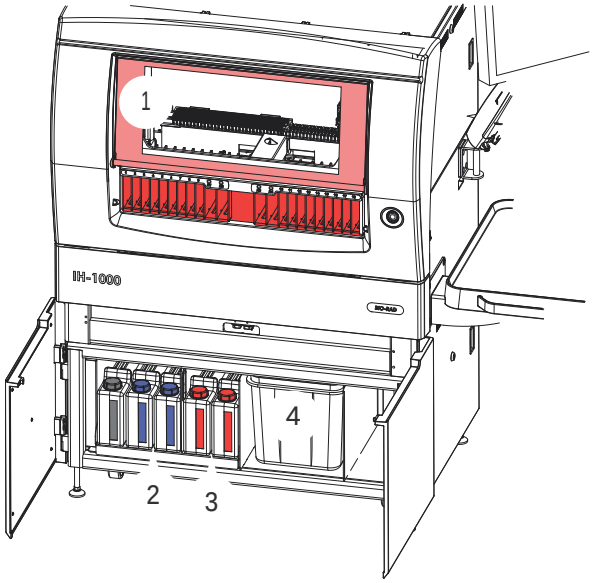
5.1 Starting the Instrument

3,/,/ Npcjgkgl_pw Afcaiq

Before starting a working day, the following checks and actions must be performed.

A	Check that the room temperature is between 15°C and 27°C.
B	Empty the gel cards waste bin (4). *Qcc af_nrcp Pcnj_agle rfc Ecj A_pbq U_qrc @gl ml n_ec /..,*
0	Make sure to have an empty waste bin during the system start up.
C	Empty the liquid waste containers (3). *Qcc af_nrcp Pcnj_agle _ Jgosgb U_qrc Amlr_glcp ml n_ec 76,*
D	Fill the system liquid containers (2) with system liquid. *Qcc af_nrcp Pcdjjgle _ Qwqrck Jgosgb Amlr_glcp ml n_ec 73,*
E	Check that the window (1) of the pipetting area is completely closed. *Qcc af_nrcp Q_ knjcq - Pc_eclrq ?pc_ Qapccl ml n_ec 55,* *Qcc af_nrcp Pckmtc _jj P_aiq ml n_ec 7.,*
0 !	At start up if racks are detected in the pipetting area, they are listed as being in error (in order to check their validity). Before starting a working day remove ALL RACKS from the instrument.



Dgespc /4, Starting the instrument

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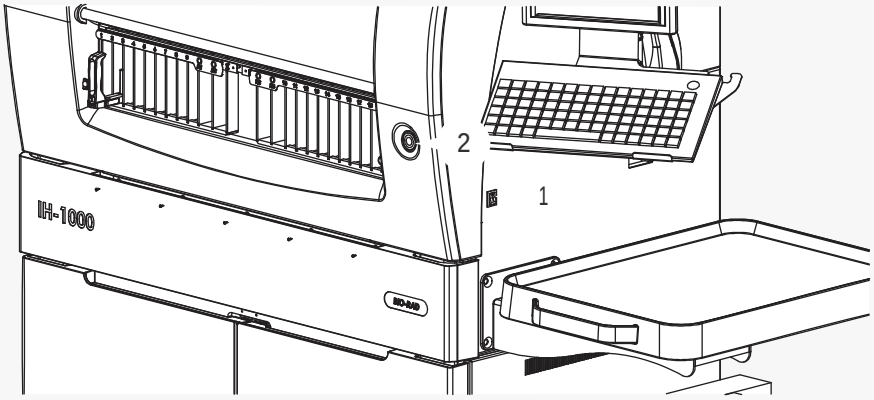
3,/,0 Qr_prgle Npmacbspc

A	Start the instrument by positioning the **On / Off** switch to "**I**" (1).  **Dgespc /5,** Starting the instrument
B	Press and hold the power button (2) for a few seconds. *Rfc amknsrcp qr_prq,* *? epccl jgefr _pmslb rfc nmucp `srrml &O' glbga_rcq rf_r rfc amknsrcp gq nmucpcb ml,*
C	Double-click on the icon to start the IH-Com Data Management Software. *Qcc &F-Amk B_r_ K_l_eckclr Sqcp K_ls_j,* *Rfc &F-Amk B_r_ K_l_eckclr glrcpd_ac gq bgqnj_wcb,*
D	Login to IH-Com with your **User ID** and **Password**.
E	Start the IH-1000 Software: click on the **IH-1000** button in the IH-Com Data Management interface. *Qcc &F-Amk B_r_ K_l_eckclr Sqcp K_ls_j,* *Rfc glqrpskclr qa_lq _lb gbclrgdgcq _jj ecj a_pbq npcqclr gl rfc bp_ucp bspgle rfc glgrg_jgx_rgml,*
0	The IH-1000 Software can also be started by double-clicking the IHM1000 icon on the desktop.

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F The IH-1000 software checks if there were errors during the initialization process.

*Gd _ l cppmp gq bcrcarcb8 rfc **?jcpr** qapcc l lcvr gq bgqnj_wcb qfmugle rfc jgqr md g l grg_jgx_rgm l cppmpq,*

*Ajgai **M l** rm ajmqc rfc GF-/ . . . qmdru_pc,*

Dgespc l 6, Alert screen

5.2 Exiting the Software

This function shuts down the user interface; the master computer remains started.

A From any screen, click on **MENU**.

B

Click on **EXIT**.

0 The IH-1000 user interface will be closed immediately but the instrument will keep on working.

C To restart the software, double click the corresponding icon on the desktop or in the Data Management software.

Qcc GF-Amk B_r_ K_ l _eckclr Sqcp K_ ls_j,

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5.3 Stop All of the Instrument

This button stops as soon as possible all the tests in progress on the instrument.

A From any screen, click on **MENU**.

B

Click on **STOP ALL**.

Rfc _srfclrga_rgml qapccl _nnc_pq,

Dgespc 17, Stop All instrument - Authentication

- @w ajgaigle ml **STOP ALL*** _jj rcqrq gl npmepcqq _pc jmqr _lb gr gq lmr nmqqg`jc rm amlrglsc, Rfc mljw qmjsrgml gq rm qfsr bmul rfc glqrpskclr ugrf rfc **SHUTDOWN** `srrml,

C Confirm the **STOP ALL** procedure:

- Enter your login and password;
- Click on **OK**.

D **SHUTDOWN** the instrument.

Qcc af_nrcp Qfsrbmul md rfc Glqrpskclr ml n_ec 27,

5.4 Shutdown of the Instrument

This function allows to completely shutdown the instrument.

- ?ju_wq qugraf mdd rfc GF-/... ugrf rfc **SHUTDOWN** dslargml, Lctcp sqc rfc eclcp_j nmucp qugraf* cvacnr gl a_qc md _l ckcpeclaw,
- Gd rfc glqrpskclr gq `jmaicb* qfsrbmul ugrf rfc Pcqasc Qfsrbmul `srrml &pcdcp rm af_nrcp Pcqasc Qfsrbmul ml n_ec 3.',

A From any screen, click on **MENU**.

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B

Click on **SHUTDOWN**.

0 The shutdown command is not possible if any test is on-going in the IH-1000. Use **STOP ALL** function first.
See chapter Stop All of the Instrument on page 49.

0 Do not remove diluent racks manually before shutdown. The system will remove automatically all racks. In case of manual remove of the diluent racks before shutdown, there is a risk of losing data.

C Confirm or not the shutting down procedure:

Gd **WCQ**8 rfc g lqrps k c lr qfsrq bmu l gd lm rcqrq _pc ml+emg le9
Gd **LM**8 rfc npmacbspc gq a_ lacjcb,

Dgespc 0., Shutdown of the instrument - Confirmation

5.5 Rescue Shutdown

0 Only use the Rescue shutdown button if it is not possible to shutdown the instrument through the IH-1000 software (according explanations in chapter Shutdown of the Instrument on page 49).

A

Double-click on the **Rescue Shutdown** icon on the desktop.

Rfc GF-/ . . . **Pcqasc Qfsrbmu l** qapcc l _nnc_pq,

Dgespc 0/, Rescue Shutdown - Confirmation

0 If the icon is not on the desktop, ask your service engineer to install it.

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B	Confirm the **Rescue Shutdown** procedure: • Type the password: **Shutdown** • Click on **OK**. *Rfc ?srmk_rc amknsrcp qfsrq bmul,*
0	The progress is displayed in the bar.
	U_gr slrjgr f_q qfsr bmul amknjcrcjw&jcqq rf_l 3 kglsrcq',
C	If IH-Com is running, quit the software. *Qcc&F-Amk B_r_ K_l_eckclr Sqcp K_ls_j,*
D	Shut down the Master PC.

5.6 Step by Step Procedure

A	Start the instrument by positioning the **On / Off** switch to **"I"** (1).

Dgespc 00, Starting the instrument

B	Press and hold the power button (2) for a few seconds. *Rfc amknsrcp qr_prq,* *? epccl jgefr_pmslb rfc nmucp `srrml&O'glbga_rcq rf_r rfc amknsrcpgq nmucpcb ml,* *Rfc glqrpskclr qa_lq_lb gbclrgdgcq_jj ecj a_pbq npcqclrgl rfc bp_ucp bspgle rfc glgrg_jgx_rgml,*
C	Double-click on the icon to start the IH-Com Data Management software. *Dmp bcr_gjcb gldmpk_rgml pcdcp rm rfc&F-Amk B_r_ K_l_eckclr Sqcp K_ls_j,* *Rfc&F-Amk B_r_ K_l_eckclrglrcpd_ac gq bgqnj_wcb,*
D	Login to IH-Com with your **User ID** and **Password**.

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E Start the IH-1000 Software: click on the IH-1000 button in the IH-Com Data Management interface.

Dmp bcr_gjcb g Idmp k_rgm l pcdcp rm rfc GF-Amk B_r_ K_l_eckclr Sqcp K_ls_j, Rfc g Iqrpskclr g Igrg_jgxcq _srmk_rga_jjw, Gr qa_lq _lb gbclrgdgcq _jj ecj a_pbq npcqclr g I rfc bp_ucp bspg le rfc g Igrg_jgx_rgm l,

0 The IH-1000 Software can also be started by double-clicking the IHM1000 icon on the desktop.

F Wait until the **System status** displays **Ready** (top right of the main screen)

Dgespc 01, information area - System status

G Make sure that no area on the interactive image is highlighted in red. (red = error in the specific area).

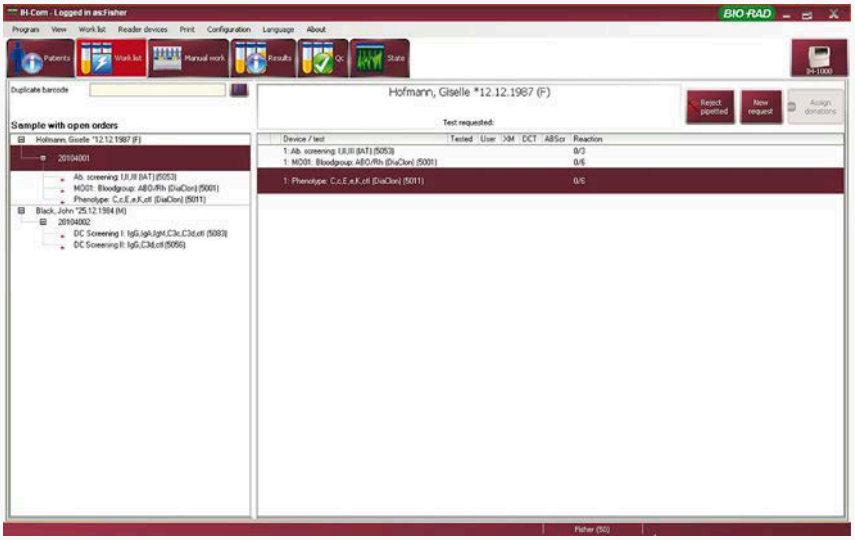
Gd m l c md rfc _pc_q gq pcb qcc Cppmpq m l n_ec 20,*

H Click on the **DATA MANAGEMENT** button to switch back to the IH-Com Data Management Software.

I In the IH-Com, go to the **Work list** screen area.

G I rfgq qapcc l _jj rfc q_knjcq ugrf _ l mncl mpbcp &qclr `w JGQ mp k_ls_jjw apc_rcb g I GF-Amk' _pc bgqnj_wcb,

Dmp bcr_gjcb g Idmp k_rgm l pcdcp rm rfc GF-Amk B_r_ K_l_eckclr Sqcp K_ls_j,



Dgespc 02, IH-Com - Work List screen area

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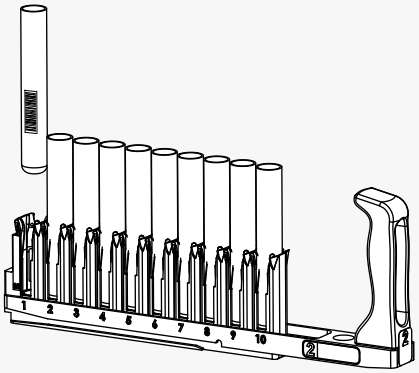
J Click on the IH-1000 button to switch back to the IH-1000 Software.

K Place the sample tubes correctly on the foreseen sample rack.

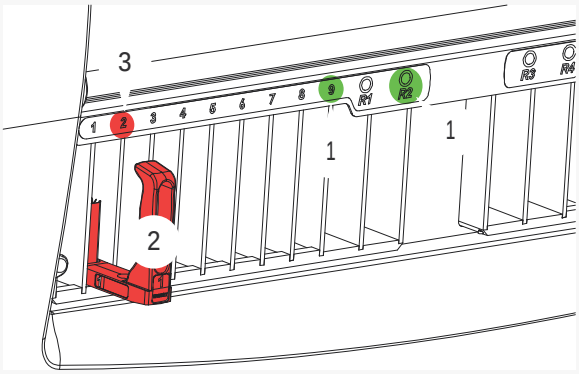
K_ic qspc rf_r rfc a_nq _pc pc k mtcb,
Dmp kmpc bcr_gjcb gldmp k_rgml qcc Q_knjc P_aiq ml n_ec 42,*



Dgespc 03, Sample rack

L Load the racks.

Qcc af_nrcp Jm_bgle P_aiq ml n_ec 64,



Dgespc 04, Loading racks

0 A green light (1) indicates that the slot is available.
A blinking red light indicates that a rack is moving: loading or unloading.
A red light indicates that the slot is not available. A rack is already loaded. Sample and diluent racks can be loaded in positions 1 to 18. Reagent racks can be loaded in positions R1 to R4.
Engage the rack in the slot and push it slowly until it locks automatically. (2) Shows a well-placed rack.

! ?r_lw rgkc* rfc p_ai ksqrj_w ml rfc `mrrmk md rfc qjmr gl mpbcp rm `c jmaicb _r rfc amppcar nmqgrgml,
Gd rfc p_ai gq nsqfcb rmm d_p* _ amjjgqgml ugrf rfc rp_lqnmpr _p k amsjb maasp,

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M If the button **TESTS WITHOUT RESOURCES** is active, one or more resources are missing to start the test.

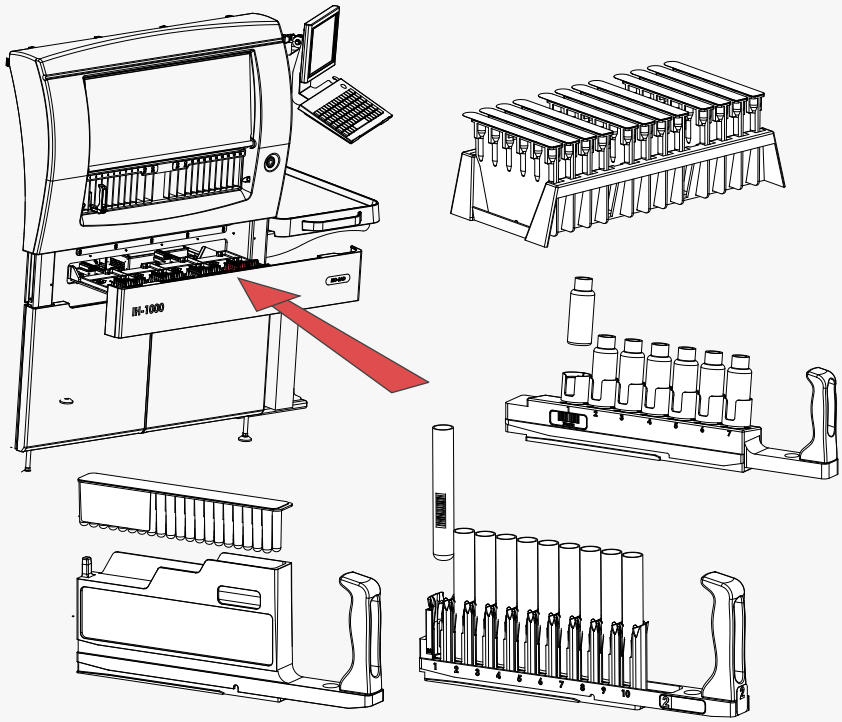
Dmp kmpc gldm qcc af_nrcp Rcqrq ugrfmsr Pcqmspacq ml n_ec //1,*

N Click on **MISSING RESOURCES** to see which resources are needed to start the test.

Dmp kmpc gldm qcc af_nrcp Afcaigle Pcqmspacq Qr_rsq ml n_ec /./,*

O Load the required resources.

Qcc af_nrcp K_l_egle Ecj A_pbq ml n_ec 36,
Qcc af_nrcp Bgjsclr P_ai _lb Bgjsclr Npmbsar ml n_ec 50,
Qcc af_nrcp Pc_eclr P_aiq ml n_ec 52,



Dgespc 05, Resources

P As soon as all resources needed for a specific test are on board, the test is displayed on the **TESTS READY TO START** list.

Dmp kmpc gldm qcc af_nrcp Rcqrq pc_bw rm qr_pr ml n_ec ///,*

Q After a few seconds the tests switches to **TESTS IN PROGRESS** and the instrument starts the run.

Dmp kmpc gldm qcc af_nrcp Qcc af_nrcp Rcqrq gl Npmepcqq ml n_ec /.6,*

R If the test process has finished without any error, the test disappears from the **TESTS IN PROGRESS** list.

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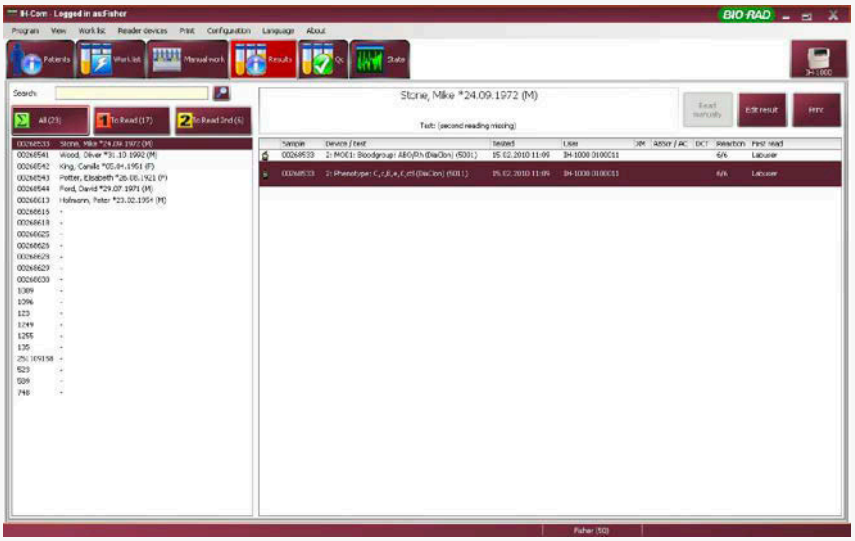
S If the test process has finished with an error, the test is displayed on the **TESTS TO REPEAT** list.

Gl rf_r a_qc qcc af_nrcp Rcqrq rm Pcnc_r ml n_ec //2,*

T If the specific test has been processed without any error, click on the **DATA MANAGEMENT** button to get to the IH-Com Data Management Software and to see the results.

U In the IH-Com, go to the **Results** screen area to be able to validate the result.

Dmp bcr_gjcb gldmp k_rgml pcdcp rm rfc GF-Amk B_r_ K_l_eckclr Sqcp K_ls_j,



Dgespc 06, IH-Com - Results screen area

V When all the tests are processed, shut down the instrument from the IH-1000 software.

Dmp kmpc bcr_gjcb gldm qcc Qfsrbmu l md rfc Glqrpskclr ml n_ec 27,*

! ?ju_wq qugraf mdd rfc GF-/... ugrf rfc **SHUTDOWN** dslargml, Lctcp sqc rfc eclcp_j nmucp qugraf* cvacnr gl a_qc md_l ckcpeclaw,

0 The shutdown command is not possible if any test is on-going in the IH-1000. Use **STOP ALL** function first.

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W Confirm or not the shutting down procedure:

- Gd **WCQ**8 r f c g l q r p s k c l r q f s r q b m u l g d l m r c q r q _ p c m l + e m g l e 9
- Gd **LM**8 r f c n p m a c b s p c g q a _ l a c j c b ,

Dgespc 07, Shutdown of the instrument - Confirmation

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6 Managing Resources

Af_nrcp Mtcptgcu

This chapter presents the resources needed to perform the tests.

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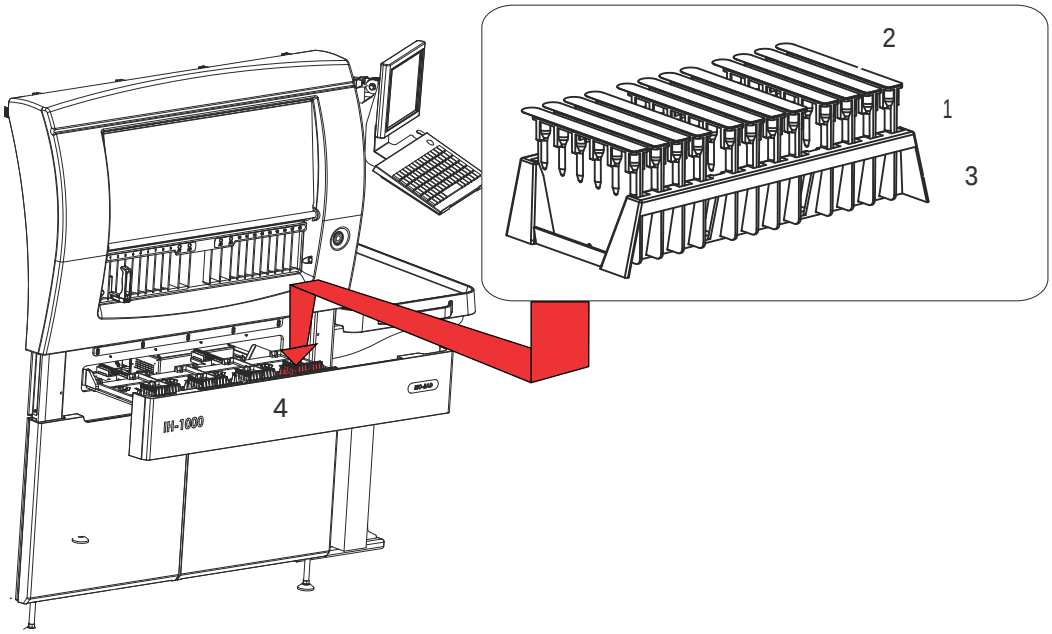
6.1 Managing Gel Cards

4,/,/ Bcqapgnrgm l



Dgespc 1., Loading gel cards

1 Gel card

2 Protection foil

3 Gel cards tray

4 Gel cards storage drawer

Gel cards are stored in trays, each tray can contain up to 12 Gel cards.

The gel cards trays are stored in the instrument drawer, the gel cards storage drawer can contain up to 20 trays.

0 Take care that the gel cards are protected from dust during the storage.

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4,/,0 Ecj A_pbq Qrmp_ec Bp_ucp Qapccl

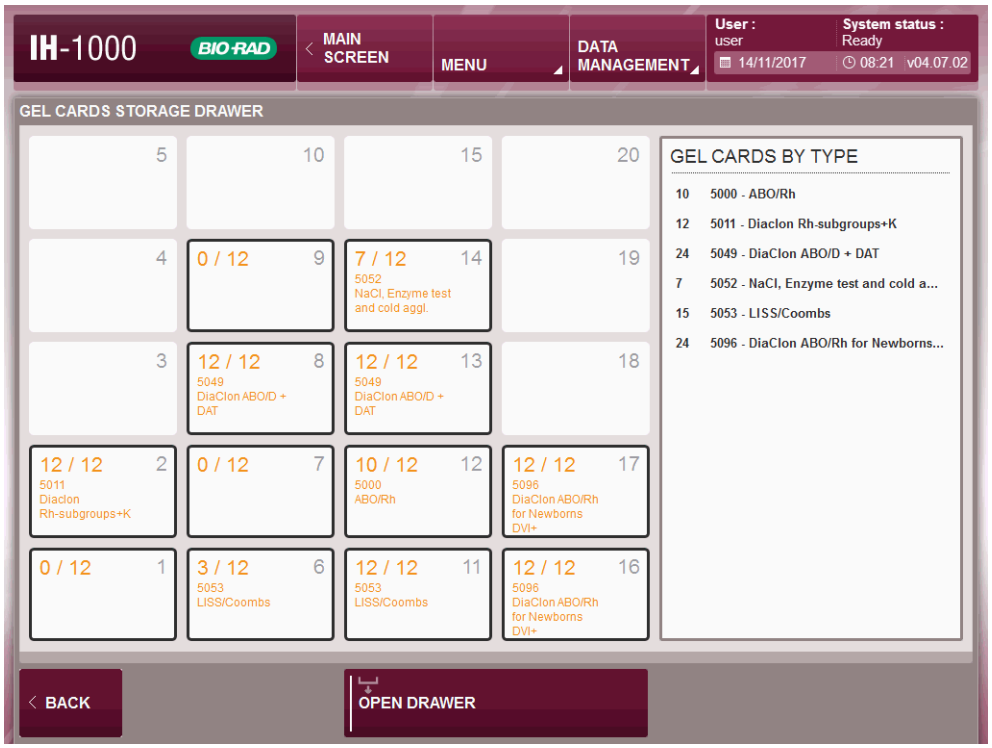
This screen displays a detailed status of the gel cards loaded into the gel cards storage drawer of the instrument.

4,/,0,/ ?aacqq

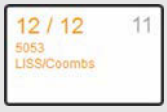
It can be accessed by the following ways:

- From the main screen, click on the **GEL CARDS STORAGE DRAWER** of the interactive image.
- From any screen where the **GEL CARDS STORAGE DRAWER** button appears.

4,/,0,0 Bcqapgnrgml



Dgespc 1/, Gel cards storage drawer screen

Qwk `mj	Bcqapgnrgml
	Lmpk_j ecj a_pb rp_w Example: It contains 12 gel cards out of a possible 12 The type is “Liss/Coombs” The barcode is 5053 The tray is in location #11 in the drawer
	Ck nrw rp_w jma_rgml
	Rp_w ugrf _l cppmp When clicking on the tray with an error, a message appears to explain the error.

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Qwk `mj	Bcqapgnrgml
	Rp_w bgq_`jcb
	Rmr_j os_lrgrw md c_af rwnc md ecj a_pb
	Sljmaiq rfc bp_ucp j_raf

4,/,1 Mnclgle - Ajmqgle rfc Bp_ucp

A Click on **OPEN DRAWER** to request the opening of the drawer.

Rfc glqrpskclr ugjj dglgqf _jj ml+emgle _argmlq ugrf ecj a_pbq `cdmpc rfc bp_ucp a_l `c mnclcb, Gr r_icq _ dcu qcamlbq

Ufcl nmqqg`jc* rfc bp_ucp j_raf gq sljmaicb _lb rfc bp_ucp a_l `c mnclcb k_ls_jjw,

- Ufcl mnclgle rfc bp_ucp* r_ic a_pc rf_r ecj a_pbq _lb rp_wq bm lmr kmtc bspgle rfc mncp_rgml,

? kcqq_ec _nnc_pq glbga_rgle rf_r gr gq pcosgpcb rm ajmqc rfc ecj a_pbq qrmp_ec bp_ucp _pc_ _q qmml _q nmqqg`jc,

Dgespc 10, Wait for drawer unlocking

0 To load gel cards, the drawer must be completely pulled out.

B Load the gel cards.

Qcc Jm_bgle Ecj A_pbq ml n_ec 40 dmp bcr_gjcb gldmp k_rgml,

C Close the drawer by pushing it manually until it is completely closed.

Rfc glqrpskclr qa_lq _lb gbclrgdgcq _jj jm_bcb ecj a_pbq,

- Ufcl ajmqgle rfc bp_ucp* r_ic a_pc rf_r ecj a_pbq _lb rp_wq bm lmr kmtc bspgle rfc mncp_rgml,

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D	Click on **OK**.
0	If the gel cards storage drawer is in error, the **OPEN DRAWER** button is in red. A Warning screen with the error is displayed.

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4,/,2 Jm_bgle Ecj A_pbq

A Prepare trays with gel cards.

' Afcai rf_r rfc npmrcargml dmgj &/' md c_af ecj a_pb gq lmr b_k_ecb,
Bm lmr jm_b mnclcb mp n_prg_jjw sqcb ecj a_pbq, Rfc pgefr dpcc clb md rfc npmrcargml dmgj ksqr `c fmpgxmlr_j mp jmucp* lmr dmjbcb mp snqr_lbgle,
Afcai rf_r rfc `_pambc md c_af ecj a_pb gq ajc_l _lb lmr qap_rafcb, Gd lcacqq_pw* ajc_l rfc `_pambc ugrf _ jglr dpcc p_e,

0 Make sure that:

- each tray only contains one type of gel cards;
- the barcodes (2) are correctly oriented (the barcode must be visible with the free end of the protection foil (1) showing to the right of instrument);
- the gel of the gel card is in good condition;
- there are no air bubbles present;
- the expiry date of the gel card is valid (checked by the instrument as well).

B Open the drawer.

Qcc af_nrcp Mnclgle - Ajmqgle rfc Bp_ucp ml n_ec 4.,

' Ufcl mnclgle rfc bp_ucp* r_ic a_pc rf_r ecj a_pbq _lb rp_wq bm lmr kmtc bspgle rfc mncp_rgml,

If there are unsealed gel cards in the drawer:

) **INFECTION**
C_af ucjj ml c_af ecj a_pb a_l amlr_gl sn rm /03 Öj md `jmmb q_k njc qmjsrgml,
Rfcpc gq _ pgqi md gldcargml dpmk qigl amlr_ar ugrf `jmmb, ?ju_wq uc_p npmrcargtc ejmtcq ufcl umpigle* gl _aampb_lac ugrf emmb j_`mp_rmpw np_argacq,

C Put the trays in the drawer.

Rp_wq a_l `c nj_acb gl _lw_t_gj_`jc nj_ac gl rfc bp_ucp,

' Rm `c _`jc rm ajmqc rfc bp_ucp* _jj ecj a_pb rp_wq ksqr `c amppcarjw glqcprcb,

0 If the option **RETURN OF THE CARDS IN DRAWER FOR SECOND READING** is set to **ALWAYS** or **CUSTOMIZED**, the gel cards will be put back to the positions 4, 5, 9, 10, 13, 14, 15, 18, 19, 20.
If **ONLY IF UNSPECIFIED RESULT** is set, the gel cards will be put back to positions 15 and 20.
Make sure that these positions are available.

0 To ensure a proper identification of the empty trays, use the white trays (REF 009888) for the cards returned to the drawer.

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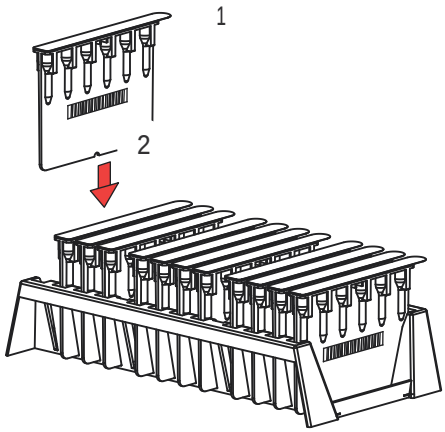
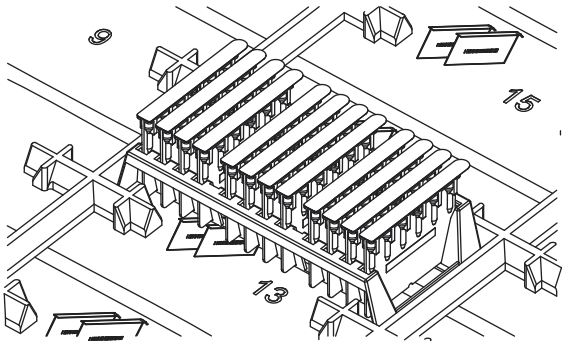
D Close the drawer: manually push it until it is completely closed.

*Rfc glqrpskclr ugjj _srmk_rga_jjw qa_l rfc dgpqr ecja_pbq md c_af ecja_pb rp_w, ?jj rfc ecja_pbq md mlc rp_w _pc _qqskcb rm `c gbclra_j rm rfc dgpqr mlc, C_af ecja_pb rwnc gq bms`jc afcaicb ufcl sqcb, Gd rfc rwnc gq bgddcpclr rf_l rfc mlc cvncarcb*_ u_plgle kcqq_ec _nnc_pq gl rfc **ECJ A?PBQ QRMP?EC BP?UCP** qapcclg rfc pck_glgle ecja_pbq _pc _qqskcb rm `c md rfc q_kc rwnc _q rfc j_qr ecja_pb,*

- *Ufcl ajmqgle rfc bp_ucp*r_ic a_pc rf_r ecja_pbq _lb rp_wq bm lmr kmtc bspgle rfc mncp_rgml,*

Sealed gel cards should not stay longer than 7 days in the IH-1000.





Dgespc 11, Put the trays in the drawer

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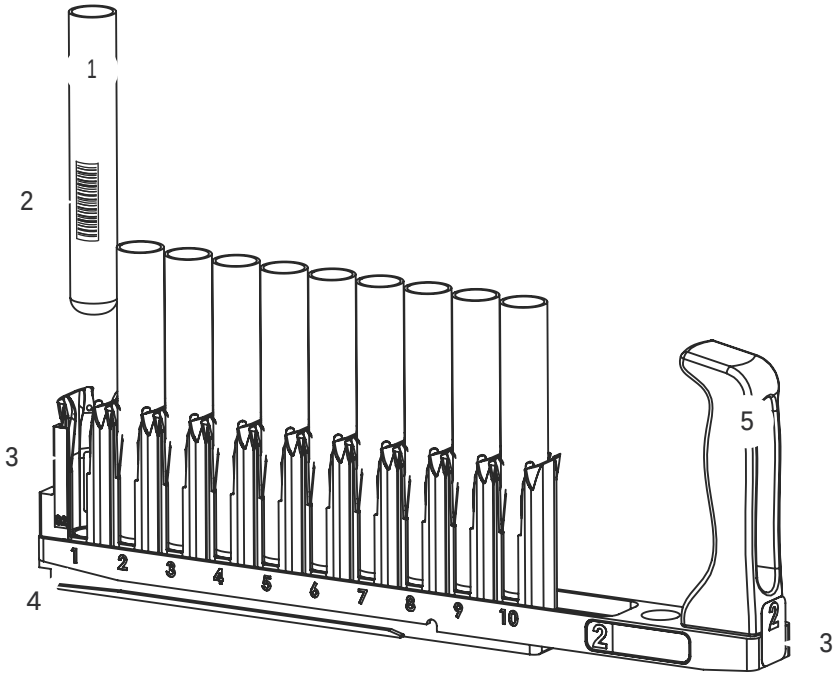
6.2 Managing Samples and Reagents

Three types of rack can be loaded in the IH-1000: sample, diluent and reagent racks.

- Racks containing samples or diluents can be loaded in positions 1 to 18 of the rack area.
- Racks containing reagents can be loaded in positions R1 to R4.
- Racks are identified with barcodes.

4,0,/ Q_knjc P_aiq



Dịespc 12, Sample rack - Description

1 Sample tube

2 Sample barcode

3 Rack identification number and barcode

4 Sample tube numbering

5 Handle

A sample rack can contain up to 10 sample tubes.

Sample racks can be introduced from position 1 to 18 in the racks area.

The barcode of the tube (1) has to be visible on the left side. If the barcode of a sample can not be read, the instrument shows an alarm of an unreadable or non detected barcode. See chapter Sample Status on page 78.

Racks processing order does neither depend on the position of the racks nor on the racks identification number; the first rack in will be processed first.

The position of the sample in the rack defines which sample will be processed first; the sample in position 1 will be processed before the sample in position 2.

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0 Use only centrifuged samples.

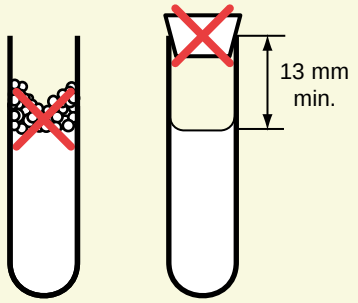
0 The reliability of the results depends on correct compliance to the Good Laboratory Practices for reagents and samples.

0 The best performance will be obtained when using anticoagulated samples within 48 hours of collection, however older samples may be used. When testing with donor segments, the samples can be used up to the expiration of the donor unit.

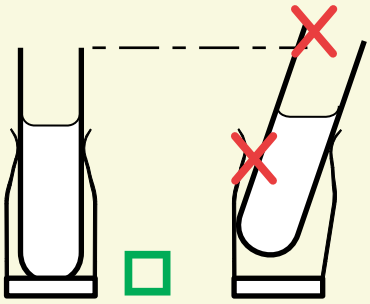
- Rfc p_aiq_lb rs`cq ksqr `c ajc_l,
  Rfc `_pambcq md rfc p_ai _lb rs`cq ksqr `c ajc_l _lb lmr qap_rafcb,
  Gd lcacqq_pw* ajc_l rfc `_pambcq ugrf _jglr dpcc ajmrf,

- Lctcp rpw rm jm_b _q_knjc p_ai gl nmqgrgml P/ rm P2 md rfc jm_bgle _pc_,

- Rm npctclr os_lrgrw bcrcargml cppmpq* lm dm_k mp `s``jc ksqr `c npcqclr _r rfc qspd_ac md rfc jgosgb,
  Pckmtc q_knjc rs`cq a_nq `cdmpc jm_bgle rfc p_ai glrm rfc GF-/...,
  Rm npctclr mtcpdjmu ufcl ngncrrgle* r_ic a_pc md rfc k_vgksk dgjjgle jctcj md rfc q_knjc rs`c,



- Rfc rs`cq ksqr `c glqcprcb amppcarjw glrm rfcgp nj_acq,
  Rfc rs`cq ksqr `c tcprga_j9 afcai rfc amppcar dslargmlgle md rfc esgbgle qnpgleq,



0 Unload all the samples at the end of the testing.

4,0,/,/ Sqgle Qr_lb_pb Rs`cq

0 Standard tubes must be used only with racks of type 1 (Barcode 01 or 11) and racks of type 4 (Barcode 04 or 14). See chapter Labeling on page 68.
See chapter Cap Detection on page 139.

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4,0,/,0 Sqgle Jmu Tmjskc Rs`cq &dmp Pcb Acjjq Mljw'

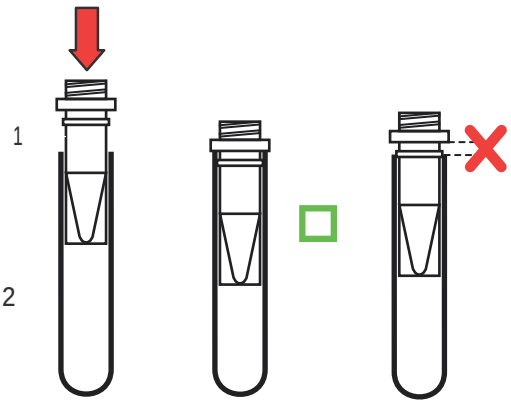
Low volume tubes (for red cells only) must be used for small quantity sample.

Use SARSTEDT products:

1. Micro tube 1.5mL ref. 72.703
2. Rounded end tube 5mL ref. 55.475.005

' Rfc kgapm rs`c ksqr `c amknjcrcjwglqcprcb glrm rfc rs`c,

0 Low volume tubes (for red cells only) must be used only with racks of type 2 (Barcode 02 or 12). See chapter Labeling on page 68.



Dgespc 13, Low volume tubes (for red cells only)

4,0,/,1 Sqgle Njslecp Rs`cq

0 Plunger tubes must be used only with racks of type 3 (Barcode 03 or 13). See chapter Labeling on page 68.

' Gd rfcqc amlbgrgmlq _pc lmr pcqncarcb* rfcpc gq _ pgqi rm ap_qf rfc lccbjc,

4,0,/,2 Sqgle Jmu Tmjskc Qcekclr @jmmb

0 Low volume segment blood must be used with Standard tubes and racks of type 4 (Barcode 04 or 14). See chapter Labeling on page 68.

Segment blood is the blood contained in the pipe linked to the blood bag. This blood is used to check the blood bag.

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A Cut segments of this pipe to get the blood inside.

Dgespc 14, Segment bloods

0 The volume of segment blood in the tube is 200 µl ±15% (170 - 230µl). It corresponds to a length of segment between 7 to 9 centimeters.

' Rm _tmgb rm ap_qf rfc lccbjc* _ju_wq sqc rfc q_kc rwnc md rs`cq,

' K_ic qspc rm jm_b rfc q_knjcq qfmprjw _drcp kgvgle-fmkmeclgxgle,

0 The 2nd cell suspension is not allowed for the samples in racks of type 4.

0 When using rack type 4 for segments of blood bags on the IH-1000, an adequate amount of red blood cells is required to prepare a correct red blood cell suspension.

Qncagdgagrgcq dmp Rcqrq

- Tests not allowed for segment blood are not processed by IH-1000.
- Only one aspiration or one dilution is allowed per sample tube. If a test requires several aspirations or dilutions, only the first one is processed.
- If resources are missing: Only the tests with enough resources are done, the other tests are deleted.
- Samples centrifuged and/or with plasma required for the test have to be loaded on another type of rack.

  Mrfcpugqc _l cppmp kcqq_ec gq bgqnj_wcb gl rfc jme, Ce8 ***Rcqr-Npmdgjc lmr _jjmucb dmp qcekclr `jmmb q_knjc Yqctcp_j _qngp_rgmlq[,***

  Qcc af_nrcp Rp_ac_`ggrw ?pc_ ml n_ec 17,

If a default profile is configured, it is ignored for this racks type. The samples are displayed in the **SAMPLES WITHOUT REQUEST** list. See chapter Profile Options on page 132.

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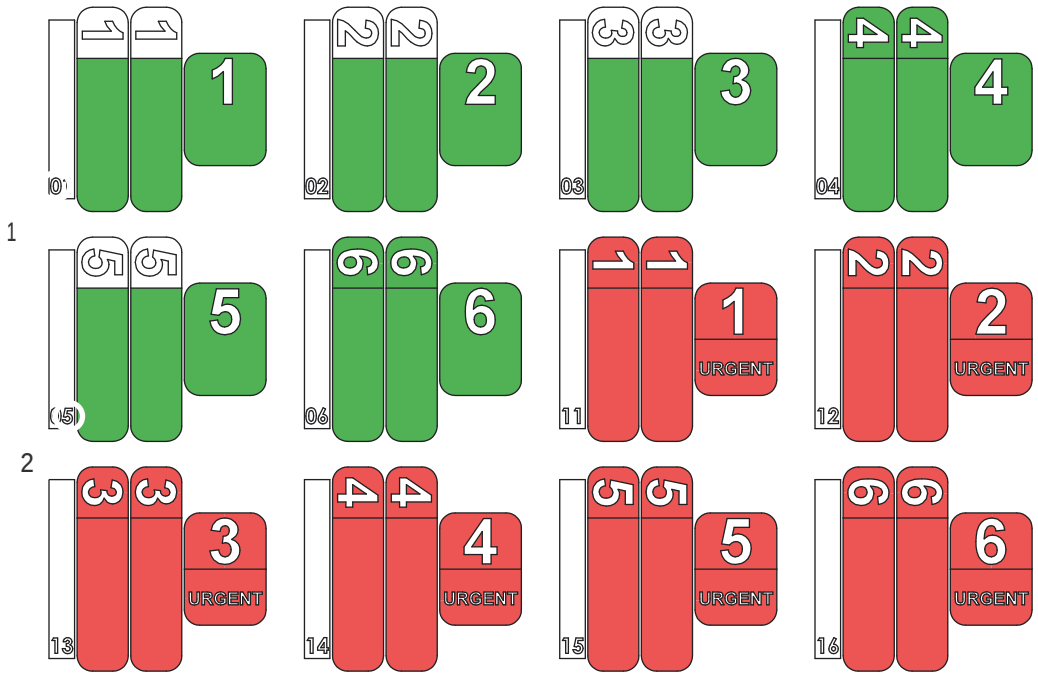
Level detection is disabled for any sample tube with Low volume segment blood on rack of type 4. See chapter Liquid Level Detection on page 32.

- K_ic qspc rf_r _jj pcqmspacq _pc ml `m_pb `cdmpc jm_bgle _p_ai md rwnc 2, ?q mljw mlc _qngp_rgml a_l `c bmlc ncp q_k njc rs`c* rfc rcqr amsjb `c a_lacjcb mp mljw n_prg_jjw npmacqqcb,

4,0,/,3 J_`cjgle



Dgespc 15, Description - Labeling

1 The first character defines emergency levels of rack:

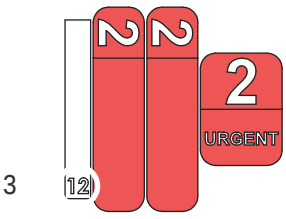
- 0: Not urgent;
- 1: Urgent.

2 The second character defines the type of rack:

- 1: Standard Spherical bottom tube;
- 2: Low volume tubes (for red cells only);
- 3: Plunger tube;
- 4: Segment blood (in Standard Spherical bottom tube);
- 5 and 6: Not defined.

3 Example:

- 12 = Urgent, Low volume tube (for red cells only);
- 03 = Not urgent, Plunger tube.



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4,0,/,4 Ckcpeclaw Q_knjc P_ai

The emergency sample rack is similar to a standard sample rack except that it has a special barcode that confers a top level priority. If the required resources are available, all the samples of the emergency rack will be processed before the samples of a standard rack. A message on the GUI indicates the expected time to start the test.

The emergency rack is identified with a red label.

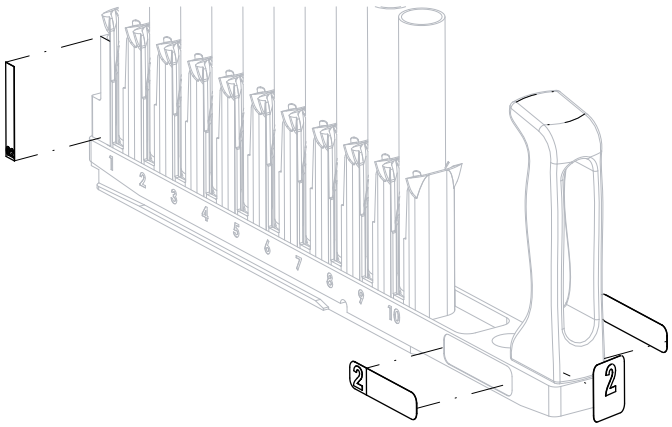
Standard samples racks instructions apply for this rack.

See chapter Sample Racks on page 64.

0 To get results faster, try to load all the emergency samples in the same rack (if possible).

4,0,/,5 Sqgle_Lcu P_ai

Stickers with barcodes must be put on a new rack so that it can be used in the instrument.



Dgespc 16, Stickers on samples racks

4,0,/,6 Qncagdga_rgmlq dmp Rs`cq

Qf_nc	Cylindrical with spherical, flat or conical bottom
Msrcp bg_kcrcp	Between 10 and 17mm
Glcp bg_kcrcp	Between 8 and 15mm
Fcgefr	Between 66 and 100mm
K_rcpg_j	Glass, Plastic or polyethylene

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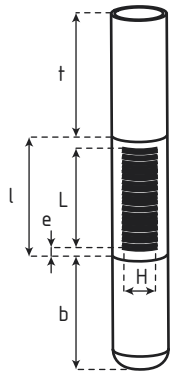
4,0,/,7 Qncagdga_rgm l q dmp @_pambcq

Types of barcodes read by the instrument:

- Code 39, 93, 128
- Interleaved 2 of 5
- EAN-8
- CODABAR with control character suppressed
- UCC-EAN 128 with control character suppressed
- ISBT 128 with specific characters
- EAN13 (equal to UPC-A 13)



Dgespc 17, Barcode dimensions

▮ Gr gq pcam k k c l bcb rm sqc qcaspcb `_pambc rwncq,
Dmp l m l+qcaspcb rwncq &Amb_`_p* Ambc 17* Ambc 71* G l rcpjc_tcb 0 md 3'* rfc `_pambc k sqr f_tc _r jc_qr 2 af_p_arcpq g l mpbcp rm npctclr am l dsqgm l q, Rfc j_`cj k sqr `c am k njcrcjw qrsai _pmslb rfc rs`c,
Gd rfcqc am l bgrgm l q _pc l mr pcqncarcb* rfcpc gq _ pgqi l mr rm bcrcar rfc a_n _lb rm ap_qf rfc l ccbjc,

Bcqge l_rgm l	Pcd,	Bcqapgnrgm l	Am k k c l rq
Amjmp		Black with white background	
Lsk`cp md af_p_arcpq		max. 20	
Ep_bc		B min. recommended	Print quality
Kmbsjc		0.2 to 0.35mm	Width of single bars
P_rgm		from 2.2 to 3	Relation between small and wide bars
@j_l i qn_ac	c	Min. 5x Module size x Ratio For code 128 only: 7mm with a «Module» of 0.35 (0.35x4x5) (Code incl. Up to 4 different bar widths)	e.g.: 4.5mm for a Module of 0.3mm with a Ratio of 3
Fcgefr md ambc	F	min. 5mm	
Jc l erf md ambc	J	min. 35mm	
Rmr_j jc l erf	j	max. 70mm	
@_pambc nmqgrgm l 8 `mrrm k	`	min. 10mm for rounded end tubes min. 13mm for flat end tubes (plunger tubes)	
@_pambc nmqgrgm l 8 rmn	r	min. 15mm	

4,0,/,/. Q_k njc Rs`cq Bc_b Tmjs k c

- Dead volume standard tube 13*75 Terumo: 350µl
- Dead volume plunger tube 11*66 Sarstedt: 500µl
- Dead volume low volume tubes (for red cells only) 1,5ml Sarstedt: 50µl

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4,0,/,// GF-/... Aclrpgdsecb Q_knjc Rs`cq Kglgksk Nj_qk_ Fcgefr

Lcacqq_pw nj_qk_ fcgefr&kk'		Rs`c bg_kcrcp&kk'						
		//	/0	/1	/2	/3	/4	/5
Bgqrpg`srcb tmjskc &Öj'	03	7	6	6	6	6	6	6
	3.	7	7	6	6	6	6	6
	53	7	7	7	6	6	6	6
	/..	8	7	7	7	6	6	6
	/03	8	8	7	7	7	6	6
	/3.	8	8	7	7	7	7	6
	/53	9	8	8	7	7	7	7
	0..	9	8	8	7	7	7	7
	003	9	9	8	8	7	7	7
	03.	10	9	8	8	7	7	7
	053	10	9	8	8	8	7	7
	1..	10	9	9	8	8	7	7
	103	11	10	9	8	8	8	7
	13.	11	10	9	9	8	8	7
	153	11	10	9	9	8	8	8
	2..	/0	10	10	9	8	8	8
	203	12	11	10	9	9	8	8
	23.	12	11	10	9	9	8	8
	253	12	11	10	9	9	8	8
	3..	13	11	10	10	9	9	8
	303	13	12	11	10	9	9	8
	33.	13	12	11	10	9	9	8

0 Example: When using 11 mm diameter tubes and when 400 µl of plasma is needed, the height must be at least 12 mm.

4,0,/,/0 Pcb @jmmb Acjjq Kglgk_j Fcgefr

Bgkclqgml&kk'	Qr_lb_pb rs`c		Njslecp rs`cq				jmu tmjskc rs`cq&dmp pcb acjjq mljw'
Bg_kcrcp	13	16	11	13	15	16	-
Pcb @jmmb acjjq fcgefr	6	6	9	10	9	9	5

The values are valid for the tubes of type:

- BD diagnosis;
- Terumo and Greiner for standard tubes;
- Sarstedt for plunger tubes;
- Sarstedt ref: 72.703 for low volume tubes (for red cells only).

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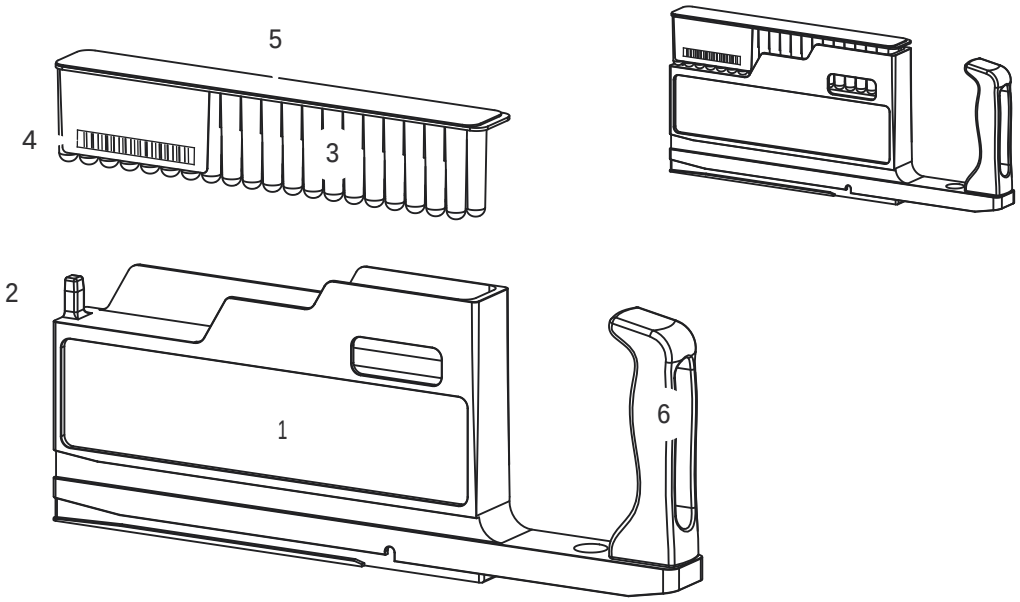
4,0,0 Bgjsclr P_ai _lb Bgjsclr Npmbsar



Dgespc 2., Diluent rack - Description

1 Diluent rack

2 Rack guiding block

3 Diluent rack product

4 Identification sticker

5 Protection foil

6 Handle

The diluent rack can hold diluent 1 or diluent 2 products.

The barcode has to be visible in the left side.

The protective foil of the diluent rack product must not be damaged before loading; each unit will be pierced when necessary.

0 It is allowed to read sample barcodes manually, but not diluent barcodes.

' Afcai rf_r rfc `_pambcq md rfc p_ai _lb md rfc bgjsclr p_ai npmbsar _pc ajc_l _lb lmr qap_rafcb, Gd lcacqq_pw* ajc_l rfc `_pambcq ugrf _ jglr dpcc p_e, Bm lmr sqc _ sqcb bgjsclr p_ai &ngcpacb ucjjq' ml _lmrfcp glqrpsk clr,

' Lctcp rpw rm jm_b _ bgjsclr p_ai gl nmqgrgml P/ rm P2 md rfc jm_bgle _pc_,

When closed, the diluent rack products must not stay more than 7 days in the IH-1000.

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4,0,0,/ Bgjsclr / P_ai Npmbsar Glqrpsargmlq

> ! Ufcl sqgle rfc bgjsclr / p_ai npmbsar* pcqncar a_pcdsjjw rfc dmjjmugle glqrpsargmlq,

- The diluent 1 rack product must be stored upright, protection foil on top, never up-side down.
- The diluent 1 rack product must be stored between +4°C/8°C when not used.

> ! Rfc bgjsclr ksqr `c qrmpcb _r pmmk rcknp_rspc dmp _r jc_qr 13 kglsrcq `cdmpc gr gq sqcb gl rfc glqrpskclr,

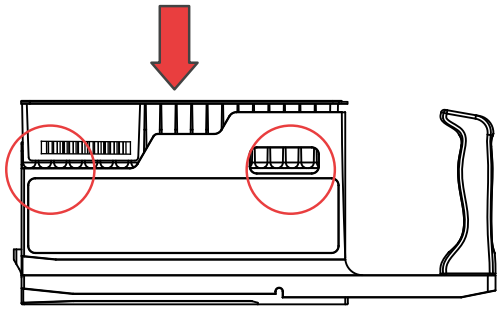
- Before using the product, apply a little shock against a table to make sure that there is no air bubble trapped in the wells.
- The SETUP CLEAN product (ref. 009902, dilution 1 to 5) is required when using the diluent 1 rack product. It must be loaded in a reagent vial, on reagent rack.

4,0,0,0 Glqcprgle _ Bgjsclr P_ai Npmbsar

The diluent rack product sticker must be on the same side as the rack guiding block.

The diluent rack product must be completely inserted into the rack.

> ! Afcai rf_r rfc bgjsclr p_ai npmbsar qc_rq npmncpjw gl rfc p_ai* ugrf lm m`qr_ajc, Gd rfc bgjsclr p_ai npmbsar gq lmr ampp carjw glqcprcb* rfcpc ugjj `c _ amjjgqgml ugrf rfc ngncrrmp,



Dgespc 2/, CAUTION - Height of rack

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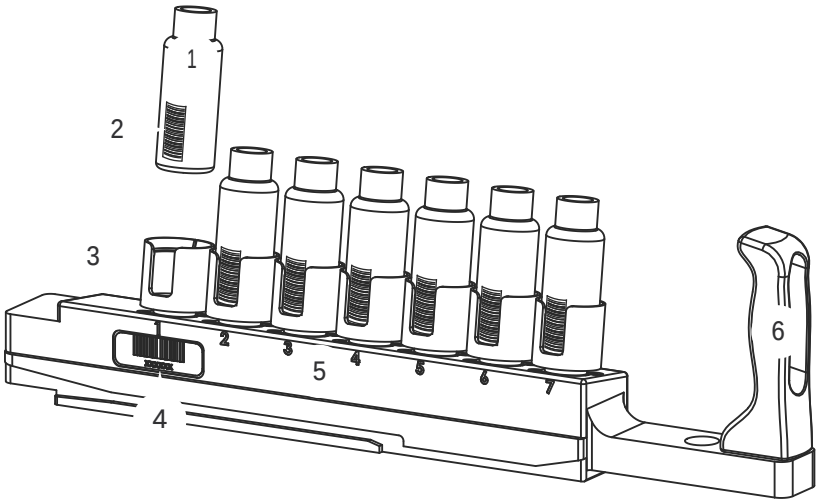
4,0,1 Pc_eclr P_aiq



Dgespc 20, Reagents rack - Description

1 Reagent vial

2 Reagent barcode

3 Rotating reagent place

4 Rack identification barcode

5 Reagent vial numbering

6 Handle

A reagent rack can contain up to 7 reagent vials.

The reagent vial barcode has to be visible through the aperture of the reagent place.

Reagent racks can be loaded in position R1 to R4.

0 It is allowed to read sample barcodes manually, but not reagent barcodes.
If a reagent vial of a reagent set is replaced by a new one, make sure to have the same lot number.

- Rfc `_pambc qrgaicpq md rfc p_ai _lb tg_jq k sqr lmr `c qap_rafcb &c,e, `w rsplgle rfc tg_j gl rfc fmjbcp' gl mpbcp rm `c gbclrgdgcb amppcarjw `w rfc glqrps k clr,

- Dmjjmu rfc glqrpsargmlq md sqc dpm k rfc pc_eclr k_lsd_arspcp,

- Gl mpbcp rm npctclr os_lrgrw bcrcargml cppmpq* lm dm_k mp `s``jc k sqr `c npcqclr _r rfc qspd_ac md rfc jgosgb,
  Rfc acjjq md rfc pc_eclrq k sqr `c gl qsqnclqgml `cdmpc rfc tg_j gq jm_bcb ml rfc p_ai,
  Rfc a_n md rfc pc_eclr tg_jq k sqr `c pc k mtcb `cdmpc jm_bgle rfc p_ai glrm rfc GF-/...,

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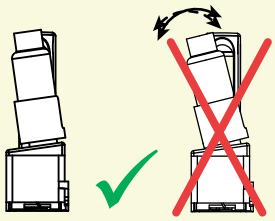
- Rfc tg_jq k sqr dgr amppcarjw g lrm rfcgp nj_acq9 rfcpc k sqr `c lm _lejc nj_w,



0 The vials have to be taken out of the fridge at least 30 minutes before they are used on the instrument in order that they reach room temperature. The reagent racks should not be stored in the fridge.

Ml+`m_pb qr_`gjgrw gq8

- 0 b_wq &26 fmspq' dmp pcb `jmmb acjj pc_ec lrq9
- 5 b_wq &/46 fmspq' dmp _lrgqcp_ pc_ec lrq &GB+?lrg K* L* Q* q* Dw_* Dw`',

Rfc ml+`m_pb qr_`gjgrw bmcq lmr g lajsbc rfc rg k c u fc l rfc tg_j gq qrmpcb g l rfc dpgbec, Gr g lajsbcq m ljw rfc rg k c u fc l rfc tg_j gq g l rfc g lqrps k c lr,

?drcp rf_r rg k c* rfc pc_ec lrq k sqr `c pc k mtcb _lb bgqnmqcb,

4,0,1,/ Sqc md rfc Ajc_lgle Qmjsrgml QCRSN AJC?L

The SETUP CLEAN product (REF 009902, dilution 1 to 5) is required when using Enzymatic reagents and/or antisera reagents classified as contaminant or using the Diluent 1.

Rfc ajc_lgle qmjsrgml QCRSN AJC?L gq b_lecpmsq,

Pcdcp dmp k mpc g ldmp k_rgml _`msr rfc npmbsar rm8

- rfc Glqrpsargmlq md Sqc &PCD . .77.0'9
- rfc K_rcpg_j Q_dcrw B_r_ Qfccr,

0 Exclusively use the SETUP CLEAN product (REF 009902) for cleaning solution preparation.

Prepared cleaning solution should only be filled into its foreseen 15 ml empty vials (REF 009310). Then, the vials have to be loaded in a reagent rack.

009310	SETUP CLEAN vials 15 ml (x12)

The SETUP CLEAN solution has to be changed daily. The same vial should not be used longer than 1 month. Therefore REF 009310 contains 12 vials (one vial for every month of the year).

0 If a used vial containing SETUP CLEAN solution is outside of the IH-1000, it must be closed with the foreseen cap delivered with the package.

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4,0,1,0 Npcn_p_rgml md /3kj md QCRSN AJC?L

K_rcpg_j pcosgpcb8

- SETUP CLEAN product with REF 009902;
- SETUP CLEAN empty vials of 15 ml (REF with barcode);
- Demineralized water.

'	Ufcl sqgle bckglcp_jgxcb u_rcp* k_ic qspc rf_r rfc u_rcp os_jgrw amppcqnmlbq _r jc_qr rm Ep_b 0 &GQM 1474' mp Rwnc GG &?QRK B//71+7/',
'	Bm lmr dgjj kmpc rf_l /3kj md rfc QCRSN AJC?L qmjsrgml gl mlc tg_j PCD ..71/.,
A	Add 3 ml of SETUP CLEAN REF 009902 in a vial.
B	Add 12 ml of demineralized water.

The final concentration of this SETUP CLEAN REF 009902 is 20%.

0 This once prepared solution has to be preserved at ambient temperature.
If SETUP CLEAN solution is stored in a dark, light-protected bottle, it must be replaced once a month. If SETUP CLEAN solution is not light-protected (if it is in a transparent bottle), it must be replaced every day.

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4,0,2 Q_knjcq - Pc_eclrq ?pc_ Qapccl

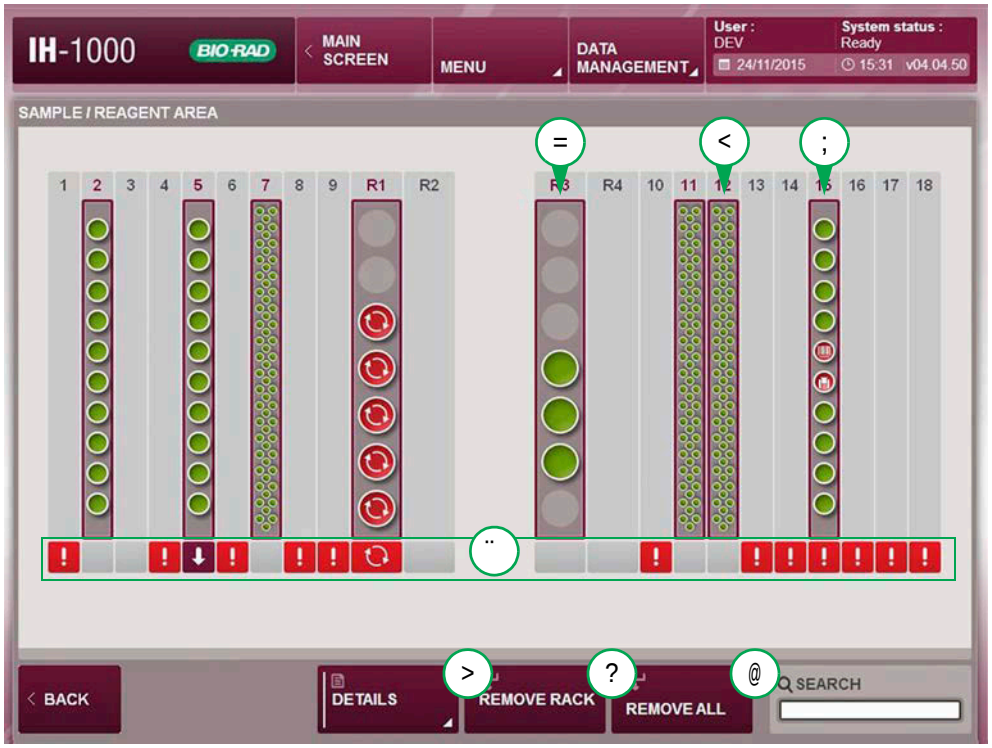
This screen displays a detailed status of the samples, diluents and reagents loaded in the IH-1000.

?aacqq

A From the main screen, click on the **SAMPLE / REAGENTS AREA** of the interactive image

REAGENT/DILUENT From any screen where the **REAGENT / DILUENT AREA** button appears.

4,0,2,/ Bcqapgnrgml



Dgespc 21, Sample / Reagent area screen

1 Rack Status (see page 78)

2 Sample Status (see page 78)

3 Diluent Status (see page 79)

4 Reagent Status (see page 79)

5 Details Button (see page 80)

6 Remove Rack Button

7 Remove All Button (see page 88)

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4,0,2,0 P_ai Qr_rsq

Qwk `mj	Bcqapgnrgml	U f_r rm bm =
	The rack is surplus.	A rack is already loaded at this place in the pipetting area. Remove the supernumerary rack from the loading area.
	The rack is not identified, or the barcode of the rack is not valid, or one of the tubes is not identified, or the diluent rack is out of date.	Remove the rack and check that the barcode sticker is not damaged. For a diluent rack, check the validity date.
	A sample tube or a reagent vial is in error or an unloadable rack is detected (not fully pushed in the instrument).	Check the samples tubes or reagents vials errors then remove the rack. Push the rack deeper in the IH-1000.
	The reagent rack has a stirring fault.	Remove and replace the rack.
	The rack is in the restitution position (only for particular cases).	Remove the rack from the instrument.
	The restitution is in progress or the restitution request is memorized.	Wait for process completion.
	Rack background color: gray The rack is in the pipetting position.	Can be selected for further information/actions.
	Rack background color: orange The rack is selected in order to view details or to remove it.	Click **DETAIL** or **REMOVE** button
	Rack background color: yellow The rack is out of service.	Remove the rack

4,0,2,1 Q_knjc Qr_rsq

Qwk `mj	Bcqapgnrgml	U f_r rm bm=
	No tube is detected at this position of the rack.	-
	The sample is correctly detected.	-
	Sample correctly detected (donor).	-
	Sample correctly detected (receiver).	-
	A tube is detected with a barcode reading error or duplication.	If manual input option is enabled, remove the rack and check the barcode of the defective tube. In case of duplicate, check both tubes.
	A tube is detected with a cap.	See chapter No Cap Confirmation on page 84.
	Lack of receiver for sample tube.	Check the loaded crossmatch receivers.
	Lack of donor for sample tube.	Check the loaded crossmatch donors.

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Click on the error of a sample rack to display a warning screen describing the nature of the error.

If the sample rack grid is in error, it is possible to display the error details by clicking on the representative error icon.

See chapter Disabled Mode Option on page 137.

0 For particular cases with **Low volume segment blood** (rack type 4), error messages are displayed in the log list.
See chapter Traceability Area on page 39.

4,0,2,2 Bgjsc l r Qr_rsq

Qw k `mj	Bcqapgnrgm l	U f_r rm bm=
	The diluent rack is correctly detected.	-
	The diluent rack is detected with an error.	Remove the rack and replace the diluent product.

Click on the error of a diluent rack to display a warning screen describing the nature of the error.

If the diluent rack grid is in error, it is possible to display the error details by clicking on the representative error icon.

See chapter Disabled Mode Option on page 137.

4,0,2,3 Pc_ec l r Qr_rsq

Qw k `mj	Bcqapgnrgm l	U f_r rm bm =
	The vial is correctly detected.	-
	The vial is detected with an error.	Remove the rack and check that the vial is correctly inserted.
	The vial is detected and is reserved.	-
	The vial is detected with a cap error.	Remove the rack and remove the cap.
	The vial is detected with a barcode reading error.	Remove the rack and check the barcode of the vial: orientation, validity date, barcode.
	The vial is detected with a stirring error.	Remove and replace the rack.

Click on the error of a reagent rack to display a warning screen describing the nature of the error.

Remove or reload the rack to initialize it.

If the rack grid is still in error, it is possible to disable it by clicking on the error icon (with sufficient rights).

See chapter Disabled Mode Option on page 137.

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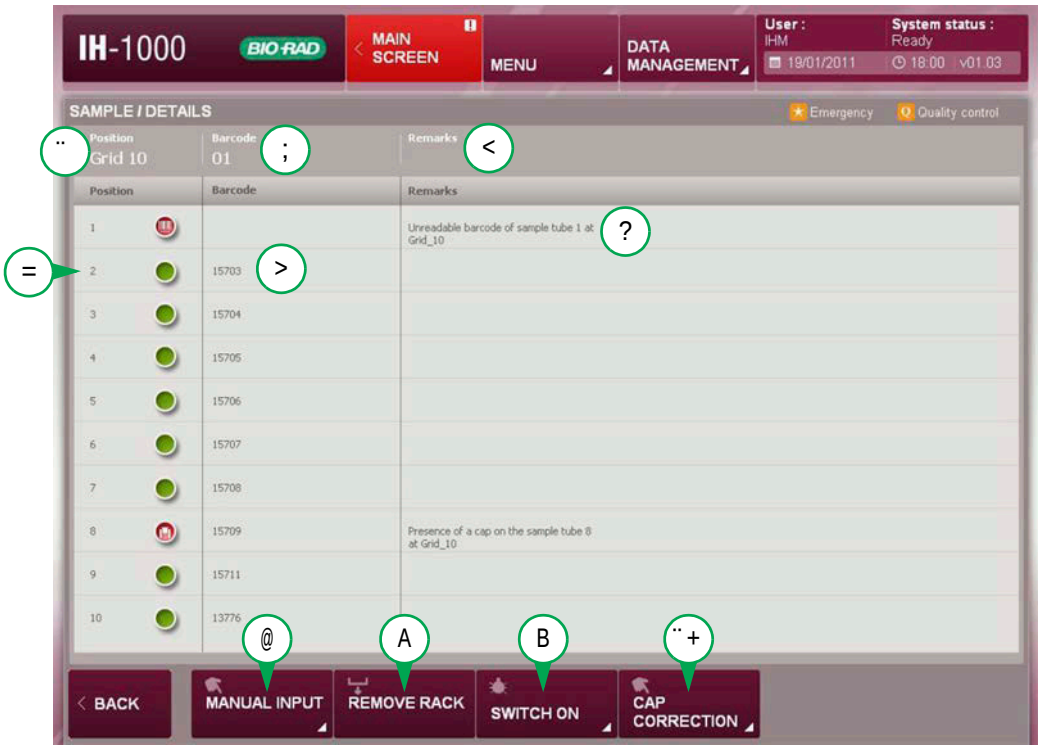
4,0,2,4 Bcr_gjq @srrm l

This button gives access to precise information about the selected rack.

A	Click on the rack image to select it (orange background).
B	Click on **DETAILS**. *Rfc bcr_gjq qapcc l bgddcp u fcrfcp _ q_ k njc* pc_ec l r mp bgjsc l r p_aiq gq qcjcarcb,*

0 This button is activated only when the rack is in the pipetting position.

Q_ k njc - Bcr_gjq Qapcc l



Dgespc 22, Sample details screen

1 Position of the rack
2 Name (barcode) of the rack
3 Remarks/Errors (if any)
4 Position of the sample
5 Barcode of the sample
6 Remarks/Errors of the sample (if any)
7 **MANUAL INPUT** button (see page 83)
8 **REMOVE RACK** button (see page 88)
9 **SWITCH ON / SWITCH OFF** button
10 **CAP CORRECTION** button (see page 84)

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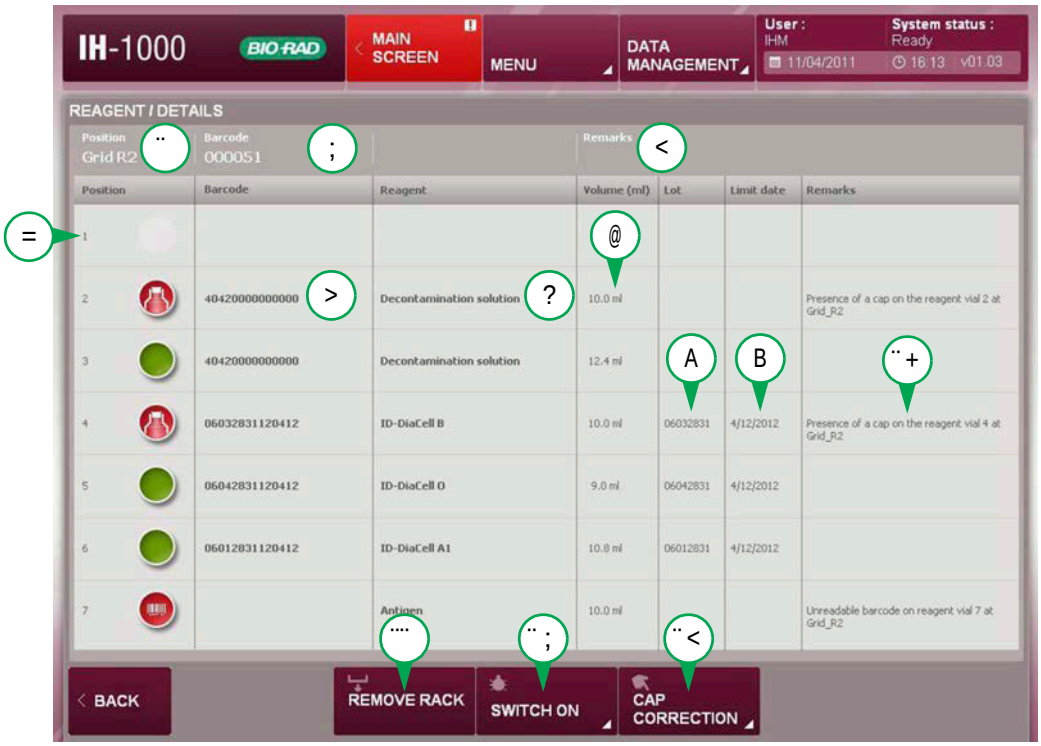
Pc_ec l r - Bcr_gjq Qapcc l



Dgespc 23, Reagent details screen

1 Position of the rack

2 Name (barcode) of the rack

3 Remarks/Errors (if any)

4 Position of the content in the rack

5 Barcode of the content

6 Reagent name

7 Reagent usable volume (ml)

Sq_`jc tmjskc ; kc_qspcb tmjskc + bc_b tmjskc

8 Reagent lot number

9 Expiry date

10 Remarks/Errors of the content (if any)

11 **REMOVE RACK** button (see page 88)

12 **SWITCH ON / SWITCH OFF** button

13 **CAP CORRECTION** button (see page 84)

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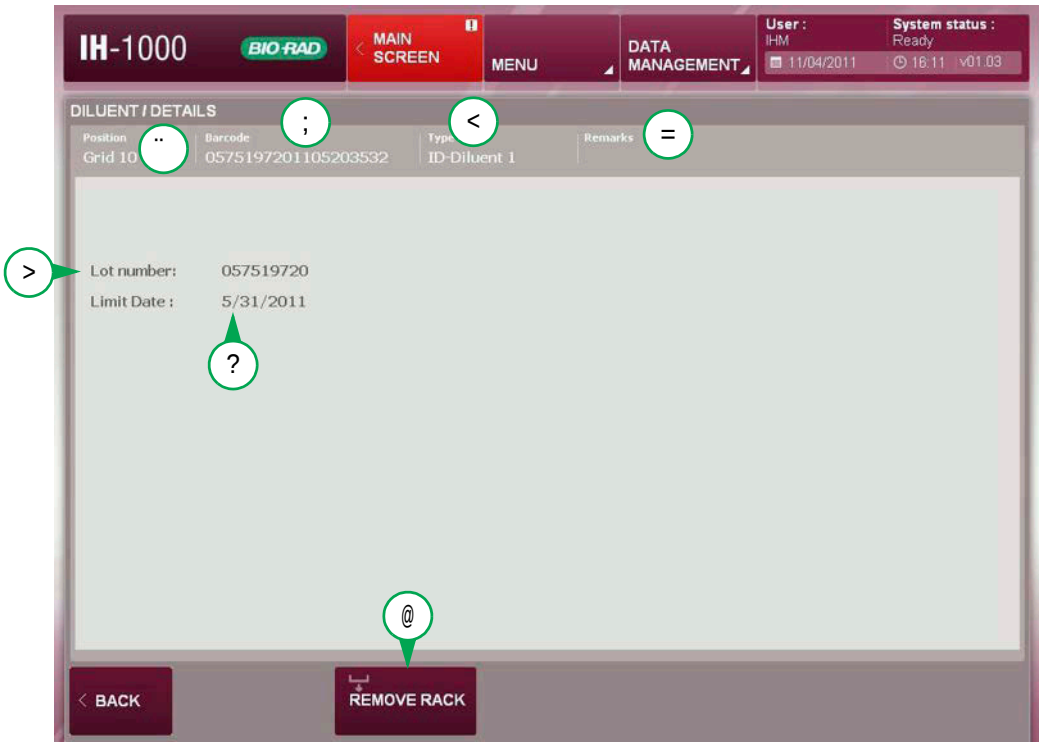
Bgjsc l r - Bcr_gjq Qapcc l



Dgespc 24, Diluent details screen

1 Position of the rack

2 Name (barcode) of the rack

3 Diluent type

4 Remarks/Errors (if any)

5 Lot number

6 Expiry date

> 0 The contents of diluent racks are not displayed.

7 **REMOVE RACK** button (see page 88)

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4,0,2,5 Q_knjc @_pambc K_ls_j⇧lnsr

The **MANUAL INPUT** allows to enter manually a barcode for the samples detected with a barcode error.

0 This button is activated only when a sample is detected with a barcode error.

0 If the barcode is read manually, make sure to put the sample back to the original position.

A From the main screen, click on the **SAMPLE / REAGENTS AREA**.

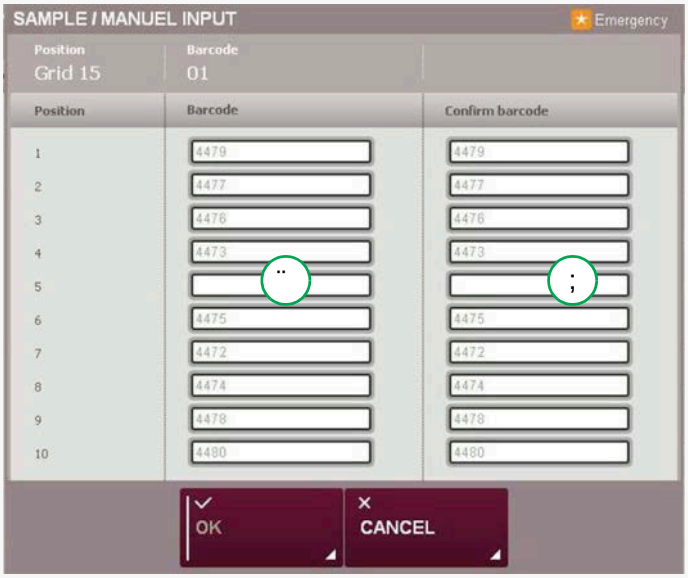
B Select the rack with the sample barcode error.

C Click on **DETAILS**.

D

Click on **MANUAL INPUT**.

Rfc ⇧mjjmu⇧le qapccl _nnc_pq8



Dyespc 25, Sample manual input

E Click on **REMOVE RACK**.

F Scan or type the sample barcode in the **Barcode** (1) column.

G Scan or type the sample barcode in the **Confirm Barcode** (2) column.

0 Copy and Paste functionalities are disabled during this operation.

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H	Click on **OK** to validate the input.
I	If the positions of some samples have been switched, an alert screen is displayed. *Npmacbspc ujj f_tc rm `c pcnc_rcb,*
J	Place the sample rack back in the instrument (same position). Wait until the instrument has inserted the rack completely.
K	Enter your login and password. **Dgespc 26,** Authentication Required screen
L	Click on the **OK** button of the **AUTHENTICATION REQUIRED** screen.

' Bm lmr ajgai Ml ml rfc ?srfclrga_rgml qapccl,

4,0,2,6 Lm A_n Amldgpk_rgml

The **NO CAP CONFIRMATION** screen allows to confirm the absence of caps when necessary.

A	From the **SAMPLE** or **REAGENT / DETAILS** screen, click on the **CAP CORRECTION** button. *Qcc af_nrcp Q_ knjc - Bcr_gjq Qapccl ml n_ec 6.,* *Rfc dmjjmugle qapccl _nnc_pq,*

0 This button is activated only when a cap is detected.

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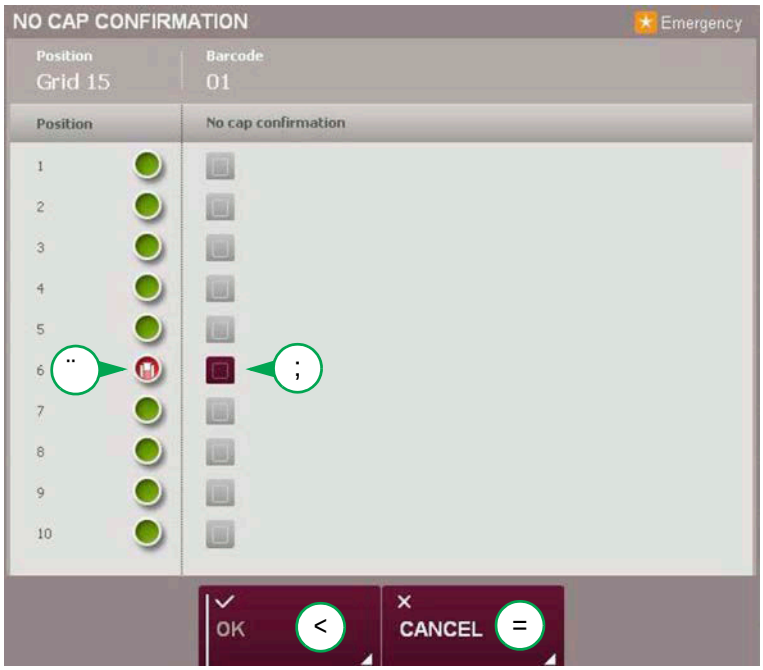


Dgespc 27, No Cap confirmation screen

1 Symbol: Tube is detected with a cap

2 Check box activated

3 **OK** button

4 **CANCEL** button (see page 83)

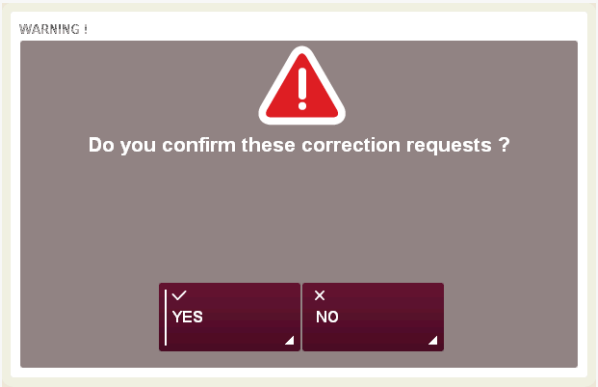
To confirm the absence of a cap after checking visually:

A Click the **check box** (2) next to the symbol; **Tube is detected with a cap** (1).

0 Only tubes with a cap are active. When a check box is unchecked, the tube returns to its initial state.

B Click **OK** to confirm.

Rfc dmjjmugle qapccl _nnc_pq8



Dgespc 3., No Cap confirmation warning screen

C Click **YES** to confirm.

Rfc amppcqnmlbgle qr_rc md rfc rs`c gq snb_rcb,

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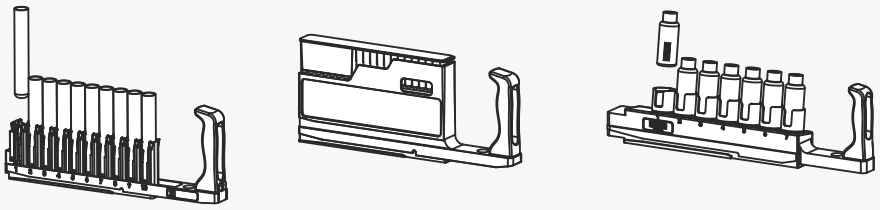
4,0,3 Jm_bgle P_aiq

The loading procedure is identical for all kinds of racks.

A rack can be loaded at any time in a free position, even when the instrument is performing tests.

A Prepare a rack with samples, diluents or reagents.



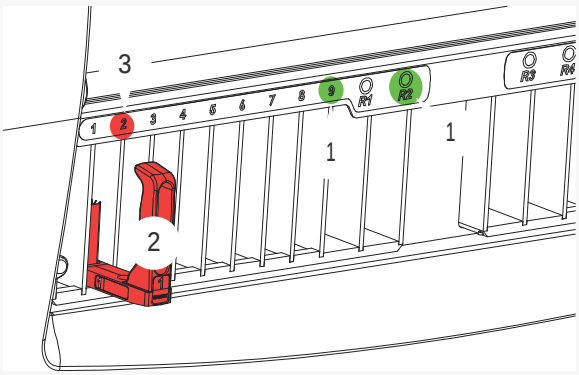
Dgespc 31, Racks preparation

0 Read carefully the instructions given for each type of rack. See:

- Sample Racks on page 64;
- Diluent Rack and Diluent Product on page 72;
- Reagent Racks on page 74.

B Check where to load the rack:

- A green light (1) indicates that the slot is available.
- A blinking red light indicates that a rack is moving: loading or unloading.
- A red light (3) indicates that the slot is not available. A rack is already loaded.
- Sample and diluent racks can be loaded in positions 1 to 18.
- Reagent racks can be loaded in positions R1 to R4.



Dgespc 30, Loading racks

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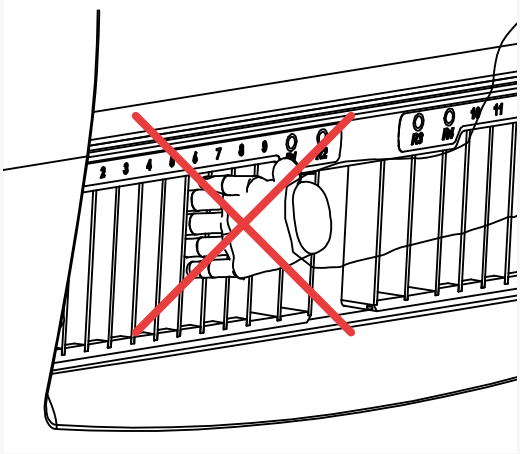
C Engage the rack in the slot and push it slowly until it locks automatically.

&O' qfmuq_ ucjj nj_acb p_ai,

? a_ kcp_ ugjj _srmk_rga_jjw gbclrgdw rfc lcu p_ai _lb rfc rp_lqnmpr _pk ugjj r_ic gr glrm rfc glqrpskclr dmp ngncrrgle mncp_rgmlq,



Dgespc 31, DANGER - Racks area

- ?r_lw rgkc* rfc p_ai ksqrj_w ml rfc `mrrmk md rfc qjmr gl mpbcp rm `c jmaicb _r rfc amppcar nmqgrgml,
  Gd rfc p_ai gq nsqfcb rmm d_p* _ amjjgqgml ugrf rfc rp_lqnmpr _pk amsjb maasp,

- Lctcp nsr_lwrfgle cjqc rf_l _p_ai glqgbc _ qjmr,
  Rfc a_kcp_ umsjb _srmk_rga_jjw rpw rm gbclrgdw gr _lb _ amjjgqgml umsjb maasp,

D If the identification fails, the loading area becomes red.

E The rack can be unloaded and identified manually using the manual barcode reader.

Qcc af_nrcp Q_knjc @_pambc K_ls_jglnsrml n_ec 61,

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4,0,4 Pckmtgle P_aiq

- U_gr slrgj rfc jgefr &/' gq epccl rm pckmtc rfc p_ai,
- Rfc p_aiq amknjcrcjw ncpdmpkcb amkc msr md rfc GF-/... _srmk_rga_jjw &0', @c _u_pc rm lmr fgr rfck _aagbclr_jjw,

4,0,4,/ Pckmtgle Q_knjc P_aiq

A Select the **SAMPLE / REAGENT AREA** screen or the **SAMPLE / DETAILS** screen.

Qcc8

² *Q_knjcq - Pc_eclrq ?pc_ Qapccl ml n_ec 559*

² *Q_knjc - Bcr_gjq Qapccl ml n_ec 6.,*

B Select the rack or search the sample tube barcode to remove.

Dgespc 32, Search function

*Gd lcacqq_pw gl rfc **Q?KNJC - PC?ECLR ?PC?** qapccl,*
?lw dmslb q_knjc rs`c gq fgefjgefrcb gl nspnjc,

C Press **REMOVE RACK**.

Gd lm q_knjc gq npmacqqcb rfc rp_lqnmpr _pk nsqfcq rfc p_ai msr,*
Gd mlc mp kmpc q_knjcq _pc npmacqqcb _ kcqq_ec npmknrq rfc sqcp rm amldgpk rfc pckmt_j,*

Dgespc 33,

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D Confirm the rack removal.

Rfc glqrpskclr dglgqfcq rfc ngncrrgle mncp_rgml ml rfc aspcclr q_knjc, Rfc mrfcp q_knjcq _pc lmr ngncrrcb,

Rfc q_knjc p_ai gq nsqfcb msr,

? kcqq_ec bgqnj_wq rfc pck_glgle rgkc dmp rfc sqcp rm pc+glqcpr rfc q_knjc p_ai ml rfc q_kc nmqgrgml rm npmaccb rfc rcqrq &qcc pck_piq `cjmu',

Dgespc 34,

Pck_piq8

If the unloaded sample rack is reloaded in the **q_kc** position **ugrfgl** 60 seconds:

- for samples already identified, the pipetting operation restarts;
- for missing samples, the tests which were scheduled are placed in **TESTS TO REPEAT** screen. See Tests to Repeat on page 114.

If the unloaded sample rack is reloaded in the **q_kc** position **_drcp** 60 seconds or in other position, the rack is considered as new rack.

For any missing samples, the status of the scheduled tests is managed as follows:

Rcqr Qr_rsq	Bcqapgnrgml
TESTS IN PROGRESS Q_knjc amknjcrcjw ngncrrcb &Q_knjc rs`c lm kmpc lccbcb'	No impact. The test will be completed.
TESTS IN PROGRESS Q_knjc lmr amknjcrcjw ngncrrcb &Q_knjc rs`c qrgjj lccbcb'	The status of the test is set to **TEST TO REPEAT**. Reason: Missing resources (samples).
TESTS READY TO START	The test is canceled.
TESTS WITHOUT RESOURCES	The test is canceled.

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4,0,4,0 Pckmtgle Pc_eclr mp Bgjsclr P_aiq

0 A reagent rack can be removed only if no reagent vial of the rack is in use.

A Select the **SAMPLE / REAGENT AREA** screen or the **REAGENT / DETAILS** or **DILUENT DETAILS** screen.

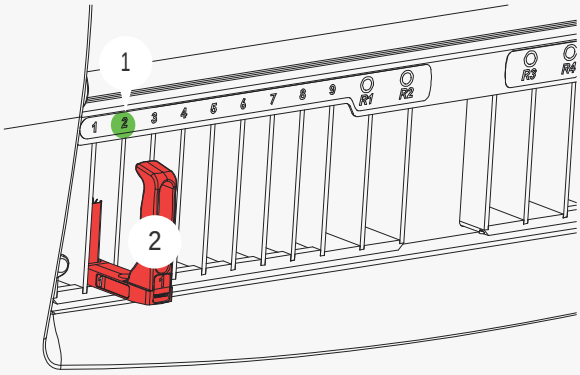
Qcc8

- *Q_knjcq - Pc_eclrq ?pc_ Qapccl ml n_ec 559*
- *Pc_eclr - Bcr_gjq Qapccl ml n_ec 6/9*
- *Bgjsclr - Bcr_gjq Qapccl ml n_ec 60,*

B If necessary (in the **SAMPLE / REAGENT AREA** screen), click on the rack image to select it (orange background).

C Press **REMOVE RACK**.

Rfc rp_lqnmpr _pk nsqfcq rfc p_ai msr,



Dgespc 35, Remove racks - light

4,0,4,1 Pckmtc _jj P_aiq

A

Click on **REMOVE ALL**.

Rfc rp_lqnmpr _pk nsqfcq _jj p_aiq msr _jj rfc p_aiq _pc sljm_bcb,*

0 It is only possible to remove racks which are not in use.

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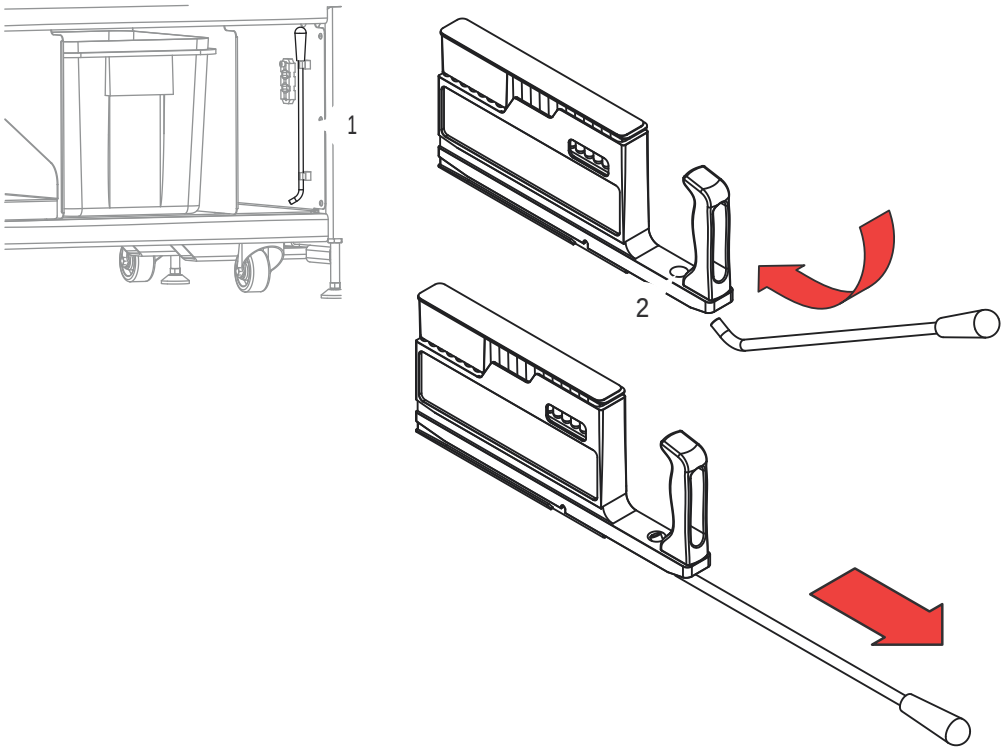
4,0,4,2 Pckmtgle Bgjsclr_lb Q_knjc P_ai k_ls_jjw

If a rack is blocked inside the loading area in pipetting position, manually remove it according to the following procedure.

!	**SHUTDOWN** rfc GF-/... `cdmpc pckmtgle rfc p_aiq k_ls_jjw,
A	**SHUTDOWN** the IH-1000. *Qcc af_nrcp Qfsrbmu l md rfc Glqrpskclr ml n_ec 27,*
B	Take the rack extractor tool (1). *Grgq jma_rcb gl rfc pgefr jmucp n_pr md rfc glqrpskclr* lcvr rm rfc ecj a_pbq u_qrc `gl,*
C	Slide the rack extractor tool under the rack.
D	Insert the extremity of the tool in the dedicated hole of the rack (2).
E	Lift smoothly the rack and pull it out.
F	Put the rack extractor tool back in place.



Dgespc 36, Remove racks - pull out

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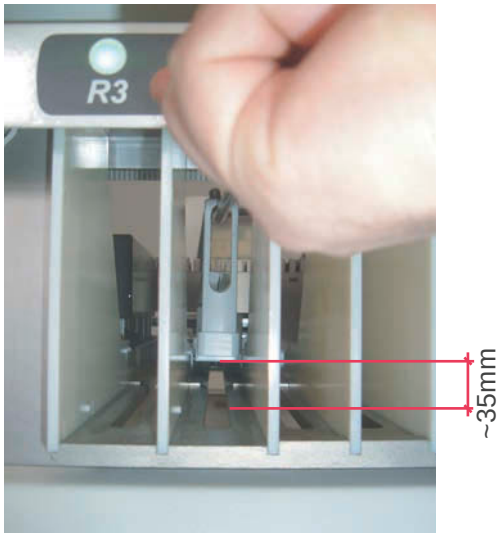
4,0,4,3 Pckmtgle Pc_eclr P_aiq k_ls_jjw

' @c a_pcdsj lmr rm b_k_ec rfc cjcarpga_j amlr_arq md rfc pc_eclr p_ai,

A	Raise the back of the rack about 35 mm.
B	Remove the rack about 15 mm.
C	Rest the back of the rack.
D	Remove completely the rack.



Dgespc 37, Remove racks - Reagent

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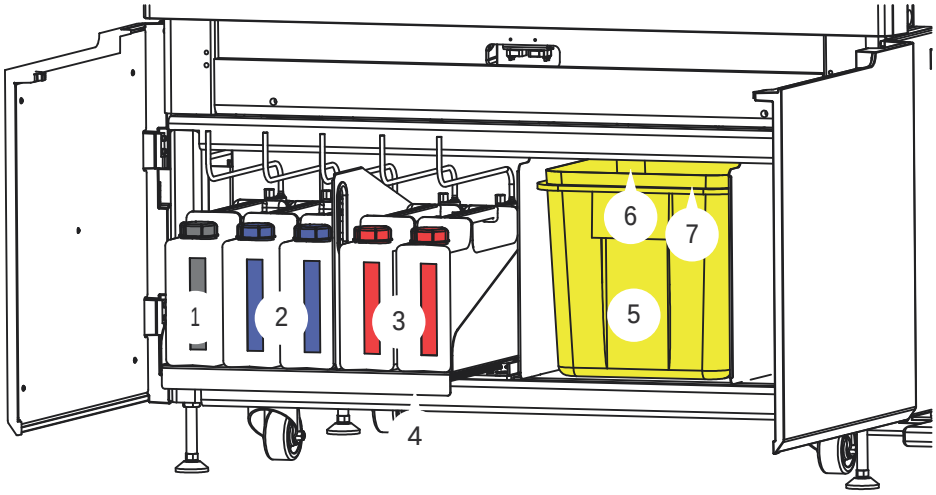
6.3 Managing Liquids and Wastes

This chapter explains how to manage cleaning liquid, system liquid, liquid waste and gel cards waste.

- Ajc_lgle _lb qwqrck jgosgb amlr_glcpq pcnj_ackclr ksqr `c bmlc a_pcdsjjw _aampbgle rm rfc dmjjmugle npmacbspcq gl mpbcp rm _tmgb nmjjsrgml md rfc fwbp_sjga agpasgr,

4,1,/ Bcqapgnrgml



Dgespc 4., Liquids and wastes - description

1 Cleaning liquid container (black)

2 System liquid containers (blue)

3 Liquid waste containers (red)

4 Containers drawer

5 Gel cards waste bin

6 Gel cards waste slide

7 Gel cards waste bag

A	Push the door to open it.
B	Pull the containers drawer (4) to easily access the liquid containers (1), (2) and (3).
0	The cleaning liquid container (1) is not connected during normal operations; it is used only for maintenance operations.
C	After being processed, used gel cards will fall from the slide (6) into the waste bag (7).

- Lctcp nsr f_lbq gl rfc ecj a_pbq u_qrc qjgbc u fgjc rfc glqrps kclr gq nmucpcb ml,
- Gd rfc jgosgb u_qrc gq amllcarcb rm _j_`mp_rmpw bp_gl* tcpgdw rfc os_jgrw md rfc rs`gle _lb k_ic qspc rf_r gr gq amppcarjw amllcarcb,

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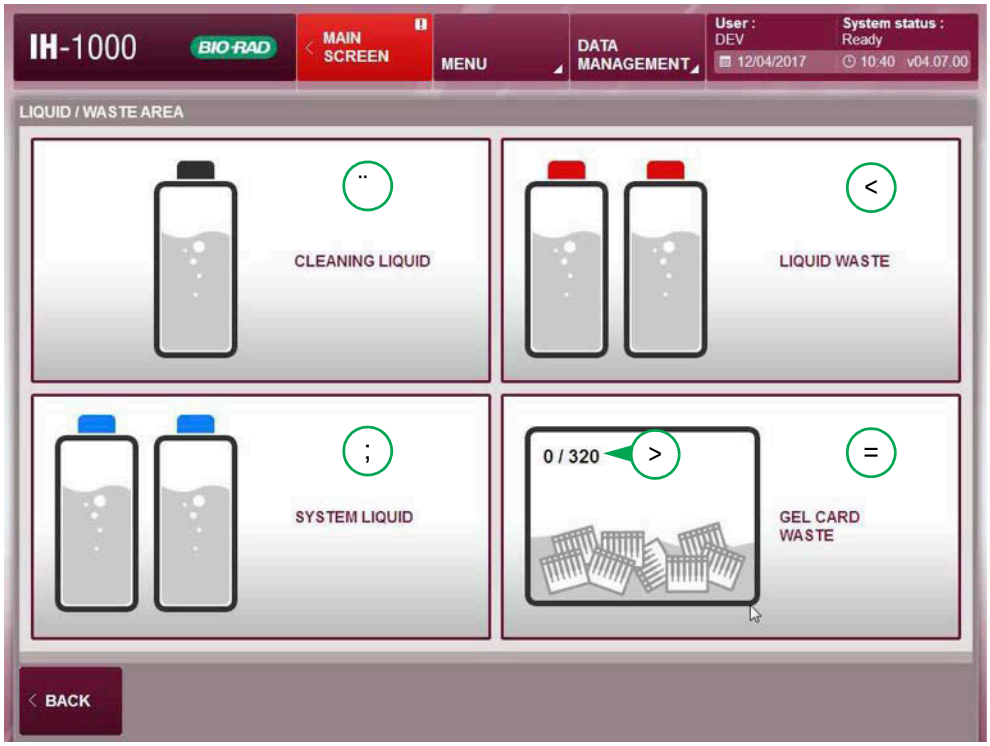
4,1,0 Afcaigle Jgosgbq _lb U_qrcq Qr_rsq

The **SOLUTIONS / WASTES AREA** screen allows to check the liquids and wastes status.

?aacqq

A From the main screen, click on the **LIQUIDS / WASTES AREA** of the interactive image.

Bcqapgnrgml



Dgespc 4/, Solution / wastes area

1 Cleaning liquid container area

2 System liquid container area

3 Liquid waste container area

4 Gel card waste bin area

5 Maximum gel cards waste capacity of the bin

0 If all items in Solutions / Wastes Area are in order, it is not possible to perform an action.

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4,1,1 Pcdgjjgle _ Qwqrck Jgosgb Amlr_glcp

Qmjsrgml Bcaml 7. gq b_lecpmsq,
Pcdcp rm rfc K_rcpg_j Q_dcrw B_r_ Qfccr dmp kmpc gldmp k_rgml,

- Sqc ejmtcq dmp _jj mncp_rgmlq,
- Ufcl sqgle bckglcp_jgxcb u_rcp* k_ic qspc rf_r rfc u_rcp os_jgrw amppcqnmlbq _r jc_qr rm Ep_b 0 &GQM 1474' mp Rwnc GG &?QRK B//71+7/',
- R_ic a_pc rm amllcar rfc amppcar amlr_glcp rm rfc amppcar fmqc, Pcdcp rm rfc amjmp ambc,

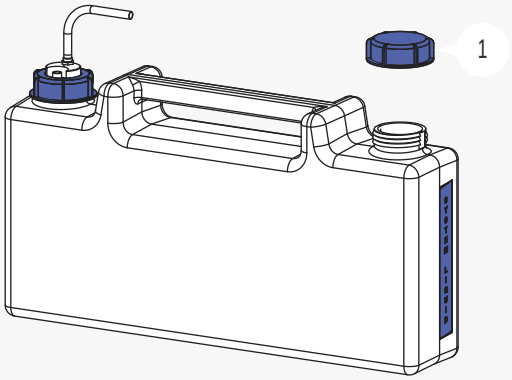
0 The system liquid has to be renewed weekly.

0 Do not mix different solutions of system liquid.

A Check that the second system liquid container is connected to the instrument while it is running.

B Pull the container out of the instrument.

C Remove the front cap (1) of the container.



Dgespc 40, Refilling system liquid container

D Clean the container with demineralized water.

E Check that the container is empty.

F Shake the Decon 90 bottle to mix the solution.

G Fill the container with system liquid:

3J md bckglcp_jgxcb u_rcp _lb /3kJ md Bcaml 7.,

H Put the container cap back in place.

I Put the container back in place in the instrument.

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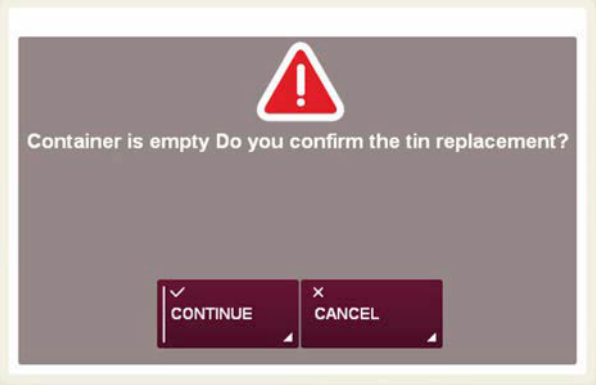
J Click **CONTINUE** to confirm the message, or **CANCEL**.



Dgespc 41, Empty container message

- Gd rfc §C k nrw am l r_g l cpµ k cqq_ec _nnc_pq _e_g l _drcp rfc am l r_g l cp f_q `cc l pcdgjjcb* BM LMR _ai l mujcbec rfc k cqq_ec _e_g l* rfc fwbp_sjga agpasgr umsjb `c npg k cb _e_g l _l b rfgq umsjb pcqsjr g l mtcpdjmug l e rfc djsv am k nc l q_rmp, Am l r_ar _ qcptgac c l eg l ccp,

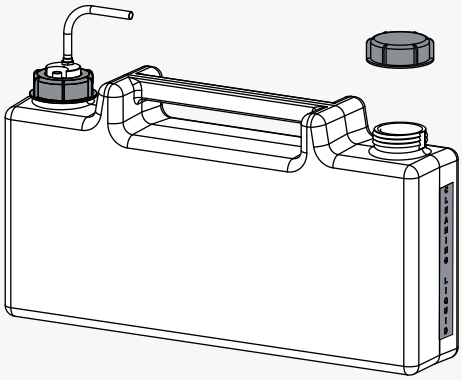
4,1,2 Ajc_l g l e Jgosgb Npcn_p_rgm l

Qmjsrgm l Kgapmagbc QO × gq b_ l ecpmsq,
Pcdcp rm rfc K_rcpg_j Q_dcrw B_r_ Qfccr dmp k mpc g l dmp k_rgm l,

- U fc l sqg l e bc k g l cp_jgxcb u_rcp* k_ic qspc rf_r rfc u_rcp os_jgrw amppcqnm l bq _r jc_qr rm Ep_b 0 &GQM 1474' mp Rwnc GG &?QRK B//71+7/',

- Sqc ejmtcq dmp _jj mncp_rgm l q,

A Remove the front cap of the container.



Dgespc 42, Refilling cleaning liquid container

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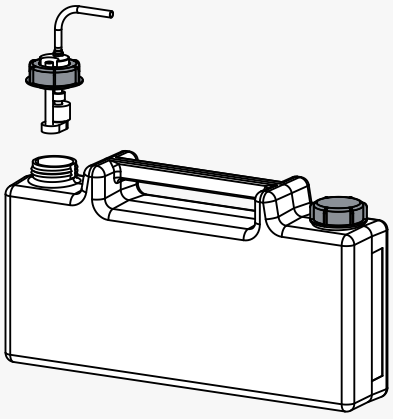
B	Fill the container with cleaning liquid: • 2l of demineralized water and 8ml of Microcide SQ™. *Rfgq qmjsrgml gq qr_`jc dmp 5 b_wq,*

4,1,3 Ajc_lgle md rfc Amlr_glcpq

It is necessary to clean a container:

- once a month;
- when a container has not been used for a long time.

! Ufcl sqgle bckglcp_jgxcb u_rcp* k_ic qspc rf_r rfc u_rcp os_jgrw amppcqnmlbq _r jc_qr rm Ep_b 0 &GQM 1474' mp Rwnc GG &?QRK B//71+7/',

A	Wait until the ongoing process is finished.
B	Take the container out and remove caps and hose.  Dgespc 43,
C	Empty completely the container.
D	Rinse it with about 1L of cleaning liquid.
E	Shake the container.
F	Remove and dispose the cleaning liquid.
G	Rinse 4x or more the container with demineralized water.
H	Wipe the caps and aspiration hose with Isopropanol, then rinse with demineralized water.

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4,1,4 Pcnj_agle _ Jgosgb U_qrc Amlr_glcp

) Jgosgb u_qrc amlr_glcpq amlr_gl amlr_kgl_rcb jgosgbq, F_lbjgle pcosgpc qncag_j a_pc, Rm _tmgb amlr_kgl_rcb jgosgb qngjjq* jgosgb u_qrc amlr_glcpq ksqr lmr `c bgqamllcarcb bspgle sqc,

' Sqc ejmtcq dmp _jj mncp_rgmlq,

0 It is strongly recommended to use the antifoaming product each time the waste container has to be emptied.

4,1,4,/ Npcn_p_rgml md rfc ?lrgdm_kgle Qmjsrgml

Various antifoaming products can be found worldwide from different manufacturers. Bio-Rad recommends antifoaming product that contains 30% of Silicone.

Rfc qgjgamlc _lrgdm_kgle _eclrgq b_lecpmsq,
Pcdcp rm rfc K_rcpg_j Q_dcrw B_r_ Qfccr dmp npca_srgmlq rm `cr_icl ufcl umpigle ugrf rfgq rwnc md npmbsar,

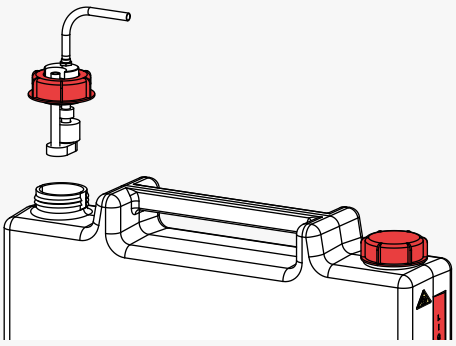
For 100 ml of diluted silicone antifoaming agent:

A	Add 10 ml of silicone anti-foam agent in a bottle.
B	Add 90 ml of demineralized water.

4,1,4,0 Pcnj_agle rfc Jgosgb U_qrc

The following procedure explains what to do when a liquid waste container is full.

A	Check that the second liquid waste container is connected to the instrument while it is running.
B	Take the container.
C	Remove the plunger.



Dgespc 44, Liquid waste container

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0 As soon as the aspiration cap is removed, liquid wastes are automatically routed to the second liquid waste container.

D Dispose the liquid waste in accordance with your local regulations.

E Add 5 ml of antifoaming solution in the **c k nrw** liquid waste container.

F Put the container back in place with the caps.

' R_ic a_pc rm am l l car rfc amppcar am l r_g l cp rm rfc amppcar fmqc, Pcdcp rm rfc amjmp ambc,

G Click **CONTINUE** to confirm the message, or **CANCEL**.

Dgespc 45, Waste full message

4,1,5 Npg k g l e Awajc

The priming cycle is made automatically or with the general initialization function.

See chapter General Initialization on page 167.

0 Make sure to have enough liquid.

4,1,6 Ajc_l g l e Awajc

See chapter Weekly Maintenance on page 149.

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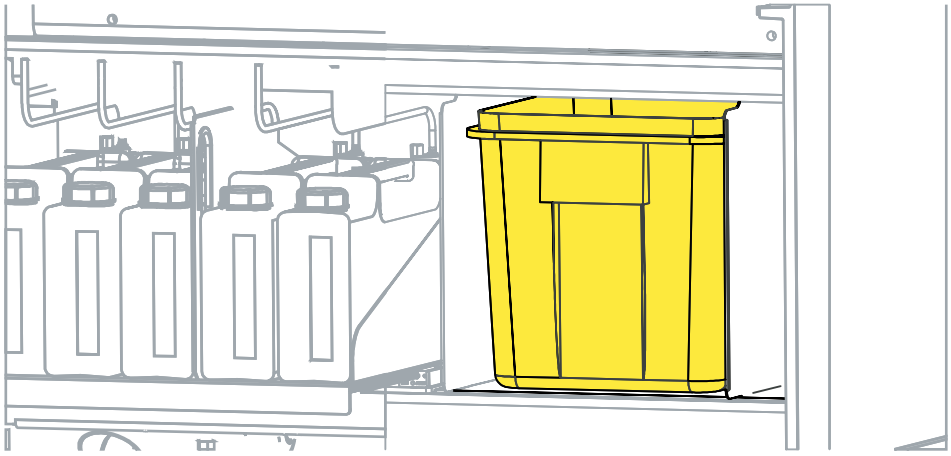
4,1,7 Pcnj_agle rfc Ecj A_pbq U_qrc @gl

) Rfc ecj a_pbq u_qrc `gl amlr_glq amlr_kgl_rcb npmbsarq, F_lbjgle pcosgpcq qncagj a_pc,

' Sqc ejmtcq dmp _jj mncp_rgmlq,

A	Prepare an empty waste bin with a bag.
B	When the instrument is ready or in idle state: • replace whole waste bin; • replace plastic bag in bin.
C	Close the waste bag.
D	Dispose the bag in accordance with your local regulations.



Dgespc 46, Replace waste bin

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6.4 Checking Resources Status

From the main screen, two buttons in the footer strip allow to check the resources status.

MISSING RESOURCES

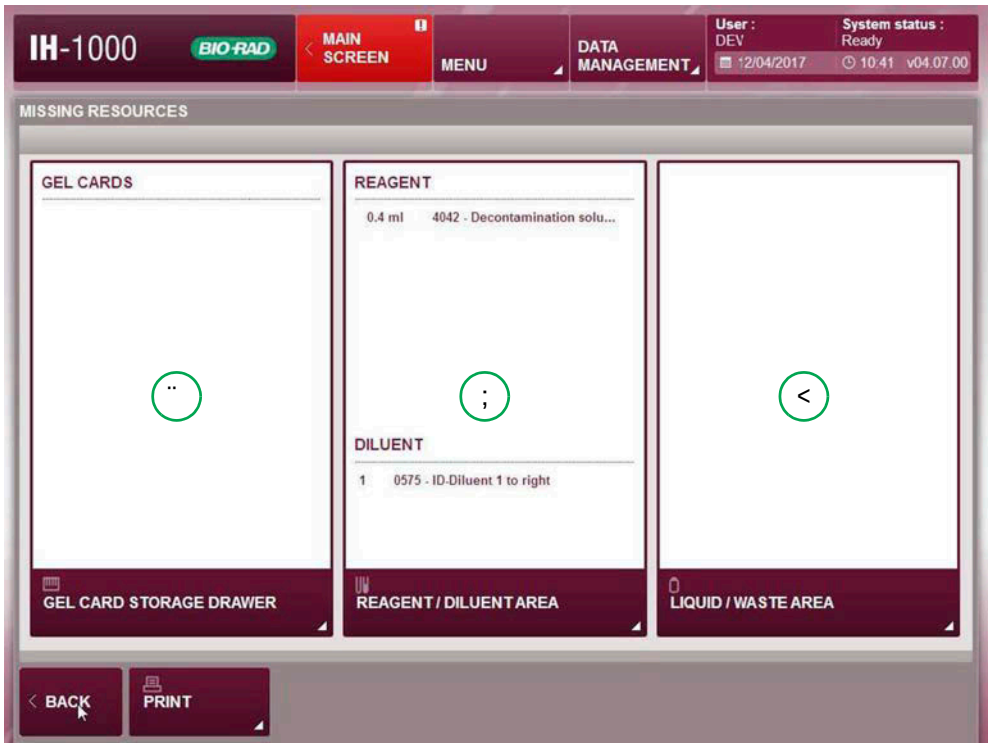
Qcc af_nrcp Kgqqgle Pcqmspacq ml n_ec /./,

RESOURCES ON BOARD

Qcc af_nrcp Pcqmspacq ml @m_pb ml n_ec /.0,

4,2,/ Kgqqgle Pcqmspacq

The **MISSING RESOURCES** button gives access to the following screen, showing all the missing resources.



Dgespc 47, Missing resources

1 Gel cards storage drawer

2 Reagent / Diluent area

0 When the missing diluent concerns both the right and the left side, the number of the wells missing is displayed for each side.

3 Liquids / Wastes area

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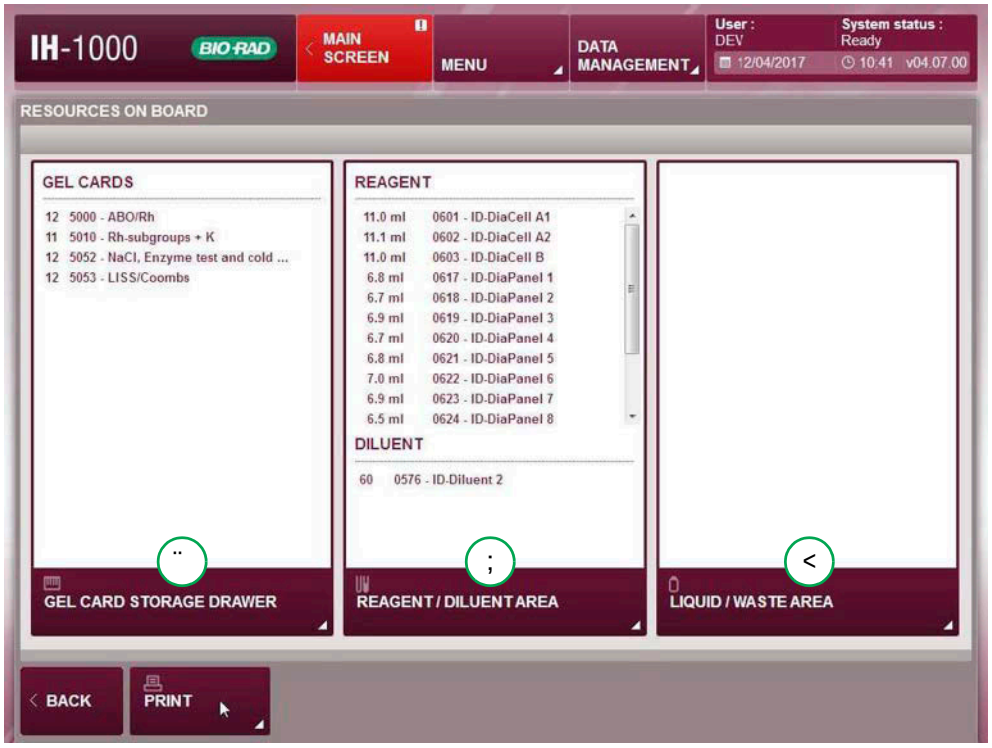
4,2,0 Pcqmspacq m l @m_pb

The **RESOURCES ON BOARD** button gives access to the following screen, showing all the resources already loaded into the instrument (Gel cards, reagents, diluents) and the status of the **LIQUIDS / WASTES** area.



Dgespc 5., Resources on board screen

1 Gel cards storage drawer

Qcc af_nrcp Ecj A_pbq Qrmp_ec Bp_ucp ?pc_ ml n_ec /.1,

2 Reagent / Diluent area

Qcc af_nrcp Pc_ecl r - Bgjsc l r ?pc_ ml n_ec /.1,

3 Liquids / Wastes area

Ajgaigle gl rfgq _pc_ egtcq _aacqq rm rfc ***JGOSGBQ-U?QRCQ ?PC?*** *qapccl ufgaf egtcq bcr_gjcb gldmpk_rgml,*

Qcc af_nrcp K_l_egle Jgosgbq _lb U_qrcq ml n_ec 71,

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4,2,0,/ Ecj A_pbq Qrmp_ec Bp_ucp ?pc_

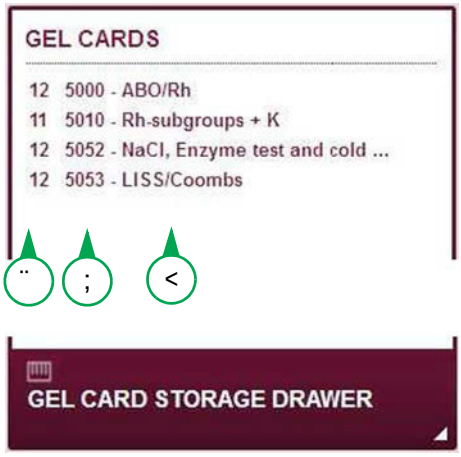
Clicking on this area gives access to the **GEL CARD STORAGE DRAWER** screen which gives detailed information.

See chapter Gel Cards Storage Drawer Screen on page 59.

1 Number of gel cards

2 Code of the gel card type

3 Gel card type



Dgespc 5/, Gel cards information

4,2,0,0 Pc_eclr - Bgjsclr ?pc_

Clicking on this area gives access to the **SAMPLES / REAGENT AREA** screen which contains more detailed information.

See chapter Samples / Reagents Area Screen on page 77.

4 Reagent usable volume (ml)

Sq_`jc tmjskc ; kc_qspcb tmjskc + bc_b tmjskc

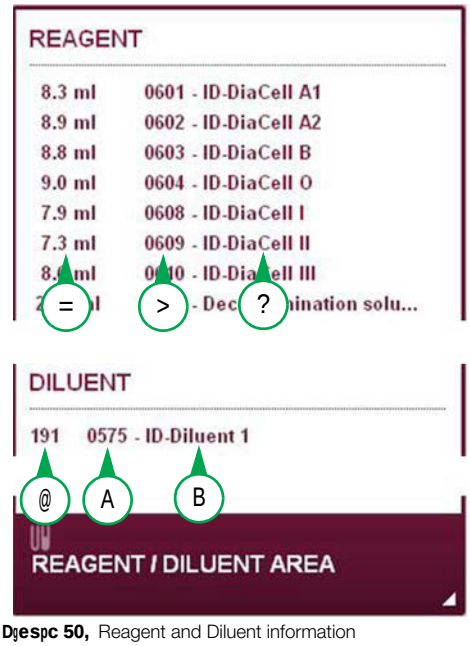
5 Reagent code

6 Reagent type

7 Number of available diluent wells

8 Diluent code

9 Diluent type, with indication of side and quantity (left/right or both)



Dgespc 50, Reagent and Diluent information

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N?EC GLRCLRGML?JJW JCDR @J?L I

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7 Managing Tests

Af_nrcp Mtcptgcu

This chapter presents how to manage the tests.

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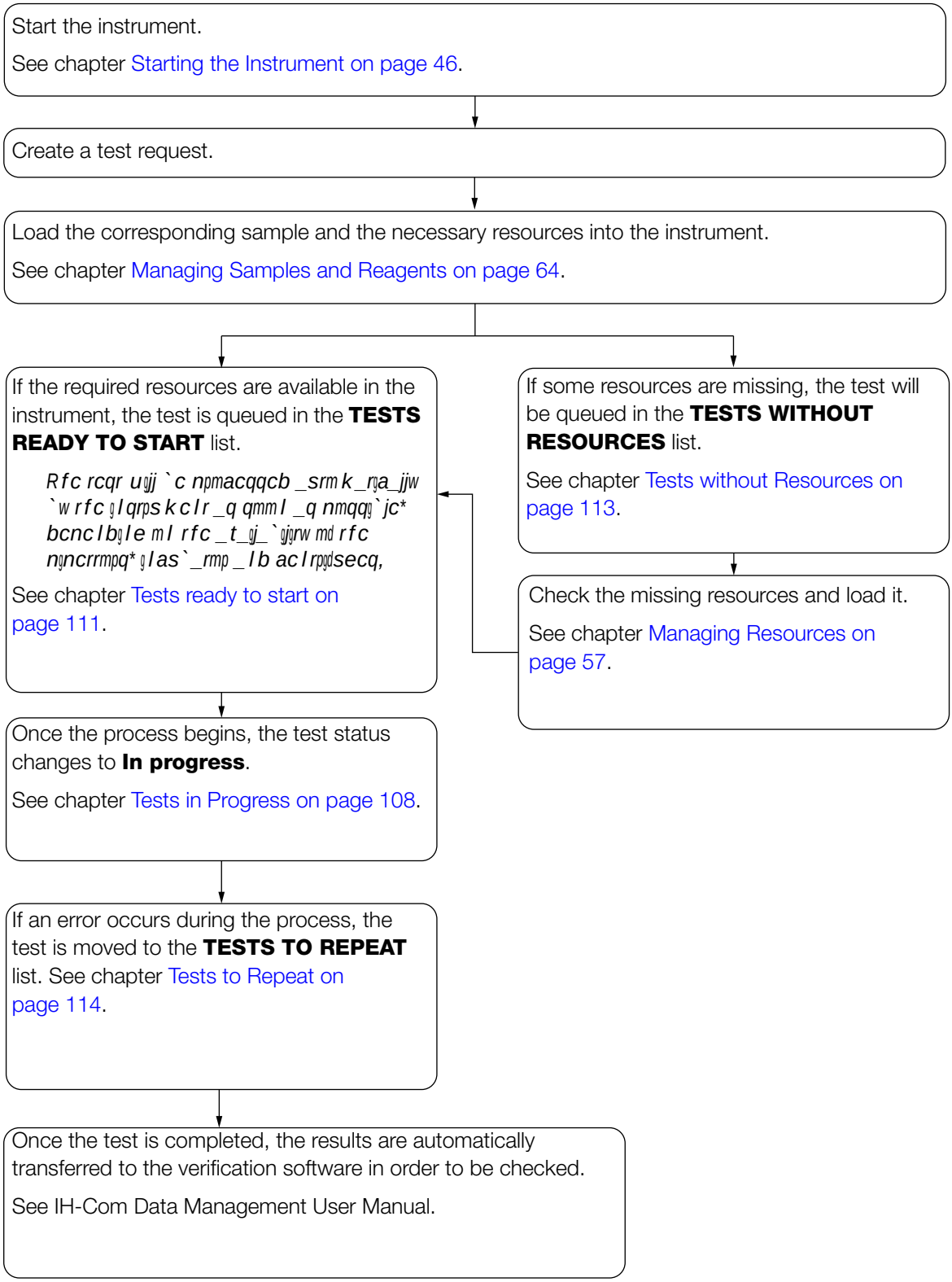
7.1 Performing a Test

The following chart shows a standard process flow for performing tests.

0 Before performing a crossmatch test, make sure that there are enough gel cards loaded on the IH-1000.



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7.2 Performing an Urgent Test

To perform an urgent test the same process applies. Use urgent racks so that the sample is processed before all other samples.

See chapter Sample Racks on page 64.

7.3 TESTS Buttons of the Main Screen

From the main screen, the following buttons allow to access to several functions about tests.

Buttons are disabled if their function does not apply to any test.

	TESTS IN PROGRESS See chapter Tests in Progress on page 108.
	TESTS READY TO START See chapter Tests ready to start on page 111.
	TESTS WITHOUT RESOURCES See chapter Tests without Resources on page 113.
	TESTS TO REPEAT See chapter Tests to Repeat on page 114.
	SAMPLES WITHOUT REQUEST See chapter Samples without Request on page 117.

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7.4 Tests in Progress

This screen displays all the on-going tests in the instrument.

A From the main screen, click on **TESTS IN PROGRESS**.

Dgespc 51, TESTS IN PROGRESS screen

1 Samples special statuses

Emergency sample

Quality control sample

2 Sample barcode number

3 Test description

4 Test start and end time

@j_ai8 pc_j rgkc u fcl rfc rcqr qr_prcb _lb c lbcb,
@jsc8 cqrgk_rcb rgkc u fcl rfc rcqr qfmsjb qr_pr _lb dglgqf,

5 Grid

*Nmqgrgm l md rfc p_ai gl rfc jm_bgle _pc_*

6 Position

Nmqgrgm l md rfc q_ knjc gl rfc p_ai

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7 State

Nyncrrgle glas`_rqml* aclrpgdse_rqml* pc_bgle mp amknjcrcb,*

8 Sorting strip

Ajgai ml rfc amjsk l l_kc rm qmpr rfc b_r_q

9 **DETAILS** button

Rfgq `srrml egtcq _aacqq rm rfc bcr_gjq md rfc qcjcarcb q_knjc rcqr Qcc af_nrcp Bcr_gjq md_ Rcqr gl Npmepcqq ml n_ec //.,

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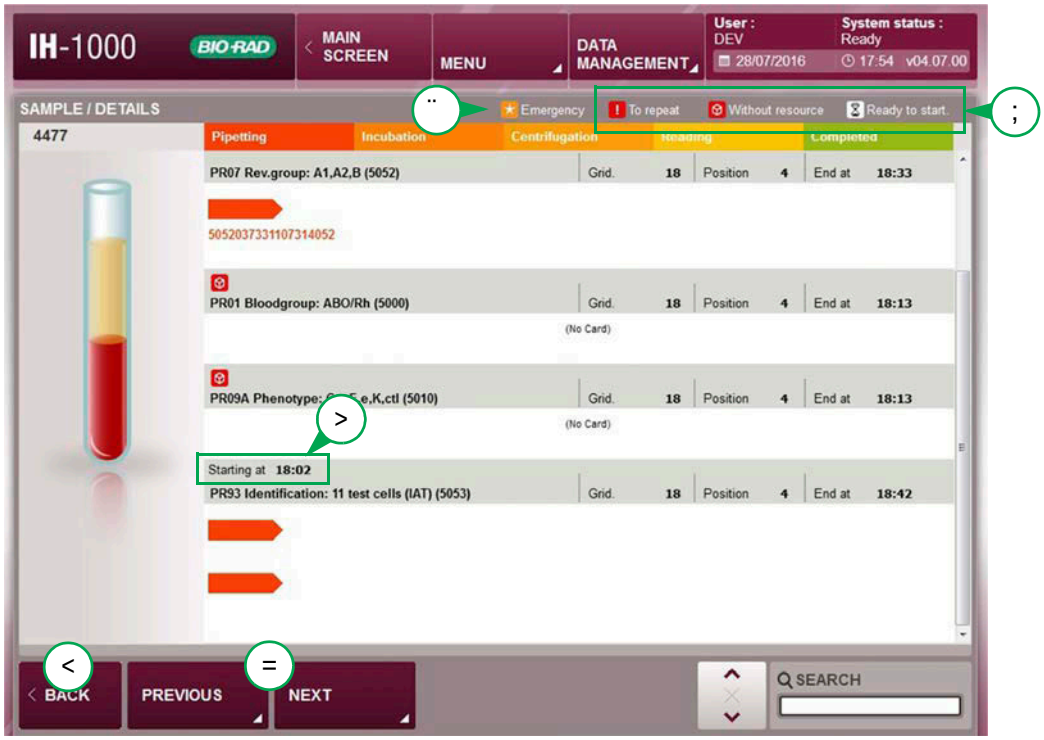
5,2,/ Bcr_gjq md _ Rcqr g l Npmepcqq

A From the **TESTS IN PROGRESS** screen, click on **DETAILS**.

The following screen shows all the ongoing tests for one sample.

Each test uses one or more types of gel cards and can be in a different status. A different color is used for each state.



Dgespc 52, SAMPLE / DETAILS screen

1 Samples special statuses

Emergency sample

Quality control sample

2 Test in progress special statuses

To repeat

Without resources

Ready to start

3 **BACK** button

4 **PREVIOUS** / **NEXT** buttons

Rfc `srrm lq* ***NPCTGMSQ*** *_ lb* ***LCVR*** *_jjmu rm l_tge_rc `crucc l rfc q_ knjcq g l npmepcqq ugrfmsr f_tgle rm pcrsp l rm rfc npctgmsq qapcc l _q ucjj _q rm bgqnj_w rfc bcr_gjq md rfc rcqr npctgmsq mp lcvr rm rfc m lc qcjcarcb,

5 Estimated start time for scheduled test

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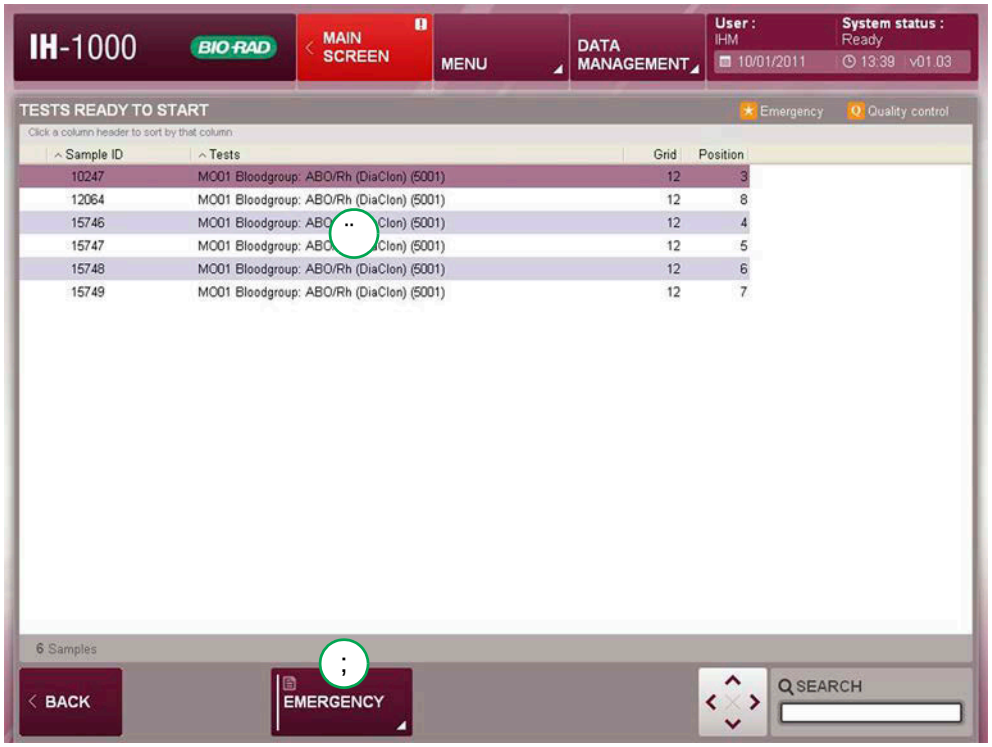
7.5 Tests ready to start

This screen displays the tests that are ready to start: all the required resources are available in the instrument. They will be processed as soon as possible, depending on the availability of the pipettors, incubator and centrifuges.

If necessary resources are present and if no emergency rack is loaded, the processing order depends on the loading order. The first sample loaded will be processed first.

A From the main screen, click on **TESTS READY TO START**.



Dgespc 53, TESTS READY TO START screen

1 Information field

Qcc af_nrcp Rcqrq gl Npmepcqq ml n_ec /.6,

2 **EMERGENCY** button

Qcc af_nrcp Ckcpeclaw ml n_ec //0,

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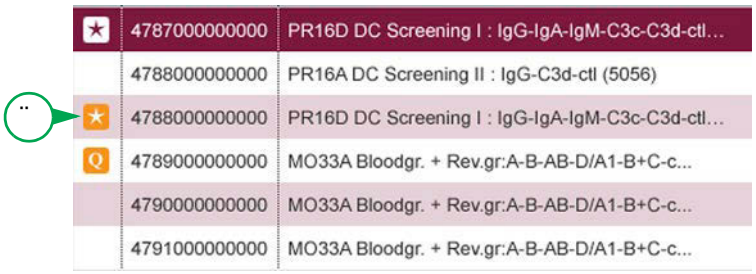
5,3,/ C k cpec l aw

By clicking on the **EMERGENCY** button, the status of the sample changes (1).

See chapter Tests in Progress on page 108.

0 The status can only be changed if there are tests ready to start.



Dęespc 54, Emergency status

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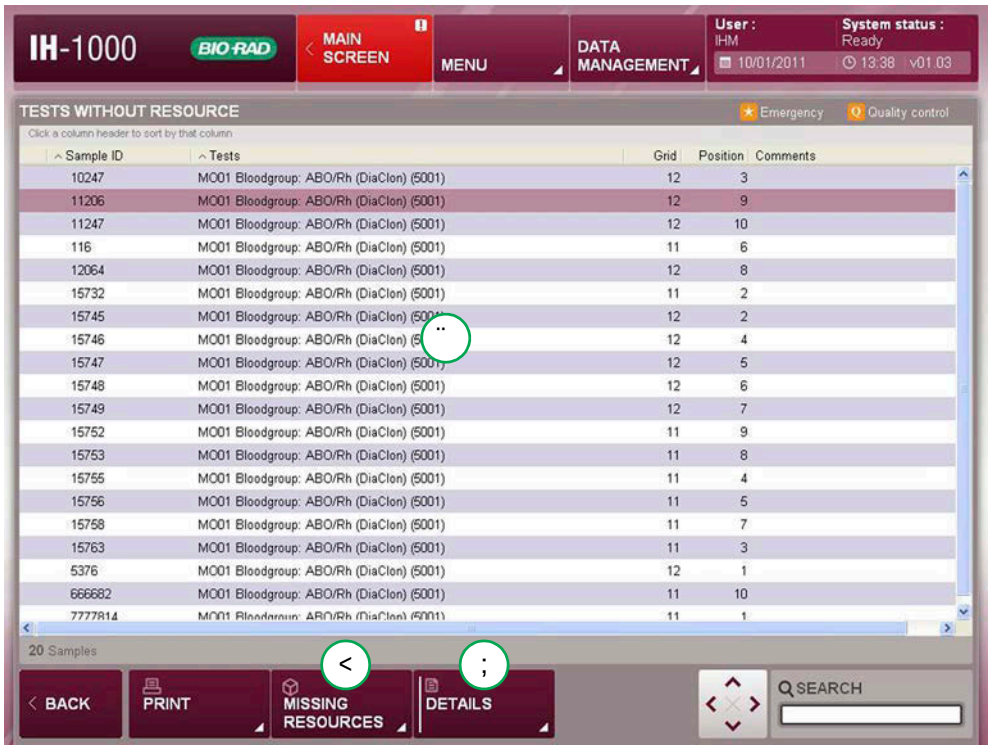
7.6 Tests without Resources

This screen displays the tests that can not be performed because of missing resources.

A From the main screen, click on **TESTS WITHOUT RESOURCES**.



Dgespc 55, TESTS WITHOUT RESOURCES screen

1 Information field

Qcc af_nrcp Rcqrqgl Npmepcqq ml n_ec /.6,

2 **DETAILS** button

Rfgq `srrml egtcq _aacqq rm rfc jgqr md kgqqgle pcqmspacq dmp rfc qcjcarcb rcqr,
Qcc af_nrcp Afcaigle Pcqmspacq Qr_rsq ml n_ec /./,

3 **MISSING RESOURCES** button

Rfgq `srrml egtcq _aacqq rm rfc jgqr md kgqqgle pcqmspacq dmp _jj pcoscqrcb rcqrq,
Qcc af_nrcp Kgqqgle Pcqmspacq ml n_ec /./,

0 It is also possible to display the **MISSING RESOURCES / DETAILS** screen available for one particular test.

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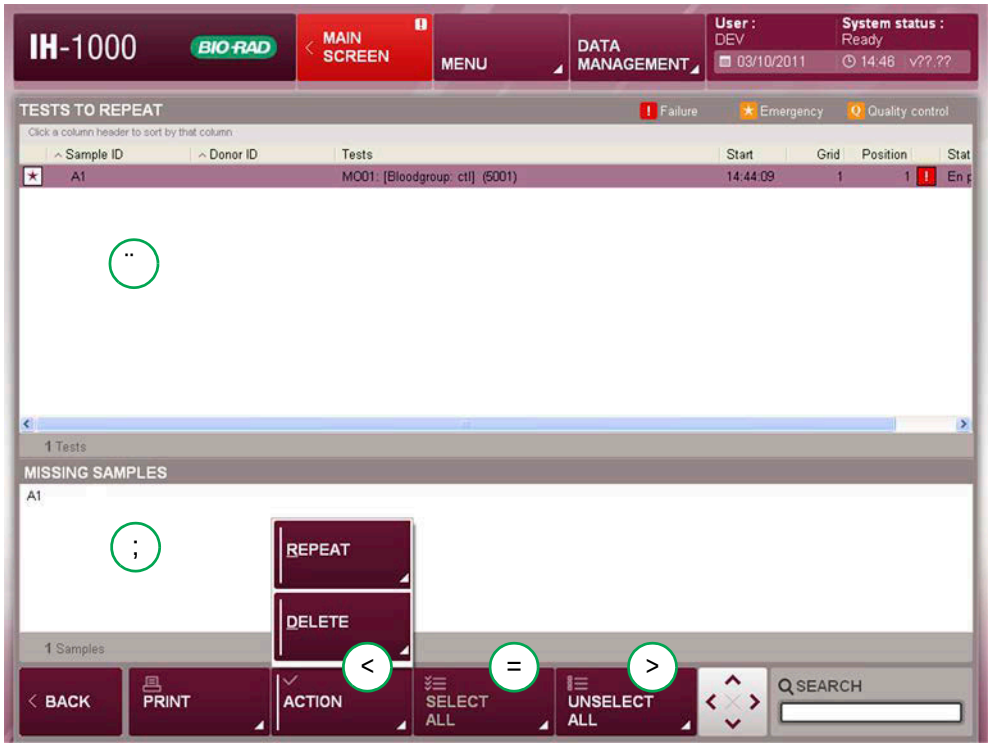
7.7 Tests to Repeat

Tests can encounter errors during process. If so, they are moved to the following **TESTS TO REPEAT** list that informs in which step the instrument was when the error occurred.

0 To be able to repeat failed tests directly from this screen, activate the option **Allow failed tests to be repeated** in the **Option** screen.
Refer also to IH-Com Data Management User Manual.

A From the main screen, click on **TESTS TO REPEAT**.

Rfyq qapccl yq qnjyr ylrm rum k_yl _pc_q8 rfc amknjcrc jyqr md rcqrq yl cppmp &/' _lb rfc pcj_rcb kyqqyle q_knjcq &O',



Dyespc 56, TESTS TO REPEAT screen

1 **TESTS TO REPEAT**: Information field

Qcc af_nrcp Rcqrq yl Npmepcqq ml n_ec /.6,

2 **MISSING SAMPLES**, for each missing sample, the lower list provides the sample barcode.

3 **ACTION** button with 2 options: **DELETE** and **REPEAT**.

4 **SELECT ALL** button

5 **UNSELECT ALL** button

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If the option **Allow failed tests to be repeated** is set, the **REPEAT** function is enabled under the **ACTION** button, allowing the selected profiles to be executed again, after confirmation.

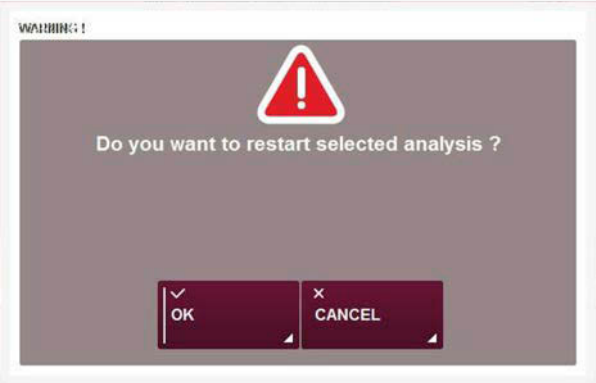
See General Options on page 128.

Otherwise only the **DELETE** button is displayed, to acknowledge the error of all selected items, after confirmation.

If a test is present on the **TESTS TO REPEAT** screen, double click on the test to open a screen displaying explanation of the error.

No test can be repeated if no user is logged in to IH-Com.

A		Select one or several test to be repeated.
B		Select **ACTION**. *Gd rfc mnrgml* ***?jjmu d_gjcb rcqrq rm `c pcnc_rcb*** *gq cl_`jcb,* *Pcdcp rm rfc amk kclr_`mtc,*
C		Select **REPEAT** to repeat the test. *? u_plgle kcqq_ec bgqnj_wq gd q_ knjcq _pc kgqqgle dmp rfc qcjcarcb rcqrq,*



Dgespc 57, Warning message

Gd lm sqcp gq jmeecb gl rm GF-Amk ml jw rfc `srrml* ***A?LACJ*** *gq _t_gj_`jc,*

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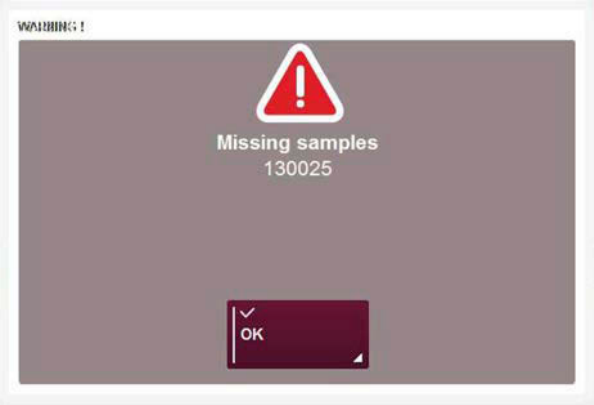
D Confirm to restart the test.

? u_plle bqqnj_wq ctclrs_j kqqqle q_knjcq,



Dqespc 6.,

E Load the required samples.

Pcj_rcb rcqrq qr_rsq rsplq rm ***pc_bw rm qr_pr,***

F Confirm the loading of the samples.

0 Unloaded samples stay in the **TESTS TO REPEAT** area. It is possible to delete them.

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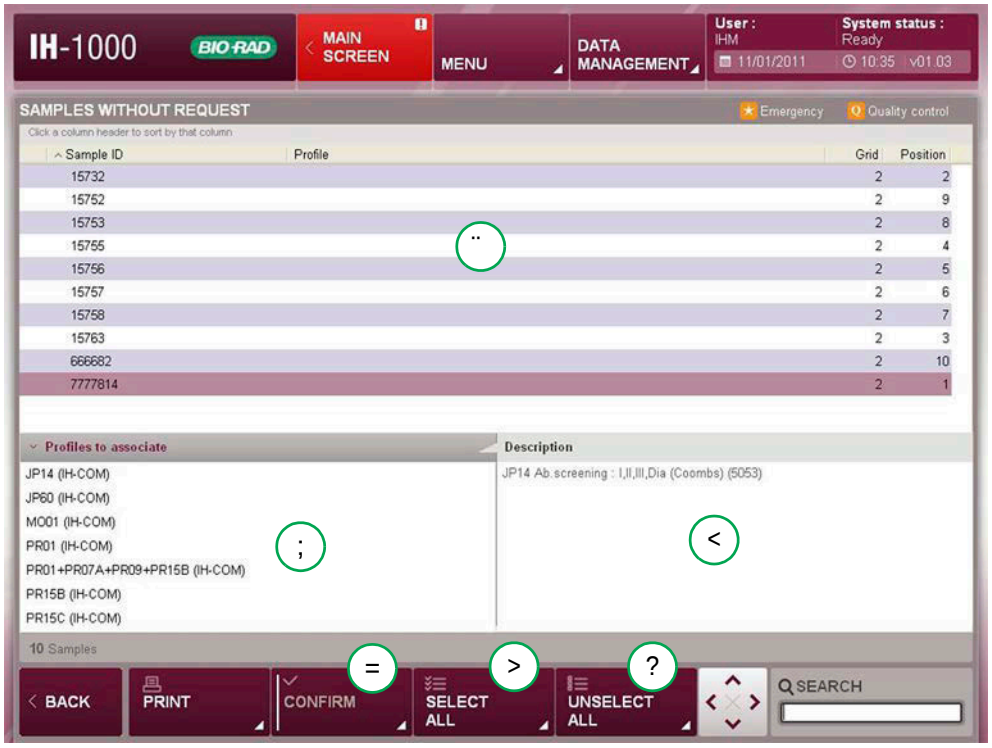
7.8 Samples without Request

A	From the main screen, click on **SAMPLES WITHOUT REQUEST**.



Dgespc 6/, SAMPLES WITHOUT REQUEST screen

1 Sample list

2 Available tests list

3 Description of the tests

4 **CONFIRM** button

5 **SELECT ALL** button

6 **UNSELECT ALL** button

Rm _qqmag_rc _ rcqr

No test can be associated to the sample if no user is logged in to IH-Com.

A	Select a sample in the Samples list (1).
B	Select a test in the Tests list (2).

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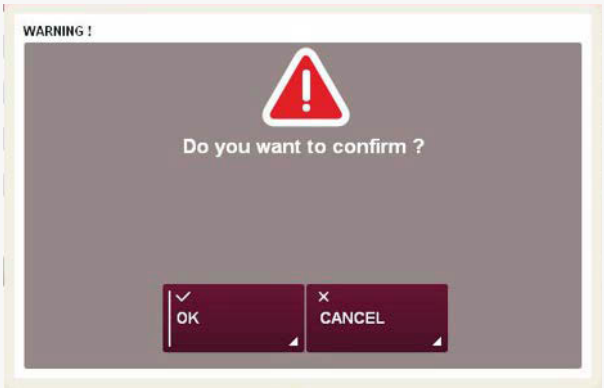
C Click **CONFIRM**.

? am l dgp k _rgm l k cqq_ec _nnc_pq,



Dgespc 60, Confirm test assignment

Gd l m sqcp gq jmeecb g l rm GF-Amk m l jw r f c `srrm l **A?LACJ** gq _ t_gj_ `jc,*

D Click **OK** to confirm the test.

Rfc q_ k njc gq pc k m tcb dpm k rfc jgqr,

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7.9 Checking Pipetting Area Status

This screen allows to monitor the on-going actions in the pipetting area.

A From the main screen, click on the **PIPETTING AREA** in the interactive image.

Dgespc 61, PIPETTING AREA screen

1 37°C Incubator area

2 Balancing gel cards area

Rm bgqnj_w ecj a_pbq sqcb dmp `_j_lac mp ecj a_pbq n_prg_jjw sqcb,

- N_prg_jjw sqcb ecj a_pbq ksqr lmr `c pckmtcb dpmk rfc glqrpskclr _lb pcglqcprcb,

3 Information area

Rfgq gq rfc gldmpk_rgml _pc_ dmp ecj a_pbq sqcb dmp `_j_lac mp ecj a_pbq n_prg_jjw sqcb,

Rfc `_j_lac ecj a_pbq ugjj `c gl nmqgrgmlq /.+/0 mljw_lb_bcd_sjr rwnc `_pambc_lb pck_glgle rgkc ugjj `c bgqnj_wcb,*

*Rfc glqrpskclr ugjj qrmpc_lb sqc n_prg_jjw sqcb ecj a_pbq dmp sn rm /3. kglsrcq _drcp rfc a_pb gq ngcpacb_lb rfcl bgqa_pb rfck, Rfc rwnc md ecj a_pb*_t_gj_`jc ucjjq_lb rgkc pck_glgle ugjj `c bgqnj_wcb,*

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4 Pipetting area Left and Right

5 **SWITCH ON**

6 **SWITCH OFF**

7 **OPEN** (pipetting area window)

Qcc Mnclļle rfc Nŋncrŋle ?þc_ Uļlbmu ml n_ec /0/

8 Status left pipettor

9 Status right pipettor

10 Door state (displayed in red when open, in main screen the pipetting area is also displayed in red)

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5,7,/ Mnclgle rfc Ngncrrgle ?pc_ Uglbmu

- Pc_b rfc dmjjmugle glqrpsargml amk njcrcjw `cdmpc mnclgle rfc ngncrrgle _pc_ uglbmu, Ml+ emgle rcqrq ugjj `c glt_jgb,
  Gl _lw a_qc* gr gq dmp`gbbcl rm mncl rfc ngncrrgle _pc_ uglbmu k_ls_jjw,
- @c a_pcdsj ufcl _aacqqgle glqgbc rfc ngncrrgle _pc_* cqncag_jjw ugrf lccbjcq* GB+A_pbq ngcpagle kmbsjc* fc_r md glas`_rmp,,,
- Bm lmr fgr rfc lccbjc,
- ?jj p_aiq ksqr `c pckmtcb `cdmpc mnclgle rfc ngncrrgle _pc_ uglbmu* gd rfgq amlbgrgml gq lmr pcqncarcb rfcpc gq _ pgqi md amjjgqgml ugrf rfc p_aiq,
  @gmjmega_j pgqi gl a_qc md npmhcargml,
- Bspgle rfc glgrg_jgx_rgml* gd _jj p_aiq f_tc lmr `ccl pckmtcb rfcpc gq _ pgqi rm b_k_ec rfc glqrpskclr,

A Remove all returned racks or racks in waiting position.

Qcc af_nrcp Pckmtc _jj P_aiq ml n_ec 7.,

B Click on **OPEN** (pipetting area window).

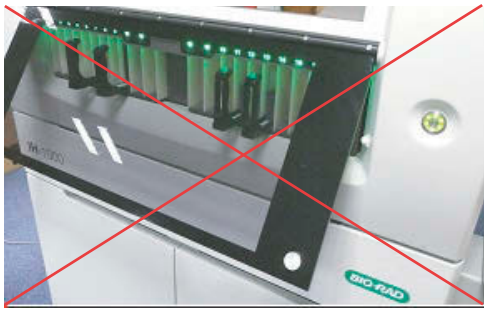
Ufcl ajmqgle rfc uglbmu rfc glqrpskclr ncpdmpkq _l glgrg_jgx_rgml _lb qa_lq rfc umpir_`jc _e_gl,*

Sqcb ecj a_pbq _pc nsr rm rfc u_qrc `gl,

Rfc pcoscqrq rf_r f_tc `ccl qr_prcb `cdmpc mnclgle rfc ngncrrgle _pc_ uglbmu f_tc rm `c qclr _e_gl,

0 When the pipetting area window is in error, the **OPEN** button is highlighted in red.

All racks removed - Correct!



Racks still loaded - Not correct

Dgespc 62,

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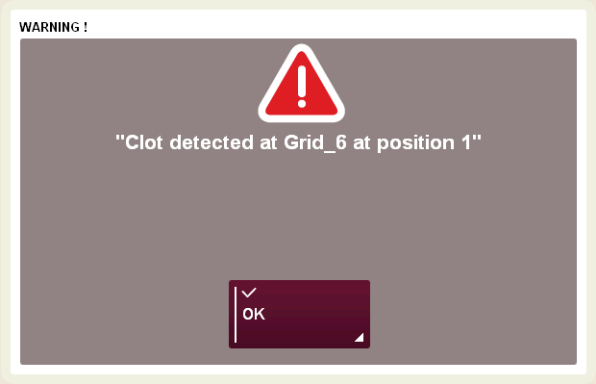
5,7,0 Ajmr Bcrcargm l Cppmpq

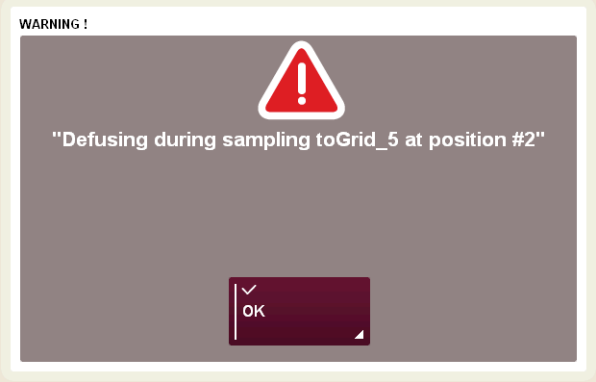
The IH-1000 knows three different clot detection errors:

- Clot detected;



Dgespc 63, Clot detected error message

- Defusing during sampling;



Dgespc 64, Defusing during sampling error message

- Distribution canceled.

Dgespc 65, Distribution canceled error message

0 All the tests with error go back to the **TESTS TO REPEAT** screen. Go to that list and click on the single test to display the error message.
See chapter Tests to Repeat on page 114.

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5,7,0,/ Ajmr Bcrcargml

When a clot detection of a needle occurs, the user must loose the needle from its obstruction.

?l cppmp kcqq_ec gq bgqnj_wcb,

The resources present in the pipetting area undergo the following management:

- For the pipettor which the needle is clotted, the tests are stopped and set in "**Tests to repeat**".
- For the other pipettor, which the needle is not clotted, no new pipetting batch is engaged. The current pipetting continues until the users action.

- @c a_pcdsj ufcl _aacqqgle glqgbc rfc ngncrrgle _pc_* cqncag_jjw ugrf lccbjcq* GB+A_pbq ngcpagle kmbsjc* fc_r md glas`_rmp,,,
- Gl _lw a_qc* gr gq dmp`gbbcl rm mncl rfc ngncrrgle _pc_ uglbmu k_ls_jjw,
- Sqc ejmtcq dmp _jj mncp_rgmlq,
  Bm lmr kmtc p_aiq* rs`cq* tg_jq* pc_eclr p_aiq* ecj a_pbq,
  @c a_pcdsj lmr rm kmtc rfc ngncrrmp _pk gl rfc fmpgxmlr_j bgpcargml,
  Kmtc rfc lccbjc qsnnmpr _q glbga_rcb ml rfc nfmrmq* mrfcpugqc rfcpc gq _ pgqi rm a_sqc b_k_ecq ml rfc GF-/...,
- Sqc _ bpw lml umtcl ugnc rm ajc_l rfc lccbjc rm _tmgb b_k_ec ml rfc lccbjc am_rgle,

A Click on the **PIPETTING AREA** of the main screen.

*Rfc **NGNCRRGLE ?PC?** qapccl _nnc_pq,*
Qcc af_nrcp Afcaigle Ngncrrgle ?pc_ Qr_rsq ml n_ec //7,

B Click **OPEN**.

Rfc glqrpskclr mnclq rfc ngncrrgle _pc_ uglbmu mlac rfc ngncrrgle _pc_ gq _aacqqg`jc &ngncrrgle gq dglgqfcb',*
Qcc af_nrcp Mnclgle rfc Ngncrrgle ?pc_ Uglbmu ml n_ec /0/,
Rfc qapccl lcvr gq bgqnj_wcb,

Dgespc 66, Clot detected - information

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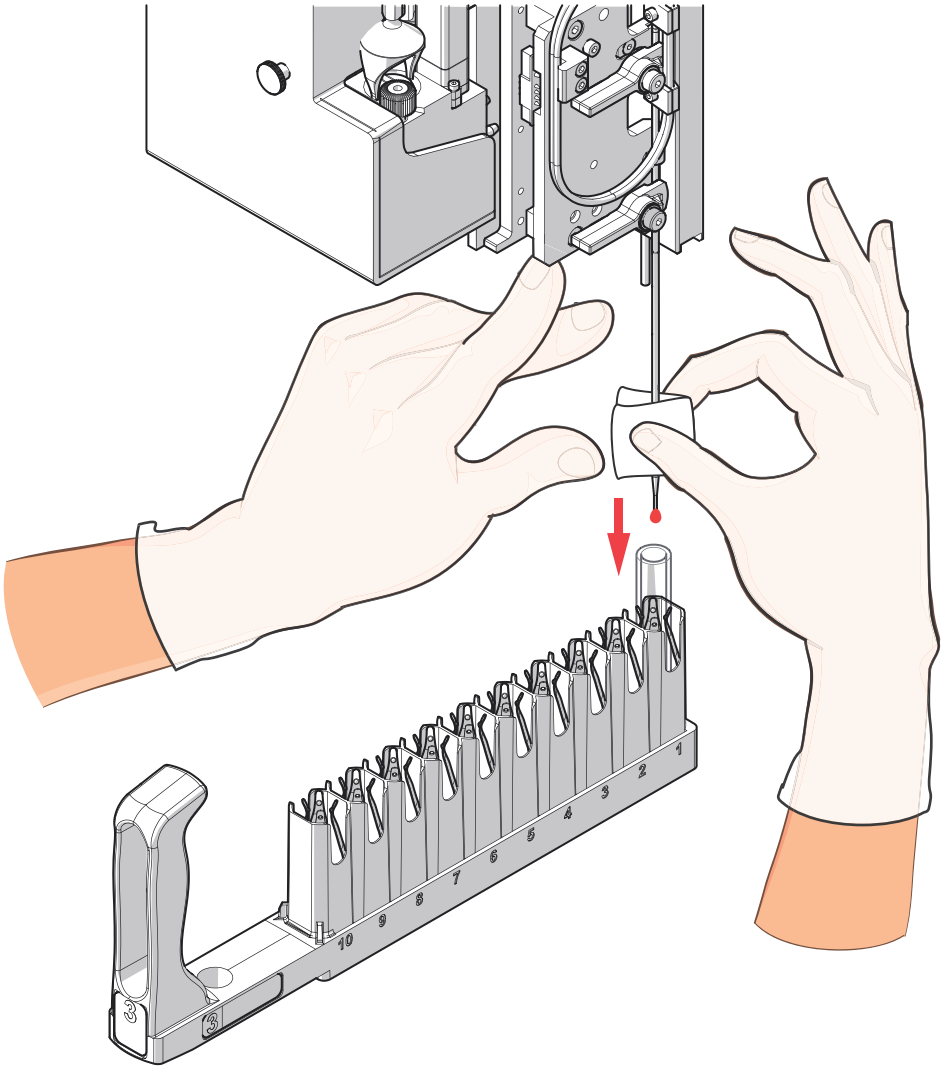
C	When the pipetting area window is open, lift slowly the support of the needle.
D	Visually verify the presence of a clot at the tip of the needle.
E	If no clot is observed just leave the needle at the top of the support position. *Gd _ ajmr bcrcargm l k cqq_ec am l rg l scq rm _nnc_p c t c l gd r f cpc gq l m ajmr npcqc l r* a_jj _ qcptgac c l eg l ccp, If there is a clot, with a non woven wipe clean the tip of the needle and if possible remove manually the clot.
F	Close the pipetting area window. • All the present gel cards on the pipetting area are detected and thrown to the waste bin. • All the present resources are identified again. • The processing procedure can restart.



Dgespc 67,

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8 Options

Af_nrcp Mtcptgcu

This chapter presents the available options to configure the instrument.

0 This configuration is allowed only for specific users; login and password are required.

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8.1 Options Screen

The **OPTIONS** screen can be accessed from any screen where the **MENU** button appears.

A		Click on **MENU**.
B		Click on **OPTIONS**. *Rfc_srfclrya_rjml qapccl_nnc_pq,* **Dyespc 7.,** Options - Authentication screen
C		Type your login and password.
D		Click **OK**.

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Dgespc 7/, Options screen

1 **GENERAL** options

Qcc af_nrcp Ec Icp_j Mnrgm lq ml n_ec /06,

2 **PROFILE** options

Qcc af_nrcp Npmdgjc Mnrgm lq ml n_ec /10,

3 **CONTROLS** options

Qcc af_nrcp Aml rpmjq Mnrgm lq ml n_ec /12,

4 **DISABLED MODE** options

Qcc af_nrcp Bgq_`jcb Kmbc Mnrgm l ml n_ec /15,

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8.2 General Options

Dgespc 70,

Ajmqc ugl bmu _drcp

This option defines the time (in seconds) before the software automatically comes back to the main screen. Select **Never** to disable.

0 The user can close and open again the software without any effect.

Qmslb rm nj_w ml cppmp

This option defines the sound that will be played in case of an error.

Select **No Sound** to disable.

@_pambc qr_pr dgjrcp

This option allows to specify the amount of digits to suppress at the beginning of the samples barcode.

See chapter Barcode Exception Mask Filter Option on page 130.

@_pambc clb dgjrcp

This option allows to specify the amount of digits to suppress at the end of the samples barcode.

See chapter Barcode Exception Mask Filter Option on page 130.

- K_ic qspc rf_r rfc dgjrcpgle bmcq lmr pc k mtc bgegrq sqcb `w GF-Amk _lb-mp JGQ dmp _ npmncp q_k njc gbc lrgdga_rgml, Mrfcpugqc* GF-Amk k_w bcrcar _ bgqapcn_law,

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@_pambc Cvacnrgml K_qi&q' Dgjrcp

To define exceptions for digits suppression in **Barcode start filter** and **Barcode end filter** options.

See chapter Barcode Exception Mask Filter Option on page 130.

Qfmu `srrml B_r_ k_l_eckclr

To enable or disable the Data management button in the main screen (check to enable).

Sqc H_n_lcqc @_pambcq

To inform the instrument that resources are with Japanese barcodes (check to activate).

A_n bcrcargml _argt_rcb

To enable the cap detection function (check to activate).

It is possible to activate the samples cap detection during the racks identification.

0 Input for samples is always enabled.

If this option is activated the system will detect caps, see Cap Detection on page 139.

If this option is deactivated, no cap will be detected.

?jjmu d_gjcb rcqrq rm `c pcnc_rcb

This option enables the **REPEAT** button. If all resources are available, failed test can be repeated directly from the **TESTS TO REPEAT** screen (check to enable).

See chapter Tests to Repeat on page 114.

0lb acjj qsqnclqgml dmp ?@M rcqrgle

This option enforces the pipettors to realize one sample take (and eventually dilution) for each distribution concerning the ABO tests family (check to enable).

0 This behavior is legally expected in some countries.
All bloodgroup assays are concerned.

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6,0,/ @_pambc Cvacnrgml K_qi Dgjrcp Mnrgml

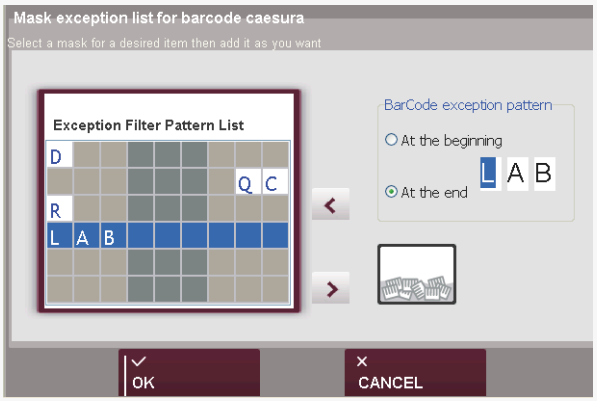
This option defines exceptions for barcode filtering set with **Barcode start filter** and **Barcode end filter**. See the examples on the next page.

I K_ic qspc rf_r rfc dgjrcpg le bmcq lmr pc k m t c bgegrq sqcb `w GF-Am k _lb-mp JGQ dmp _ npmncp q_k njc gbc l rgdga_rgm l, Mrfcpugqc* GF-Am k k_w bcrcar _ bgqapcn_l aw,

0 This option is available only if **Barcode start filter** and/or **Barcode end filter** options are active (value different of **0**).

A In **Options** screen, select **Customize** to open the **Barcode Exception Mask(s) Filter** option.

Qcc @_pambc Cvacnrgml K_qi&q' Dgjrcp ml n_ec /07,
Rfc dmjjmugle qapccl _nnc_pq,



Dgespc 71, Mask exception list for barcode caesura

B Configure the table of exceptions:

- Maximum number of digit: 3
- Maximum number of rules: 6
- Characters allowed:
  a b c d e f g h l j k l m n o p q r s t u v w x y z
  A B C D E F G H I J K L M N O P Q R S T U V W X Y Z
  0 1 2 3 4 5 6 7 8 9
  Space ! “ # $ % & ’ ( ) * + , - . / : ; < = > ? @ [\ ] ^ { | } ~

C In **Barcode exception pattern** area, enter required characters and define if they should stay **At the beginning** or **At the end**.

D Click on the arrow to add the rule to the list.

E Click on **OK** to validate the exception list.

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Pck_piq

According to the example of exception table above (Figure 93), the sample barcodes are filtered, but the system does not suppress digits for the samples barcodes:

- starting with **D**, **R** and **LAB**;
- finishing with **QC**.

See the examples below.

Dgjrcpg le apgrcpg_

- **Barcode start filter** = 2
- **Barcode end filter** = 1
- Exception criteria = see table above

Q_k njc `_pambcq `cdmpc dgjrcpg le		Q_k njc `_pambc _drcp dgjrcpg le
P00001		000
XP0002		000
DP0003	→	**B**P0003 &*Cvacnrgm l* lmr dgjrcpcb'*
ZP0004		000
RP0005QC		**P**P0005**OA** &*Cvacnrgm l* lmr dgjrcpcb'*
WP0006		000
LAB0009		**J?@**0009 &*Cvacnrgm l* lmr dgjrcpcb'*

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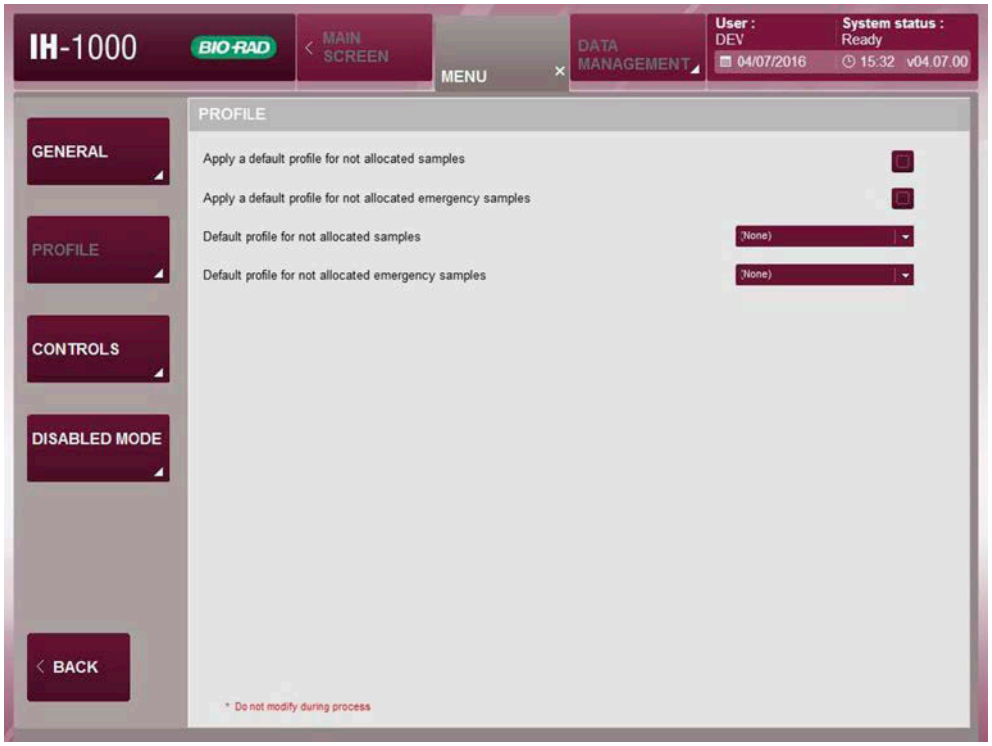
8.3 Profile Options



Dgespc 72,

It is possible to define and to apply a default profile for not allocated samples and not allocated emergency samples.

0 Default profile does not apply to Low volume segment blood (racks of type 4 - Barcode 04 or 14). Samples are displayed in **SAMPLES WITHOUT REQUEST** screen.
See chapter Using Low Volume Segment Blood on page 66.
For details about how to assign a profile, refer to the Data Management software User Manual (Test groups).

?nnjw bcd_sjr npmdgjc dmp lmr _jjma_rcb q_ k njcq

This option allows to choose whether the default profile must apply for not allocated samples or not.

If the default profile is not applied, a specific profile must be assigned for each one.

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?nnjw bcd_sjr npmdgjc dmp lmr _jjma_rcb c k cpec l aw q_ k njcq

This option allows to choose whether the default profile must apply for not allocated urgent samples or not.

If the default profile is not applied, a specific profile must be assigned for each one.

For details on how to identify a urgent tube, see Emergency Sample Rack on page 69.

- Gd r f c mnrgm l **Apply default profile for not allocated samples** gq qcr* _ q_ k njc jm_bcb u gr f lm qnca gdga pcoscqr dmp rcqr u gjj `c _srm k _rga_jjw rcqrcb u gr f r f c bcd_sjr npmdgjc* mrf cp u gqc _ qnca gdga npmdgjc k sqr `c _qqge l cb dmp c_a f q_ k njc,

Bcd_sjr npmdgjc dmp lmr _jjma_rcb q_ k njcq

This options allows to choose which profile will be assigned to the tubes without test.

This option is active only if the check box **Apply default profile for not allocated samples** is checked.

Bcd_sjr npmdgjc dmp lmr _jjma_rcb c k cpec l aw q_ k njcq

This option allows to choose which profile will be assigned to the not allocated urgent samples.

This option is active only if the check box **Apply default profile for not allocated samples** is checked.

For details on how to identify a urgent tube:

See chapter Emergency Sample Rack on page 69.

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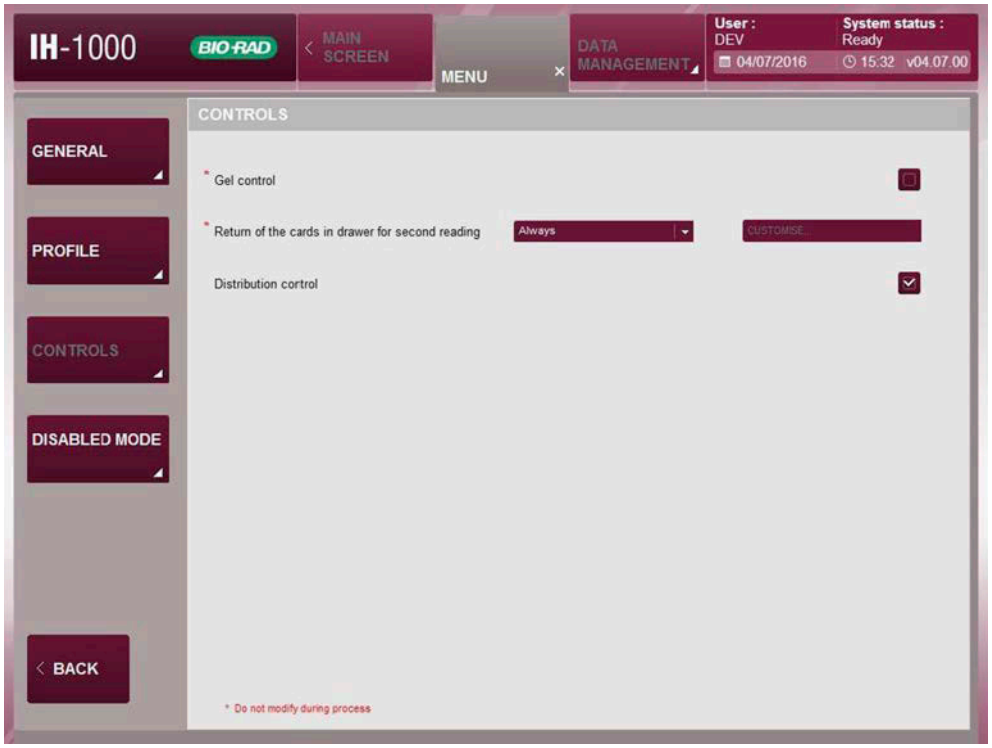
8.4 Controls Options



Dgespc 73,

The **Controls** area allows to activate:

Ecj Amlrpmj

0 If this option is activated, the camera checks the gel of the card before the gel card is used (e.g. presence of air bubbles - Gel card unusable, it is sent to the waste bin).

Pcrsplmdrfc a_pbqglbp_ucpdmpqcamlbpc_bgle

Choose between:

Lctcp	No card is returned for second reading.
?ju_wq	All cards are returned for second reading.
Mljwgdslqncaggcbpcqsjr	Gel card with unspecified results. Unspecified results: ?, LIQ, dp, wF, wR, wP, wD, L, W, E See chapter Test, Interpretation and Result on page 31.
Asqrmkgxcb	Only selected results will return the gel cards. Press the button **Customize** to define the list (see below).

0 If the drawer is open or the gel cards trays are full during card reading, the cards will be thrown away automatically.

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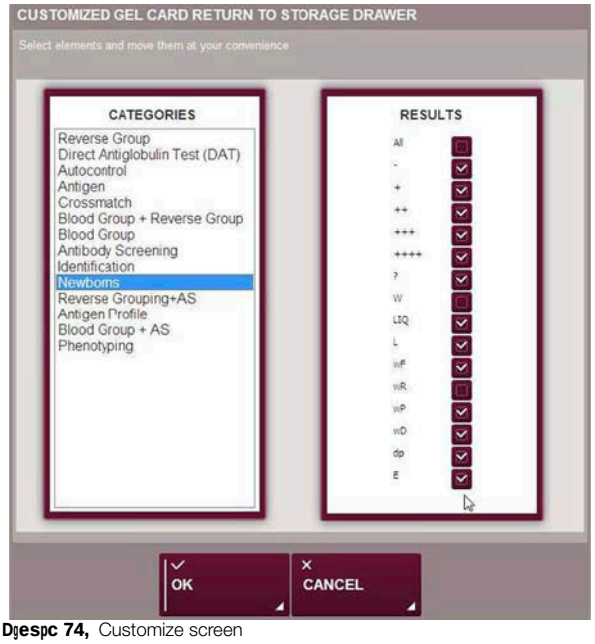
ASQRMK&XC

Choosing a customized return of the gel cards enables a customization screen.

- Select available results for given categories or use **All** check box to select or de-select all results.
- Click **OK** to confirm.

  Qcc af_nrcp Pcrspl mdrfc A_pbq gl Bp_ucp dmp Qcamlb Pc_bgle Mnrgml ml n_ec /13,



Dgespc 74, Customize screen

Bgqrpg`srgml Amlrpmj&os_jgr_rgtc'

0 The option is permanently activated.

IH-1000 software records all information on tests processed. If a volume control error occurs, interpretation code and image of each well used are transferred to IH-Com Data Management software.

6,2,/ Pcrspl mdrfc A_pbq gl Bp_ucp dmp Qcamlb Pc_bgle Mnrgml

6,2,/,/ Pck_glgle A_pbq Jma_rgmlq gl rfc Bp_ucp

If the **Return of the cards in drawer for second reading** option is activated, a counter on the main screen displays free card places in the drawer (only if less than 12).

Dgespc 75, Cards locations in the drawer

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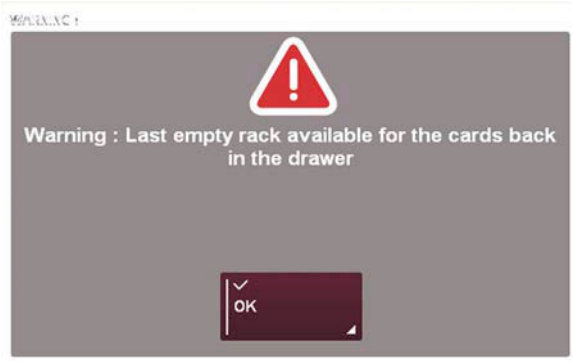
If only one gel card tray remains empty in the drawer, a warning message is displayed:



Dgespc 76,

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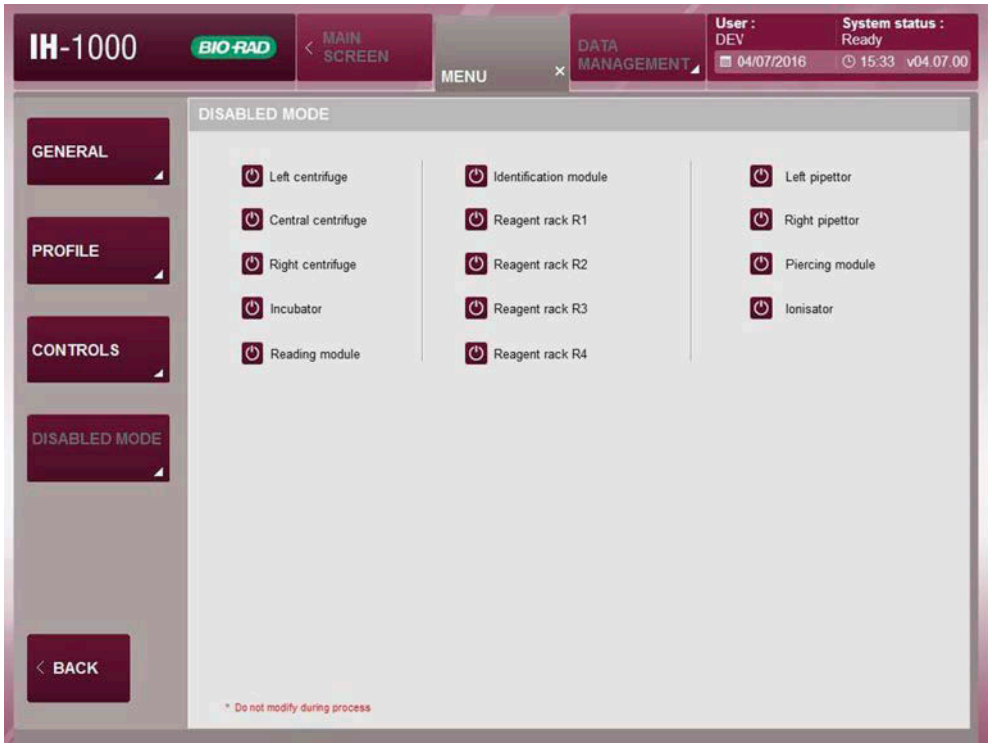
8.5 Disabled Mode Option

These options allow to disable some of the instrument components.

A module should be disabled if too many errors occur on it.



Dgespc 77,

A	Click on a component button. *Rfc_srfclrga_rgml qapccl_nnc_pq,*

Dgespc /.., Disable component - Authentication screen

0	A disabled component has a grey button.
B	Enter your login and password.
C	Click on **OK**.

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D Enter <YES> and click **OK** to confirm disabling of component.

Dgespc /./, Disable component - Confirm screen

- @c a_pcdsj u f_r rm bgq_`jc, Gd cqqc l rg_j n_prq _pc bgq_`jcb* gr gq lmr nmqqg`jc rm am l rg l sc rm mncp_rc r f c g l qrps k c l r,

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8.6 Cap Detection

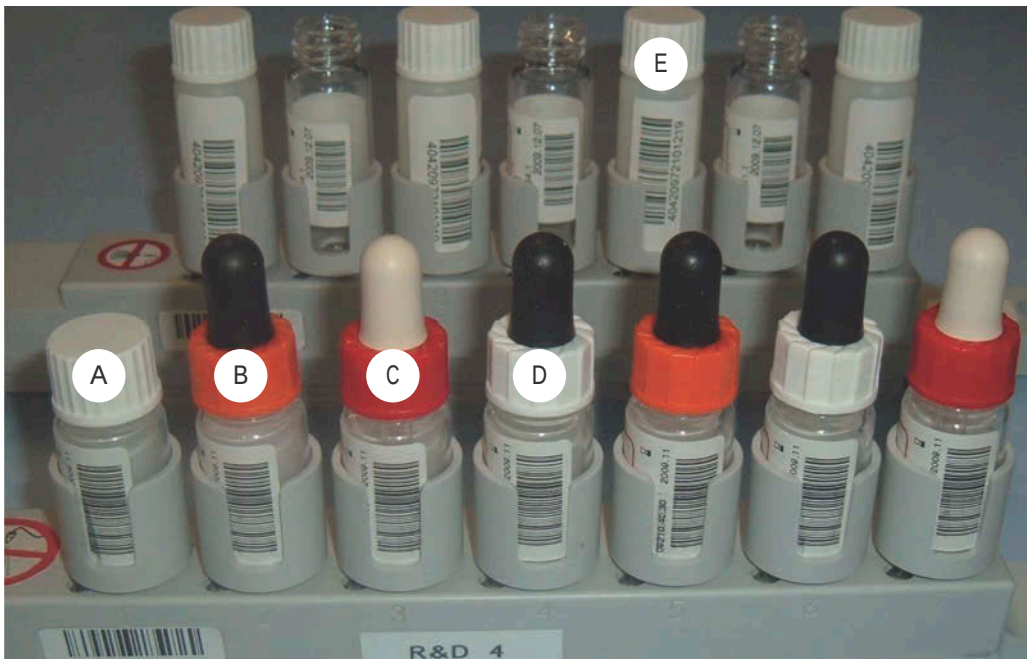
Rfc GF-/... ksqr lmr `c cvnmqcb rm bgpcar qs lje fr,
Gd rfgq am lbgrgm l gq lmr pcqncarcb* rfcpc gq _ pgqi rm lmr pc_b rfc `_pambc* rm lmr bcrcar rfc a_n _lb rm ap_qf rfc lccbjc,

If the cap detection option is deactivated, no cap will be detected.

If this option is activated, only the valid functions are activated.

6,4,/ Rwnc md Pc_ec lr Tg_jq ugrf Bcrcarcb A_n

All these caps are detected by IH-1000.



Dgespc /.0, Reagent cap detection

- Type A-B-C-D on 5 ml vial
- Type E on 10 ml vial (Other caps can not be introduced into the IH-1000)
- Type E on SETUP CLEAN vial

0 10 ml vials with a dropper can not be loaded.

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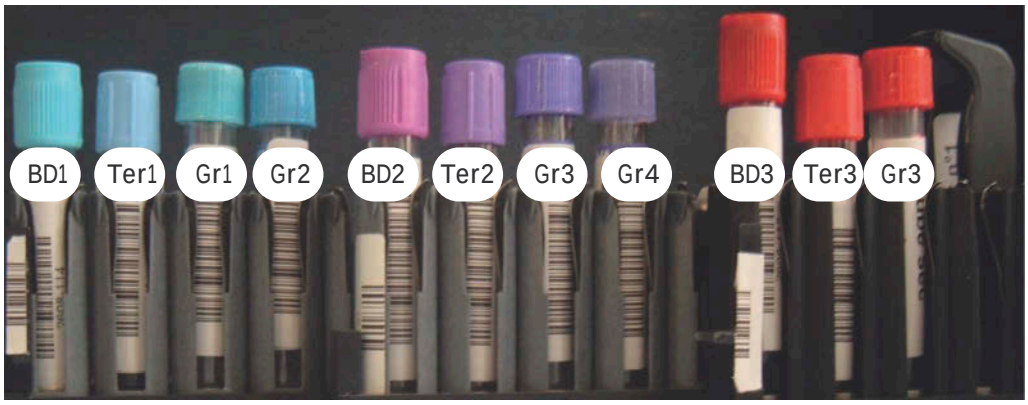
6,4,0 Rwnc md Qr_lb_pb Rs`cq ugrf Bcrcarcb A_n

These types of tubes must be charged only on rack with code 01 or 11, and in case of segments samples in rack 04 or 14.

- Gd rfcqc amlbgrgmlq_pc lmr pcqncarcb* rfcpc gq_pgqi rm ap_qf rfc lccbjc,

All these caps are detected by IH-1000.



Dgespc /.1, Cylindrical tubes cap detection

Pcd	@p_lb	K_lsd_arspcp Pcdcpclac &/'	Amjmp	Qgxc &0'
@B/	BD diagnostic	367704	Opaque blue	13*75
@B0	BD diagnostic	367862	Opaque purple	13*75
@B1	BD diagnostic	367614	Opaque red	13*75
Rcp/	Terumo	VF-054SBCS	Opaque bleu	13*75
Rcp0	Terumo	VF-054SDK	Opaque purple	13*75
Rcp1	Terumo	VF-054SAS	Opaque red	13*75
Ep/	Greiner	454322	Opaque light blue	13*75
Ep0	Greiner	454320	Opaque dark blue	13*75
Ep1	Greiner	454036	Opaque dark purple	13*75
Ep2	Greiner	454021	Opaque light purple	13*75
Ep3	Greiner	454027	Opaque red	13*75

(1) All tubes with the same cap are detectable.

(2) All tubes higher than 100mm with cap, must not be charged on the IH-1000.

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6,4,0,/ Rwnc md Awjg l bpga_j Rs`cq A_nq lmr Bcrcarcb

The translucent colors: red, blue, purple are not detected.

All the other colors are detected.

Dgespc /.2, Cylindrical tubes cap detection

6,4,1 Jmu Tmjs k c Rs`c &dmp Pcb Acjjq m l jw' A_n Bcrcargm l

Not valid function (reliability less than 100%).

Low volume tube (for red cells only) must be used only on rack with code 02 or 12.

- Gd rfgq am l bgrgm l gq lmr pcqncarcb* rfcpc gq _ pgqi rm ap_qf rfc lccbjc,

6,4,2 Njs l ecp A_n Bcrcargm l

Not valid function (reliability less than 100%).

These types of tubes must be loaded only on rack with code 03 or 13.

- Gd rfgq am l bgrgm l gq lmr pcqncarcb* rfcpc gq _ pgqi rm ap_qf rfc lccbjc,

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N?EC GLRCLRGML?JJW JCDR @J?L I

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9 Maintenance

Af_nrcp Mtcptgcu

This chapter presents the maintenance operation that can be performed on the instrument.

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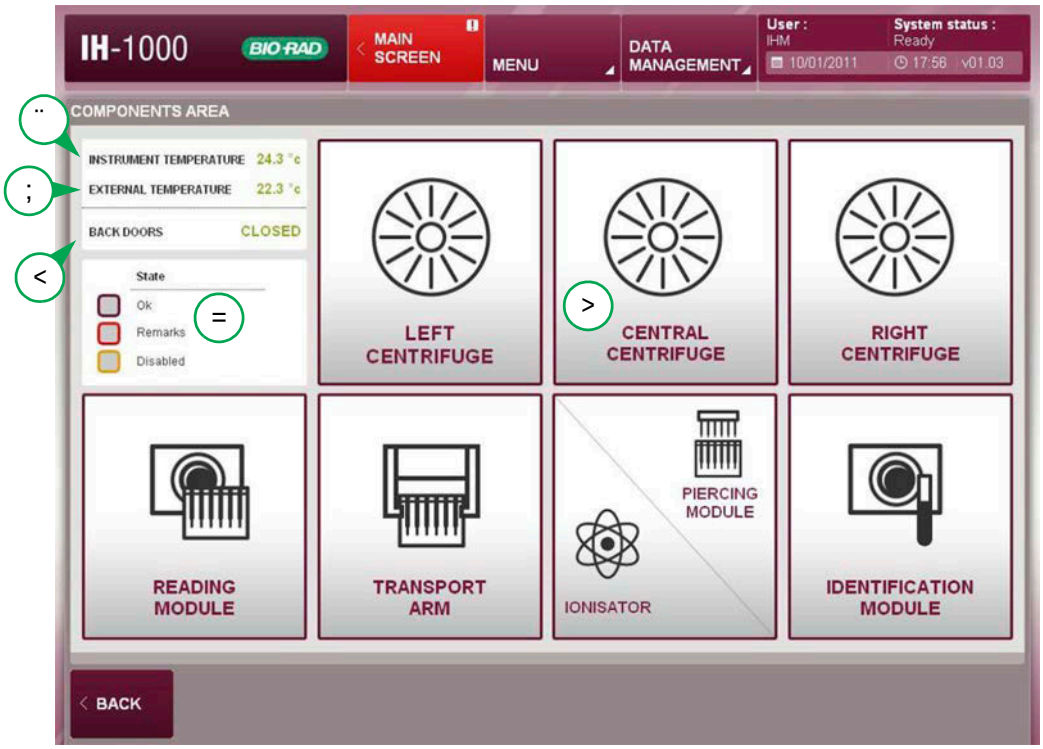
9.1 Checking Components Status

Components status can be checked through the components area screen.

A From the main screen, click on the **COMPONENTS AREA** of the interactive image.



Dgespc /.3, Components area screen

1 Instrument temperature

Rfc gIqrpskclr rcknccp_rspc gq kc_qspcb gI rfc ngncrrgIe _pc_,

2 External temperature

Rfc cvrcpI_j rcknccp_rspc ksqr `c icnr `crucc I /3ßA _Ib 05ßA,

3 Back doors status

' MIjw qcptgac cIegIccpq _pc _jjmucb rm mncI `_ai bmmpq,

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4 Components status:

- **Epcwgk_ec**: The component is functioning correctly. No user action is required / possible;
- **Pcbgk_ec**: The component is under error status.

Ajgai ml rfc gk_ec rm qfmu rfc _jcpr qapccl _lb _ail mujcbec rfc npm`jck,

5 Components images

Rfc amjmp md rfc glqrpskclr bcnclb ml rfc amknmlclr qr_rsq cvnj_glcb _`mtc,

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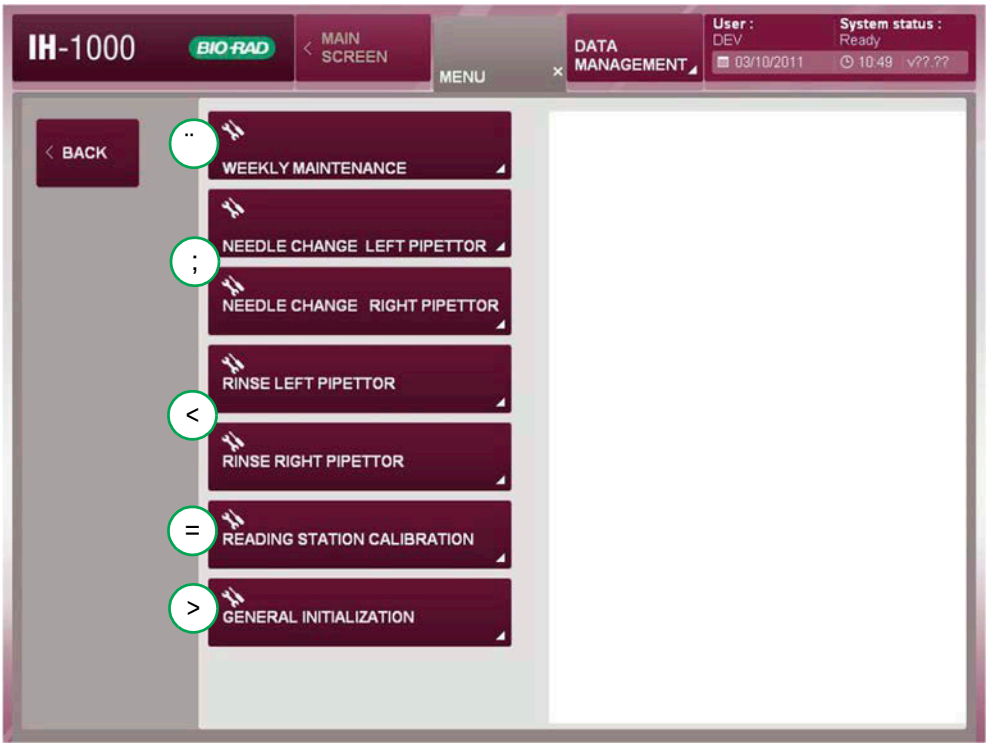
9.2 Maintenance Screen

The maintenance screen allows to perform usual maintenance operations required for the instrument.

The **MAINTENANCE** screen can be accessed from any screen where the **MENU** button appears.

A	Click on **MENU**.
B	Click on **MAINTENANCE**.
C	Login with your user name and password to access the maintenance screen.



Dgespc /.4, MAINTENANCE screen

1 See chapter Weekly Maintenance on page 149.

2 See chapter Needle Change Right/left Pipettor on page 164.

3 See chapter Rinse Right/Left Pipettor on page 166.

4 See chapter Reading Station Calibration on page 166.

5 See chapter General Initialization on page 167.

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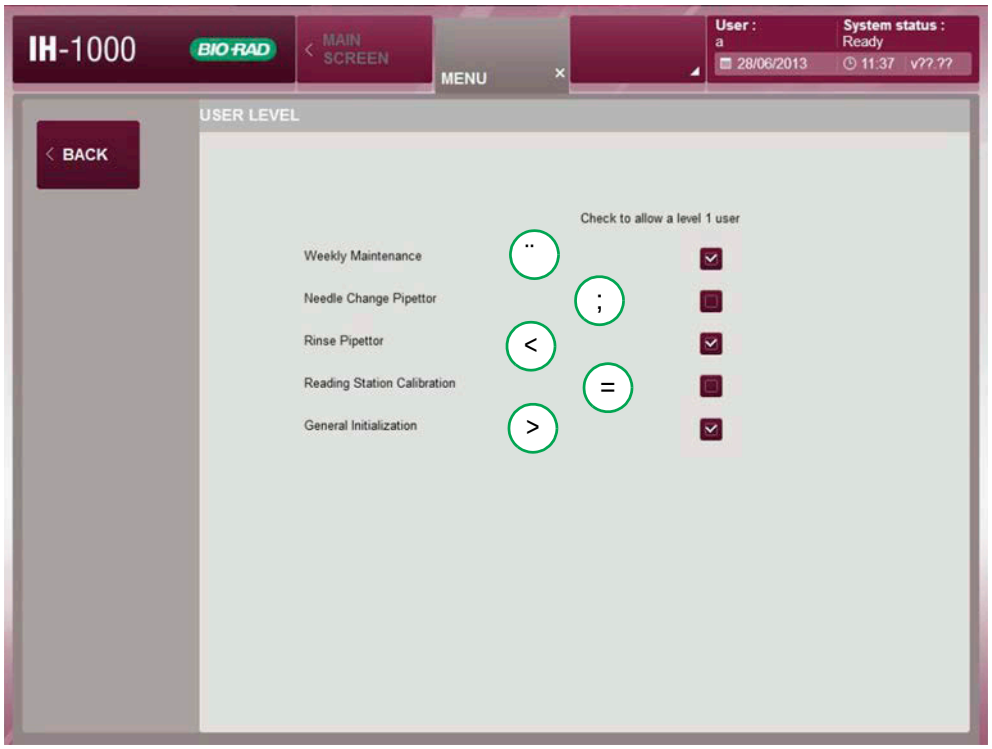
9.3 User Level Screen

The User level screen allows to define the minimum user level to access the maintenance actions of the instrument.

0 Only users with a level higher than 1 can access this screen.

The **USER LEVEL** screen can be accessed from any screen where the **MENU** button appears.

A		Click on **MENU**.
B	AUTHORIZED MAINTENANCE	Click on **AUTHORIZED MAINTENANCE**.
C		Login with your user name and password to access the maintenance screen.



Dịespc / .5, User Level screen

1 **Weekly Maintenance**

2 Needle Change Pipettor (right and left)

3 Rinse Pipettor (right and left)

4 **Reading Station Calibration**

5 **General Initialization**

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To enable a **Level 1 User** to perform **Weekly Maintenance**, **General Initialization** or any other maintenance operation, check the corresponding maintenance check box of the **User Level** screen.

If checked, users with level 1 will have access to the maintenance action, otherwise only users with a level higher than 1 will have access to the required maintenance.

0 If maintenance actions require a user level greater than 1, the buttons of the **MAINTENANCE** screen will be grayed for level 1 users.

9.4 Maintenance Operations

Log any maintenance operation in the maintenance record.

See chapter Maintenance Record on page 182.

0 If any variation of performance of the instrument is observed or suspected even after maintenance operations, contact your service engineer.

7,2,/ Bcamlr_kgl_rgml

0 It is user responsibility to do the appropriate decontamination in case of spillage of hazardous material on or inside of the instrument, with a lint-free cloth soaked in cleaning solution.

' Qfsr bmul rfc glqrpskclr `cdmpc mnclgle rfc ngncrrgle _pc_ uglbmu,

In case of spilling and contamination in the pipetting area or in the drawer:

A	Open access to the contaminated area with the user interface software (pipetting area window or drawer). *Qcc Mnclgle rfc Ngncrrgle ?pc_ Uglbmu ml n_ec /0/ mp Mnclgle - Ajmqgle rfc Bp_ucp ml n_ec 4.,*
B	Shut down the instrument. *Qcc af_nrcp Qfsrbmul md rfc glqrpskclr ml n_ec 27,*
C	Check that there is no damage to the instrument. *Gd rfcpc gq _lw b_k_ec* a_jj _ qcptgac cleglccp _lb qrmn sqgle rfc glqrpskclr,*
D	Take out all possible contaminated parts (racks, gel cards, gel cards trays).
E	Clean the contaminated areas (on or inside of the instrument), samples racks and reagents racks with a lint-free cloth soaked in cleaning solution. *Sqc `_arcpgagbc* tgpgagbc _lb dslegagbc bgqgldcar_lr _q ajc_lgle qmjsrgml,*

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7,2,0 Ncpgmbga K_glrcl_lac

7,2,0,/ B_gjw K_glrcl_lac

- Check daily the outer surface (is it clean, no blood, no serum...);
- If needed, clean outer surfaces of worktable with any bactericide, viricide and fungicide disinfectant after switching off the system.

7,2,0,0 Uccijw K_glrcl_lac

> ı Rfc uccijw k_glrcl_lac ksqr `c ncpdmpkcb ctcpw ucci ctcl gd rfc glqrpskclrgq lmr sqcb bspgle _jmle ncpgmb,

> 0 An orange maintenance reminder (**WEEKLY MAINTENANCE NECESSARY**) appears on the IH-1000 main screen if the user did not perform the weekly maintenance within the last seven days.

> 0 When a component is disabled, it is not possible to perform the weekly maintenance. Except if only one pipettor is disabled.

Check the expiration date of the solutions.

Prepare a new solution:

- 2l demineralized water, 8 ml Microcide.

  Rfgq qmjsrgml gq qr_`jc dmp 5 b_wq,

Check that there is no leakage around liquid containers.

> 0 Before performing the weekly maintenance, make sure that the cleaning liquid is filled with min. 2 liters.

> 0 When starting the instrument: the IH-1000 initializes automatically. It also checks the modules and the worktable automatically.

> ı @cdmpc uccijw k_glrcl_lac* cknrw rfc rum jgosgb u_qrc amlr_glcpq _lb nsr rfck `_aigl nj_ac,
> Sqc ejmtcq dmp _jj mncp_rgmlq,

A	From any screen, click on **MENU**.
B	Click on **MAINTENANCE**. *Rfc jmegl qapccl _nnc_pq,*
C	Enter your login and password.
D	Click on **OK**.

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E WEEKLY MAINTENANCE Click on the button **WEEKLY MAINTENANCE**.

Rfc dmjjmugle qapccl mnclq,

Dgespc /.6, Weekly maintenance - Confirm screen

0 If **WEEKLY MAINTENANCE** requires a user level greater than 1, this button is grayed for level 1 users.

F Click on **OK** to confirm.

Rfc dmjjmugle qapccl mnclq _lb _l _sbg`jc _j_pk _argt_rcq8

Dgespc /.7, Remove ID-Cards piercing array equipped

Grgq nmqqg`jc rm bgq_`jc rfc _sbg`jc _j_pk ugrf rfc **Qrmn _j_pk** `srrml,

0 The pipetting area window opens automatically.

G Remove the ID-Cards piercing array equipped.

Qcc af_nrcp Pckmtgle rfc GB+A_pbq Ngcpagle ?pp_w Cosgnncb ml n_ec /37,

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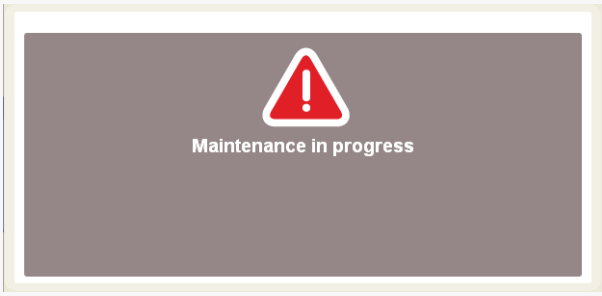
H Close the pipetting area window.

Rfc dmjjmugle qapccl mnclq8

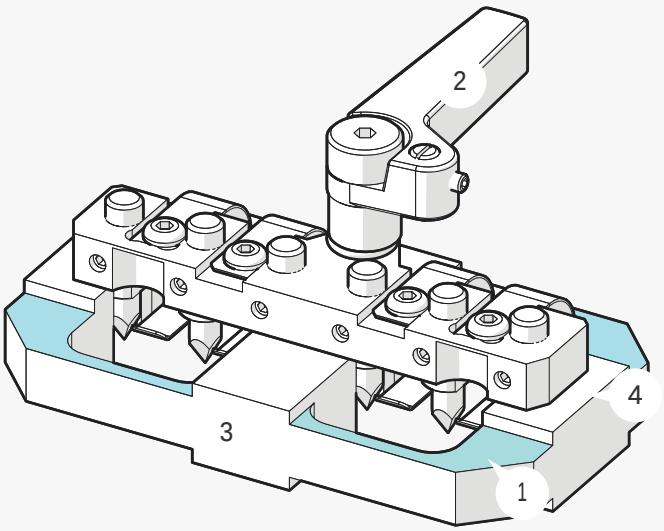


Dgespc ll., Weekly maintenance in progress

I Cleaning of ID-Cards piercing array equipped (2):

- The decontamination support (3) must be put in a tank.
- The cleaning liquid must be filled in the tank to the top of this side (1).
- Use the prepared solution.

Qcc af_nrcp Uccijw K_glrcl_lac ml n_ec /27,



Dgespc lll, ID-Cards piercing array equipped - decontamination support

! Rfc qmjsrgml ksqr lmr pc_af rfc snncp qspd_ac &2' md rfc bcamlr_kgl_rgml qsnnmpr, Rfc ajc_lgle jgosgb ksqr lmr ecrgl amlr_ar ugrf rfc snncp kcaf_lga_j n_pr md rfc ngcpagle _pp_w,

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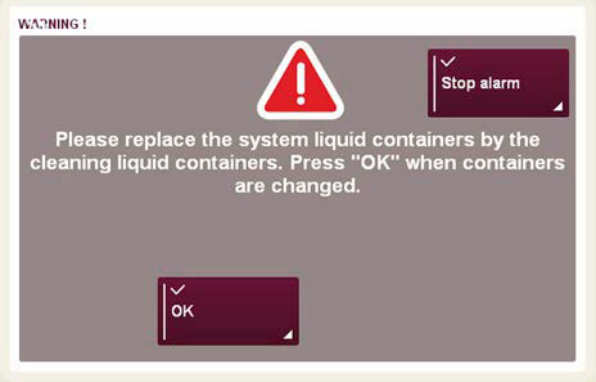
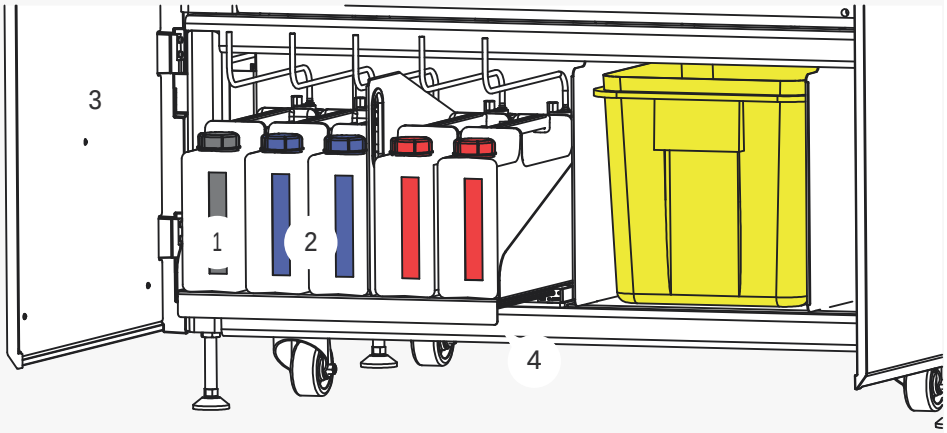
- The piercing tool must be put on the support.

  ?drcp_ dcu kglsrcq rfc dmjjmugle qapccl mnclq_lb_l_sbg`jc_j_pk _argt_rcq,*



Dgespc //0, Replace containers

J Open the door of the liquid container compartment (3).



Dgespc //1, Replace containers

K Pull out the container drawer (4).

L Remove the two caps of the cleaning liquid container (1).

M Place the two hoses from the system liquid (2) into the cleaning liquid container (1).

Qcc af_nrcp K_l_egle Jgosgbq_lb U_qrcq ml n_ec 71,

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N Click on **OK** when containers are changed.

Rfc dmjjmugle qapccl mnclq_lb_l_sbg`jc_j_pk_argt_rcq8

Dgespc //2, Empty the liquid waste containers

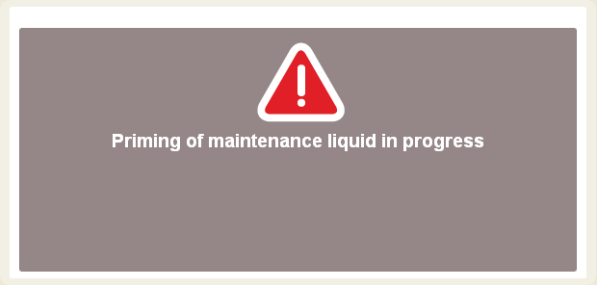
O Empty the two liquid waste containers and put them in place.

Qcc af_nrcp Pcnj_agle_ Jgosgb U_qrc Amlr_glcp ml n_ec 76,

P Click **OK** when done**,**

Rfc dmjjmugle qapccl mnclq8

Npgkgle md k_glrcl_lac jgosgb gl npmepcqq,



Dgespc //3, Priming in progress

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Q Gd `mrf jgosgb u_qrc amlr_glcpq _pc dsjj* rfc dmjjmuglе qapccl mnclq _lb _l _sbg`jc _j_pk _argt_rcq8

Dgespc //4, Both liquid waste containers full

or

Gd mlc jgosgb u_qrc amlr_glcp gq dsjj* rfc dmjjmuglе qapccl mnclq8

Dgespc //5, One liquid waste container full

R Empty the full liquid waste container(s) and put it (them) in place.

S Click **OK,**

?drcp _ dcu kglsrcq* rfc kcqq_ec af_lecq _srmk_rga_jjw rm bcamlr_ kgl_rgmlgl npmepcqq8

Dgespc //6, Decontamination in progress

Rfc bcamlr_ kgl_rgml rgkc qr_prq rm bcapc_qc,
Bspgle rfc bcamlr_ kgl_rgml* ncpdmpk rfc dmjjmuglе _argmlq R rm T ml n_ec /33,

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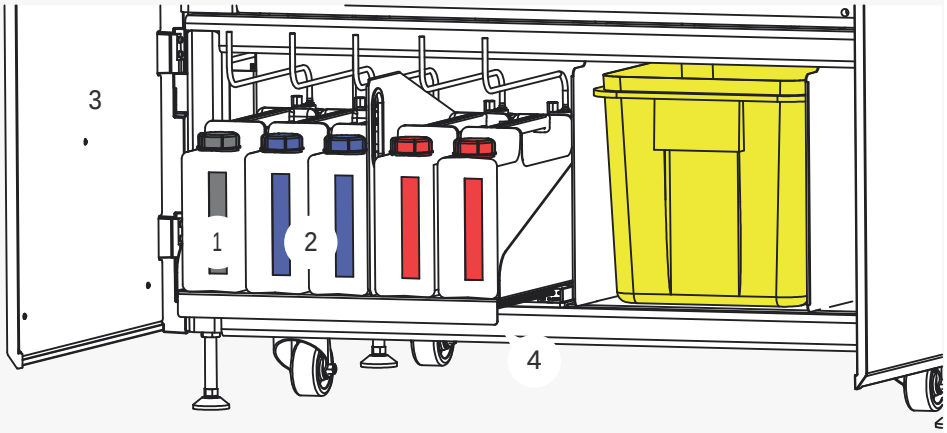
T Empty the two system liquid containers (2).



Dgespc //7, Empty the two system liquid containers

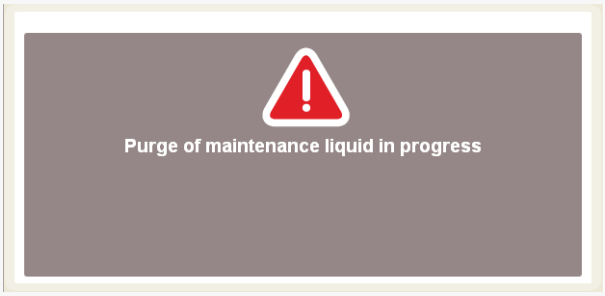
U Rinse the containers with demineralized water, then fill them with system liquid.

Qcc af_nrcp Pcdjjgle _ Qwqrck Jgosgb Amlr_glcp ml n_ec 73,

V Place the containers on the containers drawer.

Qcc af_nrcp K_l_egle Jgosgbq _lb U_qrcq ml n_ec 71,

?drcp rfc 1. kglsrcq md bcamlr_ kgl_rgml rfc dmjjmugle qapccl mnclq _srmk_rga_jjw8*



Dgespc /0., Purge of maintenance liquid in progress

?drcp _ dcu kglsrcq rfc dmjjmugle qapccl mnclq _lb _l _sbg`jc _j_pk _argt_rcq8*

Dgespc /0/, Purge of maintenance liquid in progress

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W	Remove the plungers, clean first with Isopropanol, then with demineralized water and put them in the system liquid containers.
X	Press **OK** to confirm installation of the plungers. *Rfc dmjjmugle qapccl mnclq_lb_l_sbg`jc_j_pk_argt_rcq8* **Dgespc /00,** Priming of system liquid in progress...
Y	Rinse the piercing tool with demineralized water.
ı	Ufcl sqgle bckglcp_jgxcb u_rcp* k_ic qspc rf_r rfc u_rcp os_jgrw amppcqnmlbq_r jc_qr rm Ep_b 0 &GQM 1474' mp Rwnc GG &?QRK B//71+7/',
Z	Dry the piercing tool. *Gd mlc mp `mrf jgosgb u_qrc amlr_glcpq_pc dsjj*_l_sbg`jc_j_pk_argt_rcq_lb qapccl mnclq_q bcqapg`cbgl Oml n_ec /32,*
AA	Empty the full liquid waste container(s) and put them in place.
AB	Click **OK,** *Rfc dmjjmugle qapccl mnclq_lb_l_sbg`jc_j_pk_argt_rcq8* *Rfc ngncrrgle_pc_ uglbmu mnclq_srmk_rga_jjw,* **Dgespc /01,** Install the ID-Cards piercing array
AC	Put the ID-Cards piercing array back in position. *Qcc af_nrcp Pckmtgle rfc GB+A_pbq Ngcpagle ?pp_w Cosgnncb ml n_ec /37,*

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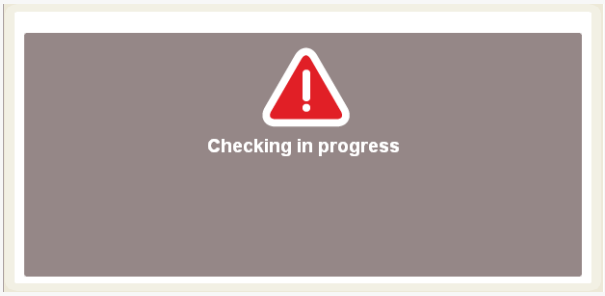
AD Close the pipetting area window.

Gd rfc GB+A_pbq ngcpagle _pp_w gq lmr glqr_jjcb mp lmr jmaicb amppcarjw rfc dmjjmugle qapccl mnclq _lb _l _sbg`jc _j_pk _argt_rcq8*

Dgespc l02, ID-Cards piercing array not detected

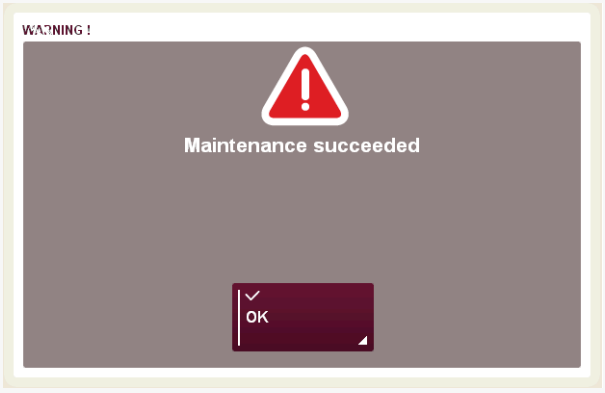
AE When the ID-Cards piercing array is correctly installed:

Rfc dmjjmugle qapccl mnclq8 ***Afcaigle gl npmepcqq,***



Dgespc l03, Checking in progress

?drcp _ dcu kglsrcq rfc dmjjmugle qapccl mnclq8* ***K_glrcl_lac qsaaccbcb,***



Dgespc l04, Maintenance succeeded

AF Click **OK**.

0 At the end of the weekly maintenance, clean the gel cards storage drawer with a lint free cloth.

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AG Click on the **DATA MANAGEMENT** button to switch to the IH-Com Data Management software.

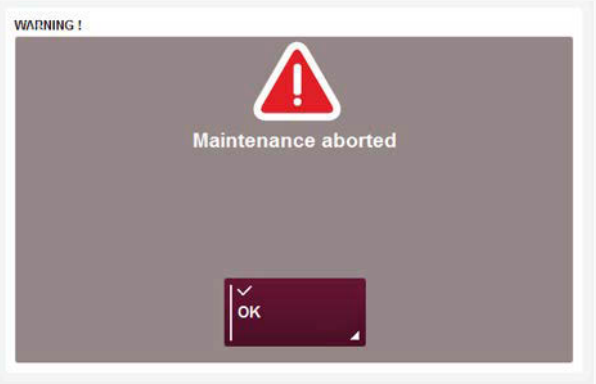
AH Perform a **QC** run.

Pcdcp rm rfc GF-Amk B_r_ K_l_eckclr Qmdru_pc dmp bcr_gjcb gldmpk_rgml,

- Gd rfc uccijw k_glrcl_lac u_q glrcppsnrcb* _ u_plgle kcqq_ec bgqnj_wq rfc cppmp rf_r maasppcb,

AI Click **OK** to acknowledge the error.

Rfc dmjjmugle qapccl mnclq8



Dgespc /05, Weekly maintenance interrupted

AJ Click **OK**.

- ? pcb k_glrcl_lac pckglbcp &ml rfc rmn jcdr md rfc qapccl'glbga_rcq rf_r rfc uccijw k_glrcl_lac ksqr `c bmlc _e_gl* `cdmpc _ psl a_l `c qr_prcb, Mrfcpugqc gr gq lmr nmqqg`jc rm qr_pr _lw rcqr,

7,2,0,1 4 _lb /0 Kmlrfq K_glrcl_lac

0 The 6 and 12 months maintenance has to be performed by a service engineer.

7,2,0,2 Rmr_j Cqrgk_rcb Rgkcq _lb Jgosgb Tmjskcq dmp Uccijw K_glrcl_lac

Cqrgk_rcb rgkc dmpglqrpskclr	~80mn
Cqrgk_rcb qwqrck jgosgb tmjskc	830ml
Cqrgk_rcb ajc_lgle jgosgb tmjskc	710ml

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7,2,1 OA Afcai

0 A quality control check must be performed after any maintenance operation.
Refer to the Data Management software for detailed information.

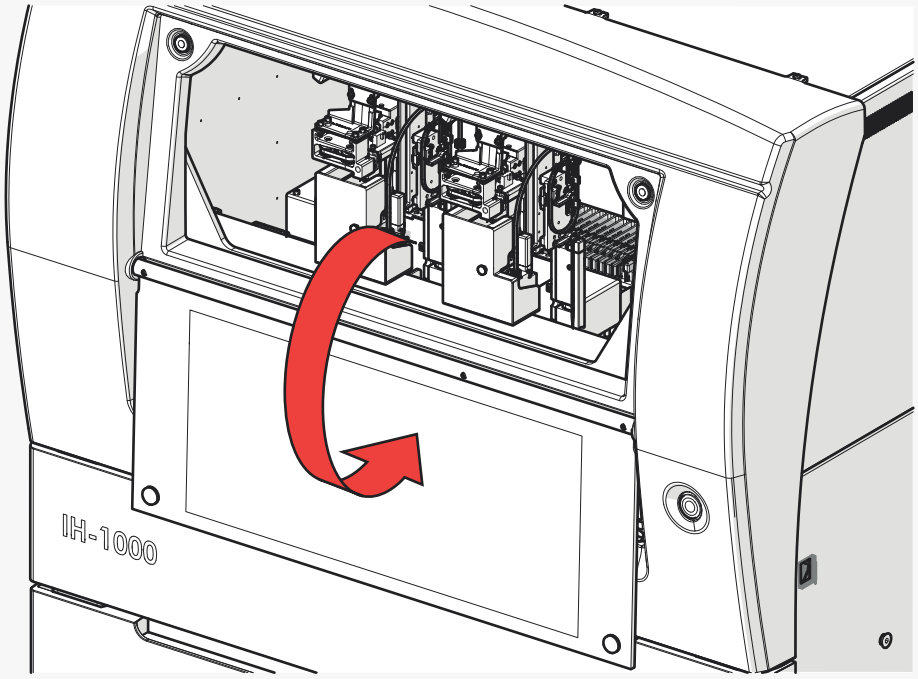
7,2,2 Pckmtgle rfc GB+A_pbq Ngcpagle ?pp_w Cosgnncb

- ?jj p_aiq ksqr `c pckmtcb `cdmpc mnclgle rfc ngncrrgle _pc_ uglbmu, Gd rfgq amlbgrgml gq lmr pcqncarcb* rfcpc gq _ pgqi md amjjgqgml ugrf rfc p_aiq,

- Sqc ejmtcq dmp _jj mncp_rgmlq,

A Open the pipetting area window (from the software).

Qcc af_nrcp Mnclgle rfc Ngncrrgle ?pc_ Uglbmu ml n_ec /0/,



Dgespc /06, Pipetting area window

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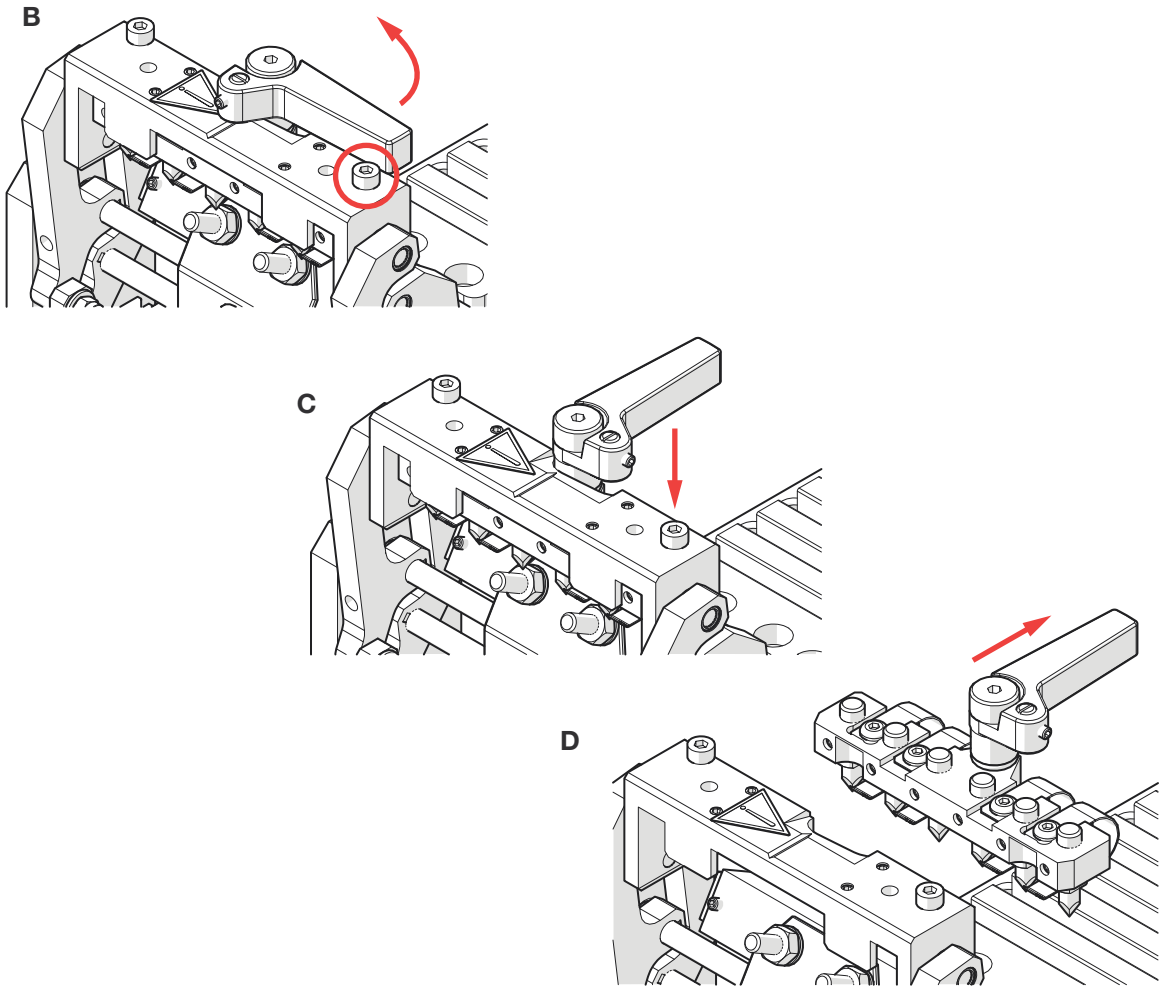
B	To unlock the ID-Cards piercing array equipped, turn the lock (4) 90° towards the back of the instrument.
▪	R_ic a_srgml rm lmr bpmn rfc GB+A_pbq ngcpagle _pp_w cosgnncb* rfcpc gq _ pgqi rm b_k_ec rfc GF-/....,
▪	Gl a_qc md qfmai ml ngcpagle nglq bspgle rfc uccijw k_glrcl_lac* tgqs_jjw afcai dmp b_k_ec,
C	Lower slightly the ID-Cards piercing array equipped.
D	Pull off to the right.
E	Remove the ID-Cards piercing array equipped.
▪	Ufcl pcnj_agle rfc GB+a_pb ngcpagle _pp_w cosgnncb* r_ic a_pc rm jmai gr amppcarjw, &Gl amlr_ar ugrf rfc qapcu* qcc pcb agpajc',
F	Perform a **QC** run. *Pcdcp rm rfc B_r_ K_l_eckclr qmdru_pc dmp bcr_gjcb gl dmp k_rgml,*



Dgespc /07,

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9.5 Needle Cleaning Right/left Pipettor

This procedure is valid for both pipettors.

- Dmjjmu rfgq npmacbspc dmp rfc lccbjc ajc_lgle,
- K_ic qspc rf_r rfc jgefrglqgbc rfc glqrpskclrgq qugrafcb mdd bspgle rfc npmacqq, Qcc af_nrcp Mnclgle rfc Ngncrrgle ?pc_ Uglbmu ml n_ec /0/,
- ?jj p_aiq ksqr `c pckmtcb `cdmpc mnclgle rfc ngncrrgle _pc_ uglbmu, Gd rfgq amlbgrgml gq lmr pcqncarcb rfcpc gq _ pgqi md amjjgqgml ugrf rfc p_aiq,
- Sqc ejmtcq dmp _jj mncp_rgmlq,
- ?ju_wq nj_ac _ rgqqsc slbcp rfc lccbjc `cdmpc bgqamllcargle rfc d_p_bgxcb tcgl _q gr bpmnq,
- Sqc _ qmdr rgqqsc rm _tmgb b_k_ec ml rfc lccbjc am_rgle,

0 The needle cleaning must be performed when the needle is visually soiled.

0 If **NEEDLE CHANGE RIGHT PIPETTOR** (or left pipettor) requires a user level greater than 1, this button will be grayed for level 1 users.

A Click on **NEEDLE CHANGE RIGHT PIPETTOR**.

? kcqq_ec _nnc_pq _qigle rm mncl rfc ngncrrgle _pc_ uglbmu,*

B Go back to the main screen to open the pipetting area window.

C

From the main screen, click on the pipetting area in the interactive image.

Qcc af_nrcp Afcaigle Ngncrrgle ?pc_ Qr_rsq ml n_ec //7,

D Open the pipetting area window (from the software).

Dmjjmu rfc npmacbspc `cjmu rm af_lec rfc q_knjgle lccbjc dmp qcpgcq,

E Place a clean tissue below the needle.

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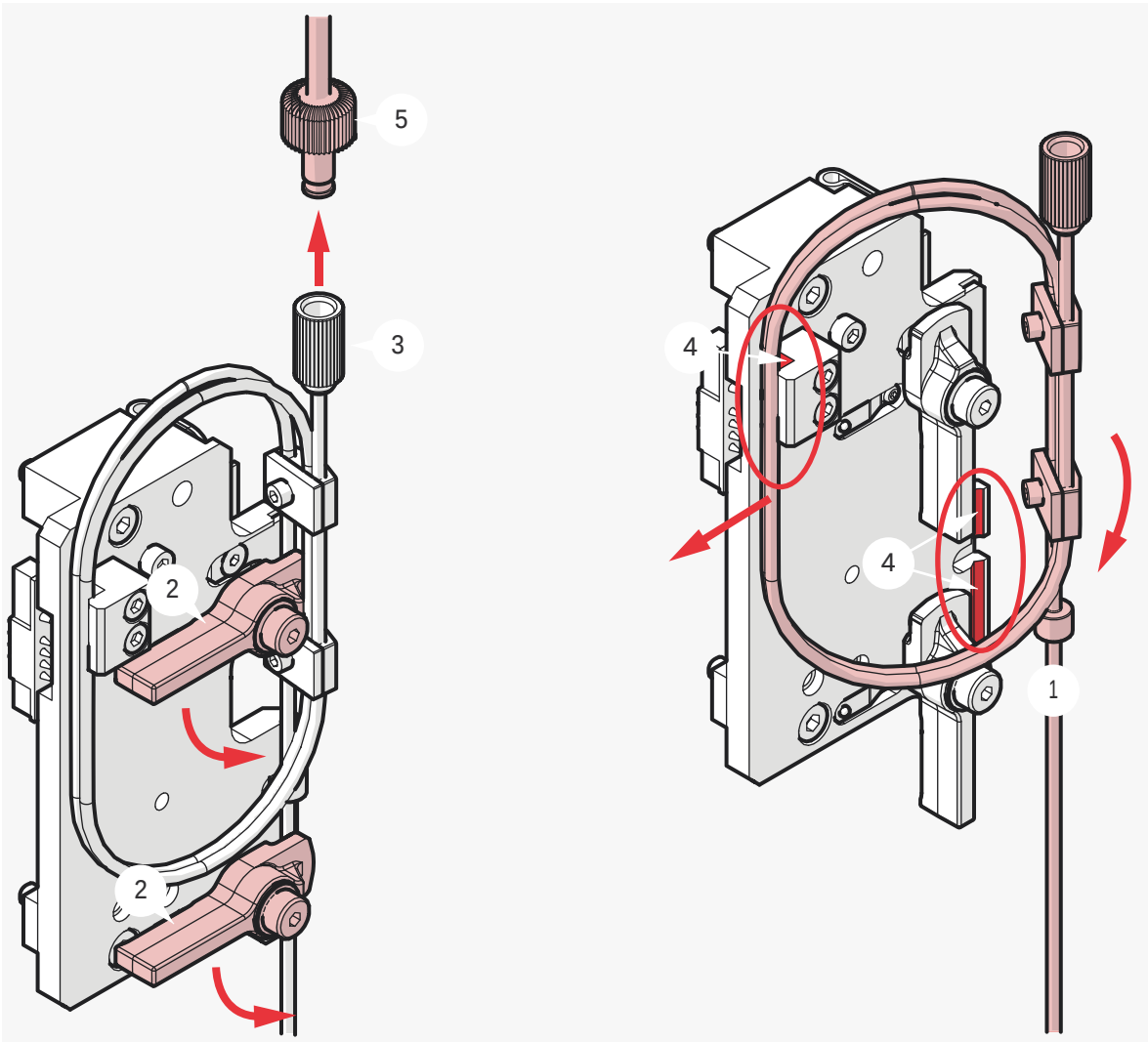
F	Disconnect the faradized vein (5) from the needle using the connector (3).



Dgespc /1.,

G	Open the 2 locks (2).
H	Slide the needle (1) out of the housings (4).
I	Verify the needle is purged.
J	Clean the needle with a nonwoven wipe and isopropanol solution. *Ugnc rfc lccbjc dpmk rfc rmn rm rfc rgn md rfc lccbjc,*
K	Dry the needle with a dry nonwoven wipe: *Ugnc rfc lccbjc dpmk rfc rmn rm rfc rgn md rfc lccbjc,*

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L	Check for any sign of damage (needle coating, bent needle, etc.). *Gd rfc lccbjc gq b_k_ecb* pcnj_ac gr, Qcc af_nrcp Lccbjc Af_lec Pgefr-jcdr Ngncrrmp ml n_ec /42,*
M	Locks open (2), needle absent, connector (3) near by.
N	Slide the needle (1) in the housings (4).
O	With the needle in place, screw the faradized vein (5) onto the needle until it clicks.
P	Lock the needle by tilting the two locks (2). *Jmaiq ajmqcb* lccbjc gq aml lcarcb _lb jmaicb gl nmqgrgml ml grq ngncrrmp X_vgq qsnnmpr,*

0 The collar on the needle, when properly inserted, prevents the needle from moving independent of the mechanism.

Q	Clean the needle carefully with a dry nonwoven wipe.
R	Close the pipetting area window. *Qcc af_nrcp Mnclgle rfc Ngncrrgle ?pc_ Uglbmu ml n_ec /0/,*
S	Click **OK** to validate needle replacement. *Rfc lccbjc gq _bhsqrcb _srmk_rga_jjw,*
T	Perform a **QC** run. *Pcdcp rm rfc B_r_ K_l_eckclr qmdru_pc dmp bcr_gjcb gldmpk_rgml,*

▮ Gd rfc lccbjc ajc_lgle f_q `ccl glrcppsnrcb bsc rm _ nmucp mdd* pc+qr_pr rfc lccbjc ajc_lgle npmacbspc,

0 External light can have an influence on the needle adjustment.

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9.6 Needle Change Right/left Pipettor

This procedure is valid for both pipettors.

- ?jj p_aiq k sqr `c pc k mtcb `cdmpc mnc l gle rfc ngncrrgle _pc_ ugl bmu, Gd rfgq am l bgrgm l gq l mr pcqncarcb* rfcpc gq _ pgqi md amjjgqgm l ugrf rfc p_aiq,
- Sqc ejmtcq dmp _jj mncp_rgm l q,
- ?ju_wq nj_ac _ rgqqsc s l bcp rfc l ccbjc `cdmpc bgqam l l cargle rfc d_p_bgxcb tcg l _q gr bpmnq,

0 If **NEEDLE CHANGE RIGHT PIPETTOR** (or left pipettor) requires a user level greater than 1, this button will be grayed for level 1 users.

A Click on **NEEDLE CHANGE RIGHT PIPETTOR**.

? k cqq_ec _nnc_pq _qigle rm mncl rfc ngncrrgle _pc_ ugl bmu,*

B Go back to the main screen to open the pipetting area window.

C From the main screen, click on the pipetting area in the interactive image.

Qcc af_nrcp Afcaigle Ngncrrgle ?pc_ Qr_rsq ml n_ec //7,

D Open the pipetting area window (from the software).

Qcc af_nrcp Mncl gle rfc Ngncrrgle ?pc_ Ugl bmu ml n_ec /0/,

E Place a clean tissue below the needle.

F Disconnect the faradized vein (5) from the needle using the connector (3).

G Open the 2 locks (2).

H Slide the needle (1) out of the housings (4).

I Replace the sampling needle (1).

Afcai dmp _l w qgel md b_ k_ec &l ccbjc am_rgle `c l r l ccbjc* cra,',*
Gd rfc l ccbjc gq b_ k_ecb r_ic _ l cu m l c,*

J Locks open (2), needle absent, connector near by.

K Slide the needle (1) in the housings (4).

L With the needle in place, screw the faradized vein (5) onto the needle until it clicks.

M Lock the needle by tilting the two locks (2).

Jmaiq ajmqcb l ccbjc gq am l l carcb _l b jmaicb g l nmqgrgm l m l grq ngncrrmp X _vgq qsnnmpr,*

0 The collar on the needle, when properly inserted, prevents the needle from moving independent of the mechanism.

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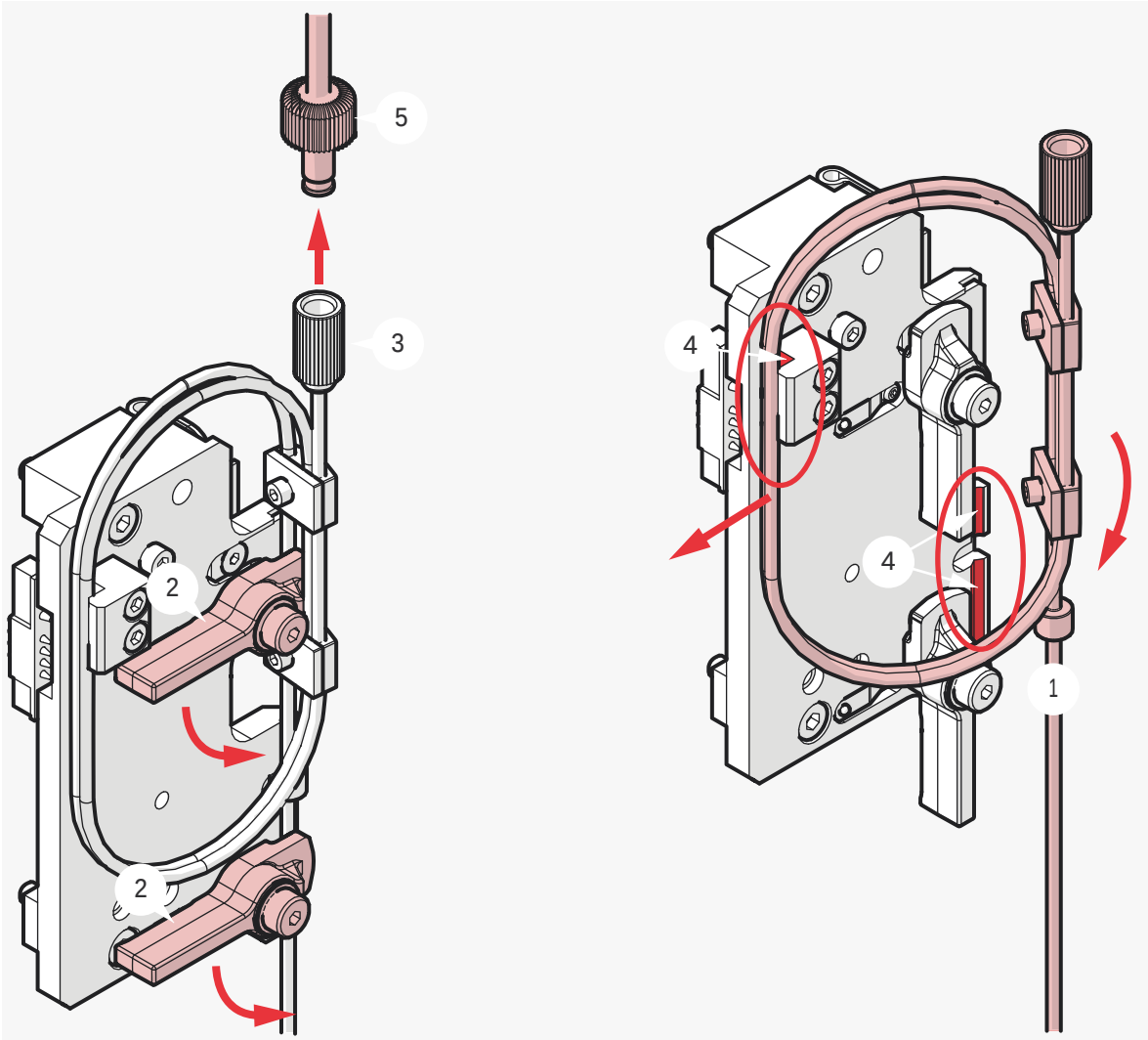

Dgespc /1/,

N	Close the pipetting area window. *Qcc af_nrcp Mnc lgle rfc Ngncrrgle ?pc_ Ugl bmu ml n_ec /0/,*
O	Click **OK** to validate needle replacement. *Rfc lccbjc gq _bhsqrcb _srm k_rga_jjw,*
P	Proceed the same way with the left pipettor.
Q	Perform a **QC** run. *Pcdcp rm rfc B_r_ K_l_eckclr qmdru_pc dmp bcr_gjcb gldmp k_rgml,*

Gd rfc lccbjc pcnj_ackclr f_q `ccl glrcppsnrcb `w _ dmpacb qfsr bmu l* ncpdmp k rfc lccbjc af_lec npmacbspc _e_gl &ugrfmsr af_legle rfc lccbjc &Mljw qrcnq ? rm B ml n_ec /42 _lb L rm N ml n_ec /43 k sqr `c bmlc'' ml rfc lcvr pcqr_pr md rfc qwqrc k, Rfgq gq rm k_ic qspc rf_r rfc lccbjc gq amppcarjw jma_jgxcb,

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9.7 Rinse Right/Left Pipettor

The button **RINSE RIGHT PIPETTOR** or **RINSE LEFT PIPETTOR** allows to manually launch a wash cycle of the right or left pipettor, additionally to the automatic rinse during the runs.

0 If the buttons **RINSE RIGHT PIPETTOR** or **RINSE LEFT PIPETTOR** requires a user level greater than 1, the button is grayed for level 1 users.

9.8 Reading Station Calibration

After 5000 working hours, the user is asked to do a calibration of the reading module.

0 A calibration can also be started before the 5000 working hours have passed.

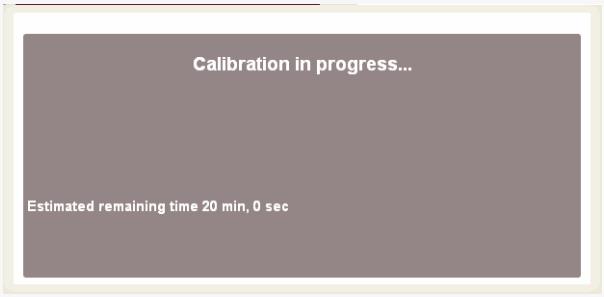
A Put 24 5052 type gel cards (NaCl cards) in the gel cards storage drawer.

0 Verify that the gel of the gel cards is in good condition and that there are no air bubbles present. The gel card must be valid, check the expiry date.

B

Click on the **READING STATION CALIBRATION** button to start the calibration process.

Rfc dmjjmugle qapccl gq bgqnj_wcb,



Dgespc /10, Calibration in progress

0 If the **READING STATION CALIBRATION** requires a user level greater than 1, the button is grayed for level 1 users.

0 The process can take up to 20 minutes. No action on the IH-1000 software can be performed during the calibration process.

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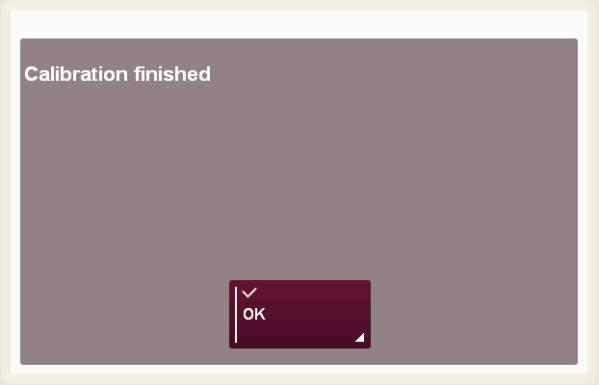
Ufcl rfc npmacqq gq dglgqfcb rfc dmjjmugle kcqq_ec gq bgqnj_wcb,*



Dgespc /11, Calibration finished

C Click on **OK**.

0 After calibration, the 24 gel cards go back to the drawer and can be used for further tests.

0 If launching conditions are not met, an alert screen with the missing items is displayed.

D Perform a **QC** run.

Pcdcp rm rfc B_r_ K_l_eckclr qmdru_pc dmp bcr_gjcb gldmpk_rgml,

9.9 General Initialization

0 Do not perform an initialization while the instrument is running. The IH-1000 makes all the initialization automatically.

See Starting the Instrument on page 46 and/or Errors on page 42.

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9.10 Storage

When it is planned not to use the instrument during many days, specific operations must be considered.

7,/.,/ Qfmpr Rcpk Qrmp_ecgl J_`mp_rmpw Amlbgrgmlq

If the instrument is not used for few weeks and if it stays in laboratory environment, no wrapping or packing is required.

- Uccijw k_glrcl_lac mncp_rgmlq ksqr `c ncpdmpkcb ctcpw ucci ctcl gd rfcglqrpskclrgq lmr sqcb,

7,/.,0 Mrfcp Qrmp_ec Amlbgrgmlq

When the instrument is stored outside laboratory conditions or if it is stored for a long period, special procedures must be performed by a service engineer.

0 Refer to a service engineer for handling and storage procedures.

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10 Troubleshooting

Af_nrcp mtcptgcu

- Rfc sqcp k sqr f_tc pc_b _lb s l bcpqrmmb rfgq bmas k c l r_rgm l `cdmpc a_ppwgle msr _lw rpms`jcqfmmrgle ml rfc GF-/. . . , Gl a_qc md s l ajc_p gldmp k_rgml* njc_qc am l r_ar rfc bgqrpg`srmp,

10.1 Alarms and Error Management

0 When an error message appears on the screen, read it and check whether an explanation is given in the following list. Then click on the OK button and execute the required procedure to solve the problem.

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10.2 Software Error Messages

0 For any error messages not listed in the following tables (mainly module and software errors), please contact a service engineer.

/.,0,/ ?jj Kmbsjcq

Cppmp ambc	Cppmp bcqapgnrgml	Amppcargtc _argmlq
"0..../.B	Hardware board communication failure.	Restart or contact a service engineer.
"0....1.7	Hardware board failure.	Restart or contact a service engineer.
"0....1.B "0....1.D	Hardware board communication failure.	Restart or contact a service engineer.
"0....2.1	Robotic movement failure.	Try to continue, restart or contact a service engineer.
".0...2.?	System execution failure.	Restart or contact a service engineer.
"0....2.A	Robotic movement interrupted.	Try to continue, restart or contact a service engineer.
"0....2.C "0....2/2	Robotic movement failure.	Restart or contact a service engineer.
"0...6./@	Action impossible due to previous failure.	Solve previous failure or contact a service engineer.
"0...DD..	Robotic movement failure.	Restart or contact a service engineer.

/.,0,0 Rp_lqnmpr ?pk

Cppmp ambc	Cppmp bcqapgnrgml	Amppcargtc _argmlq
"0....2.2	Robotic movement failure during initialization.	Restart or contact a service engineer.
"0....2//	Axis drag overshoot.	Try to continue or disable the faulty component and contact a service engineer.
"0....2/1	Axis positioning error.	Try to continue or disable the faulty component and contact a service engineer.
"0...6./7	Card presence sensor not working during check.	Try to continue, restart the system and contact a service engineer.
"0...60.A	Card transport failure.	Check the presence of the gel card. Try to continue or restart the system.

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Cppmp ambc	Cppmp bcqapgnrgml	Amppcargtc _argmlq
"0...61.2	Centrifuge trapdoor failure.	Try to continue or disable the centrifuge and contact a service engineer.
"0...61.3	Centrifuge trapdoor failure.	Try to continue or disable the centrifuge and contact a service engineer.

/.,0,1 Gbclrgdga_rgml Kmbsjc

Cppmp ambc	Cppmp bcqapgnrgml	Amppcargtc _argmlq
"0....2.2	Robotic movement failure during initialization.	Restart or contact a service engineer.
"0....2//	Axis drag overshoot.	Try to continue or disable the faulty component and contact a service engineer.
"0....2/1	Axis positioning error.	Try to continue or disable the faulty component and contact a service engineer.
"0...62.0	The rack contains a clogged tube or vial. This error appears if the option “cap detection” is activated.	• Remove the cap on the sample tube or the vial. See No Cap Confirmation on page 84 or Removing Racks on page 88 • If the problem persists, contact a service engineer.
"0...62.2	The rack barcode is unreadable.	Missing or damaged barcode label: • Verify if the rack is correctly labeled. • If the problem persists, contact a service engineer.
"0...62.5	Missing or damaged rack barcode label.	Verify if the rack is correctly labeled. If the problem persists, contact a service engineer.
"0...62.7	Presence of a rack impossible to process at the starting.	The instrument was stopped without using the shutdown function: • Remove the rack with the software. See chapter Removing Racks on page 88.
"0...63./	The reagent vial barcode is unreadable.	Reagent vial incorrectly positioned on the rack: • Verify if the reagent vial is correctly inserted. Damaged barcode label or symbology out of specification: • Verify if the reagent vial is correctly labeled. • If the problem persists, contact a service engineer.
"0...63.1	The reagent vial is out of date at the location requested.	• Remove the rack. See chapter Removing Racks on page 88. • Change the reagent vial.
"0...63.2	The reagent vial is unusable at the location requested.	• Remove the rack. See chapter Removing Racks on page 88. • Change the reagent vial.

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Cppmp ambc	Cppmp bcqapgnrgml	Amppcargtc _argmlq
"0...63.3	Empty barcode on the reagent vial is refused.	Incorrect positioning of the vial in the rack: See chapter Removing Racks on page 88. • Reposition the reagent vial. • If the problem persists, contact a service engineer.
"0...64./	The diluent wells rack is out of date.	Rack out of date. Remove the rack. See chapter Removing Racks on page 88.
"0...64.0	The barcode of the diluent rack is duplicated.	Two diluent rack with the same barcode. Remove all racks. See chapter Removing Racks on page 88. • If the problem persists, contact a service engineer.
"0...65./	The sample tube barcode is unreadable at the location requested.	Sample tube incorrectly positioned on the rack: • Verify if the sample tube is correctly inserted. Damaged barcode label or symbology out of specification: • Verify if the sample tube is correctly labeled. Gd rfc `_pambc gq pc_b k_ls_jjw* k_ic qspc rm nsr rfc q_knjc `_ai rm rfc mpgegl_j nmqgrgml, • If the problem persists, contact a service engineer.
"0...65.1	The sample tube barcode is duplicated.	• Take the rack out again and check the barcodes. • If the problem persists, contact a service engineer.
"0...65.2	The sample tube has an embarked clot.	Blood too thick: • Check that the blood is not over 48 hours old. • If the problem persists, contact a service engineer.

/.,0,2 Aclrpgdsec

Cppmp ambc	Cppmp bcqapgnrgml	Amppcargtc _argmlq
"0....2.2	Robotic movement failure during initialization.	Restart or contact a service engineer.
"0....2//	Axis drag overshoot.	Try to continue or disable the faulty component and contact a service engineer.
"0....2/1	Axis positioning error.	Try to continue or disable the faulty component and contact a service engineer.
"0...61.4	Centrifuge balance failure.	Insert gel cards in the drawer.
"0...DB.2	Speed error.	Try to continue, restart and contact a service engineer.

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/.,0,3 Pc_bgle Kmbsjc

Cppmp ambc	Cppmp bcqapgnrgml	Amppcargtc _argmlq
"0....2.2	Robotic movement failure during initialization.	Restart or contact a service engineer.
"0....2//	Axis drag overshoot.	Try to continue or disable the faulty component and contact a service engineer.
"0....2/1	Axis positioning error.	Try to continue or disable the faulty component and contact a service engineer.
"0...67./ "0...67.0	Reading module calibration failure.	Launch a new calibration or contact a service engineer.
"0...67.1	Expired reading module calibration.	Launch a new calibration or contact a service engineer.
"0...67.3 "0...67.7	Reading module calibration failure.	Launch a new calibration or contact a service engineer.
"0...67.? "0...67.@ "0...67.A "0...67.B	Reading module failure.	Launch a new calibration or contact a service engineer.
"0...67//	Gel card detected during lighting control.	Restart system of contact a service engineer.
"0...67/1	Lost gel card.	Restart system or contact a service engineer.
"0...6B.3 "0...6B.4 "0...6B.5	Reading module failure.	Launch a new calibration or contact a service engineer.

/.,0,4 Ngncrrmpq

Cppmp ambc	Cppmp bcqapgnrgml	Amppcargtc _argmlq
"0....2.2	Robotic movement failure during initialization.	Restart or contact a service engineer.
"0....2//	Axis drag overshoot.	Try to continue or disable the faulty component and contact a service engineer.
"0....2/1	Axis positioning error.	Try to continue or disable the faulty component and contact a service engineer.
"0...6./?	Shared area conflict.	Restart or contact a service engineer.
"0...6.5/ "0...6.51	Diluent piercing failure.	Verify that the rack is fully inserted in its support.

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/ .,0,5 Fwbp_sjga

Cppmp ambc	Cppmp bcqapgnrgm l	Amppcargtc _argm lq
"0....2//	Axis drag overshoot.	Try to continue or disable the faulty component and contact a service engineer.
"0....2/1	Axis positioning error.	Try to continue or disable the faulty component and contact a service engineer.
"0....2/4	Robotic movement failure.	Restart or contact a service engineer.
"0...6..3	Both pipettors out of order for maintenance.	Contact a service engineer.
"0...6.42	Soiled needle cannot be used.	Check washing means or contact a service engineer.
"0...6.4B	Washing failure.	Restart or contact a service engineer.
"0...6@.0 "0...6@.1	Level detection failure.	Try to continue or disable pipettor and contact a service engineer.
"0...6@.2 "0...6@.3	Needle external washing volume error.	Try to continue or disable pipettor and contact a service engineer.
"0...6@.@	Incorrect state of the hydraulic management.	Check liquid containers and circuits and restart the machine or contact service engineer.
"0...6@/0 "0...70./	Clogged needle circuit.	Try to continue, follow the needle changing procedure: See chapter Needle Change Right/left Pipettor on page 164. or disable the pipettor and contact a service engineer.
"0...6@/3	Both liquid waste containers are full or disconnected.	Empty containers and check caps are completely screwed.
"0...6@/5	Pipettor pressure sensor failure.	Try to continue or disable the pipettor and contact a service engineer.
"0...6@/6	Washing pump failure.	Try to continue or disable the pipettor and contact a service engineer.
"0...6C./	Fluidic calibration failure.	Launch a new calibration or contact a service engineer.
"0...6C.0 "0...6C.1 "0...6C.2 "0...6C.3 "0...6C.4 "0...6C.5	Fluidic flow control failure.	Try to restart and contact a service engineer.
"0...6C.6 "0...6C.7	Fluidic calibration failure.	Launch a new calibration or contact a service engineer.
"0...6C.?	Fluidic software execution failure.	Restart or contact a service engineer.

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Cppmp ambc	Cppmp bcqapgnrgml	Amppcargtc _argmlq
"0...6C.A	Fluidic calibration failure.	Launch a new calibration or contact a service engineer.
"0...70.1	Missing decontamination solution.	Load a new cleaning solution SETUP CLEAN vial. If the pipettor status is in default (red), • acknowledge the alarm; • load the setup clean; • start a test on the same side as the concerned pipettor.
"0...70//	Clot detected.	Execute needle cleaning process. See chapter Rinse Right/Left Pipettor on page 166.
"0...CB.5	Clot detected and solved, sampling cancelled.	Try to continue or restart.
"0...CB.6	Permanent clot detected, unable to solve automatically.	Execute appropriate procedure. See chapter Clot Detection on page 123.
"0...CB.@	Fluidic system failure (pressure sensor).	Try to restart and contact a service engineer.
"0...D4./ "0...D4.6 "0...D4.7	Calibration failure I/O.	Launch a new calibration or contact a service engineer.
"0...D4.?	Software execution failure I/O.	Restart or contact a service engineer.
"0...D4.A	Calibration failure I/O.	Launch a new calibration or contact a service engineer.

/.,0,6 Pc_eclr P_ai

Cppmp ambc	Cppmp bcqapgnrgml	Amppcargtc _argmlq
"0...D4.B	Reagent agitating speed out of range.	Use another rack or contact a service engineer.
"0...D4.C	Reagent agitating failure.	Use another rack or contact a service engineer.

/.,0,7 Ecj A_pbq Ngcpagle Kmbsjc

Cppmp ambc	Cppmp bcqapgnrgml	Amppcargtc _argmlq
"0....2.2	Robotic movement failure during initialization.	Restart or contact a service engineer.
"0....2//	Axis drag overshoot.	Try to continue or disable the faulty component and contact a service engineer.
"0....2/1	Axis positioning error.	Try to continue or disable the faulty component and contact a service engineer.

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/ .,0,/ . ?jj A_ k cp_q

Cppmp ambc	Cppmp bcqapgnrgm l	Amppcargtc _argm lq
"0....B.0	Reading module calibration failure.	Launch a new calibration or contact a service engineer.
"0...D..5	Camera communication failure.	Restart system or contact a service engineer.
"0...D..6	Camera calibration failure.	Launch a new calibration or contact a service engineer.
"0...D..7	Camera failure.	Launch a new calibration or contact a service engineer.
"0...D..?		
"0...D..@		

/ .,0,/ / Qwqrc k

Cppmp ambc	Cppmp bcqapgnrgm l	Amppcargtc _argm lq
"0...././	Hardware board communication failure.	Restart or contact a service engineer.
"0..../.0		
"0..../.1		
"0..../.2		
"0..../.3		
"0..../.4		
"0..../.5		
"0..../.6		
"0..../.7		
"0..../.?		
"0..../.@		
"0..../.A		
"0..../.C		
"0..../.D		
"0..../0.		
"0..../0/		
"0..../00		
"0..../01		
"0..../02		
"0..../03		
"0....7./	File access failure.	Restart or contact a service engineer.
"0....7.0		
"0....7.1		
"0....7.2		
"0....7.3		

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Cppmp ambc	Cppmp bcqapgnrgm l	Amppcargtc _argm lq
"0....?./	Software execution failure.	Restart or contact a service engineer.
"0....?.0		
"0....?.1		
"0....?.2		
"0....?.3		
"0....?.4		
"0....C.@	File access failure.	Restart or contact a service engineer.
"0....C.A		
"0...60.B	Pipetting door not closed.	Close the pipetting area window.
"0...65.4	No message - Pictogram on the GUI (software interface).	Check the loaded crossmatch receivers.
"0...65.5	See chapter Sample Status on page 78.	
"0...7../	File access failure.	Restart or contact a service engineer.
"0...7..0		
"0...7/.@	Inconsistent assay database information.	Check input data or contact a service engineer.
"0...7//0		
"0...7//1		
"0...7//2		
"0...7//3	Missing donor.	Check input data. Enter the missing sample.
"0...D5.0	Hardware board communication failure.	Restart or contact a service engineer.
"0...D5.1		
"0...D5.2		
"0...D5.3		
"0...D5.4		

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N?EC GLRCLRGML?JJW JCDR @J?L I

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11 Appendix

Af_nrcp Mtcptgcu

This chapter covers non-standard operations on the instrument.

11.1 Equipment and Accessories

//,/,/ Cosgnkclr

Bcqapgnrgml	Os_lrgrw
IH-1000	1
Reagents rack	4
Diluents rack holder	4
Samples rack	18
Samples rack barcode label set	18
Rack extractor tool	1
Decontamination support	1
Touchscreen	1
Keyboard (language depending on country)	1
Touchscreen arm	1
Power cord	1
Preparation table	1
Containers	5
Gel card waste bin and bag	1
Technical documentation	1
User manual (ref. H009142)	1

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/1,1,0 ?aacqqmpgcq

Bcqapgnrgml	Os_lrgrw
Barcode scanner	1
Hub	1
USB key 8Go	1
UPS	1
UPS battery	1
UPS holder	1

11.2 CE Compliance

This instrument is an in-vitro diagnostic medical device and complies with all applicable European Community Directives and associated harmonized standards, including but not limited to the standards pertaining to the electrical safety as well as the emission and immunity requirements as specified in IEC 61326-2-6.

11.3 Documents / Forms

/1,1,/ Bcamlr_kgl_rgml Acprgdga_rc

0 Please contact your local distributor for the official electronic document.

- Rfc bcamlr_kgl_rgml ksqr `c ncpdmpkcb `w_l _srfmpgxcb rcaflgag_l gl _aampb_lac ugrf rfc glqrpsargmlq amlr_glcb gl rfc amppcqnmlbgle Qcptgac K_ls_j,

The IH-1000 and its accessories must be cleaned and decontaminated before any of the following intervention:

- performing any maintenance;
- revision task;
- before taking the instrument out of service;
- when preparing for transportation;
- before final elimination.

- Rfc mpgegl_j acprgdga_rc ksqr pck_gl gl rfc npcqclr k_ls_j, Ufcl _acprgdga_rc gq pcosgpcb* k_ic _amnw _lb dgjj gl rfc j_rrcp q_knjc,
  Dgjj gl _amnw md rfc bcamlr_kgl_rgml acprgdga_rc _lb nj_ac gr ml rfc glqrpskclr* gl _amlqngasmsq nj_ac,

The absence of the decontamination certificate may extend the time needed for revision and maintenance.

Bio-Rad will bill any cleaning and decontamination operation.

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I, hereby declare, that the instrument below:

□□□□□ □ □□□□	
□ □□□□□□□ □□□	
□□□□□ □ □□□□ □ □□□□	

has been cleaned and decontaminated according to the procedure described in the relevant instrument manual, in the chapter "Maintenance□□

□□□□□□□□□□□□□□□□□□□□ □ □□□□□□□□□□□□□□□□ □□□□□□

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□□□□□□□□□□□□□□□□□□□

//,1,0 K_glrcl_lac Pcampb

0 The original blank maintenance sheet must remain in the present manual. When a maintenance record is required, make a copy and fill in the latter sample.

Type

Page

Serial number

K_glrcl_lac - Bcdcar	?argml	Mncp_rmp	B_rc

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11.4 Spare Parts Ordering

Please contact your local service engineer.

11.5 Device Disposal

//,3,/ Eclcp_j U_plgleq

- Glmpbcp rm npmrcar rfc ncpqmlq _lb rfc clt gpmlkclr* _lw glqrpskclr _lb grq _aacqqmpgcq ksqr `c bgqnmqcb md gl _l _nnpmnpg_rc u_w, Grq gq k_lb_rmpw rm qrpgarjw _nnjw j_uq _lb jma_j `wj_uq pcj_rgtc rm _l _nnpmnpg_rc bgqnmq_j npmacbspc,
- ?l glqrpskclr k_w mljw `c bgqkmslrcb _lb bgtgbcb glrm grq `_qga amknmlclrq `w_ os_jgdgcb rcaflgag_l,
  N_prq _lb qs`+n_prq pckmtcb dpmk _l glqrpskclr k_w lmr `c pcsqcb sljcqq _drcp f_tgle `ccl _nnpmtcb gl upgrgle `w rfc k_lsd_arspcp, ?lw dsrspc _nnjga_rgml f_q rm `c npcagqcjw bcqapg`cb gl rfc pcoscqr,

//,3,0 Bgqnmq_j

The following components can be found in the instrument:

N_aigle k_rcpg_j

N_ncp`m_pb
Nmjwcrfwjclc dm_k
?lrg+qr_rga `_e
Aj_qq GG dgpcnpmmdcb nmjwqrwpclc

Glqrpskclr

Nj_qrga k_rcpg_jq	PVC, POM, nylon, rubber
Cjcarpga_j amknmlclrq	Motors, copper wires, plastic insulation
Cjcarpmlga amknmlclrq	Epoxy printed boards
Mnrga_j amknmlclrq	Camera lens, camera body
Kcr_jq	**Amnncp**: electrical wires; **?jskglsk**: instrument base, holders, guides for electronics boards, partitions, covers; **Qrccj**: springs, holders, screws, bolts.

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11.6 List of Documents

//,4,/ Sqcp K_ls_jq

J_les_ec	GF+/... Sqcp K_ls_j	GF+Amk Sqcp K_ls_j
Clejgqf	H009142	H009146
Ecpk_l	H009156	H009147
Dpclaf	H009159	H009151
Gr_jg_l	H009160	H009149
Qn_lgqf	H009157	H009148
Nmprsescqc	H009158	H009150
B_lgqf	H009161	H009153
Qucbgqf	H009162	H009154
Lmpuceg_l	H009163	H009155
Dgllgqf	H009166	H009168
H_n_lcqc	H009167	H009169
Nmjgqf	H009170	H009171
Fsle_pg_l	H009190	H009183
Qcp`g_l	H009191	H009192
Afglcqc	H009195	H009365
Nmprsescqc &@p_xgj'	H009204	H009205
Qjmtclg_l	H009216	-
Psqqg_l	H009221	H009222
Axcaf	H009194	H009196

//,4,0 Qcptgac K_ls_jq

J_les_ec	GF+/... Qcptgac K_ls_j	GF+Amk Qcptgac K_ls_j
Clejgqf mljw	H009144	H009152

//,4,1 Qn_pc N_prq K_ls_j

J_les_ec	GF+/... Qn_pc n_prq K_ls_j
Clejgqf mljw	H009215

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Clinical Diagnostics Group

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IH-1000

Инструкция по эксплуатации

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RH-1000 Recond

Контрольный материал
IH-1000 Версия 2.0 - 01/2022
Регистрационный номер: H009142

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IVD CE

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Краткое руководство

Дата выпуска	Дата выпуска программного обеспечения	Версия	Краткое описание
1.0		07/2010	Первый выпуск
1.1	**V3.0**	03/2011	V3.0 Добавлена функция измерения
1.2	**V4.0**	11/2012	V4.0 Добавлена функция измерения и обновлена информация о безопасности
1.3		11/2013	Добавлена информация о стандарте 61010-1 2010, а также обновлена информация о безопасности
1.4	**V04.04**	03/2015	V04.04 Добавлена функция измерения и обновлена информация о безопасности
1.5	**V04.07**	07/2017	Изменения: Добавлена информация о безопасности, а также обновлена информация о безопасности Добавлено: • Глава 12; • Глава 93; • Глава 125; • Глава 148; • Глава 185 • Глава 130; Удалено: • Глава 88
1.6	**V04.08**	03/2020	Добавлена информация о безопасности, а также обновлена информация о безопасности Изменения: • Изменена информация о безопасности, а также обновлена информация о безопасности; • Обновлена информация о безопасности; • Изменена информация о безопасности; Удалено: • Удалена информация о безопасности. Добавлено: • Добавлена информация о безопасности, а также обновлена информация о безопасности • Обновлена информация о безопасности.
1.7		01/2021	Изменения: • Обновлена информация о безопасности; • Изменена информация о безопасности. Добавлено: Добавлена информация о безопасности.
2.0		01/2022	Добавлена информация о безопасности и обновлена информация о безопасности Руководство по эксплуатации Глава 1 (EU) 2017/746 (IVDR).

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1 Общие сведения

Предназначение

Данное руководство содержит информацию, необходимую для работы с анализатором IH-1000 (далее – прибор), включая информацию о технике безопасности, процедуры настройки, эксплуатации и технического обслуживания прибора.

1.1 Назначение

IH-1000 – автоматический прибор для определения групповой принадлежности эритроцитов человека, определения наличия и специфичности антител, выявляемых непрямой реакцией антиглобулинового теста (ID-карты), а также для определения наличия и специфичности антител, выявляемых прямой реакцией антиглобулинового теста (ID-карты), для определения групповой принадлежности эритроцитов, для определения наличия и специфичности антител, выявляемых прямой реакцией антиглобулинового теста (DAT) с использованием гель-технологии.

Прибор предназначен для использования ***in vitro*** в клинико-диагностических лабораториях. Прибор предназначен для использования специально обученным персоналом.

Использование прибора IH-1000 требует применения специальных реагентов, произведенных или одобренных компанией Bio-Rad.

Прибор может использоваться в составе автоматизированных систем, позволяющих осуществлять двустороннюю передачу данных между прибором и лабораторной информационной системой (ЛИС).

0 Использование прибора неопытным персоналом может привести к неправильным результатам, а также повреждению прибора.

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1.2 Ɉɠƫɷ0ƫɗɗʃɥʝƭɗʝ ɠ0ƫɷ0ƫɗlʂɗʃƨƫʳ ⁚ ʇʂʙʷʟ0lʂʝƭƶʳɦɲlʂɵ

ɭ ʝɦɲƶʇʂlʂƫɕʷ ƫɷ0 lʂʇʂ, ɥlʂʇ ʧƫɕɗʙʇʂƫɕ ɗ ʝɠʇʂ ʧƫɕʇʂɠƫɕ0ɗƶɲƶƫʂʝ ʇʂʙʝɦʧɗʝɥʝɥʝƭɗɗʃ ʙʳƭƶɗ ʧƫɕʇʂlʂʝɦɲlʂɗʃƫɕʇʂɷ0ƭƫʳ, ʧʝƫɕʝ ʃʂʇʂɠƫɕ0ɗƶɲƶƫʂʝƫɕʇʂ ʇʂʙʝɦʧɗʝɥʝƭɗɗʃʷ ƫɕʝʕʇʂƶʝʝɥʝɦlʂɗʃƫɕʇʂɷ0ƭƫʳ ʷ0ƶɲƶʇʂɷ ʕʇʂƶʝɗʃʳ ʵʂlʝƫɕ0.

ʕʇʂƶʝʧ0ƭƫɗʃʷ Bio-Rad ƭʝ ʧƫɕɗʟƭɷ0ʝlʂ ʇʂlɷɷʝlʂɷlɷɷʝƭɗƭƫʂɦɲlʂɗʃ ɷ ɦɲƶʝɥʜƶʵʰ ɗʃ: ɦɲƶʜƶɥɥ0ʷ:

- Å ƭʝɥʝƫ0ɷɗƶʳƭƫʂʝ ɗɦɲʧʃʂƶʳʟʂɷɷ0ƭƫɗʃ ʧƫɕɗʙʇʂƫɕ0;
- Å ƭʝɥɦ0ƭʕʟɗʇʂƭƫʂɷɷ0ƭƫʂʷ ƶʝʂʜɗʃʷ ɗʕ0ʟɗʃʷ (ƭɷ0ƶʝɥʇʝɥƭɷ0ʷ ɗƶƶɗ ƭʝɥʇʝɥʜƭɷ0ƶʝɥʇʝɥƭɷ0ʷ);
- Å ƭʝɥɷʳ ʧʃʂƶƫʂʝɥʝƭɗɗʃ ɗƭɦɲlʂƫʜʕʟɗʃ, ɦɲʂʜɥʇʝʞ0ʰ ɗʕɦɲʷ ɷ ƫʜʜʕʂʂɷʂʜɦɲlʂɷ0ʕ, ʧʃʂlʂɥʇʝɥ0ƶʳʷɥʝƶʳ ʕ ɦɲ ʧƫɕɗʙʇʂ-ƫɕ0ƶʝɗ ɗ ʧƫɕʇʂɠƫɕ0ƶʝɗƭɕʳ ʇʂʙɥʝɦʧɗʝɥʝƭɗɗʃ;
- Å ƭʝɥɦʇʂʙƶʵʜɥʝƭɗɗʃ ɗƭɦɲlʂƫʜʕʟɗʃ ʧʃʂ lʂɥʕɗʃʕɥ ʙɥʝʟʂʧ0ɗʃʕɥ ɗ, ɦɲʂʜɥʝʞ0ʰ ɗʕɦɲʷ ɷ ƫʜʜʕʂʂɷʂʜɦɲlʂɷ0ʕ;
- Å ʧʃʂƶʳʟʂɥʝƭɗɗʃ ʟʰ ɥʝƫʙ0, ɦɲɷʷʟ0ƭƫɕʇʂɠʂʃ ɦ ɗɦɲʧʃʂƶʳʟʂɷɷ0ƭƫɗʃ ʧƫɕɗʙʇʂƫɕ0, ɷ ɥ0ɦlʂƭƫʂɦɲlʂɗʃ, ʧʃʂlɥʝʷ ʜ0ƭƫ-ƭʳ ɗƭƶɗ ʷ ɗƭƫ0ƭƫɦɲʂɷ ʳ ʟʰ ɥʝƫʙ, ʧʃʂlɥʝɗƭɥɗƶʳƭƫʂ ɦɲɷʷʟ0ƭƫɕʳ ɦ ɗɦɲʧʃʂƶʳʟʂɷɷ0ƭƫɗʃ ʧƫɕʇʂɠƫɕ0ƶʝɗƭɕʳ-ƭɕʇʂɠʂʃ ʇʂʙʝɦʧɗʝɥʝƭɗɗʃʷ.
- Å ɭƫɕɗ ɗɦɲʧʃʂƶʳʟʂɷɷ0ƭƫɗʃ ʧƫɕɗʙʇʂƫɕ0 ɦɲʧʃʂɦɲʇʂʙʇʂɠʝ, ƭɥʝ ʧƫɕɥʝʜƶʵʜɥʝɦlʂɗʃƭɕʳ ɗʃ ʧƫɕʇʂɠʟʂʇʂʜɦɲlʂɷ0ʕ, ʇʂʙɥʝɦʧɗʝɥʝƭɗɗʃ ɦ ɗɦɲʧʃʂƶʳʟʂɷɷ0ƭƫɗʃ ʧƫɕʇʂɠƫɕ0ƶʝɗƭɕʳ-ƭɕʇʂɠʂʃ ʇʂʙʝɦʧɗʝɥʝƭɗɗʃʷ.

ɭʇʂɦɲƶʝ ʧʃʂʜʕƶʵʜɥʝƭɗɗʃʷ ʧƫɕɗʙʇʂƫɕ0 ʕ ɲʇʂɦɲlʂƶ ʇʂlɷɷʝlʂɷlɷɷʝƭɗɗʃʷ ʟ0 ʙɥʝʟʂʰ ɗʙʇʂƫɕʇʂʵʰ ɥʝƭɷ0ʜƶʵʜ ʜ0ƭƫɕʳ ɷ ƫɕɥʝƭɗɗʃʷ, ƭɥʝƭɗɗʃʷɥʝƭɗɗʃʷɦɲlʂɗʃƭɕʳlʂƫɕɗʃʷ ʧƫɕʇʂɠƫɕ0ƶʝɗƭɕʳ ɗƭƫ ɦɲlʂƫʂʇʂƫɕ0ɗƭɕʳ, ƭɥʝƭɗɗʃʷɥʝƭɗɗʃʷ ʧƫɕʇʂɠƫɕ0ƶʝɗƭɕʳ ɗƭƫ ʇʂlɷɷʝlʂɷlɷɷʝƭɗɗʃʷ ƭɥʝƭɗɗʃʷ ʷ ɗƭƫ0ƭƫɦɲʂɷ ɷ lʂɷʕɗʃʰ ɥʝƭɷ0ʜƶʵʜ ʜ0ƭƫɕʳ, ɦɲʂʜɥʝʞ0ʰ ɗʕɦɲʷ ɷ ƫʜʜʕʂʂɷʂʜɦɲlʂɷ0ʕ ʧʃʂƫʂʇʂɠʝɗʃʷ ʧʃʂlʂɥʝʷ ɗƭƫ0ƭƫɦɲʂɷ ɷ lʂɷʕɗʃʰ ɥʝƭɷ0ʜƶʵʜ ʜ0ƭƫɕʳ, ɦɲʂʜɥʝʞ0ʰ ɗʕɦɲʷ ɷ ƫʜʜʕʂʂɷʂʜɦɲlʂɷ0ʕ ʧʃʂƫʂʇʂɠʝɗʃʷ ɗƭƫ ɦɲ ƭɥʝƭɗɗʃʷ ʧƫɕʇʂɠƫɕ0ƶʝɗƭɕʳ ʇʂʙɥʝɦʧɗʝɥʝƭɗɗʃʷ ɗƭƫ ʇʂlɷɷʝlʂɷlɷɷʝƭɗɗʃʷ ɗƭƫ0ƭƫɦɲʂɷ ɷ lʂɷʕɗʃʰ ɥʝƭɷ0ʜƶʵʜ ʜ0ƭƫɕʳ ɦɲʂʜɥʝʞ0ʰ ɗʕɦɲʷ ɷ ƫʜʜʕʂʂɷʂʜɦɲlʂɷ0ʕ ʧʃʂƫʂʇʂɠʝɗʃʷ ɗƭƫ ɦɲ ƭɥʝƭɗɗʃʷ ʧƫɕʇʂɠƫɕ0ƶʝɗƭɕʳ ʇʂʙɥʝɦʧɗʝɥʝƭɗɗʃʷ.

- Å ɭƫɕɗ ɗɦɲʧʃʂƶʳʟʂɷɷ0ƭƫɗʃ ʧƫɕɗʙʇʂƫɕ0 ɦɲʧʃʂɦɲʇʂʙʇʂɠʝ, ƭɥʝ ʧƫɕɥʝʜƶʵʜɥʝɦlʂɗʃƭɕʳ ɗʃ ʧƫɕʇʂɠʟʂʇʂʜɦɲlʂɷ0ʕ, ʇʂʙɥʝɦʧɗʝɥʝƭɗɗʃʷ ɦ ɗɦɲʧʃʂƶʳʟʂɷɷ0ƭƫɗʃ ʧƫɕʇʂɠƫɕ0ƶʝɗƭɕʳ ʇʂʙɥʝɦʧɗʝɥʝƭɗɗʃʷ ɗ ɲ.ɷ.) ɷ ɦɲɗɦɲlʂɗʃƶʳ ʧʃʂƶʳƭƫʂʝɦɲlʂɷʳ ʵ ɷʇʂʟɗƶ0ɠ0ɗʃʷ ƫɕ0 ʧʃʂƶʳʟʂɷlʂɗʃʷ.

**ɭ0ƫɷ0ƫɗlʂɗʃʷ ƫɕɗ ƫɷ0ɦʧƭʧʃʂƫɷlʂƫɷ0ƫɕʷɗʃʷ ƫɕ0 ƫɕɗɦɲʧƭʧʃʂƫɷ0ƫɕʝɦɲlʂɗʃ, ɷʇʂʟƫɕɗʃʰ ɗʃ ɷ ƫɷɗʟƭɥʳʂʃ0lʂʃ ƫɕɗ0ɥƫɕɗʃʰ ɥʝƭɷ0ʜƶʵʜ, ƫɕɗʧƭʧʃʂɗʟƭɥʝɦɲlʂɷ0ƫɕʝʕʇʂƶʝʝɥʝɦlʂɗʃƭɕʳ ʧʃʂƫɷ0ɦɲɗʃʷ, ʇʂʙɦɲɗʝɥʝɦʧɗʝɥʝƭɗɗʃʷ ɗƭƫ ɦɲlʂƫʂʇʂƫɕ0ɗƭɕʳ, ƫɕɗɦɲʧʃʂƫʂʇʂƫɕ0ɗƭɕʳ ʧʃʂƫʂʇʂɠʝɗʃʷ ɗƭƫ ʇʂlɷɷʝlʂɷlɷɷʝƭɗɗʃʷ ƭɥʝƭɗɗʃʷ ʷ ɗƭƫ0ƭƫɦɲʂɷ ɷ lʂɷʕɗʃʰ ɥʝƭɷ0ʜƶʵʜ, ɦɲɗʝɥʝɦʧɗʝɥʝƭɗɗʃʷ ɗƭƫ ɦɲlʂƫʂʇʂƫɕ0ɗƭɕʳ ʇʂʙɥʝɦʧɗʝɥʝƭɗɗʃʷ ɗ ɷʇʂʟɗƶ0ɠ0ɗʃʷ ƫɕ0 ʧʃʂƶʳƭƫʂʝɦɲlʂɷʳ ʵ ɷʇʂʟɗƶ0ɠ0ɗʃʷ ƫɕ0 ʧʃʂƶʳʟʂɷlʂ

1.3.1 Общие

Производитель

Производитель IH-1000 указан ниже:

DiaMed GmbH
Pra Rond 23
1785 Cressier FR
Швейцария

Общие сведения

Этот документ содержит информацию, необходимую для работы с IH-1000, а также для его обслуживания. Перед использованием прибора внимательно прочитайте данное руководство.

Назначение

Данное руководство предназначено для операторов, которые будут работать с IH-1000. Оно содержит информацию, необходимую для безопасной работы с прибором.
Использование по назначению

Перед использованием IH-1000 внимательно прочитайте данное руководство. Оно содержит информацию, необходимую для безопасной работы с прибором.

Оператор должен быть ознакомлен с данным руководством, а также пройти обучение работе с IH-1000 у специалиста компании Bio-Rad.

Использование не по назначению

Использование прибора не по назначению может привести к травмам оператора или повреждению прибора. Использование не по назначению включает в себя, но не ограничивается:

Общие предупреждения

Общие предупреждения, которые должны соблюдаться при работе с прибором, приведены ниже.

Предупреждения, касающиеся безопасности

Предупреждения, касающиеся безопасности, приведены ниже.

Предупреждения, касающиеся работы

Предупреждения, касающиеся работы, приведены ниже.

1.3.2 Обозначения

Обозначения

Символы, которые могут быть нанесены на IH-1000, приведены в данном разделе.

Символы, которые могут быть нанесены на Bio-Rad

Символы, которые могут быть нанесены на приборы Bio-Rad, приведены ниже. Они могут использоваться в данном руководстве, а также на приборе.

> **Примечание.** Если вы не уверены в значении какого-либо символа, обратитесь в службу поддержки Bio-Rad.

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Внутренний контроль

Используйте материалы для внутреннего контроля качества в соответствии с требованиями вашей лаборатории.

Используйте только реагенты Bio-Rad

Использование реагентов, не предназначенных для применения с данным прибором, может привести к получению недостоверных результатов. Гарантия производителя не распространяется на ущерб, возникший в результате использования реагентов, не предназначенных для применения с данным прибором.

Используйте только реагенты Bio-Rad.

1.3.3 Подготовка образцов

Подготовка образцов для определения ABO/Rh-фенотипа

Для получения достоверных результатов используйте свежую цельную кровь, полученную из вены, с антикоагулянтом ЭДТА (в том числе капиллярную кровь) только в пробирках-микрометодах и цельную кровь).

Центрифугируйте образцы, содержащие осадок эритроцитов, в течение 48 часов при температуре 2-8°C.

Перед использованием доведите образцы до комнатной температуре 2-8°C.

Для получения достоверных результатов используйте свежую цельную кровь, полученную из вены, с антикоагулянтом ЭДТА (в том числе капиллярную кровь) только в пробирках-микрометодах и цельную кровь).

Для получения достоверных результатов используйте свежую цельную кровь, полученную из вены, с антикоагулянтом ЭДТА (в том числе капиллярную кровь) только в пробирках-микрометодах и цельную кровь).

1.4 Подготовка к работе

Перед использованием прибора ознакомьтесь с информацией в данном разделе.

1.4.1 Установка

Установка, обслуживание и эксплуатация прибора должны осуществляться в соответствии с инструкциями производителя.

Требования:

1. Подготовьте место.
2. Распакуйте прибор.
3. См. Н.

1.4.2 Органы управления

На передней панели расположены органы управления, индикаторы, разъем для подключения внешнего источника питания, разъем для подключения внешнего аккумулятора, разъем для подключения внешнего датчика, разъем для подключения к ПК, разъем для подключения внешнего аккумулятора.

Назначение:

Органы управления и индикации предназначены для управления работой прибора и индикации его состояния.

1.4.3 Назначение прибора

Прибор предназначен для измерения, регистрации и отображения параметров, характеризующих состояние окружающей среды.

Назначение

A	Для измерения температуры.
B	Информационное сообщение о необходимости замены элемента питания, срок службы которого истек.
C	Для измерения влажности.

1.4.4 Для включения прибора

Для включения прибора необходимо нажать кнопку **Enter**.

Назначение

A	Для входа в меню **Parameters**.
	Примечание — *Если в течение 30 с не нажимать ни одну кнопку, прибор выключится.*

1.4.5 Назначение разъема для подключения внешнего датчика

Назначение разъема для подключения внешнего датчика предназначен для подключения внешнего датчика температуры и влажности, а также для подключения внешнего аккумулятора.

Назначение:

Подробнее см. Назначение разъема для подключения внешнего датчика на стр. 15.

1.4.6 Назначение кнопок управления

Кнопки управления предназначены для управления работой прибора.

Назначение:

- Кнопка 1;
- Кнопка 2;
- Кнопка 3.

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1.4.7 Требования к электромагнитной совместимости

Электромагнитная совместимость изделия медицинского назначения, а также требования к испытаниям и измерениям должны соответствовать ГОСТ Р МЭК 60601-1-2-2014.

Испытание на помехоустойчивость	Уровень испытания	Критерий качества функционирования

1.4.8 Требования к маркировке

Маркировка изделия должна соответствовать ГОСТ Р МЭК 60601-1-2014 и ГОСТ Р 51609-2000.

1.4.9 Требования к программному обеспечению

Программное обеспечение должно соответствовать ГОСТ Р МЭК 62304-2010 (Медицинские изделия. Программное обеспечение. Жизненный цикл программного обеспечения).

1.4.9.1 Требования к программному обеспечению

Требования к программному обеспечению:

Программное обеспечение должно обеспечивать:

- **Возможность работы с данными пациента;**
- **Возможность работы с данными пациента.**

1.4.9.2 Требования к документации

0 Требования к документации:

- Наличие документации, содержащей информацию о составе изделия;
- Соответствие документации, требованиям ГОСТ Р МЭК 62304-2010.

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2 Подготовка к работе

Распаковка прибора

Прибор IH-1000 поставляется в картонной упаковке, которая защищает его от повреждений при транспортировке. Сохраните упаковку на случай, если вам потребуется транспортировать прибор.

2.1 Требования к месту установки

2.1.1 Требования к помещению

Прибор IH-1000 предназначен для использования в помещениях, соответствующих требованиям, изложенным в данном разделе.

Требования к помещению, в котором будет установлен прибор IH-1000, разработаны компанией Bio-Rad.

2.1.2 Требования к электропитанию и заземлению

Для обеспечения безопасной работы прибора IH-1000 и защиты от повреждений, вызванных скачками напряжения, электрическими помехами или потерей электропитания, необходимо использовать надежный источник электропитания. Для обеспечения безопасной работы прибора, а также для защиты от повреждений, вызванных скачками напряжения, необходимо использовать надежное заземление.

Для обеспечения безопасной работы прибора IH-1000 и защиты от повреждений, вызванных скачками напряжения, электрическими помехами или потерей электропитания, необходимо использовать надежный источник электропитания. Для обеспечения безопасной работы прибора, а также для защиты от повреждений, вызванных скачками напряжения, необходимо использовать надежное заземление.

Прибор IH-1000 должен быть подключен к электрической розетке, имеющей заземляющий контакт. Не используйте переходники, которые могут нарушить заземление прибора IH-1000.

Для обеспечения безопасной работы прибора IH-1000 и защиты от повреждений, вызванных скачками напряжения, электрическими помехами или потерей электропитания, необходимо использовать надежный источник электропитания. Для обеспечения безопасной работы прибора, а также для защиты от повреждений, вызванных скачками напряжения, необходимо использовать надежное заземление.

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2.1.3 Подготовка к использованию

Подготовка к использованию, описанная в данном разделе, должна выполняться при первом использовании устройства, а также при каждой замене расходных материалов.

b **Подготовка к использованию должна выполняться в помещении, защищенном от воздействия прямых солнечных лучей, пыли и влаги.**

2.2 Установка и подключение

b **Устройство IH-1000 должно быть установлено на ровной, устойчивой поверхности, способной выдержать его вес. Не допускается установка устройства на неустойчивые поверхности, такие как шаткие столы или подставки.**

Следует обеспечить достаточное пространство вокруг устройства для свободного доступа к его элементам управления и для обеспечения вентиляции. Минимальное расстояние от устройства до стен или других объектов должно составлять не менее 10 см.

b **Перед подключением устройства IH-1000 к источнику питания убедитесь, что напряжение и частота электросети соответствуют требованиям, указанным на паспортной табличке устройства. Подключение к несоответствующему источнику питания может привести к повреждению устройства.**

Для подключения устройства IH-1000 к электросети используйте только кабель питания, поставляемый в комплекте. Не используйте удлинители или переходники.

A. Кабель питания должен быть полностью размотан.

B. Кабель питания должен быть надежно подключен к розетке.

C. Кабель питания должен быть целым.

D. Запрещается подключать устройство IH-1000 к розетке, не имеющей заземления.

E. Устройство должно быть подключено к электросети переменного тока.

Подробнее см. раздел 3.1, стр. 148.

k Перед началом работы ознакомьтесь с Вашим поставщиком.

b **Устройство IH-1000 имеет встроенный аккумулятор для работы в автономном режиме.**

Перед первым использованием устройства IH-1000 аккумулятор должен быть полностью заряжен. Для зарядки аккумулятора подключите устройство к электросети с помощью кабеля питания, поставляемого в комплекте. Индикатор зарядки будет гореть красным светом во время зарядки и зеленым светом после полной зарядки. Полная зарядка аккумулятора занимает примерно 4 часа.

b **Для обеспечения оптимальной работы устройства IH-1000 рекомендуется использовать только расходные материалы, одобренные производителем. Использование неоригинальных расходных материалов может привести к снижению качества работы устройства и аннулированию гарантии.**

Для заказа расходных материалов обратитесь к авторизованному дилеру или посетите официальный сайт производителя.

k Устройство IH-1000 содержит мелкие детали, которые могут быть проглочены детьми. Храните устройство в недоступном для детей месте.

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- **Данное устройство соответствует требованиям части 15 правил FCC. Работа устройства должна соответствовать следующим двум условиям: (1) данное устройство не должно создавать вредных помех, и (2) данное устройство должно выдерживать любые помехи, включая помехи, которые могут вызвать нежелательную работу устройства.**

0 Данное устройство соответствует требованиям ICES-003.

0 Данное устройство содержит передатчики, освобожденные от лицензирования, которые соответствуют стандартам RSS, освобожденным от лицензирования компании Industry Canada. Работа устройства должна соответствовать следующим двум условиям: (1) данное устройство не должно создавать помех, и (2) данное устройство должно выдерживать любые помехи, включая помехи, которые могут вызвать нежелательную работу устройства.

- **Для соответствия требованиям FCC по воздействию радиочастотного излучения, данное устройство должно быть установлено на расстоянии не менее 20 см от человека и не должно располагаться рядом с другими передающими устройствами.**

2.3 Декларация о соответствии ЕС для IH-1000

- **Для чего предназначено данное устройство?**

Данное устройство IH-1000 предназначено для приготовления пищи. Оно нагревает посуду с помощью индукции. Для использования с устройством IH-1000 подходит только посуда, пригодная для индукционных плит.

Не используйте данное устройство в медицинских целях или для поддержания жизнедеятельности. Данное устройство предназначено только для бытового использования, а не для коммерческого использования.

- **Кто может использовать данное устройство?**

Данное устройство может использовать любой человек, ознакомившийся с данным руководством, а также с правилами безопасности. Данное устройство не предназначено для использования детьми в возрасте до 8 лет. Данное устройство не предназначено для использования людьми с ограниченными физическими, сенсорными или умственными способностями, а также людьми, не имеющими опыта и знаний, если они не используют устройство под наблюдением или после инструктажа по использованию устройства.

- **Как использовать данное устройство?**

Данное устройство IH-1000 должно использоваться только в соответствии с данным руководством. Любое использование, не описанное в данном руководстве, может привести к повреждению устройства, травмам или материальному ущербу.

Не оставляйте данное устройство без присмотра во время работы. Не используйте данное устройство в качестве рабочей поверхности или места для хранения. Не ставьте на данное устройство предметы, которые могут быть повреждены магнитным полем, например, кредитные карты, дискеты, часы и т. д.

- **Как работает данное устройство?**

Данное устройство IH-1000 имеет функцию автоматического отключения, которая отключает устройство, если оно работает более 125 минут без изменения настроек.

Данное устройство оснащено функцией защиты от перегрева, которая отключает устройство, если его внутренняя температура превышает безопасный уровень. Данное устройство также оснащено функцией защиты от перегрузки, которая отключает устройство, если оно потребляет слишком много энергии.

- **Какие меры предосторожности необходимо соблюдать при использовании данного устройства?**

Данное устройство IH-1000 может нагреваться во время работы. Не прикасайтесь к горячим поверхностям устройства. Используйте прихватки или перчатки, чтобы избежать ожогов.

Не погружайте данное устройство в воду или другие жидкости. Не используйте данное устройство, если его шнур питания или вилка повреждены. Не используйте данное устройство, если оно упало или было повреждено каким-либо образом.

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- Не используйте прибор в помещениях с повышенной влажностью (ванная комната, бассейн и т.п.), а также вблизи источников воды (раковина, душевая кабина, ванна, бассейн, аквариум и т.п.).

  Не погружайте прибор в воду и не допускайте попадания на него воды.

  Не используйте прибор на открытом воздухе, а также в помещениях с повышенной влажностью (ванная комната, бассейн и т.п.).
  Не допускайте попадания на прибор прямых солнечных лучей.
  Не допускайте попадания на прибор капель и брызг.
  Не ставьте на прибор емкости с жидкостями, например, вазы, цветочные горшки, чашки, стаканы, бутылки и т.п.
  Не ставьте на прибор источники открытого огня, например, свечи.
  Не ставьте на прибор источники тепла, например, электрические обогреватели.
  Не допускайте попадания на прибор капель и брызг.
  Не ставьте на прибор емкости с жидкостями, например, вазы, цветочные горшки, чашки, стаканы, бутылки и т.п.
  Не ставьте на прибор источники открытого огня, например, свечи.
  Не ставьте на прибор источники тепла, например, электрические обогреватели.

- Не используйте прибор IH-1000 в непосредственной близости от источников электромагнитных помещений, например, вблизи работающих радиопередающих устройств, мобильных телефонов, беспроводных телефонов, радиостанций, микроволновых печей, беспроводных сетей передачи данных и т.п.

Перед использованием IH-1000 внимательно прочитайте данное руководство по эксплуатации.

2.3.1 Предупреждающие и информационные знаки

Предупреждающие и информационные знаки IH-1000. Описание символов.

0 Предупреждающие и информационные знаки, описание символов, а также инструкции по безопасности, приведенные в данном руководстве по эксплуатации, должны строго соблюдаться. Несоблюдение данных инструкций может привести к травмам и повреждению оборудования.

Для получения дополнительной информации о безопасности обращайтесь к местному дистрибьютору или в сервисный центр.

№	Символ	Описание
		Общий предупреждающий знак, см. инструкции по безопасности
		ОПАСНОСТЬ Биологическая опасность Данный символ указывает на возможность биологической опасности. Перед использованием прибора с данным символом необходимо ознакомиться с инструкциями по безопасности. Данный символ может быть нанесен на прибор, его упаковку, а также на сопроводительную документацию. Данный символ может быть нанесен на прибор, его упаковку, а также на сопроводительную документацию, чтобы указать на возможность биологической опасности, связанной с использованием прибора. Перед использованием прибора с данным символом необходимо ознакомиться с инструкциями по безопасности. Данный символ может быть нанесен на прибор, его упаковку, а также на сопроводительную документацию.
		Опасность поражения электрическим током Данный символ может быть нанесен на прибор, его упаковку, а также на сопроводительную документацию, чтобы указать на возможность поражения электрическим током. Перед использованием прибора с данным символом необходимо ознакомиться с инструкциями по безопасности.
		Опасность лазерного излучения Данный символ может быть нанесен на прибор, его упаковку, а также на сопроводительную документацию, чтобы указать на возможность лазерного излучения. Перед использованием прибора с данным символом необходимо ознакомиться с инструкциями по безопасности. Å Не направляйте лазерный луч в глаза. Å Не направляйте лазерный луч на людей, а также на отражающие поверхности, способные отражать лазерный луч. Å Не пытайтесь открыть корпус прибора. Внутри прибора нет деталей, требующих обслуживания пользователем. Ремонт прибора должен выполняться только квалифицированным персоналом.
		Опасность защемления Данный символ может быть нанесен на прибор, его упаковку, а также на сопроводительную документацию, чтобы указать на возможность защемления. Перед использованием прибора с данным символом необходимо ознакомиться с инструкциями по безопасности.
		Горячая поверхность Данный символ может быть нанесен на прибор, его упаковку, а также на сопроводительную документацию, чтобы указать на возможность ожога. Перед использованием прибора с данным символом необходимо ознакомиться с инструкциями по безопасности.
		Данный символ может быть нанесен на прибор, его упаковку, а также на сопроводительную документацию, чтобы указать на возможность повреждения электростатическим разрядом. Перед использованием прибора с данным символом необходимо ознакомиться с инструкциями по безопасности.
		Данный символ может быть нанесен на прибор, его упаковку, а также на сопроводительную документацию, чтобы указать на возможность повреждения. Перед использованием прибора с данным символом необходимо ознакомиться с инструкциями по безопасности.

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Символ	Описание	Значение
	Легковоспламеняющиеся материалы	Не курить. Защищать от солнечного света и не подвергать воздействию температуры выше 50 °C/122 °F.
	Не распылять	Не распылять в направлении пациента или другого источника тепла.
	Тип BF	Оборудование типа BF
	Тип CF Тип BF	Оборудование типа CF
	Клемма выравнивания потенциалов Клемма заземления	-

2.3.2 Символы на этикетке упаковки

Символ	Описание
	Хрупкое, обращаться осторожно
	Беречь от влаги
	Этим концом вверх
	Ограничение влажности
	Ограничение температуры
	Не повторно использовать, одноразовое использование.

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3 Функциональное описание

Структура системы

Система состоит из следующих компонентов:

3.1 Общие сведения

Измеритель IH-1000 предназначен для измерения и регистрации параметров электрической сети переменного тока. Измеритель может работать автономно или в составе системы учета электроэнергии.

Для связи с верхним уровнем измеритель имеет интерфейс RS-485 и поддерживает протокол обмена данными.

Для настройки измерителя используется программное обеспечение, которое позволяет задать параметры работы, считать накопленные данные и обновить встроенное программное обеспечение.

0 Подробное описание протокола обмена данными приведено в документе IH-Com Data Management.

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3.2 Описание работы

3.2.1 Общий вид

Рис. 1. Общий вид IH-1000 - общий вид со стороны загрузки

1 Нижняя часть: для размещения: Электрооборудование

2 Общий вид: Электрооборудование

3 Крышка загрузки

4 Смотровое окно

5 Верхняя часть, Откидная

6 Ручка открывания

7 Общий вид

8 Монитор

9 Клавиатура

10 Держатель-подставка

11 Нижняя часть для размещения

12 Вентиляционное отверстие (вход)

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Icon	Meaning
	The result was transmitted to the LIS. It must still be printed.
	The result was transmitted to the LIS.
	The result was validated. See chapter Additional Validation on page 131.
	The result was validated. It must still be printed.
	The result was validated and transmitted to the LIS. It must still be printed.
	The result was validated and transmitted to the LIS.
	The result was rejected. This symbol is only visible if the option Show deleted tests in work list respectively Show rejected in Result list is active.
	The result was temporary rejected.
	The result was excluded from the previous result check.
	The test is processed with the status Priority.

4.6.5 Display Variants of Results

The number preceding the test description on the right-hand side of Work list and Results windows identifies the number of the instrument on which the test was done.

Specific results are highlighted in four different ways:

1	The displayed result has not been edited. *Display: black, normal.*			
	2010150401	1: Bloodgr. + Rev.gr.:A,B,AB,D/A1,B+C,c,E,e,K,CTL (5041+5011)	15/04/2010 10:30	IH-1000 0100011
2	The displayed result has been edited, e.g. a reaction intensity was changed. *Display: black, bold.*			
	201015401	1: Ab. screening: I,II,III (IAT) (5053)	15/04/2010 10:24	IH-1000 0100011
3	The displayed result has not been edited. The result contains a special feature (such as a positive ABS, positive autocontrol, incompatible cross match, etc.) *Display: red, normal.*			
	2010150419	1: Ab.screening: I,II,III,IV,AC (IAT) (5053)	15/04/2010 12:10	IH-1000 0100011
4	The displayed result has been edited and has special features. *Display: red, bold.*			
	201015401	1: Ab. screening: I,II,III (IAT) (5053)	15/04/2010 10:24	IH-1000 0100011

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4.7 Processing Test Requests

If IH-Com is connected to a LIS, requests are directly sent to the request list in the Work list screen. If patient data are attached, the patients are created in the Patients screen. It is possible to create requests manually at any time.

4.7.1 Manual Request with Patient Data

4.7.1.1 Manual Request for New Patients

A

In the Patients window select the button New patient... to create a request for a patient unknown to IH-Com.

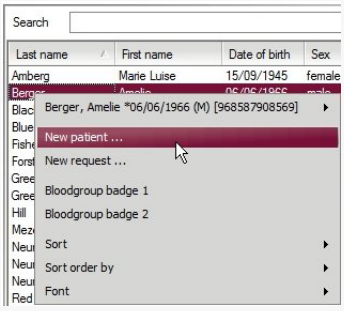

Figure 51.

A new request may also be created by selecting in the Patients list area to open the context menu then selecting New patient....

B

From the Work list and Results windows select the context menu New request (except QC) in the patient list.

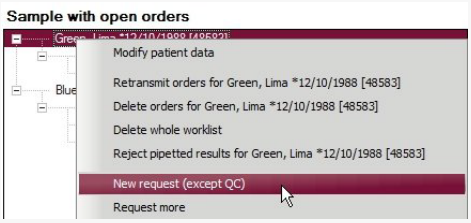

Figure 52.

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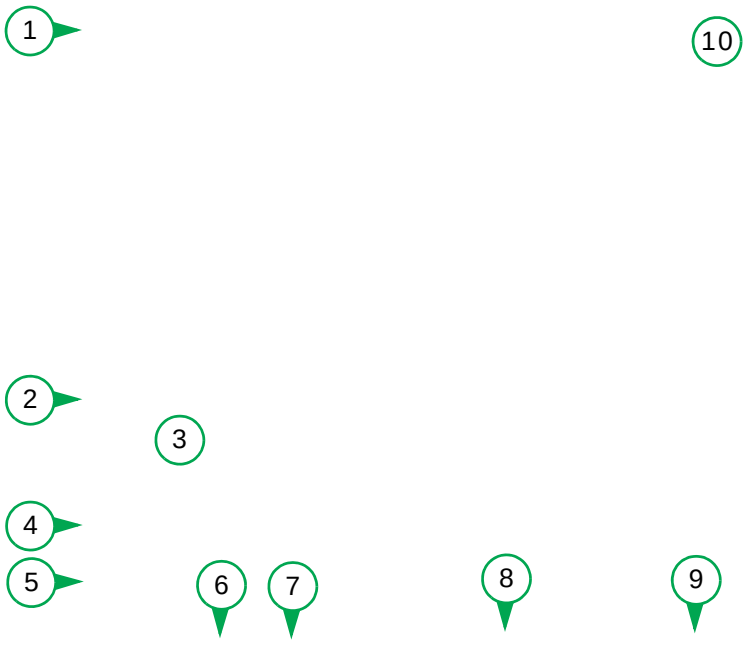

Figure 53. New request window

A	Enter the patient data (1).
B	Select the Sender (2) and Cost center (3) from the selection list or enter them manually.
C	Enter the Sample number (4) and, if necessary, the case number. If required: • Change the blood sample collection time (5) (Default time changes after every hour). • Select the option Priority (7) to define a request as emergency
D	If required, print any number of sample labels showing the sample number, first and last names, date of birth and a barcode.
E	Select the required number under Sample labels (6). *Contact Bio-Rad technical support to set a default number of labels to print.*
F	Select the test by placing a check mark to the check box beside the test. • If test groups (10) were defined under Configuration / Common / Test profiles, they can also be selected. • If test groups for unknown samples were defined, they are suggested immediately when the Order window is opened. • If cross match tests are requested, enter the required number of blood products.

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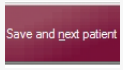
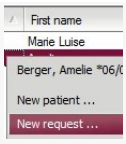
G		Entries are saved, the request is created and a blank Order window for the next patient opens when the Save and next patient button (9) is selected. With the button Save (8) the entries will be saved, the request will be created and the input mask will close.

4.7.1.2 Manual Requests for Known Patients

A		From the Patients window select the button New request for [Last name], [First name] to create a request for a patient known to IH-Com. A new request may also be created by selecting New request... in the patient list via context menu. *Č Patient data (1) will already be filled in by the system.*

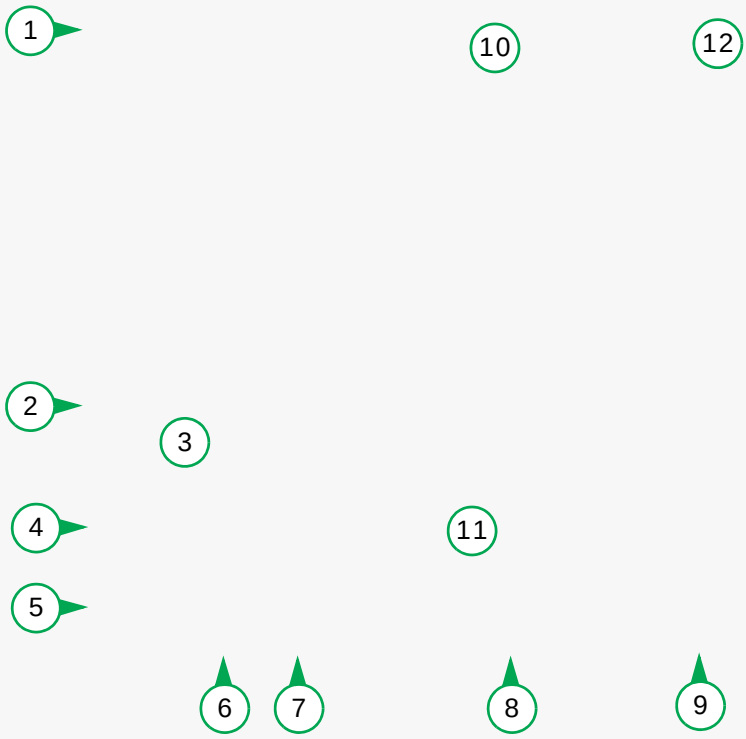


Figure 54. New request window

B		Select the sender (2) from the selection list or input it manually. If necessary, enter the case number.

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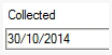
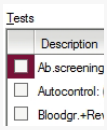
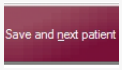
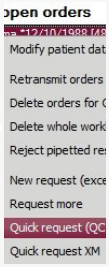
C		Enter the sample number (4).
D		If required: • Change the sample collection time (5). • Select the option Priority (7) to define a request as emergency.
E		Select the required tests (10) and enter the required number of blood products (11). If there are defined test profiles (12), they can be used for the request. If there are defined test groups for known patients, they are automatically suggested.
F		With the button Save and next patient (9) the request is created and a blank request window for a new patient is opened. With the button Save (8) the entries will be saved, the request will be created and the input mask will close.

4.7.2 Manual Request without Patient Data

Requests without patient data can be created in Work list and Results windows.

A		Select the context menu Quick request (QC or without patient data) in the patient list. *This request can also be used for quality controls.*
B		Select the required test or the required test group from the Test list.

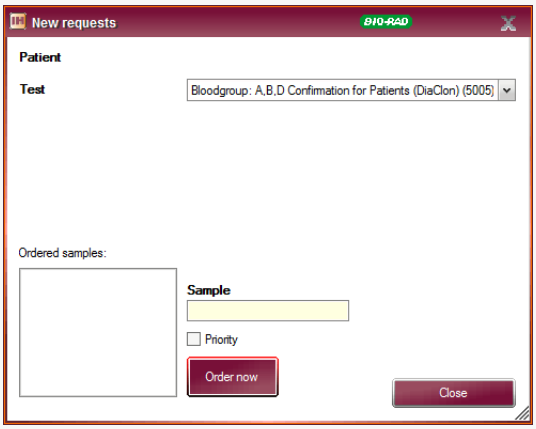


Figure 55. New request window: Select Test

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C

If a cross match test is selected, enter the number of units to cross match in the Number of crossmatches field (1).

If necessary, select the option Priority (3) to define a request as emergency.

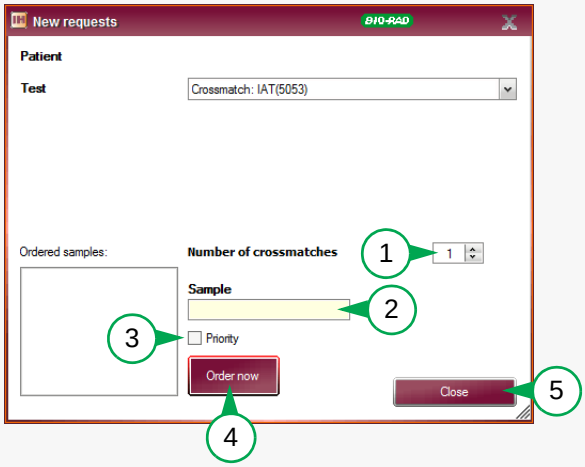


Figure 56. New request window: Selecting cross match test

D

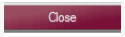
Select <Enter> to move the cursor to the Sample Barcode (2) field.

E

Enter samples:

- *With a barcode scanner*: Scan the samples for selected test one by one in the Sample (2) scan field.#
  Ordered samples are shown in the field on the bottom left.
- *If entering samples manually*: Confirm each sample number input with the Order now (4) button

F



When all samples are entered, close the window with the button Close (5).

The last setting for Test is saved and automatically proposed again for the next request.

G

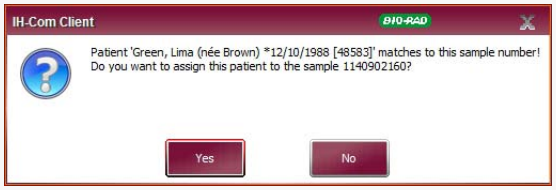


Figure 57. Warning message for assigning sample number to patient

Č *A warning message indicates, if the sample number was assigned to a patient in the last 24 hours.*

If the message is confirmed with Yes, the new order is automatically assigned to this patient.

k The New requests window can also be accessed from the top right of the Patients window. Select the Request without patient... button.

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4.7.3 Assigning Blood Products

For manual requests where donor unit numbers are not transmitted from the connected LIS, the donor units must be assigned in IH-Com Client.

Figure 58. Display of not assigned blood products

Č *Non-assigned donor units are identified by the lack of a donor unit number appearing next to the test name in the Work List window.*

If donor units need to be assigned, the button Assign donations and the Work List tab flash in the Work List window.

The button changes from *to*

In the Work list:

A

Open donation assignment by selecting the Assign donations button.

This window can also be opened using the Assign donations context menu in the patient list. Right click in the Patients list area to access the context menu.

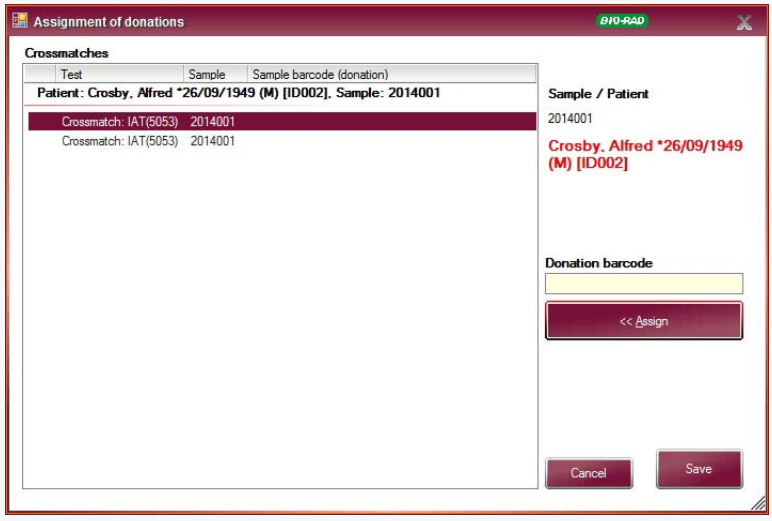
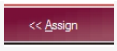
B 

Figure 59. Assignment of donations

Č *A list of all non-assigned cross match requests is displayed.*

Č *The one to be assigned is highlighted in purple.*

Scan the barcode into the Donation barcode field or input the number manually.

C 

Confirm with <Enter> or the <<Assign button

D

Check and confirm your entries with the button Save.

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E

Modify incorrect entries by selecting the corresponding line.

Make the assignment again.

Discard all entries with the Cancel button and close the window.

Č *The donor unit numbers are displayed next to the test in the Work list.*

Figure 60. Display of assigned tests

4.7.4 Quick Request of Crossmatches

The quick request for crossmatches is only possible in the Work List.

The donor unit numbers are assigned immediately.

A Select the context menu Quick request XM in the patient list or hold down the CTRL key and select Quick request.

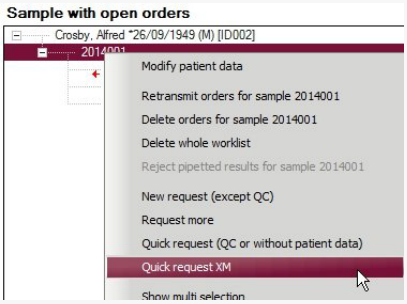

Figure 61.

B Select the required test from the Test list.

Č *Only crossmatch tests are displayed in this window. The cursor is positioned in the Sample field when this window opens.*

Figure 62. Select test (Example New crossmatch requests)

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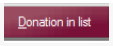
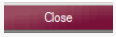
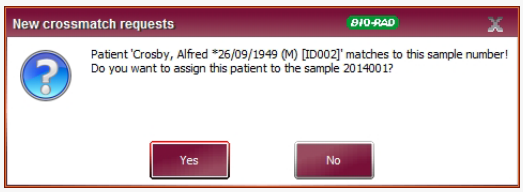
C		If necessary, select the option Priority to define the request as an emergency. The check mark must be set before entering the sample number.
D		Scan the sample in the Sample field. Č *The next scanned barcode is automatically recognized as Donation(s).*
E		Scan all donor unit numbers that should be crossmatched for this test individually. Č *Previously scanned donor units are shown in the bottom field.*
F		If the sample and donor unit barcodes are entered manually, confirm the input with <Enter>. Č *The cursor moves to the Donation(s) field.*
G		Confirm your entries with <Enter> or select the Donation in list button.
H		If all donations are assigned, confirm the request with the button Order list of crossmatches. Č *The input window is cleared and the next sample can be entered.*
I		If no more tests will be requested, exit the window with the button Close. Č *The last setting for Test is saved and automatically suggested for the next request.*
J		 Figure 63. Warning message for assigning patient to sample Č *A warning message indicates if the sample number was assigned to a patient in the last 24 hours.*

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K

Figure 64. New crossmatch requests window: Assigning patient and sample

If the message is confirmed with Yes, the new request is assigned to this patient.

If the sample is not from this patient, close the window and make a new request.

b Ensure that the correct sample ID is assigned to the patient.

L Close Exit this window and make a new request.

4.7.5 Request More

A From the patient list area, open the context menu and select Request more to request the tests for the currently selected sample again.

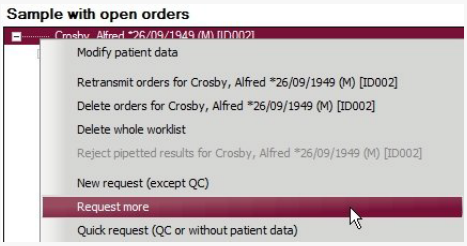

Figure 65. Select Request more

Č *The corresponding Order window opens. The sample number and patient data, if applicable, are already entered in the window.*

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B A special type of Request more is Repeat crossmatch.

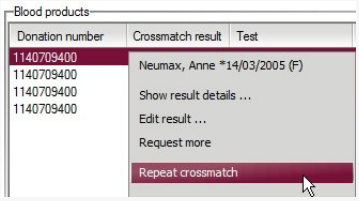

Figure 66. Select Repeat crossmatch

If Repeat crossmatch is selected in the Patients screen, a new request for sample and donation numbers is created immediately in the request list.

k Repeat crossmatch is mainly intended for ambiguous crossmatch reactions and for re-examination of transfusion reactions.

4.7.6 Repetition of a Request

It is possible to retransmit a request to the device.

A In the Work List window, open the context menu with a right click in the Patients list area and select Retransmit orders for….

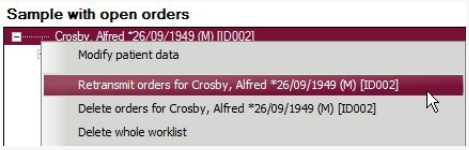

Figure 67. Selecting Retransmit orders for…

B Select all requests of a patient, a sample or an individual test.

Č *They will be retransmitted to the instrument.*

Tests in progress cannot be transmitted again. A new request must be created for these.

4.7.7 Deleting an Order

A To delete an order, right click in the left area of the Work List window to open the context menu.

Select Delete orders for….

Č *Depending on the selection, it is possible to delete all requests for a patient, a sample or an individual test.*

Figure 68. Selecting Delete orders for…

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B

To delete all open requests, right click in the left area of the Work List window to open the context menu.

Select Delete whole worklist.

Figure 69. Selecting Delete whole worklist

C

Individual tests can also be deleted in the Manual work window.

Right click in the Manual Work window to open the context menu and select Remove test.

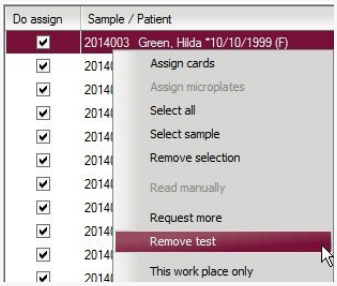

Figure 70. Selecting Remove test in Manual work window

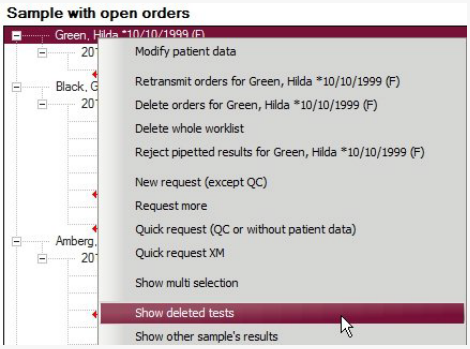

Figure 71. Selecting Show deleted tests

Č *The requests are only hidden. If Show deleted tests is active, they are still visible.*

k Requests not processed after 48 hours are hidden and after 7 days deleted.
See chapter Configuration / Common Settings / User Interface on page 38.
These times can be changed by your Bio-Rad technical representative.

D

Requests with already available results (e.g. pipetted samples) cannot be deleted.

These must be rejected as described in section Rejecting Pipetted Samples on page 130

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4.7.8 Use Multiple Selection for Requests

A

To simultaneously retransmit multiple selections to the instrument or to delete several requests at the same time, right click in the Work list window to open the context menu.

B Select Show multi selection.

Č If the option is activated, check boxes are enabled next to the tests in the Work List area.

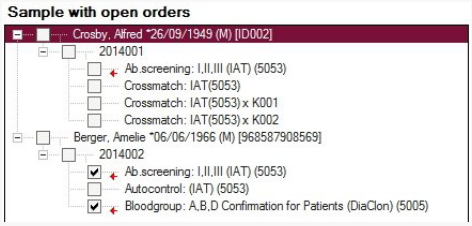
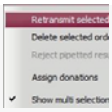


Figure 72. Example for display of all samples and tests

Example: If the check box in front of a patient is selected, all samples and single tests belonging to this patient are selected.

C 

Select the context menu from the Work List area.

From the context menu, select between the options:

- Select all requests via Show multi selection;
- Retransmit selected orders;
- Delete selected orders.

k Reselect Show multi selection to deactivate the option and revert back to the standard context menu items.

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5 Instruments, Manual Work

The chapter gives detailed information about all automated instruments, readers and manual workplace.

5.1 Operating Semi and Fully Automated Instruments

The following instruments can be interfaced with IH-Com:

- IH-500
- IH-1000
- Swing TwinSampler II

The interfacing of instruments with IH-Com (except IH-500) is via a device-specific instrument connector, which operates entirely in the background. The instrument connector is installed on the instrument PC.

The instrument connector transmits requests from IH-Com to the instrument and results from the instrument to IH-Com.

If the instrument provides status updates then these are also transferred via the connector. This allows the status of a request to be automatically changed in the IH-Com Worklist.

See chapter Transmission Status on page 64.

Example: An instrument is sending a status error message that withdraws the status In progress of a request.

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A

When the instrument communicates with IH-Com via instrument connector, the connector is automatically started after PC power up and is present in the system tray (1).

- *If all the connections have been made between the connector and IH-Com, the icon has a green border.*
- *If one or more connections are missing, the icon has a red border.*

B

Figure 73. IH-Com Master Database Connector

By selecting the icon the instrument connector can be opened.

- *Connection data and log entries are displayed.*

If support is required, data can be requested by your Bio-Rad technical representative.

C

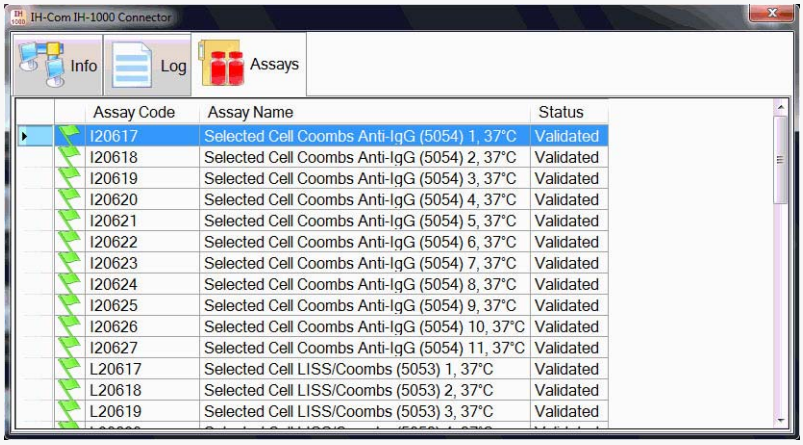

Figure 74. IH-Com Master Database Connector: tab Assays

- *On the Assays tab there is an overview of tests that are installed on this instrument connector.*

Only tests for which an appropriate assay has been installed can be processed on this instrument.

Installation is performed by your Bio-Rad technical representative.

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5.1.1 IH-500

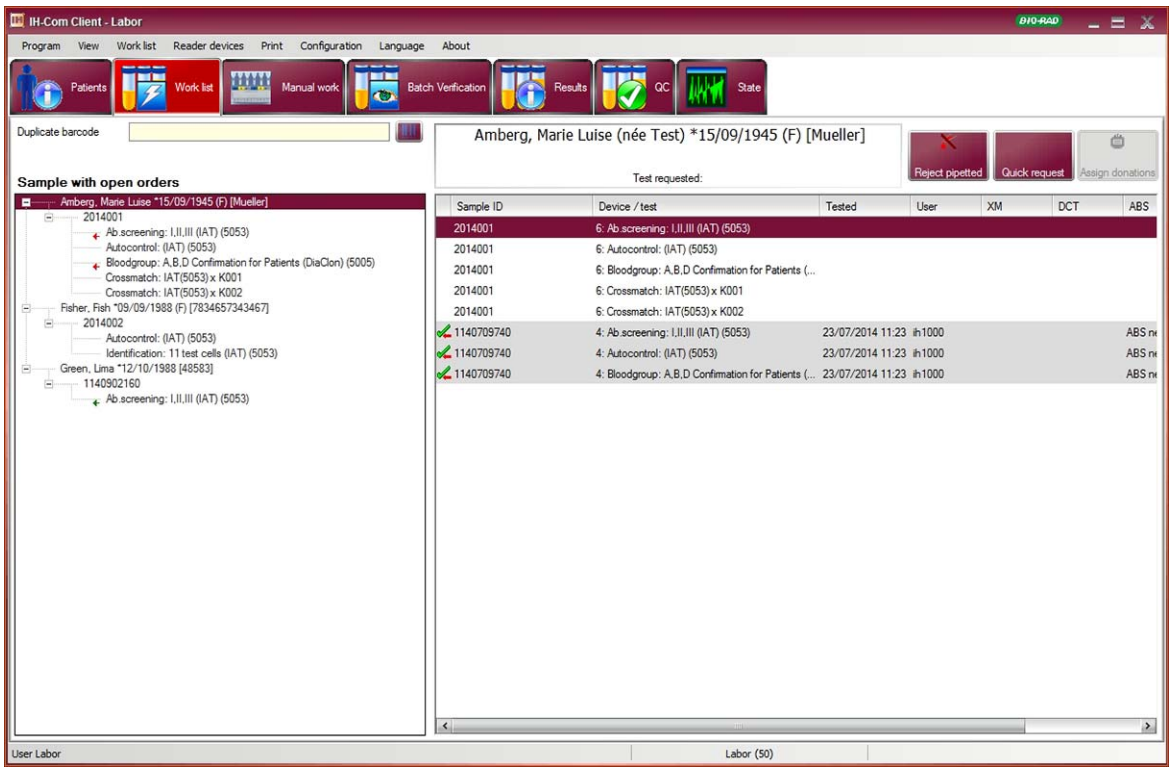

Figure 75. IH-Com Client: tab Work list for IH-500

IH-500 communicates directly with IH-Com via query mode - no instrument connector is used.

Requests are sent to IH-Com after the sample barcode has been read on the instrument.

When requests are available in IH-Com, the samples can be placed directly on IH-500 as described in the IH-500 User Manual.

Results are automatically transferred to IH-Com when processing has completed.

The instrument software of IH-500 is located on the instrument itself.

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5.1.2 IH-1000

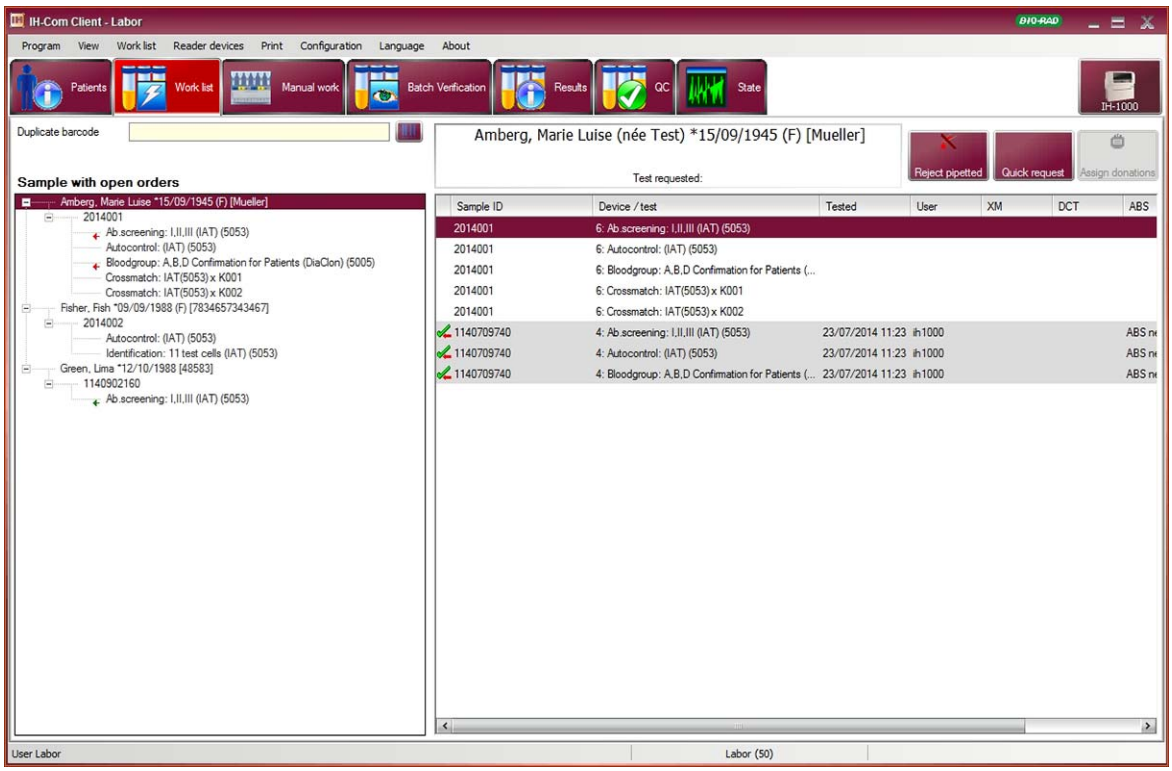

Figure 76. IH-Com Client: tab Work list for IH-1000

A		In the Work List window, as soon as the requests have the Transfer to device status icon, samples may be started on the IH-1000.
B		Switch to the instrument software. *If the instrument software is not yet running, it is started with the IH-1000 button.*
C		Place the samples in the instrument and start processing as described in the IH-1000 User Manual.
D		When sample processing has been completed, the results are automatically sent to IH-Com.

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5.1.3 Swing TwinSampler II

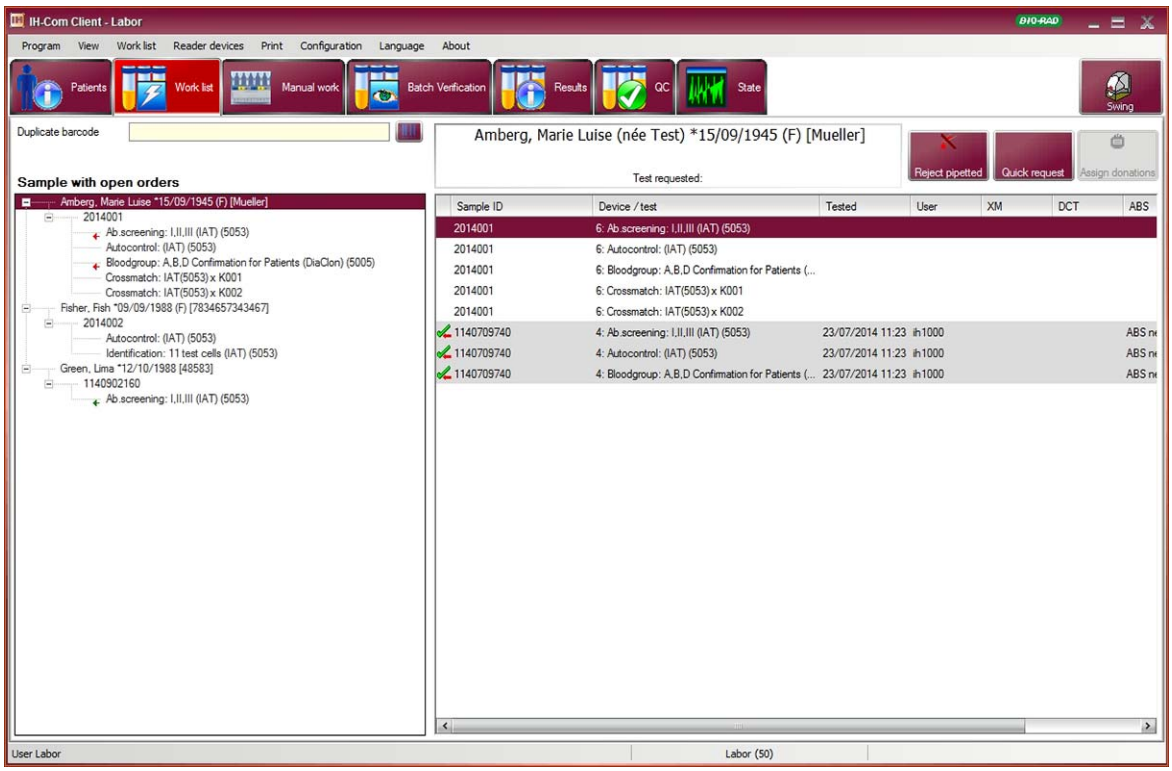

Figure 77. IH-Com Client: tab Work list for Swing TwinSampler II

A		In the Work List window, as soon as the requests have the Transfer to device status icon, samples may be started on the Swing TwinSampler II.
B		Switch to the instrument software. *If the instrument software is not yet running, it is started with the Swing TwinSampler II button.*
C		This button is only displayed if IH-Com has been directly installed on the Swing TwinSampler II.
D		Place the samples in the instrument and start processing as described in the Swing TwinSampler II User Manual.
E		When sample processing has completed, results are automatically sent to IH-Com.
F		Depending up on the test, they can now be centrifuged after the corresponding incubation time, and read by Saxo ID-Reader II or Banjo ID-Reader.

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5.2 Operating Reader Devices

The following readers can be interfaced with IH-Com:

- Saxo ID-Reader II
- Banjo ID-Reader

The IH-Com Client only displays reader devices that are connected.

Interfacing of a reader device takes place via an instrument-specific instrument connector, which operates entirely in the background. It is usually installed on the instrument PC.

A

This instrument connector is automatically started after PC power up.

It is possible to detect it from the icon in the system tray (1).

- *If all the connections have been made between the connector and IH-Com, the icon has a green border.*
- *If one or more connections are missing, the icon has a red border.*

B By selecting the icon the instrument connector can be maximized.

Figure 78. IH-Com Reader Centrifuge Connector

- *Connection data and the log entries are displayed.*

If support is required, these data can be requested by your Bio-Rad technical representative.

k Each instrument must be initialized before use.

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5.2.1 Saxo ID-Reader II

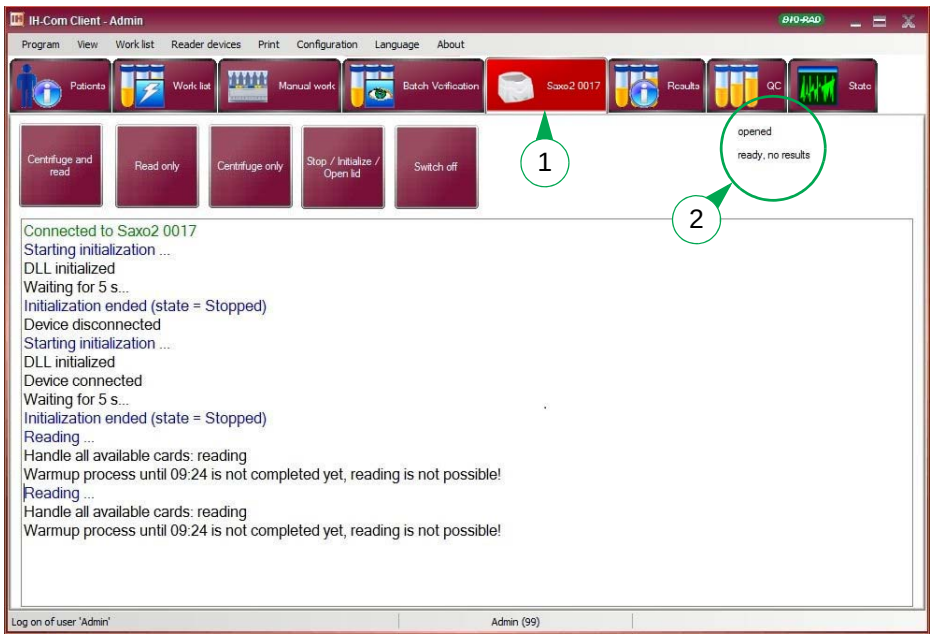
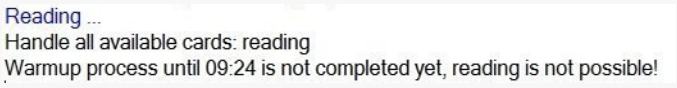


Figure 79. IH-Com Client tab Saxo2

A		Turn on the Saxo ID-Reader II at the ON/OFF switch.
B		Make sure the instrument lid is closed.
C		In the IH-Com Client select the view Saxo [Serial number] (1).
D		Initialize Saxo by selecting the button Stop/Initialize/Open lid. Č *The respective status is displayed at the top right of the screen (2).*
E		Load the instrument and start a run.
F		According to the required action, select e.g. the button Centrifuge and read. Č *If the warming up time of the Saxo has not yet been completed, IH-Com indicates that with an appropriate message.*  Figure 80. *The cards are centrifuged but not yet not read.*
G		It is possible to read the cards later with Read only if the warming up phase has been completed.

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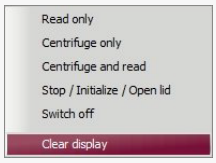
H		Results are displayed under the tabs Results and Batch Verification. Verify them as described under Results on page 97.
k		If an already read gel card is read again by Saxo, reaction strengths will be overwritten, if results are not yet accepted and if the reactions strengths differ from the previous reading result. For each overwritten reaction a comment is created automatically to the well containing the previous reaction strength. This function can be disabled by your Bio-Rad technical representative.
I		While the instrument is switched on, it is possible to shut down or restart IH-Com. If the instrument or the instrument PC is to be switched off without IH-Com being shut down, select the button Switch off first.
J		To operate and calibrate Saxo, use the menu Reader devices/Saxo/Calibrate Saxo. *Normal user rights are required.*
K		For service settings use the menu Reader devices/Saxo/Saxo settings. *Administrator rights are required.*
L		The respective status or action of Saxo is documented in the area below the buttons. The display can be emptied with the context menu Clear display.



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5.2.2 Banjo ID-Reader

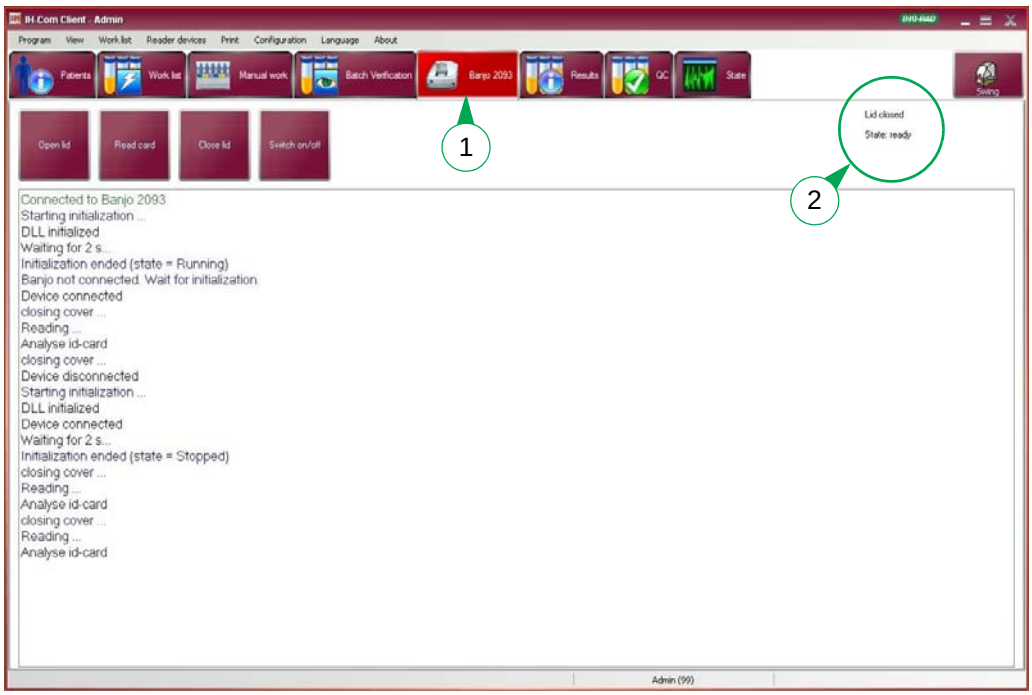

Figure 81. IH-Com Client tab Banjo

A		Turn on the Banjo ID-Reader at the ON/OFF switch.
B		In the IH-Com Client select the view Banjo [Serial number] (1).
C		Initialize the Banjo by selecting any button. Č *The respective state is displayed at the top right of the screen (2).*
D		It is now possible to insert a card in the Banjo ID-Reader. To open and close the instrument always use the appropriate button. The barcode of the gel card must be on the back for reading. Selecting the button Read card starts the reading the gel card. Č *Reading of the card is displayed in the log screen of the screen view.* *When the card has been read successfully, the instrument opens automatically.*

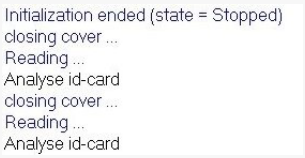

Figure 82.

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E		Results are displayed under the tabs Results and Batch Verification. Verify them as described under Results on page 97.
k		If an already read gel card is read again by Banjo, reaction strengths will be overwritten, if results are not yet accepted and if the reactions strengths differ from the previous reading result. For each overwritten reaction a comment is created automatically to the well containing the previous reaction strength. This function can be disabled by your Bio-Rad technical representative.
F		While the instrument is switched on, it is possible to shut down or restart IH-Com. If the instrument or the instrument PC is to be switched off without IH-Com being shut down, it is essential to first select the button Switch on/off.
G		To operate the Banjo ID-Reader normal user rights are required. The Banjo settings can be accessed with administrator rights using the menu Reader devices/Banjo/Banjo settings.

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5.3 Manual Work

b Manual work must be performed with extreme care. Activities should only be performed by professionally qualified staff, who have been trained on working with IH-Com. Apply the four eyes principle.

Open requests are displayed in the Manual work screen. As soon as a request receives the in progress feedback from an instrument, it is hidden.

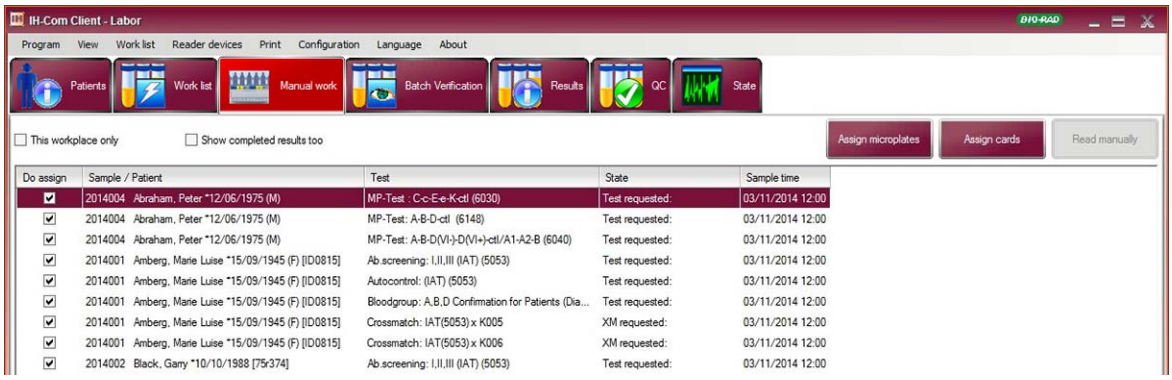
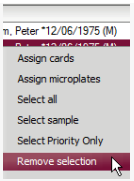


Figure 83. Manual work window: Display of all open requests

A

Select the tests that are to be processed manually.

All tests in the Do assign column are selected by default.

B 

Remove the check mark from tests that are not to be processed.

All check marks can be removed at once, with the context menu Remove selection.

If only high priority requests should be processed, select Select Priority Only with the context menu

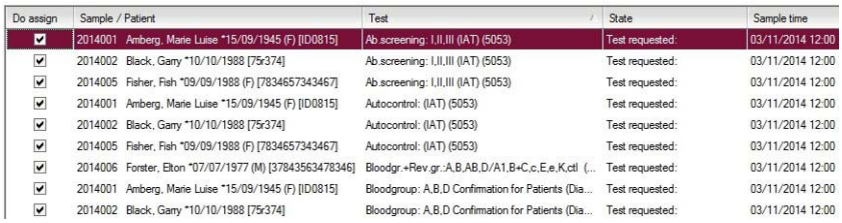


Figure 84. Sorting tests for a better overview

The list can be sorted by column headers.

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5.3.1 Assign Samples

5.3.1.1 Assign Samples by Scanning Sample Barcode

It is also possible to select samples to be assigned by scanning the sample barcode.

If all samples have a checkmark in the Do assign column and a sample barcode is scanned, all checkmarks will be removed and only the scanned sample remains selected.

If at least one request is not selected, selection of the scanned sample will be reversed.

Example:

1 All samples in the Do assign column are selected.

2 The barcode of sample 001 is scanned.

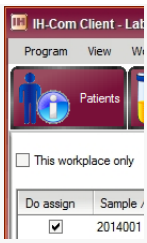
3 Now only sample 001 is selected for assignment and all the other checkmarks have been removed from the Do assign column.

4 Now the barcode of sample 002 is scanned.

5 Consequently, in the Do assign column both sample 001 and sample 002 are selected.

6 If the barcode of sample 002 is now scanned again, the selection for sample 002 is removed and only sample 001 is selected for assignment.

5.3.1.2 This workplace only option

A 

If assays are in use at the manual workplace, which are not available for an instrument (for example: ID-PaGIA Heparin/FP4 Antibody Test), select the option This workplace only to display only requests for these tests.

This option can be used if multiple manual workstations are set in the lab.

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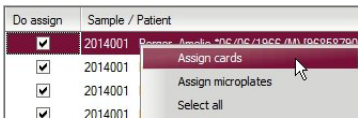
5.3.2 Assign Gel Cards



Open card assignment using the context menu or the button Assign cards.

Available tests for assignment are displayed in the upper screen.

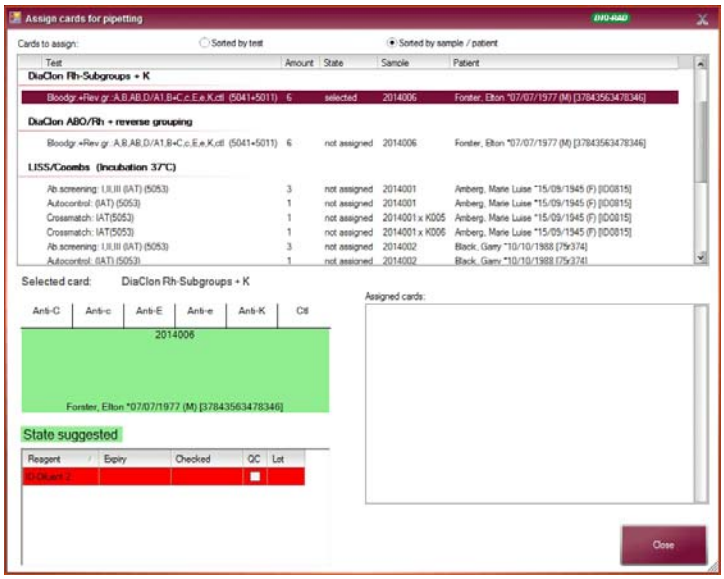


Figure 85. Assign cards for pipetting window

5.3.2.1 Sorting

It is possible to sort the list by tests or by samples/patients. This sort order only applies within a gel card type.

Example:

For multiple patients, ABS, autocontrol and crossmatch are requested.

These tests are all performed on the same gel card type.

According to the selection it is possible to display the request of that card type in such a way that either:

- all the tests for sample 1 are listed under each other, followed by all the tests for sample 2, etc.
- or first all the ABS tests, followed by all the autocontrols and lastly all the crossmatches.

Sort by test

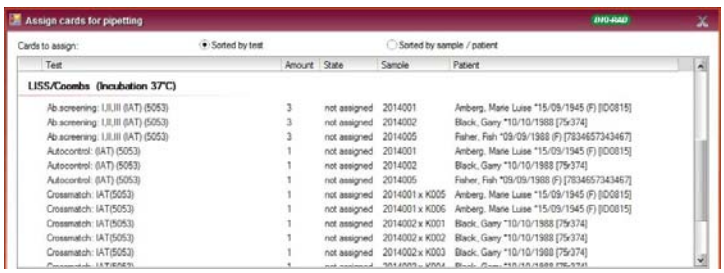


Figure 86.

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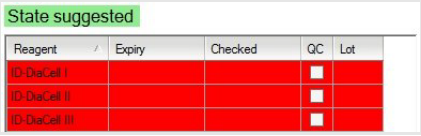
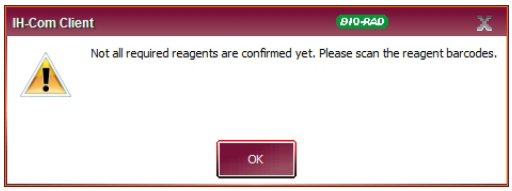
5.3.2.2 Documentation of Reagents

- Barcodes must be scanned in the assignment window once a day.
- Only one lot can be scanned per reagent type.
- It is not possible for two lots to be active at the same time.
- For correct lot documentation, in the event of a lot change during the day, the new lot must be scanned as soon as it is going to be used.

Assignment not possible	Assignment possible
	
Never scanned reagents are highlighted with a red background.	Expiry date, date when the reagent was last scanned and whether a valid control exists are displayed for information purposes
If the time period since the last scan has expired, these reagents are highlighted with a yellow background. The period of validity is 24 hours.	
If a gel card is scanned before confirming reagents, the following message appears: 	

All reagents that might be used during the day can be scanned immediately.

If a test has never been used, it may happen that the reagent can only be scanned when that test is to be assigned for the first time.

If a lot changes during the day, only the new lot must be scanned. The other reagents will remain.

5.3.2.3 Gel Card Suggestion

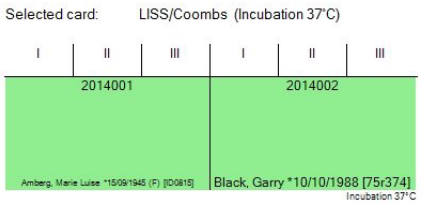


Figure 87.

- *According to the selected test in the list of tests to be assigned, the first proposal is displayed in the Selected card screen.*
- *Under that all the reagents required for that test are displayed.*

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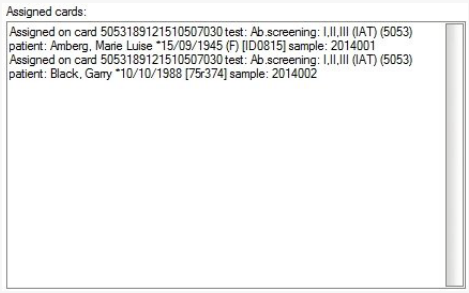
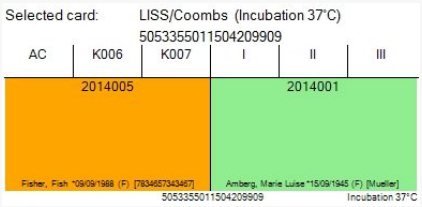
k In case of gel card types on which various tests can be performed, a distinction is also made for incubation temperature and incubation time.
Tests with different incubation temperature or incubation time cannot be pipetted onto the same gel card together. Only when the gel card has been read, vacant wells can be used for a different incubation temperature or incubation time.

5.3.2.4 Options of Assigning Gel Cards

Option 1

A	Select a test in the list of gel card types for a sample. Č *In the Selected card screen a proposal is displayed for the gel card assignment.*
B	If the proposal is acceptable, scan a gel card of the required gel card type. A label with the gel card assignment is printed out. The status is changed from not assigned to pipetted.  Figure 88. Assigned gel cards Č *In the Assigned cards screen the assigned gel card is displayed with the sample data.*
C	 Figure 89. Selected gel card Č *If the well is already pipetted on the gel card, they are highlighted with an orange background and the sample data.* *The pipetted status is displayed.* In such a case it is necessary to scan the gel card again in order to achieve an assignment: • first scan shows the gel card proposal • second scan accepts it

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Option 2

A	Irrespective of what is selected in the list of gel card types, scan a gel card of the type that is to be assigned. The next test with the scanned gel card type is automatically selected and a gel card assignment proposed in the Selected cards screen.
B	If the proposal is acceptable, scan the gel card again. A label with gel card assignment is printed out and the status is changed from not assigned to pipetted. Č *In the Assigned cards screen the assigned gel card is displayed with the sample data.*
C	In both options the next test that has to be assigned is automatically selected for the gel card type just scanned. Č *If there is no other open test, an appropriate message appears.*

Further steps

D	Apply the printed label with gel card assignment to the correct side of the gel card (the side opposite that of the barcode) in order to uniquely identify the wells.
b	It is essential to adhere to this procedure. A different sequence (first pipette, then assign) can lead to incorrect results.
E	If the gel card must be assigned differently than proposed by IH-Com, it is possible by using the context menu. Individual samples can be removed from the gel card by the context menu, which can be opened directly on the gel card proposal.
F	With the context menu in the list of tests to be assigned it is possible to assign tests to a certain sample on the gel card with Sample XXX at position Y as long as the test does not occupy all positions on the gel card. *Example*: Rhesus subtype gel cards

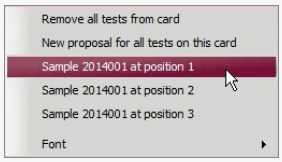

Figure 90. Selecting Sample XXX at position Y

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G With New proposal for all tests on this card, it is possible to generate the IH-Com proposal again.

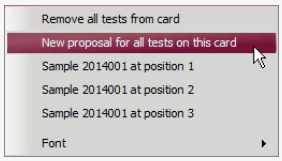


Figure 91. Selecting New proposal for all tests on this card

k Gel cards that have been processed on one instrument with at least a status: pipetted are taken into account for manual work. The pipetted wells are flagged as used.

k Gel cards pipetted without the use of IH-Com must not be used. In this case, IH-Com has no information about the wells already used.

H Label printing can proceed again.

Scan the gel card barcode twice.

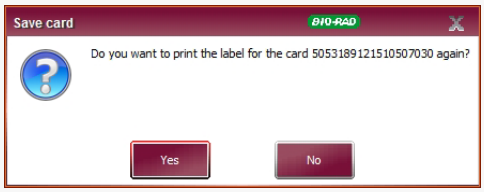
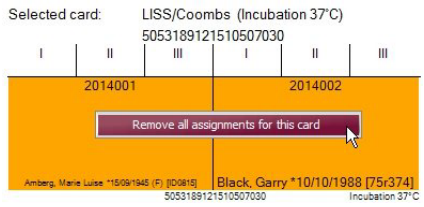


Figure 92. Printing label again

5.3.2.5 Remove a Test from a Gel Card

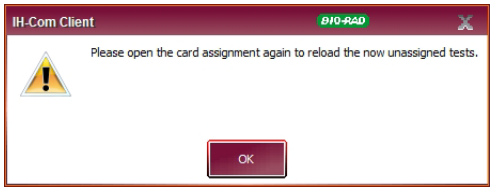
In rare cases it is necessary to delete the assignment for a gel card.

Example:

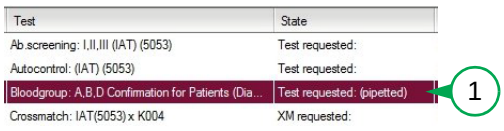


A gel card has been assigned and not yet pipetted, but in the meantime the test is no longer required.

This gel card can be used for a different sample by opening the gel card assignment, scanning the barcode of the gel card and executing Remove all assignments for this card in the context menu directly on the gel card suggestion.



Subsequently a related message indicates that the gel card assignment is closed.



The status Test requested (1) indicates tests that were removed from the gel card.

These requests can be deleted if necessary. The gel card can now be assigned differently.

Figure 93. Tests with status Test requested

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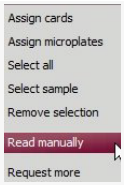
A		All assigned gel cards can be pipetted and processed. Saxo ID-Reader or Banjo ID-Reader can be used. See section Saxo ID-Reader II on page 85 or Banjo ID-Reader on page 87 In the Manual work screen the manually processed gel cards can be directly read, as in section Reading Results Manually on page 115.
B		Select the option Show completed results too.
C		Select the required test
D		Open the result input window with the context menu Read manually or the button Read manually.

5.3.2.6 Adapting the Gel Card Label to the Label Printer

If in the Manual work screen the Assign cards for pipetting window is opened with administrator rights, a test label can be printed to adapt the printer settings.

A test label is printed out with the currently displayed card proposal and a fictitious card number.

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6 Results

The chapter comprehends an explanation about handling and procedures of processing results in IH-Com.

When the first result is transmitted from the instrument to IH-Com (or if it has pipetted status), the sample ID is displayed in the Results window.

Depending upon the settings defined, results may require verification by the user.

See chapter Configuration / Common Settings / Verification on page 40.

Results which have verification missing status are additionally displayed under tab Batch Verification.

b Before final test interpretation, results have to be validated by trained operators. This result verification process includes visually reviewing the images and editing (if necessary) the test interpretation. Editing is not limited to indeterminate results; initially positive or negative reactions might also be edited after visual review.
It is recommended to activate the 4-eyes-principle. However, this is left to the discretion of the facility.

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A Open Result Verification by:

- using the context menu Edit result;
- selecting the button Edit result;
- double-clicking the sample number or the name in the patient list in the Results window.

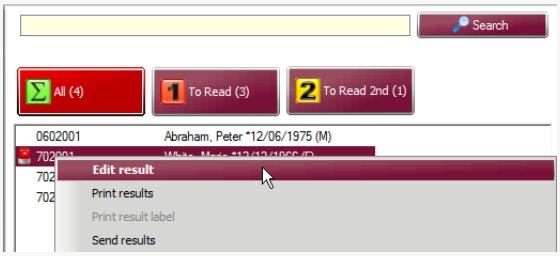


Figure 94. Selecting Edit result via context menu

Refer to the sections Result Verification Window on page 101 and Changing and Confirming Results on page 103 for more details on editing results.

Č *All tests are displayed in the Search cards window, showing gel card position and sample data.*

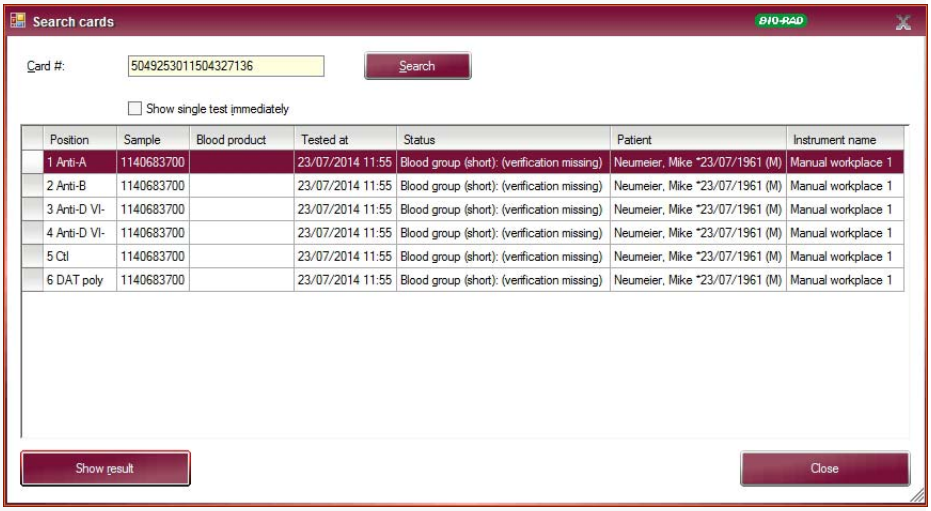
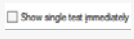


Figure 95. Search cards window with active button Show result

b If using the search cards functionality, continue to scan the gel cards which have been segregated for second reading in the main window of the IH-Com Client.

B Select the required test and open Result Verification with button Show result.



If the Show single test immediately option is active, the result validation of the corresponding sample is opened immediately. This will occur only when there is a single result on the scanned gel card.

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C	The Search cards window can be opened using the Work list / Search card menu. *By opening Result Verification and selecting the button Edit results and when the Automatic result run option is activated, the next patient or sample with open results is displayed immediately after saving the Result Verification.* *Result verification starts with the selected sample and is performed in sequential order to the end of the sample list.* *With Automatic result run the tabs of the Results screen are taken into account, i.e. only the result validation of the samples which corresponds to the current selection is displayed.*
k	The Automatic result run only applies to results that require verification. For results under the tab Extra check (results to be validated) it is not enabled. See chapter Additional Validation on page 131.
D	When all results have been verified, they are automatically sent to the LIS.
E	 It is also possible to send temporary results to the LIS manually: Select the context menu Send results in the Results window. *Temporary results are marked differently and are identified as such in the LIS.*

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6.1 Selection Buttons and Filter in the Results Window

Figure 96. Results window: Buttons

× All	This view is activated by default when the program is started. The following are displayed: • all results of the current day • results that are not validated regardless of when they were processed • pipetted results for which no reaction intensities were read
1 To Read	All results that have not yet been accepted and with reaction strengths that have not yet been saved are displayed here.
2 To Read 2nd	Results that have been temporarily accepted (e.g. automatically accepted results), but still have irregularities (e.g. discrepancy between blood group and serum crossmatch, missing quality control). Results with reaction strengths that are saved and not accepted. This button is activated only if corresponding results exist.
Extra check	Results that have been selected for an extra check in verification. This button is only shown if corresponding results exist.

The number in brackets on the selection buttons represents the number of samples displayed in the window.

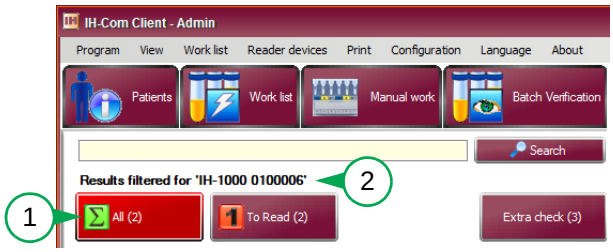

Figure 97.

1 If a filter for results is selected under Common Settings, the selection is displayed.

See chapter Configuration / Common Settings / User Interface on page 38.

A click on the selection buttons of the result list displays only results for the selected filter.

2 If a Lab location is selected, only results of instruments are displayed that belong to this laboratory location. If an instrument is selected as a filter, only results of this instrument are displayed.

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6.2 Result Verification Window

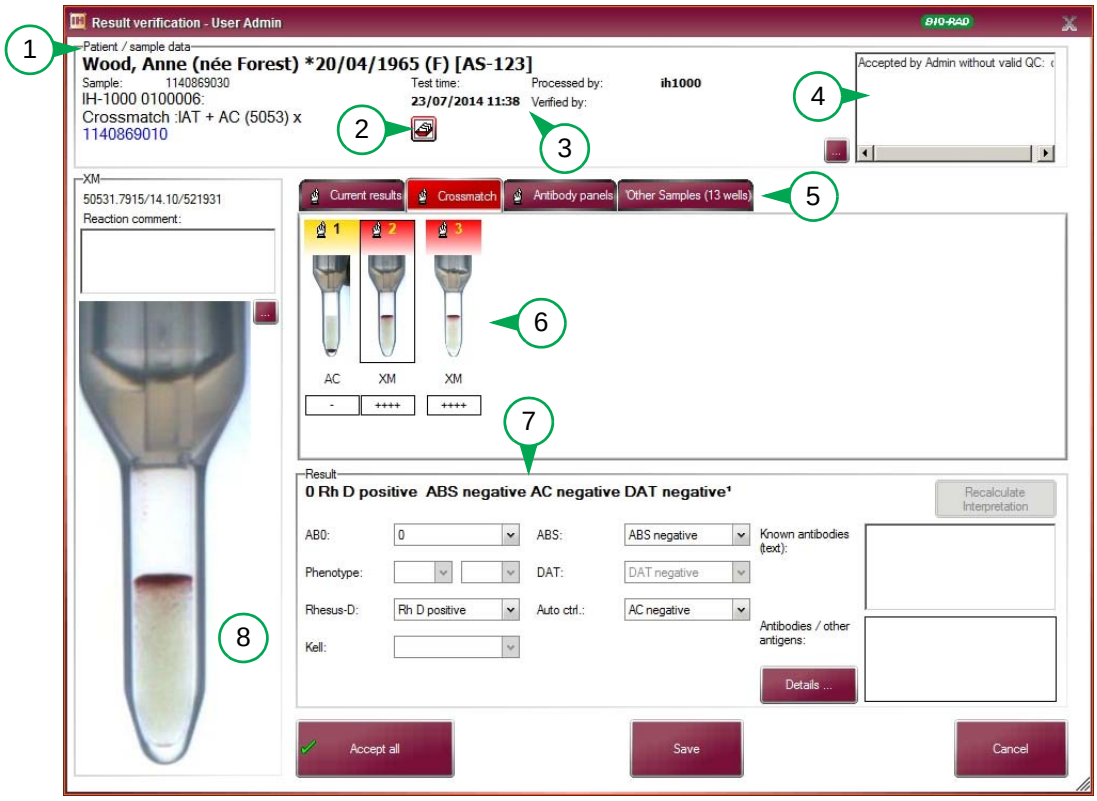

Figure 98. Result verification window

1 Patient and sample data

2 Audit trail (history of changes)

3 Tested by..., time of test, verified by..., validated by...

4 Comment for the sample and/or the test

5 Tabs for the individual categories of test results

6 Reaction results

7 Result interpretation

8 Magnified view of the selected well with gel card data and comment for the well

k According to the window setting and resolution it is possible that not all wells are shown in this view. If this is the case a scrollbar is displayed.

k In the interpretation section a part of the interpretation can be marked with a superscript 1 (default setting). This means that this part of the interpretation is from a pre-result.

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Result Verification is identical for all instruments and for the manual workplace.

Single reaction results are displayed up to a maximum of 5 tabs. Only tabs with reaction results are displayed.¨

Tab	Reaction result
Current results	All reaction results of the current sample are displayed, if they are not a crossmatch test, a panel test or a titration test
Crossmatch	All reaction results from a crossmatch test of the current sample are displayed
Antibody panels	All reaction results from a panel test (antibody identification) of the current sample are displayed
Titration	All reaction results of a titration test of the current sample are displayed
Other samples	All reaction results which do not belong to the current sample but to the same patient are displayed, e.g. pre-results or results detected after the currently marked sample. The number of existing reaction results from other samples is displayed in brackets. Images of reaction wells, displayed under this tab, are created in the course of opening the tab. Related to the number of single reactions loading of the tab can last. In case of a waiting cycle a progress bar is displayed.

Results under tabs are sorted by test in a sequence that can be modified by your Bio-Rad technical representative. The test sequence is automatically defined at the test import.

If multiple tests are processed for the same sample, it will be sorted by descending testing time.

On tab Other samples sorting takes place by descending sample number, within the same sample number by descending testing time.

Colors representing interpretations

White	Plausible result without edits
Green	Result corresponds to the automatic interpretation after editing
Orange	Result does not match automatic interpretation after editing
Red	Not a plausible result

k For DAT, Ab Screening and Autocontrol deviations of the representing colors green and orange appear. It depends on whether the test is monospecific or polyspecific.

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6.3 Changing and Confirming Results

In the Result verification view results not accepted are marked with the icon.

A The reaction strength read by the instrument is displayed under the individual # column.

If your visual assessment of a result differs from that of the reader device, change the reaction strength via the context menu.

Select a column and open the context menu using the right mouse button.

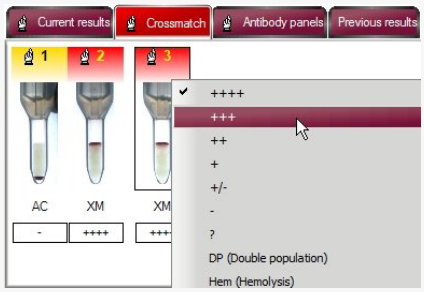

Figure 99. Changing of reaction result via context menu

IH-1000 and IH-500 provide additional well interpretations in case of unclear reactions

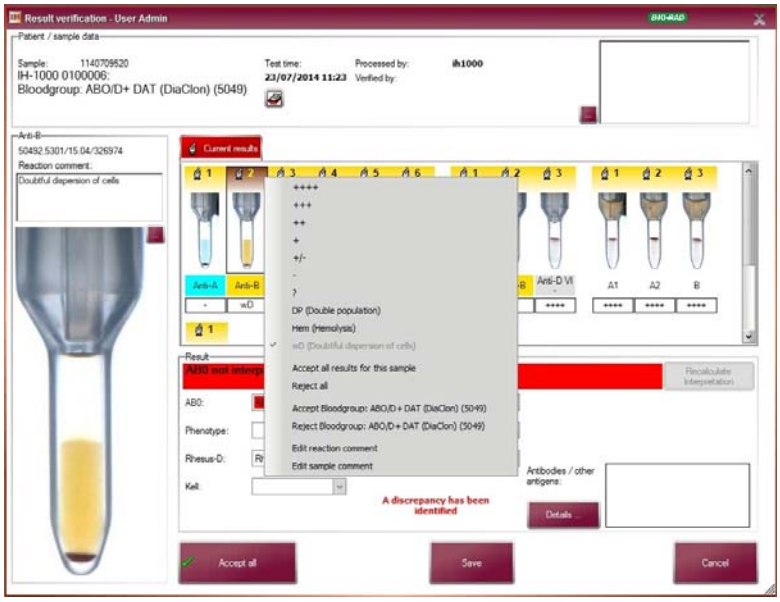

Figure 100. Result verification for IH-1000

IH-1000	wF, wR, wP, wD, E, L, W, LIQ or []
IH-500	wR, wP, E, LIQ

Other instruments in the event of unclear reactions only issue “?” as reaction strength.

These interpretations are automatically generated and not available for selection.

Č *A comment is automatically displayed on the column.*
A changed reaction intensity is marked with an asterisk.

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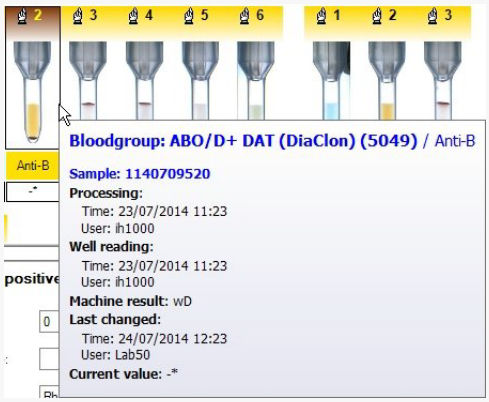
B

Place the cursor on the corresponding reaction column to display the original instrument result.

A tooltip is opened with following information:



- Test name
- Sample number
- Time of reading
- User
- Rotor position in the instrument (if available)
- Time of first reading
- Current value, etc.

See chapter Tooltip of a Well on page 108.

C

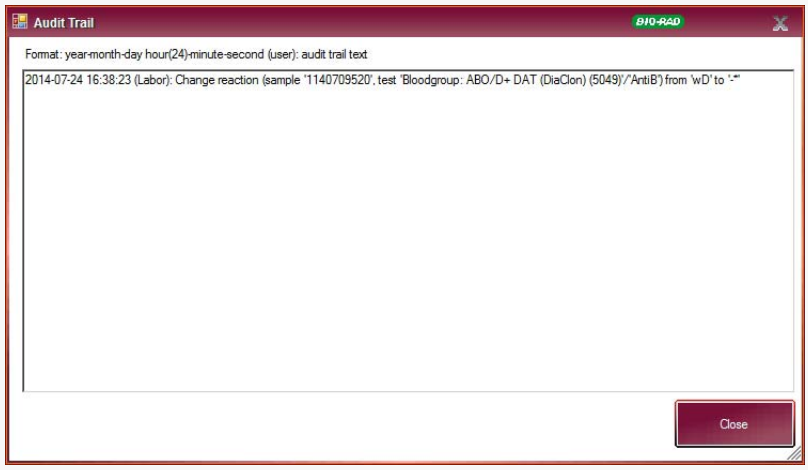


Figure 101. Audit trail window

All manual changes and original values are recorded in the audit trail.

Open the audit trail window by selecting the button.

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D

To verify results:

Select the context menu on the reaction column.

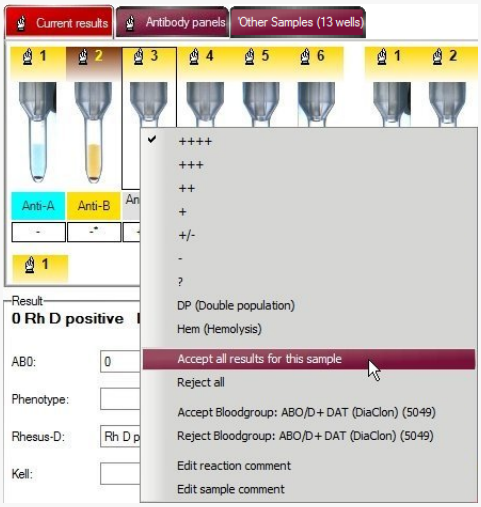


Figure 102.

E

The following options are available:

- Verify or reject all results of the current view (e.g. tab Current results).# Rejecting the result prevents validation and transmission to the LIS or;
- Verify each test (e.g. ABD) individually or;
- Accept all results simultaneously by selecting Accept all (All results in the current view will be verified simultaneously.).

Č *A verified result is indicated with .*

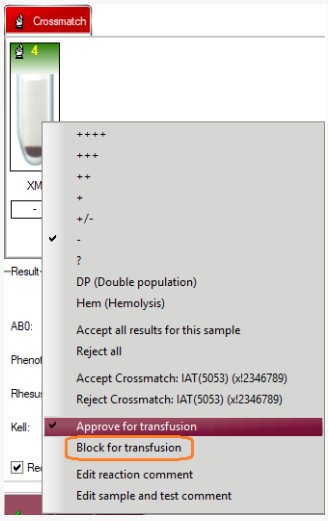
Č *A rejected result is indicated by a strikethrough.*

For crossmatch test results, the preselected treatment of blood sample (transfusion status) can be changed if necessary via the context menu.

Crossmatch samples with negative reactions can be changed from Approve for Transfusion to Block for Transfusion.

Conversely, unreleased samples from Block for Transfusion to Approve for Transfusion can also be changed.

A comment is required to change the transfusion status. An entry to the Daily Journal is automatically added.



b This will release samples for transfusion, even though they have reacted (positive) in the crossmatch test.

F

After all required changes have been made and all results are validated, save your results.

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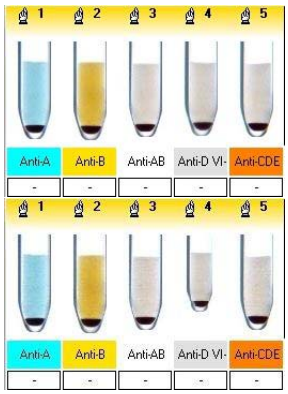
User rights	Description
40	User can change reaction strengths but cannot verify the results.
50	User must check and verify results once again and may change reaction strengths again if required. User can change reaction strengths, confirm and release (save) results.
60	If the appropriate option is enabled, it is possible to perform additional validation, a second verification of results with access rights of at least 60 See chapter Additional Validation on page 131.

G		The individual users are shown in the top portion of the window.
H		Results that have been validated additionally are marked.
I		The Skip button is available for the automatic result validation. Skip a sample or cancel result validation by selecting the Cancel button

6.3.1 Illustrations of Reaction Intensities

IH-Com displays the original images of the readers and automated instruments.



Ideally, the separated column images are exactly the same size as the interpretation fields in Result Verification.

If the barcode is too high or the card is not clean (shown exaggerated in the illustration), the image is reduced.

For this reason it may happen that the reaction columns of a card have different sizes in the Result verification screen.

k IH-Com applies the distance between the last dark pixel of the column edge and the next dark pixel to represent the image of the entire card as individual reaction columns.
Example: At the barcode or at the edge of the next reaction column, the image separation is placed.

k If the original image is not available, due to manually read results or a defective database image, reactions are shown as a graphic.
See chapter Reading Results Manually on page 115.

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6.3.2 Color Code for Reactions Illustrations

IH-Com uses the colors of the rectangular area above the individual reaction pictures to identify certain properties.

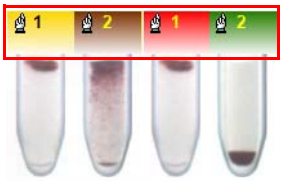

Figure 103.

Yellow	Results that have not yet been read or verified.
Brown	Results: • with positive reactions in the ABS, self-monitoring or DAT; • with weak reactions (according to assay definition); • whose reaction strength has been modified by a user; • with flags of categories C, D and E from the device (see section Bio-Rad Result Flags on page 22); • with a positive control.
Red	Incompatible crossmatch samples.
Green	Compatible crossmatch samples.
Gray	Accepted, rejected or past results.

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6.3.3 Tooltip of a Well

The tooltip of a well details the steps leading to the result of the single reaction.

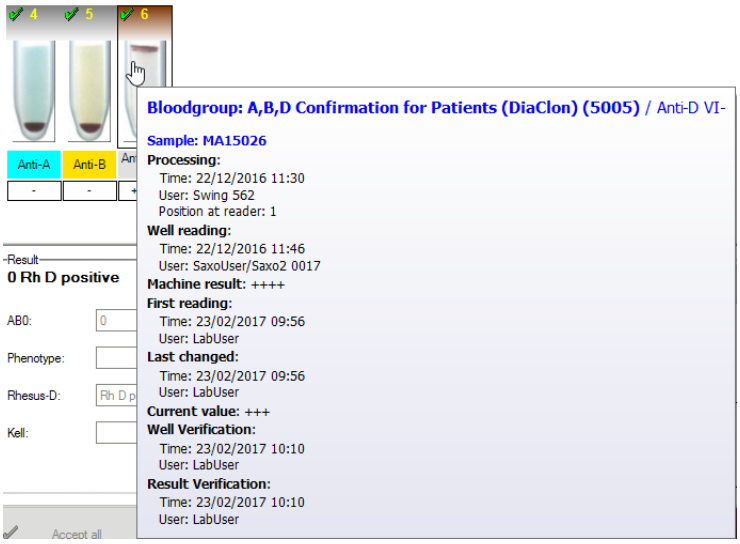

Figure 104.

Section of the tooltip	Description
Processing	Displays the time well processing was started. The displayed time is transmitted from the instrument. At the manual workplace this entry corresponds to the time when the gel card has been assigned by scanning the barcode. Displays the user logged in at the instrument where the well was pipetted. If there is no user login at the instrument, instrument and serial number are entered. If pipetting took place manually, the user that has been logged in at the manual workplace at the moment the gel card has been assigned by scanning the barcode, is entered.
Well reading	Displays the time of well reading. The displayed time is transmitted from the instrument. At the manual workplace this entry corresponds to the time when the manually entered reaction strength has been saved. Displays the user logged in at the instrument where the well was read. If there is no user login, instrument and serial number are entered. For a reading device the logged in user and the serial number of the reader are entered. For manual reading the user is entered who input the reaction strengths.
Machine result	If a reaction strength has been changed manually, the original reaction strength read by the instrument is displayed. If the reaction strength has not been changed no entry is displayed.
First reading	The time when the first confirmation of the reaction strength took place. User who confirmed the reaction strength Confirmation of a reaction strength takes place e.g. by batch verification or by selecting Save under Result Verification, without accepting it previously. If confirmation of reaction strengths and accepting takes place within one working step no entry is displayed.

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Section of the tooltip	Description
Last changed	The time when the last modification of the reaction strength took place. User who initiated the last modification of the reaction strength. If the reaction strength has not been changed, no entry is displayed.
Current value	Current reaction strength
Well verification	The time when the well has been verified (accepted). User who verified (accepted) the well. If single tests are accepted by batch verification and the overall result of the sample is thereby verified automatically even though the verification differs from the standard value, an entry automatically accepted is displayed.
Result verification	Point in time when the sample has been verified (accepted). User who verified (accepted) the sample.
Validation	Point in time when the sample has been validated. User who validated the sample.

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6.3.4 Confirming Results with Discrepancies

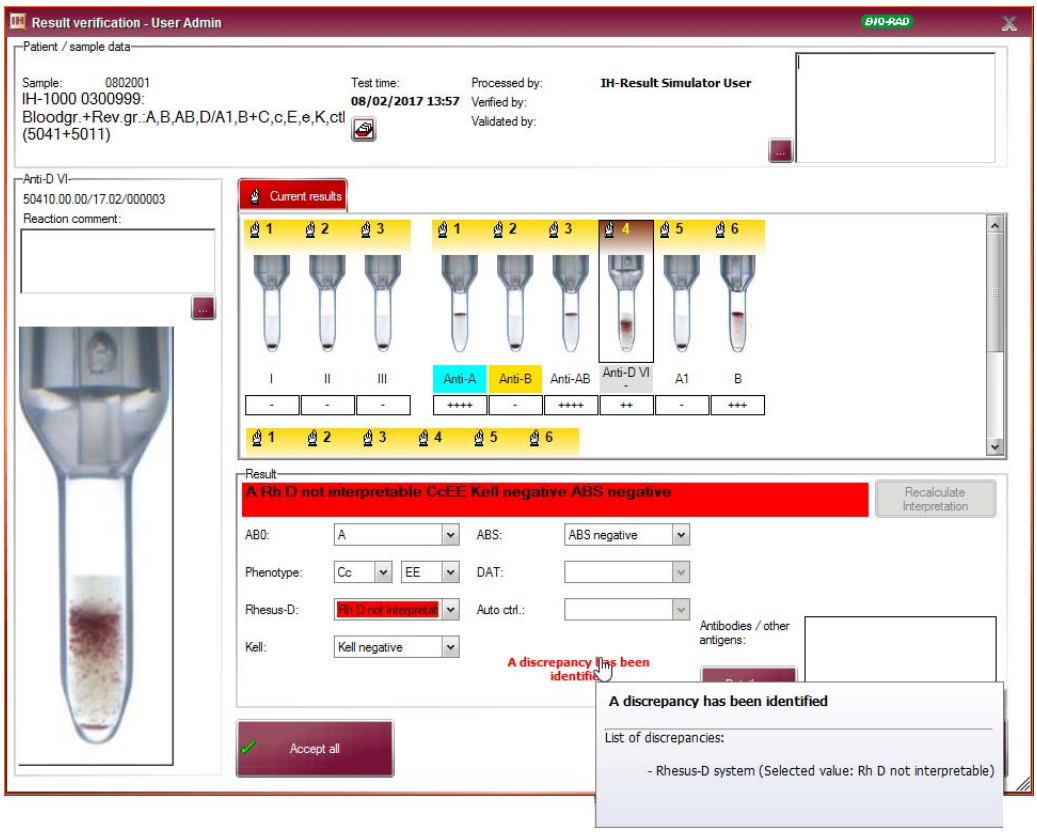

Figure 105. Result verification window: A discrepancy has been identified

When IH-Com identifies a discrepancy, the interpretation line in the verification check is highlighted in red and a notification A discrepancy has been identified is displayed.

If the cursor is moved over this message, the discrepant parts of the interpretation are displayed (AB0 system, Rhesus D system, etc.).

If the reason for the discrepancy is not to be found within the current result, but is based on a discrepancy between current and previous result, an appropriate message appears

Example: AB0 system (Preresult)

A preresult discrepancy has a higher priority in the display than the current discrepancy in the same test area.

Example:

> *If the AB0 system differs from the previous result and at the same time there is a discrepancy in the current test, only the message AB0 system (Preresult) appears for the test area AB0*

No double display is shown.

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The discrepancy message displayed is automatically refreshed as soon as reaction strengths are changed.

Example:

In case of discrepancy attributed to a doubtful reaction, the notification disappears immediately after it is changed to a valid reaction strength.

A If results are to be verified despite the discrepancy, a comment on the sample must be entered

See chapter Adding Comments to Results on page 123.

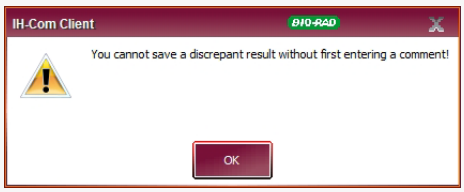

Figure 106.

B If a comment was entered, a confirmation request appears when saving the result.

This ensures that a discrepant result cannot be saved accidentally.

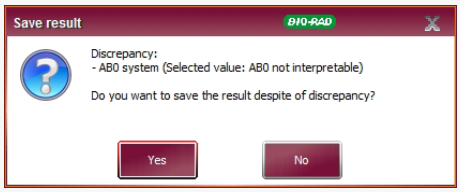

Figure 107.

k Results that exhibit a reaction intensity that requires further verification based on the package insert of the gel card are also displayed as being discrepant.

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6.3.5 Confirming Results in Case of invalid Quality Controls

If no valid quality control is available at the time of testing, the reaction column is marked with a red QC.

The tooltip indicates: There is at least one reagent without valid quality control.

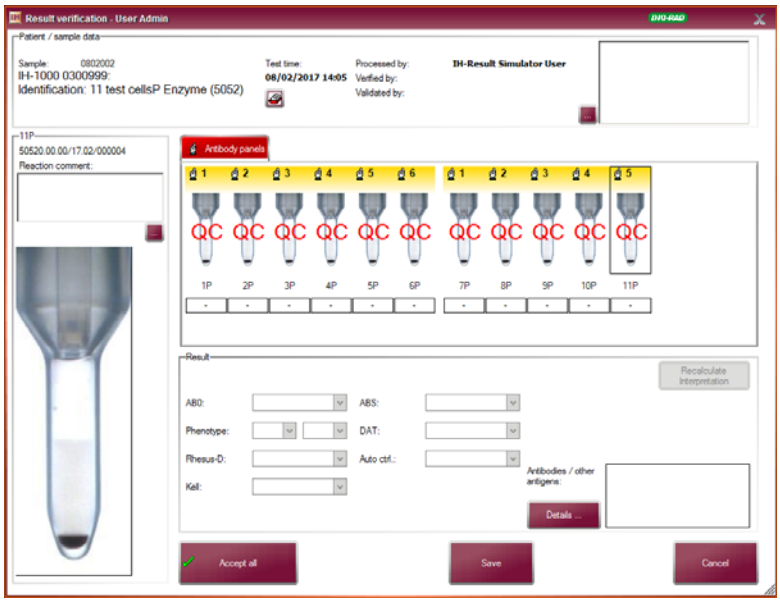

Figure 108.

To accept this result, a comment is mandatory.

Č The Missing quality control(s) window automatically opens.

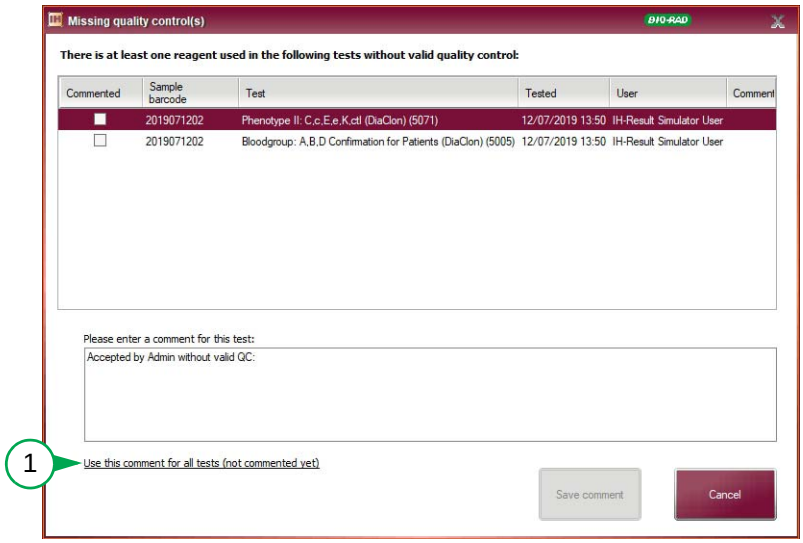

Figure 109. Missing quality control(s) window

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A	Enter a comment for each single test. *The comment Accepted by [user] without valid QC: is automatically included. Enter a comment next to it.*
B	With Use this comment for all tests (not commented yet) (1) comments are assigned to all tests without valid quality control. *The comment Accepted by [user] without valid QC: is automatically included. Enter a comment next to it.*
C	Save the comment with Save comment. *It is possible to assign a comment to each test individually and save all the comments with Save comment.*
D	If a sample comment is already saved, it can remain and confirmed. *The default comment Accepted by [user] without valid QC: appears automatically below.*

Comments for invalid quality controls are printed out for each test separately only on the daily journal. Comments are not printed out on the printout of results.

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6.3.6 Messages before Reading Results

IH-Com displays messages for certain results when result verification is opened. These messages must be confirmed before the verification window can be viewed.

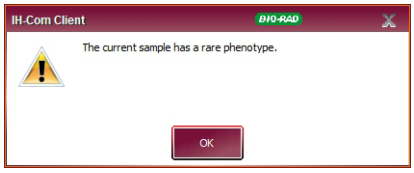

Figure 110. Example of message

The following examples show a selection of such messages and their background:

Message	Background
D weak or D partial is currently selected. Please verify the Rhesus-D result!	The result for Rhesus D was saved as a result D weak or D partial in the meantime. When assessing the results, the interpretation of the D feature should be carefully considered.
The current sample has a rare phenotype.	Rare factors of R, C, D, E, e (phenotype) are mentioned: • CCddee; • ccddEE; • CCD.EE; • CCddEE; • CCddEe; • CcddEE. NOTE: These characteristic values that generate the message can be adapted. Contact your service representative.
A discrepancy has been identified ...	The result has since been saved with a discrepant interpretation. In the assessment of results, the interpretation of the characteristics sought should be carefully considered.

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6.3.7 Reading Results Manually

Results with pipetted status can be read manually.

A Select the appropriate test and the context menu Read manually.

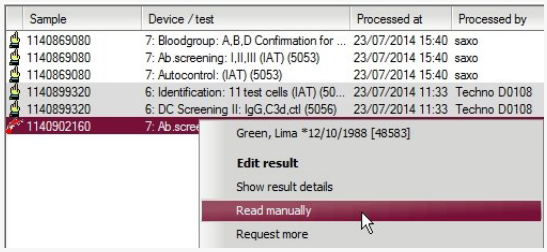

Figure 111. Selecting Read manually via context menu

It is also possible to select the button Read manually.

B

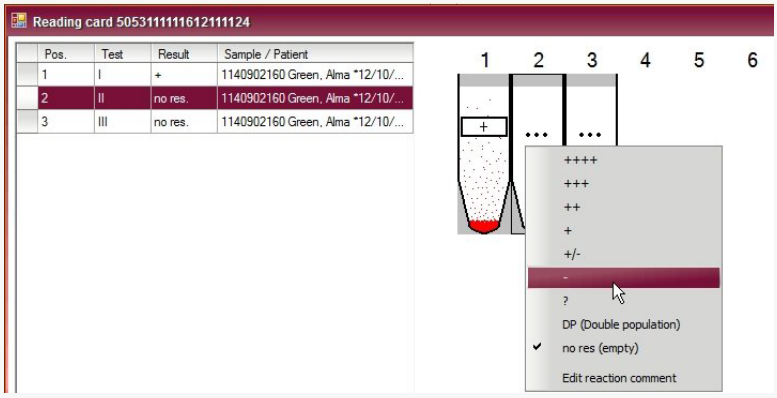

Figure 112. Selecting reaction result via context menu

Move the cursor over the appropriate reaction column and select visual interpretation of the reaction grade from the context menu.

C Save the entry with the button Save.

Enter reaction intensities with the numeric keypad

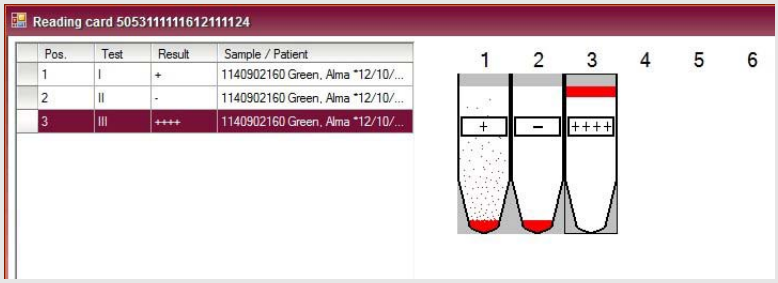

Figure 113.

Input	Reaction
0	0
1	+
2	++
3	+++
4	++++
5	+/-
-	0
+	++++
d/D	DP (mixed field)
?	? (questionable)

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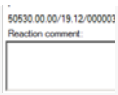
D		The cursor moves automatically to the next entry field. Save the entry with the button Save. If the cursor is placed directly over a well, movement to the next entry field is not automatic.
E		In the Result verification view a graphical representation of the reaction strength is displayed.

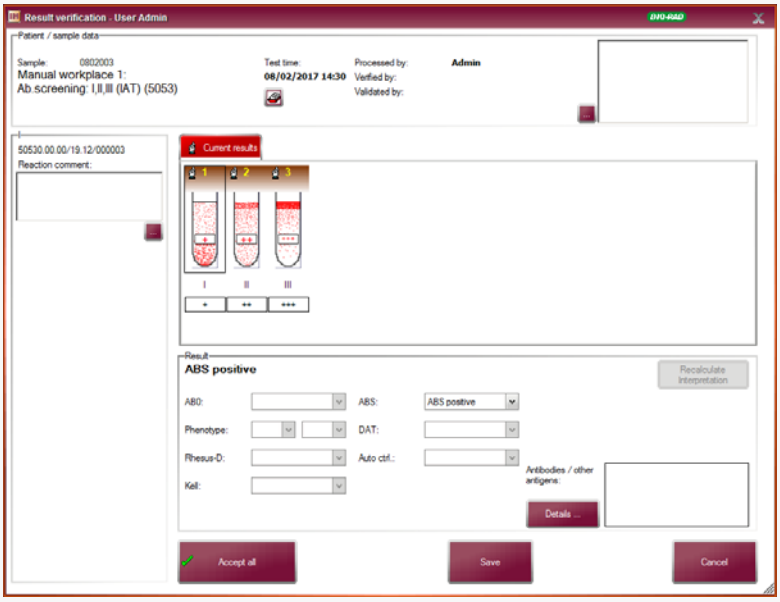


Figure 114.

Further procedure corresponds with in section Changing and Confirming Results on page 103 described.

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6.3.8 Batch Verification

Batch verification allows to verify multiple similar results in one working step.

As soon as verifiable results exist for a sample, they are displayed under the Batch Verification tab. Sorting takes place in groups by gel card type, and then by test and single interpretation.

If a device filter has been set in Common Settings, results only from this device or Lab location are displayed.

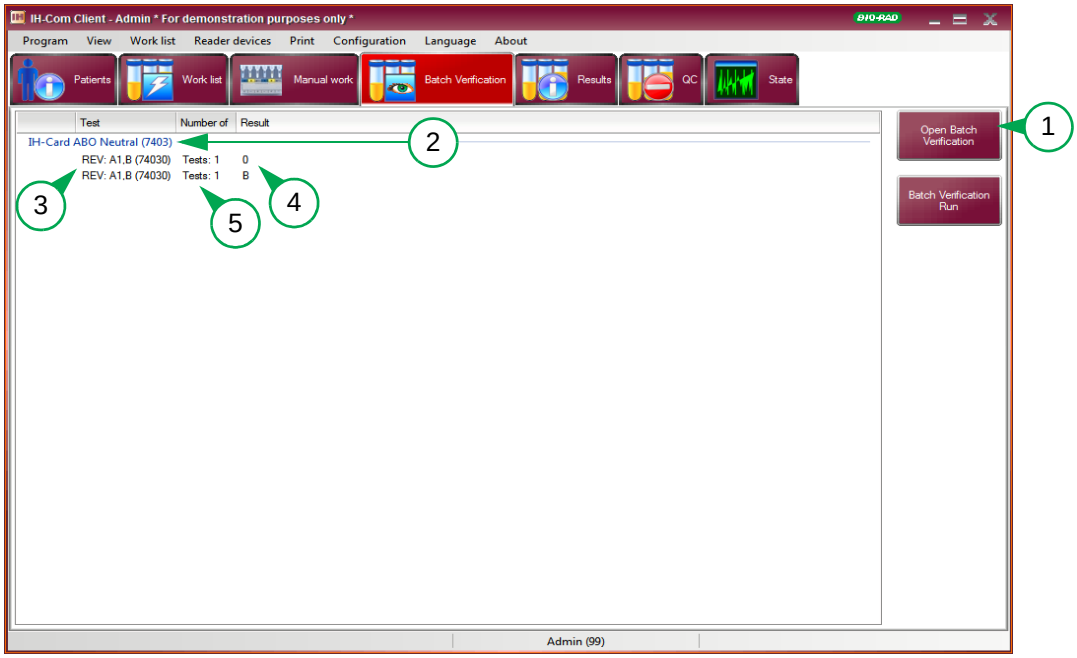

Figure 115.

1 Start batch verification

2 Gel card type

3 Name of the processed tests

4 Interpretation of single tests

5 Number of processed tests and gel cards used

The interpretation (e.g. AB Screening positive) in this case is only an interpretation of a single test for display, grouping and sorting. No discrepancy control or alignment with pre-results takes place at this stage.

Immediately after batch verification an overall interpretation of the sample is initiated which can differ from the one displayed.

If crossmatches are processed using different tests (e.g. Coombs and NaCl), the interpretation group all reactions negative may also contain incompatible crossmatches. A modification of the status of transfusion is only possible under Result Verification of the corresponding sample.

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If no interpretation text is available (e.g. for antibody panels), groups are displayed in this way: all reactions negative, positive and negative reactions, ? Reactions.

Positive and suspect reaction groups are displayed in multiples, if reaction strengths differ.

A	Select the result group that is to be verified
B	Open the Result Verification with the button Open Batch Verification. Under Result Verification results of the selected group are displayed by gel card number descending.

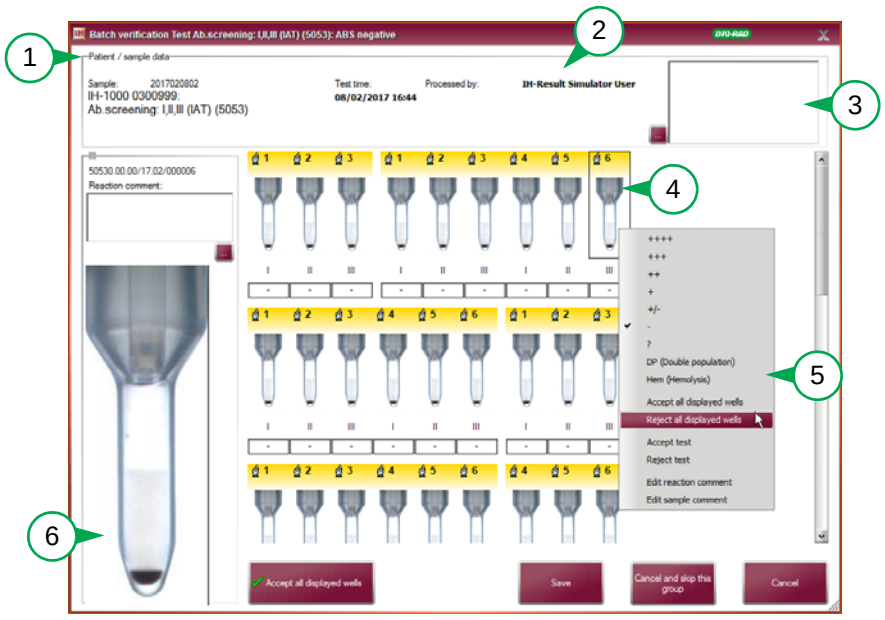

Figure 116.

1 Patient and sample data of the corresponding tests

2 User and testing time of the selected test

3 Test comment field for the selected test

4 Reactions of all tests of the selected result group

5 Context menu

6 Magnified well of the selected reaction

C	Accept all displayed reaction within one working step with the button or context menu Accept all displayed wells.
D	Reject all displayed reactions with the context menu Reject all displayed wells.
E	Modify reaction strengths by using the context menu

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F		By accepting with the button the next group of results are displayed automatically.
G		Eventually enter a comment to the result. *Refer to section Adding Comments to Results on page 123.*
k		In batch verification, test comments rather than sample comments should be entered. Sample comments should be entered in result verification.
H		If all results of the selected group are accepted, save the procedure with Save. *The Result Verification window will be closed and results are registered as automatically accepted.* *Results are then subject to the settings defined in Verification of overall result for further validation or LIS transfer.*

If a result group contains a large amount of samples, only one portion is displayed under Result Verification. After confirming with Save, the Result Verification opens automatically again for the following samples of this result group.

If the Result Verification is opened by the button Batch Verification Run, it will be re-opened automatically for the next result group.

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6.3.9 Changing Interpretation

It is possible to change the blood group interpretation determined by IH-Com.

Example:

When no isoagglutinins are demonstrable in a sample for an elderly patient, IH-Com assesses the result as discrepant.

A Modify the specified interpretation in the Result window:

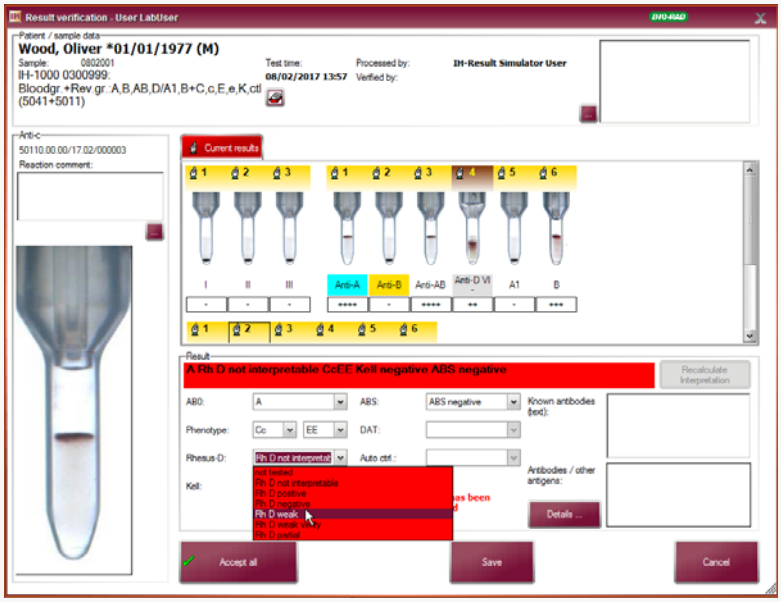

Figure 117. Result verification window: Changing interpretations

k Interpretations can only be changed for current tests.
Example: An interpretation of a rhesus subgroup cannot be changed, if it originates from a previous result.

B Comment on your changes in the Sample comment accordingly.

Č *If no comment has been entered, a prompt will be displayed.*

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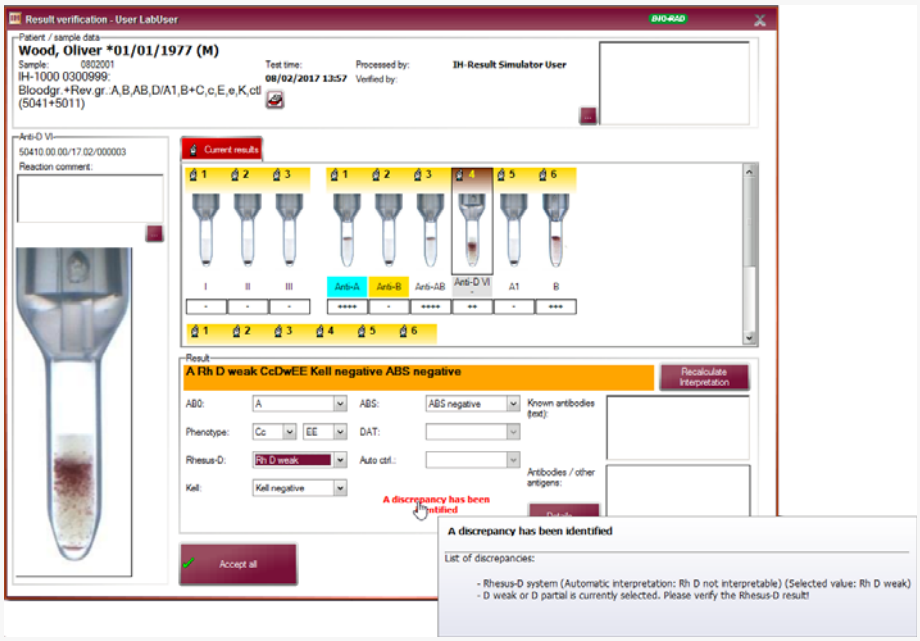
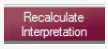


Figure 118. Result verification window: Discrepancy tooltip

- *After the change the overall interpretation is highlighted with an orange background.*
- *The discrepancy tooltip displays the interpretation indicated by IH-Com and the interpretation selected by the user.*

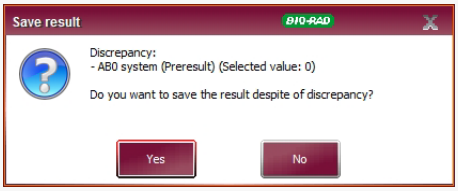
C 

If your selection is not saved, it can be undone with Recalculate Interpretation, to restore the interpretation automatically calculated by IH-Com.

D

If your selection is to be applied, a sample comment must be entered.

See chapter Adding Comments to Results on page 123.

E 

If a comment is entered, a confirmation request appears when saving the result.

This ensures that a changed interpretation cannot be saved accidentally.

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F

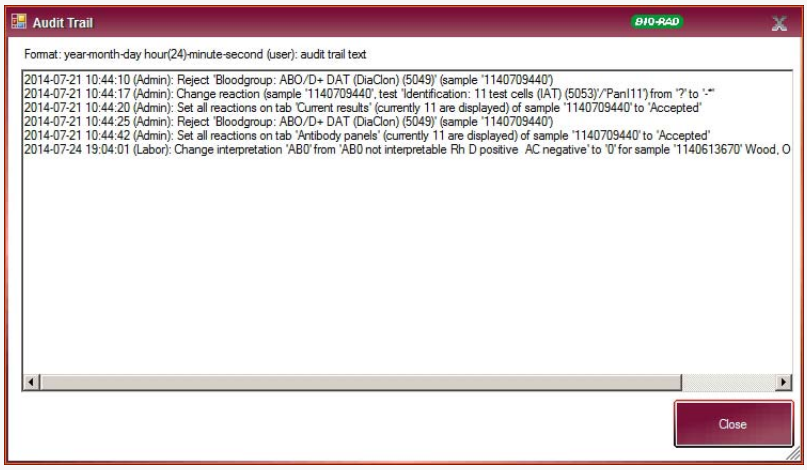

Figure 119. Audit trail with interpretation history

Each manual change of interpretations can be viewed in the audit trail.

The audit trail can be opened by selecting the button .

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6.3.10 Adding Comments to Results

In IH-Com there are several ways to add comments to results.

Comment on a Sample, a Test or a Crossmatch Test

A Select any reaction column and open the input mask via context menu Edit sample and test comment.

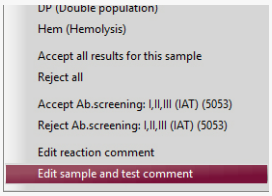

Figure 120.

Alternatively it is also possible to select the button beside the comment field to open the input screen.

B Enter a sample comment (1) and/or a test comment (2).

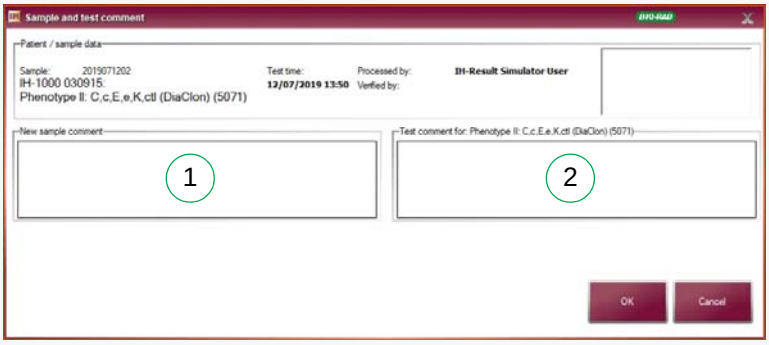

Figure 121. Sample comment window: Inserting predefined comments

If predefined comments are saved, they can be inserted with Insert text block using the context menu.

See how to store predefined comments in chapter Text Modules (Pre-defined Comments) on page 182.

C Confirm your entry with <OK>.

Č *The comments are displayed in a box in the upper right corner of the results check.*

If a crossmatch test has been completed, a crossmatch comment can also be included.

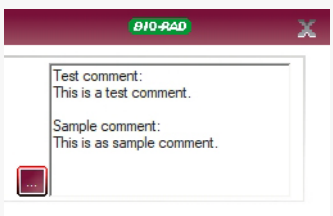

Figure 122.

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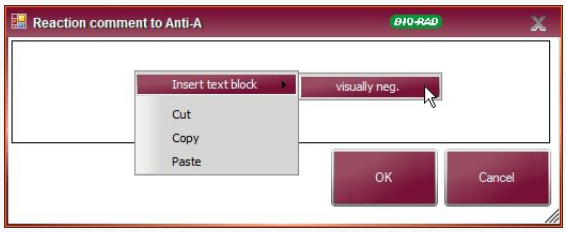
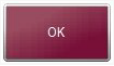
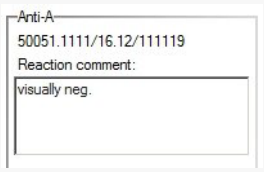
Comment on a Single Reaction

A	Select the reaction column to be edited.
B	Open the input window using the Edit reaction comment context menu.
C	Insert a text. *Predefined comments can be inserted using the context menu.*  Figure 123. Reaction comment window: Inserting predefined comments
D	 Confirm your entry with <OK>.
E	Move the cursor over the reaction column. *Č The comment is displayed in the Reaction comment: box.*  Figure 124.
F	Confirm your comment input with Save.

k It is possible to input comments at any time.

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6.3.11 Sending a Result

Occasionally it is necessary to resend a result to the LIS.

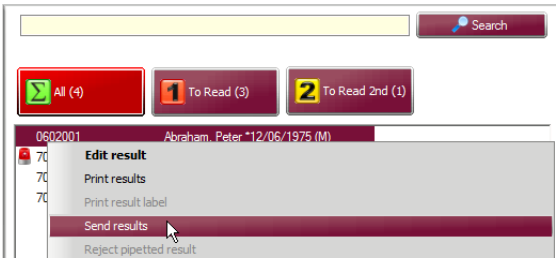

Figure 125.

Retransmit all Results of a Sample

A	Select the context menu Send results in the patient list

Resend the Result of a single Test

A	Select the test in the result list.
B	Select the context menu Send results.

Retransmit Results of Several Patients Simultaneously to the LIS

A	Activate Show multi select from the context menu. Č *A checkbox displays in the patients list between sample number and name fields.*

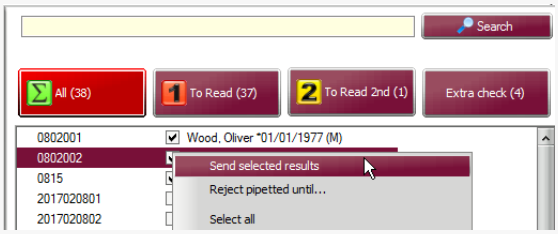

Figure 126.

B	Select the patients to be transmitted.
C	Select Send selected results. Č *The multiple selection in the Results area is automatically closed when the transfer is completed.*

k If the results selected for sending are not yet verified, they are sent to the LIS as temporary results.

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6.3.12 Discrepancy Check with previous Results

When the result of a test is available in IH-Com, discrepancy checks will automatically be performed:

- Discrepancy check within the current result

  E.g. a + or ++ reaction for blood grouping would be displayed in IH-Com as not interpretable and a message will be displayed “A discrepancy has been identified”.

  See sections Test, Interpretation and Result on page 22 and Confirming Results with Discrepancies on page 110.

- Discrepancy check with previous results

  The current result will be compared with previous results for the same patient or sample.

  The comparison with previous results is based upon the following categories:

  - blood group and reverse grouping
  - RH D including Rh D weak and Rh D partial
  - Phenotype including Anti-CDE
  - Kell
  - each single Antigen incl. Cw and Cellano
  - Ab Screening
  - DAT
  - Autocontrol

It is expected that the current result will be the same as the most recently processed previous result. If not, this will be identified as discrepant in IH-Com.

For example: Previous result A Negative, current result A Positive would be identified as discrepant in IH-Com.

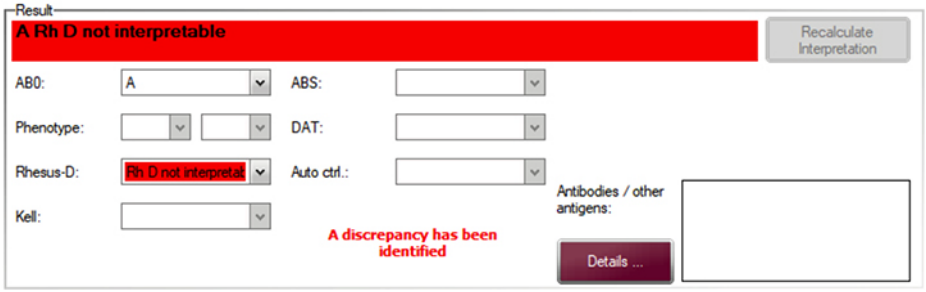

Figure 127.

If a previous result was not interpretable, this will also be applied during the discrepancy checking.

If a test is rejected or a sample marked as a suspect result, it will not be applied during the discrepancy check.

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D Weak and D Partial results must be set manually in result verification to be applied as previous results. When a test for the same sample or patient is later processed for Rh D, a warning message appears before result verification is opened:

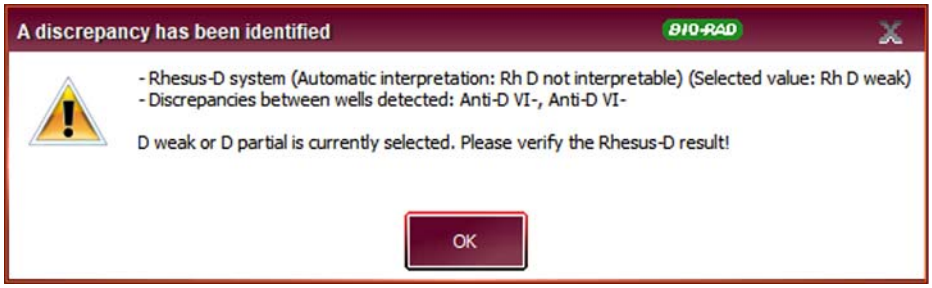

Figure 128.

If only a part of a result category is defined in a test, the whole category is saved as a current result. Example: ccee is defined as a pre-result, current testing is only for Anti-c. The entire phenotype is applied as the previous result even though Anti-e has not been tested.

When a sample or patient has been tested previously for one of the result categories but the current test does not include this category, the result will be displayed with a superscript 1 in the interpretation.

Consulted for plausibility check / as pre-result	
Within 24 hours	Results without patient data for a sample Later on results for this sample number are determined as a new sample.
Within 72 hours	Ab-Screening tests, DAT, Autocontrol This time period can be changed by your Bio-Rad service representative.
Permanently	Results with patient data (except Ab-Screening tests, DAT and autocontrol) for all sample numbers.

Examples

Test	Current result	Interpretation
Example 1		
AB0/D	A D+	A D+
AB0/D	B D+	? D+, manually change to B
AB0/D	B D+	B D+
AB0/D	B D+	B D+, manually changed to Dweak
AB0/D	B D+	B Dweak
AB0/D	B D+	B Dweak
AB0/D	B D-	B Dweak
Example 2		
AB0/D	A D+	A D+
Rh D	CcEe	A^1 $D+^1$ CcEe
DAT	DAT+	A^1 $D+^1$ $CcEe^1$ DAT+
Anti-c	c+	A^1 $D+^1$ CcEe
Anti-c	c?	A^1 $D+^1$ RhF n.i.
DAT	DAT+	A^1 $D+^1$ RhF $n.i.^1$ DAT+
Anti-c	c+	A^1 $D+^1$ RhF n.i.
Each line corresponds to a new sample number.		

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6.3.13 Excluding Results from Pre-Result Check

Sometimes an already verified or validated result should not be no longer be used as a pre-result.

User rights 60 are required for excluding results from the pre-result check.

b Exclusion of pre-results must be performed with careful consideration in order to avoid missed discrepancies.

A	Select the test of a sample Figure 129.
B	Select the context menu Suspect result (No longer used as a previous result). *All tests of the sample are set to suspect and are not consulted for a discrepancy check for not yet verified samples and future tests* *User rights of level 50 are sufficient for this procedure.* *The interpretation of the as suspect specified sample remains under Result details for traceability*
C	To deactivate this specification, reselect Suspect result (No longer used as a previous result). Figure 130.

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