Pacific Knowledge Systems

RippleDown user guide:

Report Validator v 8.1

This document focuses on RippleDown Report Validator.

Intended Use

The PKS Software, when used as a medical device, is intended to be used purely as a decision support system that provides complementary reports for patient data to qualified individuals based upon established rules set up by relevant trained customer domain experts (hereafter referred to as "domain experts").

The PKS Software generates and collates comments into a patient-centric report or workflow action based on rules created and maintained by domain experts. The PKS software presents all first-of-a-kind reports for review, modification (if applicable) and approval by the domain expert prior to release to clinicians or other individuals. Beyond this, the domain expert may automate the release of none, some or all identical reports. However, since a report may be generated and automatically approved for a case for which the domain expert has not previously considered, it is intended that the domain expert regularly review a representative sample of all output types.

It is intended that the clinicians receiving reports against patient results will consider the report in conjunction with all current and previous patient history and apply their own judgement when determining patient management. It is intended that the clinician does not rely on the existence of a report for the management of a patient.

The PKS software in itself does not provide automated diagnosis or treatment-making functions or have the capability to control, in any way, the performance of a device or to treat or diagnose any disease.

> It is the responsibility of the licensee to use the product in accordance with its intended use. In support of this, it is recommended domain experts include a statement consistent with the following on all reports.
>
> "This report has been generated using clinical decision support software. This report is intended to provide adjunctive information only and should not replace clinical judgement.

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RippleDown is distributed by Abbott Laboratories as AlinIQ CDS

RippleDown is distributed by Philips Healthcare as LABOSYS CDS

Report Validator

The Validator is a RippleDown component used for reviewing cases and their interpretive reports before they are released back to the Online Information System. Before approving a report, a Validator user is able to edit and correct a report if required. For a given RippleDown installation, some projects can be set up to use the Validator, whereas other projects may use the validation facilities provided by the Online Information System if required.

Main Screen

The main screen of the Validator shows the list of queues. There is at least one queue for each project. In addition, there may be special-purpose queues that have been setup for the project, for example, to group particular types of cases. There may also be queues corresponding to users who have had cases referred to them by other Validator users. These special-purpose queues will only appear if there are cases waiting on them to be reviewed. As well as these queues, which are for reviewing cases prior to their release to the Online Information System, there may be Copy queues for the independent offline review of some or all cases.

Each queue shows the following information:

- The project name.
- The name of the queue within the project, e.g. the user name for a referred queue.
- The number of cases waiting on the queue.
- Any users that are currently reviewing the cases on the queue. Note, several users may review the same queue simultaneously. The RippleDown server will ensure that each case will only be reviewed by one user.

Reviewing a Case

To begin reviewing the cases in a queue, double click on the required queue name. This will activate the Validator Case Viewer, in which individual cases on that queue are presented for your review.

The screen will contain the following information:

- A view of the data in the case.
- The report given by the Knowledge Base.
- Any internal comments given by the Knowledge Base.
- Any notes added by another user (if this case has been referred)

Reason for reviewing current Case

The reason why the current case was queued to the Validator is shown in between the case view and the interpretation panel.

The reasons include:

- The report has not yet been allowed for autovalidation.
- One of the report sections has not yet been allowed for autovalidation, if the autovalidation policy is based on report sections.
- The report has an autovalidation level of less than 100%.
- There is an autovalidation setting given for the case, with a level of less than 100%.
- The report has an internal comment.
- The report has an unevaluated expression or an untranslated comment.

Show Conditions for the Interpretation

The conditions used in the knowledge base to add the individual comments to the report can be viewed by selecting the Comments tab and then right clicking on the appropriate comment and selecting show conditions. The conditions will be displayed just as they are in the Knowledge Builder
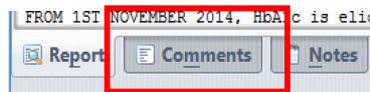
Approving the Interpretation

If you are satisfied that the current report is suitable for release, simply press the Accept button which will send that report back to the Online Information System with a flag indicating that the report is ready for release.
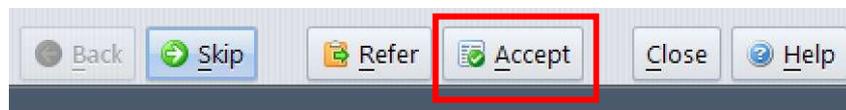
If the current report needs some modification before it can be released, edit the interpretation as required. If a complete comment needs to be added, you can pick from the list of existing comments using the Insert comment button. While making changes to the report, you have access to the Undo and redo buttons to help with the required changes.

Undo   Redo   Insert Comment
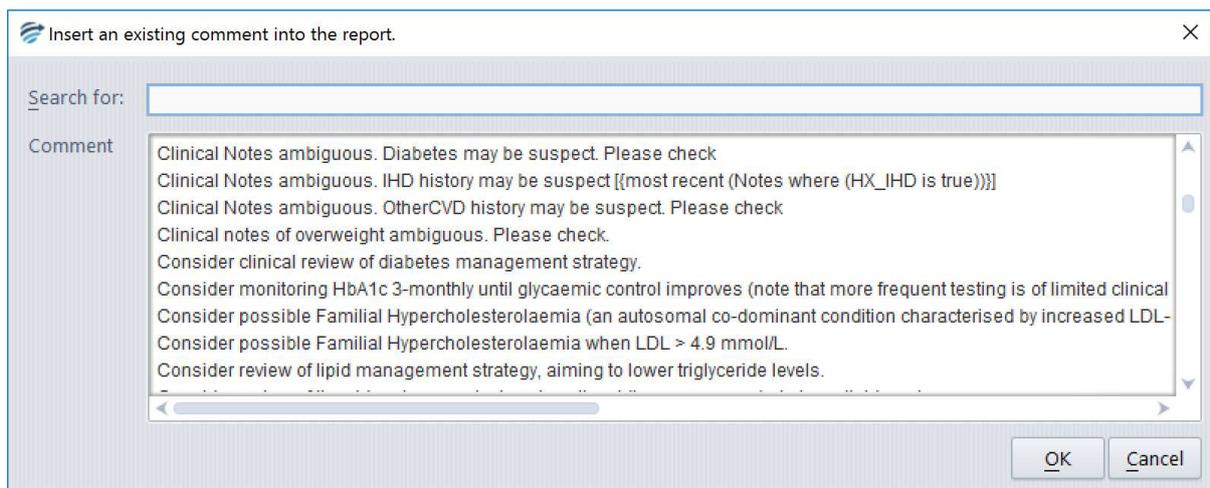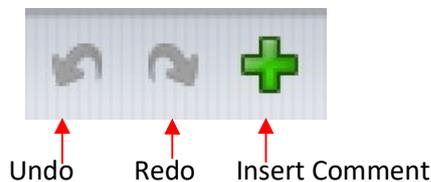
Once the edited report is ready for release, press the Accept with change button. You will then be asked to add a note as to why the report was changed. Once you press OK, the edited report will be sent back to the Online Information System with a flag indicating that it is ready for release. A copy of the case, with your reason for change, will be sent to the Rejected queue in the Knowledge

Builder. The Knowledge Builder user will then be able to update the Knowledge Base (i.e. the project) so that subsequent reports for this type of case will be correct.
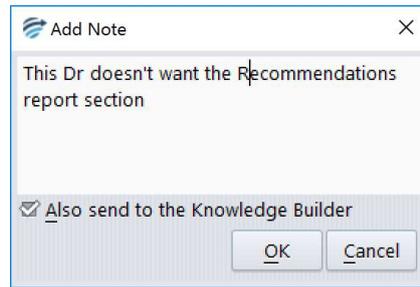
Once you have approved a report, it will immediately be sent back to the Online Information System. If you believe that you might have mistakenly approved an inappropriate report, contact your System Administrator immediately.

Referring a Case

If there is another Validator user who should check the report, the case can be referred to that person's queue. Click the Refer button and then select a specific user's queue. Your IT administrator can associate email addresses with each user so that the user is informed by email of the arrival of a case in their queue.
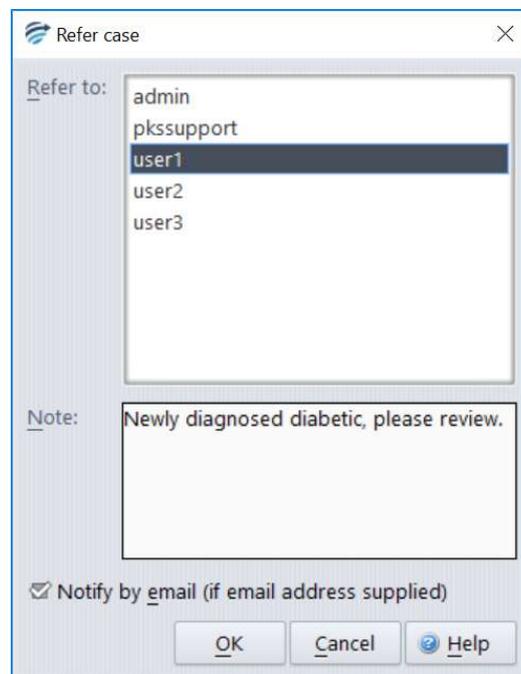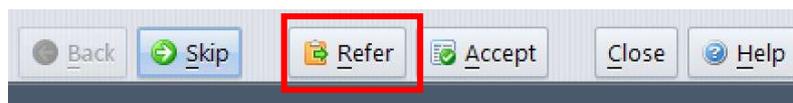
Skipping a Case

If you wish to deal with the case at another time (e.g. when some pending tests have been completed), you can press the Skip button.

The case will be available next time you review the queue. The latest version of the test results will be shown at that time.

Previous Cases

Press the Previous button to look at cases you have previously approved, referred or skipped on this queue, in this current session. Please note, you will not be able to change a report that you had previously approved or referred.
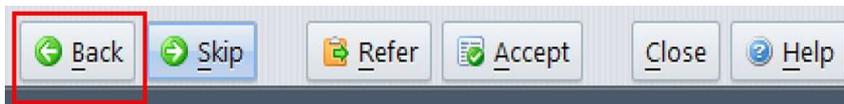
Finding a Case

By default, cases are presented for review in the order they are received into RippleDown. If however you want to review a particular case that you believe is on this queue, use the Find Case menu item in the File menu and search by case number
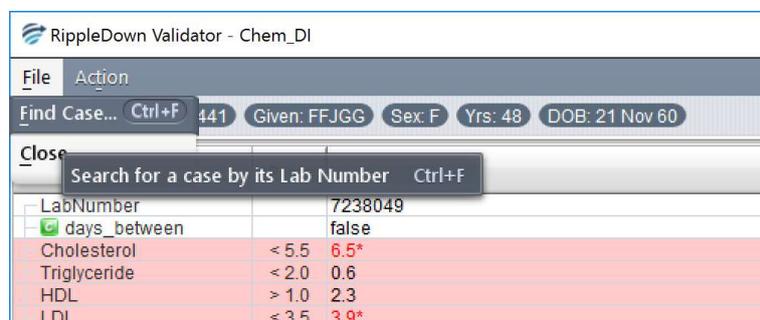
Logging out of the queue

When a Validator user starts reviewing a queue, a batch of up to 10 cases is immediately sent from the RippleDown Server to the Validator session as a "buffer" behind the scenes. This is done so that when the Validator user approves a case, the next case can be shown immediately, without having to ask the RippleDown Server for another case. As the Validator user approves cases, the RippleDown Server automatically tries to keep the Validator workstation buffer full of cases. Once you have finished reviewing cases on a queue, it is important to close the queue by clicking the Close. Any cases that have been queued to you but not yet reviewed will be returned to the RippleDown server and so will be accessible by other users. A Validator session will automatically Logout once a specified amount of time has elapsed without any interaction by the user.