

E-Consent

Release 1.8.0

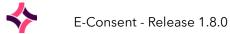
Release Notes



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Document Control

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1 Introduction

1.1 Purpose

This document will outline the functional changes made to this release. It will detail any new features, enhancements to existing functionality and list changes made due to existing functionality not working as expected.

1.2 Audience

This document is primarily for external stakeholders, so they have a clear understanding of what has changed within the application's functionality, installation procedures and dependencies compared to previous releases.

Other information about this release may be available through training materials and help files which are beyond the scope of this document.

1.3 Previous Release

The previous release of this product was as follows:

Version: 1.7.1

Date: 25/Oct/22

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2 Functionality added in this release

The following features and enhancements are included in this release:

2.1 Update Form 4 to DoH 2009 guidance

Previously the wording for form 4 (patients lacking the capacity to consent) was based on 2001 guidance from the Department of Health - this was <u>updated in 2009</u> to reflect the Mental Capacity Act (2005) and needed to be updated in eConsent to align with this.

Current text:

Assess	sment of patient's capacity	
	I confirm that the patient lacks capacity to give or withhold consent to this procedure or course	of

- ☐ The patient is unable to comprehend and retain information material to the decision; and/or
- The patient is unable to weigh this information in the decision-making process; or
- ☐ The patient is unconscious

treatment because:

Further details (excluding where patient unconscious)

New text:

Assessment of patient's capacity (in accordance with the Mental Capacity Act)
I confirm that the patient lacks capacity to give or withhold consent to this procedure or course of treatment because of an impairment of the mind or brain or disturbance affecting the way their mind or brain works (for example, a disability, condition or trauma, or the effect of drugs or alcohol) and they cannot do one or more of the following:

understand information about the procedure or course of treatment
retain that information in their mind
use or weigh that information as part of the decision-making process, or
communicate their decision (by talking, using sign language or any other means)

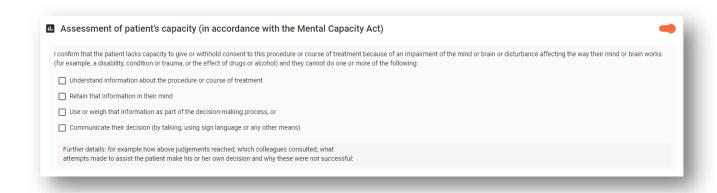
Further details: for example how above judgements reached; which colleagues consulted; what attempts made to assist the patient make his or her own decision and why these were not successful:

"B Assessment of patient's capacity (in accordance with the Mental Capacity Act)
I confirm that the patient lacks capacity to give or withhold consent to this procedure or course of treatment because of an impairment of the mind or brain or disturbance affecting the way their mind or brain works (for example, a disability, condition or trauma, or the effect of drugs or alcohol) and they cannot do one or more of the following:
understand information about the procedure or course of treatment
retain that information in their mind
use or weigh that information as part of the decision-making process, or
□ communicate their decision (by talking, using sign language or any other means)
Further details: for example how above judgements reached; which colleagues consulted; what attempts made to assist the patient make his or her own decision and why these were not successful."

Government reference document

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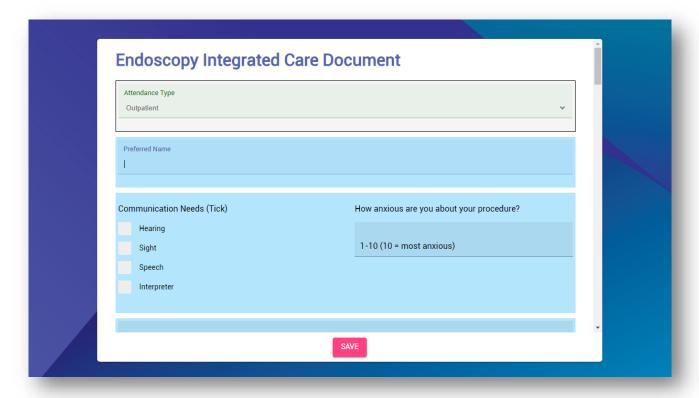


eConsent 1.8.0

2.2 Patient Facing Medical Forms

Medical forms in eConsent previously required a patient to be present within the Trust to complete the data entry with the option to send the patient a link to a PDF of the current form state. In 1.8.0 the patient can be sent a link to a live form and have the option of completing some or all fields remotely, including signature capture. The Trust can designate certain fields to hide and/or lock for local completion only.

The form status in eConsent will show when a form has been accessed and when remote data entry has been received. A new analytics report allows a user to review forms that have been accessed and those which are still awaiting completion.



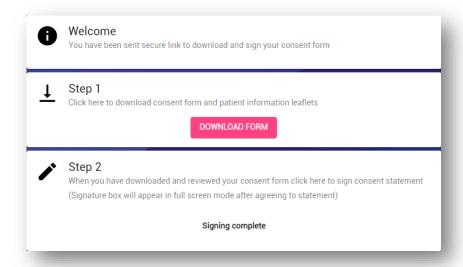
Patient facing form example

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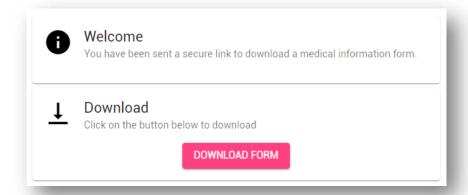


2.3 Alternate patient portal text for medical forms

Medical forms sent via the patient portal were shown in the context of a regular consent form which meant that the description text was potentially confusing. Alternate text is now used when the system detects it is a medical form not a consent form.



Patient Portal - standard consent



Patient Portal - medical form

2.4 Add mailing status to medical forms

Medical forms did not have status or mailing history records in the way that standard consents do. This has been added so that the following statuses are shown for medical form links:-

Status history section:
AWAITING CONFIRMATION
CANCELLED
CONFIRMED
COMPLETED

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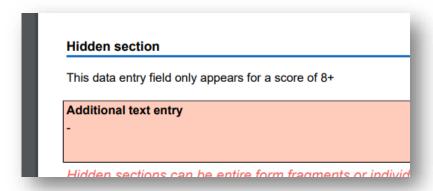
Effective date: [11/07/2023]

Mail history section: EMAIL SENT REMOTE ACCESS SUCCESS REMOTE ACCESS FAILURE

REMOTE ACCESS LOCKED
REMOTE FORM DOWNLOADED
REMINDER EMAIL SENT BY SYSTEM

2.5 Add colour background and border options to Medical Form

Forms can now be formatted with coloured sections and/or borders - these will appear both on the electronic form and on the rendered PDF.



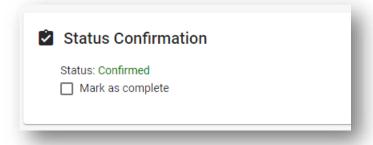
2.6 Medical form image decorator

Forms can now include images up to 10kb in size - these will appear both on the electronic form and on the rendered PDF.

2.7 "Complete" form status and update button

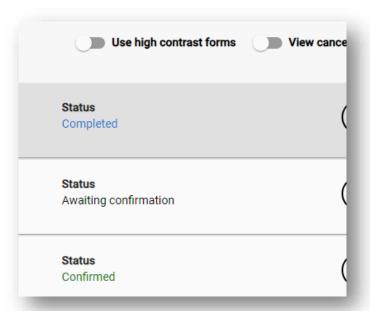
A new status of "Completed" has been added which allows users to *optionally* update the patient consent history to indicate that the procedure/treatment the consent was intended for has been completed. This additional step in the consent process is intended to prevent consents which are no longer current from being mistakenly considered as still valid (e.g. for a procedure which has already been performed but is required again).

This option does not appear for medical forms.



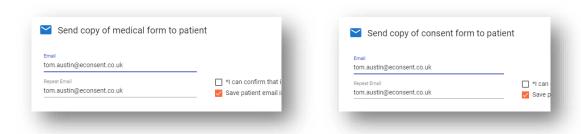
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2.8 Alternate text for Medical Form e-mail

The system will now differentiate between "consent form" and "medical form" when selecting to send a link to the patient. The e-mail text can also now be configured differently based on whether it is a consent or medical form link being sent.



2.9 Prevent e-mail app re-sending if patient signature populated

Previously the e-mail app would resend the patient link e-mail at regular intervals as a reminder until the remote patient signature received status was updated. However, if the patient had already signed the form at point of creation this did not prevent the re-sends from occurring. This has now been corrected so that a form which has a patient signature will not be resent.

2.10 Add patient list breakdown to procedure report

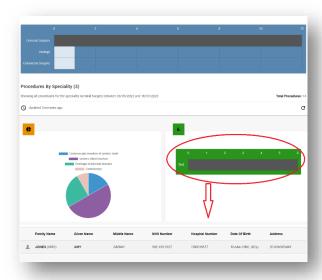
Previously the **Consent Form Usage and Breakdown** report could be expanded as far as showing the clinical user. Based on a customer request the report now has a further section that shows the list of patients relating to the number of consents created by that selected user.

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Clicking a clinician will now show a list of their assigned patients based on the selected procedure. Clicking on a patient will redirect to the patients consent form page. If you then click the back button then the consent form report will be reloaded from session automatically.



2.11 Form auto-complete option

Medical forms can now be flagged to auto-complete on save. The effect of this is that the system sets a form status as confirmed *once all mandatory fields have been completed*, whether or not these are filled in remotely.

This allows the user to bypass the standard form confirmation step for forms where it is appropriate to auto-complete once certain mandatory fields have been completed.

When a form that has the auto complete flag set to true will be marked as completed when the patient saves the form on the patient portal and the hospital part is completed, whichever is the latter.

2.12 Add patient completed flag and Hospital completed flag

Since patient facing forms allow sections to be completed remotely the system will now record remote and local section completion separately.

Status history:	Mail history:
• 10-Jul-2023: (test.user) Awaiting confirmation (CURRENT)	• 10-Jul-2023: (test.user) Email sent to patient
• 10-Jul-2023: Patient section completed	• 10-Jul-2023: (REMOTE) Remote access attempt has succeeded

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2.13 Incomplete medical forms report

Report to show patients who have incomplete medical forms assigned. This is available via the analytics button and filterable by date range (default one month) and form name (with option to show all). The report breaks down forms by status as follows:-

- COMPLETED AND CONFIRMED
- AWAITING CONFIRMATION
- PATIENT COMPLETED
- ACCESS SUCCESSFUL
- ACCESS LOCKED
- ACCESS FAILED
- NOT ACCESSED

Selecting one of the above categories shows a clickable patient list.

The report can be found on the analytics page and is called "Remote Medical Form Access Breakdown". This report will show all medical forms where an email has been sent to the patient for filling out remotely. The report can be used to track the progress of all medical forms based on a given criteria: Start Date, End Date, Form Status(optional) and form name(optional).

If you click on a status from the bar chart the patient table will appear displaying all patients with a medical form assigned to the selected status. If you click on the patient you will be taken to the selected record.

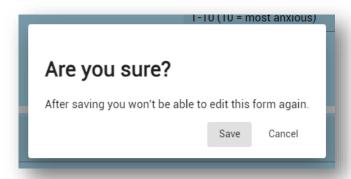
2.14 Allow user to re-activate procedures in admin app

Marking a procedure as **Inactive** in the Procedure editor (by removing the **Active** flag) caused the procedure to no longer appear on the selection list. This meant that the user was unable to re-activate the procedure.

Provided a filter on the procedure editor so the user can toggle between active and inactive procedures.

2.15 Patient portal pop up before submitting medical form

Patient pop up before form submission to warn that once the data is saved they will not be able to change it.



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2.16 Optimise patient portal for mobile devices

Improvements to dynamic resizing were made for use with devices with various screens sizes accessing the patient portal screen. Changes were also made to allow the signature pad to dynamically resize to work optimally on mobile/tablet devices.

2.17 Remove "Current" flag from e-mail status

The "Current" flag was being applied to e-mail and postal status updates which it was not intended for. The flag will now only appear next to the most recent of the following statuses: -

- AWAITING
- CANCELLED
- COMFIRMED
- COMPLETED

2.18 Remove dummy patient demographic data from PDF preview

It was considered useful to be able to produce a printed copy of a consent procedure without any patient demographic details for use in the case of a system outage. The dummy demographic data which was previously included on form previews is now left blank to facilitate this.

2.19 Action required status for medical forms

A new action required icon has been included for medical forms where further action is needed before the form can be marked as complete.



2.20 Improve email error handling

In the event of an e-mail link failing to send an error is now shown to the user and the failed to send email status will be shown in the history section.

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2.21 Option to cancel confirmed forms

Once a form has been confirmed it cannot be cancelled - this can be confusing if a form has been confirmed in error and it would be useful for the confirming user could change the confirmation status. There is now the option to cancel a confirmed consent form or medical form. (Note only the user who confirmed can cancel the form).

2.22 Rich Text data entry

New medical form data entry type allowing for Rich (formatted) Text entry. Rich text will now display on the PDF output for medical forms. Also updated the form renderer to ensure that any content pasted in will remove all formatting (text only). This will ensure that the content is always rendered correctly on the PDF and patches the possible cross site scripting vulnerability.

2.23 New Anaesthesia Type

Requirement for a new "Gas and Air" anaesthesia option - this appears in the list below Sedation and local anaesthesia and will trigger a standard form 1 or 2 dependant on patient age.

Nitrous oxide and oxygen (Entonox)

2.24 Allow form to be saved without filling mandatory fields

Previously mandatory medical form fields had to be be completed when a form was first generated. However, it would be more appropriate (especially in the context of patient facing forms) to allow mandatory fields to be left blank <u>until</u> the form is marked as complete.

Validation is no longer forced when saving and an empty form can now be saved.

Validation will now be fired on confirmation. If validation fails then a failed validation prompt will be displayed. A medical form can only be confirmed if all validations pass.

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3 Fixes to existing functionality in this release

The following fixes are included in this release:

3.1 Form 4 spelling mistake

Selecting the radio button for "Assessment of patient's capacity..." is missing a space in the description: "...capacity to give or withhold consent to this procedure or or or treatment because..."

Assessment of patient's capacity (in accordance with the Mental Capacity Act)

I confirm that the patient lacks capacity to give or withhold consent to this procedure or course of t eatment because their mind or brain works (for example, a disability, condition or trauma, or the effect of drugs or alcohol) and they can
☐ Understand information about the procedure or course of treatment
Retain that information in their mind

3.2 Correct minor grammar error in patient portal

Corrected minor grammatical error in patient portal text.



3.3 Pre-eConsent 1.6 risk rendering issue

When downloading a pdf consent form that was created before e-consent 1.6.0, the risks were not being rendered on the PDF. Risks were still shown in the patient consent summary so this was only an issue if a historic form needed to be re-printed. The PDF output will now render risks on consent forms created before 1.6.0

3.4 Procedure List: <NULL> is shown in Minimum Grade field

In Admin - Procedure List, <NULL> was showing in Minimum Grade field, the default value should leave blank.

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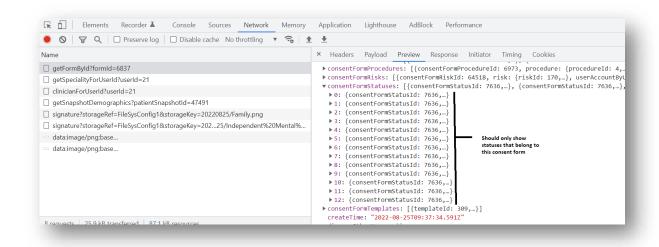
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3.5 Payload issue when editing a form (slow loading)

When editing a form the payload return included all statuses which caused the edit page to take a long time to load. This has been resolved.



3.6 Child patient signature missing warning

In 1.7.0 when confirming consent the system warns if the Patient signature is missing for patients <16yrs - this is incorrect since the patient signature is only mandatory if the patient is an adult (16yrs+)

Child patient signature warning will now not show if the patient is < 16 unless the form 1 override has been selected to allow the patient to sign as an adult.

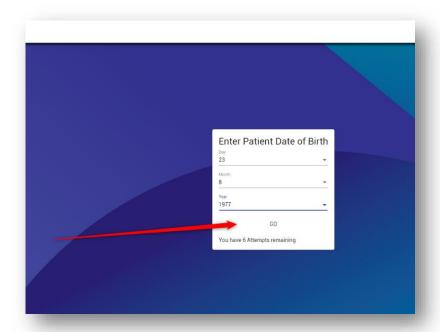
Guardian signature warning will now not show when the guardian signature has been uploaded on the second stage of consent.

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3.7 The "GO" button on Download Portal does not turn Active

The GO button does not change colour to indicate that it is active when data have been selected for DDD/MM/YY. This has now been changed to be consistent with other screens.



3.8 Patient <16yrs with competence unable to sign main form

Marking a patient <16yrs as competent to sign should allow them to sign as the patient on the main eConsent form. However, the system asks for a mandatory "printed name" even though there is no freetext box to enter this.

The patient should be able to sign the form without this prompt preventing it. It was possible to work around this issue as the patient could sign in the second stage screen. The issue has now been resolved so that the patient can sign in either context.

3.9 Not all Admin Users are able to update eConsent Forms

Any admin user whether with Clinician code or not should be able to update a consent form status.

This bug only relates to the editing of forms - specifically the ticking and signing of the second stage consent (click the edit icon and check the "As a health professional, by checking the box I confirm that the patient has reviewed the details of the treatment, she/he has signed this document and wishes to take the following action." statement - then sign.)

- A user without a clinician code can now complete the final confirmation of an existing consent form

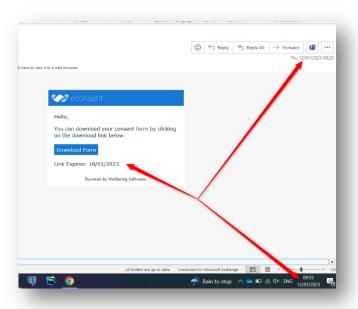
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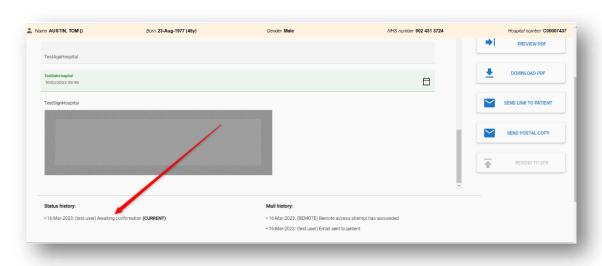
3.10 Electronic Consent reminder emails resetting expiry date

The reminder email was resetting the expiry date to 7 days from when the reminder was sent. This has been resolved so that the expiry date remains the same and the system will stop resending emails if login is locked by too many failed attempts.



3.11 Status History for Patient Form not updating

Status History section of Patient Form did not update when the patient completed their form. "Patient Section Completed" status is now showing on the medical form summary.



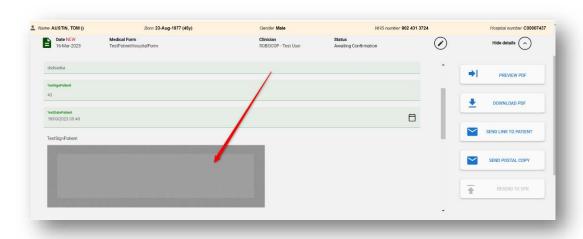
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3.12 Validation failing for Signature on Medical Form

It was possible to bypass Signature validation on Medical Form by first, signing the pad, going full screen, then clear it and confirm the form.

The clear button on the full screen view on the signature pad is now working correctly and clicking clear will no longer bypass the validation.



3.13 Consent form 4 not generating with Sedation and local anaesthesia

Missing Incapacitate master template_id in the Anaesthesia table in the DB. This was causing an error when trying to generate a Consent form 4 with Sedation and local anaesthesia selected. Fixed issue with consent form 4 not generating if sedation and local anaesthesia is selected as the anaesthesia type.

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4 System Requirements and Supported Platforms

See attached Magentus Warranted Environment Specification v2.6



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