O–RADS (v2022) Clinical Guidance Module

Executive Summary

The **O-RADS (US) Clinical Guidance module (v2022)** is a structured decision support application embedded within Microsoft Nuance PowerScribe. It provides radiologists with real-time, guideline-concordant O-RADS ultrasound (US) category assignment and management recommendations for ovarian and adnexal lesions evaluated on pelvic ultrasound. The module encodes the complete decision logic from the latest American College of Radiology's (ACR's) Ovarian-Adnexal Reporting and Data System for Ultrasound (O-RADS US) v2022 guideline.

The module operates within the PowerScribe Clinical Guidance framework. It supports input via dropdown selectors, image maps, and voice entry, with each selection mapped to a discrete lexicon element defined by the guideline. The module dynamically resolves the appropriate O-RADS category (0–5) based on encoded rule pathways and inserts appropriate impression, management recommendation, and citation text into the radiologist's report. Logic has been directly derived from the 2023 revision of the O-RADS v2022 consensus criteria. The module also includes an interactive decision flowchart that presents a comprehensive logic map of O-RADS classification, with each terminal node representing a valid category. Clicking on a node of the image map auto-fills the structured input fields and triggers output generation.

This document defines the design, logic structure, input specification, output schema, interaction model, and validation plan for the O-RADS (US) module. It is intended for implementation stakeholders including clinical informaticists, software engineers, quality assurance specialists, and regulatory reviewers.

Clinical and Technical Scope

Clinical Scope

The module encodes the complete risk stratification and management framework defined in the ACR O-RADS US v2022 guideline as updated in 2023. It supports categorization of ovarian and adnexal lesions in the context of pelvic ultrasound examinations performed in both premenopausal and postmenopausal women. The decision logic accounts for both ovarian and extraovarian findings being assessed for risk of malignancy, incorporating physiologic variants, classic benign lesions, cystic lesions with or without solid components, and solid lesions.

The tool is for evaluation/characterization of indeterminate lesions seen on pelvic ultrasound considered as potentially malignant. Lesions included in scope:

- Normal ovary with or without physiologic findings
- Hemorrhagic cysts, dermoid cysts, endometriomas, paraovarian and peritoneal inclusion cysts, and hydrosalpinx
- Cystic lesions stratified by locularity, size, vascularity, and wall/septation morphology

- Solid lesions with ≥80% solid composition, stratified by contour, vascularity, and presence of shadowing
- Mixed lesions with both cystic and solid components
- Lesions in pre- or postmenopausal patients, including unknown menopausal status
- Management recommendations ranging from follow-up intervals to referral to gynecologic oncology

The logic conforms as exactly as possible to the published guideline without local modifications or institution-specific heuristics.

Technical Scope

The module is implemented with the PowerScribe Clinical Guidance (CG) framework. It is accessible during report creation via voice or macro trigger. Input is collected through an interface using structured fields, each linked to a defined lexicon value. Voice navigation is supported for all selectable fields.

Generated output populates the Impression section as natural language text, optionally including an embedded citation to the O-RADS (US) v2022 publication. The impression content is dynamically assembled based on selected features and the resulting O–RADS category, with grammatical variation to support narrative readability.

An optional interactive flowchart is available within the module interface. This image map presents the full logic structure of the guideline. Users may navigate this map directly by selecting lesion descriptors, which then resolve to a category and sync back to the structured form.

Out of scope for this module:

- Customization of management recommendations based on patient-specific clinical context.
- Audit trail or analytics features beyond native PowerScribe infrastructure.
- Multi-lesion summarization or lesion prioritization logic.

Guideline Background and Source Authority

The O-RADS (US) Clinical Guidance module (v2022) is derived from the **ACR's Ovarian-Adnexal Reporting and Data System for Ultrasound (O-RADS US) v2022**, as published in the *Radiology* journal in September 2023 (Strachowski et al.). This guideline defines a standardized lexicon, decision framework, and management schema for the classification of adnexal lesions identified on US.

Purpose of the Source Guideline

O-RADS (US) was developed to:

- Standardize US terminology for describing ovarian and adnexal lesions
- Assign numeric risk categories (0–5) based on sonographic morphology and Doppler characteristics
- Link each risk category to a management recommendation based on validated malignancy probabilities
- The v2022 update incorporates:
    - Enhanced definitions for physiologic and classic benign lesions

- Revised locularity criteria (addition of “bilocular” category)
- Incorporation of shadowing as a benign feature in certain solid lesions
- Updated guidance for technically inadequate studies (O-RADS 0)
- New recommendations for short-interval follow-up of O-RADS 3 lesions
- Alignment with SRU consensus definitions and O-RADS MRI where applicable

The guideline has been validated in retrospective and prospective studies and demonstrates strong interobserver agreement, including among less experienced readers.

Implementation Scope within the Module

This module encodes the guideline in full, without omission or modification. The decision logic reflects all assessment categories:

- O-RADS 0: Technically inadequate
- O-RADS 1: Normal ovary or physiologic finding
- O-RADS 2: Almost certainly benign (<1% risk)
- O-RADS 3: Low risk (1–<10%)
- O-RADS 4: Intermediate risk (10–<50%)
- O-RADS 5: High risk (≥50%)

It supports categorization of:

- Classic benign lesions: hemorrhagic cyst, dermoid, endometrioma, paraovarian cyst, peritoneal inclusion cyst, hydrosalpinx
- Cystic lesions without solid components: characterized by morphology, size, and vascularity
- Cystic lesions with solid components: stratified by papillary projections and color score
- Solid lesions: stratified by shadowing, vascularity, and contour

For cases involving multiple lesions or bilateral findings, the module should be applied to the most worrisome lesion.

Each input and rule in the module maps directly to a lexicon term, measurement criterion, or logic branch defined in the v2022 publication.

Citation

Strachowski LM, Jha P, Phillips CH, et al. *O-RADS US v2022: An Update from the American College of Radiology*. Radiology. 2023;308(3):e230685. doi:10.1148/radiol.230685

Available online: https://pubs.rsna.org/doi/10.1148/radiol.230685

Data Inputs

The O-RADS (US) Clinical Guidance module v2022 accepts a fixed set of structured inputs that correspond to lesion characteristics defined in the O-RADS US v2022 lexicon. All inputs are collected via a controlled interface using dropdown menus, image maps, or voice-selectable fields. No free-text entry is permitted.

Each input field is associated with a discrete internal field ID, permissible value set, and conditional display logic. The input structure ensures that all data required for unambiguous O-RADS category assignment is captured at the point of use.

Input Field Definitions

See Table 1.

Required Fields and Conditional Logic

- **Required universally**: evaluation complete
- **Required for solid or complex lesions**: vascularity score, outer contour, shadowing present
- **Required for papillary projections or septations are visible**: papillary projection count, septation count
- **Displayed conditionally**:
  - Ascites/nodularity is only displayed when a lesion is detected
  - Inner margins is required for multilocular or multilocular-solid lesions
- **Unilocular/multilocular lesions**: echoes/septations is required

Complete user input is validated, and errors prevent category computation and output text generation. To avoid the warning message, 'Please input more data,' the module requires a complete and logically coherent set of inputs sufficient to traverse the decision tree and compute an O-RADS category. This includes:

- Evaluation complete = Yes (required to activate the module)
- A valid selection for lesion type (physiologic, classic benign, or indeterminate)
- For indeterminate lesions: all key morphological features relevant to the selection type (e.g., locularity, presence of solid components or papillary projections, vascularity score, outer contour, inner margins, shadowing, septations, and echoes)
- Menopause status and lesion size (used to finalize O-RADS classification and follow-up recommendations)

The "Please input more data" message will appear if any combination of these fields is incomplete or inconsistent in a way that prevents endpoint resolution. This validation is handled at the evaluation level, not at the individual field level. Once all required inputs are provided and the logic completes successfully, this message will be automatically replaced with the final O-RADS category and structured impression text.

Decision Logic and Category Assignment

The O-RADS (US) Clinical Guidance module v2022 encodes the full categorical logic defined in the ACR O-RADS US v2022 guideline. All decision pathways are implemented as deterministic logic trees. The module accepts structured inputs and assigns a single O-RADS category (0–5) per lesion based on predefined conditional rules. No probabilistic or user-overridable scoring is applied.

Inference Structure

- Logic is implemented as a branching rule engine.
- Each terminal node resolves to a single O-RADS category.
- All pathways are mutually exclusive.
- Category assignment is computed automatically once all required inputs are present and validated.

Scope of Encoded Logic

The module supports:

- Classification of cystic, complex, solid, classic benign, and physiologic lesions.
- Differentiation based on locularity, size, contour, vascularity, shadowing, and papillary projections.
- Escalation based on presence of ascites or peritoneal nodules.
- Inclusion of technically inadequate studies (O-RADS 0) and normal findings (O-RADS 1).
- Categorization of nonvisualized ovary, when applicable.
- Assignment of separate scores for multiple lesions (no summary logic applied).

All rules, threshold values, and logic sequences follow the v2022 guideline as exactly as possible.

Edge Cases and Overrides

- If required inputs are missing or the study is technically limited, the module cannot assign an O-RADS category and will display a general warning (i.e., 'Please input more data').
- If no lesion is present, the module assigns O-RADS 1.
- Ascites or peritoneal nodules, when present with a lesion that would otherwise be classified as O-RADS 2 or 3, escalate the classification to O-RADS 5.
- Acoustic shadowing can downgrade a solid lesion's risk, but only if the lesion is solid, has a smooth outer contour, and shows minimal or moderate vascularity (color score CS1-CS3).
- Input conflicts (e.g., incompatible morphology combinations) result in a validation failure at the evaluation level, preventing output and triggering a user-visible warning.

Logic Transparency

The underlying logic tree is mirrored in an interactive image map through a flowchart interface available to the user. Terminal nodes are clickable and correspond to complete logic branches. Selecting a node in the flowchart automatically populates the structured form fields and triggers category assignment.

Generated Report Text

The O-RADS (US) module generates structured output that is rendered in PowerScribe as formatted narrative text within the impression section of the radiology report. Output includes the final O-RADS category assignment, a standardized management recommendation, and a citation to the O-RADS US v2022 guideline.

Output Structure

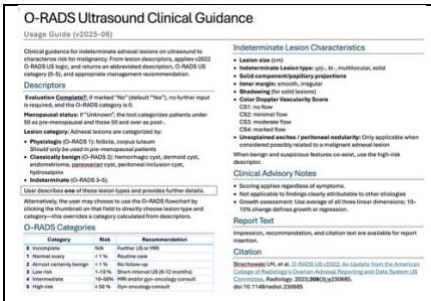
Each output instance contains the following components:

- Category statement:
  Template: *"O-RADS (US) category [n]: [category description]"*
  Example: *"O-RADS (US) category 3: Low risk (1%–<10%)"*
- Management recommendation:
  - Generated using predefined, category-specific text derived from the guideline.
    Example: *"Consider follow-up ultrasound in 6 months if the lesion is not surgically excised."*
- Citation line (optional):
  "Management based on ACR O-RADS US v2022 (Strachowski et al., Radiology 2023)."
- Exception handling: If required inputs are incomplete or the logic cannot resolve a final classification, no category or recommendation is displayed. Instead, the system shows a placeholder warning: *'Please input more data'* This message remains visible until all required and logically consistent inputs are provided and the logic completes successfully.

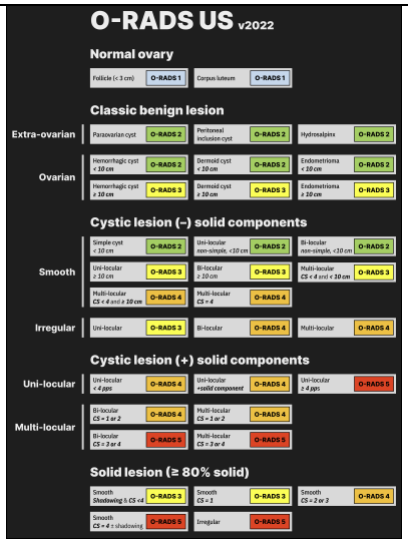
No report section outside the Impression is modified.

User Reference Material

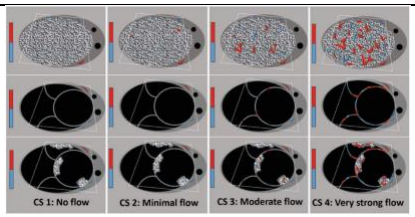
Within the tool, the user has access to several references to aid in their use of the tool, both logistically and clinically.



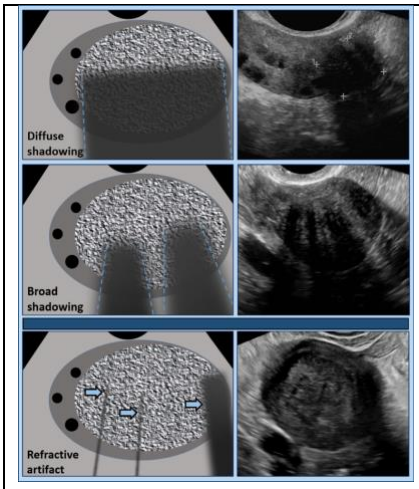
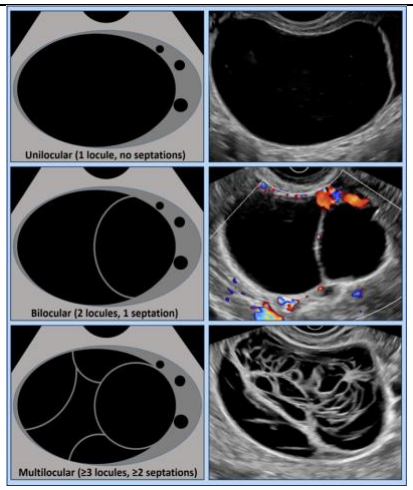
Module use quick reference guidelines.



Flowchart of O–RADS logic, also available for interaction.



Reference image: color score.

 Reference image: shadowing.	 Reference image: cyst loculations.	

Display Label	Type	Permissible Values	Notes
Evaluation Complete?	Choice	Yes, No	Required to enable module use
Menopausal Status	Choice	Premenopausal, Postmenopausal, Unknown	Affects follow-up duration for O-RADS 2/3 lesions
Lesion Size (cm)	Numeric	>0	Used for management thresholds and O-RADS 2 vs. 3 assignment
Laterality	Choice	Left, Right	Describe the finding in the left or right ovarian or extra-ovarian region
Lesion Type – Physiologic	Choice	Follicle (≤3 cm), Corpus luteum	Determines O-RADS 2\1
Lesion Type – Classic Benign Lesion	Choice	Typical hemorrhagic cyst, Dermoid cyst, Endometrioma, Paraovarian cyst, Peritoneal inclusion cyst, Hydrosalpinx	Determines O-RADS 2
Lesion Type – Indeterminate Lesion	Choice	Unilocular, Multilocular, Solid (≥80%)	Triggers detailed risk assessment pathway; lesion features (locularity, solid parts, projections, etc.) must be evaluated
Solid component or papillary projections?	Choice	Solid component, 1-3 papillary projections, 4 or more papillary projections, No solid component or papillary projection	Required if solid components or papillary projections are present
Inner margins	Choice	Smooth, Irregular	Risk-stratify multilocular and multilocular-solid lesions; smooth vs. irregular margins influence O-RADS score
Internal echoes or incomplete septations	Choice	Yes, No	Required for unilocular and multilocular lesions; presence of internal echoes or incomplete septations increases risk
Outer Contour	Choice	Smooth, Irregular	Required for solid lesions
Color Doppler Vascularity Score	Choice	CS1 (no flow), CS2 (minimal flow), CS3 (moderate flow), CS4 (marked flow)	Required for all solid or complex lesions
Acoustic shadowing	Choice	Yes, No	Used primarily for solid and complex lesions
Unexplained ascites ± peritoneal nodularity	Choice	Yes, No	Escalates to O-RADS 5 if seen with lesion
O-RADS Flowchart	ImageMap	All possible selections available in the module	Display visual pathway to final O-RADS classification

Table 1: Summary of input fields.