Embedding a RAG-based model to support dietary planning and nutritional insights in a regulated software as a medical device to support diabetes and obesity management

Abhimanyu Kumbara, MS[1], Mansur Shomali, MD, CM[1], Ayush Chaudhary, MS[1], Catherine Brown, MD, RD, CDCES[1], Anand Iyer, PhD[1]
[1]Welldoc, Columbia, Maryland,USA

BACKGROUND AND AIMS

Effective dietary management is a cornerstone for optimizing glycemic management and facilitating weight reduction in patients with diabetes and obesity (1). To address the complexities of personalized nutrition in chronic care, we developed an advanced, dual-model Retrieval-Augmented Generation (RAG) artificial intelligence (AI) system. Crucially, this system was engineered as a regulated Software as a Medical Device (SaMD) in full conformance with FDA regulations to ensure clinical safety and efficacy.

METHODS

Our initial RAG-based model provides dynamic meal planning support as illustrated in Figure 1. By grounding the AI in established nutritional guidelines, the model synthesizes and generates personalized meal plans driven by a comprehensive set of patient-specific parameters. These inputs include meal type preferences, dietary restrictions, continuous glucose trends, longitudinal weigh trends, current medication regimens, and daily physical activity levels.

Complementing the meal planner, a second specialized RAG model processes this same multi-modal physiological dataset alongside the patient's logged dietary intake, as illustrated in Figure 2. This secondary model evaluates the consumed meals against the user's specific metabolic data to deliver actionable, AI-driven insights. It provides contextual recommendations and targeted food substitutions designed to stabilize glycemic response and support weight management.

Figure 1: Dynamic Meal Planning RAG Architecture

Synthesizes hyper-personalized meal plans grounded in guidelines and patient parameters.

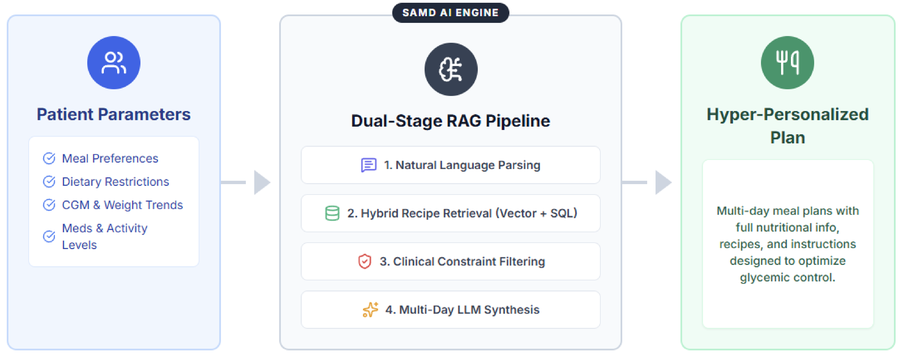
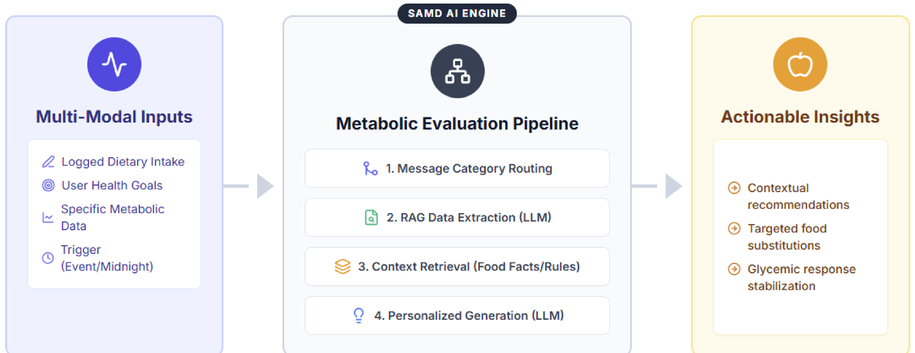


Figure 2: Specialized Nutritional Insights RAG Architecture

Evaluates consumed meals against metabolic data to deliver actionable, targeted guidance.



RESULTS

Clinical Validation & Model Performance: To ensure clinical safety and efficacy as a regulated Software as a Medical Device (SaMD), both the AI Meal Planner and Food Insights models underwent rigorous internal verification and validation testing.

Model Evaluation Process & Target Pass Rate The evaluation process assessed the AI-generated outputs against a defined set of established nutritional guidelines and complex patient-specific parameters. To meet regulatory and clinical compliance, a minimum Target Pass Rate of 70% was established.

System outputs were evaluated by clinical reviewers and scored on a qualitative scale. For an output to be considered a "Pass," it had to achieve a clinical rating of "Fair", "Good", or "Excellent". This threshold ensures that the AI consistently delivers medically sound nutritional guidance while effectively mitigating the risk of AI hallucinations.

Table 1: AI Model Clinical & Adherence Evaluation Results

AI Feature	Total Test Cases Evaluated	Target Pass Rate	Achieved Pass Rate	Evaluation Metrics	Validation Status
AI Meal Planner	68 (Random Sample)*	70%	**78%**	Measures how well meal plans follow core planning rules, such as including enough different food groups for a balanced meal based on user goals and constraints.	**Pass**
AI Food Insights	226	70%	**74%**	Measures how well the AI-generated personalized nutritional insights adhere to established clinical and content rules (166 out of 226 passing tests).	**Pass**

CONCLUSIONS

- By utilizing a RAG architecture within an FDA-compliant framework, the risks of AI hallucinations are mitigated while delivering a scalable, regulatory-compliant solution.
- The Meal Planner demonstrated strong adherence to complex dietary restrictions and meal balance rules, achieving a 78% pass rate.
- The Food Insights model successfully evaluated consumed meals against specific metabolic data to deliver actionable insights. By meeting the "Fair" or better criteria, the model achieved a 74% pass rate, validating its safety for deployment in chronic care scenarios.
- This approach empowers patients with hyper-personalized, medically sound, nutritional guidance for effective disease management.

REFERENCES

1. American Diabetes Association Professional Practice Committee. 8. Obesity and Weight Management for the Prevention and Treatment of Diabetes: Standards of Care in Diabete—2026. Diabetees Care. 2026;49(Suppl 1):S166-S182