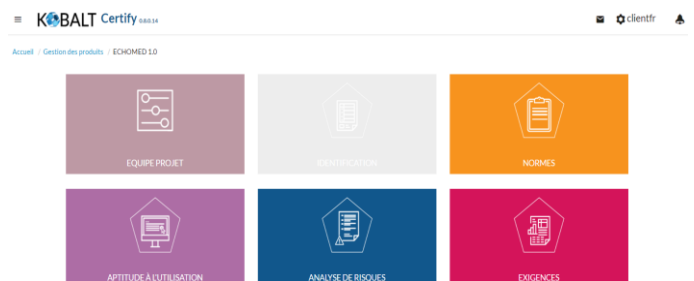


- ✓ **SIMPLIFY** the tasks associated with your certification process  
*With Certify software suite, we help manufacturers succeed in their certification*
- ✓ **OPTIMIZE** your evaluation processes by the testing laboratories  
*Certify is a complete and integrated platform*
- ✓ **ALIGN** your records and reports according to the expectations of the testing laboratories  
*Your files are structured and complied with the applicable standards and methodologies*
- ✓ **MAINTAIN** your product approval and registration  
*The files are versioned and follow your organization*
- ✓ **CAPITALIZE** your learning  
*Your files are archived and remain searchable and duplicable. You stay focused on your business*

Accessible online and highly secure, Certify is composed of several interconnected modules:

- **Risk analysis:** full integration of the ISO 14971 methodology
- **Suitability:** full integration of the IEC 62366 methodology
- **Standards:** smart extract of technical standards into requirements and associated traceability
- **Requirements:** Management and traceability of the design requirements to the associated test reports
- **Identification:** details of the device according to the different standards and classifications
- **Project:** Resource management and task following





## USABILITY

The Usability module allows you to:

- Comply with IEC 62366
- Define the lifecycle steps of your device
- Define scenarios and usage functions
- Identify key service functions
- Assess the type of impact of a problem
- Automatically link a main service function to a requirement or risk
- Generate your reports

Status	UID	Ordre	Etape	Description	Interface	Partie du corps	Environnement	Utilisateur
	1	1	Stockage	Stockage du dispositif avant livraison	Carton	Mains	Entrepôt	Logisticien
	2	2	Transport	Transport du dispositif du lieu de stockage jusqu'au client	Carton		Auton Bateau	Transporteur
	3	3	Installation	Installation du dispositif chez le client	Carton Poignées	Mains	Hopital Clinique	Ingenieur Biomedical Commercial
	4	4	Utilisation	Utilisation du dispositif	Ecran tactile Sonde	Torse Mains	Hopital Clinique	Medecin Infermieri
	5	5	Maintenance	Maintenance du dispositif		Mains	Hopital Local SAV	Techniciens SAV
	6	6	Démarçonnment	Démarçonnment du dispositif				



## RISKS ANALYSIS

The Risk Analysis module allows you to:

- Comply with ISO 14971
- Managing your criticality matrix
- Define the risk management plan
- Identify the hazardous phenomena arising from your applicable standards or design
- Assess dangerous situations
- Define risk reduction options and measures and link them to requirements
- Define residual risk and collateral risks
- Generate your reports

Status	UID	Risque	Séquence d'événement perceptible ou cause	Situation dangereuse	Dommages	Personne impactée	Probabilité	Gravité	Risque
	C1617	H1275	Fraction de brancher le dispositif	L'utilisateur entre en contact avec le courant	Electrocution		Rare	Catastrophe	3
	C1616	H1270	Fraction de Soulever et placer le dispositif dans le carton	Effort trop important et répétitif de l'opérateur	Lumbago	Charge logistique	Probable	Important	3
	C1520	H1200	Fraction de Lire le résultat sur l'écran	Confusion entre les valeurs des 2 paramètres	Mauvais diagnostic	Patient	Occasionnel	Critique	3
	C1519	H1199	Fraction de Déballer le produit du carton (en le basculant)	Chute du dispositif sur l'utilisateur	Hématomes	Commercial	Rare	Important	3
	C1502	H1188	Linage est incorrecte	Le médecin fait un mauvais diagnostic	Mauvaise prise en charge pouvant conduire au décès du patient	patient	Occasionnel	Critique	3

Let's meet !

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